Blood Glucose, Ketone Body & Uric Acid Tester

Instructions for Use

BEIJING LEPUMEDICAL TECHNOLOGY CO., LTD.

Table of Contents

Thank you for selecting our product. This *Instructions for Use* will elaborate the usage and notes of Blood Glucose, Ketone Body & Uric Acid Tester. In order to ensure its correct use, please read this Instructions carefully before use.

I. Product Overview

1. Product name: Blood Glucose, Ketone Body & Uric Acid Tester

2. Scope

The Blood Glucose, Ketone Body & Uric Acid Tester is used in conjunction with the matched glucose test strip, ketone body test strip and uric acid test strip produced by the Company for in vitro test on the concentration of blood glucose, ketone body and uric acid in the fresh whole blood collected from the fingertip capillary. Also, it can be used with the matched glucose test strip (glucose dehydrogenase method) to test the concentration of glucose in the venous whole blood.

This product is only used to test the effect on controlling glucose, ketone body and uric acid in patients' blood samples, but cannot be used for the diagnosis and screening of diseases, nor can it be used as the basis for the adjustment of therapeutic drugs.

3. Description of model and classification:

Tester model / Similarity/difference	Poctor M3100	Poctor M3101
Size	94.5mm*61.5mm*23.5mm	
Weight	64.5g	
Power source	DC3.0V (two batteries CR2032)	
Circuit	Non-detector circuit	Detector circuit
Program	No impedance calculation method, no HCT correction function	Impedance calculation method, HCT correction function
Power consumption	2.5 mA	3 mA

4. Suitable reagent

Tester model	Poctor M3100	Poctor M3101
Matched reagent	Glucose Test Strip (Glucose Oxidase Method)(model: GO S1100) Glucose Test Strip (Glucose Dehydrogenase Method)(model: GDH S1101) Ketone Body Test Strip (β-hydroxybutyrate Dehydrogenase Method)(model: KT S1100) Uric Acid Test Strip (Electrochemical Method)(model: UA S1100)	Glucose Test Strip (Glucose Oxidase Method)(model: GO S1101) Glucose Test Strip (Glucose Dehydrogenase Method)(model: GDH S1101) Ketone Body Test Strip (β-hydroxybutyrate Dehydrogenase Method)(model: KT S1101) Uric Acid Test Strip (Electrochemical Method)(model: UA S1100)

Note: This device is suitable for the above test strips only. If the device cannot be used as per the manufacturer's instructions, the protection provided by it may be destroyed. Except for the supporting test strips, the two models have the same structure, display and operation steps.

5. Test Principle

This tester is developed in the electrochemical principle. The test strip inlet can recognize different types of test strip by connecting the pin on the test strip lead and the remaining modules exhibit the same functions when testing blood glucose, ketone body and uric acid. During test, the potassium ferricyanide solidified in the reaction zone of glucose test strip, coenzyme NAD and potassium ferricyanide in the reaction zone of ketone body test strip and potassium ferricyanide in the reaction zone of uric acid test strip respectively undergo redox reaction with glucose, ketone body (β-hydroxybutyrate) and uric acid in the blood sample to generate micro-currents. The main circuit board obtains the concentration values of blood glucose, ketone body and uric acid by measuring and converting the micro-currents, and then displays the values on the display screen.

6. Contraindications

None.

7. Applicable People and Intended Use Environment

This product can be used by professionals, non-professionals with related disease or their family members who can proficiently operate it at home or in medical institutions for monitoring blood glucose, ketone body or uric acid.

8. Working Conditions

Ambient temperature: 5℃~40℃; relative humidity: 10%~85%; atmospheric pressure: 86 kPa~106 kPa;

9. Precautions

- In order to ensure its correct use, please read this Instructions carefully before use.
- Place the Blood Glucose, Ketone Body & Uric Acid Tester and test strip out of children's reach
- Please store and use the device and test strip at the time and in the environment specified by the Instructions.
- Disinfect the blood collecting device and site
- Please use the test strip matched with the Blood Glucose, Ketone Body & Uric Acid Tester
- Please do not reuse the test strip
- Properly dispose of the used test strip and blood collection needle
- This instrument is applicable to in vitro testing only
- During testing, please judge the test process and results through listening and watching and operate the device according to its prompt

II. Product Composition

1. Main components

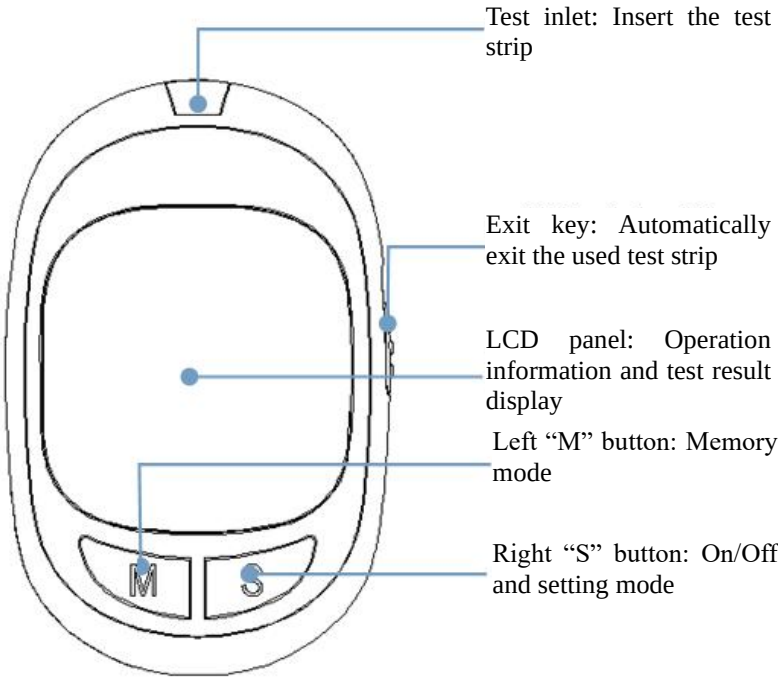


Fig. 1 Schematic Diagram of Blood Glucose,
Ketone Bodv & Uric Acid Tester

The Blood Glucose, Ketone Body & Uric Acid Tester is composed of a main unit and the main unit comprises a circuit board, a function button, a display screen, battery and a test strip inlet and a shell.

2. Schematic Diagram of Blood Glucose, Ketone Body & Uric Acid Tester Components

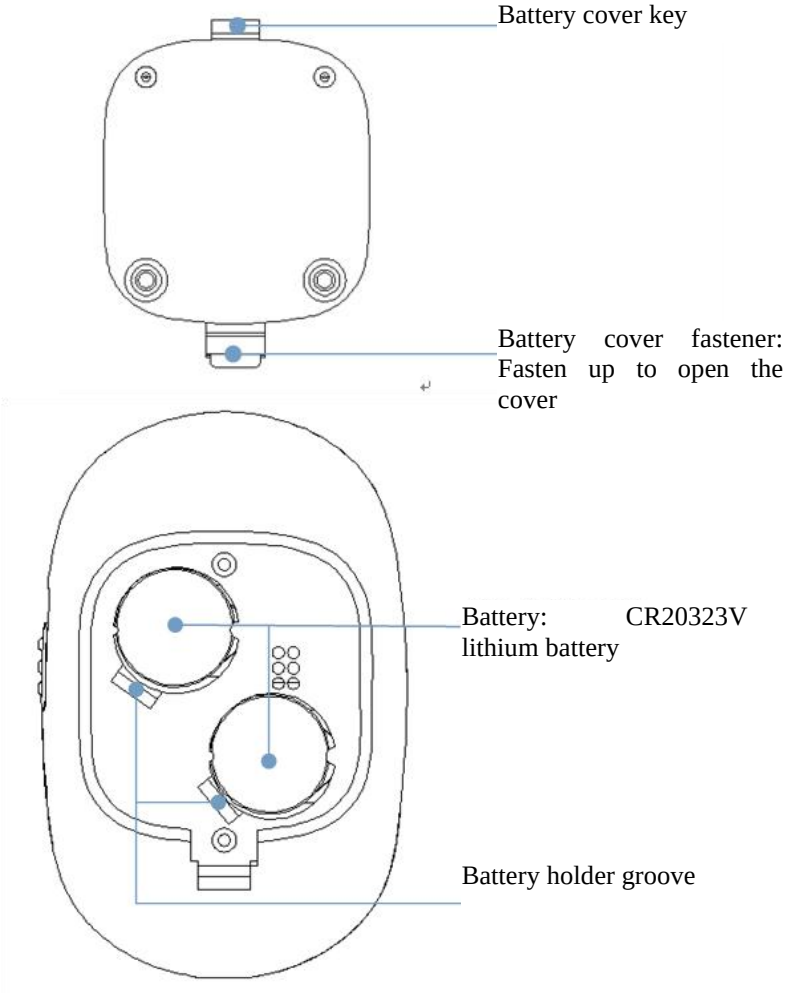


Fig. 2 Rear View of Blood Glucose, Ketone Body & Uric Acid Tester

Note:

The Blood Glucose, Ketone Body & Uric Acid Tester manufactured by Beijing Lepu Medical Technology Co., Ltd. (hereinafter referred to as “the Company”) can be used only with the electrochemical series glucose test strip, ketone body test strip and uric acid test strip.

The used test strips may have bio-hazard and environmental pollution, please store them in a special container.

3. Packing list

SN	Composition	Unit	Quantity	Content
1	Main unit	Set	1	Circuit board, function button, display screen, test strip inlet and shell
2	Battery	Nos.	2	3V lithium battery (CR2032)
3	Lancing device	Nos.	1	———
4	Instructions	Copy	1	———
5	User guide	Copy	1	———
6	Warranty card	PCS	1	Warranty
7	Certificate of qualification	PCS	1	Qualification information

III. Display Description

Please compare the displayed diagram on the display screen of your Blood Glucose, Ketone Body & Uric Acid Tester with this diagram. If they are identical, it means that the display screen works normally. After power-on every time, the display screen will display all patterns quickly. If the Blood Glucose, Ketone Body & Uric Acid Tester is in the power-off status, press any key (S/M), the display screen will display all patterns.

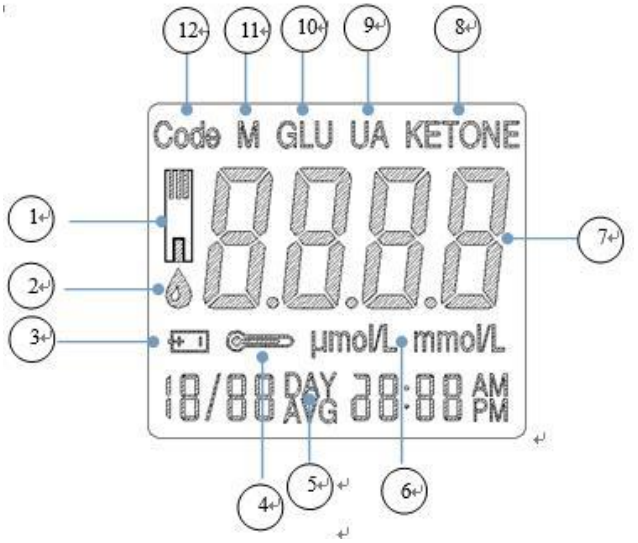


Fig. 3 Schematic Diagram of Blood Glucose, Ketone Body & Uric Acid Tester Screen

1. Test strip symbol	7. Result display zone
2. Blood drop symbol	8. Ketone body test item
3. Battery symbol	9. Uric acid test item
4. Temperature symbol	10. Blood glucose test item
5. Average value display	11. Memory mode
6. Measuring potential symbol	12. Number symbol

Note:

1) When the battery symbol flickers, it means the battery power will be used up; you can continue to use the tester, but you should replace its battery as soon as possible. When the screen displays E-1 and battery symbol, it means that the Blood Glucose, Ketone Body & Uric Acid Tester cannot be used any longer and you must replace its battery;

2) Take out the battery if the instrument is not used for a long time;

3) After replacement, set the time again. It is unnecessary to set the date and other parameters. The test results stored in the Blood Glucose, Ketone Body & Uric Acid Tester will not lose due to battery

replacement.

IV. Operations

1. Battery installation

When you want to use the tester, you should install two 3V lithium batteries (CR2032) in advance. Please use 3V lithium batteries (CR2032) other than any other type or model of battery; otherwise, the tester may be damaged.

Steps:

(1) Hold the tester with one of your hands and face its back upward. Open the battery cover with your thumb and remove the battery cover.

(2) Push the battery to right side, and cause it to leave the installing groove.

(3) Load new batteries. Keep the positive symbol "+" upward.

(4) After you hear a "beep", the screen picture will appear, indicating the battery installation is successful.

(5) Install the battery cover back. The battery is installed.

Note:

1. Please do not use poor quality or expired battery, so as not to cause test error. When you discard the used battery, please observe the local regulations.

2. Take out the battery if the instrument is not used for a long time;

3. After replacement, set the time again. It is unnecessary to set the date and other parameters. The test results stored in the tester will not lose due to battery replacement.

2. Year/month/date/hour/minute settings

Slightly press the "S" key on the upper right of the tester for more than 2s; after a "beep" is heard, the tester will automatically enter the setting mode. Please set the tester as per the following guide, please note: "M" key and "S" key are the main operation keys.

2.1 Year setting

1) When setting, the tester will display flickering year "2012", which means the year of 2012.

2) Slightly press the “M” key on the left of the tester; when clicking it once, the figure displayed by the tester will increase by 1 until the correct year appears.
3) Please press the “S” key on the right of the tester to set the year, when the tester will automatically enter the month setting (the tester will flicker to display “month”).

2.2 Month setting

1) Slightly press the “M” key on the left of the tester; when clicking it once, the figure displayed by the tester will increase by 1 until the correct month appears.
2) Please press the “S” key on the right of the tester to set the month, when the tester will automatically enter the date setting (the tester will flicker to display “date”).

2.3 Date setting

1) Slightly press the “M” key on the left of the tester; when clicking it once, the figure displayed by the tester will increase by 1 until the correct date appears.
2) Please press the “S” key on the right of the tester to set the date, when the tester will automatically enter the hour setting (the tester will flicker to display “hour”).

2.4 Hour setting (12-hour system is automatically set for the product when delivering)

1) Slightly press the “M” key on the left of the tester; when clicking it once, the figure displayed by the tester will increase by 1 until the correct hour appears.
2) Please press the “S” key on the right of the tester to set the minute, when the tester will automatically enter the hour setting (the tester will flicker to display “minute”).

2.5 Minute setting

1) Slightly press the “M” key on the left of the tester; when clicking it once, the figure displayed by the tester will increase by 1 until the correct minute appears.
2) Please press the “S” key on the right of the tester to set the minute, when the tester will automatically enter the unit selection.

3. Testing

Tester number and test item setting

The Blood Glucose, Ketone Body & Uric Acid Tester can be used with the matched test strip only after coded. The tester must be re-coded every time when it uses a test strip with a different code. There are three types of different test strips: glucose test strip, ketone body test strip and uric acid test strip. The test strip blood inlet should be kept in the same direction with the screen; after the test strip is inserted, there will be blood drip prompt, indicating the test strip is correctly inserted for subsequent operations. Each tube (or box) of test strip is coded and provided with test items. The packing box of test strip contains CODE number to correct the tester code. When the test strip is inserted into the tester, please confirm the code displayed on the tester screen is identical to that marked on the tube (or box) of test strip.

Steps:

1. Check whether the code/test items displayed on the tube (or box) of test strip are identical to the CODE number/test items.
2. Insert the CODE number into the tester inlet, confirm whether the tester test item/code is identical to the CODE number test item/code.

A. Blood glucose test item:

a) Check whether the code/test items displayed on the instrument are identical to the test strip tube (or box) and code.

b) Remove the CODE number, “GLU” will appear on the tester, indicating the blood glucose test item and code are set successfully.

B. Ketone body test item:

a) Check whether the code/test items displayed on the tester are identical to the code on test strip tube (or box) and CODE number.

b) Remove the CODE number, “KETONG” will appear on the tester, indicating the ketone body test item and code are set successfully.

C. Uric acid test item:

a) Check whether the code/test items displayed on the instrument are identical to the test strip tube (or box) and code.

b) Remove the CODE number, “UA” will appear on the tester, indicating the uric acid test item and code are set successfully.

Note: When remove the CODE number, the tester will display “E-E”, indicating the CODE number has a problem. Please operate the coding program again; if “E-E” still appears, please contact our after-sales department for help.

3.1 Preparation before testing

Please follow the instructions to ensure accurate test results. The materials include:

- Tester
- Test strip
- Lancing device

Instruction for use of lancing device: Turn the lancing device to an appropriate depth.

Notes: If venous blood is to be collected, it is necessary to do so by a professional healthcare provider. The venous blood can be collected in a tube with heparin sodium or lithium heparin or ethylene diamine tetraacetic acid (EDTA) and use it within 30 min.

3.2 Testing steps

3.2.1 Fingertip blood collection

Follow the instructions of lancing device, properly install the blood collection needle and adjust it to an appropriate needling depth. Wash your hands with warm water and soap, dry and disinfect them and collect blood with the needle before gently rub the blood collecting site to make it full engorgement.

Precautions:

1) Wash your hands with warm water, warm our fingers, and rub the fingers gently to increase the blood volume of the fingers, so as to easily get the right amount of blood drops.
2) Do not disinfect with disinfectant containing “iodine” such as iodine tincture.

Device preparation: If there is a big difference between the storage temperature of Blood Glucose, Ketone Body & Uric Acid Tester and the test environment temperature, it is necessary to condition the instrument and test strip in the test environment temperature for more than 30 min before testing. There is a temperature sensor near the test strip of the tester inlet, so please do not hold it here when testing.

- Unscrew the front cover of the lancing device counterclockwise, insert the blood collection needle base into the middle groove and make sure it is installed properly.
- Unscrew the protective cover at the top of the blood collection needle, then screw on and lock the front cap of the lancing device, and rotate the blood collection depth button according to the thickness of individual skin. The larger the marked number, the deeper the penetration of the needle.
- Pull the drawbar of lancing device backward once to prepare for blood collection.
- Wash your hands thoroughly with soap, dry them, clean and disinfect your fingertips with alcohol, and then collect blood after your fingertips are completely dry.
- Take out the test strip from the test strip box and cover the test strip box immediately to ensure the dry environment of the test strip in other test strip tubes (or boxes).
- Insert the contact line of the test strip into the tester inlet, and the tester will start automatically.
- Hold the lancing device firmly against the fingertip blood collection site, and press the button on the side of the lancing device. When you hear a “click”, it means that the blood collection has been completed.

3.2.2 Venous blood collection

- If venous blood is to be collected, it is necessary to do so by a professional healthcare provider. The venous blood can be collected in a tube with heparin sodium or lithium heparin or ethylene diamine tetraacetic acid (EDTA) and use it within 30 min.

3.2.3

- The test items and code are displayed on the tester.
- Confirm whether the code/test items displayed on the tester are identical to the tube (or box) code/test items.
- Blood glucose is displayed as GLU, ketone body, as KETONE and uric acid, as UA.
- If different with the items to be tested, please re-code as per (the tester code).

Note:

- Any test must be performed within 3 min; if the tester does not execute any instruction within 3 min, it will power off automatically. Please unplug the test strip and insert it into the tester again to

power on the device.

- Do not use the used test strip; if the used test strip is indented into the tester, the tester will display "E-U". Please use a new test strip for testing.
- If the test strip is inserted into the tester incorrectly, the tester will not work normally.

Warning:

- Do not use the used blood collection needle.
- Pleased use the certified blood collection needle to ensure safety.

Blood glucose test steps

1) Insert the glucose test strip into the tester and prepare the fingertip blood sample according to the lancing device instructions and test steps.
2) When the test sample is fresh fingertip capillary whole blood, please rub the fingertip to form a drop of blood; do not squeeze hard, wipe off the first drop of blood, and use the second drop of whole blood sample for testing. The blood volume is not less than 0.6μL when using the matched glucose test strip (glucose oxidase method) and not less than 1μL when using the matched glucose test strip (glucose dehydrogenase method) for testing. Blood glucose level should not be tested with blood from other parts (such as palm, forearm, etc.) except fingers. When the matched glucose test strip (glucose dehydrogenase method) is used to test the venous whole blood sample, the venous whole blood sample must be collected by professional medical personnel into heparin sodium or heparin lithium test tube or ethylenediamine tetraacetic acid (EDTA) test tube and used within 30 min. Do not use the test tube containing fluoride or oxalate to collect blood samples.
3) Touch the blood with the blood inlet of test strip; when you hear a "beep", the blood enters the test strip successfully.
4) When the tester begins to count down, and after the test is finished, the tester displays the test result.
5) The test strip can be automatically removed from the tester by gently pushing the button, or the test strip can be removed by hand and discarded in the biomedical waste container.
6) Please note: Put the used blood collection needle into the protective cap, and then carefully dispose of the used blood collection needle or place it in a biomedical waste container according to the instructions for use of the lancing device.

7) After the test, record the test results in your own diabetes or related logs.
8) Insert the ketone body test strip and uric acid test strip into the inlet of the tester according to the blood glucose test steps.

Ketone body test steps

1) According to the pre-test preparation in 3.1 and the test steps in 3.2, collect blood from the fingertip, and the blood volume is not less than 1μ L. Insert the ketone body test strip into the inlet of the tester.
2) Touch the blood with the blood inlet of test strip; when you hear a “beep”, the blood enters the test strip successfully.
3) When the tester begins to count down, and after the test is finished, the tester displays the ketone body test result.

Uric acid test steps

1) According to the pre-test preparation in 3.1 and the test steps in 3.2, collect blood from the fingertip, and the blood volume is not less than 2μL. Insert the uric acid test strip into the inlet of the tester.
2) Touch the blood with the blood inlet of test strip; when you hear a “beep”, the blood enters the test strip successfully.
3) When the tester begins to count down, and after the test is finished, the tester displays the uric acid test result.

Note:

- The fingertip blood test data of Blood Glucose, Ketone Body & Uric Acid Tester is all calibrated by referring to the plasma test data. The blood glucose level in the plasma is about 11% higher than that in venous whole blood, which is not caused by the error of instrument accuracy.
- Please note: after the test strip tube is opened to take out the test strip, please cover the tube cap immediately to prevent moisture, and record the first opening date on the label of the test strip bottle. After the test strip tube is opened, the test strips should be used up within 3 months; otherwise, there will be test deviation.
- The test strip taken out must be used within 3 min. If the test strip is exposed to air too long before testing, there will be test deviation.

- The blood sample to be tested must be carefully placed in the correct position of the test strip. Please follow the test steps to avoid incorrect operation.
- Do not suck blood samples twice (incl.) onto the same test step, which may cause inaccurate test results.
- Please test with a sufficient blood sample volume.

Special message:

Item	Lo	Hi
Concentration of blood glucose	<1.1mmol/L(20mg/dL)	>33.3mmol/L(600mg/dL)
Concentration of ketone body in blood [mmol/L (mg/dL)]	<0.2mmol(2.08mg/dL)	>8.0 mmol/L(83.2mg/dL)
Concentration of uric acid in blood[μmol/L (mg/dL)]	<200 μmol/L(3.3mg/dL)	>1200 μmol/L (20.0mg/dL)

Note: "Lo" indicates that the test value is lower than the lowest range that the instrument can detect, and "Hi" means that the test value is higher than the highest range that the instrument can detect. When the test result is "Lo" or "Hi", it may be caused by improper operation. Please confirm the test step again and then confirm the result.

3.3 Precautions after testing

Note:

- Please check your system performance regularly or when you have doubts about the test results.
- Falling, impact or other violent damage may lead to abnormal function of the tester. At this time, stop using the tester.
- Do not use the tester under the interference of magnetic field, electromagnetic field and radiation.

Warning:

- In any case, please do not dismantle the tester.
- Please discard the used blood collection needle and test strip as per the local law.
- The used test strip, blood collection needle and other articles are stained with blood. If the user has infectious diseases, used test strip, blood collection needle and other articles may be the source of infection. Rubber gloves must be worn to treat blooded articles as possible biomedical wastes.

3.4 Quality control procedure

When users suspect that the monitoring system of blood sugar, ketone body and uric acid is not working properly, they should carry out quality control test. The Company provides the control material with QC level 1 and QC level 2 for this type of glucose test strip, ketone body test strip and uric acid test strip. Generally, QC level 1 can be used to judge whether the monitoring system is in normal working condition. When the test results of QC level 1 meet the requirements but the user still suspects that there is something wrong with the monitoring system, the test of QC level 2 can be carried out.

Source of control material: Provided by Beijing Lepu Medical Technology Co., Ltd. If you have any doubt, please call 400 060 1160.

a) Glucose test strip (glucose oxidase method)

The monitoring steps for the control material are as follows:

1. Confirm that the test is carried out within the range of temperature 10℃ ~ 35℃, test humidity < 85% and test altitude < 3000 m (10000 ft), and if exceeding this range, the test results will be inaccurate;
2. If there is a big difference between the storage temperature of the tester and glucose test strip and the test temperature, it is necessary to condition the tester and test strip in the test environment temperature for more than 30 min before testing.
3. Take out the glucose test strip from the test strip tube, and cover the tube cover immediately after taking out the test strip in the tube;
4. Insert the electrode end of the test strip into the inlet of the tester, and the tester will automatically start up;
5. Insert the CODE number matched with the test strip into the CODE number slot of the blood glucose meter. Make sure that the code displayed on the screen of the blood glucose meter is the same as the code on the test strip tube. If it is different, please check whether it is the CODE number matched with this test strip. Otherwise, please call 400 060 1160;
6. Shake the control material well before opening the bottle, and drip a drop of quality control solution on a non-absorbent plane; after the blood glucose meter displays the blood adding instruction, within 2 min, gently touch the quality control solution with the sample adding end of the test strip, and the quality control solution will be sucked into the test strip immediately.
7. The instrument will automatically test after counting down for 8s, and the test results will appear on the display screen.

8. Acceptable range of QC results: Compare the test results with the QC range on the label of control material bottle. Only when the test results are in the QC range, it means the blood glucose monitoring system works normally. If the test results are no in the range, first see whether there is misoperation and whether the test strip is in the validity period. If the reason is not found yet, please call 400 060 1160 for help.

b) Glucose test strip (glucose dehydrogenase method)

The monitoring steps for the control material are as follows:

1. Confirm that the test is carried out within the range of temperature 10℃ ~ 45℃, test humidity 10%~85%, and if exceeding this range, the test results will be inaccurate;
2. If there is a big difference between the storage temperature of the tester and glucose test strip and the test environment temperature, it is necessary to condition the instrument and test strip in the test environment temperature for more than 30 min before testing.
3. Insert the matched CODE number of the test strip into the CODE slot of the tester. Make sure that the code displayed on the screen of the blood glucose meter is the same as the code on the test strip tube (or box). If it is different, please check whether it is the CODE number matched with this test strip. Otherwise, please call 400 60 1160;
4. Take out the glucose test strip from the test strip tube (or box), and cover the tube cover immediately after taking out the test strip in the tube;
5. Insert the electrode end of the test strip into the inlet of the tester, and the tester will automatically start up;
6. Shake the control material well before opening the bottle, and drip a drop of quality control solution on a non-absorbent plane; after the tester displays the blood adding instruction, within 3 min, gently touch the quality control solution with the sample adding end of the test strip, and the quality control solution will be sucked into the test strip immediately;
7. The instrument will automatically test after counting down for 5s, and the test results will appear on the display screen.
8. Acceptable range of QC results: Compare the test results with the QC range on the label of control material bottle. Only when the test results are in the QC range, it means the blood glucose monitoring system works normally. If the test results are no in the range, first see whether there is misoperation

and whether the test strip is in the validity period. If the reason is not found yet, please call 400 060 1160 for help.

c) Ketone body test strip (β-hydroxybutyrate dehydrogenase method)

The monitoring steps for the control material are as follows:

1) Confirm that the test is carried out within the range of temperature 10℃ ~ 45℃ and humidity 10%~85%, and if exceeding this range, the test results will be inaccurate;
2) If there is a big difference between the storage temperature of the tester and ketone body test strip and the test environment temperature, it is necessary to condition the instrument and test strip in the test environment temperature for more than 30 min before testing.
3) Insert the matched CODE number of the test strip into the CODE slot of the tester. Make sure that the code displayed on the screen of the blood glucose meter is the same as the code on the test strip tube (or box). If it is different, please check whether it is the CODE number matched with this batch of test strip. Otherwise, please call 400 60 1160;
4) Take out the ketone body test strip from the test strip (or box), and cover the tube cover immediately after taking out the test strip in the tube;
5) Insert the electrode end of the test strip into the inlet of the matched tester, and the tester will automatically start up;
6) Shake the control material well before opening the bottle, and drip a drop of quality control solution on a non-absorbent plane; after the tester displays the blood adding instruction, within 3 min, gently touch the quality control solution with the sample adding end of the test strip, and the quality control solution will be sucked into the test strip immediately;
7) The instrument will automatically test after counting down for 10s, and the test results will appear on the display screen;
8) Acceptable range of QC results: Compare the test results with the QC range on the label of control material bottle. Only when the test results are in the QC range, it means the ketone body monitoring system works normally. If the test results are no in the range, first see whether there is misoperation and whether the test strip is in the validity period. If the reason is not found yet, please call 400 060 1160 for help.

d) Uric acid test strip (electrochemical method)

The monitoring steps for the control material are as follows:

1) Make sure that the test is carried out within the range of temperature 10℃ ~ 35℃, test humidity < 85% and test altitude < 3000 m (10000 ft), and if exceeding this range, the test results will be inaccurate;
2) If there is a big difference between the storage temperature of the tester and uric acid test strip and the test environment temperature, it is necessary to condition the instrument and test strip in the test environment temperature for more than 30 min before testing;
3) Insert the matched CODE number of the test strip into the CODE slot of the tester. Make sure that the code displayed on the screen of the blood glucose meter is the same as the code on the test strip tube (or box). If it is different, please check whether it is the CODE number matched with this batch of test strip. Otherwise, please call 400 060 1160;
4) Take out the uric acid test strip from the test strip (or box), and cover the tube cover immediately after taking out the test strip in the tube;
5) Insert the electrode end of the test strip into the inlet of the tester, and the tester will automatically start up;
6) Shake the control material well before opening the bottle, and drip a drop of quality control solution on a non-absorbent plane; after the tester displays the blood adding instruction, within 3 min, gently touch the quality control solution with the sample adding end of the test strip, and the quality control solution will be sucked into the test strip immediately.
7) The instrument will automatically test after counting down for 20s, and the test results will appear on the display screen.
8) Acceptable range of QC results: Compare the test results with the QC range on the label of control material bottle. When the test results are in the QC range, it means the uric acid monitoring system works normally. If the test results are no in the range, first see whether there is misoperation and whether the test strip is in the validity period. If the reason is not found yet, please call 400 060 1160 for help.

4. Result query

The Poctor series blood glucose, ketone body & uric acid testers can automatically store 600 groups of data, including the test results of blood glucose, ketone body, uric acid and sample solution. In addition, it

can provide the average value of blood glucose in 7, 14, 21 and 28d. The blood glucose memory ranges from M01 to M400, while the uric acid and ketone body memory from M01 to M200. Please call the test results in memory according to this Instructions.

1. Make sure that there is no test strip is inserted into the tester.
2. Before viewing the memory mode, the tester must be re-coded with a different CODE number every time. There are three types of different CODE number: Blood glucose, ketone body & uric acid.
3. Gently press the “M” key on the left of the tester. When you hear a “beep”, the tester will enter memory mode after push-through presentation.

Note:

- The memory saves all the test results of blood glucose, ketone body, uric acid and sample solution.
- The tester has no average test value of uric acid and ketone body.
- When the tester enters memory mode, if a test strip is inserted, the test tester will automatically switch to the test item.

V. Storage and Maintenance

If the test strip is sensitive to the ambient high temperature and humidity, the test results may be affected by improper storage and use. Please store the tester according to the conditions specified in "XI Product Parameters"

Note:

- Please store the tester, test strip, CODE number and QC solution at room temperature.
- Please do not expose the tester, test strip, CODE number and quality control solution beyond their respective specified conditions (see the instructions for storage and use of test strip for details).
- Do not freeze or refrigerate the tester and test strip. Wipe the outside of the tester with a paper towel or a soft cloth without uncut thread ends to keep it clean. If the tester is not used for a long time, remove the battery.
- If there is some foreign matter on the surface of Blood Glucose, Ketone Body & Uric Acid Tester, do not clean it with corrosive organic solvent such as gasoline; wipe with a soft cloth dipped with 75% alcohol and neutral detergent.

VI. Warranty

In normal use, this instrument can be replaced within 1 year.

VII. Restrictions

General restrictions

Please pay attention to the restrictions in the use of Blood Glucose, Ketone Body & Uric Acid Tester to obtain correct results:

1. Only for in vitro testing of blood glucose, ketone body and uric acid.

2. Please do not expose the test strip in the conditions of high humidity or direct solar radiation. Please do not freeze or refrigerate the test strip.

3. The test strip is for single use. Please do not reuse it.

4. Please keep your hands and needling sites clean and dry, and take and operate the test strip with

clean and dry hands.

5. Please do not operate the tester near a mobile phone to avoid the interference of electromagnetic waves.

7.1 Restrictions on blood glucose test

Please pay attention to the following restrictions in the use of test strip to obtain correct results:

The test results of this instrument can only be used for blood glucose monitoring, but cannot be used as the basis for diabetes diagnosis. Referring to the opinions of therapists and diabetes experts, we should not violate the physician's scientific medical rehabilitation guidance only based on the blood glucose concentration results detected by this instrument. When the test results inconsistent with symptoms are obtained by using this instrument, you should immediately go to the hospital for reexamination. Please accept laboratory testing regularly and compare the test results with the laboratory. The following factors will affect the accuracy of the test results of Blood Glucose, Ketone Body & Uric Acid Tester:

- Abnormal HCT (test the blood glucose concentration by glucose oxidase method; Testing with the Poctor M3100 Tester Glucose Test Strip (model: GO S1100), HCT in the blood sample exceeds the range of 30%~50%; testing with the Poctor M3101 Tester Glucose Test Strip (model: GO S1101), HCT in the blood sample exceeds the range of 20%~70%. Testing the glucose concentration by glucose dehydrogenase method: Testing with the Poctor M3100 Tester Glucose Test Strip (model: GDH S1101), HCT in the blood sample exceeds the range of 30%~55%; testing with the Poctor M3101 Tester Glucose Test Strip (model: GDH S1101), HCT in the blood sample exceeds the range of 30%~70%.)
- Small-molecule reducing substances, e.g. VC (antiscorbutic vitamin) (the content in the blood is higher than 5 mg/dL)
- Serum uric acid content is higher than 10 mg/dL;
- Hyperlipidemia (cholesterol content is higher than 300 mg/dL)
- Metabolic disorders and severe dehydration.

7.2 Restrictions on ketone body test

Please pay attention to the following restrictions in the use of ketone body test strip to obtain correct

results:

- When the test sample should be fresh fingertip capillary whole blood, please rub the fingertip to form a drop of blood; do not squeeze hard, wipe off the first drop of blood, and use the second drop of whole blood sample for testing. The blood volume for testing should be no less than 1μL.
- Do not press the test strip with your fingers, so as not to block the test strip sample inlet to draw blood sample.
- Interferents: Interferents such as acetaminophen, ascorbic acid, captopril, dopamine, ibuprofen, levodopa, gentisic acid, uric acid, unconjugated bilirubin, cholesterol and triglyceride will not affect the ketone body test results within the concentration range recommended by NCCLS.
- HCT: Testing with the Poctor M3100 Tester ketone body test strip (model: KT S1100), HCT in the blood sample exceeds the range of 30%~55%; testing with the Poctor M3101 Tester ketone body test strip (model: KT S1101), HCT in the blood sample exceeds the range of 30%~70%.

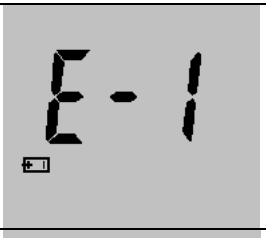
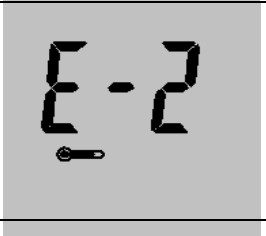
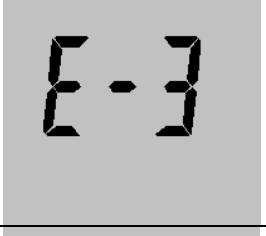
7.3 Restrictions on uric acid test

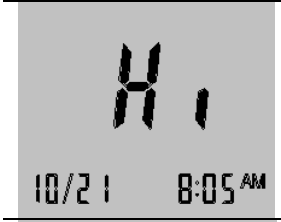
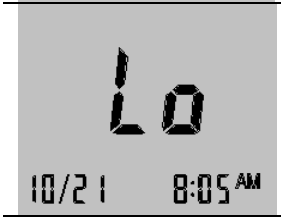
Please pay attention to the following restrictions in the use of uric acid test strip to obtain correct results:

- Please use fresh fingertip capillary whole blood for testing, do not use serum or plasma.
- HCT: Testing with the Poctor M3100 and Poctor M3101 uric acid test strips (model: UA S1100), HCT in the blood sample exceeds the range of 30%~55%.
- The uric acid test strip can be used to test at a height of 10,000 ft above sea level, and has no influence on the test results.
- Interferents: The following drugs have no influence on the test results in their range of physiological or pharmacodynamic concentration: Acetaminophen, ascorbic acid, dopamine, ibuprofen, levodopa, tetracycline and creatinine will not affect the test results within the concentration range recommended by NCCLS.
- Under the condition of slowing down peripheral blood circulation, including but not limited to severe dehydration, shock or hyperosmotic speed (with or without ketosis), hypertension, the test result of uric acid may be wrong.
- The uric acid test strip is used for testing fresh fingertip capillary whole blood; wrong test results may be obtained if using serum or plasma for the same purpose.

- Hyperlipemia test sample: Total cholesterol as high as 10.34mmol/L(400mg/dL) will not affect the test results. Samples of patients with hyperlipidemia have not been tested, so it is not recommended to use UA S1100 uric acid test strip for testing.

VIII. Error Message and Troubleshooting

Problem appearing on	the display screen	Solution
	Low battery power	Please replace the battery as soon as possible (refer to Page 3)
	Too high or too low temperature of Blood Glucose, Ketone Body & Uric Acid Tester	Move the Blood Glucose, Ketone Body & Uric Acid Tester to the place with the temperate in the range (5℃~40℃), 20 min later, condition the Blood Glucose, Ketone Body & Uric Acid Tester and the test strip to and ambient temperature and carry out test.
	The inserted test strip has been used	Discard the used test strip and then use a new test strip for testing. After a flickering “blood drop” pattern is displayed on the screen, start to draw in the blood sample.
	The Blood Glucose, Ketone Body & Uric Acid Tester has no test strip code available	Remove the test strip and insert a new test strip. If the problem still exists, please contact our customer service department.

	• Insert the test strip code into the Blood Glucose, Ketone Body & Uric Acid Tester	Remove the test strip and then use a new test strip for re-testing. Refer to the Instructions for Use and follow the testing steps carefully. If the problem still exists, please contact our customer service department.
	The test results of blood glucose, ketone body & uric acid are higher than the range of the instrument	• Clean your hands and blood collecting site and use a new test strip for re-testing. • If the test results are still “Hi”, please consult with your physician or professional healthcare provider.
	The test results of blood glucose and uric acid are lower than the range of the instrument	• Use a new test strip for re-testing. • If the test results are still “Lo”, please consult with your physician or professional healthcare provider.
The display screen is blank after startup of the Blood Glucose, Ketone Body & Uric Acid Tester	• If the Blood Glucose, Ketone Body & Uric Acid Tester is not used, it will automatically power off after 3 min to save battery power. • Battery may be replaced.	Press S key to start up the Blood Glucose, Ketone Body & Uric Acid Tester again; if the Blood Glucose, Ketone Body & Uric Acid Tester is started within less than 3 min, the display screen will display an empty battery symbol. Please replace the battery.
The test results have unit error	It will affect the accuracy of the test results.	Please contact our customer service department.
After startup of the Blood Glucose, Ketone Body & Uric Acid Tester, the display screen does not display all the patterns.	The Blood Glucose, Ketone Body & Uric Acid Tester may have a fault.	In the power-off status of Blood Glucose, Ketone Body & Uric Acid Tester, press the M button. Compare the patterns displayed on the screen with those in Page 6. If there is discrepancy, please contact our customer service department.

IX. Blood Glucose, Ketone Body & Uric Acid Test System Performance

9.1 Instrument measurement repeatability:

The precision of blood glucose system repeated test results meets the requirements in 9.1.

Table 9.1 Measurement repeatability of blood glucose system

Test range	Precision
< 5.5 mmol/L (< 100 mg/dL)	*SD* < 0.42 mmol/L (< 7.7 mg/dL)
≥5.5 mmol/L (≥100 mg/dL)	*CV* < 7.5%

The precision of ketone body system repeated test results meets the requirements in 9.2.

Table 9.2 Measurement repeatability of ketone body system

Concentration of ketone body [mmol/L (mg/dL)]	Precision
0.2~1.0 (2.08~10.4)	CV(%) should be no more than 10%
1.0~2.0 (10.4~20.8)	CV(%) should be no more than 10%
4.0~8.0 (41.6~83.2)	CV(%) should be no more than 10%

The precision of uric acid system repeated test results meets the requirements in 9.3.

Table 9.3 Measurement repeatability of uric acid system

Serum uric acid [μmol/L (mg/dL)]	Precision
200~400 (3.3~6.7)	CV(%) should be no more than 10%
600~800 (10.0~13.3)	CV(%) should be no more than 10%
1000~1200 (16.6~20.0)	CV(%) should be no more than 10%

9.2Accuracy of tester system

95% of the deviation of blood glucose system test results meets the requirements in 9.4.

Table 9.4 Accuracy requirements

Test range	Allowable deviation

≤4.2 mmol/L (≤75 mg/dL)	No more than ±0.83 mmol/L (±15 mg/dL)
> 4.2 mmol/L (> 75 mg/dL)	No more than ±20%

95% of the deviation of ketone body system test results meets the requirements in 9.5.

Table 9.5 Accuracy requirements

Concentration of ketone body [mmol/L (mg/dL)]	Allowable deviation
0.2~2.0 (2.08~20.8)	The relative deviation should be no more than 20%
2.0~4.0 (20.8~41.6)	The relative deviation should be no more than 20%
4.0~8.0 (41.6~83.2)	The relative deviation should be no more than 20%

95% of the deviation of uric acid system test results meets the requirements in 9.6.

Table 9.6 Accuracy requirements

Serum uric acid [μmol/L (mg/dL)]	Allowable deviation
200~400 (3.3~6.7)	The relative deviation should be no more than 20%
400~800 (6.7~13.3)	The relative deviation should be no more than 20%
800~1200 (13.3~20.0)	The relative deviation should be no more than 20%

9.3 Control material measurement with the tester

Precision of control material in blood glucose test: The coefficient of variation (CV) should be within 10%.

Precision of control material in ketone body test: The coefficient of variation (CV) should be within 10%.

Precision of control material in uric acid test: The coefficient of variation (CV) should be within 10%.

9.4 Measurement range

The blood glucose measurement range is 1.1~33.3 mmol/L.

The ketone body measurement range is 0.2~8.0 mmol/L.

The uric acid measurement range is 200 ~1200 umol/L.

9.5 Measurement time

The blood glucose measurement time is less than 10s.

The ketone body measurement time is less than 15s.

The ketone body measurement time is less than 25s.

9.6

Safety level: Transient overvoltage facilities are not applicable, and the rated pollution level is Grade 1. According to GB 4793.1-2007 *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*, YY 0648-2008 *Safety requirements for electrical equipment for measurement control and laboratory use — Part 2-101: Particular requirements for in vitro*

diagnostic (IVD) medical equipment and GB 4793.9-2013 *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 9: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*;

Climate and environment grouping: Climatic environment Ⅱ Group; mechanical environment Ⅱ Group. Environment test shall be carried out according to the applicable clauses in GB/T 14710-2009 *Environmental requirement and test methods for medical electrical equipment;*

Electromagnetic compatibility grouping: The equipment is I Group Class B product, according to the applicable clauses in GB/T 18268.1-2010 *Electrical equipment for measurement, control and laboratory use—EMC requirements—Part 1: General requirements* and GB/T 18268.26-2010 *Electrical equipment for measurement, control and laboratory use—EMC requirements—Part 26: Particular requirements—In vitro diagnostic (IVD) medical equipment.*

X. Safety Classification

This tester, with the internal direct current 3V, cannot be used in the conditions with a mixture of flammable and narcotic gases and nitrous oxide.

When the equipment is used in dry environment, especially in dry environment with artificial materials (artificial fabrics, carpets, etc.), it may cause damaging electrostatic discharge and lead to wrong conclusions.

It is recommended to evaluate the electromagnetic environment before use.

It is forbidden to use the device near the source of radiation; otherwise, it will interfere with its normal working.

XI. Product Parameters

Test samples	Fresh fingertip whole blood, venous whole blood
Test scope	Blood glucose 1.1~33.3mmol/L(20~600mg/dL) Uric acid 200~1200μmol/L(3.3~20.0mg/dL) Ketone body 0.2~8.0mmol/L(2.08 ~ 83.2mg/dL)
Sample volume	Glucose (glucose oxidase method)≥0.6μL(mL) Glucose (glucose dehydrogenase method)≥1.0μL(mL) Uric acid≥2.0μL(mL) Ketone body ≥1.0μL(mL)
Measurement time	The blood glucose measurement time is less than 10s; the ketone body measurement time is less than 15s, and the uric acid measurement time is less than 25s.
Operating temperature	10~40℃blood glucose, 10~40℃ketone body, 10~35℃uric acid
Relative humidity	<95%
Memory capacity	600 groups of test results (blood glucose 400 groups; ketone body 100 groups; uric acid 100 groups)
Battery	Two 3V lithium batteries
Size/weight of tester	94.5*61.5*23.5mm (L, W, H)/about 64.5g (including battery)

Transportation conditions	Transportation temperature -20℃~55℃, relative humidity ≤75%; prevention from violent shock, rain and sun exposure in the process of transportation.
Storage conditions	Storage temperature -20℃~55℃, relative humidity ≤75%, in the well-ventilated environment without corrosive gas.

XII. Fault Prompts

1. Disinfection with iodine tincture or disinfectant containing "iodine" will lead to inaccurate test values. Please use 75% alcohol for disinfection.
2. After disinfection, if collecting blood with wet hands, the blood sample cannot form drops, which will lead to the dilution of the blood sample or the test strip cannot suck blood normally.

Note: When the disabled or patients with severe conditions use the tester, it is necessary to monitor closely.

The tester can be used only as per the intended use described in the Instructions.

XIII. Recommended Reference Ranges of Blood Glucose, Ketone Body & Uric Acid

- **Reference range of concentration of blood glucose**

According to the recommendations of American Diabetes Association (ADA) in 2012, to prevent complications of chronic metabolic diseases, blood glucose, blood pressure and blood fat should be detected and treated as early as possible; self-screening of the above conditions and target value control should be done on a daily basis. The recommended reference range is as follows:

Item/unit	Normal value	Target value
Preprandial blood glucose (mmol/L)	<5.6	3.9~7.2
Postprandial (2h) blood glucose (mmol/L)	<7.8	<10

- **Reference range of concentration of ketone body**

The exact standard of β-hydroxybutyrate level in the blood has not yet been established. *Modern Clinical Biochemistry and Laboratory* believes that the normal range of β-hydroxybutyrate in fasting serum

of healthy people is 0.0 mmol/L ~ 0.3 mmol/L. Combined with product characteristics, the Company believes that the normal range of β-hydroxybutyrate in fasting blood of healthy people is 0.2 mmol/L ~ 0.3 mmol/L.

- **Reference range of concentration of uric acid**

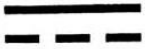
Healthy people produce about 750 mg uric acid every day, of which about 500 mg is excreted by kidney and the rest is excreted by large intestine through bile. When a kidney disease occurs, uric acid — the final product of protein, cannot be discharged smoothly, excessive uric acid will accumulate in blood, that is, hyperuricemia. When the uric acid value in male blood is higher than 7 mg/dl and that in female blood higher than 6mg/dL, this condition is asymptomatic hyperuricemia.

	Normal value of uric acid (umol/L)
Male	202 μmol/L ~ 416 μmol/L
Female	200 μmol/L ~ 339 μmol/L

Note: When the disabled or patients with severe conditions use the tester, it is necessary to monitor closely.

The Blood Glucose, Ketone Body & Uric Acid Tester can be used only as per the intended use described in the Instructions.

XIV. Label and Graph, Symbol and Explanation on the Package

Symbol	Explanation	Symbol	Explanation
	Protected from rain		DC
	If there are some matters that should be paid attention to in the product, please refer to the accompanying document		IVD

XV. Manufacturer Information

[Registrant /enterprise name] Beijing Lepu Medical Technology Co., Ltd.

[Address] Building 7-1,No.37,Chaoqian Road,Changping District,Beijing,102200,P.R. China.

[Address of manufacturing site] Floor 5, Building 7-1, No. 37 Chaoqian Road Changping District，Beijing 102200 P.R.China

Tel: +86-10-80123100 Website: en.lepumedical.com

[Date of production] refer to the nameplate or outer package.