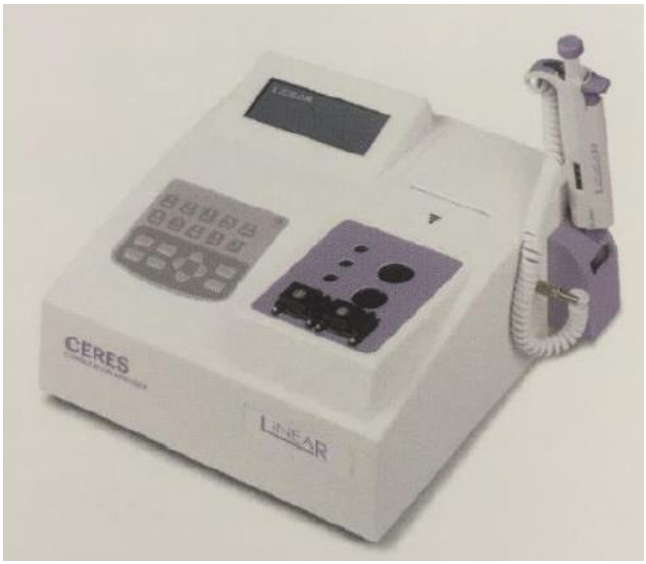
CERES

User's Manual

Coagulation Analyzer



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How to use this manual

Thank you very much for being the user of CERES Coagulation Analyzer. Before operate this instrument, please read this manual carefully.

This user's manual is for the CERES Coagulation Analyzer from LiNEAR Company, including the contents of instrument installation, daily operation, maintenance, etc

The functions of insrtruments with difference versions or configurations may be different.

Please reserve all packing materials for storage, transportation and return to fctory for maitenance.

If any problems come into existence, please contact the distributors

Meanings of markers

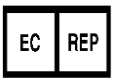
Warnings: It indicates that if no attention is paid to this marker with misoperation of this instrument, the casualties and severe injuries of the using personnel or severe property loss might be caused.

Note: It indicates that if no attention is paid to this marker with misoperation of this instrument, it will be caused that the using personnel are injured, the output results are influenced or the loss is applied to the properties.

Points for attention for diagnosis

Cautions: This product is a clinical inspection instrument used for inspection. The clinical diagnosis based on the test results shall be implemented by the doctor according to the clinical symptoms, combining other inspection results.

Main graphical representations used on this instrument

Symbols on the instrument	
	This means that the labeled item could lead to personal injury and/or damage to the analyzer. The symbol is labeled beside the power outlet and some external interface.
SN	The symbols for "SERIAL NUMBER", The serial number shall be after or below the symbol, adjacent to it.
	The symbol means the product is in vitro diagnostic medical device.
	The symbol indicates the manufacturer and its address, after which are shown its name and address.
	The symbol indicates EU representatives of the manufacturer and their addresses, after which are shown their names and addresses.
	CE Certification
	The symbol indicates biological pollution, marked in the part where the instrument contacts the clinical reagent. The symbol appears in black side and yellow background.

Symbols on the sales packaging	
	The symbol means that the environment of instruments must be damp proof in the course of transport, and instrument must be kept in a dry environment.
	This means that instrument should handle with care in the course of transportation, so as not to damage it.
	The symbol means the instrument packaged should not be upended at any time
	The symbol means that the level piled up can't exceed 8 layers, as not to damage instrument.
	The symbol indicates temperature range of the analyzers during storage and transportation.

Warnings and security attentions

This instrument is only provided for in vitro diagnosis, please carefully read the following warnings before use. They are required to be strictly followed.

Warnings: please carefully read the following security attentions before use this instrument.

- **This instrument has no components which the users can maintain by themselves. Please do not dismount the instrument yourself when there are malfunctions**
- **This instrument shall not be used on the high-temperature, high-humidity site where the oil or corrosive substances exist.**
- **If the smoke, peculiar smell and sound appears while using, the power supply must be immediately cut off. Meanwhile, the inspection apply shall be immediately presented towards the distributors and the agents of this company. If the instrument continues to be used under this circumstance, the misfire, electric shock or casualties of personnel might be caused.**
- **The bloods, reagents and metal pieces shall be avoided from entering the interior of this instrument, or the short circuit or misfire with smoke generation will be caused. If abnormality happens, the power supply shall be immediately cut off and the plug of the power supply is extracted from the power socket. Meanwhile, the inspection apply shall be immediately presented towards the distributors and the agents of this company.**
- **The operator shall not touch the electronic lines in the instrument; especially there will be a danger of electric shock when they are touched by a wet hand.**
- **The rubber gloves are required to be worn and the prescriptive tools and parts must be used when the instrument is maintained and checked. When the operation ends, please wash your hands using disinfection solutions, or the infection, electric shock or scald might be caused to the part of the skin which contacts with the bloods.**
- **When the samples are handled, the great care shall be paid and the rubber gloves must be worn, or the infections might be caused. If the samples enter the eyes or wounds, they shall be immediately washed using a large amount of clear water and inspected by the doctor.**

Usage of reagents

- **The reagents shall be avoided from contacting with the skins and clothes when the operation is carried out.**
- **If the reagents enter the eyes immodestly, they should be immediately washed to be clean using a large amount of clear water and inspected by the doctor.**
- **If the reagents are wrongly drunk, the help shall be immediately obtained from the doctors and simultaneously a large amount of water shall be drunk so as to vomit the reagents.**
- **If the hands or skins are touched with the reagents, they shall be immediately washed to be clean using a large amount of clear water.**

- **The waste products such as used test tubes, other instruments and consumables, etc shall be appropriately handled as the medical waste products or infectious waste products. If the pollution is caused by bloods, the infection might be generated by pathogens.**

Voltage, connection and grounding of power supply

- **The power supply and grounding environment of this instrument are assured to be good and stable.**
- **The plug of the power supply shall not be inserted into the power socket which is not available for the voltage requirement stated in the backplate of instrument, or the misfire or electric shock might be caused.**
- **When the instrument is installed, the power supply cable as accessories attached to the machine must be used and the good grounding shall be assured, or the misfire or electric shock might be caused.**
- **DO NOT damage the insulation protection skins of the power cord. DO NOT pull the power cord with efforts or hang heavy articles on it, or the short circuit or open circuit might be caused.**
- **When the peripherals are connected, the power supply must be first cut off, or the short circuit or open circuit might be caused.**

The pharmaceutical affairs law prescribes that refitting medical instruments is forbidden.

CONTENTS

1. Instrument Introduction

1.1 Product introduction

1.1.1 Product name Coagulation Analyzer

1.1.2 Product model CERES

1.1.3 Product features

1) CERES is an analytical instrument used to measure multiple cruor parameters. It collects the sample data through the principle of photoelectricity induction and can be widely applied in the field of clinical diagnosis for bleeding and thrombotic diseases, thrombolysis and anticoagulation treatment and monitoring and observation of curative effect, etc.
2) Multiple programmable items are built in and a large capacity of historic data storage.
3) Two separate test channel, test two samples at the same time.
4) The data management and analysis can be carried out through the computer connected with the instrument by using LiNEAR coagulation laboratory management system. (optional)
5) The specially designed measuring cell shading system puts an end to the interference of the external stray light.
6) The measurement can be started simultaneously in two modes of auto start by signal from electronic pipette and manual start.
7) Friendly English user interface, sound and light prompts are applied to each step of operation.

1.1.4 Requirement of EMC

 Caution:

- CERES Coagulation Analyzer is a Class A equipment. CERES Coagulation Analyzer complies with the requirements of emission and immunity requirements described in EN 61326-1:2013 and EN 61326-2-6:2013.
- You are obliged to ensure the electromagnetic compatibility environment for the equipment to make the equipment work normally.
- We suggest that you assess the electromagnetic environment before using the equipment.

 Warning:

- CERES Coagulation Analyzer is designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

1.2 Performance, structure and composition of products

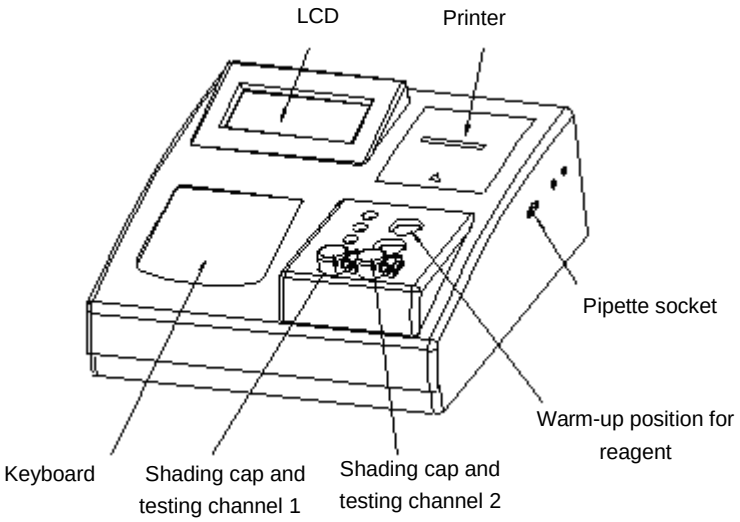
It is composed of the optical part, the precise photoelectric sensor, the computer control system, etc.

1.3 Application scope of products

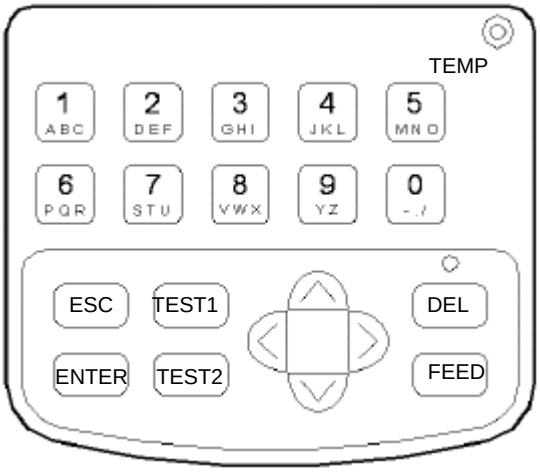
It is suitable for the medical organizations to implement the inspection of thrombus and hemostasis and can provide the reference indexes for the diagnosis of the bleeding and thrombotic diseases, the monitoring of the thrombolysis and anticoagulation treatment and curative effects.

1.4 Instrument structure

1.4.1 Front view of instrument



1.4.2 Brief introduction of operating keyboard



Temperature indicator light: It indicates the measured channel temperature. The indicator light is on indicates that the constant temperature controller has already controlled the channel temperature to be within the measurable range.

Numbers from 0 to 9: Numeric entry key; the characters can be entered under the specific circumstance simultaneously and the corresponding characters are displayed below the numeric keys.

TEST1: Control key for channel 1

TEST2: Control key for channel 2

ESC: Press to exit

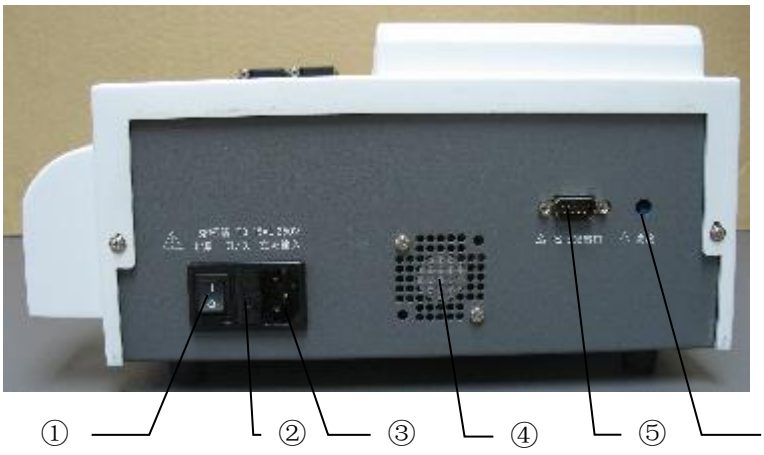
ENTER: Press to confirm

DEL: Press to delete

FEED: Paper-feeding key of the printer

☑, ☑, ☑, ☑: are respectively Up key, Down key, Left key and Right key

1.4.3 Rear view of instrument



① Switch:	Turn on or off the power supply
② Fuse:	If the power is still not delivered after the power supply is turned on, check the fuse of the instrument
③ Outlet:	It is used to be connected with AC power cord.
④ Fan:	System fan
⑤ RS-232:	The serial communication interface is connected with PC to carry out the communication.
⑥ Knob for adjusting contrast:	It is used to adjust the contrast ratio of LCD.

1.5 Technical specifications

Warm-up position for sample:	4
Warm-up position for reagent:	2
Testing channel:	2
Display:	LCD
Operating mode:	thin film keyboard
Printer:	Built-in printer
Temperature of warm-up groove:	37℃
Interface:	RS-232 bidirectional communication port, connection port of electronic pipette
Weight:	4kg
Dimensions:	280mm(L)×310mm(W)×160mm(H)
Power supply:	110V/220V～; 50Hz/60Hz
Fuse:	T3.15AL250V, Φ5×20
Operating environment:	10℃～30℃; Relative humidity≤70%
Storage environment:	-10℃～40℃; Relative humidity≤80%

2. Instrument install

2.1 Instrument unpacking

Unpack and remove materials for transportation. Store the packing carton and packing material for the future use when the instrument needs to be repackaged.

1) Take out the analyzer from the package box.
2) Remove the packing materials and take out the analyzer from the plastic bag.
3) Check the accessories attached with the machine in the packaging box and make sure that the following are included:

- CERES Analyzer
- User's manual
- Packing list
- Warranty certificate
- Product certificate of approval
- Other accessories: Power cord, reserved fuse, etc (according to packing list)

Cautions: If any parts are found to be lacked and damaged or not in accordance with the packing list, please contact the sellers.

2.2 Environment requirement:

Find a place without direct sunlight on working site. Select a worktable with flat surface and enough space to accommodate CERES.Avoid shock on the table (for example, when a centrifuge is placed on the table).

Cautions: the temperature of the working temperature of the instrument shall be from 10℃ to 30℃, the relative humidity shall be smaller than 70%.

In order to assure the normal working of the instrument, it is forbidden to be placed at the following places:

- Places where the temperature changes extremely.
- Extremely hot or cold places.
- Places where large amount of dust exists.
- Places in the vicinity of electromagnetic equipment that generates magnetic field.

2.3 Requirements of power supply

- 110V/220V~

- 50Hz/60Hz
- 80VA

Note:

- ***The AC power supply is required to be well grounded (zero-to-earth voltage＜5V).***
- ***The AC power supply must be stable and the instrument is forbidden to load the same power supply with the electric apparatuses with a large rated power***
- ***When the power cord is extracted, the body of the plug but not the power cord is required to be hold.***
- ***If the smoke, peculiar smell or strange sounds are found to be emitted from the instrument, please immediately turn off the power supply and contact with the sellers.***

3. Start-up

Turn on the switch on the back of the instrument, the system is initialized and automatically enters the main menu, which is shown as Figure 3-1.

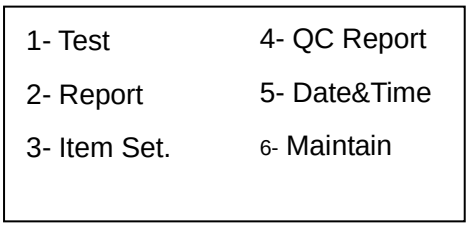


Figure 3-1 main menu of system

"1-Test": press **1** key to enter the sample test program;

"2- Report": press **2** key to enter the programs such as processing of patients' information, query and printing of test report, etc;

"3-Item Set": press **3** key to enter the settings program for item parameters;

"4-QC Report": press **4** key to enter query and processing program for quality control report;

"5-Date & Time": press **5** key to display current date and time program of the system;

"6-Maintain": press **6** key to enter the processing program for function of system maintenance;

Press **ESC** key to query the related information of the machine, including model, software version, machine name, serial number, etc. Press any other key to return to the main menu.

After the temperature of the instrument automatically rise to 37℃, the "Temp" indicator light is on and you can run tests on the instrument.

4. Item Settings

Press **1** key in "Item set." menu to enter the menu for item parameter settings, which is shown as Figure 4-1

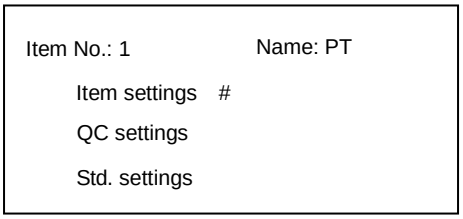


Figure 4-1 Item selection menu

Item No.: select item number; select by <, > keys or input item number directly, The corresponding abbreviation of the item name is displayed in the name column. After the number is entered, press **ENTER** key to enter the selection menu and the cursor points to the name column.

Cautions: after the item is entered, the menu of parameter settings can be entered only after the "ENTER" key is pressed.

Name: the abbreviation of the English name corresponds to the displayed item number. The items number from 1 to 16 are fixed items of the system and their name cannot be changed; the characters can be directly entered as the name of the other items

Item Settings: Set the test parameter of the item

QC Settings: Set the parameters of the quality control

Std. Settings: standard settings set the test parameter of the standards

Select the item settings, QC settings or standard settings by V, ^ keys and the sign "#" is displayed at the right side of the selected item; press **ENTER** key to enter the corresponding settings menu.

4.1 Test mode for coagulation point (percentage)

The percentage test mode is used for the test of coagulation time.

The level of scattered light when the reagents are just added in and the coagulation reaction does not begin is 0% and the level of the scattered light is 100% after the coagulation reaction ends. The coagulation time is obtained from the coagulation curve when the scattering light level reaches the predetermined percentage. (As Figure 4-2, the coagulation point is set at the position of 50%, user can adjust the percentage of coagulation point of each item according to the practical conditions. The smaller value of the percentage is, the shorter time for test result is).

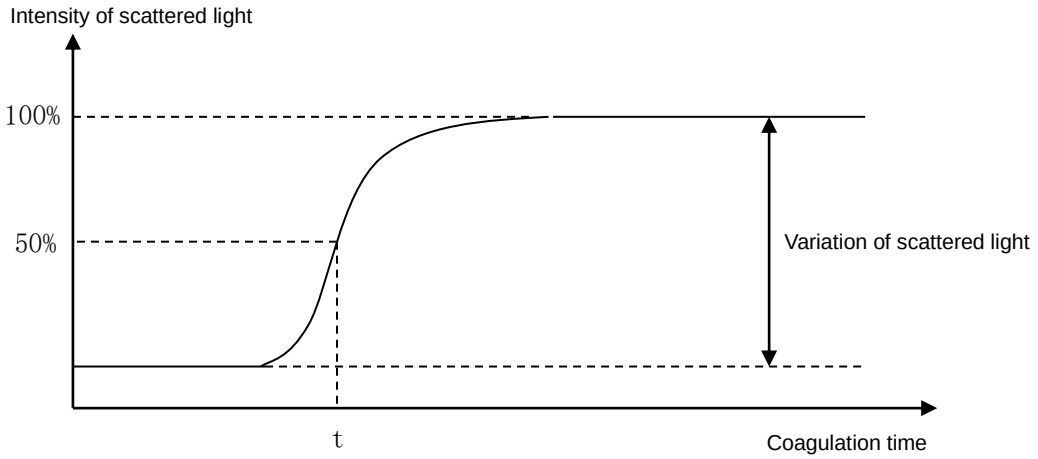


Figure 4-2 Diagram of coagulation curve

4.2 Item parameter settings

The reference values of the testing parameters for the commonly used item are shown as Table 4-1 and the practical test shall be carried out according to the instructions of reagent.

Table 4-1 Parameter table for reagent

Item	Sample Volume (ul)	Reagent Volume (ul)	Warm-up time 1 (s)	Warm-up time 2 (s)	Remarks
PT	50	100	180	0	
APTT	50	50	180	300	CaCl2 50ul
TT	50	50	180	0	
FIB (Clauss)	100	50	480	0	The sample is diluted according to the ratio 1:10. If the test results are out of the linear range, change the ratio to 1:5 or 1:20 according to the specific conditions
F2,F5,F7,F10	Same as PT				Same as above
F8,F9,F11,F12	Same as APTT				Same as above

Select item. Select "item settings" and press **ENTER** key to enter the menu for settings the testing parameter of the item, which is shown as Figure 4-3. Move the cursor by ▽, △keys and select by ◁, ▷ keys or input directly.

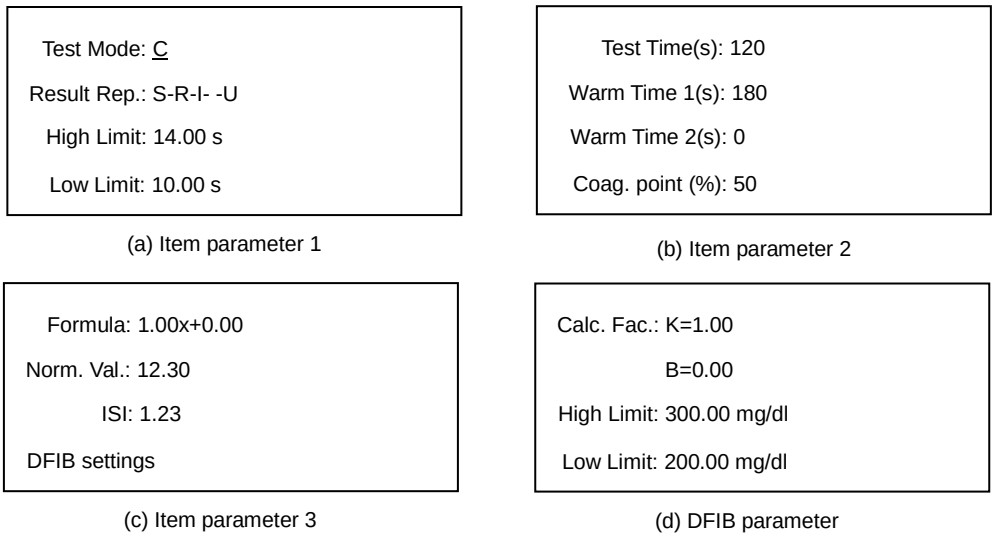


Figure 4-3 item test parameter

- Test Mode: the test method for item is selected, which is respectively C or B. Wherein C represents the coagulation method and B represents the coagulation plus estimating method; only the item PT is available for Method B (estimate the FIB item).
- Result Rep.: the abbreviation of result representation, the output and representation form of the test results; wherein: S- is the representation method of "second" and R- is the abbreviation of PTR, which represents the original time ratio of the thrombin. I- is the abbreviation of INR, which represents the International Normalized Ratio (INR). %- is the representation method of the percentage activity; U- represents the representation method of concentration. Move the cursor by ▽, △keys and select the corresponding representation method by ◁, ▷keys.

Cautions:

- ***Only the % representation method or U representation method can be selected. They two can no exist at the same time.***
- ***Only when the % representation method or U representation method is selected, the standard settings and test exist.***

- High Limit: the upper limit of the normal reference value
- Low Limit: the lower limit of the normal reference value
- Test Time: the longest time of the blood coagulation; if the coagulation endpoint is still not detected when this time is passed, it shall be handled as time-out.
- Warm Time 1: Time for warm-up the sample.
- Warm Time 2: warm-up time after the sample is mixed with reagent.
- Coag. Point: the abbreviation of coagulation point, the coagulation point is a percentage that the reaction variation used to specify the coagulation time takes in the whole variation. The coagulation point percentage of each item is adjusted so as to make the test result approach the true value. Default value is 50%.

- Formula: the abbreviation of correction formula, it corrects the value of the test time. The time vale after being corrected = value of test time*k + b, the unit is second.

Note: After the b value is entered, the positive and negative values can be shifted by <, >keys. (The k vale is not available for negative values.)

- Norm. Val.: the abbreviation of normal value, determination of normal reference value, test 20 normal samples, calculates the average value (second).
- ISI: the value of international sensitivity index ISI is entered according to the reagent instruction.
- DFIB settings: the FIB result of the corresponding sample can be obtained by calculation through PT test and the user can select whether to display the calculated FIB value in the PT test results according to the requirement. (If FIB needs to be calculated through PT test, select B as the test method and set the related parameters).
- Calc. Fac.: the abbreviation of calculation factor, the FIB concentration of the sample can be calculated through PT measured time while the PT test is carried out. The FIB result calculated according to the PT measured time is signed as DFIB. The conversion formula is: DFIB concentration= PT measured time*K+B. The user needs to adjust the calculation factor according to the practically measured results.

Cautions: after the K value or B value is entered, the positive and negative values can be shifted by<, >keys.

- High Limit, Low Limit: it specifies the reference range of DFIB. It will be judged that whether the DFIB results are beyond the range according to this value when the report is printed, thus giving the approriate prompt.

After various parameters are set, press **ENTER** key to save the modifications and return; press **ESC** Key to return without saving.

4.3 QC parameter settings

Select items. Select "QC settings" and press **ENTER** key to enter the menu for settings the quality control test parameters, which is shown as Figure 4-4. Move the cursor through the ▽, △ keys and select by the ◁, ▷ keys or directly input the number.

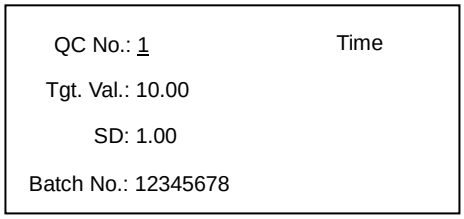


Figure 4-4 QC parameter settings

The default QC type is time. When the selected item is the quantitative item, the QC type can be also selected to be quantitative. Three QCs of different levels can be entered for each item. When the QC type is changed, the corresponding QC data of this item will be changed.

QC No. 1, 2 and 3 can be selected; they respectively represent three QCs of different levels.

Time: time is the QC type as default; select time or quantity by ◁, ▷ keys

Target value, SD and batch number are entered according to the reagent instruction.

After various parameters are set, press **ENTER** key to save the modifications and return; press **ESC** key to return without saving.

4.4 Calibration parameter settings

The units of the test results of different items are as following; wherein ★ represents the test results can be obtained of each item.

Item	Time(s)	Ratio	INR	% Activity	Quantity
PT	★	★	★	★	
APTT	★	★			
TT	★	★			
FIB	★				★
F2	★			★	
F5	★			★	
F7	★			★	
F8	★			★	
F9	★			★	
F10	★			★	
F11	★			★	
F12	★			★	
Heparin	★				★
APC-R	★	★		★	
Protein S	★			★	
Protein C	★			★	

In item settings, the "Standard Settings" exists only when the % representation method or the U representation method is set. (Calibration function)

Select item. Select "Std. Settings" and press **ENTER** key to enter the menu for settings of standard parameters, as shown in Figure 4-5. Move the cursor by ▽, △ keys and select by ◁, ▷ keys or directly input.

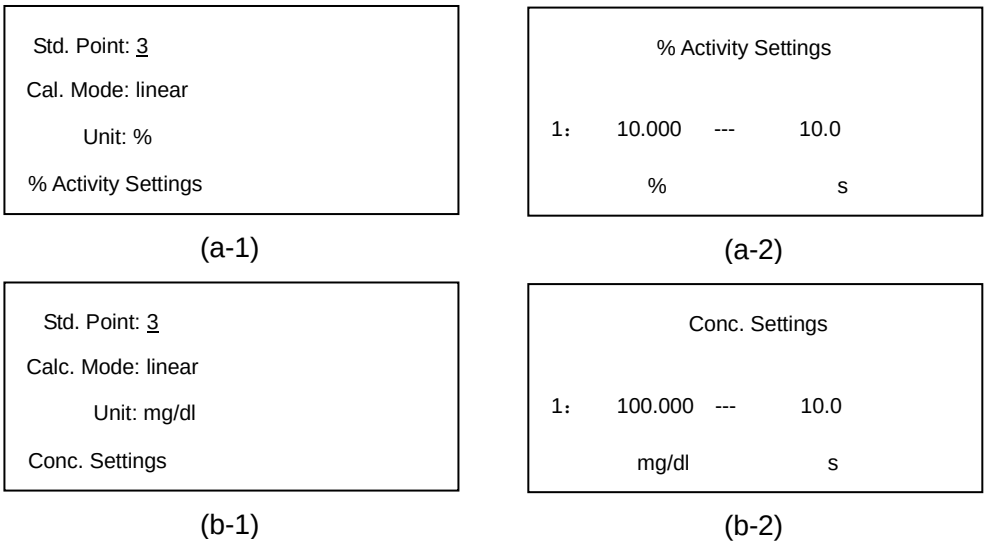


Figure 4-5 standard parameter settings

Std. Point: the abbreviation of standard points, select the number of the standards; 2 to 6 standards are allowed to be set for the item need calibration (at least two standards).

Calc. Mode: the abbreviation of calculation mode, respectively three modes such as linear (linear regression), DLSL (double logarithmic straight line), DLPL (double logarithmic polygonal line), etc.

Unit: when the % representation method is selected, only % activity unit can be selected and the settings of percentage activity and time of the corresponding standards, percentage activity and time can be implemented, which is shown as Figure 4-5 (a-2); when the U representation method is selected, the units such as g/l, mg/dl, mg/l, IU/ml, etc can be selected and the settings of the concentration and time of the corresponding standards, which is shown as Figure 4-5(b-2).

After various parameters are set, press **ESC** key to return without saving; pressing **ENTER** key, the validity of entered parameters will be checked. The concentration parameters in the standard parameters of this instrument are entered manually; the time parameters can be directly entered and also can be automatically stored through test.

If the concentration and time parameters are manually entered: the monotonicity of the concentration and time must be assured (progressive increase or progressive decrease), or the standard parameters are incorrectly set. The display information is shown as Figure 4-6(a). Press **ENTER** key or **ESC** key to return without saving

If the concentration parameters are manually entered, the time parameters are automatically stored according to test result: the concentration parameters are required to be entered in the progressive increasing or decreasing order and the time parameters are all required to be zero (no time parameter can be entered, or the system will judge it error and will not save). In the process of test, select the standard test and select the reagent of the corresponding concentration to carry out the test.

If the standard parameters are correctly set, the system prompts whether to print the standard parameter after the **ENTER** key is pressed, which is shown as Figure 4-6(b). Select whether to print by <, > keys. Press **ENTER** key to print and return.

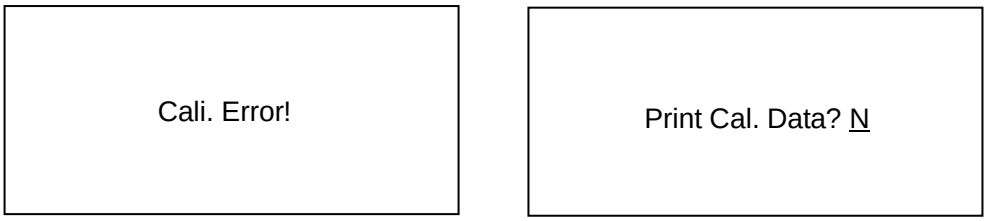


Figure 4-5 information of standard settings

4.4.1 Percentage activity

Taking the example of PT:

% activity	Dilution proportion	Standard plasma (ul)	Normal saline (ul)
100	-	200	-
50	1:2	200	200
25	1:4	100	300
12.5	1:8	50	350

4.4.2 Quantitative

Taking the example of FIB: (assuming that the concentration of the calibration solution FIB is 250mg/dl)

FIB concentration (mg/dl)	Dilution proportion	Standard plasma (ul)	IBS (ul)
500	1:5	200	800
250	1:10	100	900
125	T1:20	50	950
62.5	1:40	25	975

4.5 User-defined item

16 fixed items are built in the instrument and the user can define 14 test items. The specific steps of the item definition are as follows:

1. Select any item number in the range from 17 to 30; press **ENTER** key; if this item does not exist, an automatic prompt is given out and the user determines whether to add this item, which is shown as Figure 4-6.

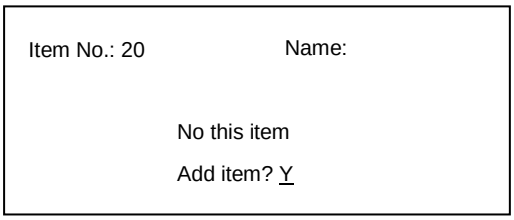


Figure 4-6 User-defined items

2. Select Y or N by <, > keys. When Y is selected, new items will be added pressing **ENTER** key, or they will not be added. The settings of the rest parameters are the same as the fixed items.

4.6 Display total number of items

Press 2 key to get into the "Total No. of Items" menu in "parameter settings" menu, as shown in Figure 4-7.

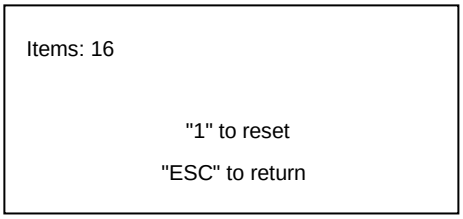


Figure 4-7 query of total number of items

Items: it displays the current number of items set for the instrument, including 16 fixed items and N user-defined items.

Pressing 1 key can restore the default value and will delete all user-defined items at the same time. Before the default value is restored, the system will prompt the user whether to carry out the restore operation. At this time, Y or N can be selected by <, > keys and then press **ENTER** key to restore the default value.

4.7 Delete test item

Press 3 key in the "Item Set." menu to get into the "Delete Item" menu, as shown in Figure 4-8. Only the user-defined items can be deleted, the item whose number from 17 to 30. Enter any number from 17 to 30 in the item number column and the corresponding name abbreviation is displayed in the name column at the right side. Press **ENTER** key to automatically delete.

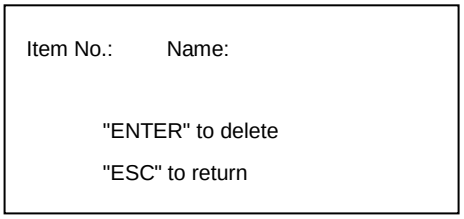


Figure 4-8 delete the test item

5. Sample test

The warm-up time would be continued for 15 to 30 minutes after the instrument is started up on the usual conditions. If the temperature does not reach the predetermined range, the temperature indicator light will not be on and the normal test can't be executed. Please make sure that the temperature when the test is going on is assured to reach the predetermined range, or the accuracy of the results will be influenced!

5.1 Test settings

Press key **1** at main menu to enter test settings, as shown in figure 5-1. Move the cursor by ▽, △ Keys and select content by ◁, ▷ keys.

Channel 1	Channel 2
Item: 1	Item: 3
Name: PT	Name: TT
Test: Sample	Test: Sample

Figure 5-1 Test settings

Channel: The left side of the screen displays the test item and settings of channel1, while the right side displays the test item and settings of channel 2.

Item: Select the number of test item, its abbreviation will be displayed at the name column

Test: Select the test content, there are sample, control and standard.

After you confirm the settings, press to **ENTER** to enter test procedure.

5.2 Test

5.2.1 Test procedure

Test channel 1 is controlled by Key 1 while channel 2 controlled by key 2; the two channel works separately, their procedures are the same. We take the procedure of channel 1 for example:

1. Press **Test 1**, the status column of channel 1 displays "Please add sample";
2. After adding sample, press **Test 1** to stat prewarming; the status column of channel 1 displays "Sample prewarming…", the "XX:XX" displays the remaining time for sample prewarming; press **Test 1** again to cancel prewarming;
3. After sample prewarming, status column of channel 1 displays " Please add reagent";
4. After adding reagent 1, press **Test 1** to start mixed prewarming; status column of channel 1 displays "Mixed prewarming…", the "XX:XX" displays the remaining time for mixed prewarming; press **Test 1** again to cancel prewarming;
5. After mixed prewarming, status column of channel 1 displays "Please add reagent";
6. After adding reagent, press **Test 1** or confirm by electronic pipette to start test; status column of channel 1 displays "Testing…", the "XX:XX" at right side displays the remaining time; press **Test 1** again to cancel test;

7. After testing, status column of channel 1 displays the test result by the format of "Second-Ratio-INR-%-Quantitative; if the test is out of time or there is any error, it will display "Out of time!".
8. Press **Test 1**, the test result will disappear, system prepare for the next test, the sample number will increase by 1 automatically.
9. The test procedure of channel 2 is the same, just controlled by **Test 2** key.

Note:

- ***Only when the temperature meets requirements, you can start normal test.***
- ***When adding reagent, you shall operate according to the regulations, make sure no air bubbles, and keep consistency of your action. In order to ensure the precision of test result, please press Test 1 or Test 2 as soon as you add the reagent; or use electronics pipette to add reagent.***
- ***If there is no "Prewarming time 2" (the value is 0) in parameter settings, the step 3, 4 will be skipped.***
- ***After finished one test, you shall press Test first to set channel parameters, after that you can enter normal test procedures.***
- ***While ask the user to add reagent 1 or reagent, system will give out a sound signal as prompt, and displays the remaining time for current operation at the right up corner of screen.***

5.2.2 Sample test

Select "Sample" at test settings to enter sample test procedure, as shown in figure 5-2.

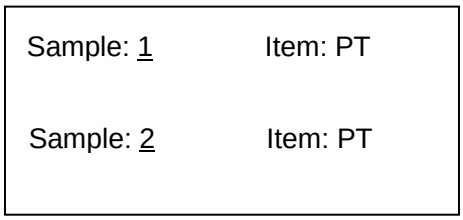


Figure 5-2 Sample test

The upper part of the screen displays the content and status of channel 1; the lower part of screen displays the content and status of channel 2.

Sample: The number of current test sample, select by<, > key or input the number directly; its range is 1~6000.

Item: Displays the abbreviation of current test item.

The detailed test procedure please refers to "5.2.1 Test procedure"; the test result will be saved to patient database automatically.

Note:

- ***At the same day, patients should have different sample numbers; different patient can not have the same sample number.***
- ***The "*" in front of the test result means that it is out of range.***

5.2.3 QC test

Select "Control" at test settings to enter QC test procedure, as shown in figure 5-3.

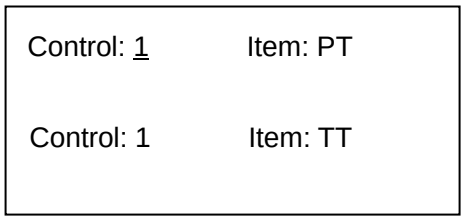


Figure 5-3 QC Test

The upper part of the screen displays the content and status of channel 1; the lower part of screen displays the content and status of channel 2.

Control: The number of current control, select by<, >key or input the number directly; its range is 1~3.

The detailed test procedure please refers to "5.2.1 Test procedure"; the test result will be saved to QC database automatically.

5.2.4 Standard test

Select "Standard" at test settings to enter standard test procedure, as shown in figure 5-4.

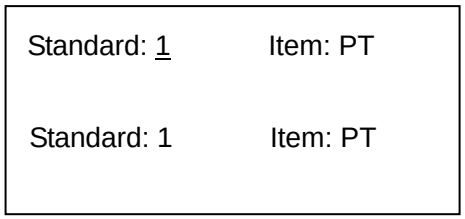


Figure 5-4 Standard Test

The upper part of the screen displays the content and status of channel 1; the lower part of screen displays the content and status of channel 2.

Standard: The number of current standard, select by<, >key or input the number directly; its range is 1~6.

The detailed test procedure please refers to "5.2.1 Test procedure"; the test result will be saved as concentration of standard into parameters of corresponding item.

6. Report

Press **2** key in the main menu to get into the menu of result report, which is shown as Figure 6-1. Get into the submenu by **1**, **2**, **3** and **4** keys.

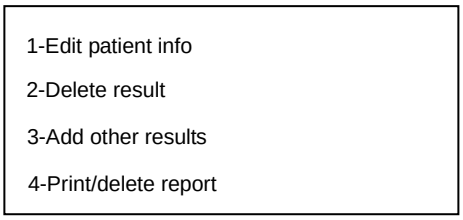
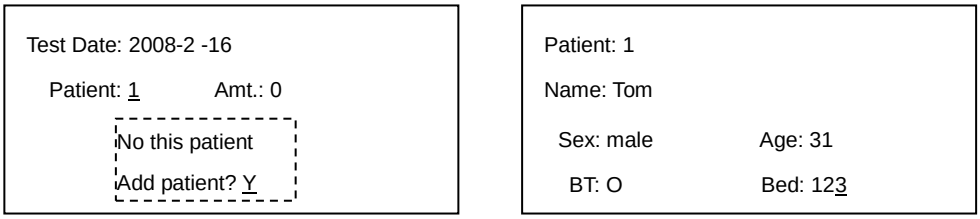


Figure 6-1 main menu for result report

6.1 Edit information of patients

Press **1** key to get into the menu for editing the information of patients, which is shown as Figure 6-2.



(a) Add patient (b) The information of the patient

Figure 6-2 patient information editing

Test Date: it is the test date of the patient; select by ⟨, ⟩ keys or directly enter the number.

Patient: patient number, it is the number of the patient whose information need to be edited; select by ⟨, ⟩ keys or directly enter the number.

Amt.: amount, the number of patients stored in the system on the current test date.

When the number of the patients whose information needs to be edited does not exist, the system prompts the user whether to add this patient, shown as Figure 6-2(a). Select Y or N by ⟨, ⟩ keys. When Y is selected, press **ENTER** key to add new patient, if not, the patient will not be added.

Name: directly enter English characters, no more than 14 characters.

Sex: select by ⟨, ⟩ keys.

Age: directly enter or select by ⟨, ⟩ keys.

BT: the abbreviation of blood type, select A, B, AB and O through the ⟨, ⟩ keys.

Bed: the abbreviation of bed number, directly enter.

After finished the edition, press **ENTER** key to save and return, press **ESC** key to return without saving.

6.2 Delete result

Press **2** key to get into the menu for deleting the test results, which is shown as Figure 6-3.

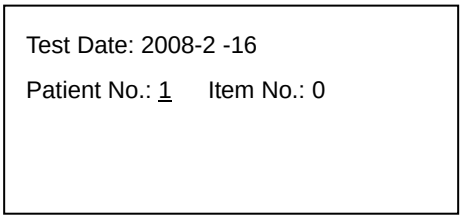


Figure 6-3 delete test result

Test Date: the test date of the patient; select by <, > keys or directly enter the number.

Patient: patient number, the number of the patient who need to delete some test results; select by <, > keys or directly enter the number.

Items: the total number of the items tested for the patient on the current test date.

After the test date and patient number are entered, the system will automatically query and display the number of the query results in the "item number" column.

Change the patient number by ∨ key; query the test result of the patient through the <, > keys.

Press **ENTER** key, the system display "Delete result? N" at the bottom of the screen; select Y or N by <, > keys; selecting Y, press **ENTER** key to delete the currently displayed result for the current patient; press **ESC** key to return.

6.3 Adding other results

Press **3** key to get into the menu for adding test results, shown as Figure 6-4.

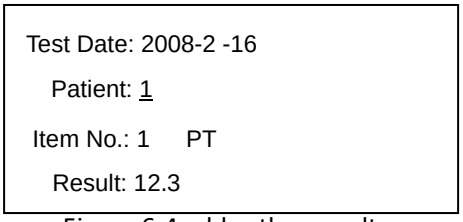


Figure 6-4 adds other results

Test Date: the test date of the patient; select by <, > keys or directly enter the number.

Patient: patient number, the number of the patient who requires to add some result; select by <, > keys or directly enter the number.

Item No.: select by <, > keys or directly enter the number. The corresponding name is displayed at its right side.

Result: enter the result needing to be added

Press **ENTER** key to save the result into the corresponding data of the patient; in the process of saving, the information of "Saving…" is displayed at the bottom right corner; if the item doesn't exist, the information of "No item" is displayed; press **ESC** key to return.

6.4 Print/Delete report

Press **4** key to enter the menu for processing the report, shown as Figure 6-5.

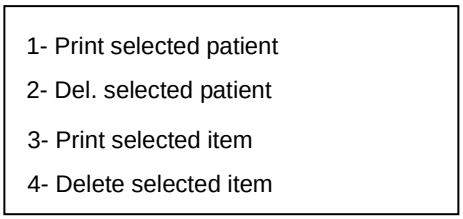


Figure 6-5 print/delete report

6.4.1 Print selected patient

Press **1** key to get into the menu for printing the selected patient, shown as Figure 6-6.

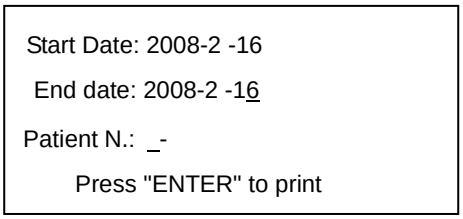


Figure 6-6 prints the selected patient

Start Date: the beginning date need to be queried; select by <, > keys or directly enter the number.

End Date: the result date need to be queried; select by <, > keys or directly enter the number.

Patient N.: the abbreviation of patient number, the patient number need to be queried; "-" represents the patient whose number ranges from No. A to No. B; select by <, > keys or directly enter the number.

After the start date, end date and range of the patient numbers are determined, press **ENTER** key to print the patient date stored in the instrument and the information of "Printing…" is displayed at the bottom of the screen; press **ESC** key to return.

6.4.2 Delete selected patient

Press **2** key to get into the menu for deleting the selected patient, shown as Figure 6-7.

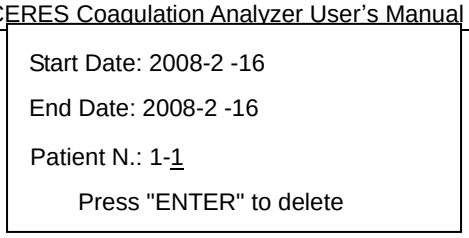


Figure 6-7 delete the selected patient

Start Date: the beginning date need to be queried; select by <, > keys or directly enter the number.

End Date: the result date need to be queried; select by <, > keys or directly enter the number.

Patient No.: the patient number need to be queried; "-" represents the patient whose number ranges from No. A to No. B; select by <, > keys or directly enter the number.

After the start date, end date and range of the patient numbers are determined, press **ENTER** key; a prompt of "Delete? N" is displayed at the bottom of the screen, select by <, > keys whether to delete the patient data. If "Y" is selected, then pressing **ENTER** key will delete the patient data stored in the instrument and display "Deleting…" at the bottom of the screen; if not, the data will not be deleted. Press **ESC** key to return.

6.4.3 Print selected item

Press **3** key to get into the menu for printing the selected item, shown as Figure 6-8. Print the test data in the range of the test date in items.

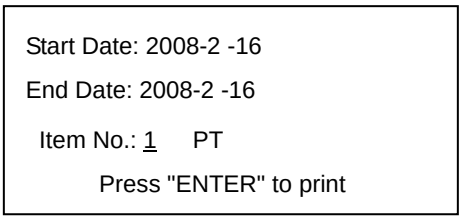


Figure 6-8 print the selected item

Start Date: the beginning date need to be queried; select by <, > keys or directly enter the number.

End Date: the result date need to be queried; select by <, > keys or directly enter the number.

Item No.: item number need to be queried. The item name is displayed at the right side of the item number; select by <, > keys or directly enter the number.

After the start date, end date and item number are set, press **ENTER** key to print the test date stored in the instrument and display "Printing…" at the bottom of the screen; press **ESC** key to return.

6.4.4 Delete selected item

Press **4** key to get into the menu for deleting the selected item, shown as Figure 6-9. Delete the test data in the range of the test date in items.

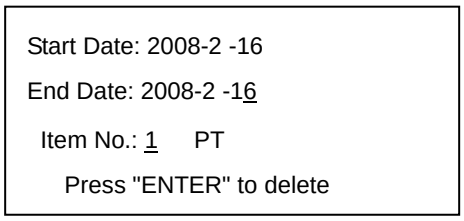


Figure 6-9 delete the selected item

Start Date: the beginning date need to be queried; select by <, > keys or directly enter the number.

End Date: the result date need to be queried; select by <, > keys or directly enter the number.

Item No.: item number need to be queried. The item name is displayed at the right side of the item number; select by <, > keys or directly enter the number.

After the start date, end date and range of the patient numbers are set, press **ENTER** key; a prompt of "Delete? N" is displayed at the bottom of the screen, select whether to delete data by <, > keys. If "Y" is selected, then pressing **ENTER** key will delete the test data stored in the instrument and display "Deleting…" at the bottom of the screen; if not, the data will not be deleted. Press **ESC** key to return.

7. Quality control report

Press **4** key in the main menu to get into the menu for quality control report, shown as Figure 7-1. Enter the corresponding menu by **1**, **2** keys.

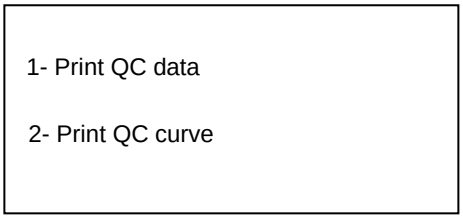


Figure 7-1 main menu for QC report

7.1 Print QC data

Press **1** key to get into the menu for printing the QC data, shown as Figure 7-2.

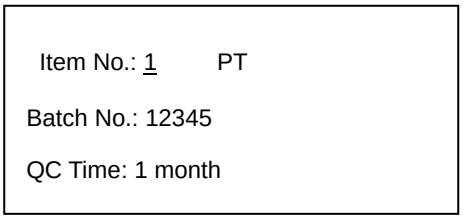


Figure 7-2 prints the quality control data

Item No.: the item number needs to be queried. The corresponding name is displayed at the right side of the item number; select by <, > keys or directly enter the number.

Batch No.: the QC batch number needs to be queried.

QC Time: all quality control data is printed in some time range that means the corresponding time range which is generated by pushing the time forward from the current date; it can be selected to range from 1 month to 6 months and is 1 month as default.

After the item number, QC batch number and QC time are entered, press **ENTER** key to query and automatically print the quality control data in this QC time range; press **ESC** key to return.

7.2 Print QC curve

Press **2** key to get into the menu for printing the QC curve, shown as Figure 7-2. The parameters are the same as the printed QC data. Refer to "7.1 Printing QC data" for the information of the specific settings.

After the item number, QC batch number and QC time are entered, press **ENTER** key to query and automatically print the QC curve in this QC time range; press **ESC** key to return.

8. System maintenance

Press 6 key in the main menu to get into the system maintenance menu, which is shown as Figure 8-1. Get into the corresponding menus by 1, 2, 3, 4, 5 and 6 keys.

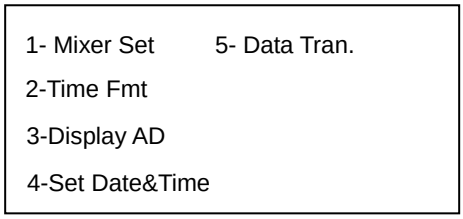


Figure 8-1 main menu for system maintenance

8.1 Mixer settings

Press 1 key to enter the settings menu for agitator motor, which is shown as Figure 8-2

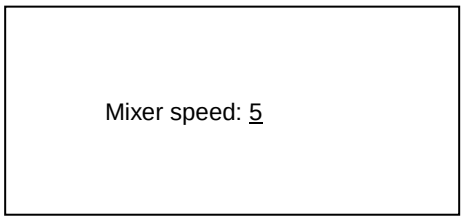


Figure 8-2 mixer settings

Select the mixer speed by <, > keys. It ranges from 0 to 10; wherein the speed decreases in order from 0 to 10. Press **ENTER** key to save settings and return; press **ESC** key to return without saving.

8.2 Time format

Press 2 key to enter the menu for settings the time format, which is shown as Figure 8-3. The 12 or 24-hour display format is selected.

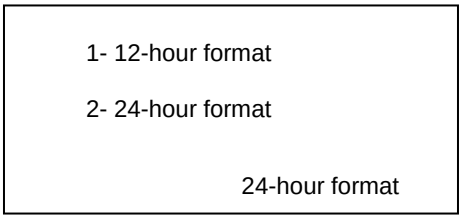


Figure 8-3 time format

Press 1 key to select the 12-hour display format and press 2 key to select the 24-hour display format. Meanwhile, the settings condition is displayed at the lower right corner of the screen.

Press **ENTER** key to save and return, press **ESC** key to return without saving.

8.3 Display AD

Press **3** key to enter the menu for the status of the system sampling channel, which is shown as Figure 8-4. The sampled data of the system is displayed in real-time.

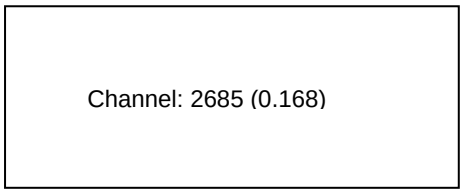


Figure 8-4 display AD value

Display format: real-timely sampled numerical value of the signal (corresponding ABS numerical value);

Press **ENTER** key or **ESC** key to return

8.4 Set Date and time

8.4.1 View date and time

If you just want to view the current date and time without modification, you can directly press **5** key in the main menu.

8.4.2 Date and time settings

In the system maintenance menu, press **4** key to get into the date settings menu, which is shown as Figure 8-5.

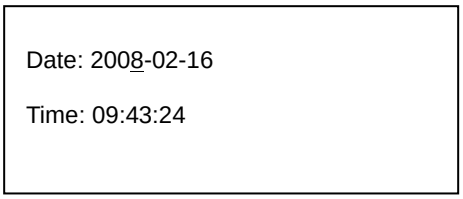


Figure 8-5 set the date and time

Date: select by <, > keys or directly enter year, month and day.

Time: select by <, > keys or directly enter hour, minute and second.

Press **ENTER** key to save and refresh the date and time; press **ESC** key to return.

8.5 Data trasnfer

Press **5** key to enter the menu for data transfer, which is shown as Figure 8-6. This function is only available for the compatible externally connected software.

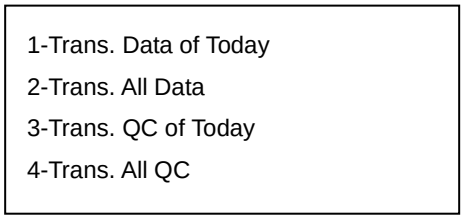


Figure 8-6 window for data transfer

8.5.1 Transfer data of today

Press **1** key to automatically transfer the data tested on current day; the status of "Trans. data of today…"is displayed in the process of transfer and the status of "Data trans. finished!" is displaying after the transfer ends.

Press **ENTER** key or **ESC** key to return

8.5.2 Transfer all data

Press **2** key to automatically transfer all test data stored in the instrument; the status of "Transfer all data…" in the process of transfer and the status of "Data trans. finished!" is displaying after the transfer ends.

Press **ENTER** key or **ESC** key to return

8.5.3 Transfer QC of today

Press **3** key to automatically transfer quality control data tested on current day; the status of "Transfer QC of today…"is displayed in the process of transfer and the status of "Data trans. Finished!" is displaying after the transfer ends.

Press **ENTER** key or **ESC** key to return

8.5.4 Transfer all QC

Press **4** key to automatically transfer all quality control data tested on current day; the status of "Transfer all QC…"is displayed in the process of transfer and the status of "Data trans. Finished!" is displaying after the transfer ends.

Press **ENTER** key or **ESC** key to return

9. Instrument maintenance

9.1 General

CERES is a precise clinical analytical instrument. In order to make the instrument kept in good state, the daily maintenance work is required to be well done. Maintenance of CERES is very simple, but it should be carried out carefully.

9.2 Cleaning the analyzer

- Keep instrument working environment clean.
- Neutral detergent and wet cloth can be used for cleaning the surface of analyzer.
- Please use a soft cloth to clean the LCD.

Cautions: Do not let the analyzer be exposed to any solvent, oil, and other corrosive substances.

9.3 Changing the parts of the instrument

The specific steps for changing the fuse are as follows:

1) Pull out the power cord.
2) The fuse is installed in the fuse box beside the power switch which is at the back of the instrument. Pull out the box cap to change the fuse of the same specification.

Fuse specification: T3.15AL250V.

Warnings: The fuse of the specification above must be used. Make sure that the power has already been cut off before the fuse is changed.

3) Close the cap of the fuse box and restart the machine.

9.4 Trouble shooting

Trouble	Causes	Shooting
Instrument cannot be started up	Something wrong with the power supply. The time period between the start-up and reboot is too short.	Check if instrument is powered on Check if power plug gets loose or falls off Check fuse Check voltage. Wait for more than 30 seconds to restart the machine after shutdown.
Optical channel errors	The optical patch devices are damaged or the service life is reached.	If the same error occur after the machine is rebooted, please contact seller to change or maintain the devices
	The testing cup is not inserted to the bottom.	When the testing cup is placed, it shall be pressed slightly to the bottom.
Printer cannot print		Check if there is no paper Check if the printer cable is normally connected

Cautions: If user can't solve the problem or some problem occurs for many times, please contact the seller.

Appendix I: Input method for English characters

Because the number of the keys on the keyboard of the instrument is limited, various numeric keys are defined for multiple uses as one key when the English letters or signs are entered. The detailed introduction to the usage is as follows:

Various numeric keys and English letters are both identified on the keys. The specific corresponding relationships are shown as the following table:

	key1	key2	key3	key4	key5	key6	key7	key8	key9	key0
Continuously press for 1 time	A	D	G	J	M	P	S	V	Y	.
Continuously press for 2 times	B	E	H	K	N	Q	T	W	Z	-
Continuously press for 3 times	C	F	I	L	O	R	U	X	Blank	/
Continuously press for 4 times	1	2	3	4	5	6	7	8	9	0
Continuously press for 5 times	a	d	g	j	m	p	s	v	y	.
Continuously press for 6 times	b	e	h	k	n	q	t	w	z	-
Continuously press for 7 times	c	f	i	l	l	r	u	x	Blank	/

After the input is confirmed, it will be shifted to the input of the next character if you wait for 2 seconds; or press the [>] key to automatically shift to the status of inputting the next character.

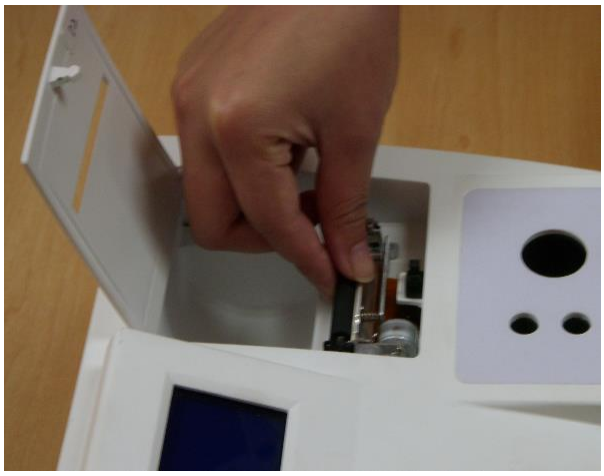
Appendix II: instructions for testing and sampling operations

Cautions: after the testing cup is put in the testing channel, press it slightly with hands to make sure that it reaches the bottom, or the test might be influenced, causing wrong results.

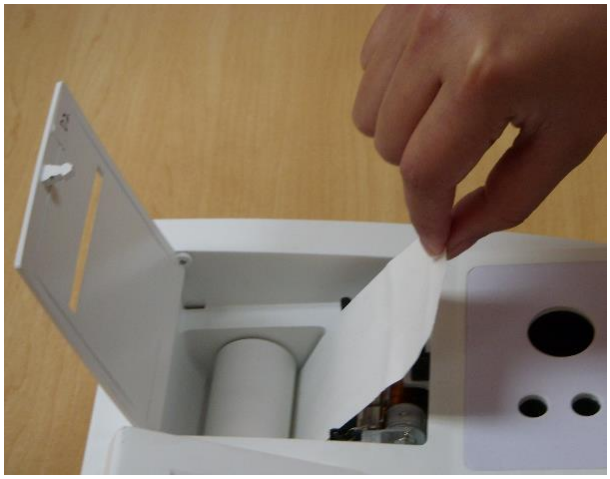
1. When the reagent is tested, it must be shaken to be mixed up.
2. Fib and APTT reagents can't be warmed-up.
3. The plasma bottle can't be warmed-up.
4. The dissolved QC and reagents can be used only when they are stabilized for 10 minutes and are required to be shaken to mix them up when being used;
5. The label on the bottle indicates the standard value of QC Fib when the dilution is carried out in the ratio which is one to ten;
6. The accurate warm-up time is required to be assured;
7. NEVER open the shading cap and shake the reaction cup in the process of reaction;
8. Requirements for adding plasma:
    a. Use the inverse suction method to add sample.
    b. The pipette head shall be attached to the margin of the bottom of the reaction cup when adding sample.
    c. The speed of adding sample shall be low and smooth.
    d. It is required to be assured that the gas bubbles do not exist at the bottom;
9. Requirements for adding reagents:
    a. The head of the electronic pipette shall be tightly attached to the groove of the sampling platform, the step of the pipette head is clamped with the upper margin of the groove and the lower end of the pipette head is tightly attached on the side wall of the reaction cup.
    b. After the right hand is in a stable and smooth pose, the left hand presses **ENTER** key to trigger the sampling signal and at the same time the right hand immediately add the sample.
    c. After the adding sample, the shading cap shall be well closed;

Appendix III: Instructions for installing paper of built-in printer

1. Use fingers to press the silkscreen of the printer, which is shown as the position that the arrow-head points in the following picture.
2. Lift the printer cover, take off the arbor of the printer, and pay attention to keep it clean.

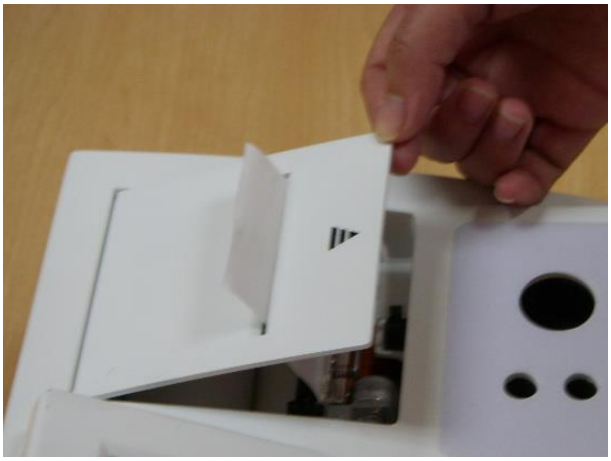


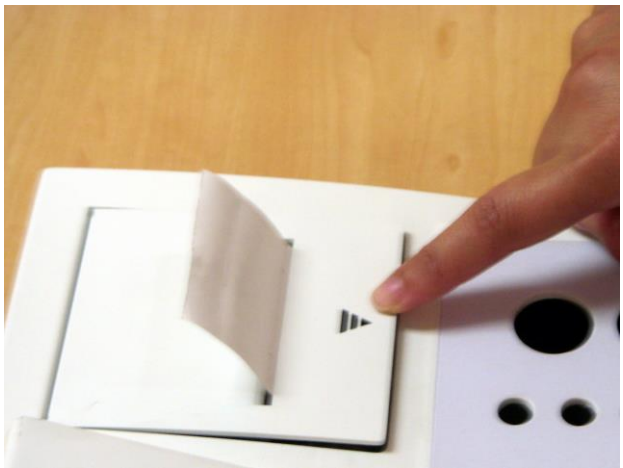
3. Load the thermal printing paper and pull an appropriate length of paper.



4. Mount the gear of the printer in the printer.

5. Lead one end of the thermal printing paper through the opening of the printer cover and press the printer cover down.





Appendix Ⅳ: Name and concentration of toxic and hazardous substance or element in product

Part name	Toxic / hazardous substance or element					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr (VI))	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Built-in PCB	×	o	o	o	o	o
Casing	×	o	o	o	o	o
Display screen	×	o	o	o	o	o
Optoelectric component	×	o	o	o	o	o
Internal wire	o	o	o	o	o	o
Accessories	×	o	o	o	o	o

o: Contents of this toxic/hazardous substance in all homogenous material of the component are below limit stated as per SJ/T11363 standard.

×: Content of this toxic/hazardous substance at least in one homogenous material of the component is out of limit stated as per SJ/T11363 standard.