# Electronic Blood Pressure Monitor (Arm Type)

# **User manual**



Mode: KWL-B01L

Please read this instruction manual carefully before use

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#### 1. Introduction

Thank you for purchasing the Blood Pressure Monitor KWL-B01L. This blood pressure monitor is to be worn on your Arm

The blood pressure monitor uses the oscillometric method of blood pressure measurement. When the cuff deflates, this monitor senses the pressure pulsations of the artery underneath the cuff. The pulses are called oscillometric pulses. The electronic pressure sensor displays a digital reading of blood pressure.

Please read this instruction manual thoroughly before using the unit.

Please keep this user manual for future reference.

For specific information about your own blood pressure, CONSULT YOUR DOCTOR.

#### 2. Indications for useAnd how it works

Working principle

Principle of pressure reduction oscillography

The Arm type Blood Pressure Monitor is non-invasive blood measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the arm. It can be used by medical professionals or at home. The cuff circumference is limited to 22-32 cm.

## 3. Safety information

## 3.1 Warning

- DO NOT adjust medication based on measurement values from this blood pressure monitor.
   Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High Blood Pressure.
- When the patient is the prospective operator, the patient through the blood pressure
  measurement for self-judgment, self-treatment is dangerous, should be explained by
  professionals measured blood pressure values, self-judgment may lead to deterioration of the
  disease.
- It is forbidden for infants, children, mental patients and animals to touch or use them
- The monitor is not intended to be a diagnostic device.
- Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pregnancy, pre-eclampsia, renal diseases. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- Do not use the device on the injured arm or the arm under medical treatment.

- Do not apply the cuff on the arm while on an intravenous drip or blood transfusion.
- Do not use the device with other medical electrical (ME) equipment simultaneously.
- Do not use the device in the area of high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanner. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT use this monitor in oxygen rich environments or near flammable gas.
- Please ask your doctor about your normal blood pressure for right direction before take you
  take the measurement by yourself.
- This product applies only for adults. Please keep the unit out of reach of of infants, toddlers or children.

#### 3.2 Caution

- If the cuff causing any discomfort, please turn off the equipment by press the on/off button and consult with your physician.
- Patients with severe blood pressure circulatory disorders, blood diseases, please use under the guidance of a doctor. The pulse shown by this sphygmomanometer is not suitable to act as a frequency setter for the determination of heart rate!
- This product contains cuff links to the trachea longer, may cause the user the risk of strangulation, when the treatment of children, be sure to closely monitor.
- The sphygmomanometer has sensitive electronic component, so do not use the sphygmomanometer directly in the presence of strong electromagnetic interference (e.g., near a mobile power supply, microwave oven, etc.) as this may lead to distortion of accuracy.
- Do not take a blood pressure test if the cuff appears to be broken. Otherwise it may damage the skin.
- The accuracy of the sphygmomanometer has been rigorously tested and it is generally recommended that the sphygmomanometer be calibrated every 1 years to ensure proper functioning and accurate measurement.
- Do not take blood pressure measurements on the arm of the mastectomy or lymphadenectomy side
- Fifteen. Working Environment: avoid electromagnetic interference, vibration and noise environment, when the equipment from the ambient temperature of 20 ° C, the time between the minimum or maximum storage temperature of the equipment after use and the time it takes for the equipment to be ready for its intended use is 4 hours.
- If necessary, the company can provide the relevant circuit diagrams, component lists, drawings, calibration details, etc., please contact the vendor or the company's after-sales service department consultation.
- Do not forcibly crease the cuff excessively, continuous cuff pressure may lead to blood flow interference and result in harmful injury to the patient.

- DO NOT take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- Do not apply of the cuff over a wound, as this can cause further injury.
- Consult with your physician before using this monitor on a arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This
  may result in incorrect operation of the monitor and/or cause an inaccurate reading. The
  pressurization of cuff can temporarily cause loss of function of simultaneously used monitoring
  medical electrical (ME) EQUIPMENT on the same limb.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- Remove the cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 12 inches (30 cm) of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This
  may damage this monitor.
- Don't store or use the monitor and cuff under the sunshine, high or low temperature and humidity (Refer to chapter 11), or someplace which maybe get in touch with fire or water.
   Otherwise, it may cause inaccurate reading.
- DO NOT use this monitor in a moving vehicle such as in a car.
- This monitor is calibrated at the time of manufacturing, if the monitor is used according to the instruction, periodic recalibration is not required. If it is inaccuracy often, please contact your retailer or customer Services.
- Do not disassemble, repair, or remodel the main unit or the cuff of the blood pressure monitor by yourself. If necessary, contact your retailer or customer Services.
- Do not drop the monitor or subject device to strong shocks or vibrations.
- ONLY use this monitor on persons whose arm circumference is within the specified range of the cuff.
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
- DO NOT use this monitor after the durable period has ended.

#### 3.2FCC Caution

#### **FCC Part 15.19**

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
- This device must accept any interference received, including interference that may cause undesired operation.

#### FCC Part15.21

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

#### FCC Part 15.105

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. Verification of harmful interference by this equipment to radio or television reception can be determined by turning it off and then on. 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 receiver.
- Connect the equipment into an outlet on a different circuit to that of the receiver's outlet.
- Consult the dealer or an experienced radio/TV technician for help.

## FCC RF Radiation Exposure Statement

- This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- 2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
- 3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

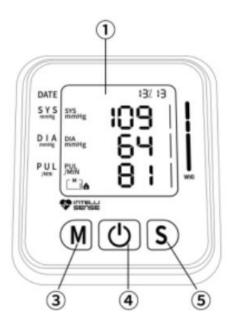
# 4. Explanation of mark or symbols

፟ 大	Applied part of type BF
	Refer to instruction manual
<b>2</b>	Disposal in accordance with Directive 2002/96/EC (WEEE)
MR	This device has not been tested for use in an MR environment and should not be used exposed to MR environments while patients are wearing the device. Keep it outside the MRI scanner room.
SN	Serial number
$\sim$	Date of manufacture
	Manufacturer
I	Contents of the distribution packages are fragile therefore it shall be handled with care.
Ť	Distribution packages shall be kept away from rain and be kept in dry conditions.
<u>11</u>	This is the correct upright position of the distribution packages for transport and/or storage.
IP22	IP code of the device: this device's grade of against ingress of solid foreign objects ≥ 12.5mm diameter (and the against access to hazardous parts with finger); the grade of waterproof is dripping (15° tilted).
FCC	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.

# 5. General description

## 5.1 Main components



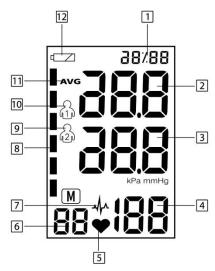


- ① Display
- ② Arm band hole
- 3 Memory key
- 4 Switch / measure key
- 5 Setting key

#### Remark:

- 1. Setting key: the system can be set by combining with memory key.
- 2. Switch / measure: start or stop the measurement button.
- 3. Memory key: view the stored memory value or combine with the setting key to set the system.

# 5.2 LCD display



Item	Name	Item	Name
1	Time / date	7	Irregular pulse icon
2	Systolic blood pressure	8	WHO blood pressure classification
			display
3	Diastolic blood pressure	9	User 2
4	Pulse rate	10	User 1
5	Heartbeat symbol	11	Average Value
6	Number of memory / storage	12	Low battery display
	groups		

#### 6. Accessories

Only use original accessories. Check whether the contents of the delivery are complete.

Parts	Quantity	Part no.:	Life expectancy
Main unit (with cuff)	1pc	KWL-B01L	5 years
User Manual	1pc	KWL-QX-16	5 years

#### 7. The use of lithium batteries

When battery power is lower than  $3.5V\pm0.1V$  the symbol of low voltage battery " $\square$ " is flashing, Please charge it immediatelyp. If the battery power is lower than  $3.4V\pm0.1V$ , then the monitor will switch off automatically to prevent inaccurate measurement.

#### Note:

- The battery can be used at least 90 times when fully charged
- Products in the charging process, can not be turned on and used.
- Be sure to use battery charger supply voltage DC 5V, otherwise may cause danger.
- Please charge it once when it is not used for a long time (more than 1 month).
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with

your physician immediately;

- If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with your physician.
- Please charge the product when the power is too low.
- Please do not put the product into the fire.
- Connect the Charger, the Charger as part of the ME equipment, battery charger to ensure compliance with GB9706.1 requirements.
- Blood pressure can not be measured while the device is being charged.
- Rechargeable battery is built-in lithium battery, non-removable.
- If the pressure does not stop during the measurement, please press the power button immediately. If not handled in a timely manner, there may be risks.

#### 8. Directions for use

## Before taking a measurement

To ensure a reliable reading follow these recommendations:

- Don't smoke or drink pungent drinks such as coffee or wine, or do strenuous exercise for 30 minutes before measure your blood pressure.
- At least rest for 5 minutes in a stable environment before measurement.
- You must repeat the measurement at least two times for accuracy, and take at least 5 minutes rest before next measurement.
- Measurements should be taken in a quiet place.
- The suitable cuff circumference is 22cm ~ 32cm.
- Remove tight-fitting, thick clothing and any accessories from your arm while taking a measurement.
- Sit on a chair with your feet flat on the floor. Rest your arm on table so that the arm is at the same level as your heart. Please don't move your body during the measurement, if you are standing and lying down during the measurement, please take note.
- Remain still and do not talk during the measurement.
- Keep a record of your blood pressure and pulse rate readings for your physician. A single
  measurement does not provide an accurate indication of your true blood pressure. You need to
  take and record several readings over a period of time. Try to measure your blood pressure at
  the same time each day for consistency.
- Use the same arm (normally left) when repeat the measurement, and if it is your first time to measure your blood pressure.
- Patients with arrhythmia and atherosclerosis should not measure by their self if there is no any medical staff there.
- Avoid any electromagnetic interference or noise interference during measurement.

#### 8.1. Preparation before use

- 1) Check the monitor to ensure that the main unit and cuff are free from damage and cracks.
- 2)Please do not put the product near an electrified object to avoid electric shock
- 3) Check whether the display is complete when the LCD screen is fully display.
- 4) When the instrument power is too low, you should try to start charging.
- 5) Spray the 70% isopropyl alcohol to inner side of the cuff by the spray bottle from a distance of about 10cm. Make sure the entire contact surface is sprayed with alcohol and then air-dried.

#### 8.2 System Settings

At the power off status (standby mode), Short press the [Set button] to into the system setting mode. In this mode the User 1"1" symbol on the upper left corner will flash.

#### 8.2.1 Setting the User:

Pressing the memory button to switch between user 1" or user 2 " ress the Set button to confirm the selection and enter into the year setting interface.

#### 8.2.2 Setting the time:

**Setting the year**: On the interface of time setting, the number of year "such as 20:20" flashes, press the [Memory button] to select the year, each press will add one year, once the year was added to 20:99, the number will jump to initial number "20:20". press the set button to confirm your selection and enter into the month setting interface.

**Setting the month**: On the interface of month setting, the number of month "such as 01" flashes, press the [Memory button] to select the month, each press will add one month, once the month was added to "12", the number will jump to initial number "01". press the Set button to confirm your selection and enter into the date setting interface.

**Setting the date**: On the interface of date setting, the number of date "such as 01" flashes, press the [Memory button] to select the date, each press will add one date, once the date was added to "31", the number will jump to initial number "01". press the Set button to confirm your selection and enter into the hour setting interface.

**Setting the hour**: On the interface of hour setting, the number of hour "such as 01" flashes, press the [Memory button] to select the hour, each press will add one hour, once the hour was added to "23", the number will jump to initial number "00". press the Set button to confirm your selection and enter into the minute setting interface.

**Setting the minutes**: On the interface of minute setting, the number of minute "such as 01" flashes, press the [Memory button] to select the minute, each press will add one minute, once the minute was added to "59", the number will jump to initial number "00". press the Set button to confirm your selection and enter the voice setting interface.

Note: If the time is not adjusted, the system displays the default time.

#### 8.2.3 Selecting the blood pressure unit

On the Voice setting interface (i.e. PR mode), press memory button to choose the unit between "mmHg" and "KPa". When the high and low blood pressure positions display 0, the unit is mmHg; when the high and low blood pressure positions display 0.0, it means the unit kPa. Press the [memory] key to change the unit. After selection, press the Set button to confirm the selection, press the Set button again to exit the setting mode.

#### 8.2.4 Setting Voice:

On the Voice setting interface (i.e. SP mode), press memory button to open or close the voice talking function. LCD display and flash "ON" means the sound function is on, and " OFF" indicates mute. After selection, press the Set button to confirm and enter the blood pressure unit selection interface

#### 8.2.5 Delete the stored data

In the shutdown state, short press the [memory button] key to enter the memory query mode, and then long press the [memory] key to clear the current user's memory data. (it can be selected the user by short pressing the setting key in the off state)

#### 8.2.6 Save the setting

After setting, press [On /off] button to save the setting

Remark: During the setting process, you can press the [On/off] button to save and exit the setting mode at any time.

#### 8.3 Measure blood pressure

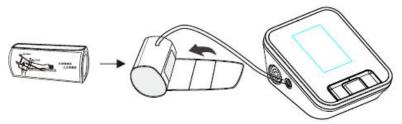
#### 8.3.1 Preparation before measurement

- In order to avoid affecting the accuracy of the sphygmomanometer, please do not eat, smoke or exercise before taking the blood pressure measurement. Please sit quietly for 10 minutes before taking the blood pressure measurement.
- 2) If you have any clothes on your arms, please keep them away.
- 3) Choose the hand that you want to take blood pressure measurement (usually the left arm), and ask you to use the same arm and the same part for measurement in the future.
- 4) The suitable arm circumference is 22cm ~ 32cm.
- 5) Try to measure your blood pressure regularly at the same time every day, because blood pressure changes with time.
- Factors affecting blood pressure measurement
  - a) If the user supports the arm hard, it may raise the blood pressure reading.

- b) f the cuff around the arm is lower than the horizontal height of the heart, the blood pressure will be higher. The correction method is: reduce 0.8 mmHg for each cm difference in vertical distance; on the contrary, if the cuff is higher than the horizontal height of the heart, add 0.8 mmHg for every 1 cm difference in vertical distance.
- c) Too loose or too tight cuffs can cause false readings.
- d) In different postures, different environments and different physical conditions, the measured blood pressure values will be different.

#### 8.3.2 Installation the cuff

1). Open the cuff, put one end of the cuff through the iron ring, and firmly insert the air pipe plug of the cuff into the sphygmomanometer host.



Cuff measurement range: 22cm-32cm

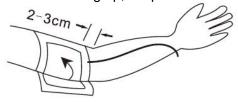
Before installing accessories, please confirm whether the specifications and model (Model number:M12115) of accessories are consistent with the original manufacturer's regulations. Please use the parts specified by our company to avoid affect the accuracy of test results. If necessary, please contact the seller or manufacturer at 0769 82913997.

#### 2). Wear Cuff

- a) Coil the arm strap to the exposed left arm, and the outlet of the hose should be aligned with the little finger on the palm.
- b) Tighten the arm band and fasten it. The arm band should not be rolled too tightly or too loose. It is most suitable to put a finger in it.
- c) When measuring, put your elbow on the table, palm up, relax, and keep the height of arm band and heart consistent.

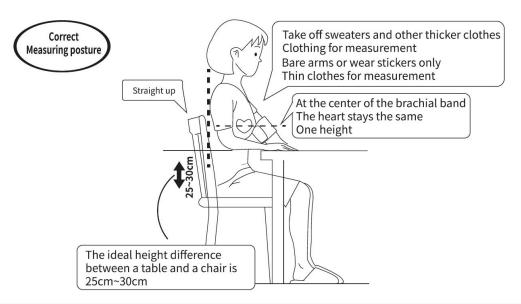


d) With the palm of the left hand facing up, wrap the arm band 2-3cm away from the joint.



#### 8.3.3 Sitting Correctly

- a. Please sit in a room with suitable temperature for measurement. Your body should be relaxed as much as possible and your sitting posture should be natural. You shall sit in a chair with your legs uncrossed and your feet flat on the floor. Sit with your back and arm being supported.
- b. Please keep the middle of cuff at the level of the right atrium of the heart as shown in the figure below, If the monitor is too high above your heart, your blood pressure will be artificially low. If the monitor is too low below your heart, your blood pressure will be artificially high.



c. Relax your arm and hand. Do not bend your arm back, clench your fist, or bend your arm forward.

#### 8.4 Taking a Measurement

After the armband has been appropriately positioned on the arm, you can start measuring:

#### 8.4.1 Press the [On/off] button.

All symbols appear on the LCD for 2s before starting the measurement. The full display of LCD is the same as chapter "5.2 LCD display". If the sound is turned on, the user will be reminded by voice, "attention! Please make sure that the bandage is at the same height as the heart part, do not move and speak, and start the measurement now".

#### 8.4.2 Start to measure

Remain still and do not move or talk until the entire measurement process is completed. The monitor will automatically measure your blood pressure according to the following procedure:

Measurement	Description
sequence	

1	After full display and voice broadcast, The "0" flashes continuously. When the flashing ends, the motor starts to inflate the cuff. LCD screen displayed as right fig.:	① M 147. 13
3	During inflation, the increasing cuff pressure is continually displayed by LCD.	□ M 14% 13 □ D D D D D D D D D D D D D D D D D D D
4	After automatically reaching an individual pressure, the pump stops and the pressure slowly falls. The cuff pressure is displayed during the measurement and Heartbeat symbol "" flashes.	(1) M 14% 13  KPa mmHg  KPa mmHg  KPa mmHg
6	When the measurement has been concluded, the measured systolic and diastolic blood pressure values, as well as the pulse value will be displayed.	1 M 38788

#### Remark:

- According to different blood pressure fluctuations of each person, the monitor will automatically pressurize to the pressure value suitable for you and stop pressurizing.
- Please keep still during the whole measurement process. Do not speak or move your arm.
- After the measurement, the monitor will automatically display and store them.
- If the voice function was opened and finished measurement, the voice will be talking as "Your diastolic blood pressure is XX mmHg, systolic blood pressures is XX mmHg, pulse rate is XX

beats per minute. According to the standards of the world health organization, your blood pressure is normal (high / low / minor high / minor low / If your blood pressure continues to be high, please consult your doctor). Thanks for using and wishes you have a good health."

- If you can't wrap the cuff around the left hand, wrap it around the right arm.
- The blood pressure can differ between the right arm and the left arm, and the measured blood pressure values may be different. We recommend to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician as to which arm to use for your measurements.
- Repeated measurement will lead to arm congestion and affect the measurement results. The improvement method: hold the left hand high and hold the first several times, or take off the cuff and rest for at least 5 minutes, and then measure.

#### 8.4.3 Turn off

Press the [On/off] button to turn off the monitor.

The monitor will shut down automatically in about 35 seconds without any operation after the measurement.

#### Note:

If it is necessary to interrupt a blood pressure measurement for any reason (e.g the patient feels unwell), the [On/off] button can be pressed at any time. The device then immediately lowers the cuff pressure automatically. In addition, you can also stop by removing the cuff in case of emergency.

#### 8.5 Blood pressure prompt function:

The monitor has the function of blood pressure prompt, which can indicate the corresponding blood pressure range through the blood pressure prompt bar:

Display of Prompt bar	Systolic blood pressure (SYS)	Diastolic blood pressure (DIA)
	<100mmHg	<60mmHg
	100mmHg-119mmHg	60mmHg-79mmHg
	120mmHg-139mmHg	80mmHg-89mmHg
	140mmHg-159mmHg	90mmHg-99mmHg
	160mmHg-179mmHg	100mmHg-109mmHg
	≥180mmHg	≥110mmHg

#### 8.6 Blood pressure classification for adult

Blood pressure classification according to 2017 Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults, there is four levels for blood pressure classification and two hypertensive crises: emergencies and urgencies as following:

BP classification		Systolic (mmHg)	Diastolic(mmHg)
BP classification	Normal blood pressure	<120	And <80
Classification	Elevated blood pressure	120-129	And <80
	Hypertension: Stage 1	130-139	Or 80-89
	Hypertension: Stage 2	≥140	Or ≥90
hypertensive crises	Hypertensive urgency	>180	Or >120
CHOOC	Hypertensive	>180+ target	Or >120+ target
	emergency	organ damage	organ damage

**Remark:** Contact your physician for specific information about your blood pressure. Self diagnosis and treatment which use measured results may be dangerous. Follow the instructions of your physician or licensed healthcare provider.

#### 8.7 Prompt function of irregular heartbeat

This monitor can detect the situation of irregular heartbeat. In the measuring process, if the appearance of this "your symbol signifies that an irregular heartbeat was detected, it means that the result may deviate from your normal basal blood pressure. This indicator is only a caution, it is important that you be relaxed, remain still and do not talk during measurements. Please repeat the measurement.

An irregular heartbeat rhythm is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while your monitor is measuring blood pressure. If the "^\" symbol appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend you to consult with and follow directions of your physician.

#### Note:

If you have severe arrhythmia, it is very likely that you will not be able to measure the blood pressure.

#### 8.8 Voice broadcast function

During the measurement, if you turn on the voice function, the monitor will broadcast the following content:

#### Voice broadcast

Triggers for making the	Content of Voice broadcast
-------------------------	----------------------------

voice broadcast		
Before measuring	attention! Please make sure that the bandage is at the same height as the	
	heart part, do not move and speak, and start the measurement now"	
After measuring	Your diastolic blood pressure is XX mmHg, systolic blood pressures is XX	
	mmHg, pulse rate is XX beats per minute. According to the standards of	
	the world health organization, your blood pressure is normal (high / low /	
	minor high / minor low / If your blood pressure continues to be high, pleas	
	consult your doctor). Thanks for using and wishes you have a good health.	
Low battery	There is insufficient power. Please replace the battery.	

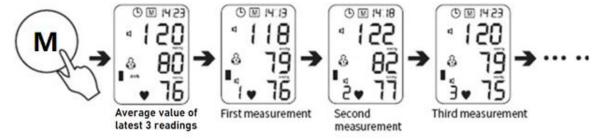
Note: XX is the voice content corresponding to the measured actual value.

#### 8.9 Memory function

#### 8.9.1 Query function

After each measurement, the monitor will automatically store the measured data. View memory value:

- Follow chapter 8.2 to select the user group (user 1 or user 2) that needs to view the memory value.
- At the power off status (standby mode), press [Memory] button to enter the memory query mode.
- The LCD shows the average value of the latest three measurements. Press the memory button step by step to view the measured values of each time in sequence.



- If no measurement before, the measurement data is "--\--";
- When there are less than 3 measurements, the latest set of measurements will be displayed after pressed [Memory] button.

**Note:** This monitor automatically stores each result. Each unit stores 99 sets measurements for 2 users, totally 198 sets (User 1 and 2).

#### 8.9.2 Clear the memory

- When the memory capacity is full, the old measured data will be covered by new data.
- **Delete single group memory:** Press the [Memory] button to select the memory group to be deleted, press and hold the [Set] button for 5 seconds, and "DEL" will display on the top right of the LCD, and then press the [Memory] button again to delete the current memory group.
- Delete all memories: In the power off status (standby mode), press and hold the [Memory] button

for 3 seconds, and then hold the [On/off] button, after the " EE " appears on the screen, release the

[Memory] button and [Set] button at the same time to delete all memory groups.

#### 9. Clean and Maintenance

#### 9.1 Cleaning

#### 9.1.1 Clean the monitor:

- 1) Keep the monitor and cuff in the giftbox when no use.
- 2) Make sure the monitor is off prior to cleaning.
- Clean the monitor with soft wet cloth with neuter cleaner. Do not use any abrasive or volatile cleaners.
- 4) Never immerse the monitor or any component in water.

Note: The soft wet cloth should not be squeezed out of water to avoid water enter inside the monitor when cleaning.

#### 9.1.2 Clean the cuff:

- 1) Pull out the cuff from the monitor.
- 2) Using a spray bottle, moisten a soft cloth towel with the bleach or detergent mix until it is fully saturated. Squeeze any excess moisture from the cloth to avoid any dripping or potential oversaturation of the cuff.
- Wipe all surfaces of the blood pressure monitor cuff thoroughly, making sure to clean the inside and outside of the cuff.
- 4) Using a dry cloth, gently wipe away any excess moisture they may remain on the blood pressure cuff. Lay the cuff flat in an unrolled position and allow the cuff to air dry.

#### 9.2 Maintenance

- 1) We do not authorized any institutions or individuals to maintain and repair of the product. If you suspect that the products have any questions, please contact the manufacturer or distributor to handle the case.
- 2) The user must not attempt any repairs to the device or any of its accessories. This may cause an inaccurate reading. Please contact the retailer for repair.
- 3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

#### Remark:

- Do not to twist the cuff.
- Do not press the on/off button before wear the cuff in a right way.
- Do not apart or refit the monitor and cuff.
- Do not drop the monitor.
- > Please charge it once when it is not used for a long time (more than 1 month).

#### 9.3 Calibration

The blood pressure monitor is initially calibrated at the time of manufacturing. If this monitor is used according to the use instruction, periodic re-adjustment is not required. If any time your doubt the accuracy of measurement, please contact distributor or manufacturer, the contact information see the last page to get any supports.

The service life (i.e.working life) of the monitor is 5 years. Once the service life of monitor was exceeds 5 years, please change a new blood pressure monitor.

#### 9.4 storage

Keep your monitor in the giftbox when not in use.

• Store your monitor in a clean, safe location.

Do not store your monitor:

- · If your monitor is wet.
- In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach. Please store the products according to the requirements of "storage condition" in chapter "11.Technical specifications".
- · In locations exposed to vibrations or shocks.

## 10. Error Messages and Trouble shooting

In case of any fault (or abnormal condition) during use, it can be eliminated according to the following inspection points:

Display/Problem	CAUSE	CORRECTION
The LCD display ERR1	The arm cuff is not applied	Apply the arm cuff correctly then take
	correctly	another measurement. Refer to chapter
		8.3.
	Air is leaking from the arm	Check if the arm cuff connection is good
	cuff	and there is no air leak.
		If the situation continues, Contact
		manufacturer or distributor
The LCD display ERR2	Signal interference	Remove anything that may interfere the
or ERR6:		pulse detection, such as cloth, loud
		sound and electromagnetic wave
		emitted from other electronic
		equipment, etc. Make sure no
		other electrical device is within 30 cm.
The LCD display ERR3:	Abnormal measurement	Please measure again.
	results	
The LCD display ERR4:	The armband is too loose or	Apply the arm cuff correctly then take

leaking air (the pressure is	another measurement. Refer to chapter	
less than 30mmhg in 10	8.3.	
seconds)	If the situation continues, please	
	contact manufacturer or distributor	
The air tube inside the	Please contact manufacturer or	
device is blocked	distributor	
The arm cuff is overinflated	Do not touch the arm cuff while taking a	
exceeding 300mmHg.	measurement.	
Batteries are low.	Refer to Chapter 7.	
Bad Device	Please contact the manufacturer or	
	distributor	
Blood pressure varies constantly. Many factors including stress, time		
of day, and/or how you apply the arm cuff, may affect your blood		
pressure. Review chapter 3 a	and chapter 8.	
The battery is exhausted	Replace the battery with a new one	
The battery is exhausted	Replace the battery with a new one	
Incorrect battery installation	Re-install the batteries and ensure that	
	the positive and negative poles are not	
	reversed	
Press the On/off button to turn the monitor off, then press it again to		
take a measurement. If the problem continues, Please charge.		
If the problem still persists, please contact manufacturer or distributor.		
	less than 30mmhg in 10 seconds)  The air tube inside the device is blocked The arm cuff is overinflated exceeding 300mmHg. Batteries are low. Bad Device  Blood pressure varies constated of day, and/or how you apply pressure. Review chapter 3 at The battery is exhausted  The battery is exhausted Incorrect battery installation  Press the On/off button to turtake a measurement. If the pressure is a measurement. If the pressure is a measurement.	

Note: please contact the distributor or manufacturer if you can't solve the problem, do not dissemble the unit by yourself.

# 11. Technical specifications

Name	Arm type Blood pressure monitor	
Model	KWL-B01L	
Measurement method	Oscillometric method	
Measurement site	Arm	
Operating conditions	Temperature: 5℃~40°C, Relative humidity≤85%RH,	
	Atmospheric pressure range: 70~106kPa	
Storage conditions	Temperature: -20℃~+55°C, Relative humidity≤93%,	
	Atmospheric pressure range: 50-106kPa	
Cuff pressure display range:	0~300 mmHg	
Measuring range:	Blood Pressure: 0mmHg~295mmHg;	
	Pulse rate: 40 to199 beats/min	
Accuracy:	Blood Pressure: ± 3 mmHg;	
	Pulse: ± 5 % of display reading	

Measuring resolution:	1 mmHg	
Inflation	Automatic by electric pump	
Deflation	Automatic rapid deflation	
Memories recall	Automatically stores the last 99 measurements for 2	
	users (total 198)	
Display	72X63(mm) LCD Display	
Dimensions of main unit	106 (W) x 126 (L) x 65(H) mm	
Weight	About 210g (batteries are not included)	
Battery	DC 3.7, ( Lithium batteries)	
Switch off	Automatically turn off after 35 seconds	
Measurable arm	22cm~32cm	
circumference		
Protection against electric	Internally powered ME equipment	
shock		
Service life (i.e. working life)	5 years	
Shelf life	No shelf life requirement	
Ingress of waterproof	IP22	
Applied part	Type BF (arm cuff)	
Software version	KWL-B01L-062-V1.2	
No Sterilize requirement		
Not category AP / APG equipment		
Mode of operation: continuous		

#### Note:

This monitor is clinically investigated according to the requirements of ISO 81060-

2:2018. In the clinical validation study, 6 subjects were used for determination of diastolic blood pressure.

This monitor has not been validated for use on pregnant patients.

# 12. Disposal



Dispose of at public collection point in the EU countries - 2002/96/EC WEEE Directive.

Dispose of your monitor and other components according to applicable local regulations.

Unlawful disposal may cause environmental pollution.

Disposal of used batteries should be carried out in accordance with local regulations.

## 13. Electromagnetic Compatibility

#### Statement:

The equipment with following ESSENTIAL PERFORMANCE is intended used in Home healthcare environment and professional healthcare facility environment.

#### **Essential Performance:**

According to IEC 80601-2-30: 2018, we have conducted EMC testing base on the following essential performance:

 Change in the reading for the measurement of the cuff pressure at any point of the nominal measurement range shall not be greater than 2mmHg (0.3kpa) during and after exposure to non-transient phenomena and after exposure to transient phenomena.

If Essential Performance is lost or degraded due to electromagnetic disturbances, this may result in inaccurate measurement and lead to mislead patients, please read below important information before to avoid possible electromagnetic disturbances.

#### Warning:

- Using cell phone or microwave oven, HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction or lead to loss of essential performance, which means that the measurement accuracy will be affected.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor.
   Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, transducers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

#### Caution:

- Security, antitheft, and radiofrequency identification (RFID) devices. Some electromagnetic anti-theft systems and metal detectors such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect the monitor. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect the monitor. Please do not use monitor near these places. If you have to go through one of these devices, turn off your monitor. Before each usage, checking the status of your monitor to ensure it can operating normally.
- Using short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) and electrocautery devices near this product may cause malfunction or lead to loss of essential performance, please do not use monitor near these equipment. Before each usage, observing the device to verify that they are operating normally.

Guidance and manufacture's declaration – electromagnetic emission			
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.			
Emission test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emission CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments other than	
Harmonic emissions IEC 61000-3-2	Not applicable	domestic and those directly connected to the public low-voltage power supply network that supplies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	buildings used for domestic purposes.	

Guidance and manufacturer's declaration — electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or			
the user of the device s	hould assure that it is u	used in such an environment	
Phenomenon	Basic EMC standard or test method	Professional healthcare facility environment	Home healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	
Radiated RF EM fields	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80%AM at 1kHz or 2Hz	10V/m 80MHz-2.7GHz 80%AM at 1kHz or 2Hz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances".	
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m; 50 Hz or 60Hz	

Recommended separation distances between			
portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.			
The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum			
distance between portable and mobile RF communications equipment (transmitters) and the device as			
recommended below, according to the maximum output power of the communications equipment.			
Rated maximum	Separation distance according to frequency of transmitter		
(m)			

	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless						
	communications equipment					
Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM <sup>c)</sup> ±5kHz deviation 1kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217Hz	0.2	0.3	9
810		GSM800/900				
870	1	, TETRA 800,		2	0.3	28
930	800-960	CDMA 850,				
1720		GSM1800;				
1845		CDMA 1900;	Pulse			
1970	1700- 1990	GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	modulation b) 217Hz	2	0.3	28
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217Hz	2	0.3	28
5240 5500 5785	5100- 5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217Hz	0.2	0.3	9

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) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) 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.

## 14. Warranty

Thank you for purchasing the product! To ensure the excellent quality of this product, we will provide you with free maintenance service if you find any performance failure caused by manufacturing process or raw materials. When purchasing, please fill in the warranty card and ask for the Purchase voucher from the purchasing shop as the warranty voucher.

#### Warranty

#### 1. First, in order to provide better after-sales service to consumers, we promise:

- In case of any performance failure of the product within 7 days from the date of sale, the
  consumer may choose to return, replace or repair the product. We will provide customer
  with the return, replacement or free maintenance service according to the requirements of
  the consumer.
- 2) In case of performance failure within 8 to 15 days from the date of sale, consumers can choose to replace or repair the product free of charge.
- 3) Within one year from the date of sale, if the product is used according to the correct method, our company will provide maintenance free of charge in case of performance failure. Within two years from the date of sale, if the product is used according to the correct method, in case of performance failure, our company will provide maintenance and only charge the material fee.
- 4) For the above product return cycle, we will send the repaired products to consumers within 15 working days from the date of receiving the defective products returned by customers. If the product can not be repaired during the warranty period, we will replace the same or upgraded product for the customer.

#### 2. The following situations do not apply to our Warranty, including but not limited to:

- 1) Artificial damage to products, including: improper use, abuse, negligence, or defect/damage caused by not operating according to the user manual.
- 2) Products repaired, debugged, replaced or modified by personnel not authorized by the company's service center.
- 3) Not our products.
- 4) Products used for more than two years from the date of sale.
- 5) The company will not be responsible for any bad or damage caused by natural disasters, force majeure, unforeseen events and other factors beyond the control of the company.

#### 3. Maintenance cost

- 1) During the warranty period, our company will provide free maintenance for the products that are confirmed to be within the warranty scope by our maintenance personnel.
- 2) Beyond the warranty period, our company will provide free maintenance for the products with non important components damaged. For the replacement of important components, we will charge the material cost of important components.
- 3) Return to factory for repair: consumers bear the cost of return logistics.

#### Warranty card

Warranty card		
Product model:	product SN No.:	

Version Number: 1.0 KWL-ABP-01-12

Sales shop:	Purchase date:
Customer name:	Customer telephone:
Customer postcode:	Customer email:
Customer address:	
Fault description:	



# Manufacturer information:

Company name: Dongguan Kang Wei Le Electronic Science and Technology Co., Ltd.

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