MH-50B Semi-Auto Chemistry Analyzer

USER MANUAL



Add: No.5 Hepanxiang, Jinhua, Zhejiang, China 321001 Tel: 86-579-82373070 Fax: 86-579-83533099 Website: <u>www.mossinstruments.com</u>

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Chapter 1 Introduction

1.1 Test principle

The Bio-chemical analyzer is mainly used for the quantitative analysis of the clinical bio-chemical items, it applies to the Lamber- Beer law:

 $A=Kbc=lg(I_0/I)$

Among them:

A: Absorbance

K: Absorbent Index

B: Liquid layer's Thickness

C: Solution's Consistency

Io: Incident light's Strength

I: Transmit light's Strength

According to the above formulas, under the condition of the certain liquid layer's thickness and incident light's strength, as long as test the strength of transmit light which goes through the liquid layer, so we can calculate the consistency of the given solution.

1.2 Technical Criterions

Use Condition:

Temperature: 0 - 40 °C; Relative humidity: 10 - 90 %; Applied elec. Power: Interflow 220V±10%; Conserved Transportation Condition:

Temperature: 0 - 40 °C; Relative humidity: 10 - 90 %; Amount of saved items' parameters: ≤ 70 Solidify items' parameters in out-firm : 50 units, described largely in "Chapter 4"

The result numbers instrument can save: 200 patients or quality control

The result numbers each patient can save: ≤30 units items

Absorbing samples volume:<600ul

Inner Printer: 36 bits thermal printer(wide:80mm)

(Printer paper: Thermic , 80mm

Screen: 240*128 dots graphic LCD

Communications connector: RS-232)

1.3 Structure Introduction

1.3.1 Main components view



1.3.2 Scratch map of operation panel-board



1.3.3 Back Scratch Map





Turn on the instrument, it will show the main menu which is consists of 6 submenus, the operator can select a menu by digit keys or by cursor keys (If you use the cursor keys, the color of the menu frame will become dark while the color of the letters will become light, then press the "ENTER" key to enter the menu); you can enter the corresponding menu directly by pressing the digit keys as 1-6.

In daily work, the operator mainly operates the first, second and third items, you can do sample test by operating the first item, and print result report by operating the second item, and edit, examine, print the result report by operating the third item.

Chapter 2 Installation

2.1 Work Environment

This equipment is a precise instrument, so the environment must add to certain requirement in order that the instrument can be used normally and get accurate results.

The concrete requirement such as follows:

Environment temperature:10°C~30°C $\hfill Relative humidity: 20\% {\sim}80\%$

Atmospheric pressure: 86KPa~106Kpa

Voltage: A.C.220V+22V Frequency: 50Hz+3Hz

Floor-line: specially floor-line of medical instrument, the resistance of connecting the earth must be less than 0.5Ω .

Additional requirements: the instrument must be put in a platform which has enough room, stable level without any vibration; the situation should avoid the equipments such as fans, air conditioners etc in order not to aeffect the accuracy of temperature control; it is prohibited to be installed in the environment which is in high temperature, sunlight shines directly or has much dust; also it can not be put with the equipments which have big efficiency, heavy interference such as the centrifuges, refrigerators, thermostats etc in the same room or use the same elec. Power socket.

2.2 Instrument Installation:

1)Open the instrument's packing box. Check carefully whether the instrument, replacements in the box match the packing list. If there is any shortage or damage, contact the suppliers quickly;

2)Get out the instrument cautiously after checking carefully, then put it on a stable, smooth work platform;

3)Connect the earth-pole to the floor which is on the right side of the back of instrument by specially medical earth-line;

4)Get the elec. Power line out, connect one line to the elec. Power socket which is in the middle of the back panel, then connect the other line to the three-line plug which has installed earth-line;

5)Find a waste-liquor bottle, put the waste-liquor tube into the waste bottle;

6)Use a beaker or other container to get a cup of DI water;

7)Open the elec. Switch in the back panel;

8)Incubate at least 15 minutes after turning on the instrument's elec. on;

9)Follow the English introduction to operate

Chapter 3 Operation

3.1 Flow chart



3.2 Common operation

3.2.1 Switch the elec. Power on,and incubate the instrument for 15minutes at least;

3.2.2 Test sample: Prepare the sample and reagent according to the reagent manual, enter the first item in main menu after its reaction time add to the requirement minutes,:'1-Test sample' to test the given sample;

3.2.3 Result report: after testing all items, press 'menu' key to enter the main menu, and press digit key '3' to enter the third item: "Result Report", select "1-edit patient's info", input each patient's info.

3.2.4 Print Report: After editing all patients' info, press 'MENU' back to the "Result Report" board, press digit key '4' to print or delete patients' results; If you only need to print one patient's result, press the digit key '2' in the main interface, then input the given patient's number to print; also you can press the digit number '8' in the Test items' interface, then input the given patient's number and print directly;

3.2.5 Clean the pipe: clean the tube with CLEAN after you finish operation;

3.2.6 Power off the instrument: Finish all procedures, then cut off the elec. power.

3.3 Test Sample

Press 1 to enter into the menu "Test sample" interface, the system will show:

| ALT | ALP | GOT | r-GT | TP | | |
|----------------------------|------|------|------|-----|--|--|
| ALB | Tbil | DBIL | TTT | BUN | | |
| CRE | UA | CO2 | NH3 | GLU | | |
| тсно | HDLC | LDLC | TG | LDH | | |
| AMS | CL | Са | Mg | Cu | | |
| | | | | | | |
| | | | | | | |
| PRESS ARROW TO SELECT TEST | | | | | | |

Press ' \uparrow " \downarrow " \leftarrow " \rightarrow ' to select test, there are more items can be selected:

| Zn | | Р | K | Na | CO2CP | |
|----------------------------|------|-------|-------|-------|-------|--|
| Fe | ; | HGB | RBC | GRP | A/G | |
| U | DBIL | IGG | IGM | C3 | CHE | |
| C۲ | < | BU | U-PRO | U-Hb | U-GLU | |
| U- | URO | U-BIL | U-KET | U-NIT | U-PH | |
| | | | | | | |
| | | | | | | |
| PRESS ARROW TO SELECT TEST | | | | | | |
| | | | | | | |

Press 'ENTER' key to enter the interface of "absorb clean liquor".

1. Absorb the clean liquor

Enter the interface of "Absorb clean liquor", the screen will display as follows:

| TEST CODE: | 2 | ALP | |
|------------|---------|---------|----|
| SAMPLE NO: | | | |
| PRINT:OFF | | | |
| | ASF | P RINSE | |
| WAVELENGTH | l: 340r | ım | |
| ZERO: 4 1 | ST | D: 1 | 00 |
| | | | |
| | | | |

Put the CLEAN (DI water or NaOH liquor), press 'ENER' key , the instrument starts to absorb the CLEAN;

Press 'CLEAN' key to clean again if one time is not enough, it can clean for many times;

Press the "\]' to stepwise 'Absorb clean liquor" to enter next step directly if it needn't cleaning;

Press 'MENU' key back to the main menu.

2. Absorb DI water

The system will automatically enter the "Absorb DI water" interface to test absorbance if test items with END-point method, the screen will display:

| TEST CODE | : 2 | ALP | | |
|-----------|------------|-------|-----|--|
| SAMPLE NO | : | | | |
| PRINT:OFF | | | | |
| | <u>ASP</u> | DI WA | TER | |
| WAVELENG | TH: 340 | Dnm | | |
| ZERO: 4 | 1 5 | STD: | 100 | |
| | | | | |
| | | | | |

Put DI water, and press 'ENTER' key, the instrument starts to absorb DI water and test absorbance.

| TEST CODE: | 2 | ALP | | |
|--------------|------------|--------------|----|----------------|
| SAMPLE NO: | | | | |
| PRINT:OFF | | | | |
| | <u>ASP</u> | BLANK | | |
| WAVELENGT | H: 340n | m | | |
| ZERO: 4 1 | ST | D: 1 | 00 | Showe offer |
| ORIGINIAL VA | 1116. | 5440 — | | |
| | LUL. | 5440 | | finishing test |
| | | | | |

It will prompt you to absorb DI water after filter-wheel rotated in order to adjust absorbance.

3. Absorb clean liquor

When you test the item for the first time, you need to do Blank Test and Standard Test, the system will enter into "absorb clean liquor" interface automatically after finishing cleaning or finishing absorbance test.

Put clean liquor, press "ENTER" key, the instrument starts to absorb clean liquor, it will test the absorbance and original value of Blank liquor, the test result will be shown in the chart.

| TEST CODE: 2 ALP | |
|----------------------|-----------------------|
| SAMPLE NO: | |
| PRINT:OFF | |
| ASP STANDARD | |
| WAVELENGTH: 340nm | |
| ZERO: 4 1 STD: 100 | |
| BLANK ABS: 0.000 | Shows after finishing |
| ORIGINAL VALUE: 5445 | -Blank Test |

4. Absorb standard liquor 1

Put standard liquor, press "ENTER" key, the instrument starts to absorb clean liquor, it will test the absorbance and original value of Blank liquor, the test result will be shown in the chart.



Press "CLEAN" key to clean again.

Press "BLANK" key to test the blank liquor again.

Press "STANDARD" key to retest standard liquor again.

Press "MENU" key back to main menu.

5. Absorb sample liquor

If the instrument ever do the Blank Test and Standard Test for the item, it will enter into "Sample Test" interface after cleaning and testing absorbance just as the above chart. If it is the first time to test the item, you should do the Blank Test and Standard Test before testing the samples.

| | TEST CODE: 2 ALP | |
|-----------------|--------------------|---------------|
| Shows the first | SAMPLE NO: 6 | |
| patient no — | PRINT:OFF | |
| automatically | ASP SAMPLE | |
| | WAVELENGTH: 340nm | |
| | ZERO: 4 1 STD: 100 | Shows after |
| | ABSORBANCE: 0.154 | finishing the |
| | RESULT: 37 mmol/L | -Sample Test |

Press the "ENTER" key to absorb the sample to do the test when "Absorb standard liquor" twinkles continually. The test result will be shown in the above chart, the system will change to the next patient of the same item to test automatically;

You can do the follow operations in this interface (When "Absorb sample liquor" twinkles continually) Press 'Standard', 'Blank', 'Clean' keys to do the same operation

Press the digit key'6' to enter the item and select interface to test other items:

Press the digit key'7' to alter the patient No., just show as follows:

SAMPLE: 6

NEW SAMPLE NO:

Press the digit key '8', the screen will show as follows:

| TEST COD | DE: | 2 | ALP | | |
|-----------|------|------|------|-----|--|
| SAMPLE N | 10: | | 6 | | |
| PRINT:OFI | = | | | | |
| SAMPLE N | 10: | | | | |
| WAVELEN | GTH: | 340r | nm | | |
| ZERO: 4 | 1 | S | ΓD: | 100 | |
| ABSORBA | NCE | 0.15 | 4 | | |
| RESULT: | 37 | mm | ol/L | | |

Input "Patient No." and press "ENTER" key, the system will print the patient's result report instantly, press "MENU" key back to "Test Sample" interface;

Press the digit key '9' to setting the item's coefficients;

Press the 'MENU' key back to main menu.

If the item applies Kinetics method, the screen will show the reaction curves when you test the standard and samples, such as follows:



Press "ENTER" key, the screen will show the recent curve to observe it better, press "MENU" key to return. Or the screen will be back to "Absorb sample liquor" interface to check the result and test next time after finishing this step

3.4 Test Example

3.4.1 Test ALT/GPT with Kinetic method

1) Installing the parameters in the menu "EDIT TEST" according to the reagent manual as follows:

| TEST CODE: 1, | TEST NAME: ALT/GPT , | REAGENT SUPPLIER: HUILI |
|--------------------|-------------------------|-------------------------|
| FACTOR: 1746, | UNIT: u / L , | METHOD:DYNAMIC |
| TEMP: 37°C , | DECIMALS: 0, | WAVELENGTH: 340nm , |
| REAGENT BLANK: N, | SAMPLE BLANK: N | HIGHT: 36.0, |
| LOW: 8.0, | LINEARITY RANGE: < 500, | DELAY TIME: 30S, |
| INTERVAL TIME: 40S | ASP TIME: 300, | SAMPLE POINTS: 2, |
| STANDARD: 0, | | |

2) Input the digit '1' in "Test Sample" interface. select '1-LIVER TEST' then select the ALT, the screen will show "Absorb clean liquor", put the CLEAN, then press "ENTER" key to start the clean operation.

3) The screen will show "Absorb sample liquor", please assure the patient No., press the digit '7' to

modify the patient No. and press "ENTER" key. Put the sample and press 'ENTER' key to test the sample liquor.

4) The instrument will show the velocity curve in the reaction process after absorbing sample liquor:



If you want to check the curve carefully, press 'ENTER' key before the curve disappeared (before the reaction is finished), the screen will show the reaction curve, press 'MENU' key to quit the curve. Or the screen will stepwise to the next interface of "Absorb sample liquor" to do the next test after the screen shows the curve.

5) If you want to test other items, press the digit '6' key, then select the corresponding items, the instrument will enter the item to test automatically.

3.4.2 Test total protein TP by one-standard end-point method

1. Setting the item's parameters in the "EDIT TEST" menu according to the reagent manual as follows:

| TEST CODE: 5 , | TEXT NAME: TP , | REAGENT SUPPLIER: HUILI |
|-------------------|-------------------------|-------------------------|
| FACTOR: 0, | UNIT: g / L , | METHOD:E-END POINT |
| TEMP: 37°C | ,DECIMALS: 0, | WAVELENGTH: 546nm , |
| REAGENT BLANK: Y, | SAMPLE BLANK: N | HIGHT: 82.0, |
| LOW: 62.0, | LINEARITY RANGE: < 100, | DELAY TIME: 4S, |
| INTERVAL TIME: 2S | ASP TIME: 300, | SAMPLE POINT:1 |
| STANDARD: 1, | STD 1: 70.0 | |

2.Select the "LIVER ITEM" in "TEST SAMPLE" interface, press the '↓' to page down, press digit key '1'to select the "TOTAL PROTEIN". The screen will show "Absorb clean liquor", then put the CLEANand press the "ENTER" key to start the clean operation.

3. The screen will show "Absorb DI water" after finishing cleaning, put the DI water and press 'ENTER' key to do the absorbance, the screen will show "Absorb blank liquor" after finishing testing, put the Blank liquor and press the "ENTER" key to assure the operation.

4.The screen will show "Absorb standard liquor" (Press the "STANDARD" key to turn to the "Absorb standard liquor" interface if the screen show "Absorb sample liquor"), put standard liquor and press "ENTER" key to test it and calculate the parameters.

5.The screen will show "Absorb sample liquor" after finishing testing standard liquor, press the digit key'7'to modify the patient No, then put the corresponding patient's sample and press 'ENTER' key to test the sample liquor.

3.4.3 Test ALT/GPT by multi-standard end-point method

1) Setting the parameters in the menu "EDIT TEST" according to the reagent manual as follows:

| TEST CODE: 1, | TEXT NAME: ALT/GPT , | REAGENT SUPPLIER: MAIKE |
|-------------------|-------------------------|-------------------------|
| FACTOR: 0, | UNIT: u / L , | METHOD: END-POINT |
| TEMP: 37°C , | DECIMALS: 0, | WAVELENGTH: 505nm , |
| REAGENT BLANK: Y, | SAMPLE BLANK: N | HIGHT: 40.0, |
| LOW: 5.0, | LINEARITY RANGE: < 100, | DELAY TIME: 5S, |

2,

| INTERVAL TIME: 10S | ASP TIME: 300, | SAMPLE POINT: |
|--------------------|----------------|---------------|
| STANDARD No.: 5, | STD 1: 0.0 | STD 2: 50.0 |
| STD 3: 109 | STD 4: 209, | STD 5: 406. |

2) Select the "LIVER TEST" in the "TEST SAMPLE" interface, press the digit key '1' to select "GPT". The screen will show "Absorb clean liquor", put the CLEAN and press 'ENTER' key to start the clean operation. Put the DI water to test absorbance after finishing operation.

3) The screen will show "Absorb blank liquor" after testing, put the "Blank liquor" and press the "ENTER" key to assure the operation.

4)Now the screen shows "Absorb standard liquor 1" (Press the 'STANDARD' key to turn to "Absorb standard liquor 1" interface if it shows "Absorb sample liquor"), put the standard liquors 1-5 successively, then press 'ENTER' key to test the standard liquor to calculate the parameters.

5) The screen shows "Absorb sample liquor" again after testing the standard liquor, press the digit key '7' to modify the patient's No, put the corresponding patient's sample and press 'ENTER' key to test the sample liquor.

Attention: The edit item(end-point) do not need to test the standard liquor after the first time, also you can retest the standard liquor to assure the parameters. It is better to test the blank liquor before testing the item everyday to get accurate results.

3.5 RESULT REPORT

Input the digit key '3' in the main menu to enter the "RESULT REPORT" menu as follows; you can do the EDIT.MODIFY.PRINT.DELETE etc. operations of the patient's result in this menu.

| 1-EDIT SAMPLE | 4-PRINT/DELETE |
|---------------|----------------|
| 2-DEL RESULT | 5-TRANSMIT |
| 3-ADD RESULT | 6-RECEIVE |
| | |

3.5.1 Edit the patient's information

You can input each patient's name, gender, age and blood type according to this function. First, the screen will display:



You can input the serial number directly or use the '↓' key to search for the patient's No , then press "ENTER" key, the system will show as follows if the No. you input is not existed in the internal memory:

SAMPLES SUM: 15 SAMPLE NO: 1234 THE SAMPLE DOESN'T EXIST! 'MENU' TO RETURN 'ENTER' TO CREATE NEW

The system will establish the patient's record in the internal memory if the answer is 'Y' or press 'ENTER' key, then turn to next step, the system will be back to the Inputting Patient's No. interface if the answer is 'N'.

The system will enter into next step after discovering patient in internal memory or creating new patient,

The chart is as follows:



NAME: You can input 8 letters at most here. Press 'ENTER' key to confirm.

GENDER: Select correct option of MALE / FEMALE / INFANT/NONE by cursor key ' \leftarrow ' or ' \rightarrow '. AGE: Input number 0-199.

BLOOD GROUP: Select: A / B / AB / O by cursor key ' \leftarrow ' or ' \rightarrow '.

If the No you input is existed in memory, the system will show the information which has been saved in memory, you can modify at freedom and press 'Menu' to return, you can not input the patient's telephone No and address, But there is space in the RESULT REPORT for you to add.

3.5.2 Delete the results

You can delete the wrong result in TEST RESULT according to this function.

You can input the existed patient's No, press 'Enter' key to enter the modify interface directly, or press ' \downarrow ' to enter search interface to find the patient.

The search interface is as below:



The first row shows the existed patients sum, the second row shows the searched patient's No, the third row shows the total results of the patient, press "ENTER" key to enter MODIFY interface:

| | SAMPL | .E NO: 12 | 34 CHARLES | | |
|-----------------------|-------|-----------|---------------|--------|--|
| The test amount | TESTS | AMOUN | NT CURRENT | FORMER | |
| of the patient | | 2 | 2 | 0 | |
| The result No in | SEQ | TEST | RESULT | UNIT | |
| patient's all results | - O | ALT | 2345 — | u/L | |
| | REF R | RANGE(| 0- 40) | | |
| Normal values range | PI | RESS 'EN | ITER' TO DELE | TE | |

You can see the patient's result with ' \uparrow ' ' \downarrow ' keys, see the last or the next patient's result with ' \rightarrow ' ' \leftarrow ' keys, please press 'ENTER' key when the screen shows the given result if the result is not needed. Whenever press 'MENU' key it can return to the last interface.

3.5.3 Add other results

Some tests can not be done in this analyzer but the results must be sent out concurrently, so you must use other instruments to define the test according to the function.

In the 'RESULT REPORT' menu, press '3' to select 'Add other results', input patient No. or press ' \downarrow ' to search the patient No., then press 'ENTER' key.

It will suggest 'CREAT NEW ITEM' if you input an patient No. which is not existed, Press 'Y' or 'ENTER' to creat the patient No., press 'N' and 'MENU' to quit. Press 'ENTER' key to enter 'ADD OTHER RESULTS' interface:

SAMPLE NO: 1234 TEST CODE:5 TP RESULT: 4.<u>5</u>

First, the cursor will stop at the back of the 'ITEM CODE' in the second row, input the item No. then press 'ENTER' key it will show the item name in the third row and show the result in the fourth row, the cursor will stop at the back of the result, it will show the radix point if there is decimal(the definition of decimal is introduced in 'EDIT TEST'->definition of test item).

Please input the results getting from other methods, if the selected item is yin and yang opposite representation, you can select '+'. '-'. or " with ' \leftarrow ' ' \rightarrow ' cursor keys in the result, then input the numbers of '+'or '-' at the back of 'AMOUNT'(4 numbers at most); if the selected item is 'SUBTRACTION' or 'DIVISION', you should not input the value there, the instrument will look up the needed data in the patient's results automatically and calculate the item's result; press 'MENU' to return to the last interface.

3.5.4 Print/Delete Report

Select '4-PRINT/DELETE' in the 'RESULT REPORT' it will show the interface as below:

PRINT APPOINTED SAMPLE
 PRINT ALL SAMPLES
 DELETE APPOINTED SAMPLE
 DELETE ALL SAMPLES

1.Print the appointed patient

You can select this function if you only want to print the certain patient, you can input the patient No. to print directly; or press '\ightarrow' key to startup the searching function either, then press 'ENTER' key to print the patient's report, press 'MENU' key to return.

2.Print all patients

a. The system offers the function of printing all patients' reports to input the report easily.

| START DATE(MMDD): | |
|-------------------|--|
| END DATE(MMDD): | |
| | |

When you input the end date, the system starts to look up all storage files in the internal memory, it starts to print for each patient if it finds the result is fit for the condition until finishing printing; if you want to stop printing in midway, you must close the system.

When the system suggests you input the start date, press 'ENTER' key directly to print all results in internal memory, then it will show:

PRINT ALL SAMPLES Y?_

Print all results in internal memory instantly with pressing 'Y' or 'ENTER'.

Return to 'START DATE:' state with pressing 'N' or 'MENU'.

3.Delete the appointed patient report

You can delete the file and all storage result of the appointed patient in internal memory by selecting this function. First the system suggests inputting the patient No.

You can input with cursor keys or use searching function, then press 'ENTER' key to delete. If the system find the existed number in internal memory, press 'ENTER' key, it will delete the patient directly without any hint, so be careful when you input the No. or use searching.

4.Delete all patients' file

This part is the same as "Print all patients' report", the first one is to delete, the second one is to print, it can not recover after deleting, so be careful.

Chapter 4 Programme

This chapter mainly introduces how to set the reagent's test parameters when you use it for the first time. It explains that setting the parameters again according to the reagent manual after replacing the reagent every time to get the right result.

Select 'EDIT TEST' in main menu to enter this function interface which includes 4 functions:

1-TEST SETUP 2-ADD TEST NAME 3-DELETE TEST NAME 4-DELETE TEST

1). Test item definition

Its main function consists in inputting the operation parameters of every test item into the instrument in order it can carry out the test function according to the correct instruction.

Dependent item definition

Press key '1' to enter '1-TEST SETUP', select the item, the system shows:



(1). Input a code of 1—3 bits in the cursor, it can not be 0, press 'ENTER' key if it is 1 bit or 2 bits, it is a dependent test item if the code is less than 200, it is a combination test if it is more than 200 or equal to 200. Input the test code, press 'ENTER' key, the test item name will be shown at the back of the name, you can use ' \rightarrow ' ' \leftarrow ' keys to change the tests name; use ' \rightarrow ' ' \leftarrow ' keys to select the reagent supplier, there are 9 consent suppliers(Test name and suppliers name can be modified .added or deleted in the menu of "ADD NAME" and "DELETE NAME", they can not be modified here) Select the supplier's name, press 'ENTER' key to enter the next interface:

| 1 ALT |
|-------------------------|
| FACTOR: 0 |
| UNIT: u/L |
| METHOD: <u>KINETICS</u> |
| |
| PRESS '←' '→' TO SELECT |

(2). Now the cursor is at the back of the 'COEFFICIENT', you can modify or input the test coefficient(factors) from '0—59999', if you input the number from 1bit to 5 bits, please press 'ENTER' key or press ' \downarrow ' key directly to turn to the next item.

(3). Select unit with ' \leftarrow ' ' \rightarrow ' keys, press ' \downarrow ' or 'ENTER' key to enter into next item, there are 11 units to select: None.u/L.u/mL.umol/L.g/L.mg/L.mg/DI.g/ml.g/DI.X10(12)/L.

(4). Select analyze method with ' \rightarrow ' ' \leftarrow ' keys at the back of 'METHOD'. There are 6 methods to select: E-ENDPOINT.K-KINEMIC.B-DOUBLE-WAVELENGTH.C-SUBTRACTION.D-DIVISION.H-YIN and YANG OPPOSITES.

This instrument can do all above tests, so please care that if the reagent is fit for the instrument when you buy the reagent. Press ' \downarrow ' or 'ENTER' key to enter into the next screen:



(5). This instrument has Temperature Control system, you can select " $37^{\circ}C$ " or " $30^{\circ}C$ " or "ROOM-TEMP" state with ' \leftarrow ' ' \rightarrow ';

(6). Input the needed decimals at the back of 'DECIMAL', input 2 digits at most, input 0 if there is no decimal;

(7). Select the needed wavelength of the test item at the back of 'WAVELENGTH 1' by ' \rightarrow '

`---` ; When the 'ANALYZE METHOD' select 'DOUBLE-WAVELENGTH', it will show 'WAVELENGTH

2:', There are 8 wavelengths to select: 340nm.380nm.405nm.492nm.510nm.546nm.578nm.620nm ;
(8). Install 'REAGENT BLANK' and 'SAMPLE BLANK' according to the reagent manual; press
'ENTER' key or '_' key to enter into the next item:

| | 1 ALT | REFERE | ENCE RAN | GE |
|-------|---------|--------|----------|--------|
| | GENERAL | MALE | FEMALE | INFANT |
| HIGH: | 40 | 40 | 40 | 40 |
| LOW: | 0 | 0 | 0 | 0 |
| | | | | |
| | | | | |

(9).You can install the item's reference value, this instrument allows to input 4 different reference values according to the clinic application, if you have installed the patient gender, the system will transfer the corresponding reference value, or it will transfer the common reference normal value. Then press 'ENTER' or ' \downarrow ' key to enter into next item.

1 ALT LINEAR RANGE:< 600 DELAY TIME: 60S INTERVAL TIME: 60S DATA NO: 2 ASP TIME: 250 PRESS ' \leftarrow ' ' \rightarrow ' TO SELECT

(10). Find the reagent's linear time in the reagent manual, select "<" or ">" with cursor key ' \rightarrow 'or ' \leftarrow ', press 'ENTER' key to enter into the next item, input number "200".

(11). Find the "DELAY TIME" and "TEST TIME" in reagent manual section of "TEST METHOD", input the times in the 2 positions. Do not modify the sampling time, it is only efficient for this test without any influence for other tests. Standard is 0 for kinemics, standard is 1 for general reagent, you must install the standard for multi-standard reagent; press 'ENTER' or ' \downarrow ' key to turn to next item after installing the standard.

(12). You can install the item's standard or standard curve in this interface.

Press 'ENTER' or ' \downarrow ' key to turn to next item after installing the standard. The system will suggest 'Save modification?' Press 'Y' or 'ENTER' key to save, or press 'N' key; The system will be back to this section's beginning state after input all needed condition, now you can input or modify the next test item.

Attention: a. If the test method you selected is : SUBTRACTION, press '↓' or 'ENTER' key, it will show:

Y= A + B + C – D – E – F Y= 2 +<u>57</u> + 46 – 0 – 0 – 0

Input all test codes under A.B.C.D.E.F, the corresponding codes for A.D must be existed, the decimal of all tests must be equal, or it can not get correct result.

b. If the test method you selected is: DIVISION, press 'ENTER' or ' \downarrow ' it will show:

Г

Input all test codes under A.B, the corresponding codes for A.B must be existed, the decimal of all tests must be equal, or it can not get correct result.

2). Add new test name

You can add names of item combination or supplier for this operation, it will show:



Input item name directly and press 'ENTER' key to save. Press 'MENU' to exit.

Add names of combination and suppliers is close to add item name. You can select the added name in the corresponding section of "TEST SETUP".

3). Delete test name

You can delete the needless item name or item, If there is item in patient result, please delete it firstly, or it will show wrong suggestion. It will show:



Press 'ENTER' to delete the current test name.

4). Delete test

You can delete the needless item, it will show as below after entering this interface:

| ALT | ALP | GOT | r-GT | TP | |
|----------------------------|------|------|------|-----|--|
| ALB | Tbil | DBIL | TTT | BUN | |
| CRE | UA | CO2 | NH3 | GLU | |
| ТСНО | HDLC | LDLC | TG | LDH | |
| AMS | CL | Са | Mg | Cu | |
| | | | | | |
| PRESS ARROW TO SELECT TEST | | | | | |
| PRESS 'ENTER' TO DELETE | | | | | |

Press cursor key to select the test, press "ENTER" to delete it.

5). Example of edit test

(1). Endpoint

For example: edit the test parameter of GPT according to GPT manual produced by CHANGCHUN HUILI "GPT End Color Method Reagent Manual" (See in Appendix).

- 1. Enter into "EDIT TEST" interface in main menu.
- 2. Press '1' to enter into "TEST ITEM DEFINITION" interface, input 1 in TEST CODE(You can look up the solidified item amount and name of the instrument in item form , the item No. is 1).Press 'ENTER' key.
- 3. Select "GPT" with cursor keys ' \leftarrow ' ' \rightarrow ' in "NAME", press 'ENTER' key to enter into next item.
- 4. Select "HUILI" WITH CURSOR KEYS '←' '→' IN "REAGENT SUPPLIERS".
- 5. Input 0 in "COEFFICIENT", do BLANK TEST and STANDARD TEST after editing, the system will setting the value automatically.
- 6. Explain "NORMAL VALUE: 8—50u/L" in manual, you will know the reagent test unit is u/L. Search the supplier with cursor keys '←' '→', press 'ENTER' key or '↓' to turn to next item.

- 7. In the manual's "TEST METHOD", you will see "TEST BY ENDPOINT", it shows the test method of the reagent is "ENDPOINT", select the method with '←' '→', then enter into next item.
- 8. Please setting the temperature to "37°C" in the position which doesn't point out the temperature range in "TEST METHOD".
- 9. Setting the decimal according to the normal decimal value, for example: In the reagent "NORMAL VALUE: 8—50u/L", no decimal, you can setting the decimal to 0.
- 10. There is "WAVELENGTH: 510nm" in "TEST METHOD", select 510nm with cursor keys '→' '←' in "WACELENGTH".
- 11. It requires "REAGENT BLANK IS 0" in manual, setting reagent blank to 'Y', setting sample blank to 'N'.
- 12. This manual requires "NORMAL VALUE: 8—50u/L", there isn't special requirement for people, so you can setting "COMMON USE" "INFANT" "MALE" "FEMALE" to "HIGH RESTRICITION" to 50 and "LOW RESTRICITION" to 8.
- 13. There is "LINEARITY≤300u/L" in "TECHNICAL INDEX", select "<" with cursor keys '←' '→' in setting "LIEARITY RANGE", press 'ENTER' then input "300".
- 14. General, you can setting "DELAY TIME" to 5 in ENDPOINT method, "INTERVAL TIME " is 10, "SAMPL TIME" IS 300, "SAMPLPOINTS" IS "2"
- 15. General reagent is single-standard if there is no special explain, input "1" in "STANDARD". If you want to enter into next item, input "STANDARD 1:", input 100 here.
- 16. Press 'Y' to assure the operation, the system will save the setting automatically.
- 17. Manual original script is as follows:

GPT ENDPOINT Colorimetric Manual

1. USE:

It belongs to the LIVER COMMON TEST ITEMS, all kinds virosis acute hepatitis raise remarkably, chronic hepatitis active period raise slowly, other hepatitis raise with different degree.

2. PRINCIPLE:

GPT acts on ALALINE and a-KETOGLUTARIC ACID, it accelerates the reaction speed with accelerant,

it produces PYRUVIC ACID, PYRUVIC ACID and 2,4 DPRN will be developed under ALKY, test Absorbance with 510nm wavelength, calculate GPT's activity with international unit.

3. REAGENT CONTENT AND STORAGE

GPT Base material powder (100ml); GPT Developer (100ml); 4N NaOH (100ml);

STANDARD LIQUOR (100u/L). The above reagents stable at 2—8°C for 1 year.

4. PRODUCE OF REAGENTS AND STABILITY

Dissolve the GPT Base material powder with DI water 100ml, stable for storing it at 2-8°C for 1 month, effective for freeze storing for 1 year. Add 900ml DI water to 4N NaOH(100ml), effective for long-term. Other reagents can be used directly.

5. TESTING REQUIREMENT: fresh serum.

6. TEST METHOD AND PROCEDURE:

6.1 HANDWORK:

| | SAMPLE TUBE | STANDARD TUBE | REAGENT BLANK TUBE |
|-----------|-------------|---------------|--------------------|
| SERUM | 50 | - | - |
| STANDARD | - | 50 | - |
| LIQUOR ul | | | |
| GPT BASE | 250 | 250 | 250 |
| METERIAL | | | |
| LIQUOR ul | | | |

Mixing, 37°C for 30 minutes or 50°C for 15 minutes, then add GPT developer 250ul into every tube, 37°C for 15 minutes or 50°C for 6 minutes, get all tubes , add diluted NaOH 2.5ml, lay them aside for 3 minutes, test wavelength 510nm. Adjust REAGENT BLANK to 0, test absorbance of sample tube and standard tube.

SAMPLE TUBE GPT u/L = A sample/A standard X 100

6.2 SEMI-AUTO ANALYZER TEST BY ENDPOINT:

Operation procedure is the same to HANDWORK.

Adjust wavelength: 510pm, Adjust REAGENT BLANK to D.

Standard 100, Absorb standard liquor(Attention: Electric knob instrument sample the standard liquor then modify the standard to100). It will show the test result after absorbing the sample liquor one-by-one.

7. NORMAL VALUE:8-50

8. TECHNICAL INDEX AND NOTICE EVENTS:

BLANK ABSORBANCE A_{510nm} <0.3, CV: 4.7%, LINEARITY ≤300u

Attention: Keep the standard liquor airproof without pollution. Write down the factor value testing for first

time for the instrument which has factor function, input factor, test sample tube's consistency without doing standard tube

(2). Kinetic

For example: GTP/ALT velocity reagent manual, input parameters in turn as follow:

| TEST CODE: 1 | NAME: GTP/ALT | REAGENT SUPPLIER: HUILI |
|--------------------|-----------------------|-------------------------|
| COEFFICIENT: 1746 | UNIT: u/L | METHOD: KINEMIC |
| TEMP CONTROL: 37°C | DECIMAL: 0 | WAVELENGTH: 340 |
| REAGENT BLANK: N | SAMPLE BLANK: N | HIGH REF.: 36 |
| LOW REF.: 8 | LINEARITY RANGE: <500 | DELAY TIME: 30S |
| INTERVAL TIME: 40S | SAMPLE TIME: 300 | SAMPLE POSITIONS: 2 |
| | | |

STD.: 0

The circles in reagent manual shows how to confirm the parameters. REAGENT BLANK, SAMPLE BLANK, SAMPLE TIME, SAMPLE POSITION, STD. have not explained in reagent manual, please explain the setting according to the manual.

GTP/ALT VELOCITY REAGENT MANUAL

1. PRINCIPLE: L-ALALINE +a-KETOGLUTARIC ACID ALT PYRUVIC ACID+ GLUTAMIC ACID, PYRUVIC ACID + NADHLDH → L- LACTIC ACID + NAD⁺

When the wavelength is 340nm, test NADH absorbance decrease value every minute, calculate ALT activity value.

2. REAGENT CONTENT, SIZE AND SPECIFICATION:

a) Single vial: 2 kit descriptions : 10ml X 10, 18ml X 10.

b) Two vials: It is consisted of RI and RIL with different kit descriptions, 10ml X 5, 18ml X 5.

3. Storage and Effective Date: 2-8°C, effective date is 12 months.

4. Reagent Mixing

Single vial: It can be used after dissolving with DI water according to the specification, Reconstituted reagent is stable for 3 days at 2-8°C.

Two vials: Pour the RII and cushion to the RI bottle, dissolve them then use, effective date is 3 days.

5. TEST METHOD

| | | | _ | _ | | | | | |
|----------|----------------|-----------------------|---------|--------|-------------|---------|---------|-------|---------|
| PARA | ŴAVĘ | METHQ | TÉM | ØELAY | ŢÉST | REACTI | REAGENT | SAMPL | FAC∖ |
| MET | LENG | $ \not \! p \rangle$ | ¢ \ | /тіме\ | TIME \ | ON | VOL. | E | TOR \ |
| ER | ТН | | °C | | / \ | DIRECTI | UI. | VOL. | |
| SIZE | nm | | | | | ON | | UI. | |
| ISP-I II | 340 | Kin | 37/30 | 30 | 40 | - | 500 | 50 | -176 |
| | | | | | Λ / | | | | 8 |
| Beckma | \$40 / | Kin / | \$7/30/ | \30 / | 40 / | - | 500 | 50 | \-241 / |
| n700 | \square | | | | | | | | \z / |

Attention: Icterus patient's best ratio of serum to reagent is 1:20, factor is -3376.

Calculate Formula: u/I= \triangle A/min X (10³ X Vr) / (6.22 X Vs)

 \triangle A/min: Change value of absorbance every minute

Vr: Total Vol. for reaction liquor

Vs: Sample Vol.

6. Normal value: 37°C: 8-36 u/L 30°C: 4-28 u/L

7. Reagent characters and technical specifications:

1) Characters: This reagent is packed with screw-mouth plastic bottle, it has long effective date. The double-bottle reagent is made to cushion with high purified DI water, it solves the unpurified DI water of user and pollution of microorganism. The cushion is installed in R II bottles with certain quantity according to the specification.

2) Technical specifications:

3) The ratio of this reagent to Beckman reagent is γ : 0.994, in one group CV: 2.8%

Special note: Please write down and save the tested item parameters to avoid the system's internal memory to be disturbed by environment.

Chapter 5 Q. C and Reference Value

The aim of Q.C. is to test, control the precision degree of the test; supervise the change of stability; improve the conformity of sample test result about one group or between two groups in common test work; it will assure the reliability of the test result for every patient sample.

You need to test Q.C. material in "TEST SAMPLE", then print Q.C. curve and result in "Q.C. REPORT". "Q.C. REPORT" menu:

1-SELECT Q.C. TEST 2-SELECT Q.C. No. 3-PRINT Q.C. CURVE 4-PRINT Q.C. RESULT

5.1 Preparation

- 1.1 Select Q.C. material: The Q.C. material dry powder produced by professional supplier;
- 1.2 Prepare Q.C. material: Dilute the Q.C. dry powder according to the manual, lay it aside for 20 minutes, use it after it becomes stable.

5.2 Test Q.C. material

2.1 Press '2' to enter "TEST SAMPLE" submenu in main menu, input the item No. of the Q.C. item(For example: if the item is GPT, input '1'), press 'ENTER' to assure. It will suggest "ABSORB SAMPLE LIQUOR" after absorbing the clean water, then press '7' to setting the patient No., such as 59000(It's better to setting it as 59XXX to avoid to confuse it with normal patients; please remember the No. because it will be used in the follow procedures), then test the prepared Q.C. material according to the method of testing sample.

2.2 Enter "RESULT REPORT" submenu after finishing testing, press '1' to enter "EDIT PATIENT INFORMATION", select the Q.C. patient No., such as 59000, Input the item name (For example: GPT) in "NAME" to check and print. Press 'menu' to quit, it is the whole test procedure of Q.C..

2.3 Later, you only need to operate the first step to test the item's Q.C. result, Be care that the item No. and patient No. should be the same to the setting of the first time test completely. Enter "Q.C. REPORT" submenu to print the curve and result when there are more than 5 test results of the patient.

5.3 Print the curve and result of Q.C.

3.1 Enter "Q.C. REPORT", select the item No. of the Q.C. in the operation '1—SELECT Q.C. ITEM' and setting the target value. You can evaluate or consult other materials.

3.2 Select the corresponding patient No. such as 59000 in the operation '2- SELECT Q.C. No.'

3.3 Carry out the Operation '3'.'4'to print the Q.C. curve and result (Including MEAN and SD) after carrying out operation '1'.'2'.

3.4 When you test and print the Q.C. curve and result later, you should define the target value

according to the last Q.C. result.

Attention: 1. The operation for all patients in every test are the same except the test items. Select the patient No. and the same test items for each test, you can not test other items for the appointed patient No., or it will not print the correct Q.C. curve and result.

2. If there is not target value for the Q.C. material, you can test it for 10 times continually to assure all items' target values, then calculate the MEAN and SD as the target value and deviation. The target value should be ascertained when you change new reagent.

3. Because the normal value range for different areas and different people are different, also the instruments are different, other range only can be reference. Please creat the normal range fit to this area's people!

Chapter 6 System Installation

This menu mainly consists in "MAINTAIN" submenu. Press '6' to enter it in main menu:

| 1-TEMP ADJ | 5-ABSORBANCE |
|---------------|---------------|
| 2-CLEAN TIME | 6-DATABASE |
| 3-ADC | 7-UPDATE |
| 4-PRT AND COM | 8-CLOCK SETUP |
| | |

1. Temperature Rectify

SET TEMPERATURE: 37.00 CELL TEMPERATURE: 36.99 FAN STATE: OFF 0-CONTROL/UNCONTROL TEMP 1-TURN ON/OFF FAN

You can change or install temperature with ' \rightarrow ' ' \leftarrow 'keys with 1°C unit, or ' \downarrow ' ' \uparrow ' keys with 0.1°C. test temperature to observe the movement of the colorimetric cell.

2. Clean Time

You can set the clean time in '0—999' at will according to this function, this installation must clean the tube, the consent value is 700, it can be adjusted according to the actual event. 3. ADC

It shows the internal AD transfer parameter of the instrument, repairmen use it in repairing.

4. Printer and communication

PRT AND COM

1-PRT SETUP 2-COM SETUP

4.1 Set Printer

a. Print Content:

✓ 1-PRINT ALL RESULTS2-PRINT CURRENT RESULTS

Select '1—PRINT ALL RESULTS', then to print report in 'RESULT REPORT', it will print all patients and results in internal memory.

Select '2— PRINT THE RESULTS THAT DAY', then to print report in 'RESULT REPORT', it will print all patients and results in internal memory for that day. (General select mode 2)

b. Print Format:

✓ 1-AUTO PRINT ALL OFF 2-AUTO PRINT ON

You can select the time to print the report.

(1) If you don't print report during test, setting the print state to '1';

2 If you print a report for every sample, setting the print state to '2'.

c. Modify report head, select 'MODIFY REPORT HEAD' interface as below:

INPUT REPORT HEADER: ______EK-50 REPORT

The second row shows the modified report head the last time. If there is no modification, the consent report head is "EK-50 REPORT", it will recover to consent "EK-50 REPORT" when recovering the system.

You can input 20 characters most for this.

d. Setting doctor's autograph

1-SAVE DOCTOR'S NAME 2-SET DEFAULT DOCTOR'S NAME 3-DELETE DOCTOR'S NAME

Enter "SAVE DOCTOR'S NAME" to add a doctor's autograph, select "SET DEFAULT DOCTOR'S NAME" to install a consent doctor's autograph and print it in report list, enter "DELETE DOCTOR'S NAME" to delete a doctor's autograph. The installation result will be shown at the last row of the report list after installing the consent doctor's autograph.

1 SAVE DOCTOR'S NAME

Input the doctor's autograph when it suggests "Please input doctor's autograph", it can't be more than 8 characters, the input method state is shown in the right under side of screen(Consent: ENGLISH), press "MENU" to enter "INPUT METHOD SELECTION" interface, or select other input methods. It can save 10 doctors' names at most, if it is more than 10, system will suggest "MEMORY IS FULL, DELETE IT THEN SAVE".

② SET DEFAULT DOCTOR'S NAME

The consent state is "NO INSTALLATION AUTOGRAPH", if you print the doctor in report list, press ' \leftarrow ' ' \rightarrow ' to search the saved doctor's name, press "ENTER" to install and press 'MENU' to quit. ③DELETE DOCTOR'S NAME

Press ' \leftarrow ' ' \rightarrow ' to search name after entering "DELETE DOCTOR'S AUTOGRAPH" interface, press "ENTER" to delete and press "MENU" to quit.

4.2 SET Serial com.

BAUD RATIO:<u>1</u>9200 PARITY:DISABLE SERIAL:OFF

Setting the Serial com., select the parameters with ' \rightarrow ' ' \leftarrow '.

There are 5 BAUD RATIOS to select: 19200, 9600, 4800, 2400, 1200;

Input the BAUD RATIO, press 'ENTER' or '↓' to select parameters of PARITY.

There are ODD, EVEN, NONE to select for PARITY.

Select "ON" or "OFF" for 'Serial com.', install the parameters of 'Serial com.' as the one in the interface, install the 'Serial com.' with the same method for every time to power on, all 'Serial com.' state must be installed to asynchronous communication.

5. Absorbance Test

It will show:

MEASURE ABSORBANCE ASP DI WATER

Operate according to the screen's suggestion, the aim is to assure the variety of absorbance between different periods, then rectify. Each wavelength will show 'OK!' in ABSORBANCE test. Or it will suggest 'FAIL' and need to be adjusted. Introduced largely in chapter 7 "MAINTENANCE".

6. Edit patients' file

The internal memory will be effected because of some reason, then it will save wrong data, it will effect result report if without modification, this function is as follows:



A: The amount of patients saved in the system, range: 1-255;

B: The actual amount of patients detected by the instrument.;

C: Current position of patients' file: range 0-249

D: Patient No., range:1-9999

E: Saved patient's sample, range: 0-30

(1) In normal condition, A should be equal to B, now '1' key is useless. In actual application, because there are too many disturbance factors especially the moment of turning on and turning off, it is instability in the twinkle of power on and power off, now it is very easy disturbed to make mistake. It will suggest wrong information after detecting the mistake, now you need adjust the patients' file with

handwork modification, or it will show wrong result.

Method: Press '1', the cursor will appear in A, modify the value in A equal to the one in B then press 'ENTER' key to correct the mistake.

(2) If you delete the patient's information in patients' file, search the patient with ' \downarrow ' ' \uparrow ', the patient No. will be shown in D, press '2' to delete the patient.

Attention: This operation can not be recovered, so be careful. If you delete the appointed result of the patient, operate in "RESULT REPORT".

(3) Press 'MENU' back to last menu.

7. Set the time

Enter "CLOCK SETUP" menu, it will show:

HR FORMAT 1-12 Hr <u>√</u>2-24 Hr DATE: 2008-01-01 TIME: 12:01:10 '←"→'CHANGE HR FORMAT NUM KEY CHANGE TIME

a>. Time Format: HOUR-MINUTE-SECOND XX: XX: AM: MORNING

PM: AFTERNOON

If it is 24 HOURS SYSTEM, XX is blank.

b>. Date Format: YEAR-MONTH-DATE

c>. Press 'MENU' if you don't modify the time and date, don't press 'ENTER', or it will effect the time's correctness.

8. System Reposition

When the system is disturbed by other reasons, this function can help you to reposit the system be back to out-firm installation. Input '99999' in 'UTILITY' to startup the function, it will ask you:

PRESS '1' TO RESET SYSTEM PRESS '2' TO RESET REPORTS

PRESS 'MENU' RETURN

Press '1' to reposit the system, then press 'Y' twice;

Press '2' to clean the patients file, then press 'Y' twice;

Press 'MENU' to return.

All patients' information and results will be lost after reposition in internal memory, so be careful.

Chapter 7 Maintenance

7.1 Maintenance

Maintenance and Utilities of EK-50 BIOCHEMISTRY ANALYZER is as follows:

1. Keyboard use

It requires 'TOUCH' keyboard, there is no sound when pressing each key, only sound for pressing then loose it, so the operator shouldn't press keys heavily.

2. Maintenance for every day

Clean the tube with DI water repeatedly after testing sample every day to get rid of residual reagent and serum, protein especially remain thing in the cliff of colorimetric cell. The tube should be full of DI water at last.

3. Maintenance for every week

Clean the tube with DI water after testing sample twice, then absorb the CLEAN once (Main Component: NaClO, diluted it to 5%), let the CLEAN stay in the tube for 10 minutes, cleaning the tube with DI water for 3 times. At last it should be full of DI water.

4. Cleaning instrument's appearance

Wipe the instrument appearance with wet cloth (Turn the electricity power off).

Attention: Clean the instrument with clean water, neutral purge reagent or non-causticity scour, but it can't be cleaned with organic reagent or hot water, or it will be distorted or damaged.

| phenomena | cause | Method |
|--------------------|---|---|
| | a) The pump doesn't work | a) Tight the screw of the pump |
| Eail absorbing | b) Loose pipe | b) Cut down a part of the pipe's tie |
| Fail absorbing | c) Absorbing time is zero | c) Install the ASP TIME again |
| | d) The pipe is damaged | d) Change the pipe(Appendix) |
| | a) The power doesn't supply | a) Turn on the power |
| No Display | b) The electricity doesn't work | b) Check the power socket |
| | c) Signal display line is loose | c) Check the display cable |
| | | Adjust the contrast adjustor |
| Dark Display | The contrast of the display is changed with the environment. | Contrast adjustor |
| | | a) change the new paper |
| No Printing | a) No paper. | b) install the paper again |
| NO FINANG | c) Thermal print paper is in reverse | c)install the paper again |
| Fail Absorbance | a) Do not absorb DI water b)There are bubble in the colorimetric cell. c) Dirty colorimetric cell d) The lamp is aging | Test it with DI water a): Clear the bubble in colorimetric cell b): Clean the colorimetric cell with CLEAN c): Change the lamp |
| | a) No absorbance when power on b) Invalidate reagent | a) Absorbance again b) Change validity reagent |
| | c) Inadequate ASP quantity | c) Adjust the ASP quantitv≤600uL |
| Instable | d) No STD. | d) Test the BLANK and STANDARD again |
| results | e)Improper wavelength | e) Test another wavelength |
| | f) Absorb air into reagent to get high | f) Operate carefully and standard |
| | result | |

7.2 Trouble and Handle

Appendix 1: Input Method

The correspondent relation of cursor keys to ENGLISH characters are as follows:

| 1→ A,B,C | | | | | | | | |
|--|---------------------|--|--|--|--|--|--|--|
| 2→ D,E,F | | | | | | | | |
| 3→ G,H,I | | | | | | | | |
| 4→ J,K,L | | | | | | | | |
| 5→ M,N,O | | | | | | | | |
| 6→ P,Q,R | | | | | | | | |
| 7→ S,T,U | | | | | | | | |
| 8→ V,W,X | | | | | | | | |
| 9→ Y,Z,(null) | | | | | | | | |
| 0→ -,.,/,α,β,γ,δ,ε,ζ,η,θ,ι,κ,λ,μ,ν,ξ,ο, | ,π,ρ,σ,τ,υ,φ,χ,ψ,ω. | | | | | | | |
| Press '1' key one time and you will get A. | 1A | | | | | | | |
| Press '1' key twice quickly and you will get B. 1 & 1B | | | | | | | | |
| Press '1' key three times quickly and you will get C. | 1 & 1 & 1 C | | | | | | | |
| | _ | | | | | | | |

You can get the others alphabet and mark with the analogy......

Appendix 2: Change the printer-paper

① Open the printer cover interface, press 'FEED', press it again to stop it after output the residual paper, get the surplus paper out.

② Put the new Paper Scroll in Paper Groove, the thermal printer paper are different in two sides, so pull the end of paper out when the thermal side downwards;

③ Take the roll axis out upwards, put the thermal side under the roll axis as the chart, the paper's direction should be vertically with the one of the roll axis, it avoids the printer paper locked so that it can't print normally;



④ Install the print roll axis, put the gear in the right side of the printer, then put another side and press it to lock it tight;

⑤ Press 'FEED', adjust it if the paper can't get out or it's direction is not vertically with the one of roll axis, or it can't work; press 'FEED' to stop it after print a segment(When paper get out of the cover board)

6 Pull the paper out of the cover board, close it;

Attention: "FEED" function consists in Main menu, Test sample interface, Waiting keyboard input interface, "PRINT/DELETE RESULT REPORT" interface and Q.C. report interface can be used in "RESULT REPORT", close "FEED" function in other interfaces.

Appendix 3: Change Pump Pipe

- 1. Wring the 2 screws with screwdriver in the left side of the back, take the panel board out, there is a black tube called Pump Pipe;
- 2. Slide the upper side of the Pump Pipe out of the gap;
- 3. Pull out the white ties connect with Pump Pipe's two sides;
- 4. Get a new Pump Pipe, connect the 2 ties with the Pump Pipe correspondent;
- 5. Put one side of Pump Pipe in the flute, push another side from the upper flute according to the middle part;
- 6. Close the upper board, tight the screws;

Appendix 4: Clean the colorimetric cell

- 1. Prepare a cup of DI water or alcohol, put the sample tube into the liquor;
- 2. Press '6' to enter "Utilities" submenu in main menu, then press '3' enter "ADC" interface;
- 3. Press '8', clean;
- 4. If use alcohol, discharge the residual alcohol in tube with pressing '8', change DI water twice;
- 5. Press 'MENU' to return to the main menu after cleaning;

Appendix 5: Change Lamp

- 1. Open the upper board.
 - ♦Wring the two screws on the front side in underneath board and back board;
- ♦ Slide the upper board for a segment distance along the instrument (Don't touch the sample tube), get the upper board and put it on the right side.
- 2. Find a black box near the sample tube, it is Lamp box;
- 3. Wring the 2 screws(A.B)in the top of the Lamp box with screwdriver, get the Lamp box out;
- 4. Wring the 2 screws(C.D)in Lamp holder with screwdriver;
- 5. Wring the 2 screws(E.F),get the Lamp light out;
- 6. Replace the new lamp with old lamp, tight screws(E.F)
- 7. Tight 2 screws(C.D)
- 8. Put the Lamp box back to the place, tight the 2 screws;
- 9. Close the upper board, tight the screws.



Appendix 6: Com. protocol

Hardware condition: Connect 2 communication instruments' RS-232C ties together with RS-232C cable, or connect the instrument to PC instrument's COM port.

Serial communication state:

BAUD ratio: 19200, 9600, 4800, 2400, 1200;

WORK MODE: 0(SYNCHRONISM), 1, 2, 3, 4(ASYNCHRONISM)

PARITY: ODD, EVEN, NONE;

WORK STATE: SEND, RECEIVE, DUPLEX OPERATION.

Concentration values are sent in packets with the following format: Blank originality data:

| BI | 1 | 1 | 1 | 2 | 1 | 1 | 3 | 1 | 1 | 1 | 3 | 1 | 1 | 1 |
|----|-----|-----|-------|-------|-----|------|------|------|-------|------|------|--------|-------|------|
| ΤE | | | | | | | | | | | | | | |
| ΤY | Fra | ver | Instr | Instr | Fra | Fram | Pat | Item | Mea | Resu | DAT | decima | check | Fram |
| PE | me | sio | ume | ume | me | е | ien | num | sure | lt | А | I | sum | е |
| | he | n | nt | nt | len | num | t ID | ber | state | type | | | | end |
| | ad | | type | num | gth | ber | | | | | | | | |
| | | | | ber | | | | | | | | | | |
| CO | FA | 01 | 01 | 01 | 0-7 | 0-7F | 0-7 | 80H- | D0 | D3 | 0-7F | E0-E4 | D7=0 | FBH |
| DE | | | | | F | | F | 8FH | | | each | | | |

Standard absorbance or result absorbance:

| BI | 1 | 1 | 1 | 2 | 1 | 1 | 3 | 1 | 1 | 1 | 3 | 1 | 1 | 1 | 1 |
|----------|----------|-----|------------|----------------------------|------------|-------------|----------|-------------|------------------------|----------------|--------------|-----------|-------------|---------------------|------|
| ΤE | | | | | | | | | | | | | | | |
| ΤY | Fra | ver | Instr | Ins | Fram | Fram | Pat | Test | Ме | Re | DAT | deci | Unit | ch | Fram |
| PE | me | sio | ume | tru | е | е | ien | Num | as | sul | А | mal | | ес | е |
| | He | n | nt | me | Leng | Num | t ID | ber | ure | t | | | | k | End |
| | ad | | Туре | nt | th | ber | | | Sta | Ту | | | | Su | |
| | | | | Nu | | | | | te | ре | | | | m | |
| | | | | mb | | | | | | | | | | | |
| | | | | er | | | | | | | | | | | |
| CO | FA | 01 | 01 | 01 | 0-7F | 0-7F | 0-7 | 80H- | D1- | D4 | 0-7F | E0-E | C0H-C | D7 | FBH |
| DE | | | | | | | F | 8FH | D2 | | each | 4 | FH | =0 | |
| CO DE | ad FA | 01 | Туре 01 | nt Nu mb er 01 | th 0-7F | ber 0-7F | 0-7 F | 80H- 8FH | Sta te D1- D2 | Ty pe D4 | 0-7F each | E0-E 4 | C0H-C FH | Su m D7 =0 | F |

The result:

| BI | 1 | 1 | 1 | 2 | 1 | 1 | 3 | 1 | 1 | 1 | 3 | 1 | 1 | 1 | 1 |
|----|-----|-----|-----|-------|------|-----|-------|------|-----|-----|------|------|-------|----|------|
| ΤE | | | | | | | | | | | | | | | |
| ΤY | Fra | ver | Ins | Instr | Fram | Fra | Patie | Test | Ме | Re | DAT | deci | Unit | ch | Fram |
| PE | me | sio | tru | ume | е | me | nt ID | Num | as | sul | А | mal | | ec | е |
| | He | n | me | nt | Leng | Nu | | ber | ure | t | | | | k | End |
| | ad | | nt | Num | th | mb | | | Sta | Ту | | | | Su | |
| | | | Ту | ber | | er | | | te | ре | | | | m | |
| | | | ре | | | | | | | | | | | | |
| CO | FA | 01 | 01 | 01 | 0-7F | 0-7 | 0-7F | 80H- | D2 | D5 | 0-7F | E0-E | C0H-C | D7 | FBH |
| DE | | | | | | F | | 8FH | | | each | 4 | FH | =0 | |

| NUM | TEST CODE | CODE | NUM | TEST CODE | CODE |
|-----|-----------|------|-----|-----------|------|
| 1 | 1 | 81H | 8 | 8 | 88H |
| 2 | 2 | 82H | 9 | 9 | 89H |
| 3 | 3 | 83H | 10 | 10 | 8AH |
| 4 | 4 | 84H | 11 | 11 | 8BH |
| 5 | 5 | 85H | | | |
| 6 | 6 | 86H | | | |
| 7 | 7 | 87H | | | |

Test code: (80-0xBF, 64 codes at most)

Unit code:

| NUM | NAME | CODE | NUM | NAME | CODE |
|-----|----------------|------|-----|-----------|------|
| 0 | | C0H | 8 | g / d L | C8H |
| 1 | u / L | C1H | 9 | g / m L | C9H |
| 2 | u / m L | C2H | 10 | Leu/uL | CAH |
| 3 | u mol/L | C3H | 11 | X1012 / L | CBH |
| 4 | m mol/L | C4H | 12 | | ССН |
| 5 | g / L | C5H | 13 | | CDH |
| 6 | mg/L | C6H | 14 | | |
| 7 | mg/dL | C7H | 15 | | |

| | Measure State | | Result Type | | | | |
|-----|---------------|------|-------------|-------------|------|--|--|
| NUM | NAME | CODE | NUM | NAME | CODE | | |
| 1 | BLANK | D0H | 1 | originality | D3H | | |
| 2 | STANDARD | D1H | 2 | Absorbance | D4H | | |
| 3 | SAMPLE | D2H | 3 | Consistence | D5H | | |

Attention:

a)Use originality to test BLANK, no unit;

b)Use absorbance to test, no unit, data is 3*N bites for N standards;

c) Use no unit absorbance and unit consistence to test;

d) Absorbance value: turn the decimal to left for 3 bites;

e) Consistence: turn the data to left for (D _{decimal}—0xE0)bites;.

f) The CRC check begins with the start bite of FA and end with front one bite of the check sum;

g) Item's result data bite and patient No. are $((D_0\&7F) << 14) + ((D_1\&7F) << 7) + (D_2\&7F);$

h) The frame length is which begins with the item type bit and end with the front one bit of the check sum.

i) The first frame's No. is 1, and it will add 1 when send one frame till 0x7f, then begins with 1 again.

j) The instrument sends data to the serial when the screen shows the result report. For example, it will send data automatically when get the result in "TEST SAMPLE" and "RESULT REVIEW".

Appendix 7: Items List:

| Code | Abbreviation | Code | Abbreviation | | |
|------|-----------------|------|--------------------|--|--|
| 1 | ALT | 26 | Zn | | |
| 2 | ALP | 27 | Р | | |
| 3 | GOT | 28 | К | | |
| 4 | γ-GT | 29 | Na | | |
| 5 | ТР | 30 | CO ₂ CP | | |
| 6 | ALB | 31 | Fe | | |
| 7 | TBIL | 32 | HGB | | |
| 8 | DBIL | 33 | RBC | | |
| 9 | TTT | 34 | GRP | | |
| 10 | BUN | 35 | A/G | | |
| 11 | CRE | 36 | UDBIL | | |
| 12 | UA | 37 | IGG | | |
| 13 | CO ₂ | 38 | C3 | | |
| 14 | NH ₃ | 39 | IGM | | |
| 15 | GLU | 40 | CHE | | |
| 16 | ТСНО | 41 | СК | | |
| 17 | HDLC | 42 | BU | | |
| 18 | LDLC | 43 | U-PRO | | |
| 19 | TG | 44 | U-Hb | | |
| 20 | LDH | 45 | U-GLU | | |
| 21 | AMS | 46 | U-URO | | |
| 22 | CL | 47 | U-BIL | | |
| 23 | Са | 48 | U-KET | | |
| 24 | Mg | 49 | U-NIT | | |
| 25 | Cu | 50 | U-PH | | |