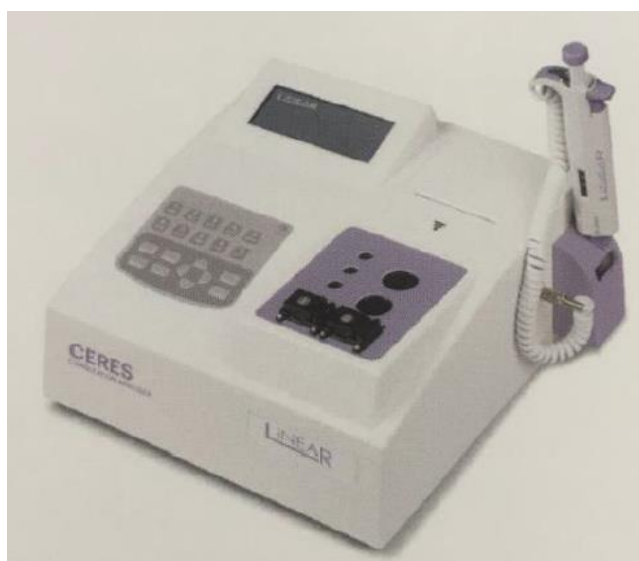

CERES

Service Manual

Automated Coagulation Analyzer



LiNEAR

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Declaration

LiNEAR Company holds final explanation right for Service Manual.

LiNEAR only considers its responsibility for safety, reliability and performance after compliance with full requirements as follows:

1. Assembly, operation, extension, re-adjustment, improvement and repair are done by duly authorized technician by LiNEAR;
2. Relevant electric equipment meet national standard;
3. Product service is done under **this** Service Manual.

Repair service

Free service includes:

Free service is only conferred to these products under warranted service regulations by LiNEAR Company.

Scope of charge service:

1. LiNEAR shall execute charge service for product excluded from warranty regulations by LiNEAR Company;
2. Even if during warranty period, LiNEAR still execute charge service for such conditions resulted from following reasons (i.e. artificial factor, misuse, excessive power voltage specified for product, natural disaster beyond control, part or consumables replaced without prior approval for LiNEAR, or machine repaired by not duly authorized person by LiNEAR.

User Instruction

User for Service Manual

User for Service Manual includes customer service engineer for LiNEAR or service technician well-trained or duly authorized by LiNEAR Company.

Notice:

User must understand information specified in Manual, and technician properly operates instrument only after well-trained by manufacturer.

How to use the Manual

User must carefully read this Manual, and prevent from potential loss or harm.

User must carefully read all alerts and warnings (blackface letter).

Manual content

This Manual is CERES Automated Coagulation Analyzer Service Manual. It introduced structural principle, installation procedure, basic theory, maintenance and repair method and troubleshooting for CERES Automated Coagulation Analyzer. Please provide with service under Service Manual.

Symbol Note:


Safety symbol


Safety symbols outlined in the following list used in Service Manual shall be used along with these symbols and texts.


Symbol	Meaning
Warning:	Alert user to operate under description; otherwise maybe result in physical injury.
Infection danger by biology:	Alert user to operate under description; otherwise maybe result in infection danger by biology.
Caution:	Alert users to operate under description, otherwise maybe result in damage to system or affect test result.
Notice:	It is used to highlight important information in operation procedure or one used to alert user pay attention to.


Label and Silk-print description


CERES Automated Coagulation Analyzer has meaning of label and silk-print as follows:


 Product serial number


 Product manufacture date


 Manufacturer


 Equipment of In Vitro diagnosis (IVD)


 Warning: danger of biological infection

 Notice: may cause physical injury or damage to instrument.

 Grounding protection

 Validity of environmental use: 20 years.

 Switch on (mains power)

 Switch off (mains power)

Safety consideration

To safely use this system, please carefully read following safety considerations. Any operation if breach for following safety considerations may cause damage to system or physical injury.



Warning:

Preventive measures provided by this system maybe fail if user fails to use it under instruction issued by LiNEAR Company.

Electric shock!

To warn electric shock, please comply with following considerations!



Warning:

While analysis department switches on mains power, non-authorized repair technician must not open up face cover.

Spill of reagent or sample onto instrument may cause failure for instrument or electric shock, please do not place any sample or reagent onto such instrument.

Prevent moving part from causing physical injury

To prevent moving part from causing physical injury while system runs, please comply with following considerations.



Warning:

While running, do not contact with moving parts, which include sample filling arm and catcher arm.

While running, do not insert finger or hand into open part.

Prevention from damage by biology

To effectively prevent from damage by biology, please comply with following considerations:



Danger by biological infection:

Improper use of sample may cause infection, please do not directly by hand contact with sample, Control, calibration mixture. While operating, must wear glove, wear smock to take preventive action for infection. If necessary, wear protective goggles.

In case if sample carelessly contacts with physical skin, please immediately handle it under user work standard, and follow doctor's advice.

Prevention from chemical danger



Warning:

Some reagent or cleaning liquid may injure to physical skin, please carefully use them to prevent hand or smock contacting with them. If so carelessly, please immediately flush them by soap and water. If into physical eye carelessly, please immediately flush by lots of water and then ask oculist for medical advice.

Dispose of waste cup

To prevent waste liquid from environmental pollution or physical injury, please comply with following considerations while disposing of waste cup.



Danger of infection for biology:

Reagent, control, calibration cleaning liquid or some substance in waste liquid is governed and controlled under pollution regulations or emission standard. Please comply with local emission standard and consult responsible reagent manufacturer.

While disposing of waste cup, must wear glove and wear smock to prevent from infection. If necessary, wear protective goggles.

Dispose of instrument

Please dispose of waste analyzer under following requirement.



Warning:

Some substance in waste analyzer is governed and controlled under pollution regulations. Please comply with local waste disposal standard to dispose of waste analyzer.

Use consideration

To correctly and effectively use the system, please carefully read following considerations.

Use for System



Warning:

This system is used to diagnose bleeding and thrombus disease, treat and monitor and test and observe medical effect for thrombolysis and blood clot, and used in relevant clinic diagnosis industries. Please consult with LiNEAR Company for other use excluded in such application above.

While executing clinic judgment under analysis result, please consider clinic symptom or other test result at the same time.

Operator



Warning:

This system is only for professional inspector (well-trained by LiNEAR or its agent), doctor or lab operator.

Use environment



Caution:

Please correctly install this system under installation environment specified in this Use Instruction. Installation and use of the system under condition not specified maybe acquire unreliable result, and may cause damage to the system.

Prevention from electromagnetic wave and noise



Caution:

Please do not install equipment that emits noise around the system, please switch off equipment (i.e. mobile phone, radio transceiver) in the room where the system places, and do

not use other CRT display around the system, otherwise, interruption for noise or electromagnetic wave maybe cause failure for system.

Do not use other medical instrument around the system; electromagnetic wave emitted from the system may cause failure for other medical instrument around the system.

Use for system



Caution:

- (1) Please use the system under Operation Instruction, improper use maybe cause incorrect measurement result, even may cause damage to system or physical injury;
 - (2) Before use first time, please calibrate it and execute control and confirm with correct operation for system;
 - (3) While use of system, must follow QC program, otherwise, it fails to assure reliable result;
 - (4) Must not open up sunshade cover during analysis;
 - (5) Must not replace reagent or cuvette during analysis;
 - (6) RS-232 port for instrument is used to transmit test result by standard serial port or after link with other computer;
 - (7) Please do not use U disk with virus, prevent computer virus from damage to software or data, please do not make computer for other use or link with internet;
 - (8) Do not touch display, mouse or keyboard by wet hand or physical hand after adhering to chemical drug;
 - (9) Do not again turn on power supply for instrument within 10 seconds after turning off it, otherwise, the system maybe enter protection status. Please again turn on power supply only after turning off mains power in case if the system accesses to protection status.
-

Computer and printer



Notice:

As for computer and printer use consideration, please refer to its operation description.

Peripheral equipment



Warning:

Peripheral equipment (including computer and printer) must have been certified with CCC (S&E) certificate, peripheral equipment failed to meet requirement maybe cause failure to run the system or cause physical injury.

System maintenance



Caution:

- (1) Please execute system maintenance according to relevant description specified in this user instruction. Incorrect maintenance measure may cause incorrect analysis result, even cause
-

damage to system or physical injury.

(2) Some dust may be accumulated on the surface. While cleanup, please immerse some water and make it dry and lightly wipe its surface and immerse some soap liquid if necessary before use clean soft cloths. Do not use alcohol and relevant organic solvents. After cleanup, please wipe out surface by dry cloths. Before cleanup, please switch off power supply for this system, and pull out outlet of power supply wire; while cleanup, please take necessary action to prevent water dripping the system, otherwise this may cause damage to the system or physical injury.

(3) Replace main part (i.e. sampling needle, mixing motor, injector component), make necessary calibration analysis.

Parameter setup



Caution:

The system needs to set up quantity of sample, reagent and test time and relevant parameters. While their setup, please comply with relevant description specified in this user instruction, and refer to Instruction provided along with reagent.

Sample



Caution:

(1) Please use fully separated plasma sample. This may affect analysis result if some blood cells exist in blood plasma sample. Medicine, anticoagulant and anti-corrosive agent existed in sample may interrupt some analysis result;

Hemolysis and chyle particle in sample maybe affect analysis result, this may alter sensitivity under test curve;

(2) Please take correct action to store sample. Incorrect sample storage may alter constituent structure and incorrect analysis result for sample;

(3) To prevent sample from volatilization, please do not open sample for storage for long time. If sample volatilizes, this may cause incorrect analysis result;

(4) Some samples may not be analyzed under test parameter or reagent used. So, please consult with relevant reagent manufacturer for these samples;

(5) For purpose for demand of analysis, if this needs to pre-treat with some samples, please consult with relevant reagent manufacturer;

(6) The quantity of sampling is required during test by instrument, so please confirm with proper quantity of sampling under relevant description specified in Operation Instruction while sampling;

(7) Before analysis, please confirm if sample is placed at correct sample area, otherwise this may not obtain correct result.

Reagent, calibration and control



Caution:

(1) This needs proper reagent, calibration and control before use of this system for analysis;

(2) Please select and use adaptable reagent for this system. In case of being hard to determine if reagent is available for use, please consult with reagent manufacturer or LiNEAR or its dealer;

(3) Please comply with relevant description specified by reagent manufacturer before use and storage for reagent, calibration and control. Even during validity, improper storage for reagent, calibration liquid and QC liquid may cause failure to obtain correct test result or the best system performance;

(4) After replacement for agent, please execute calibration analysis. This may not obtain correct analysis result without proper calibration analysis;

(5) While analysis, cross infection for reagent may affect analysis result. Please consult with relevant reagent manufacturer for further information about reagent cross infection.

Data backup



Notice:

This system can automatically store data into CF card in computer, however, data deletion for computer CF card or damage to CF card because of other reasons may cause failure to recover data. Please regularly execute backup analysis data and measurement parameter into other mobile memory device.

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Chapter 1 Instrument Description

1.1 Product Features

1. CERES is a coagulation analyzer. It will collect the sample data by the principle of photoelectric induction, and it can be widely used in the clinical diagnostics, such as the diagnosing of the bleeding and thrombotic diseases, monitoring the thrombolysis and anticoagulation treatment, as well as observing the curative effect.
2. Built-in a number of programmable items, large-capacity storage of historical data.
3. Built-in thermal printer to print English comprehensive report, with reference range.
4. Tailor-made test position shading system, which can prevent the interference from the outside light.

1.2 Instrument Parameters

Sample pre-warm position	4
Reagent pre-warm position	2
Test channel	2
Display	192×64 graphic LCD display
Operation mode	Foil keypad
Printer	Internal thermal printer
Fore-warmer temperature	37 °C
Interface	RS-232 bidirectional communication port, sampling gun holder (optional)
Weight	4kg
Dimensions	280mm (L)×310mm (W)×160mm (H)
Power Supply	a.c.220V ± 22V, 50Hz ± 1Hz
Fuse	3.15AL250V, Φ5 × 20
Working environment	10 °C ~ 30 °C; relative humidity ≤ 70%
Storage environment	-10 °C ~ 40 °C; relative humidity ≤ 80%

Chapter 2 Instrument Installation

2.1 Instrument unsealing

Unpack the package of the instrument and remove the materials for transport. Save the packing box and the packaging materials well, for your convenience in the future of re-packaging the instrument.

- 1) Take out the instrument from the box.
- 2) Take away the packaging materials, and take out the instrument from the plastic packaging bag.
- 3) Check the items in the box and confirm that the following items are within the box:
 - ♦ CERES mainframe
 - ♦ User's Manual
 - ♦ Packing List
 - ♦ Guarantee card
 - ♦ Product acceptance certificate
 - ♦ Accessories: Power cable, spare fuses, etc. (subject to packing list).

Note: If the items are inconsistent with the packing list or have any defects, please contact with the supplier.

2.2 Environmental Requirements

In your workplace, select a place without direct sunlight. The surface of the worktable should be flat, with enough space for placing CERES, and free of big shock (such as a place where a centrifuge is placed).

Note: The instrument working environment temperature should be 10 °C ~ 30 °C, and the relative humidity should be less than 70%.

In order to ensure the normal operation of the instrument, it is prohibited to place the instrument in the following places:

- ♦ A place with extreme temperature changes
- ♦ A place of particular heat or special cold
- ♦ A place of a large number of dusts
- ♦ A place close to the magnetic field of electromagnetic devices

2.3 Power Requirements

- ♦ a.c.220V±22V
- ♦ 50Hz±1Hz
- ♦ 80VA

Note:

- ♦ The AC power supply must be well grounded (zero ground voltage <5V).
- ♦ The AC power must be stable, and it is prohibited to share power supply with the appliances of high power.
- ♦ When unplug the power cable, please seize the plug itself, rather than the power cable.
- ♦ If the instrument is found to have smoke, smell or abnormal sounds, immediately turn off the power, and contact the maintenance service center immediately.

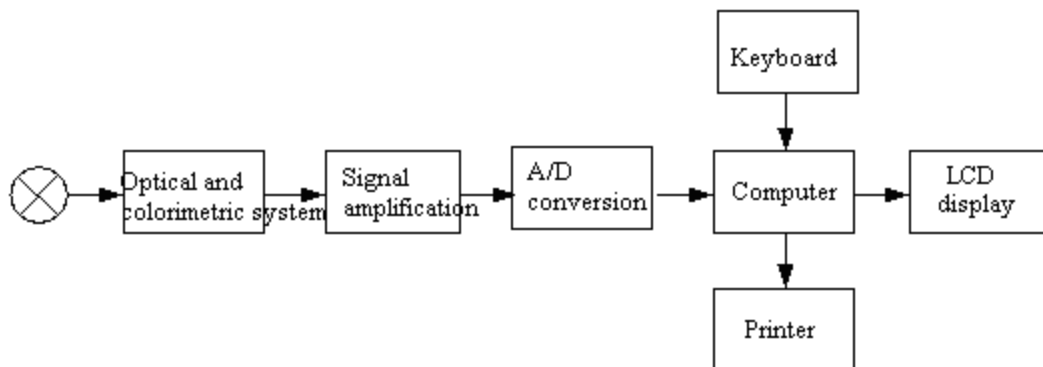
2.4 Start Installation

Connect the instrument to the power supply

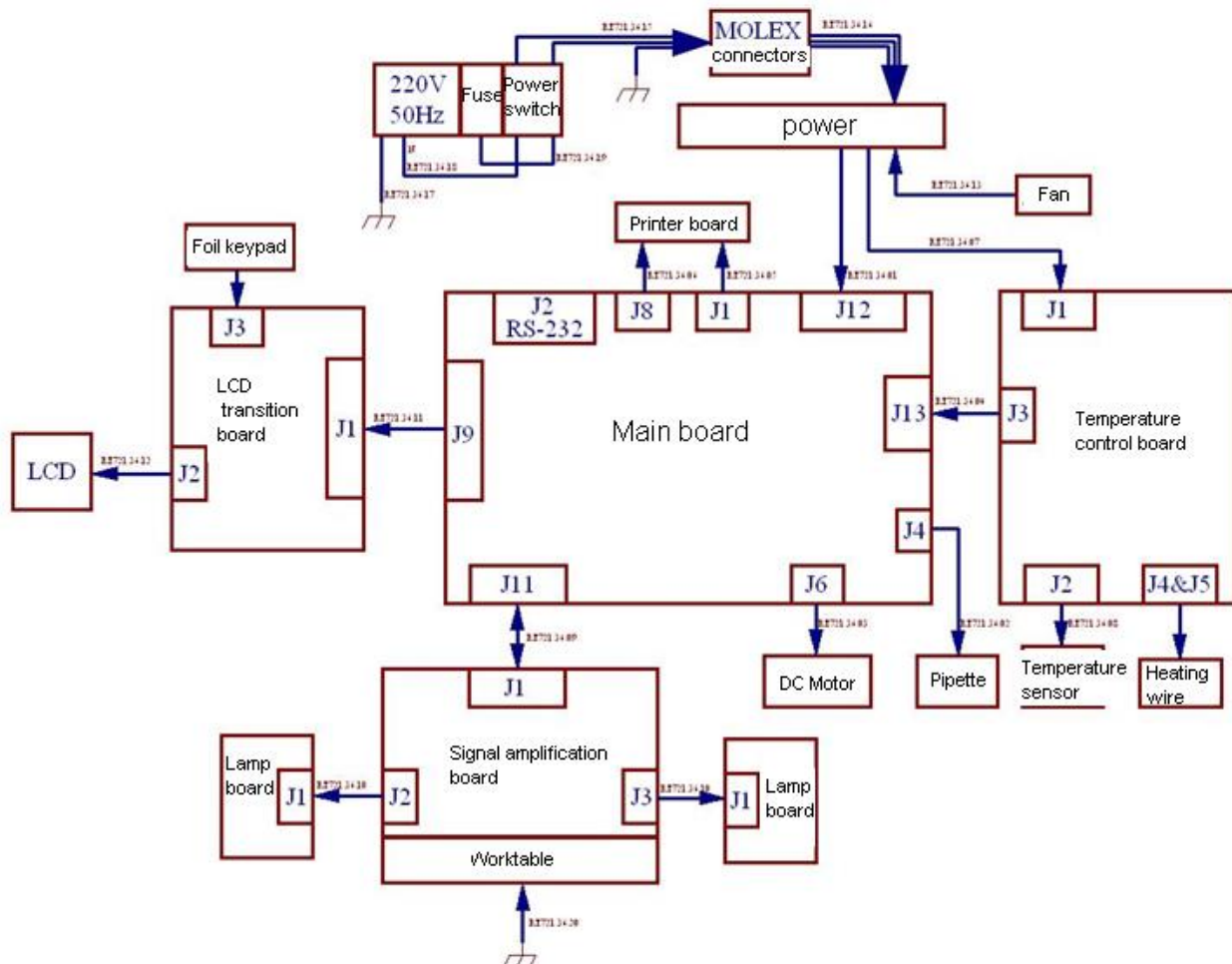
- 1) Plug one end of the power cable into the power socket of the instrument.
- 2) Plug the other end of the power cable into an AC power socket.

Chapter 3 Functional Description

3.1 CERES Functional Block Diagram



3.2 CERES Harness Interconnection Scheme



3.3 Power Function Description

The power of CERES machine is provided by the switching power supply module, using the high-frequency PWM conversion technology, so the power is featured with small size, light weight, high efficiency, high reliability, high load regulation rate, as well as high power regulation rate, while two grade transformation is used for the source power structure. One grade is the single-ended fly back current mode AC/DC transformation, and the other grade is DC/DC Buck converter, so that the DC power supply of two-channel output is featured with high voltage accuracy and regulation rate.

The power supply module will output two-way DC power, and the usage of each way power is as follows:

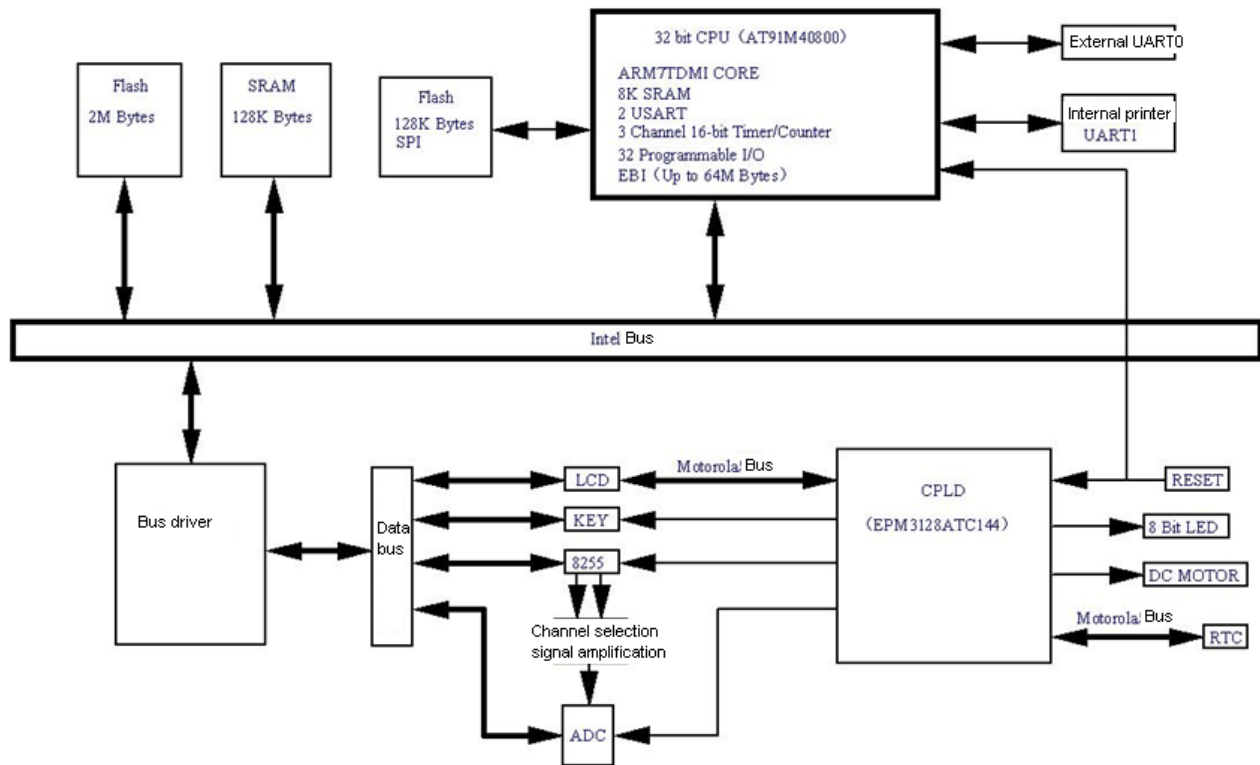
- | | | |
|------|-----------|---|
| CH1: | 5.0V/8.0A | Supply power for the main board, the temperature control board, and the fan |
| CH2: | 12V/4.0A | Supply power for the temperature control board |

3.4 The function description of the main board

3.4.1 The function introduction of the main board

1. As the system platform, it will provide the hardware environment for the system software running.
2. Provide connection interfaces to connect the signal pre-amplifier board and the temperature control board, and process the data collected by the signal pre-amplifier board. Provide I/O system interfaces, and the supported I/O interfaces include: two RS232 ports, using for the internal serial port printer and the external RS232 interface respectively, one keyboard panel interface, one 192×64LCD display interface.

3.4.2 The functional block diagram of the main board



3.4.3 The main board principle introduction

As shown above, the main board consists of the following main parts:

1. The basic platform for the system operation will be constituted by MCU, SRAM, Flash memory and CPLD, and the system software will be built in the Flash Memory. System will extend 2M Byte Flash memory and 128K Byte SRAM through the EBI bus. Flash memory and SRAM will be mapped through the CPU internal address Bank area. CPU basic frequency is 25MHz. When the system is started up, the program will be directly run within the Flash Memory.

2. Serial communication port

There are two serial communication ports in the main board: RS232 port is composed by the serial port 0 on the MCU, which is connected with the PC for updating the external programs, but the serial port 1 is used for the connection of the internal printer.

3. Programmable logic devices

Programmable logic unit will be used to complete the logic control of all parts of the system, and the address of the system has been distributed. Through the device, 8 LED indicator control ports and IO port have been extended,

including the DC motor port, LCD interface, 8255 port, and the signal pre-amplifier port.

4. Scan Keyboard

The keyboard scan logic is that a dedicated keyboard scan chip is used to drive 4×5 scan keyboard, detect the key-pressing operation.

5. Power Conversion Circuit

The system power is the +5V power provided by the main board. The main board needs +5 V and +3.3V mixed power supply. Therefore, the main board will conduct the power conversion between +5V and +3.3 V.

3.4.4 Potentiometer adjustment

1. LCD Contrast Adjustment: adjust the potentiometer VR2 by an I-shaped screwdriver, the voltage of the test point TP_CONSTR should be -7.5V.
2. Signal Adjustment: observe the test point TP_SigCOM by a oscilloscope, in the case of no test cup, if the measured channel voltage is V_c , adjust the potentiometer VR1 until the voltage value of the middle pin of the potentiometer VR1 reaches $V_c - 10\text{mV}$.

3.5 The function description of the light emission board

The light emission board will provide light for the system detection.

3.6 The function description of the signal pre-amplifier board

3.6.1 The function introduction of the signal pre-amplifier board

The signal pre-amplifier board will convert the light signal of the light emission board into an electrical signal, and transmit the pre-amplified signal to the main board.

3.6.2 The signal pre-amplifier board principle introduction

The optical diode converts optical signal from the light emitting board into electrical signal. Since the electrical signal from the optical diode is extremely weak, the signal is pre-amplified by the operational amplifier featuring high impedance. To obtain the same lighting Intensity of both channels, the both light sources are connected in series.

3.7 The function description of the LCD transfer board

Transfer the LCD signal and the membrane keyboard signal to the main board.

3.8 The function description of the temperature control board

3.8.1 The function introduction of the temperature control board

1. The thermostat board is used as the platform of thermostat system, providing the hardware conditions for temperature control software run.
2. The thermostat board provides the interface to connect the main control board, which is used to heat the workbench. The thermostat board provides operation temperature of $37\pm 1^{\circ}\text{C}$ for the sample test. The Temperature Reach signal is transferred to the main control board when the temperature is stable, and the temperature indicator on the casing is lit.

3.8.2 The temperature control board principle introduction

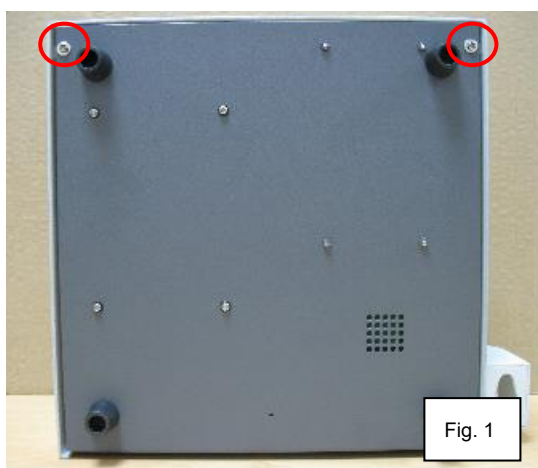
The temperature control system is composed by AT89S51 MCU, the clock frequency is 12MHz, and the program is built in the on-chip Flash memory. When the system starts, the program will run in the Flash memory directly.

Chapter IV Parts Replacement

4.1 Disassembly of Instrument

Operating procedures:

1. Switch off the power supply and unplug all wires.
2. Put a piece of soft silk on a clean, flat table, turn over the instrument on the silk to avoid damaging the outer surface of plastic top cover.
3. As Fig. 1 shows, remove the two screws securing the top cover with a philips screwdriver.

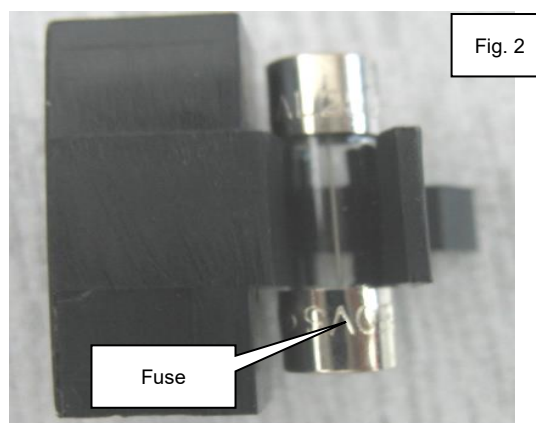
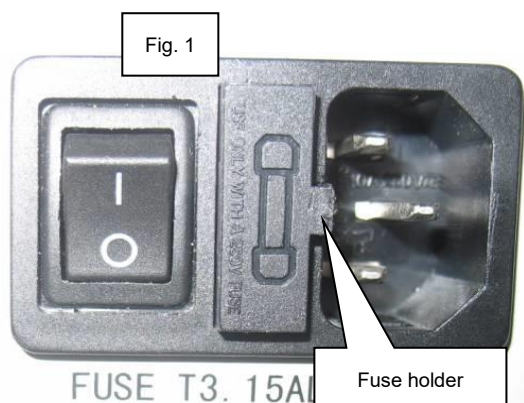


4. Remove the two screws on the back of the instrument as shown in Fig. 2, and lift the top cover of the instrument carefully.

4.2 Replacement of Fuse

Operating procedures:

1. Switch off the power supply and unplug the power cord.
2. Pry up the fuse holder with a screwdriver, and you will see the fuse as shown in Fig.2.

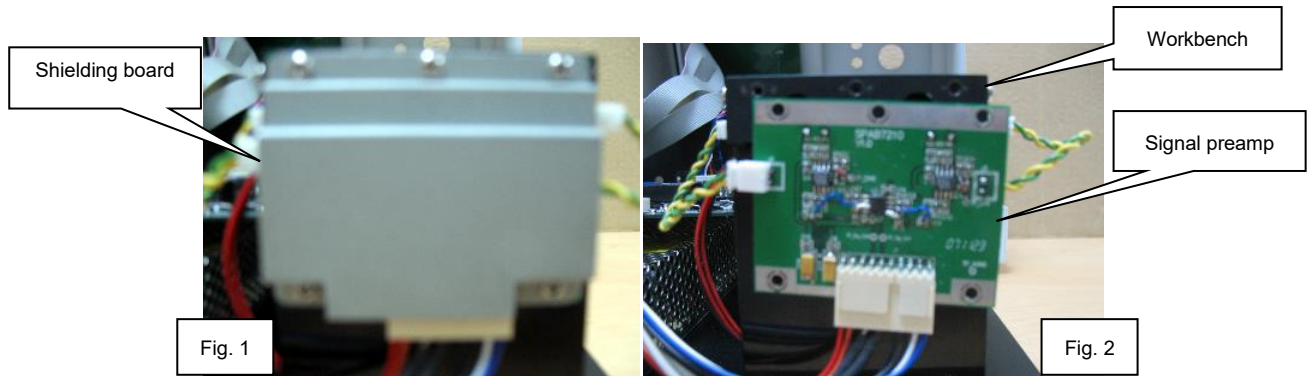


3. Replace the fuse with the one with the same specifications, and install the new one in the same way.

4.3 Replacement of Signal Preamp Board

Operating procedures:

1. Switch off the power supply, unplug the power cord and open the top cover, and you can see the shielding board and signal preamp on the workbench component as shown in Fig. 1.

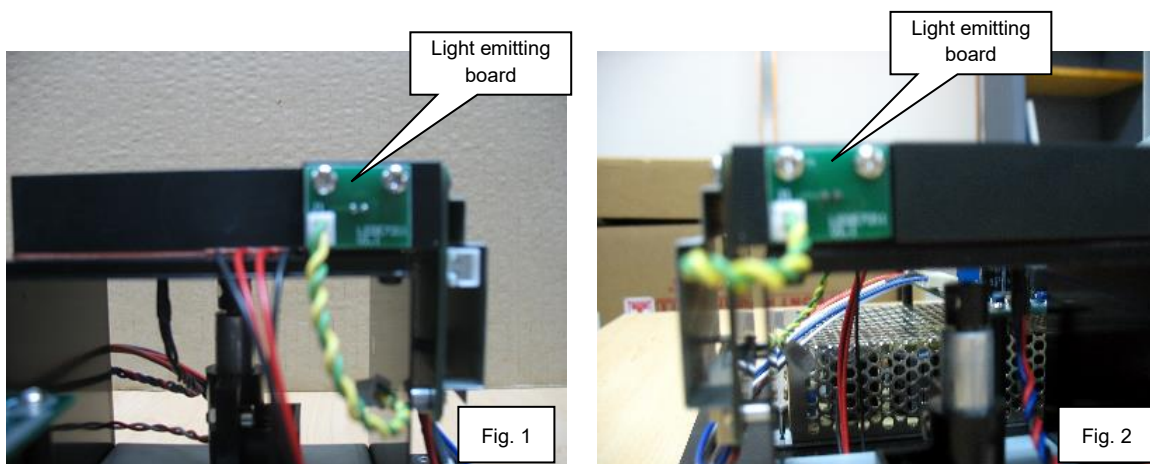


2. Remove the five securing screws on the shielding board and remove the shielding board, and you can see the signal preamp board as shown in Fig.2.
3. Replace the signal preamp with the one with the same specifications, and install the new one in the same way.

4.4 Replacement of Light Emitting Board

Operating procedures:

1. Switch off the power supply, unplug the power cord and open the top cover of the instrument, and you will see the light emitting board located on the left and right sides of the workbench as shown in Figs. 1 and 2.



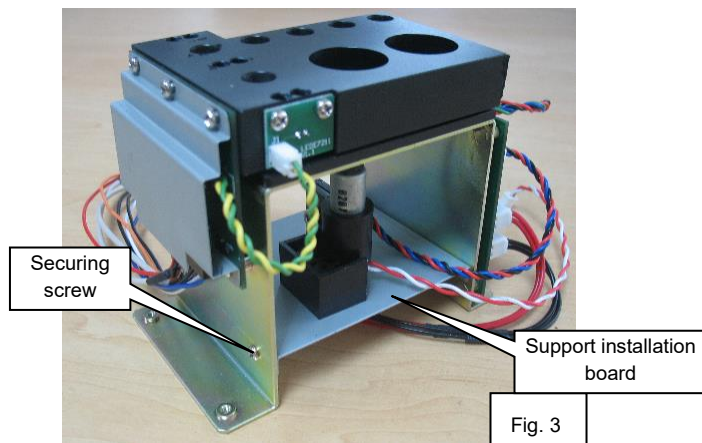
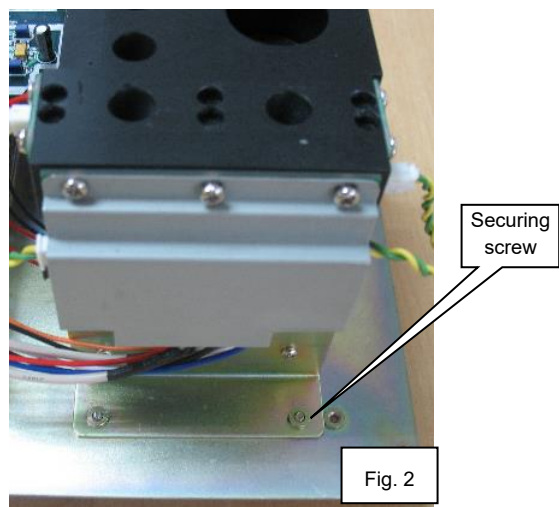
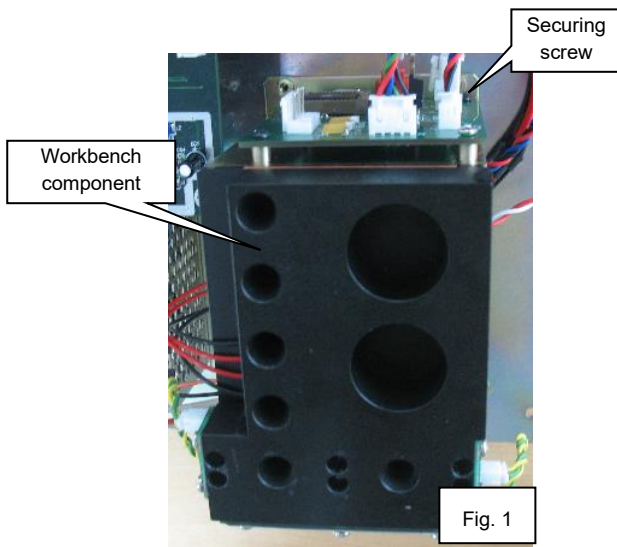
2. Remove the two securing screws on the desired light emitting board, remove the light emitting board and disconnect the wire harness.
3. Replace the light emitting board with the one with the same specifications, and install the new one in the

same way.

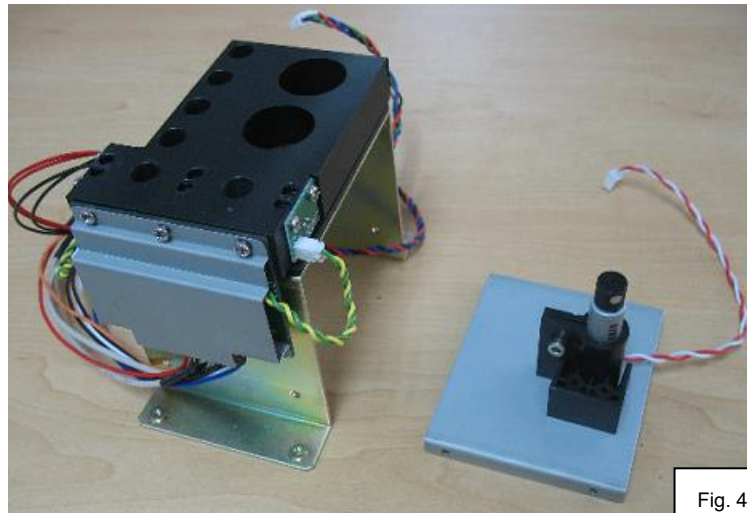
4.5 Replacement of Temperature Sensor

Operating procedures:

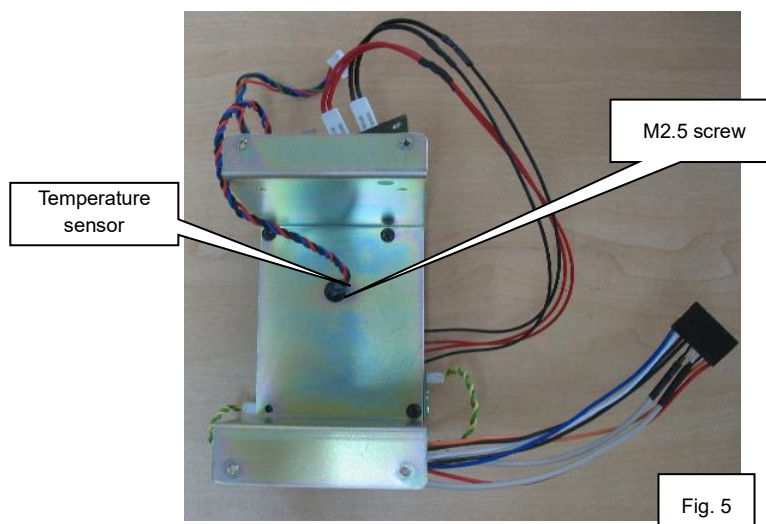
1. Switch off the power supply, unplug the power cord and open the top cover of the instrument, and you will see the component of the workbench.
2. Remove the four securing screws of the workbench component and remove the workbench component as shown in Figs. 1–3.



-
3. Remove the four screws securing the support installation plate as shown in Fig. 3, and remove the support installation plate as shown in Fig. 4.



4. Turn over the workbench component, remove the M2.5 screw as shown in the figure below, and then remove the temperature sensor as shown in Fig. 5.

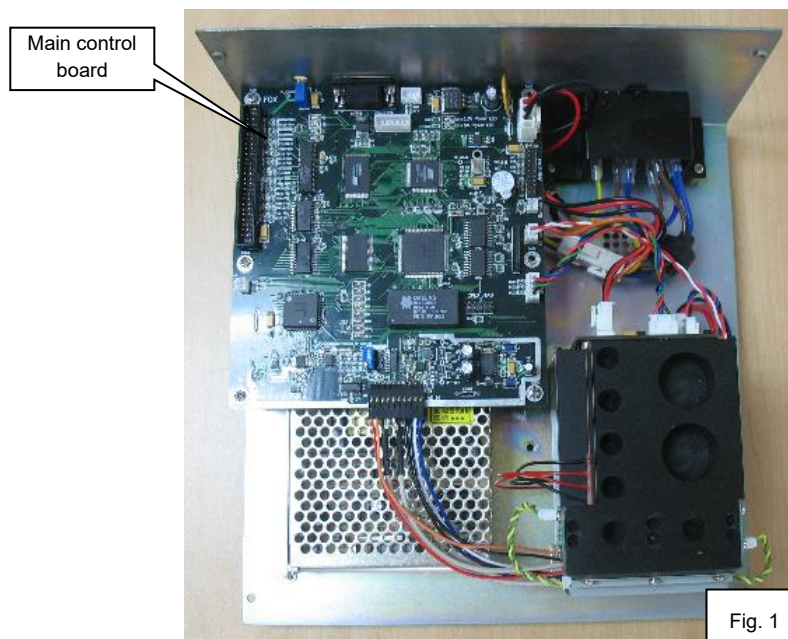


5. Replace the temperature sensor with the one with the same specifications, and install the new one in the same way.

4.6 Replacement of Main Control Board

Operating procedures:

1. Switch off the power supply, unplug the power cord and open the top cover of the instrument, and you will see the main control board as shown in Fig.1.

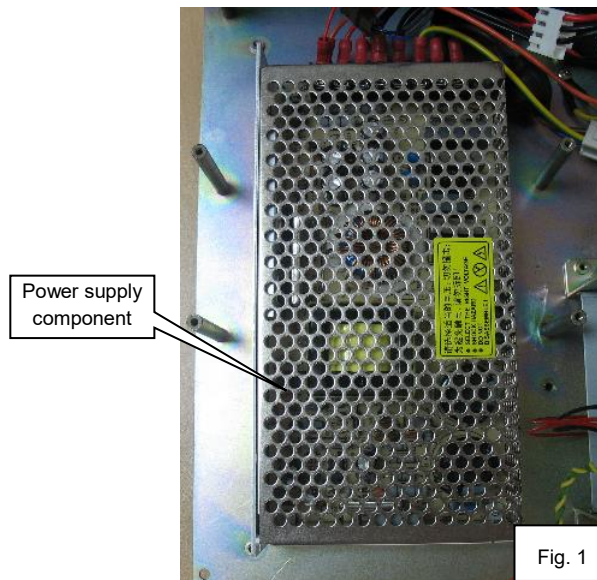


2. Remove the securing screws of the main control board, unplug the plug on the board carefully, and remove the main control board.
3. Replace the main control board with the one with the same specifications, and install the new one in the same way.

4.7 Replacement of Power Supply Component

Operating procedures:

1. Switch off the power supply, unplug the power cord and open the top cover of the instrument, and you will see the power supply component as shown in Fig.1.

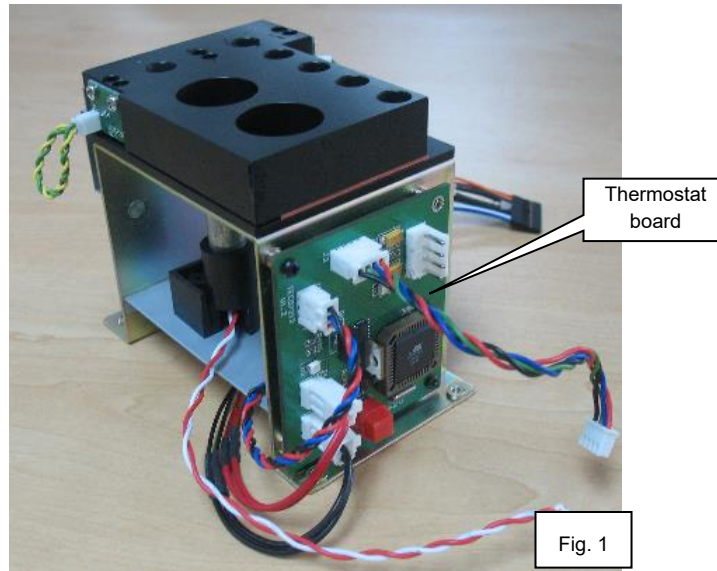


2. Remove the securing screws of the power supply component, unplug the plug carefully and remove the power supply component.
3. Replace the power supply component with the one with the same specifications, and install the new one in the same way.

4.8 Replacement of Thermostat Board

Operating procedures:

1. Switch off the power supply, unplug the power cord and open the top cover of the instrument, and you will see the thermostat board on the back of the workbench component as shown in Fig.1.

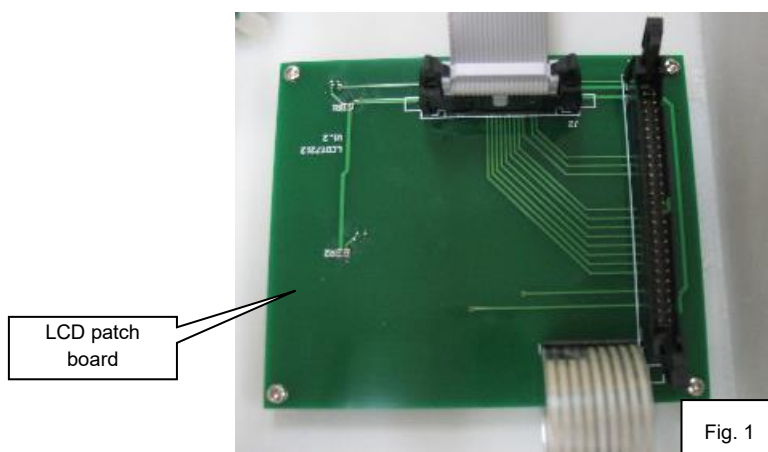


2. Remove the workbench component, remove the securing screws of the thermostat board, unplug the plug carefully and remove the thermostat board.
3. Replace the thermostat board with the one with the same specifications, and install the new one in the same way.

4.9 Replacement of LCD Patch Board

Operating procedures:

1. Switch off the power supply, unplug the power cord and open the top cover of the instrument, and you will see the LCD patch board as shown in Fig.1.



2. Remove the connection to the LCD patch board, remove the four screws securing the LCD patch board, and remove the LCD patch board.
3. Replace the LCD patch board with the one with the same specifications, and install and connect the new one in the same way.

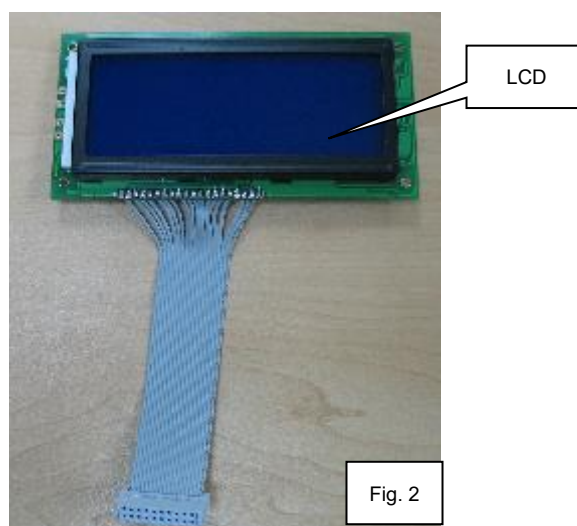
4.10 Replacement of LCD

Operating procedures:

1. Open the top cover of the instrument, remove the securing screws of the LCD, and unplug the wire as shown in Fig.1.



2. Replace the LCD with a new one and reinstall in the same way.



Chapter V Care & Maintenance

5.1 Overview

CERES is a precision clinical analyzer. To remain it in good conditions, daily maintenance is necessary. Maintenance of CERES is very simple, but it should be carried out carefully.

5.2 Cleaning of Instrument

- ♦ Keep the operating environment of the instrument clean.
- ♦ Use neutral detergent and wet cloth to clean the surface of instrument.
- ♦ Please use a soft cloth to clean the LCD.

Note: Do NOT expose the instrument to any solvent, oil, and other corrosive substances.

Chapter 4 Simple fault handling

Failures	Countermeasure
Switch on the instrument but the instrument is not energized. (Indicators on the panel of the instrument are not lit, the fan does not rotate, and the screen has no display.)	Check whether 220V power supply is normal. Check whether the fuse is blown out. Check whether the switch is damaged. Check whether the power supply component is damaged.
Switch on the instrument with it energized, but the instrument is not started. (The power indicator is lit, but the screen has no display and the system does not have startup indication sound.)	Check whether the voltage of power supply is normal. The main control board may be damaged. Replace the main control board.
No display after startup (The startup indication sound is heard, but the screen has no display.)	Replug (or replace) the ribbon cable of the LCD and the data cable between main control board and LCD patch board to find out the poor or damaged connection. The LCD may be damaged. Replace the LCD. The main control board may be damaged. Replace the main control board.