

Automatic Arm Electronic Blood Pressure Monitor

Instructions for use

Thank you for choosing LEPU products.

Dear user:

Thank you for choosing this product!

Foreword:

At present, about 270millionpeople around the world have hypertension, one of the diseases that seriously affect people's health. Massive clinical practice and medicine research over decades have brought up effective measures for the prevention and treatment of hypertension, but due to the “low awareness rate, low medication rate and low control rate” , hypertensioncontributes to a large portion of disability and mortality very year.If you have hypertension, the WHO recommended checking your blood pressure regularly, and taking medication to control the blood pressure. You can live with ease if your blood pressure can be controlled at the reasonable level. Monitor your blood pressure, and follow the doctor’ s order on medication to prevent complications, that is all you need to do to enjoy your life like anyone who is not suffering hypertension. If your blood pressure is stable, it is recommended to measure it once a day; if your blood pressure fluctuates, measure it three times a day or follow the doctor's advice. These simple precautions can greatly reduce the potential hazards posed by hypertension.

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Chapter1 Chapter 1 Safety Precautions

●1.1 Warnings

- Do not make self–diagnosis and self–treatment based on the measurement results of this device. Seek and follow the doctor's advice.
- Patients with severe blood circulation disorders and blood diseases should use this device under the guidance of a doctor.
- Patients who use a pacemaker should use this device under the guidance of a doctor.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation ,weak pulse or irregular heart rhythm; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre–eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading. Patients with these conditions should use this device under the guidance of a doctor.
- When the airbag is over–inflated for a long time, there may be risks.
- Do not use this monitor on infants, toddlers, children (less than12 years old) or persons who cannot express themselves.
- Do not apply the arm cuff on your arm while on an intravenous drip or blood transfusion.
- Do not use this monitor in oxygen rich environments or near flammable gas.
- Do not use this monitor in oxygen rich environments or near flammable gas.
- Do not use it for purposes other than measuring human blood pressure.
- Only use the standard cuff that comes with the main unit; otherwise the measurement may be inaccurate. With a cuff located upon the user's upper arm; 1/2 inch above the elbow over the artery as indicated on the cuff.

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- Repeated measurements may cause symptoms such as hyperemia and swelling in patient arm.
 - Please use it in the operating and storage environment described in this manual; otherwise the measurement may be inaccurate.
 - the application of the CUFF over a wound, as this can cause further injury
 - Do not use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
 - Only use cables that comes as spare parts of this device.
- Other accessories and cables may result in higher electro-magnetic emission or lower electromagnetic immunity.
- To help avoid strangulation, keep the air tube and AC adapter cable away from infants, toddlers and children.
- AC Adapter (optional accessory) Handling and Usage
- 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.
- Battery Handling and Usage
- Keep batteries out of the reach of infants, toddlers and children.
 - Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
 - 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.

















- Use of accessories, transducers and cables 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.”
- 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

●1.2 Cautions

- The blood pressure shall only be interpreted by the doctor. Self-judgment and self-treatment made by the patient based on the measurement result may pose danger to the patient.
- Do not disassemble, repair or modify the device or cuff by yourself.
- Do not expose this device to high temperature, humidity, dust and direct sunlight.
- Do not drop or subject this monitor to strong shocks or vibrations.
- Do not crease the arm cuff or the air tube excessively.
- Only use the arm cuff on persons whose arm circumference is within the specified range of the cuff.
- Only use the approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect readings.
- This monitor complies with IEC 80601 –2–30:2018.
- Do not fold or kink the air tube while taking a measurement. This may cause an injury by interrupting blood flow.
- Consult with your physician before using this monitor on an 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.
- Consult with your physician before using this monitor if you have had a mastectomy or lymph node clearance.
- Do not take measurements more often than necessary because bruising, due to blood flow interference, may occur.

- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- Do not use this monitor on an injured arm or an arm under medical treatment.
- 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 blood pressure measured by this device is equivalent to that obtained with auscultation method, with its error meeting the requirements of ISO 81060-2:2018
- This device meets the relevant requirements of the IEC 60601-1-2. standard on electromagnetic compatibility.
- The user should install and use this device according to the information about electromagnetic compatibility provided in the accompanying document.
- Portable and mobile RF communication equipment may affect the performance of this product. When using this product, avoid strong electromagnetic interference (for example, keep it away from mobile phone or microwave oven).
- For the electromagnetic compatibility guide and manufacturer's declaration, refer to the section EMC.
- According to the safety level when used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide, this device is non-AP/APG type.
- The device has passed rigorous accuracy test in factory. It is generally recommended to calibrate the device every two years. Do not perform any maintenance by yourself.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State.

1.3 Symbol description

| Symbol | Description | Symbol | Description |
|---|--|---|---|
|  | Caution |  | Upward |
|  | Keep dry |  | Direct current |
|  | Type BF applied part |  | Fragile, handle with care |
|  | Manufacturer Limit four-storey |  | Date of manufacture No step |
|  | Limit four-storey |  | No step |
|  | Disposal instructions for electronic devices |  | Refer to instruction manual |
|  | CE Mark And Identification Number Of Notified Body |  | Authorized Indicates the authorized representative European Community |
|  | MR unsafe |  | Medical Device |

●1.4 Environmental protection

The company designs and manufactures this device in accordance with the requirements on safety and environmental protection. If the product housing is not removed, when the equipment is used in a proper way, this device will not cause any harm to personnel or the environment. Under conditions permitted by laws or regulations, if materials that may cause harm to the environment must be used, they must be disposed of properly as specified by laws and regulations.

Warning: 

- Do not dispose of waste generated by this device together with industrial or household waste.
- In accordance with the requirements of laws and regulations on environmental protection, the waste generated by this device and the scrapping of this device at the end of its service life should be handled properly.
- Reusable materials can be recycled by a qualified recycling company to reduce environmental pollution. For details, please contact our company's after-sales service department or dispose of them following the rules of your local waste management authority.

Chapter 2 Description and Structure

●2.1 Instructions for use

· 2.1.1 Description of device

The Automatic Arm Electronic Blood Pressure Monitor, including LBP70C and LBP70D, can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult patient with arm circumference ranging from 22 cm to 32 cm (8.7 inches to 12.6 inches) or 22cm to 42cm (8.7 inches to 16.5 inches) by the oscillometric technique. User can select the blood pressure unit mmHg or KPa.

· 2.1.2 Medical indications

The device is a digital monitor intended to measure the diastolic, systolic blood pressures and pulse rate in adult patient population by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the upper arm of which the circumference includes 22 cm to 32 cm (8.7 inches to 12.6 inches) or 22cm to 42cm (8.7 inches to 16.5 inches). It can be used in hospital environment or at home.

· 2.1.3 Disease or Medical Condition

There is no specific disease or medical condition, and it is only intended for diastolic, systolic blood pressure and the pulse rate measurement.

· 2.1.4 Intended patient population

The device can be used for adult, and not intended for pregnancy and preeclampsia population.

· 2.1.5 Intended uses

The device is intended to be used by physician, nurse, professional caregiver or layperson who can distinguish body part and is with basic read and understand capacity.

●2.2 Clinical Benefits to be Expected

Accurate blood pressure level diagnosis.

●2.3 Residual Risks

· You may experience the effects of incorrect measurement values, such as hypotension, stroke, even threat to life, which is mainly caused by unconscious mis-operation, but the accuracy of product has been verified and validated based non-clinical test and clinical data, so such circumstance rarely occurs.

· You may experience congestion, feel unwell or peripheral vascular block due to the malfunction of cuff, but the cuff has been tested according to IEC 80601-2-30:2018, so its basic safety and performance have been verified, so such circumstance rarely occurs.

· The product may cause skin allergy or irritation due to different constitution of the individual, its biocompatibility has been verified by test according to ISO 10993 series standards, so such circumstance rarely occurs.

· The product may cause cross infection for it is intended to be reused, we have included the current cleaning method in section 8 of this manual, so such circumstance rarely occurs when you strictly follow the instructions.

· You may be burned, even death due to malfunction of this active device, it has been designed and tested according to IEC 60601-1:2005+A1:2012, so its basic safety and essential performance have been verified, so such circumstance rarely occurs.

· The product may cause you injury when its surface is rough or with sharp corner/edges, it has been designed and tested according to IEC 60601-1:2005+A1:2012, so its basic safety and essential performance have been verified, so such circumstance rarely occurs.

· The product may cause environment pollution when it is disposed irregularly, we have included instructions of disposal in section 1.4 of this manual, so such circumstance rarely occurs when you strictly follow the instructions.

The product is equipped with broadcast function, which is indicated as “△” on the display, if it causes inconvenience to you or makes you feel hearing impairment, you can turn off this function according to the method in section 3.3 of this manual. At the same time, the sound level of the product has been designed and controlled based on IEC 62366-1:2015 and EN 60601-1-6: 2010+A1:2015, to ensure it can be heard and not cause much noise to the user, so such circumstance rarely occurs.

●2.4 Composition

The monitor consists of the PCBA, pressure transducer, operation keys, pump, control valve, LCD screen, cuff, batteries and optional accessory AC adapter. The two models have the same intended use, working principle, measuring range, accuracy, cuff, component and appearance. They are only different in power supply. Model LBP70C is powered by 4 AA alkaline batteries or AC adapter, while model LBP70D is powered by rechargeable lithium-polymer battery or AC adapter.

●2.5 Monitor and Cuff

2.5.1 Illustration of Monitor

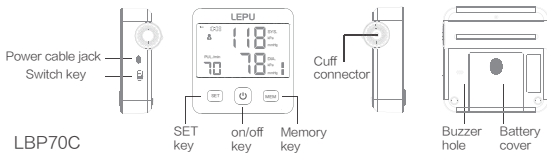


Figure 1 Illustration of LBP70C

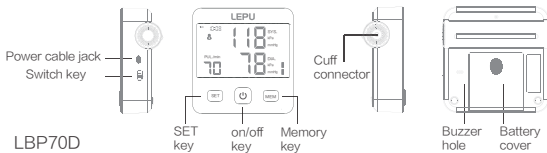


Figure 2 Illustration of LBP70D

2.5.2 Illustration of Cuff

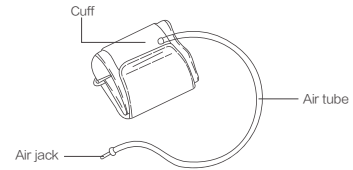


Figure 3 Illustration of Cuff

●2.6 Display and symbols

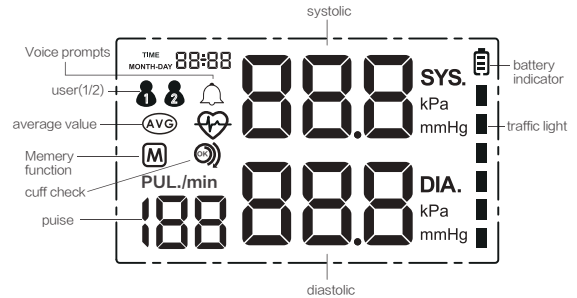


Figure 4 Display and symbols

●2.7 Packing list

LBP70C

| Item | Quantity |
|------------------------------|-------------|
| 22-42 cm (8.7" -16.5") cuff | 1(Standard) |
| 22-32 cm (8.7" -12.6") cuff | 1(Optional) |
| 4 × 1.5V AA battery | 1 |
| Power supply cable | 1 |
| User manual and certificate | 1 |
| Main unit | 1 |
| Adaptor | 1(Optional) |

LBP70D

| Item | Quantity |
|------------------------------|-------------|
| 22-42 cm (8.7" -16.5") cuff | 1(Standard) |
| 22-32 cm (8.7" -12.6") cuff | 1(Optional) |
| Power supply cable | 1 |
| User manual and certificate | 1 |
| Main unit | 1 |
| Adaptor | 1(Optional) |



Chapter 3 Preparation before Use

●3.1 Installing/replacing batteries

Install the batteries before the first use. The battery compartment is located on the back of the device. Install the batteries in the following steps (Figure 5):

- (1) Open the battery cover.
- (2) Insert the battery and make sure that the + and - poles of the battery fit the battery holder.
- (3) Close the battery cover.
 - Install 4 AA alkaline batteries.
 - Use the same type of batteries. Do not mix old and new batteries.
 - When this device is not used for a long time, remove the batteries.
 - After replacing the batteries, reset the time, date, etc.

●3.2 Low battery indication

●When the “” symbol is displayed on the screen, the blood pressure meter can still be used but the battery is running low. When the “” symbol is displayed on the screen, the battery is depleted. Replace the batteries before performing new measurements.

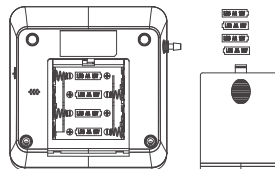


Figure 5

Skip the steps above if you have purchased LBP70D model, which is powered by a lithium battery.

●3.3 Setting unit and voice switch

In the power-off state, press the [Setting] button once to enter the setting mode:

- (1)Setting unit: when mmHg or kPa is flashing (in Figure 7), press the [Memory] button to switch between mmHg and kPa, and then press the [Setting] button to confirm the unit and enter the voice switch setting interface.
- (2)Setting voice switch: when ON or OFF is flashing (Figure 8), press the [Memory] button to switch between ON and OFF to turn on /off the voice announcement, and press the [Setting] button to enter the year setting interface.

●3.4 Setting date and time

- (1) Setting date and time: when the year number is flashing (Figure 9), each time you press the [Memory] button, the number will increase by 1; when the desired year is set, press the [Setting] button to confirm and enter month setting. Use the same method to set up the month/day/hour/minute (Figure 10/11).
- (2) When the hour/minute setting is completed, press the

[Setting] button to save the settings and shut down the device.

Note: during the setting process, you can press and hold the [ON/OFF] button to exit the setting mode. The completed settings will be saved before the device shuts down.

●3.5 Select the user

Switching user mode: switch between user mode 1 or user mode 2 by sliding the switch on the right side of the main unit.



Figure 6



Figure 7



Figure 8

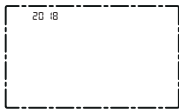


Figure 9

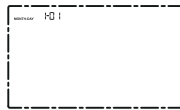


Figure 10

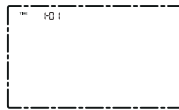


Figure 11

Chapter 4 Measuring Blood Pressure

● 4.1 Preparing to take a measurement

In order to ensure the accuracy of the measurement results, follow the recommendations listed below:

- Do not eat, drink, smoke or exercise before the measurement. Try to have a rest of 10 minutes before taking the blood pressure. Please keep relax as much as possible and not talk during the measurement procedure
- Do not move your arm and remain still until the entire measurement process is completed. Avoid measuring when you are emotionally stressed.
- Do not wear thick clothing. Expose the arm for about five inches above the elbow. Remove any restrictive clothing

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from the arm.

- Take a rest of at least 30 seconds between two measurements, so that the blood pressure could return to the state before measurement. You can extend the waiting time according to your physical conditions.
- Try to measure blood pressure regularly at the same time of the day, because blood pressure changes naturally many times a day.

●4.2 Common errors

Note: Comparable blood pressure measurements always require the same conditions. Conditions should always be quiet.

- All efforts by the user to support the arm can increase blood pressure. Make sure you are in a comfortable, relaxed position and do not flex any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
- If the arm artery lies considerably lower or higher than the heart, an erroneously high or low blood pressure will be measured. Each 15 cm (6") difference in height between your heart and the cuff results in a measurement error of 10 mm Hg.
- Cuffs that are too narrow or too short result in false measurement values. Selecting the correct cuff is extremely important. Cuff size is dependent upon the circumference of the arm (measured in the center). The permissible range is printed on the cuff.
- A loose cuff or a sideways protruding air pocket causes false measurement values.
- With repeated measurements, blood accumulates in the arm, which can lead to false results. Consecutive blood pressure measurements should be repeated after a 1 minute pause or after your arm has been held up in order to allow the accumulated blood to flow away.

●4.3 How to use the cuff

Arm circumference should be measured with a measuring

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tape in the middle of the relaxed upper arm and make sure the maximum measurement size of the selected cuff must be larger than the arm circumference

- (1) Insert the cuff air jack into the port on the main body.
- (2) Wrap the cuff around a bare arm (roll up your sleeve or wear short sleeves). The air outlet of the tube should be on the extension line of the middle finger.
- (3) It is recommended to take blood pressure on your left arm since the arm is more relaxed, but you can also use your right arm.
- (4) The cuff should not be too loose or too tight. It is appropriate to leave a finger's distance between the cuff and arm. Keep the bottom of the cuff 1cm~2cm above the elbow.

- Do not bend the cuff and air tube forcefully.
- When removing the air tube from the main body, hold the connector rather than the tube.
- Do not inflate the cuff before wrapping the cuff around your arm.
- If the cuff is leaking, replace it in time.
- In order to measure blood pressure accurately, use the cuff provided by the manufacturer. Non-original parts may cause measurement error.

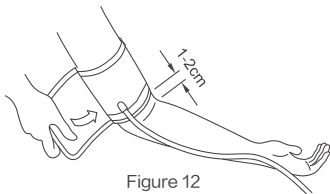


Figure 12

Comment

If it is not possible to fit the cuff to your left arm, it can also be placed on your right arm. However, all measurements should be made using the same arm. Comparable blood pressure measurements always require the same conditions (relax for several minutes before a reading).

4.4 Measurement posture

As shown in the figure below, the cuff should remain at heart level for accurate blood pressure reading. Sit upright and keep your shoulder and arm in relaxed position. Do not move your body or arm.

- (1) comfortably seated
- (2) legs uncrossed,
- (3) feet flat on the floor,
- (4) back and arm supported
- (5) middle of the cuff at the level of right atrium of the heart

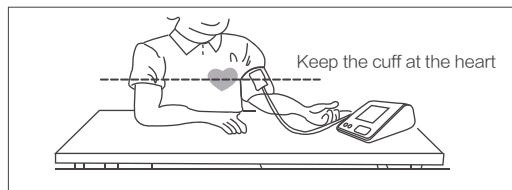


Figure 13

●4.5 Measuring blood pressure

After wrapping the cuff properly, you can take your blood pressure with the following steps (mmHg is used in this example):

- (1) Press the [ON/OFF] button once to select User 1 or User 2, referring to the section 3.5 Select the user. All symbols in the LCD display will be lit for 2 seconds.
- (2) The inflation process starts. The current pressure value is displayed at the low-pressure position, with the pressure rising gradually (Figure 14).
- (3) When the inflation pressure reaches the maximum value, the inflation motor stops working and the pressure will be released in steps. During the measuring process, the air pressure in the cuff is displayed on the LCD display (Figure 15).
- (4) When the pulse rate is detected, a flashing symbol "♥" appears on the LCD display (Figure 15).

(5) After the measurement is completed, the systolic pressure, diastolic pressure, pulse rate and unit are displayed on the screen, and they are also saved to memory. You will hear the voice announcement of the measurement results if you have turned on the voice switch, as shown in Figure 16. A colored column on the right of the screen indicates the pressure levels, which are defined in Figure 18.

(6) If you want to take another measurement, short press the [ON/OFF] button once. Long press the [ON/OFF] button to shut down. If there is no operation, the measurement result is displayed for 1 minute before the device automatically shuts down. It is recommended to take 3 times of blood pressure measurement in a row, with an interval of about 30s between measurements. After three measurements are completed, press the [Memory] button once to view the average value of the measurements (Figure 17).



Figure 14



Figure 15



Figure 16



Figure 17

⚠ Note:

- Do not make self-judgment based on the measured results. Consult a doctor to explain the measured blood pressure and accept the doctor's guidance.
- A colored column on the right of the screen indicates the pressure levels, which are defined in Figure 18. The following standards for assessing high blood pressure (in adults) have been established by the 2018 ESC/ESH Guidelines for the management of arterial hypertension.

- If you experience any discomfort during measurement, such as when the airbag is over-inflated, press the [ON/OFF] button to stop the measurement and turn off the device immediately.
- Repeated measurements cause arm hyperemia, which affects the measurement result. You can take off the cuff and take a rest of 30s before another measurement.

| | | |
|--------|--|--|
| Red | | Systolic pressure \geq 180 mmHg and/or diastolic pressure \geq 110 mmHg |
| | | 179mmHg \geq systolic pressure \geq 160 mmHg and/or 109 mmHg \geq diastolic pressure \geq 100 mmHg |
| Yellow | | 159 mmHg \geq systolic pressure \geq 140 mmHg and/or 99mmHg \geq diastolic pressure \geq 90 mmHg |
| | | 139 mmHg \geq systolic pressure \geq 130 mmHg and/or 89 mmHg \geq diastolic pressure \geq 85 mmHg |
| Green | | 129 mmHg \geq systolic pressure \geq 120 mmHg and/or 84mmHg \geq diastolic pressure \geq 80 mmHg |
| | | Systolic pressure $<$ 120 mmHg and/or diastolic pressure $<$ 80 mmHg |

Figure 18

●4.6 Memory value

1. View measurement values

This device can save 90 sets of measurement values for 2 users each. You can view the previous measurement results.

(a) Press the [Memory] button in the power-off state to enter the Memory mode. The average values of the last three sets of measurement results and the symbol “” are displayed on the screen (Figure 19).

(b) Press the [Memory] button again. The LCD screen displays the serial number and the date of the latest set of measurement results for about 1 second (Figure 20), and then displays this set of measurement results (Figure 21).

(c) Repeat step b) to display the earlier memory data in sequence. You can also view the later memory date in sequence by pressing the [Setting] button.



Figure 19



Figure 20



Figure 21

2. Deleting data

Before you delete the data saved on this device, make sure the data is not useful in the future. The best practice is to keep a written record of the measurement results over time which is useful when you see your doctor. Data can be deleted by the following operations.

(a) Press and hold the [Memory] button for 3 seconds in the power-off state, and when the LCD screen shows flashing "CL" characters (Figure 22), release the [Memory] button.

(b) Press the [Setting] button again to confirm deleting all data saved by the selected user (Figure 23).

(c) To delete all data saved by the other user, press the [Setting] button to switch to the other user, and repeat the above steps. (For LBP70C/D model, slide the sliding switch on the right side of the main unit, and repeat the above steps).

Press the [ON/OFF] button at any time to exit the data-deleting operation and shut down. This device cannot delete data by separate entries.



Figure 22



Figure 23

3. Full memory

When the memory has stored 90 results, a new, measured value is stored by overwriting the oldest value.

●4.7 Stop a measurement

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 and enters sleep mode.

●4.8 Irregular heartbeat (IHB) detector

The appearance of this symbol indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal basal blood pressure – repeat the measurement. In most cases, this is no cause for concern. However, if the symbol appears on a regular basis (e.g., several times a week with measurements taken daily), we advise you to tell your doctor.

Please show your doctor the following explanation:

Information on frequent appearance of their irregular heartbeat symbol

This instrument is an oscillometric blood pressure monitor device that also analyzes pulse frequency during measurement. The instrument is clinically tested.

If pulse irregularities occur during the measurement, the irregular heartbeat symbol is displayed with the measurement.

If the symbol appears frequently or if it suddenly appears more often than usual, we recommend the patient seek medical advice.

The instrument does not replace a cardiac examination but serves to detect pulse irregularities at an early stage.

●4.9 Charging

If your model uses a built-in removable lithium battery, do not replace it without authorization. When necessary, ask a professional to replace the battery. Use the supplied power supply cable and the DC adaptor (6V, 600mA) to charge the lithium battery.

Chapter 5 Error Message

The product may fail to finish measurements when an error occurs, with an error code displayed at the low-pressure position. Follow the following table to solve the problem:

| Code | Reason | Solution |
|------|---|--|
| E1 | The initial pressure in the cuff is too high. | Check whether the air in the cuff is fully discharged. |
| E2 | The tube is folded. | Check the tube to prevent folding at a sharp angle. |
| E3 | The cuff is not connected or arranged properly. | Make sure the cuff is wrapped properly with its tube connected correctly. |
| E4 | There is leakage in pump, valve, cuff, or tube. | Make sure the cuff is wrapped properly with its tube connected correctly. |
| E5 | The tube is folded or there is defected hardware. | Check the tube to prevent folding at a sharp angle. |
| E6 | It takes more than 120s to finish one measurement. | Take a new measurement. If the problem persists, replace the batteries. |
| E7 | Too much signal noise or irregular pulse rate. | Do not move your body or arm during measurement. |
| E8 | The pulse signal is too weak or the cuff is too loose. | Do not wear thick clothing. Make sure the cuff is wrapped properly. |
| E9 | The pulse signal strength is greater than the allowed range. | 1. Make sure the cuff is wrapped correctly. 2. Replace the batteries. |
| E10 | The measured value exceeds the measuring range. | 1. Make sure the cuff is wrapped correctly. 2. Replace the batteries. |
| E11 | Sensor works abnormally. | Contact the dealer or manufacturer. |
| E12 | The cuff pressure is greater than the upper limit of safe pressure. | Make sure you are taking measurement in appropriate method. |
| E13 | The patient moves around during measurement. Pulse rate is irregular. | Remain still during measurement. Check the tube to prevent folding at a sharp angle. |
| E15 | The pulse rate is too high to be measured reliably. | Wrap the cuff properly. Make sure you are taking measurement in appropriate method. |
| E16 | The cuff connector is not inserted. | Insert the cuff connector. |

Chapter 6 Troubleshooting

If any problem occurs to this device during use, please perform the corresponding checks carefully and take the corresponding measures if necessary.

| Faults/Errors | Checks and Measures |
|---|---|
| The LCD screen does not respond when you press the [ON/OFF] button after installing the battery. | <ol style="list-style-type: none"> 1. Check whether the battery is installed under correct polarity (indicated by "+" and "-" marks). 2. If the fault still exists, reinstall or replace the battery. |
| Repeated failures to measure blood pressure, or too low or too high measured blood pressure values. | <ol style="list-style-type: none"> 1. Rewind the cuff correctly. 2. Check whether there is thick clothing on the measuring part of your arm (for example, the sleeve is rolled up to the measuring position); if yes, remove such clothing. 3. Make sure you are quiet and completely relaxed when performing blood pressure measurements. |
| The cuff fails to reach the expected inflation level within the specified time, or cannot be pressurized. | <ol style="list-style-type: none"> 1. The air tube connector is not inserted correctly into the air tube interface of the product. Please re-insert it correctly. 2. The cuff leaks air. Please purchase a new cuff from the manufacturer. |
| The measured blood pressure values are different from that measured in the hospital, or the measured values change from day to day. | <ol style="list-style-type: none"> 1. The blood pressure values may change due to your physical and mental conditions at the time of measurement, and thus may be different if measured at different times. 2. Record the daily changes of your blood pressure values and consult a doctor. |

NOTE

● A healthy person may also have fluctuating blood pressures. The important thing is that you must be quiet when performing blood pressure measurements, and only compare the values measured under the same physical and mental conditions.

● If you have performed the above checks and followed the correct measuring method, but the fluctuation of blood pressure values still exceeds 15mmHg or you can hear an uneven heartbeat rhythm sometimes, please consult a doctor.

● If you encounter any problem when using this device, please consult your local dealer or medical expert. Do not disassemble or repair this product without authorization! Any unauthorized disassembly or repair will void the warranty!

Chapter 7 How is blood pressure measured?

● 7.1 What is blood pressure, and why does it fluctuate?

Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and frequency of the heart (pulse), as well as the width of circulatory blood vessels is altered. Blood vessel width is affected by fine muscles in the blood vessel walls.

Your level of arterial blood pressure changes periodically during heart activity. During the "blood ejection" (Systole), the value is highest (systolic blood pressure value). At the end of the heart's "rest period" (Diastole), pressure is lowest (diastolic blood pressure value).

Blood pressure values must lie within certain normal ranges in order to prevent particular diseases.

Blood pressure is too high if your systolic blood pressure is over 160 mm Hg and/or your diastolic pressure is above 100 mm Hg, while at rest. In this case, please consult your

physician immediately. Long-term values at this level endanger your health due to continual damage to the blood vessels in your body.

If your systolic blood pressure values are between 140 mm Hg and 159 mm Hg and/or the diastolic blood pressure values are between 90 mm Hg and 99 mm Hg, consult your physician. Regular self-checks are necessary.

If you have blood pressure values that are too low (i.e., systolic values under 105 mm Hg and/or diastolic values under 60 mm Hg), consult your physician.

Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. You can detect possible changes in your values early and react appropriately.

If you are undergoing medical treatment to control your blood pressure, keep a record of values along with time of day and date. Show these values to your physician.

Never use the results of your measurements to independently alter the medication prescribed by your physician.

● 7.2 What can I do to change my blood pressure?

(a) Consult your doctor.

(b) Increased blood pressure values (various forms of hypertension) are associated with considerable health risks over time. Arterial blood vessels in your body are endangered due to constriction caused by deposits in the vessel walls (arteriosclerosis). A deficient supply of blood to important organs (heart, brain, muscles) can result from arteriosclerosis. Furthermore, the heart will become structurally damaged with increased blood pressure values.

(c) There are many different causes of high blood pressure. We differentiate between the common primary (essential) hypertension and secondary hypertension. The latter group can be ascribed to specific organ malfunctions. Please consult your doctor for information about the possible origins of your own increased blood pressure values.

(d) There are measures which you can take to reduce and

even prevent, high blood pressure. These measures must be permanent lifestyle changes.

(1) Eating habits

· Strive for a normal weight corresponding to your age. See your doctor for your ideal weight.

· Avoid excessive consumption of common salt.

· Avoid fatty foods.

(2) Previous illnesses

· Consistently follow all medical instructions for treating illness such as:

· Diabetes (diabetes mellitus)

· Fat metabolism disorder

· Gout

(3) Habits

· Give up smoking completely.

· Drink only moderate amounts of alcohol.

· Restrict your caffeine consumption (e.g., coffee).

(4) Physical constitution

· After a preliminary medical examination, do regular exercise.

· Choose sports which require stamina and avoid those which require strength.

· Avoid reaching the limit of your performance.

· With previous illnesses and/or an age of over 40 years, please consult your doctor before beginning your exercise routine. You must receive advice regarding the type and extent of exercise that is appropriate for you.

Chapter 8 Maintenance and Calibration

(1) Do not expose the product to high temperature, high humidity, dust or direct sunlight.

(2) There is an air-tight air bag inside the cuff. Please use the cuff carefully and do not pull or twist it.

(3) Do not use any abrasive or volatile cleaners.

Use a soft dry cloth or a soft cloth moistened with 3% neutral soap to clean your monitor and arm cuff twice, 3 mins for

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each time. The dosage is about 15ml each time.

It is recommended to clean the device once a day before use.

Do not wash or immerse your monitor and arm cuff or other components in water.

Do not use gasoline, thinners or similar solvents to clean your monitor and arm cuff or other components.

(4) Use the air tube with care. Do not pull or pinch it forcefully, or hold it close to any objects containing sharp corners or edges.

(5) Do not drop or discard the product. Protect the product against strong vibration.

(6) If the product has been put aside for a long time, please turn it on every two months for testing purpose.

(7) Do not disassemble the product! Otherwise, the product may lose good accuracy due to calibration problems.

(8) The disposal and destruction of the scrapped product and used battery should comply with the national disposal rules for electronic products.

(9) It is recommended to calibrate the product after 2 years of use, in order to ensure the accuracy of measurements.

Chapter 9 After-sales Service

After-sales service organization: Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.

After-sales service address: North side of floor 3, BLD 9 BaiWangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District 518055 Shenzhen, Guangdong, CHINA

After-sales service telephone: 400-868-3888

Chapter 10 Limited Warranty

The warranty period of this device is 3 years from the date of sale (the date of manufacture is indicated on the product

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label), and the warranty period of the cuff is 1 year. Any damage caused by your incorrect or careless use, failure to follow our operating instructions or transfer of the device to other users, or by battery leakage, shall void the warranty. We will not provide free warranty service for the following failures caused by your personal reasons. For repair services beyond warranty, we will charge you according to our charging policy.

- (1) Failure caused by unauthorized disassembly or modification of the product.
- (2) Failure caused by accidental fall of the product during use or transportation.
- (3) Failure caused by lack of reasonable maintenance.
- (4) Failure caused by your failure to follow the operating instructions provided in this Manual.

Chapter 11 Product Specifications and Registration Information

11.1 Product safety specification

| Parameter | Specification |
|------------------------|--|
| Shock protection type | Equipment supplied with internal power |
| Shock protection grade | Type BF |
| Operating mode | Continuous |
| Movement level | Transportable equipment |
| EMC group | Class B, Group 1 |

11.2 Product environment specification

| Environment | Specification |
|------------------------------|--|
| Temperature range | Operating temperature: 5°C ~ 40°C |
| | Storage/transport temperature: -20°C ~ +55°C |
| Humidity range | Working humidity: 15% ~ 85% |
| | Storage/transport humidity: ≤93% |
| Operating air pressure range | Working air pressure: 70 kPa ~106 kPa |
| | Storage air pressure: 50 kPa ~106 kPa |

11.3 Product hardware specification

| Parameter | Specification |
|----------------------|--|
| Product name | Automatic Arm Electronic Blood Pressure Monitor |
| Product model | LBP70C, LBP70D |
| Size | LBP70C/LBP70D: About 128(L) mm x 126.3(W)mm x 52(H) mm |
| Weight | LBP70C: About 465g (including battery) LBP70D: About 407g (including battery) |
| Display screen | Segmented LCD display screen |
| Power supply | LBP70C:d.c.6V (4 batteries, AA) LBP70D: 2200mAh Rechargeable lithium battery AC adaptor input: 100~240V Output: 6.0V,600mA (optional) |
| Data Storage | Up to 90 sets of measurements can be stored |
| Monitor service life | 5 years |
| Cuff service life | 2 years |

11.4 Product measurement specification

| Parameter | Specification |
|-----------------------------|--|
| Measuring position | Upper arm |
| Measurement rang | Static pressure: 0~280 mmHg/ 0~37.3 kPa; SYS:(60~255) mmHg/ (8.0~34.0) kPa DIA: (30~195) mmHg/ (4.0~26.0) kPa Pulse rate: 40 to 199 bpm |
| Cuff pressure display range | (0~299) mmHg/ (0~39.9) kPa |
| Measuring method | Non-invasive oscillometric |
| Resolution | 1mmHg/0.1kPa |
| Unit | mmHg/kPa |
| Laboratory Accuracy | Blood Pressure: ± 3 mmHg/ ± 0.4 kPa Pulse rate: ± 5% |

Chapter 12 EMC

Table 1

| Guidance and manufacturer' s declaration – electromagnetic emissions | |
|--|------------|
| Emissions test | Compliance |
| RF emissions CISPR 11 | Group 1 |
| RF emissions CISPR 11 | Class B |
| Harmonic emissions IEC 61000–3-2 | Class A |
| Voltage fluctuations/ flicker emissions IEC 61000–3-3 | Comply |

Table 2

| Guidance and manufacturer' s declaration – electromagnetic Immunity | | |
|---|---|---|
| Immunity Test | IEC 60601–1-2 Test level | Compliance level |
| Electrostatic discharge (ESD) IEC 61000–4-2 | ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air | ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |
| Electrical fast transient/burst IEC 61000–4-4 | ± 2 kV for power supply lines ± 1 kV signal input/output 100 kHz repetition frequency | ± 2 kV for power supply lines Not Applicable 100 kHz repetition frequency |
| Surge IEC 61000–4-5 | ± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode | ± 0.5 kV, ± 1 kV differential mode Not Applicable |
| Voltage dips, short interruptions and voltage | 0 % UT; 0.5 cycle. At 0° , 45° , 90° , 135° , 180° , 225° , 270° | 0 % UT; 0.5 cycle. At 0° , 45° , 90° , 135° , 180° , 225° , 270° |
| variations on power supply input lines IEC 61000–4-11 | and 315° . 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0° . 0 % UT; 250/300 cycle | and 315° . 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0° . 0 % UT; 250/300 cycle |
| Power frequency magnetic field IEC 61000–4-8 | 30 A/m 50Hz/60Hz | 30 A/m 50Hz/60Hz |
| Conducted RF IEC61000–4-6 | 3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | 3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz |
| Radiated RF IEC61000–4-3 | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | |

Table 2

| Guidance and manufacturer' s declaration – electromagnetic Immunity | | | | | | | | |
|--|----------------------|--------------|--|---------------------------------|-------------------------|--------------|---------------------------|---|
| | Test Frequency (MHz) | Band (MHz) | Service | Modulation | Modulation (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) | |
| Radiated RF IEC61000–4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment) | 385 | 380 – 390 | TETRA 400 | Pulse modulation 18 Hz | 1,8 | 0.3 | 27 | |
| | 450 | 430 – 470 | GMRS 460, FRS 460 | FM ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 | |
| | 710 745 780 | 704 – 787 | LTE Band 13, 17 | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 | |
| | 810 | 800 | GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 | |
| | 870 | | | | | | | |
| | 930 | – 960 | | | | | | |
| | 1720 | 1 700 | GSM 1800; CDMA 1900; | Pulse modulation 217 Hz | 2 | 0.3 | 28 | |
| | 1845 | | GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | | | | | |
| | 1970 | – 1 990 | | | | | | |
| | | 2 400 | Blue-tooth, WLAN, 802.11 b/g/n, RFID, 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 | |
| | | 2450 – 2 570 | | | | | | |
| | | 5 240 | 5 100 | WLAN 802.11 a/h | Pulse modulation 217 Hz | 0,2 | 0.3 | 9 |
| | 5 500 | | | | | | | |
| | 5 785 | – 5 800 | | | | | | |

Chapter 13 Guide of E-instruction

Software and hardware requirements needed to display the instructions for use in electronic form are shown as:

Computer:

| Configuration item | | Requirements |
|------------------------|-----------------|--|
| Hardware configuration | CPU | Intel Pentium4 and above |
| | RAM | 256M and above |
| | Hard disk space | 20G and above |
| Systems platform | | Windows platform (compatible with Windows XP, Windows 7, Windows 8 & 8.1, Windows 10, compatible with 32-bit & 64-bit) |
| Required software | | Adobe Acrobat Reader or pdf reader software of the same type |

Mobile phone:

| Configuration item | Requirements |
|--------------------|--|
| System platform | Android 4.0 and above or IOS 5.0 and above |
| Required software | Adobe Acrobat Reader or pdf reader software of the same type |

Instruction for use download site: http://www.lepu-care.com/CEsmsxz/index_121.aspx

If you cannot download it on the website, please contact the manufacturer:


Tel: +86 0755-86952278 Fax: +86 0755-86952278

Note:

When the manufacturer's instruction for use is updated, it will be uploaded timely. For it is difficult to trace to every end user to inform the change, especially the layperson, so we advice the customer to browse and check it regularly.

SIZE: 85mm x 140mm
 材质80g书纸,字体颜色
 85%黑色,钉装

| H. REVISION 历史版本 | UPDATE 更改内容 | DESIGNER 设计/更改者 | DATE 发审日期 |
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|--|--|---|--|---|--|----------|--|
| LEPU 乐普 深圳乐普智能医疗器械有限公司 | | PART NAME | | LBP70说明书CE | | | |
| | | MATERIAL | | 80g书纸 | | | |
| These Drawings and specifications are the property of Shenzhen Lepu Intelligent Medical Equipment Co.,Ltd and shall not be reproduced or used as the basis for the manufacture or devices without permission | | MODEL : | | . | | | |
| | | PROCESS | | 骑马钉 | | | |
| DIMENSIONAL TOLERANCES ± | | PROJECTION | | PART NO: REVISION: A0 DATE: 2021/5/11 | | | |
| | |  | | | | | |
| | | UNITE | | | | mm | |
| | | SCALE | | | | 1:1 | |
| | | SIZE | | | | DESIGN | |
| | | CHECKED | | | | APPROVED | |
| REMARK | | RoHS | | SHEET 1 OF 35 | | | |