

Coagulation Analyzer PT-M1-11

Instructions for use



Statement

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Before installing or using the Coagulation Analyzer for the first time, please be sure to read all the documents accompanying the product carefully. This will be helpful for you to use this product better. If this product is not operated according to the instructions and requirements of this manual, or the product is misused due to misunderstanding or other reasons, Lepu Medical Technology (Beijing) Co., Ltd. (hereinafter referred to as "Lepu") will not be liable for any loss arising therefrom.

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1、Product Introduction

1.1 Product description

Product name: Coagulation Analyzer

Product model: PT-M1-11

1.2 Intended use

This product is an in-vitro diagnostic medical device, which is used in conjunction with a prothrombin time test card. Clinically, prothrombin time (PT) is used to reflect the status of extrinsic coagulation pathways and common pathways. This product is used to test prothrombin time (PT).

Patient population: people with abnormal blood coagulation or are administered oral anticoagulants over a long period and have their blood coagulation function needing to be monitored regularly.

Intended user:

- Medical professionals can use the product.
- Non-professionals (or their families) should use the product under the guidance of professional doctors. Test results should not be used for diagnostic or therapeutic decisions. Consumers should communicate relevant questions or doubts with medical personnel after obtaining test results.

Intended use environment: Hospitals or home.

Operating environment:

- Ambient temperature: 10-35℃ ;
- Relative humidity: ≤80% ;
- Atmospheric pressure range: 86 kPa~106 kPa;

Contraindications: None found.

1.3 Operating principle

When a whole blood sample is dripped on the test card, the blood sample gradually coagulates, its electrical conductivity changes accordingly, and as a result, the current value changes. The analyzer tests this process and calculates the prothrombin time of the sample and then displays the results on the screen.

The prothrombin time test will vary greatly depending on test method used, and the test results will be different. In order to balance this difference, the World Health Organization (WHO) has established the international normalized ratio (INR) as a standardized reporting method for monitoring the PT of the patients administered oral anticoagulant drugs for treatment, so the results measured with different thromboplastin reagents are comparable.

When performing the prothrombin time test, the Coagulation Analyzer reports the prothrombin time (PT) and the international normalized ratio (INR).

1.4 Safety instructions

- Please read the operation manual carefully before use.
- The blood coagulation analyzer is used in conjunction with the matching prothrombin time test card (dry chemistry method) (the matching test card is manufactured by Lepu Medical Technology (Beijing) Co., Ltd. and is sold separately).
- Keep the blood coagulation analyzer and the matching test card out of the reach of children.
- Disinfect non-disposable blood collection devices and blood collection units.
- Do not reuse the test card.
- The used test card and lancet should be disposed of properly.
- The blood coagulation analyzer is only applicable to in-vitro tests.
- Do not use the blood coagulation analyzer if it does not work properly or has been damaged.
- Do not use the blood coagulation analyzer outdoors.

1.5 Precautions, limitations, and the statement on electromagnetic compatibility

1.5.1 Precautions

- Observe routine safety operation rules of a laboratory. The used test card should be disposed of as biological waste.
- Remove the batteries if it is unlikely the equipment will be used for a period of time.
- Used batteries should be recycled according to local regulatory requirements.
- Do not touch the surface of the test area during use.
- For in-vitro diagnosis only.

1.5.2 Sample collection

- Use fresh capillary blood in the test.
- When collecting fingertip blood, do not over-squeeze the fingertip. Otherwise, interstitial fluid will be released into the blood, resulting in inaccurate test results.
- When collecting fingertip blood, be sure that the fingertip is dry. Otherwise, residual alcohol will cause hemolysis and result in inaccurate test results.

1.5.3 Limitations of the test method

- Like all experimental tests, any diagnosis or treatment decision cannot be based on a single test result or method.
 - Prevent liquid from flowing into the analyzer.
 - The analyzer is a precision instrument. Damage or improper use may cause malfunction. Be careful to use it.
 - The analyzer should be placed in a carry bag or secure container during transportation.
 - Do not place the analyzer in an environment below -20°C or above 55°C .
-

- When performing the test, do not insert any other brands of test cards into the analyzer.

1.5.4 Statement on electromagnetic compatibility

- The device meets the emission and immunity requirements of EN 61326-1:2013 and EN 61326-2-6:2013.
- Evaluate the electromagnetic environment before using the device.
- Do not use this device near strong radiation sources (such as unshielded RF sources). Otherwise, normal operation of the device may be interfered.

2、 Product Composition

2.1 Accessories

The product includes the following accessories:

A Coagulation Analyzer, quick operation card, warranty card, instructions for use, Certificate of Conformity, and four AA/1.5V alkaline batteries.

Notes:

Do not use other power adapters to connect this instrument, otherwise it may be damaged.

Four standard AA/1.5V alkaline batteries are used as the power supply for the instrument.

2.2 Product diagram



Figure 1 Product exterior diagram

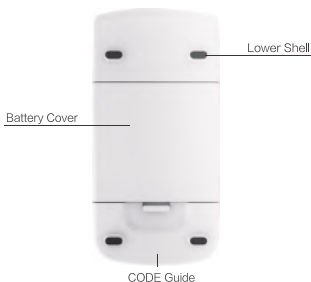


Figure 2 Product back diagram

3、Operation flowchart

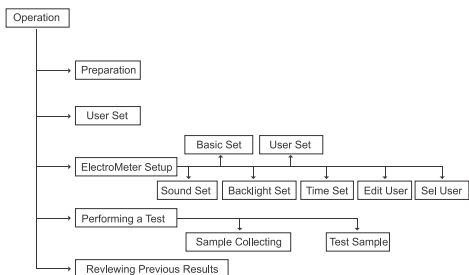


Figure 3 Operation flowchart

4、Preparations for the test

Before using the Coagulation Analyzer, prepare the following items:

- Coagulation Analyzer
- Prothrombin time (PT) test card
- Lancet
- Alcohol swab

5、Turning the Instrument On/Off

5.1 Connect the power supply

Place four AA/1.5V alkaline batteries in the battery chamber on the back of the instrument.

5.2 Turn on the instrument

After the instrument is turned on for the first time, the time setting interface will start after a “beep”. In the settings interface, you can set parameters. See 6.2 for details of that operations.



Figure 4 Time setting

To perform the test immediately, insert a CODE card that matches the Prothrombin time (PT) test card into the CODE card slot of the analyzer. If no CODE card is inserted, the screen will display a prompt to remind you of inserting a CODE card.

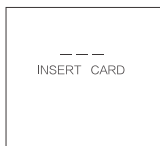


Figure 5 Insert a CODE card

If a CODE card has been inserted, the analyzer will display the value of the CODE card, and enters the card insertion interface after 1s. Under the card insertion interface, press the left key to quickly enter the time setting interface, and press the right key to quickly query historical data. See 6.4 for details of these operations. If you do not do any test now, you can press "Power Off" to turn off the instrument.

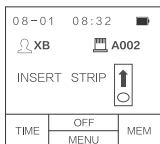


Figure 6 Card insertion interface

Note: The current battery level is displayed in real time in the upper right corner of the card insertion interface. If the battery level is low, the instrument will prompt "E001" and the battery icon will blink constantly.

If the instrument is in sleep state, it can be awaked in the following way:

- When the On/Off button is pressed, the screen will show the card insertion interface

5.3 Turn off the instrument

In the card insertion interface, press "Power Off", and the instrument will be turned off.

Note: The instrument automatically enters sleep state after it has been idle for more than 3 minutes. In the sleep state, press the "On/Off" button, and the instrument will enter the card insertion interface.

6、Set the instrument

6.1 Menu interface

When the instrument is in a sleep state, press the "On/Off" button, and the system will enter the card insertion interface. Press the "Menu" button, and the menu interface will appear.



Figure 7 Menu interface

6.2 Basic settings

In the basic settings interface, you can use the left and right buttons to set backlight, prompt tone and time. Press "OK" to start setting. Press "ESC" to return to the menu settings interface.



Figure 8 Basic settings

1、 Backlight setting

In the backlight setting interface, press the left or right button to turn the backlight on or off. Press "OK" to complete the setting and return to the basic settings interface. If you want to cancel the setting, press "ESC".



Figure 9 Backlight setting

2、 Prompt tone setting

In the prompt tone setting interface, press the left or right button to turn the prompt tone on or off. Press "OK" to complete the setting and return to the basic settings interface. If you want to cancel the setting, press "ESC".



Figure 10 Prompt tone setting

3、 Time setting

In the time setting interface, you need to set year, month, day, hour, minute and second in sequence. The item to be set will blink. Press the left button, and the number will decrease. Press the right button, and the number will increase. Press "OK", and the setting of this item is completed. Press "Local Time", and then the correct numbers will be displayed.



Figure 11 Time setting

6.3 User setting

In the user setting interface, you can carry out user modification and user selection settings.



Figure 12 User setting

1、 User modification

In the user modification interface, press the left or right button to select a user. After pressing “OK”, the selected user can be deleted or modified. If delete is chosen, user data will be cleared. If modify is chosen, the user modification interface will start. See the “User modification” operation below for details.



Figure 13 User modification

2、 User selection

In the user setting interface, user selection can also be performed, so the user can identify the tester. If there is no record of current user, select “+” to add user and enter the username setting interface.

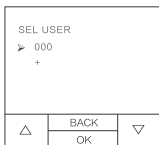


Figure 14 User selection

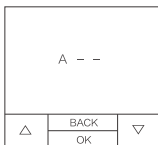


Figure 15 Username setting

In the username setting interface, the user can select an appropriate username consisting of 0–9 or A–Z by pressing the left and right button. A username cannot be blank, otherwise the interface will display “Invalid username”. If the currently set username has already existed, the interface will display “Existing username”, you need to reset the new username.

6.4 Data browsing

In the data browsing interface, historical data will be arranged in chronological order. You can use the left or right button to select the data to be viewed, and press “OK” to confirm the viewing.



Figure 16 Data browsing

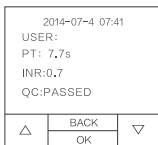


Figure 17 Data viewing

6.5 Control test

The PT control solution is used in conjunction with the prothrombin time (PT) test card to verify the performance of the system. It is recommended to perform two levels of testing for each control. See the control liquid manual for details of the control test operation information.

Please use the control liquid provided by Lepu Medical Technology (Beijing) Co., Ltd. to perform the control test.

6.6 Data deletion

In the data deletion interface, you can press the left or right button to choose whether to delete the data. If “Yes”, the product will perform data deletion, and the interface will display the deletion progress bar. If “No”, the product will return to the menu settings interface.



Figure 18 Data deletion

7、Test

7.1 Preparations

- If the product is used for the first time, place four AA/1.5V batteries in the chamber, and close the battery cartridge cover. Please pay attention to the battery polarity.
- Insert the CODE card from the prothrombin time test card packaging box into the CODE card slot of the instrument. (A CODE card is provided in each box of test cards. Please be sure to use the CODE card with a matching number of the prothrombin time test card.)
- Press the “On/Off” button. After test interface appears, the code will be displayed at the top right of the display. Please check whether the code displayed on the LCD is consistent with that on the prothrombin time test card. If not, first, check whether the inserted CODE card and prothrombin time test card are taken from the same box. If yes and the codes are still inconsistent, stop the test and unpack a new prothrombin time test card for a new test.
- Take out a prothrombin time test card and insert the test card in the direction indicated by the arrow on the interface. If the card is inserted successfully, the system will automatically enter the user selection interface. If the test card has been inserted into the instrument before it is turned on, the system will directly enter the user selection interface.

7.2 Heating

After the user identity is validated, the system will automatically enter a heating state.

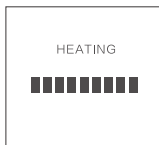


Figure 19 Heating

After heating is complete, the screen will prompt to add the blood sample. You must complete the sample addition within 3 minutes. Otherwise, it will cause an E008 error (sample addition timeout).



Figure 20 Blood sample dripping

7.3 Blood sample collection

Blood can be collected with a disposable lancet (sold separately).

7.3.1 Improve blood circulation

Before blood collection, warm hands with hot water or near a hot plate, or massage the finger while keeping the hand below heart level.

7.3.2 Sample collection

- Wipe the fingertip with alcohol. Collect blood after the alcohol has evaporated.
- Remove the lancet cap and firmly attach the end of the lancet to the part that has been disinfected.
- Gently press the ejector, and then with a sound of spring release, puncture is completed.
- Put the used lancet in an appropriate container.
- After the blood sample is added to the test card, use a sterile swab to press the puncture site to stop bleeding.

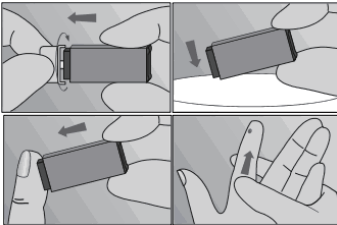


Figure 21 Sample collection

Notes:

- Collect capillary blood from the lateral edge of a finger because the least pain will be suffered in this way.
- After puncture, massage the finger from which blood will be collected until a blood droplet forms. Do not squeeze the finger forcibly.
- The addition of the blood droplet to the test strip must be completed within 15s after the finger is punctured. Blood sample addition beyond that time will result in false test results because blood coagulation has already started.

7.4 Test

Keep the instrument level. Collect a blood droplet hanging from the fingertip and add it to the sample addition port of the test card. The instrument automatically starts testing. During this test, do not move the instrument or test card and do not press the operation buttons on the panel.



Figure 22 Blood dripping

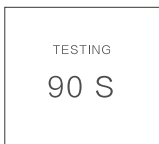


Figure 23 Testing



Figure 23 Data processing

When the test is completed, the instrument will issue a "beep" and then display the test results along with the patient number on the screen. Press "ESC", the instrument will return to the main interface. If the test card is not removed, it will prompt you to remove the test card.

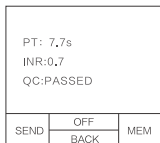


Figure 24 Test results

Note: Test results, patient numbers, batch numbers, and date and time settings are automatically saved. The system can save up to 200 sets of results.

7.5 Test results and notes

- Normal range

Through a large number of healthy samples tested, the normality range of testing: INR is between 0.7-1.4.

- Abnormality range

The treatment range for patients varies from person to person. The appropriate treatment range: INR is between 2 and 4.5, and may be below or above this range.

- Unexpected results

When the test result is not in the expected range, it may be due to some special causes.

Solution: When unexpected results are obtained, retest with a new test card. If you get repeated results, contact the doctor immediately.

7.6 End of test

After the test is completed, place the used test card in an appropriate container. When the instrument is not used, it is recommended to turn it off to save power.

8、 Bluetooth function

When the Coagulation Analyzer completes a test, click the "Upload" button, and the Bluetooth on the instrument will be turned on automatically to enable the instrument to be connected to a phone.

Alternatively, after the test is completed, return to the card insertion interface and click the "Record" button to display the historical data. Use the left and right buttons to select the data you want to view. Press the "OK" button to view the data. After the data are displayed, click on "Upload", and the Bluetooth of the instrument will be turned on automatically and the instrument can be connected to the phone.

9、 Cleaning

- Wipe the surface of the instrument gently with a damp cloth. If necessary, use a swab with a small amount of alcohol, absorbent paper, and a cloth to clean the instrument appropriately.

- The wiped portion should be completely air-dried and any lint or fluff remaining on the surface of the instrument should be removed.

Note: To avoid system damage, please observe the following:

- 1、 Prevent liquid from flowing into the instrument.
- 2、 Do not spray anything into the instrument. Do not immerse it in any liquid: it may damage the internal components of the instrument and as a result, it will not work properly.

10、 Main technical parameters















Parameters	Indicator
Test range	INR:0.7-6.0
Accuracy (r)	INR:0.7-1.9 (Deviation: ± 0.3 ; $r \geq 0.95$) 2.0-4.5 (Deviation: ± 0.8 ; $r \geq 0.95$) 4.6-6.0 (Deviation: ± 1 ; $r \geq 0.95$)
Repeatability (CV%)	INR: 0.7-6.0 ($\leq 10.0\%$)
Preheating time	$\leq 3\text{min}$
Temperature control	$37.0^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$
Sample addition quantity	$\geq 10\mu\text{L}$
Test time	90s
Power supply	4 AA/1.5V alkaline batteries
Storage	200 sets of data and the test date and time
Power-saving mode	The instrument will turn off automatically if there is no any operation within 3 minutes.
Instrument dimension	145mm*69 mm*33 mm (length*width*height)
Display	128*128 LCD
Weight	About 160g (excluding the AA batteries)
Operating environment	10-35°C; humidity: $\leq 80\%$
Storage environment	-20-55°C; humidity: $\leq 90\%$ (no mist)
Service life	Three years
Production date	See the label

11、Prompts and troubleshooting

The following table lists the problems that may be encountered during the use of the Coagulation Analyzer and their simple solutions. If the problem cannot be solved by using the corresponding method, please contact the supplier or manufacturer.

Prompt	Meaning	Solution
E001	Battery low	Replace the batteries
E002	Instrument heating timeout	Turn off the instrument for 5 minutes at 10–35° C
E003	Abnormal temperature	Be sure that the instrument is used at 10–35° C
E004	Insufficient sample addition	Retest with a new test card and be sure that the blood addition quantity is not less than 10uL.
E005	QC is not passed	1、 Be sure that the test card is within its shelf life 2、 Be sure to use the correct Code card
E006	PT value calculation error	Retest with a new test card
E007	The INR is below the normal range	Retest with a new test card
E008	Sample addition timeout	Be sure to complete the sample addition within 3 minutes after the sample addition prompt
E009	Too early sample addition	Use a new test card. Add the sample after the instrument displays the sample addition prompt.
E010	Wrong Code card; replace it	Check if the Code card has expired
E011	The card was pulled out during the self-test of the instrument	Insert the correct code card
E012	Abnormal test card	Retest with a new test card
E013	The external control test is not passed	Be sure that the test card and the control card are within their shelf life

12、 Interpretation of symbols

Symbol	Description
	Manufacturer
	Authorized representative in the European Community
	Date of manufacturer
	Use-by date
	Serial number
	Biological hazard
	In vitro diagnostic medical device
	Consult instructions for use
	Temperature limit
	Caution
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Direct(battery) current

13、 Maintenance

- The Pharmaceutical Affairs Law stipulates that the modification of medical instruments is prohibited.
- Maintenance personnel not authorized by the company shall not disassemble the instrument and perform maintenance.

14、 Warranty

Lepu Medical Technology (Beijing) Co., Ltd. warranties for defects in materials and technologies within one year from the date of purchase. This warranty cannot guarantee uninterrupted operation of the instrument.

Lepu Medical Technology (Beijing) Co., Ltd. does not make any other warranties and expressly disclaims any implied warranties of merchantability, non-infringement, or applicability to a particular purpose.

The only parts which the user can replace or dismount are the batteries and the back cover of the battery cartridge. Tampering with other parts of the instrument, misuse of the instrument or not using the instrument in accordance with the instructions for use will make the warranty invalid. This warranty does not apply to any damage arising

from improper preservation, or accidents, alteration, tampering or misuse. Before returning any defective instrument, you must obtain an "Authorized Return" and return directives given by Lepu Medical Technology (Beijing) Co., Ltd. Please phone us for technical support.

The shelf life of this product: Three years.

Production date: See the label.

All liabilities of Lepu Medical Technology (Beijing) Co., Ltd. relating to the instrument, no matter any legal claims or any claims based on the fair use statement, are not limited to the purchase price of the instrument. In any circumstances, Lepu Medical Technology (Beijing) Co., Ltd.'s joint liabilities include accidental, indirect, special, consequential, punitive damages or compensation, or any remedial measures taken by its distributors aware of the possibility of such claims or losses.

15、 The manufacturer and after sales service unit

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