Automatic Upper Arm Blood Pressure Monitor

HL858A1-LT

INSTRUCTION MANUAL

PLEASE READ THIS INSTRUCTION MANUAL COMPLETELY BEFORE OPERATING THE DEVICE

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CE 2797 MD IP 22 RoHS REACH

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Importer

Distributor

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Medical Disclaimer

This manual and product are not meant as a substitute for advice provided by your doctor.

You are not to use the information contained herein, or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your healthcare provider.

Intended Use

This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as pulse rate. The measurement position is at human being's arm.

All values can be read out in one LCD panel. The device is designed for home use and recommended for use by adults aged 18 years and older with upper arm circumference ranging from 9 inches to 22 inches (approx.23 cm to 56 cm) and for home use.

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

Type of Use/ Reuse

Reusable

Intended User

The Automatic Upper Arm Blood Pressure Monitor is intended for adult user, for home environment use and the patient is the intended operator.

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?

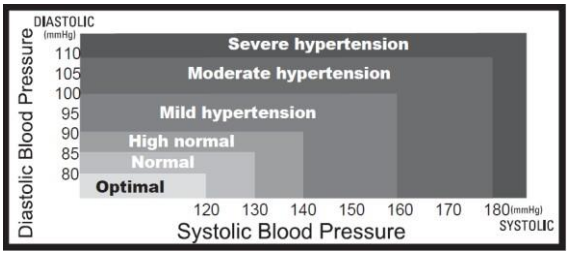
Having one's blood pressure measured by a doctor in a hospital or a clinic is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure to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

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



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

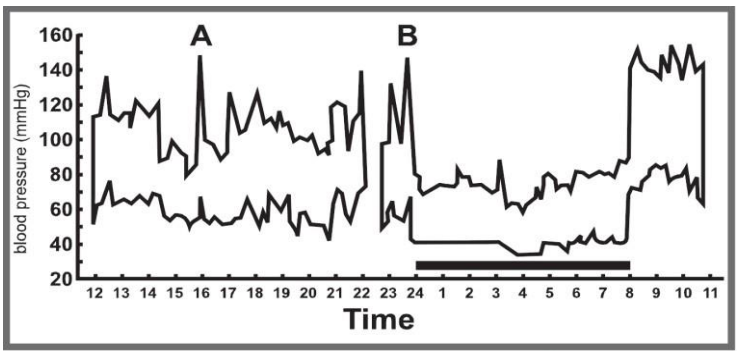
B. Variations in blood pressure:

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

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

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

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



(Direct arterial pressure recording in unrestricted man.

Beven, Honour & Stott: Clin. Sci. 36:329. 1969)

Contra-indications

General Contraindications:

- Severe Trauma or Surgery on the Arm: Avoid using a blood pressure cuff on an arm that has experienced severe trauma or surgery, especially if it involved blood vessels or nerves.
- Presence of an Arteriovenous (AV) Fistula: Do not take blood pressure on an arm with an AV fistula, common in patients undergoing hemodialysis.
- Recent Mastectomy or Lymph Node Removal: Avoid blood pressure measurement on the side of a recent mastectomy or lymph node dissection to reduce the risk of lymphedema.
- Skin Conditions: Do not place the cuff on areas with severe burns, open wounds, or infections.
- Fractures or Orthopedic Injuries: Avoid measuring blood pressure on an arm with a fracture or significant orthopedic injury.
- Wounds: Never place the cuff over a wound to avoid further injury or discomfort.
- Prone to Hematoma: Individuals prone to hematomas should avoid using a blood pressure cuff, as the pressure may worsen bruising.
- Pregnancy: Blood pressure may vary during pregnancy. Do not use with pregnant patients, especially if you have high blood pressure or pre-eclampsia.

Always consult a healthcare professional if you have the following conditions:

- Intravenous Treatments or Venous Catheters: Avoid using the cuff on an arm with an intravenous line or venous catheter to prevent complications.
- Diabetes, Liver Disorders, or Vascular Narrowing: Conditions like diabetes, liver function disorders, or vascular narrowing (e.g., atherosclerosis) can cause anomalous values. Seek medical advice before monitoring your blood pressure.
- Blood Disorders or Circulatory Disorders: If you have conditions like hemophilia, severe circulatory disorders, or are on blood-thinning medication, consult your doctor.
- Pacemakers: The blood pressure monitor does not affect pacemakers, but the pulse rate displayed may not be accurate for checking pacemaker frequency.
- Severe Heart Rhythm Disorders or Cardiac Arrhythmias: The oscillometric measurement method may produce inaccurate values or may not work at all in such cases. Consult your doctor before using a blood pressure monitor if you suffer from these conditions.
- Severe Peripheral Vascular Disease: Blood pressure readings may be unreliable in patients with significant peripheral vascular disease due to impaired blood flow.
- Always consult your doctor about if the user have had a mastectomy or lymph node clearance.
- If you have kidney disease, severe hypertension, very low blood pressure, chills, tremors, please consult your healthcare professional before using the device.

⚠CAUTION

- This product is suitable for use in the home healthcare environment.
- The patient is an intended operator, who can operate the device by himself or herself, not necessarily by a physician or operator.
- The product is not intended for infants or individuals who cannot express their intentions.
- 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.
- Frequent measurements can cause injury due to blood flow interference. Beware of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure due to kinking of connection tubing.
- To allow your blood vessels to return to the condition prior to taking the measurement, please wait at least 3 ~ 5 minutes between measurements. You may need to adjust the wait time according to your personal physiological situation.
- Using both the device and monitoring medical equipment (ME) on the same limb may cause device malfunctions or inaccurate measurements.
- Ensure that the operation of the automated sphygmomanometer does not result in prolonged impairment of patient blood circulation.
- Improper operation of an automated sphygmomanometer may impair blood circulation over time. Please consult the manual for correct usage or contact healthcare professionals or the local distributor for assistance if instructions are unclear.
- Keep the device out of reach of pets and children to prevent risks such as strangulation from cable entanglement.
- Protect the device and cuff against contact with pets, pests in order to avoid damage.
- Do not apply the cuff over wounds to avoid further injury.
- To prevent potential allergic reactions, avoid direct contact between the device and any wounds. If you experience any skin allergy or irritation in the area where the device is applied, please discontinue its use immediately.
- Only use the cuff provided by the original manufacturer to ensure safety and accuracy.
- This device is not designed for use in ambulances, helicopters, or professional healthcare environments.
- Consider the electromagnetic compatibility of the device (ex. power disturbance, radio frequency interference etc.) Please use it indoor only.
- Do not drop the product and avoid any strong impacts.
- Cuff pressure should be maintained between 0 – 300 mmHg, with a reduction rate of ≤30 seconds as per IEC 80601-2-30 standards.
- Modification of this equipment is prohibited.
- Not suitable for use in presence of flammable anesthetic mixture with air or with Oxygen or nitrous oxide.

- Measurement considerations:
  - Any reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiological condition.
  - If unexpected readings are obtained, follow the protocol outlined in the device manual.
  - Avoid compression or restriction of the connection tubing.
- Do not clean, replace batteries, remove/install the power adapter, or remove/install the arm cuff while the blood pressure monitor is in use, as it may affect measurement results or damage the device.
- Under abnormal operating conditions, the temperature of normally accessible surface (all enclosure except for bottom side) may reach up to 47°C. If you encounter this situation, please contact the local distributor or the manufacturer for assistance.
- The use of accessories, detachable parts, or materials not described in the Instructions for Use (IFU) may compromise the performance, safety, or reliability of the device. Always use only the recommended components and accessories as specified in the IFU to ensure proper function and safety.

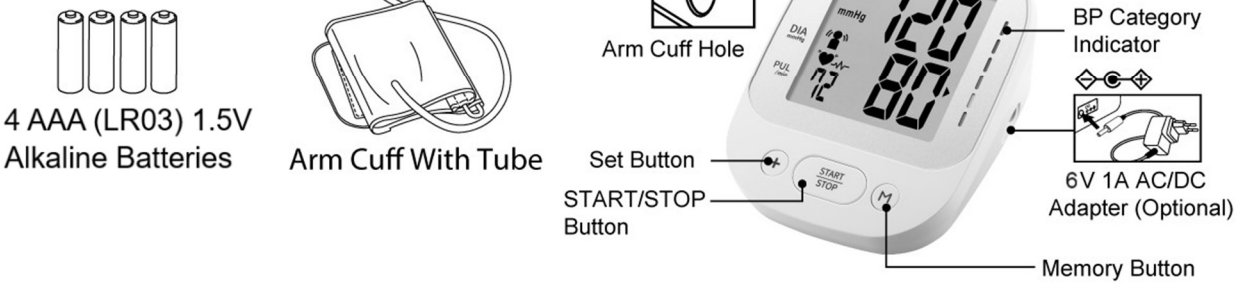
Important Information before Use

1. Only a physician or qualified healthcare professional should interpret your blood pressure measurements, considering your medical history.
2. Avoid smoking, eating, medication, alcohol, or physical activity 30 minutes before taking a reading.
3. Wait 30 ~ 45 minutes before measurement if you've just consumed caffeinated beverages or smoked cigarettes.
4. Perform measurements in a quiet, relaxed setting while seated comfortably.
5. Please rest for at least 5~10 minutes before taking the measurement, and wait until stress subsides if you're feeling stressed, allow blood vessels to return to normal.
6. Remove any constrictive clothing or jewelry that could interfere with cuff placement.
7. Keep the monitor stable, remain still, and avoid talking during the measurement for accurate results.
8. Consistently record your daily blood pressure and pulse readings on a chart.
9. Take readings at the same time daily, as recommended by your physician, for accurate trend monitoring.
10. Always take measurements on the same limb.
11. Always ensure that the cuff is positioned at the level of the heart. If not, measurements may vary considerably.
12. Check the appearance of all display segments, followed by time and date, indicates that the device is carrying out an automated check and is ready for use. Check the device overview for completeness
13. Consult a healthcare professional if you experience measurement errors due to a very weak or irregular pulse.
14. If you wish to **stop the measurement** for any reason at any time by pressing the POWER button. The inflation or measurement process is interrupted and cuff pressure is automatically released.
15. Users are recommended to measure their blood pressure 1 to 4 times per day, depending on individual health conditions and doctor's advice.

16. Avoid exposing the device to extreme temperatures, humidity, altitudes, dust, or direct sunlight, as these conditions may cause malfunction or damage.
17. Never open the device. The device must not be modified or dismantled, and must not be repaired by the user. Repairs may only be carried out by an authorized specialist.
18. Adhere to the storage and operating conditions specified in the 'Technical Specification'. If the device has been stored outside of the specified temperature and humidity range can affect measurement accuracy as well as the function of the device, allow it to adjust for two hours before use.
19. When the ambient temperature is 20 °C, at least 1.5 hours without condensing observed is required for the blood pressure monitor to warm from the minimum storage temperature between uses until the blood pressure monitor is ready for its intended use.
20. When the ambient temperature is 20 °C, at least 1.5 hours without condensing observed is required for the blood pressure monitor to cool from the maximum storage temperature between uses until the blood pressure monitor is ready for its intended use.
21. Use the correct cuff size for your arm to ensure accurate readings. A cuff that is too small or too large can affect measurement accuracy.
22. For assistance in setting up, using, or maintaining the blood pressure monitor or installing the cuff, or to report unexpected operation or events, please contact the local distributor for immediate help. If the issue remains unresolved, please contact the manufacturer.
23. Report any serious device-related incidents to the local distributor, authorized representative, manufacturer and the competent authority.
24. The device is an internally powered equipment.
25. The device is for continuous operation with short-time loading.

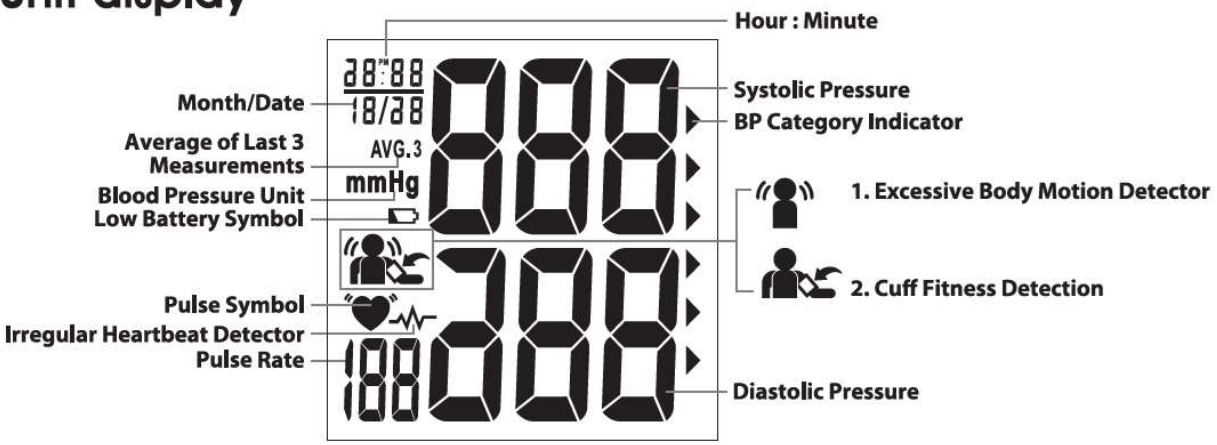
Device Overview

Part Names and Product Components



Symbol Definitions

Unit display



Symbol Definitions

SYMBOLS	Definitions
 Low Battery Symbol	This symbol appears when the battery power is excessively low or the polarity reverses.
	➔ We suggest you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.
 Pulse Symbol	Once pulse is detected, the symbol flashes with each pulse beat.
	➔ Our suggestion: Please do not talk or move during measurements.
 Irregular Heartbeat Detector	This symbol appears when an irregular heartbeat was detected.
	➔ Our suggestion: Please do not talk or move during measurements. Repeat the measurement after resting for at least 5 minutes, and restart your measurement while sitting down comfortably and quietly. If symbols appear frequently, please contact your physician.
 Excessive Body Motion Detector	Displayed if body movement is detected during measurement, especially on the arm that the cuff is worn on. Notice: The measured blood pressure reading may not be accurate if the icon is displayed.
 Cuff Fitness Detection Symbol	Displayed if the cuff was wrapped incorrectly, which is too tight or too loose. This function aids in detecting if the cuff is wrapped properly.
 BP Category Indicator	The arrowhead points out the specific BP Category that your measurement reading fits in.
 Average of Last 3 Measurements	This symbol appears when LCD displays average value of last 3 readings.

Features

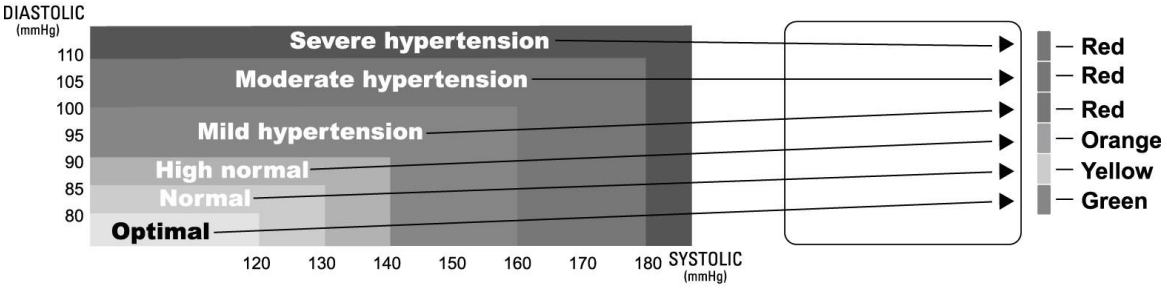
◆ BP Category Indicator

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

Stages of Blood Pressure Levels*		Systolic (mmHg)	Diastolic (mmHg)	Color	Recommendations
Grade 3	Severe Hypertension	≧180	≧110	Red	Retake the measurement. If the result remains the same, consult a doctor immediately and repeat the blood pressure measurement within one day, and again within one week, depending on the clinical situation.
Grade 2	Moderate Hypertension	160 ~ 179	100 ~ 109	Red	Retake the measurement. If the result remains the same, consult a doctor immediately. Serial blood pressure measurements should be repeated over the course of one month.
Grade 1	Mild Hypertension	140 ~ 159	90 ~ 99	Red	Undergo regular check-ups with a doctor, who will provide advice on lifestyle modifications. Confirm progress within two months.
High-Normal		130 ~ 139	85 ~ 89	Orange	Undergo regular check-ups with a doctor, who will provide advice on lifestyle modifications. Recheck in one year.
Normal		120 ~ 129	80 ~ 84	Yellow	Conduct self-assessments. Schedule a doctor's recheck every 2 to 5 years. (For patients over 75 years old, annual health check-ups are recommended.)
Optimal		< 120	< 80	Green	

*Source: WHO, 2003

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



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

Features

Note !
The blood pressure category indicator, based on WHO guidelines, serves as a general guide for understanding non-invasive blood pressure measurements. It is not intended for precise classification of blood pressure levels.
While the device provides useful information, it is not designed to diagnose hypertension. For an accurate diagnosis and medical advice, please consult your physician.

◆ 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 neither designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmic problem. In order to filter the unstable status of user and avoid affecting the detection of heart rate from any movement, shaking or talking in the beginning of measurement, the method of averaging heartbeat intervals of subject device is calculated with the three proper heartbeat pulses detected in the beginning of measurement and that is different from a strict mathematical averaging of all recorded intervals.
- At least 3 beats with 25% or greater difference from the average heartbeat interval will generate the IHB icon on the screen.

Features

◆ Talking Function

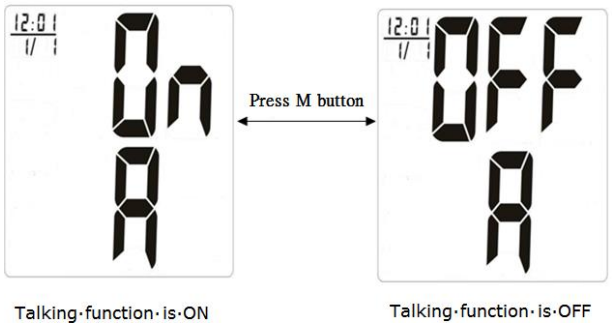
The device features a Talking Function, for you to hear your measurement results.

◆ Turning Talking Function ON/OFF

A. After time setting, press the + button to enter talking function setting, the default setting of this function is ON.

B. Press the **M** button to turn ON or OFF talking function.

C. When settings are done, press the + button to save the settings and switch to standby mode.



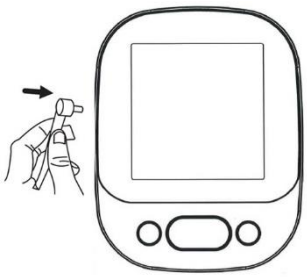
Applying the Cuff

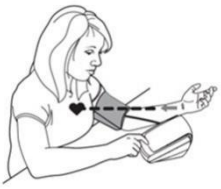
◆ BEFORE APPLYING THE CUFF

- ❑ Wrap the cuff on a bare arm or over thin clothing. Thick clothing or a rolled up sleeve will cause inaccurate blood pressure measurements.
- ❑ Sit on a chair comfortably, put your feet flat on the floor and lay your forearm on the table, make sure your back and arm supported, legs uncrossed, so that the cuff is at the same level as your heart.
- ❑ Press your brachial artery approximately 1 inch (2 ~ 3 cm) above the elbow on the inside of your left arm to determine where your strongest pulse is.
- ❑ The cuff should not be plugged into the monitor until after the cuff is applied to your arm.

Note:

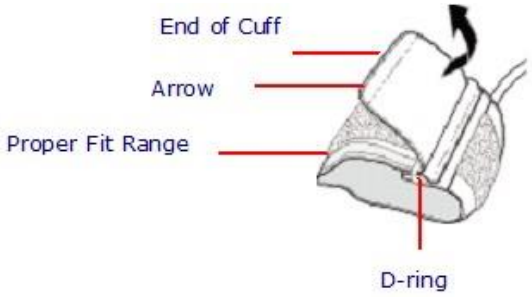
Blood pressure naturally varies from one arm to the other; therefore, measure your blood pressure on the same arm to ensure comparability of the two readings.



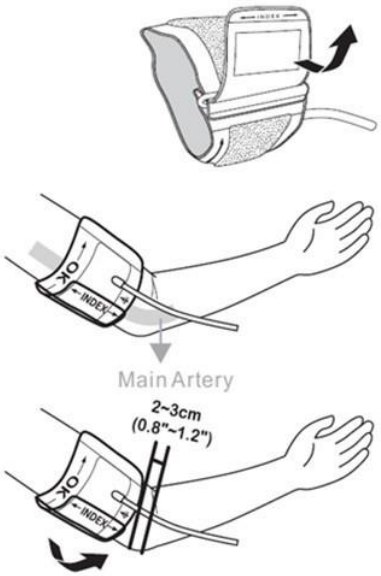


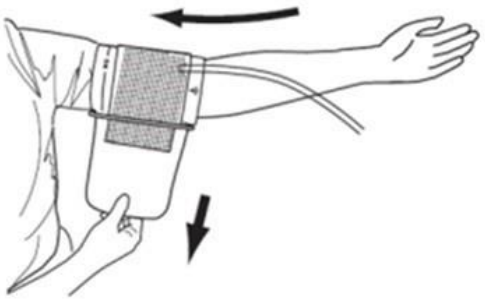
◆ APPLYING THE CUFF

- 1. Remove any constrictive clothing or jewelry that may interfere with cuff placement.
- Use only the approved arm cuff for this device. Use of other arm cuffs may result in incorrect measurement result.
- 2. Slide the end of arm cuff furthest from the tube through the metal ring to a loop. The smooth cloth should be on the inside of the cuff. If the cuff is located correctly, the Velcro will be on the outside of the cuff and metal ring will not touch your skin.



- 3. Put left arm through the cuff loop. The tube should lie over the brachial artery on the inner part of the arm. The bottom edge of the cuff should be 2 ~ 3 cm (approx. 1 inch) above the inner elbow.





- 4. Pull the end of the cuff so that it tightens evenly around your arm, allowing room for 2 fingers to fit between the cuff and your arm.

- 5. Please make sure the cuff do not slip during measurement, and the arrow falls within the Proper Fit Range.
- 6. When the cuff is positioned properly, press the Velcro firmly against the pile side of the cuff.
- 7. Relax your arm and turn your arm upward. Make sure there are no kinks in the air tube.
- 8. Plugged the cuff into the monitor, make sure it's fully plugged.

Note !

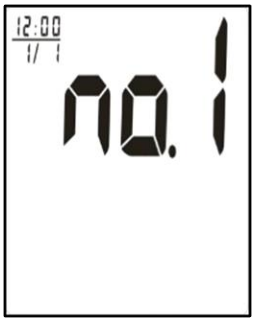
- If you have any infectious skin disease or the device is used by users with infectious skin disease, please do not continue using the device.
- Before using the device, user should check the appearance of cuff. If you notice blood or other soil on cuff, please do not use this device.
- If there is one of above situations, please dispose the device without reuse.
- Fit the cuff snugly, leaving enough space for 2 ~ 3 cm (1 inch) between the inner elbow and the lower edge of the cuff, or the measurement may not be accurate.
- In case the cuff kept pumping up non-stop, unwrap the cuff at once.
- Do not wrap the cuff around any body part other than your arm.
- Do not use this device if your arm has any wound or injury, especially after surgery on the arm. Otherwise, it may cause infection at the surgical site or further injury. Please use the device after the wound has healed.
- Do not bend or fold the cuff excessively.
- Inflate the cuff only after it has been positioned properly around the arm.

Measurement Procedure

◆ Switching on the monitor

A. Put in 4 AAA (LR03) 1.5V alkaline batteries or plug in the AC/DC adapter, all segments appear on the screen for 3 seconds.

B. The monitor will automatically turn to standby mode.



STANDBY MODE

◆ Setting year, date and time

A. To enter setting mode, press **+** button for 3 seconds under standby mode. The YEAR digit flashes.

B. Press **M** button to set current year. Press **+** button to confirm the year and switch to MONTH setting. Press **M** button to set current MONTH.

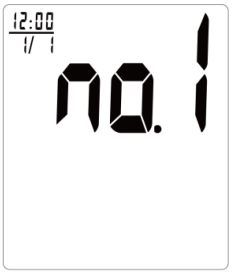
C. Continue to set current DATE (varies from 1 to 31), HOUR (12, 1,……12^{PM}, 1^{PM}……,11^{PM}) and MINUTE (00,01……,59) by following Step B.

D. Users can adjust YEAR-MONTH-DATE-HOUR-MINUTE in an orderly manner. Press **+** button to save the settings and switches to Talking Function setting. For more information about Talking Function setting, please refer to page 13, Talking Function.

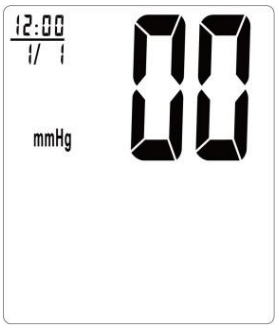
Measurement Procedure

◆ Taking a measurement

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



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



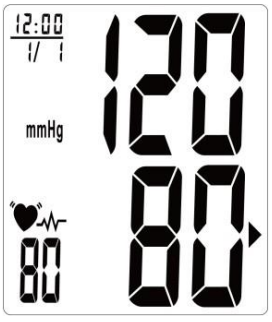
C. All display symbols appear on the screen for 1.5 seconds. After all symbols disappear, the display will show "00". The monitor is "Ready to Measure" and will automatically inflate to the level that is right for you.

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

Note !

- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, press **START/STOP** button. The cuff will deflate immediately after the button is pressed.
- The monitor will automatically switch to sleeping mode if no operation in 1 minute.

E. After the monitor has determined your blood pressure and pulse rate, the cuff automatically deflates. Your results including systolic pressure, diastolic pressure, pulse rate and corresponding BP Category Indicator, Irregular Heartbeat Detector and Excessive Body Motion Detector (if any) will be displayed with date and time for 1 minute and saved to memory automatically.



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

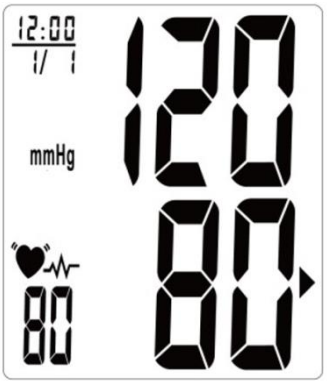
Memory Function

◆ Storing data

After each measurement, the results including systolic and diastolic pressure, pulse rate and corresponding BP Category Indicator, Irregular Heartbeat Detector and Excessive Body Motion Detector (if any) with the time and date will be automatically stored.

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

◆ Recalling data



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

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

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

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

◆ Erasing data

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

B. Press **M** button to enter memory mode.

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

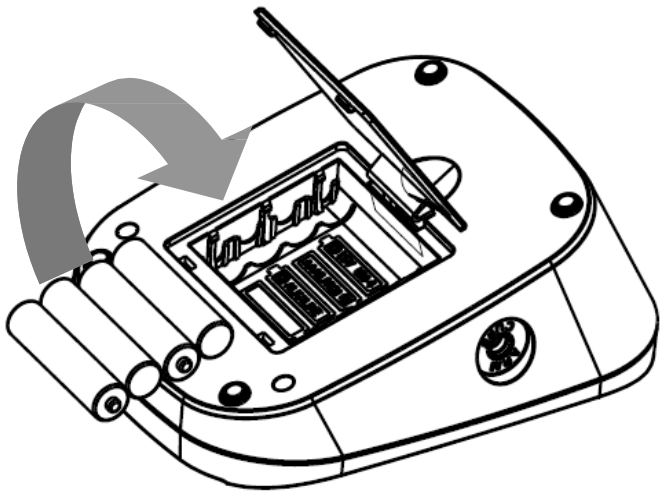
D. To confirm the data in the selected user has been erased, press **M** button and no data should appear.

Note: <u>The data CANNOT be restored once deleted</u>

Installing Batteries

When LOW BATTERY SYMBOL "  " appears or the device does not respond, it's time to change the batteries.

1. Avoid combining different types of batteries — alkaline, standard (carbon-zinc), or rechargeable (nickel-cadmium) — as this can reduce battery life or cause the device to malfunction.
2. Open the battery compartment by sliding off the cover.
3. Replace all worn-out batteries with new ones and do not mix new and used batteries.
4. Insert 4 AAA (LR03) 1.5V alkaline batteries, ensuring the "+" and "-" ends match the markings inside the battery compartment.
5. Close the battery compartment securely.



⚠ **CAUTION:**

■ Choking hazard
- ◆ Small children could swallow batteries and suffocate on them. Keep batteries out of the reach of children.

■ Risk of explosion
- ◆ Do not throw batteries into a fire.
- ◆ If battery is replaced by an incorrect type.

■ Batteries must not be charged or short-circuited

■ If a battery has leaked, wear protective gloves and clean the battery compartment with a dry cloth. If liquid from a battery cell comes into contact with skin or eyes, clean the affected area with water, and seek medical attention if necessary.

■ Protect batteries from excessive heat.

■ Do not disassemble, open or crush batteries

NOTE: Battery-operated

- Battery Disposal: Batteries are hazardous waste and should not be disposed of with household garbage. Properly discard worn-out batteries at a recycling site according to local regulations.
- Avoid disposal near small children or heat, and prevent children from accidentally swallowing batteries.
- Battery Removal: If the unit will not be used for more than 1 month, it is recommended to remove the batteries to prevent leakage.
- Memory and Settings: Replacing the batteries will not delete stored memories. However, if the AC/DC adapter is unplugged and the unit is without batteries, the date and time settings will need to be reset. Plugging in the AC adapter while the batteries are still in the monitor can also cause the time and date to reset. After replacing the batteries, reset the date and time as needed.

Using the AC/DC adapter

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

Note !

- No batteries are needed when operating with an AC/DC adapter.
- Please unload the batteries when operating with an AC/DC adapter for an extended period of time.
- Leaving the batteries in the compartment for a long time may cause leakage, which may lead to damage of the unit.
- Recommend adapter specification, do not use otherwise:

  Manufacturer: Zhongshan Baolijin Electronic Co. Ltd.

  Model: BLJ06L060100P-V

  Rating:

  Input: 100-240V, 50/60 Hz, 0.2 A

  Output: DC 6V, 1A, 

  Classification: Class II

Note !

- When you use the blood pressure monitor with AC/DC adapter, do not position the device to make it difficult to disconnect the adapter plug.
- DO NOT use the AC adapter if this monitor or the AC adapter cable is damaged. If this monitor or the cable is damaged, turn off the power and unplug the AC adapter immediately.
- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.

Safety information concerning the device

■This blood pressure monitor is made of high-quality electronic precision components. The accuracy of the measured values and the lifetime of the device depend on careful handling.

■Protect the device from violent shaking, hitting or vibrations and do not let it drop on the ground.

■Do not operate the device near strong electromagnetic fields and keep it away from radio equipment and mobile phones. Portable and mobile high-frequency and communication devices, such as telephones and mobile phones, can impair the functionality of this electronic medical device.

Notes on electromagnetic compatibility

■The device is suitable for environments listed in these Instructions for Use.

■It may only be possible to use the device to a limited extent in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.

■Avoid using this device directly beside other devices or stacked on top of other devices, as this could result in faulty operation. However, if it is necessary to use the device in the manner described above, this device and the other devices must be monitored to ensure that they are working properly.

■ The use of accessories other than those specified or provided by the manufacturer of this device may result in increased electromagnetic emissions or a decrease in the device ‘s electromagnetic immunity and lead to faulty operation.

■ Failure to comply with the above can impair the performance characteristics of the device.

Notes on disposal

■To protect the environment, empty batteries must not be disposed of in

household waste. Please comply with the relevant waste disposal regulations or use public collection points.

■This product is subject to European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) and is marked accordingly. Never dispose of electronic equipment in your household waste. Please consult the local regulations regarding the proper disposal of electrical and electronic products in your area. Proper disposal protects the environment and public health.

Cleaning and Disinfecting

To maintain your device in optimal condition and prevent damage, or contamination please adhere to the instructions below:

- ❑ Always remove the power supply from the machine before cleaning.
- ❑ Wash your hands with warm water and soap for at least 20 seconds before cleaning.
- ❑ Clean the monitor daily or whenever visible dirt is observed. Use only a soft, dry cloth or a soft cloth moistened with a mild (neutral) detergent. Avoid using thinner, alcohol, heavy detergents, or solvents.
- ❑ It is recommended to clean and disinfect the cuff regularly or after each use, especially when used by different users, to prevent infection:
  - To clean the cuff, gently wipe the entire surface, inside and out, with a cloth moistened with water or a mild (neutral) detergent. Avoid submerging the cuff in water.
  - To disinfect the cuff, spray its surface thoroughly with a compatible disinfectant, such as 75% ethanol, then allow it to air dry completely before the next use.
- ❑ Ensure that both the device and cuff are completely dry, free from stains or body fluids, before the next use.
- ❑ Store the monitor in its case to protect it from external influences and maintain recommended conditions for long-term use.

Note !

- This device come into contact with intact skin but not mucous membranes requires low or intermediate level disinfection.
- This blood pressure monitor is not waterproof. Do not immerse it into water.
- Do not allow water or any other liquids to enter the device. Submerging the monitor or cuff in water or applying excessive moisture can damage internal components and lead to malfunction.
- After cleaning and disinfection, check the cuff and device for any damage. If damage is found, do not use them for blood pressure measurement.

Limited Warranty

Notes on checking calibration

Every H&L device has been carefully tested for measurement accuracy and designed for a long service life. It is recommended to check the device's accuracy every 3 years. To arrange calibration or repair:

- Calibration Service: Contact H&L or an authorized service provider for details on where to send your device.
- Proof of Purchase: Include proof of purchase with your device.
- Fees & Authorized Providers: Calibration should be carried out by the manufacturer or authorized service providers at the user's expense.

Troubleshooting

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/CORRECTION
Unit does not turn on when **START/STOP** button is pushed.	Worn-out batteries	Replace them with 4 new 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.
	Did you talk or move during measurement?	Measure again. Keep arm steady during measurement.
	Shaking of the arm with the cuff on	
E1 Measuring Error Symbol	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.
E2 Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.
E3 Measuring Error Symbol	Can't determine blood pressure measurement data.	Wrap the cuff properly and keep steady. Measure again.
	Cuff is worn improperly, or the shape of the upper arm is unusual (for example, the circumferences of the upper part of the upper arm is noticeably larger than the lower part of the upper arm; or the middle part of the upper arm is noticeably larger than the upper part and lower part of the upper arm), excessive gap might exist between the arm cuff and the arm.	Wrap the cuff 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.
 Excessive Body Motion Detector **Notice:** The measured blood pressure reading may not be accurate if the icon is displayed.	Body movement is detected during measurement, especially on the arm that the cuff is worn on. e.g. Talking, moving or shaking of the arm with the cuff on while measurement.	Measure again. Keep arm steady during measurement.
	Cuff is worn improperly, or the shape of the upper arm is unusual (for example, the circumferences of the upper part of the upper arm is noticeably larger than the lower part of the upper arm; or the middle part of the upper arm is noticeably larger than the upper part and lower part of the upper arm), excessive gap might be exist between the arm cuff and the arm.	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.
 Cuff Fitness Detection Symbol	The cuff was wrapped incorrectly (for example too loosely or too tightly).	Please reference "Applying the Cuff "section to wrap the cuff correctly.
Note: If "EP" appears on the display, just return the device to your local distributor or importer.		

Technical Specification

Model Number	HL858A1-LT
Measurement Method	Oscillometric
Rated Range of Cuff Pressure	0 ~ 300 mmHg
Rated Range of Determination	40 ~ 280 mmHg
Measurement Range of Pulse Rate	40~199 beats/minute
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5 % Max.
Display	Liquid Crystal Display
Memory	240 Memory Total for 2 Users
Unit Dimensions	5.51 x 4.33 x 2.22 inch (L x W x H) 140 x 110 x 56.5 mm (L x W x H)
Unit Weight	273 g ± 5 g (9.62 oz ± 0.18 oz) (Cuff and batteries excluded)
Cuff Size	Health & Life NC-01: Normal size cuff (9"~13" / 23~33cm) For arm size of 23~33cm (Optional) Health & Life UC-01: Universal Cuff (9"~17" / 23~43cm) For arm size of 23~43cm (Optional) Health & Life ELC-01: Extra Large cuff (17"~22" / 43~56cm) For arm size of 43~56cm
Applied Part	Type BF (Arm cuff)
Storage/ Transportation Environment	Temperature: -25 °C ~ 70 °C (-13 °F ~ 158 °F) Humidity: ≤ 93 % R.H. Atmospheric pressure: 700hPa ~ 1060hPa
Operation Environment	Temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F) Humidity: 15 % ~ 93 % R.H. Atmospheric pressure: 700hPa ~ 1060hPa
Power Supply	1.DC 6V, 4 × 1.5V AAA (LR03) alkaline batteries 2.DC 6V, 1A AC/DC adapter (Optional)
Battery Life	Approx. 250 measurements
Shelf Life (battery)	2 years (Temperature: 20 ± 2°C; Relative humidity: 65 ± 20%RH)
Expected service life	3 Years / 10,000 measurements
Sleeping Mode	Without any operation for 1 minute, device automatically shuts off.
Accessories	4 AAA (LR03) Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Pouch

*** Note: After 3 years life time or 10,000 measurements, device material may experience degradation, measurement accuracy may vary. The contents of this manual and the specifications of the device covered by this manual are subject to change for improvement without notice.**

Explanation of symbols

CE 2797 This blood pressure monitor complies with the Regulation (EU) 2017/745 and bears the CE mark. This blood pressure monitor also complies with mainly following standards (included but not limited):

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

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

Symbol	Explanation
CE 2797	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745
RoHS	This product fulfilling the requirements of the RoHS Directive 2011/65/EU.
REACH	This product fulfilling the requirements of the REACH Directive EC 1907/2006 and its amendments, do not contain Substances of Very High Concern in concentration above the limit of 0.1 %. No substance(s) is/are present in the parts of the product above the concentration of 0.1 % weight by weight.
	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.
	Disposal information: Should you wish to dispose of the article, do so in accordance with current regulations. Details are available from your local authority. WEEE 2012/19/EU Directives
	The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.
	Manufacturer
	Date of manufacture  YYYY-MM-DD or YYYY-MM

EU REP	Authorized representative in the European Community
LOT	Batch code (Lot number) (2YYM0XX)
SN	Serial number (YYMMXXXXXXX)
IP22	This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm ø and greater and against vertically falling water drops when enclosure tiled up to 15°)
	Humidity limitation
	Temperature limit
	Atmospheric pressure limitation
	Non-ionizing electromagnetic radiation
MD	Medical Device
	Caution
	Keep dry
	Keep away from sunlight
	Country of Manufacture
#	Model Number
	Importer
	Distributor
UDI	Unique Device Identifier

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

Appendix

- **Guidance and manufacturer's declaration – electromagnetic emissions**

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

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

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

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	In the case of air discharge testing, the climatic conditions shall be within the following ranges: Ambient Temperature:15℃~35℃, Relative Humidity:30%~60%.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC Power port ±1 KV Line to Line	AC Power port ±1 KV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle At 0°,45°,90°,135°,180°,225°,270°and 315°. 0 % UT; 1 cycles 70 % UT; 25/30 cycles 0 % UT; 250/300 cycle	0% UT; 0.5 cycle At 0°,45°,90°,135°,180°,225°,270°and 315°. 0 % UT; 1 cycles 70 % UT; 25 cycles 0 % UT; 250 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Appendix

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

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

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq.	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq.	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3 (Proximity fields from RF wireless communications equipment IEC 61000-4-3)	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz,Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz,Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	**Recommended separation distance** Considering to reduce the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = 6/d\sqrt{P}$ where *P* is the maximum power in W, *d* is the minimum separation distance in m, and *E* is the IMMUNITY TEST LEVELS in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

Appendix

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

Test frequency (MHz)	Modulation	IMMUNITY TEST LEVEL (V/m)
385	Pulse modulation 18 Hz [a)]	27
450	FM ± 5 kHz deviation 1kHz sine [b)]	28
710	Pulse modulation 217 Hz [a)]	9
745		
780		
810	Pulse modulation 18 Hz [a)]	28
870		
930		
1720	Pulse modulation 217 Hz [a)]	28
1845		
1970		
2450	Pulse modulation 217 Hz [a)]	28
5240	Pulse modulation 217 Hz [a)]	9
5500		
5785		

NOTE:
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m, The 1 m test distance is permitted by IEC 61000-4-3.

a). The carrier shall be modulated using a 50% duty cycle square wave signal.
b). AS an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Blood Pressure Diary

Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	
Date：	Time：		☐Before ☐After	Meal
Systolic / Diastolic：			Pulse：	

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