Getein 1160

Immunofluorescence Quantitative Analyzer

Service Manual

Preface

This manual is for the maintenance of Getein 1160 Immunofluorescence Quantitative Analyzer and is intended for the use of service engineers for maintenance and repair only. Please be sure to read all chapters of this manual before operating the instrument.

Copyright

Statement

This manual is written in accordance with the Regulations on the Administration of Medical Device Instructions and Labels.

Getein Biotech reserves the right to modify the content of the manual without prior notice.

Service engineers are requested to pay close attention to the information provided in the manual. Only technicians specifically trained by the manufacturer should perform proper operation of the instrument.

Warranty and Maintenance Service

We warrant that all products manufactured are free from defects in materials and production process.

The warranty applies only to instruments that are used, operated, handled, and maintained properly in accordance with the instruction manual (provided to the user at the time of purchase), and no warranty will be given for products that have been altered without our permission. Problems caused by improper or incorrect operation by the user, including accident, abuse, misuse, carelessness, water quality, and other problems not related to the instrument itself, are not covered by the warranty. The warranty period is subject to the provisions of the sales contract.

Service Life

The service life of the instrument is 8 years (continuous working time of not more than 8 hours per day) in the case of standard operation and proper maintenance.

Technical Support

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Content

Chapter 1 General Information

This manual contains the detailed information on the maintenance of Getein 1160 Immunofluorescence Qualitative Analyzer. Before maintaining, please read carefully the service manual as the information is vital to the service person for ensuring high quality and reliable performance of the system.

1.1 Personnel Requirement

This manual is applicable to personnel with the following qualifications:

- Have comprehensive knowledge about electrical circuit;
- Have comprehensive knowledge about reagents;
- Have comprehensive knowledge about quality control;
- Have comprehensive knowledge about troubleshooting;
- Be able to operate the analyzer skillfully;
- Be able to use basic mechanical tools and understand technical terms.

1.2 Manual Introduction

Content	Chapter
Instrument installation procedure of Getein 1160	Chapter 2 Transportation and Storage
Structure and component description of Getein 1160	Chapter 3 System Overview
Main module and two assembly's description of Getein 1160	Chapter 4 Primary Module
Electrical and electronic circuit description of Getein 1160	Chapter 5 Hardware
Software installation and communication protocol of Getein 1160	Chapter 6 Software
Function testing and instrument debugging of Getein 1160	Chapter 7 System Maintenance
Instrument Maintenance of Getein 1160	Chapter 8 Instrument Maintenance
Terminologies, and circuit diagram of Getein 1160	Appendix

1.3 Operational Precautions

The following operational precautions, limitations, and hazard warnings are provided:

- Use only dedicated test cards with the analyzer. Read and follow the package insert supplied with each test kit before using.
- Be sure to wear protective clothing and other appropriate protective equipment when handling samples and wastes and maintaining the instrument.
- If special treatment is required before discharging wastes, please refer to local regulations for disposal.
- Do not look directly into the lens of the barcode reader when the instrument is powered on.
- Please respond and handle all alarms and error messages timely.
- To prevent personal injuries, wear rubber gloves when touching sharp parts.
- If the instrument spills or leaks liquid, immediately disconnect the power.
- To avoid electromagnetic and noise interference, do not place the instrument near equipment that can generate excessive noise, and do not use medical devices near the instrument that is susceptible to EMF (voltage) that can cause malfunction.

1.4 Symbols

Failure to follow proper safety procedures can result in personal injuries or instrument damage. The table below lists the symbols used in the service manual and their meanings.

Name	**Description**
 Note	Highlight or provide additional information.
 Warning	The occurrence may cause personal injuries to operators, patients, or people around.
 Warning; Biological hazard	Areas of the instrument and associated fluid handling equipment may contain potentially infectious substances.

1.5 Biosafety

Operators should follow the instructions below, and otherwise there is a potential risk of biocontamination.

- All items (samples, controls, etc.), and areas in contact with these substances may be biologically contagious. Operators should follow laboratory safety practices and wear personal protective equipment (e.g., lab coat, gloves, etc.) when in contact with relevant items and areas.

- Instrument which ought to be discarded must be disposed of according to local regulations.
- Do not come into direct contact with blood samples.
- Operators are obliged to comply with national and local regulations regarding the discharge or disposal of wasted samples, test cards, etc.
- In the event of instrument malfunction and needing repair, the instrument surface and the possibly contagious components such as the card entrance and the waste card container should be disinfected and cleaned (75% alcohol is recommended) to avoid biological contamination and other hazards during handling or repair.

1.6 EMC

Definition: EMC (electromagnetic compatibility) is the ability of a device to suppress electromagnetic interference from other devices while not causing similar electromagnetic radiation interference to other devices.

- This instrument meets the emission and immunity requirements.
- It is recommended to evaluate the electromagnetic environment before running the instrument; keep it away from strong electromagnetic interference sources to avoid affecting the normal operation of the instrument.
- The use of devices that emit radio waves (such as cellular phones, transceivers and mobile radio-controlled toys, etc.) near this analyzer may cause the analyzer to malfunction. Please disconnect the power supply of these devices near this analyzer.
- When installing this analyzer, keep it away from other electronic devices.
- Be sure to use the cables provided or designed by Getein Biotech and connect cables in accordance with installation procedures.
- Please use the specified peripheral devices that can be connected to this analyzer, and avoid using non-specified devices. Otherwise, the EMC performance of this analyzer may be degraded.
- Please remind the users not to make any modification to this analyzer. Unauthorized modification from users may degrade the EMC performance of this analyzer. Modifications on this analyzer include changes in cables, system installation/layout, system configuration/components and the method of fixing the system/parts.
- Please make sure that all screws are tightened after the repairing work. Loose screws may also cause the degradation of EMC performance.

1.7 Environmental Requirements

Please be sure to treat and discharge the waste liquid, remaining test samples and other residuals after instrument use in accordance with requirements of national regulations and local environmental organization.

1.8 Laser Description

The laser scanner used in the instrument belongs to class I of laser products.

The laser source is the barcode scanner. The instrument is marked with label "Warning; Laser beam" and "Class I laser products".

Warning: If you do not use, maintain or operate the device as required, harmful radiation exposure may be caused. Do not remove the cover when using the instrument. During the maintenance of the instrument, please take measures to protect you from laser radiation.

Chapter 2 Transportation and Storage

2.1 Transportation and Storage Conditions

This analyzer is stored in a carton for transportation, and the personnel in charge shall handle the product according to labels on the package. The following labels should be observed during transportation.

Table 2.1 Labels on the package

Label	Description
	This way up
	Fragile, handle with care
	Staking limit by number
	Keep dry
	Keep away from sunlight

Transportation and storage conditions:

Temperature: -40℃ ~+55℃

Relative humidity: ≤93%

Air pressure: 50.0kPa ~ 106.0kPa

Operating conditions:

Temperature: -10℃ ~+35℃

Relative humidity: ≤70%

Air pressure: 50.0kPa ~ 106.0kPa

Power supply: AC 100V-240V~±10%

Frequency: 50Hz~60Hz±1Hz

2.2 Installation Requirements

1) Space requirement

- Instrument dimension: 299mm×276mm×152mm
- The instrument is usually placed on a laboratory table in a position with enough space for maintenance.
- The instrument is operated from the front side and the wasted card container is at the instrument left side. Leave enough room for operation when installing the analyzer.
- There are heat dissipation holes on both sides of the instrument. Make sure that there are no obstacles on both sides so as not to affect the heat dissipation.
- The instrument switch and power connector are located at the back of the instrument. Please do not place the instrument in a position where it is difficult to press the power switch or to unplug the power plug.

2) Environmental requirement

- The instrument should be placed in an environment that is free from dust, mechanical vibration, loud noise sources and power interference.
- Keep the instrument away from brush-type engines, flashing fluorescent lamps and electrical contact equipment that are frequently switched on and off.
- Avoid direct sunlight or placing it near heat and wind sources.
- Well grounded
- Indoor use.

3) Instrument weight

Analyzer: 4kg

It should be put on a flat laboratory table.

4) Power supply

Voltage: AC 100V-240V~±10%

Frequency: 50Hz~60Hz±1Hz

Max power: 60VA

2.3 Installation Steps

Note: All accessories and consumables of the instrument are provided by the manufacturer. The use of accessories and consumables from other manufacturers may affect the stability and precision of the instrument and cause potential personal injuries.

1) Open the analyzer package

Check the accessories against the packing list. Please open the packing box carefully to avoid damaging the optical and electronic components.

Note: The packing box should be opened only under the supervision of the agent's engineer. Do not take out the instrument from the box until the agent's engineer arrives.

2) Remove the screws

Take out the analyzer, and loosen the screw counterclockwise at the right side of the analyzer as shown in the figures below.

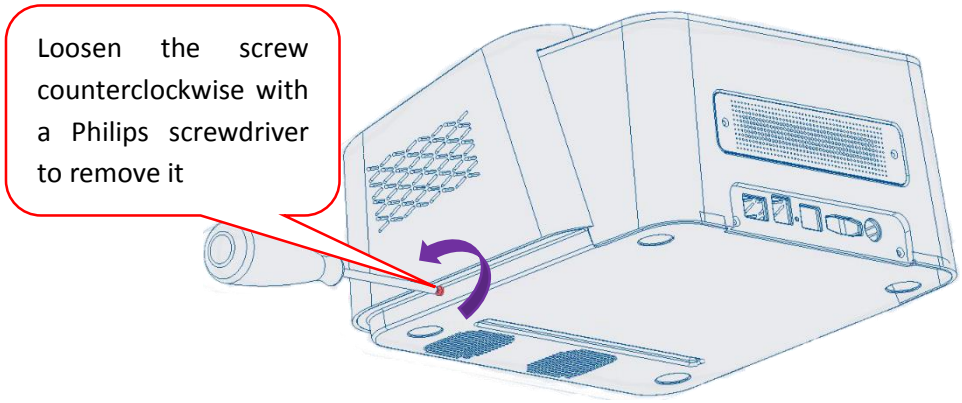


Figure 2-1

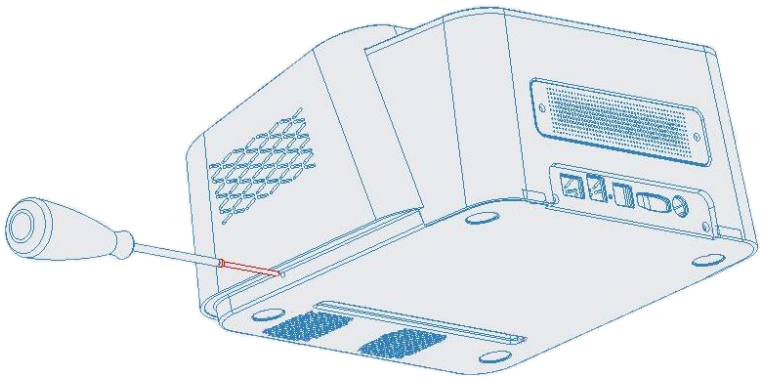


Figure 2-2

3) Connect the power

Put the analyzer on the table and the printing paper into the built-in printer. Plug one end of the power cord into the analyzer back and the other end into a power outlet.

2.4 Instrument Startup

1) Check before startup

Please follow these steps to check and confirm that the analyzer is ready for use before turning on

the power switch.

- Cable checking: Be sure that there are no broken cables or exposed copper wires, also confirm that the power plug has been safely connected to the qualified power outlet. Otherwise, change the power cables or use another outlet.
- Printer Checking: Be sure that printing paper is enough and correctly placed.

2) Turn on the instrument

- Turn on the power switch after appearance checking.
- The screen displays initialization interface. Getein 1160 automatically checks hardware and optical system.
- The Main interface appears after system initialization.

Chapter 3 System Overview

3.1 Technical Specifications

The following table describes the technical parameters of Getein 1160.

Table 3.1 Technical Parameters

1. Dimensions
299 mm (L) × 276 mm (W) × 152 mm (H)
2. Net weight
4kg
3. Analysis principle
Immunofluorescence Assay
4. Test speed
50 T/H at most
5. Data input
10.1-inch LED touch screen; resolution: 1280 × 800
6. Data output
Screen Printer GP Information Management Software
7. Data storage
100,000
8. Operating environment
Temperature: 10～35℃ Humidity: ≤70% Air Pressure: 70.0 kPa～106.0 kPa Transient Voltage: Class II Power Supply: AC100V ~ 240V±10% Frequency: 50Hz~60Hz±1Hz

9. Instrument blank count
The voltage of the blank QC card detected by the instrument should be less than 100 mV.
10. Linearity
r ≥ 0.95 in the detection range from 0 mV to 15,000 mV
11. Repeatability
Coefficient of variation of repeated measurement: CV ≤ 2% within range [100-15000] mV CV≤10% within range [0-100) mV
12. Stability
The voltage variation of the same standard card with a fixed concentration tested within 1 hour should be less than 10%.

Table 3.2 Sample parameters

1. Sample type
serum, plasma, whole blood, capillary blood, urine, stool, swab, saliva, and cerebrospinal fluid
2. Sample volume
10 ~ 200 ul, depending on the assay
3. Sampling method
Manual sampling

Table 3.3 Test parameters

1. Reagent type
Test card
2. Storage condition
Store at room temperature and avoid light; no need to refrigerate
3. Incubation of test card
Inside/outside incubation, up to 15 minutes
4. Incubation temperature control

Incubate at constant temperature
5. Reaction position
Plate type: 4 incubation positions, 1 emergency position
6. Measuring light source
Laser
7. Detection range
0 ~ 15000 mV
8. Wavelength range
635 ± 5 nm

3.2 Instrument View

Fig. 3-1 Front view of the instrument

Fig. 3-2 Side view of the instrument

3.3 Analyzer Components

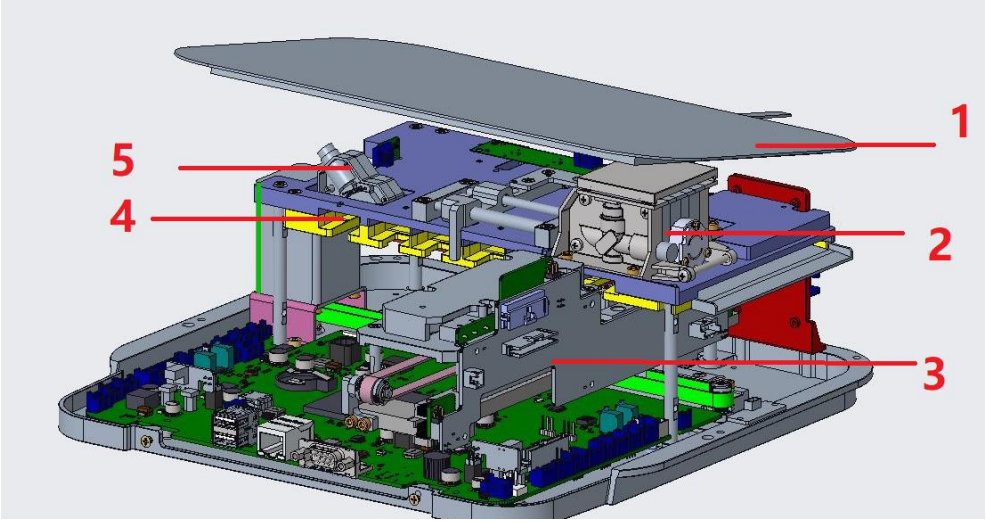


Fig. 3-3 System Components

1. Display screen

10.1-inch LCD color touch screen with 1280 × 800 resolution.

2. Optical path acquisition component

This analyzer contains a fluorescence detection optical path component for fluorescence detection.

Fig. 3-4 Optical path acquisition component

3. Card-pushing device

The card-pushing device enables the horizontal movement and up-down movement of a test card. A microswitch is placed within the device to determine if the test card is grabbed into the device.

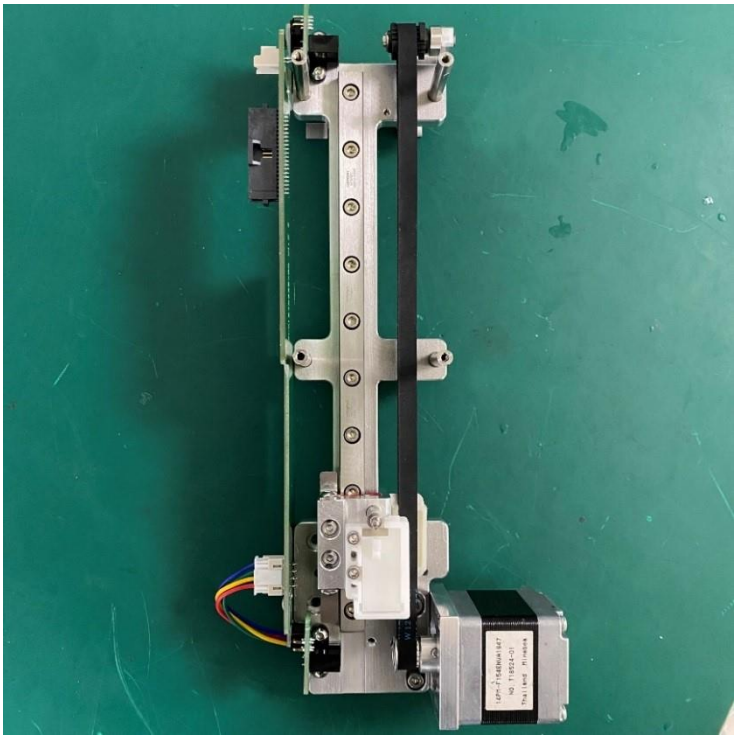


Fig. 3-5 Card-pushing device

4. Incubation module

This module contains six test card slots: the first one is the card entrance slot, which is followed by four incubators, and the last slot is the emergency slot and test slot, and also card exit slot.

The test card is inserted into the entrance slot, and then a microswitch determines whether the card is inserted properly. Then, the test card is delivered to the inner side of the card-pushing device by the card-grabbing device.

The four incubators provide a constant temperature environment for the test card to incubate. When

there is an emergent test task, the test card is measured through the temporary channel. The temporary channel also serves as a card discarding channel, where the measured cards are temporarily stored and dropped into the waste card container from this channel.

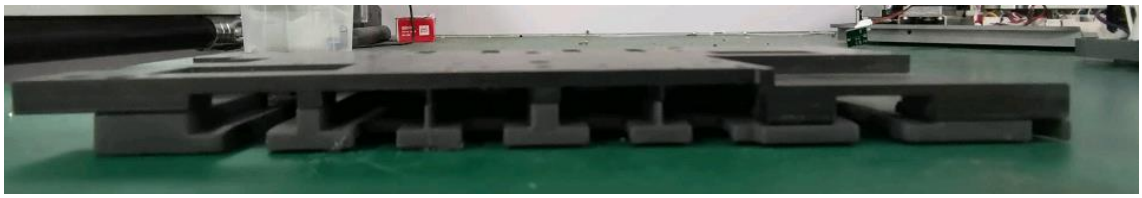


Fig. 3-6 Incubation module

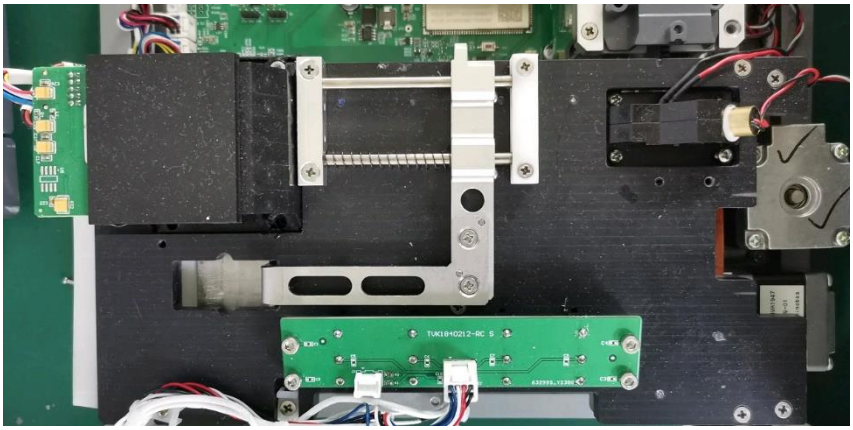


Fig. 3-7 Card-discarding device

5. Sub optical path component

The analyzer automatically identifies test items through the sub optical path component, which is installed on the entrance channel of the incubation module. When the test card is taken to the sub optical path position, the sub optical path automatically scans the barcode on the card to identify the test item.

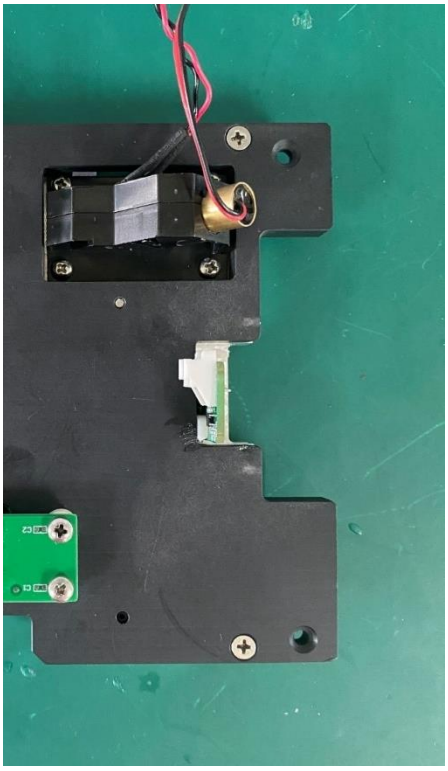


Fig. 3-8 Sub optical path component

Chapter 4 Primary Modules

4.1 Incubation Module

The Incubation module is shown in the figure below.

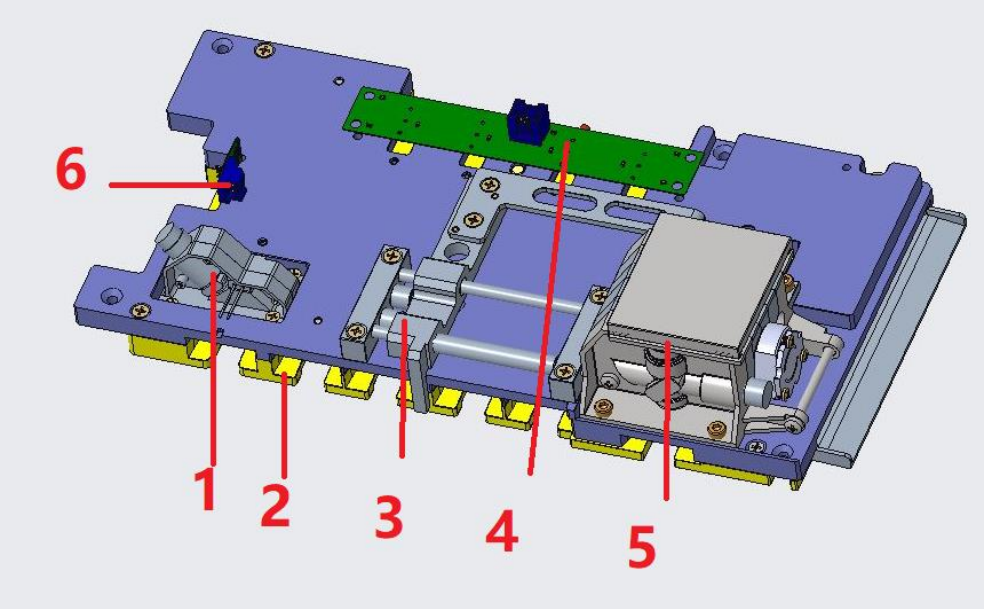


Fig. 4-1 Reaction module

Functional components:

1. Sub optical path component: scan the barcode of the test cards and automatically identify the test items.
2. Incubator: incubate the test cards.
3. Card-discarding device: discard the wasted test cards.
4. Incubator microswitch: check if there is any test card in the incubator.
5. Main optical path component: detect test cards.
6. Reflective plate: check if a test card is inserted.

4.2 Card-pushing Device

Card-pushing device is shown in the figure below.

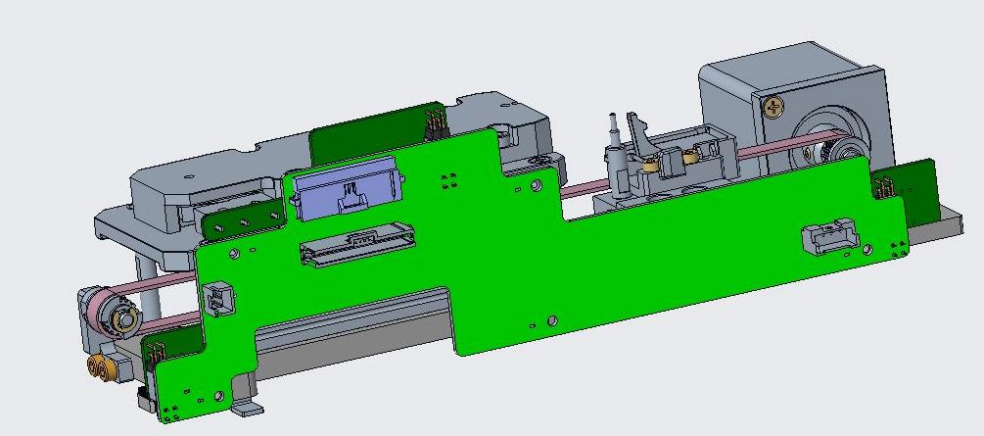


Fig. 4-2 Card-pushing device

Function: move horizontally and vertically.

4.3 Base Plate Module

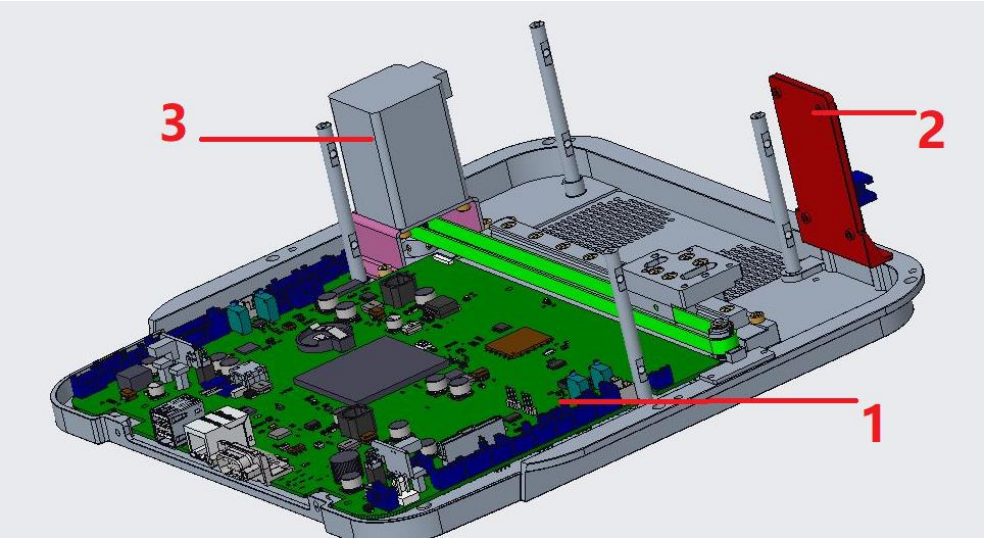


Fig. 4-3 Base plate module

Functional components:

1. Base board: serve as the instrument circuit for instrument running and motor controlling.
2. RFID card board: receive RFID parameters.
3. Horizontal motor: move horizontally.

4.4 Upper Cover Module

The upper cover module is shown in the figure below.

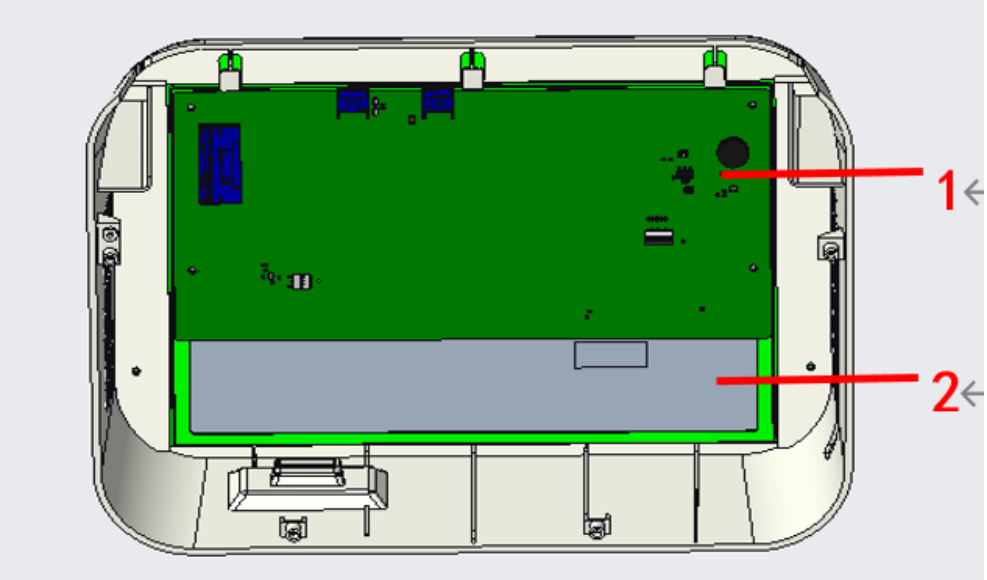


Fig. 4-4 Upper cover module

Functional components:

1. Display board: supply power for display.
2. Display: showing analyzer operation interfaces

4.5 Back Cover Module

The back cover module is shown in the figure below.

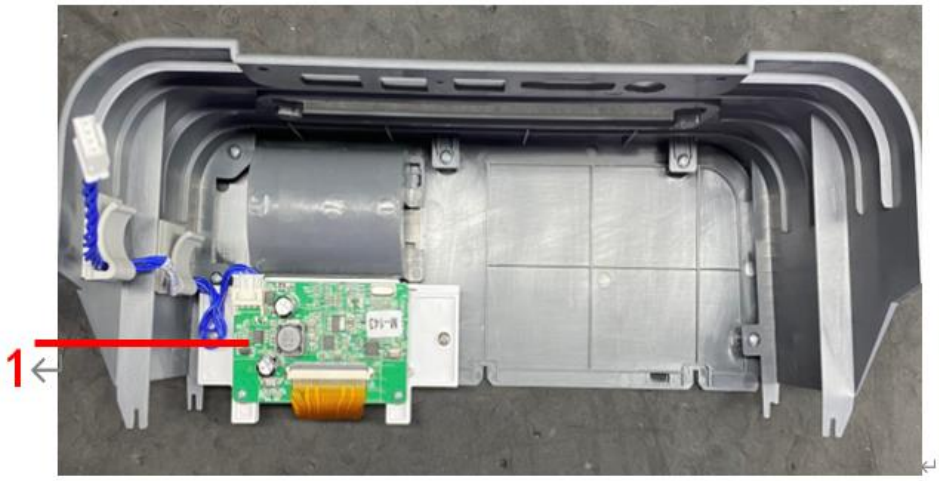


Fig. 4-5 Back cover module

Functional component:

1. Printer: print test results.

Chapter 5 Hardware

5.1 Full View

The hardware PCBs are connected to the structural parts. The PCBs mainly include X/Y axis arm board, base board, card-in optocoupler (OC) board, incubator switch board, RFID board and amplification board. The internal view of the instrument is shown in Figure 5-1.

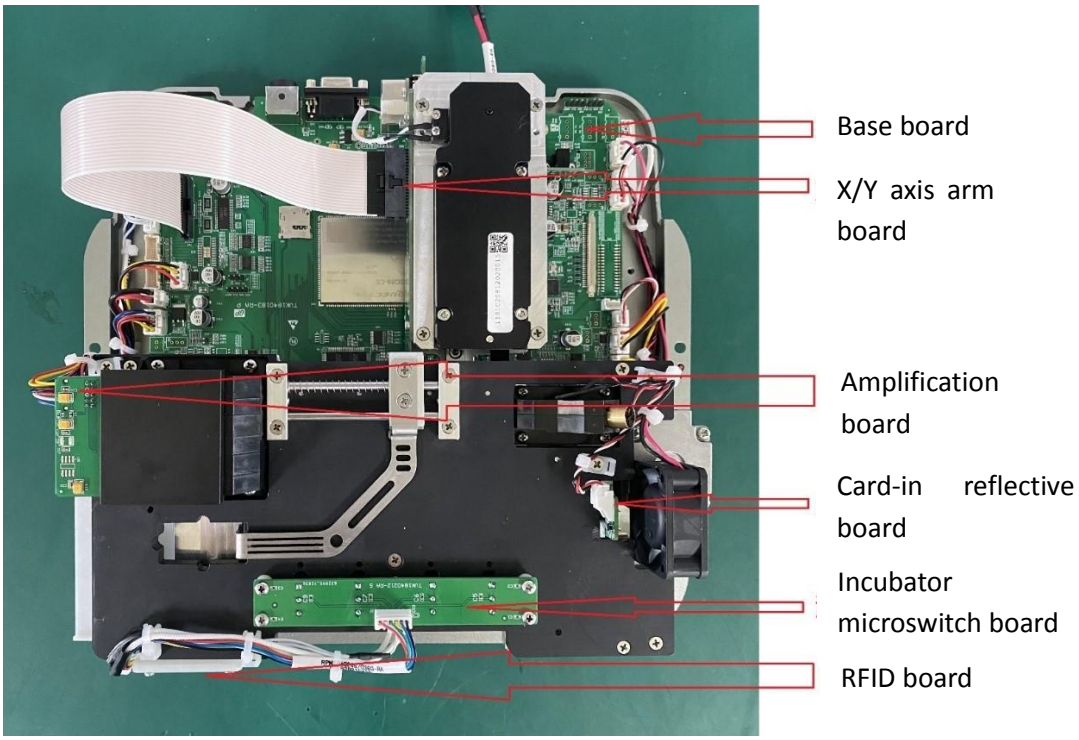


Fig. 5- 1 Internal view of the instrument

Table 5-1 PCB List

Circuit board	Code	Quantity
Base board	ROA1840455	1
Base board optocoupler board	ROA1840367	2
X/Y axis arm microswitch board	RPM1840195/0050	1
X/Y axis arm board	ROA1840235	1
X/Y axis arm optocoupler board	ROA1840367/2	2
Incubator microswitch board	ROA1840212	1
RFID board	ROA1840451	1
Card-in reflective board	ROA1840433	1

Fluorescence amplification board	ROA1840089	1
Screen back board	ROA1840193	1

5.1.1 Base Board

The base board is shown in Figure 5-2.

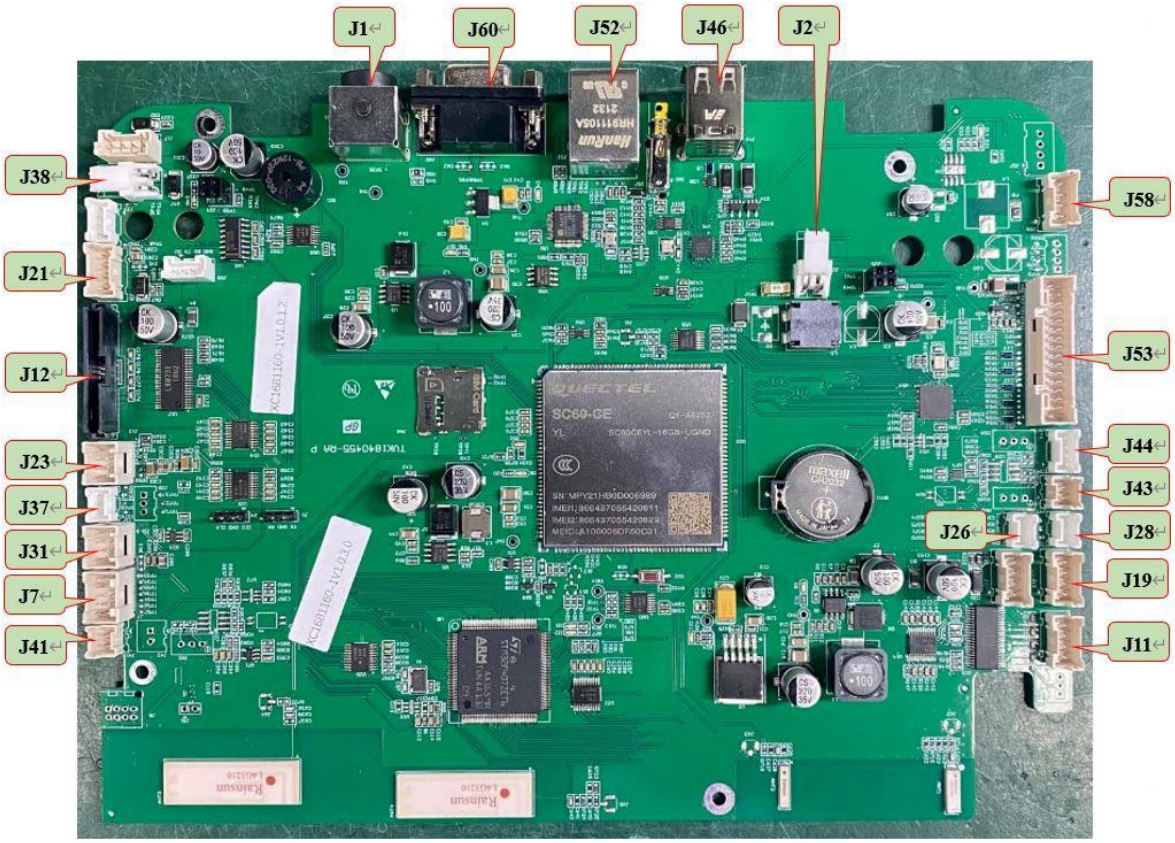


Fig. 5- 2 Base board layout

Table 5-2 Port description

Port No.	Wiring Harness	Connection (code)
J38	/	Heating band (RPM1840566/1)
J21	/	Left fan on base plate module (RPM1840569/0330)
J12	RPM1681149/0230	X/Y axis arm board (J1)
J23	RPM1840149/0410	Incubator switch board
J37	/	Temperature sensor (RPM1840179/0400)
J31	RPM1840149/0250	RFID board

J7	RPM1840151/0140	Fluorescence amplification board
J41	/	Main laser (RPM1840141/0120)
J1	/	Power port
J60	/	RS232 port
J52	/	Ethernet port
J46	/	USB port
J2	/	Rocker switch wire (RPM1840492/0020)
J58	RPM1840054/0220	Printer board
J53	RPM1840511/0230	Screen back board (J1)
J44	/	Sub optical path PD wire (RPM1840152/0220)
J43	/	Sub laser (RPM1840156/0210)
J26	RPM1840245/0450	GT1160 card-discarding device out of step detection microswitch board (ROA1840706)
J28	RPM1840352/0230	Card-in reflective board
J19	/	Right fan on base plate module (RPM1840569/0190)
J11	RPM1840493/0070	Card-pushing motor on base plate module

5.1.2 X/Y axis Arm Board

The X/Y axis arm board is shown in Fig. 5-3.

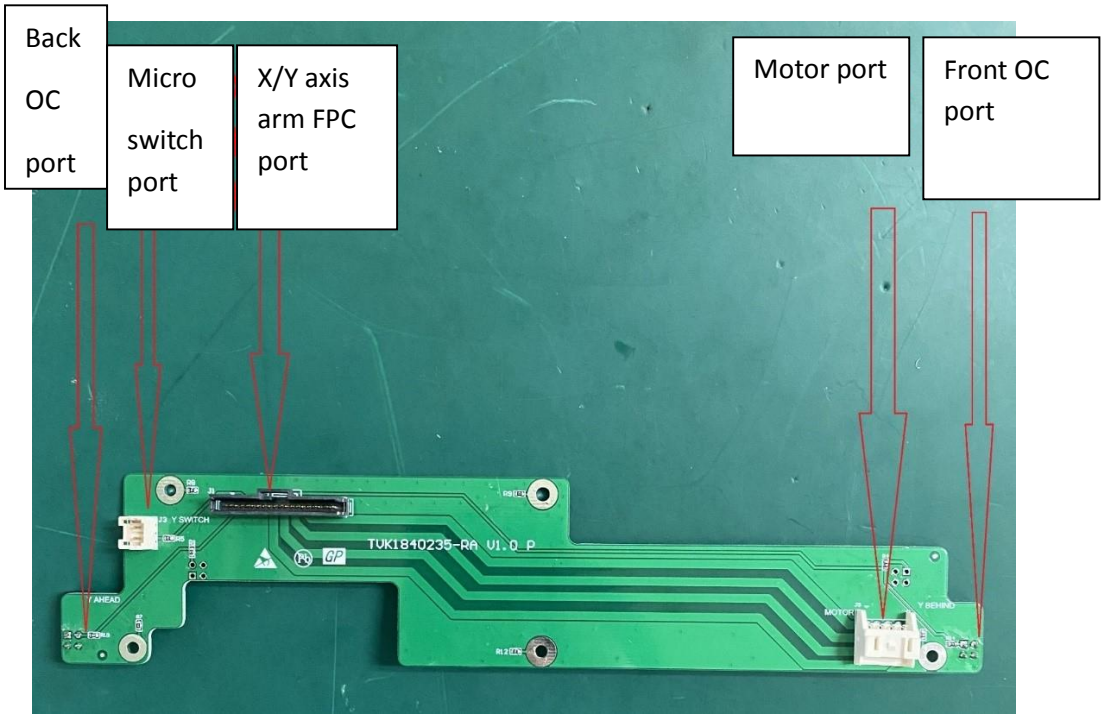


Fig. 5-3 X/Y axis arm layout

5.1.3 Fluorescence Amplification Board

The fluorescence amplification board is shown in Fig. 5-4.

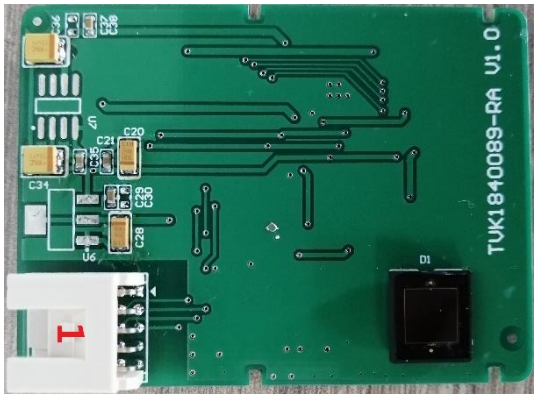


Fig. 5-4 Fluorescence amplification board layout

J1 is connected to J7 on base board. D1 is a photoelectric cell, which adopts the optical principles to detect the test cards.

5.1.4 Screen Back Board

The screen back board is shown in Fig. 5-5.

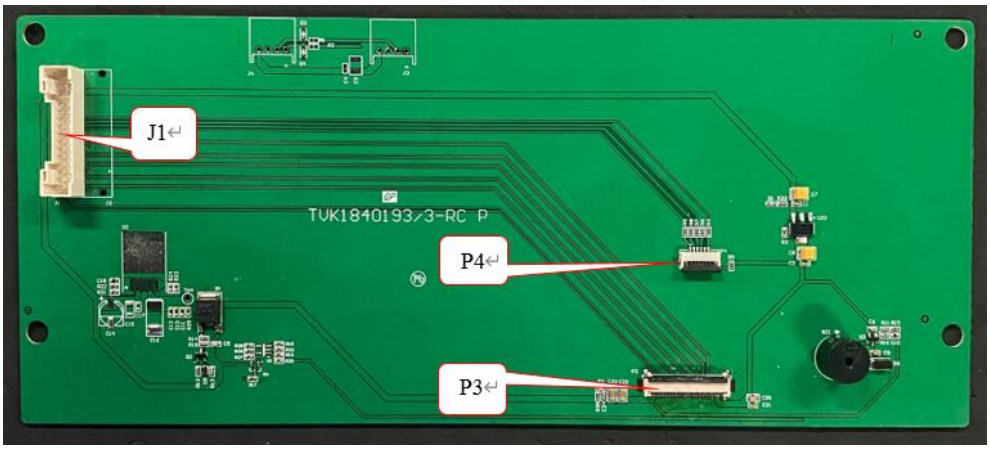


Fig. 5-5 Screen back board layout

Table 5-3

Port No.	Wiring Harness	Connection (code)
J1	RPM1840511/0230	Mainboard (J53)
P4	/	Display wire harness
P3	RPM9020024/0050	Display

5.1.5 Incubator Microswitch Board

The board is used to indicate if there is any test card in the incubator. The board is shown in Fig. 5-6.

Fig. 5-6 Incubator microswitch board layout

5.1.6 RFID Card Board

The RFID card board is shown in Fig. 5-7. The test item parameters are entered by the swiping of the card.

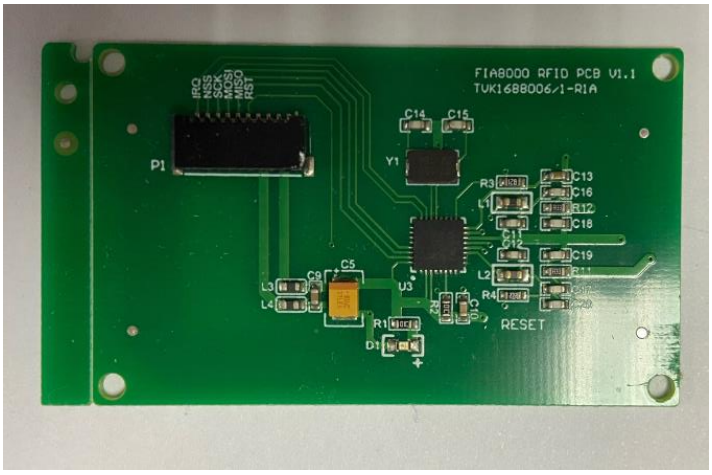


Fig. 5-7 RFID card board layout

5.1.7 Printer Board

The printer board is shown in Fig.5-8. The printer board is connected to the screen back board to print the test results.

Fig. 5-8 Printer board layout

5.1.8 Card-in Reflective Board

The card-in reflective optocoupler at the card entrance is shown in Fig. 5-9. It is used to determine whether a test card is inserted into the analyzer.

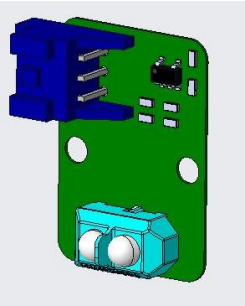


Fig. 5-9 Card-in reflective optocoupler layout

5.1.9 Optocoupler Board

The optocoupler board is shown in Fig. 5-10.

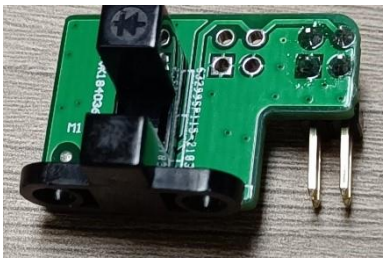
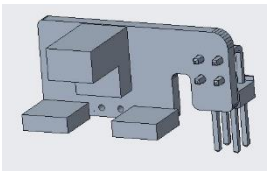
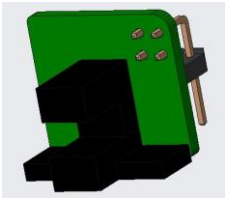
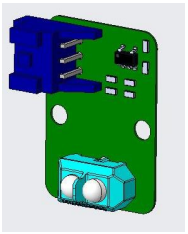


Fig. 5-10 Optocoupler board layout

Please refer to Table 5-4 for the location, model, three-dimensional shape and use count of each optocoupler board.

Table 5-4 List of Optocoupler Board Usage

Location	Code	Three-dimensional shape	Use count
X/Y axis arm front/back OC	ROA1840367/2		2
Base board left/right OC	ROA1840367		2

Card-in reflective optocoupler	ROA1840433		1

5.2 Schematic Diagram of Circuit Connection

The circuit connection diagram is shown in Fig.5-11.

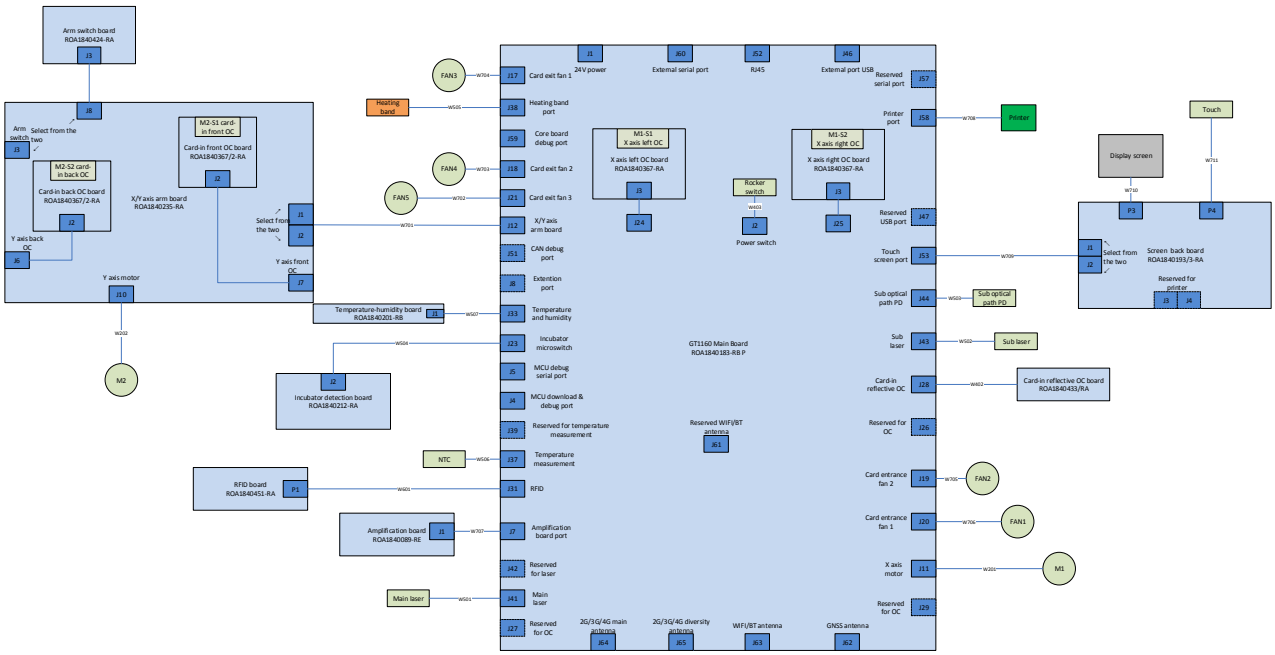


Fig. 5-11 Circuit connection

Chapter 6 Software

6.1 Operating Environment

6.1.1 Android System

This analyzer is based on the Android system for software and application development. The Android provides an open, diverse, versatile and secure operating environment, which facilitates the user interface development.

6.1.2 Software Installation

1. The installation steps are as follows:
2. After the successful burning of Android system, connect cables and power on the instrument, and an interface will appear as shown in Fig. 6-1. Insert the USB flash drive to display the root directory. The app file to be installed is named as XXX.apk. Click the file manager icon to install the app.

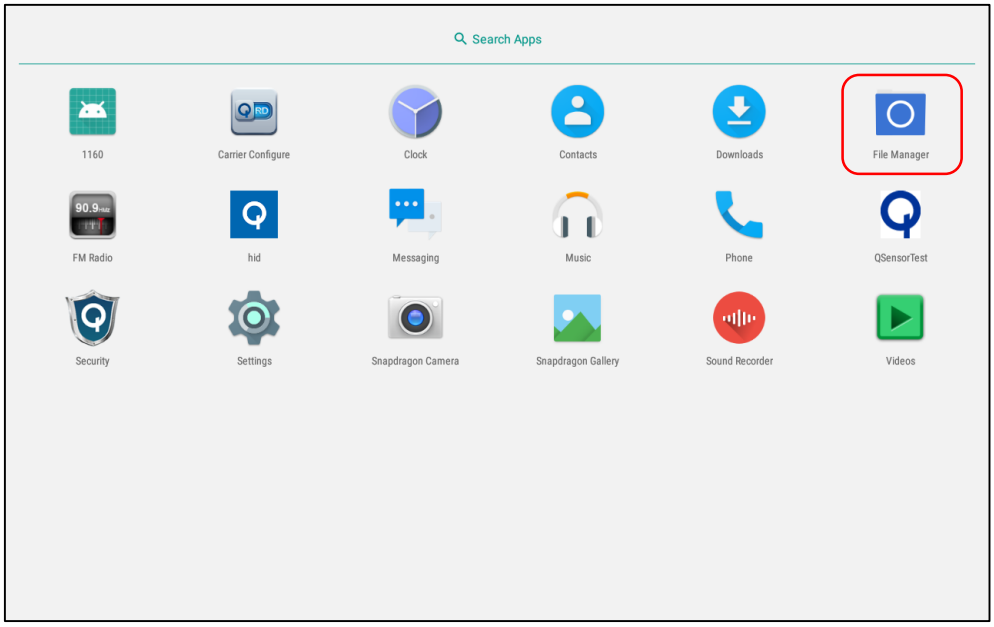


Fig. 6-1 File Manager

3. After entering the file manager, click  on the top left corner as shown in Figure 6-2, select and open the USB flash driver icon and open the USB drive, and choose the app file (the app file is issued by the after-sales support).

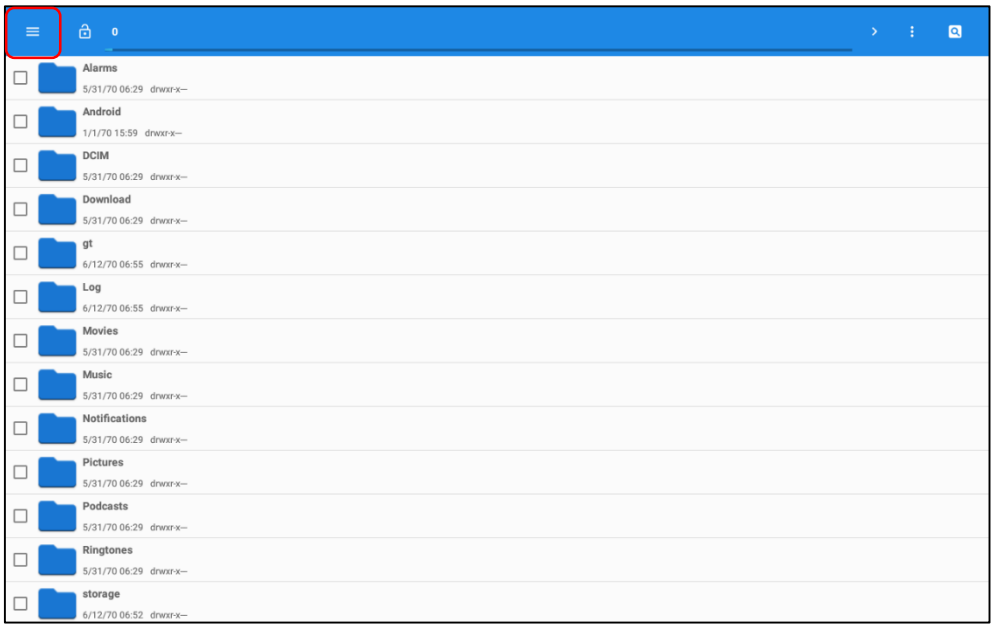


Fig. 6-2

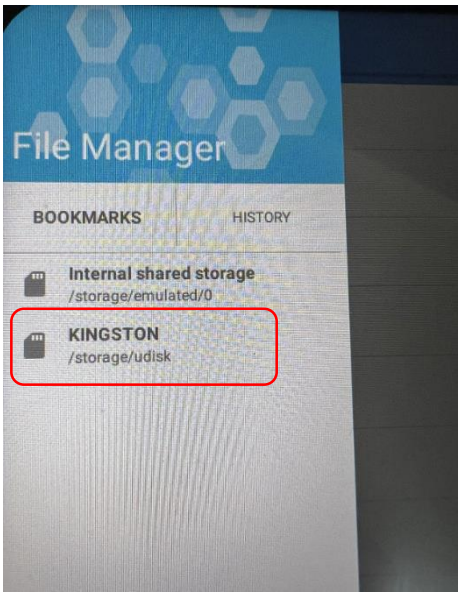


Fig. 6-3 Select the USB drive

4. Open the USB flash driver file folder and select the target apk file.

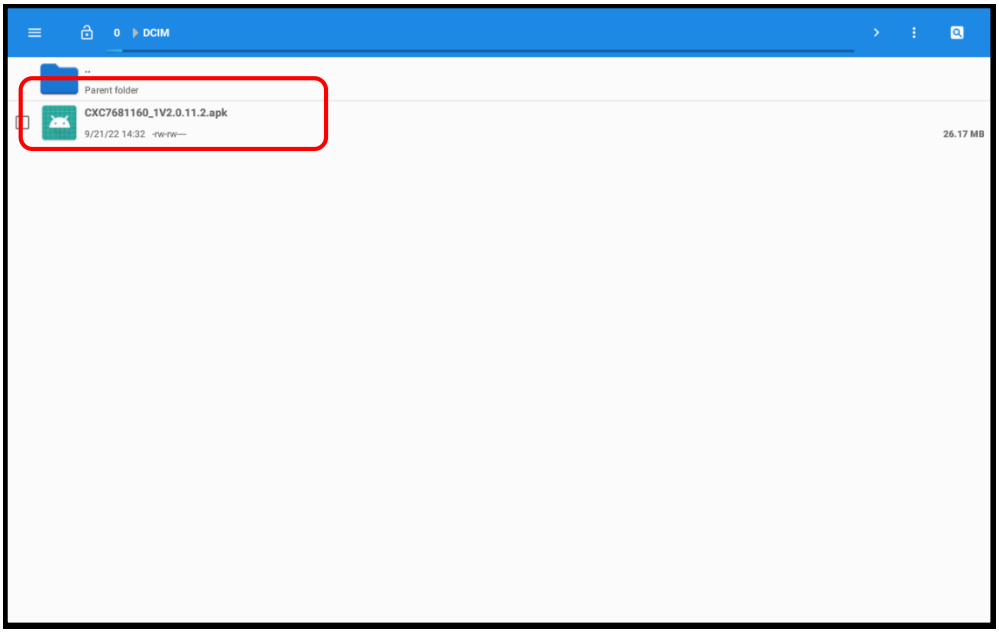


Fig. 6- 4 apk file

5. Click the file, and an installation prompt as shown in Fig 6-5 will pop up. Click the Install button, and wait for the installation to complete.

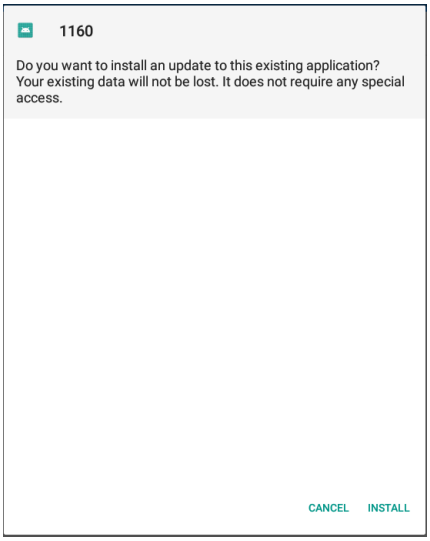


Fig. 6- 5 Installation

6.2 Network Communication Protocol

6.2.1 Communication Setting

Enter the Settings menu and click **Communication Setting** on the left, as shown in Fig. 6-6.

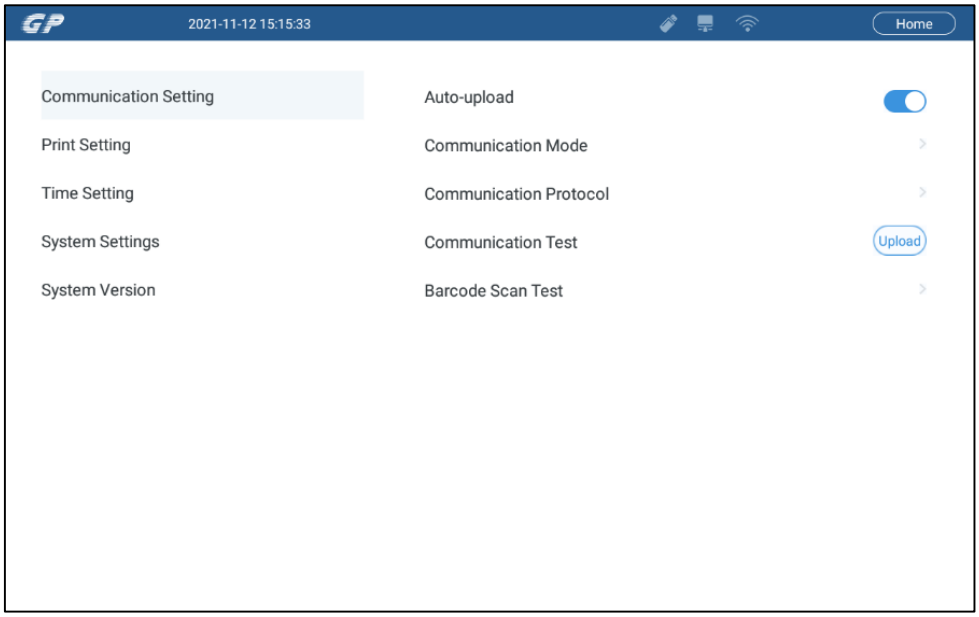


Fig. 6-6 Communication Setting

6.2.2 Communication Operation

Upload test results to the receiving system

After the instrument is successfully connected to the computer, click the Upload icon in the Result interface, and all the uploaded results will be displayed in the receiving software.

Chapter 7 System Maintenance

7.1 Maintenance Screens

The system debugging and maintenance functions are only open to the company's after-sales technicians to debug the instrument parameters. It isn't suggested that the users modify the parameters. Click Maintenance on the main interface. Then, an interface pops as shown in Fig. 7-1.

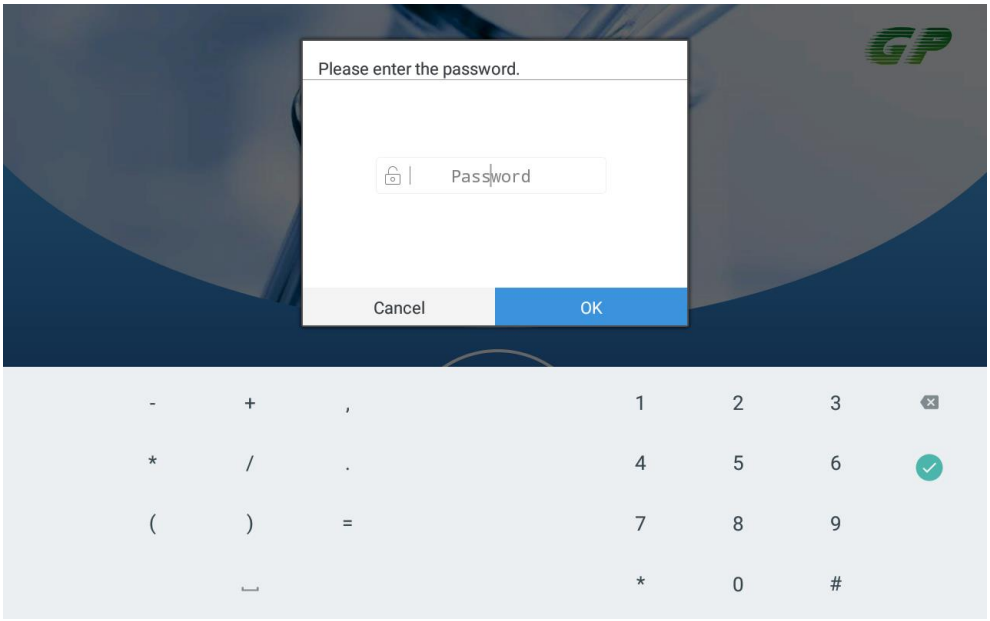


Fig. 7-1 Enter password

Enter the password **588588** to enter the Maintenance interface. The interface includes System Debugging, Optical Path Debugging, Instrument Debugging, QC Parameter, System Settings, Software Update, System Version, and Exit Debugging, as shown in Fig. 7-2.

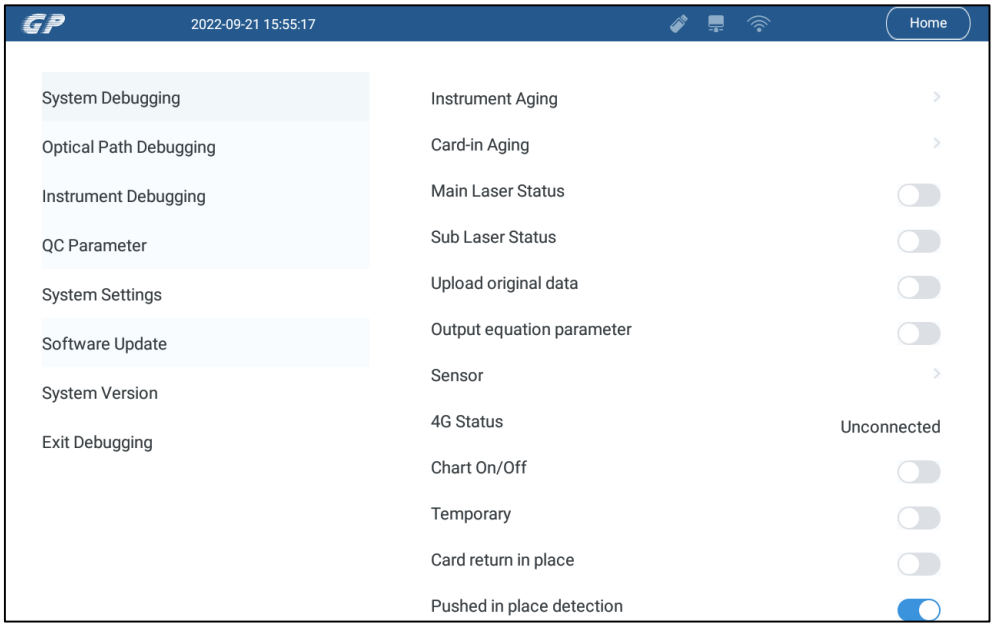


Fig. 7-2 Maintenance

7.2 Optical Path Adjust

7.2.1 Main Optical Path Step Adjustment

Follow the steps below to adjust main optical path step:

1. Click Maintenance - Optical Path Debugging, and select Laser 1 of Laser Select.
2. Click Instrument Debugging - Main Optical Path Step Adjust.
3. Insert the step-count card that has been tested by the standard instrument and click Get. If the default value of current sampling point position is not 7200, click Reset.

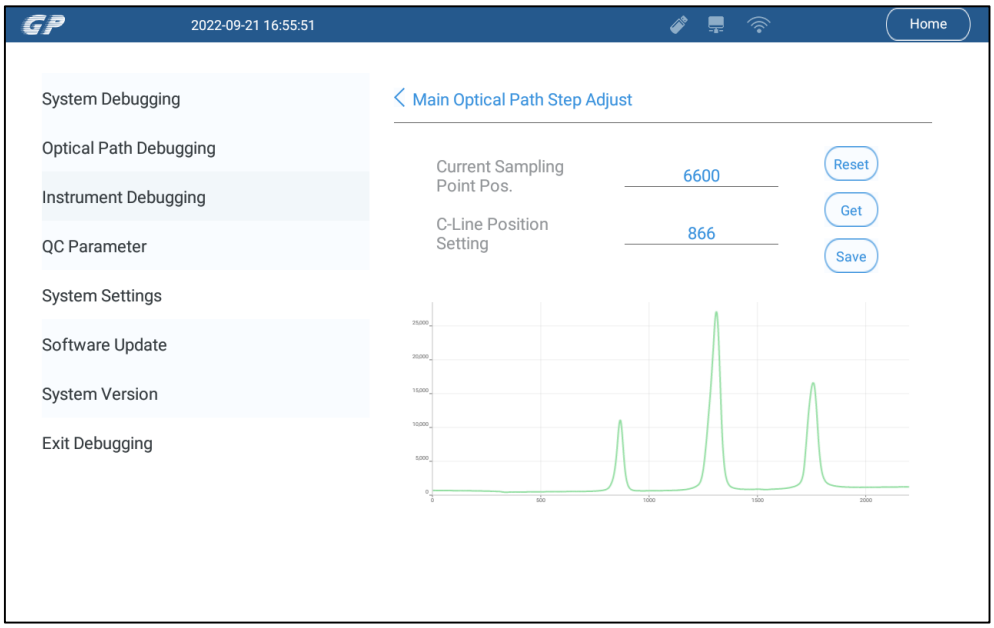


Fig. 7-3 Main optical path adjustment 1

4. If the acquired C-line position is not close to the value measured by the standard instrument, set it as the value tested by standard instrument and click Save. The interface prompts that the value is saved successfully. If the value entered is incorrect, click the Reset button to re-acquire and re-enter the value.

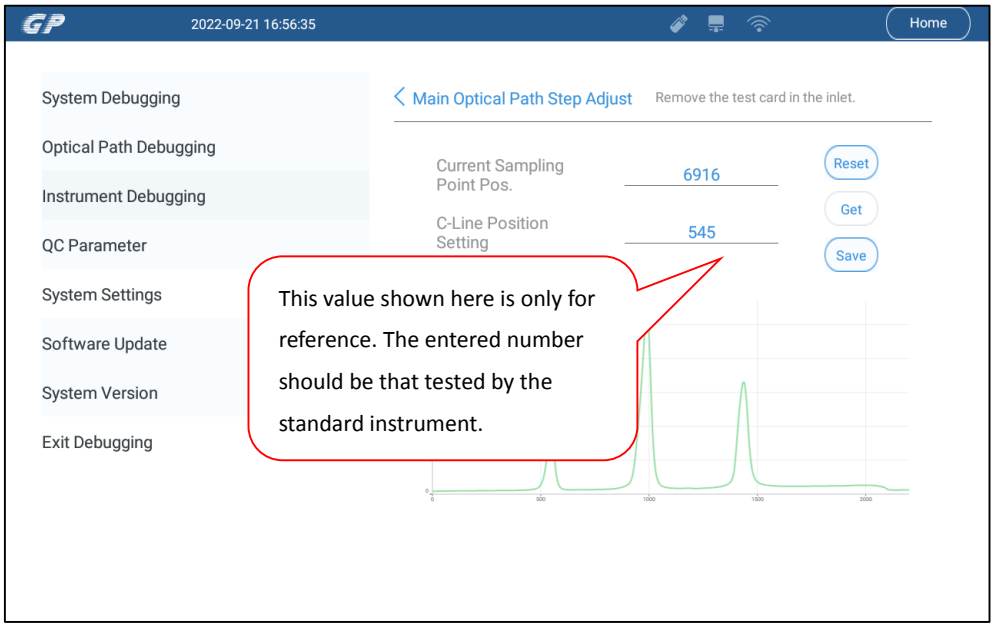


Fig. 7-4 Main optical path adjustment 2

5. Re-acquire the C-Line position (the test value of the instrument to be tested ≤ the test value of the standard instrument ± 10).

7.2.2 Measurement Coefficient Adjustment

Follow the steps below to adjust the measurement coefficient:

1. Click Maintenance - Optical Path Debugging, and select Laser 1 of Laser Select.
2. Click Instrument Debugging – Measurement Coefficient Adjust.
3. Insert the a small, medium and large standard cards one by one and click Get. Enter the values of each card tested by the standard instrument in Target Value (Input T Lines first, then comma and the background value).

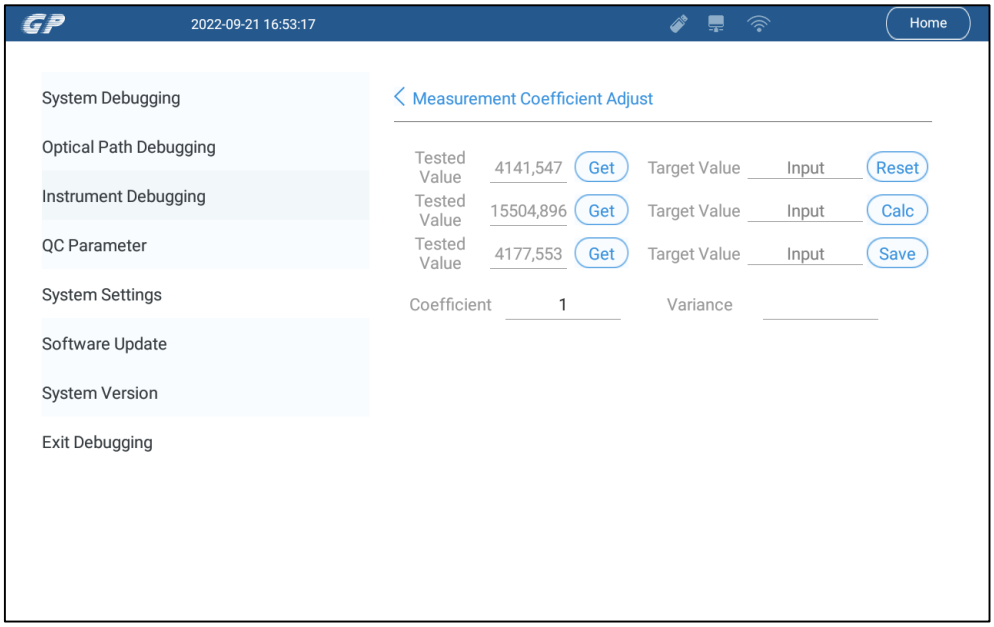


Fig. 7-5 Measurement coefficient adjust 1

4. Click Calc, and the measurement coefficient is required to satisfy: 0.35 ≤ the coefficient ≤ 0.70 and the variance < 0.01.

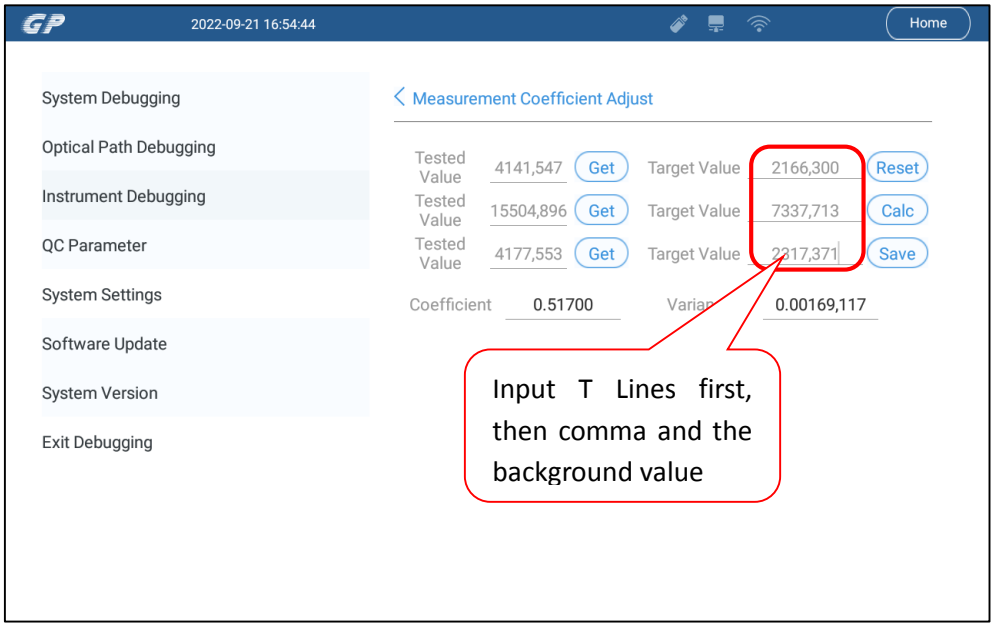


Fig. 7-6 Measurement coefficient adjust 2

7.2.3 Voltage Test

Perform voltage test according to the following steps:

1. Click Maintenance - Optical Path Debugging.
2. Select Laser 1 in the drop-down list of Laser Select.

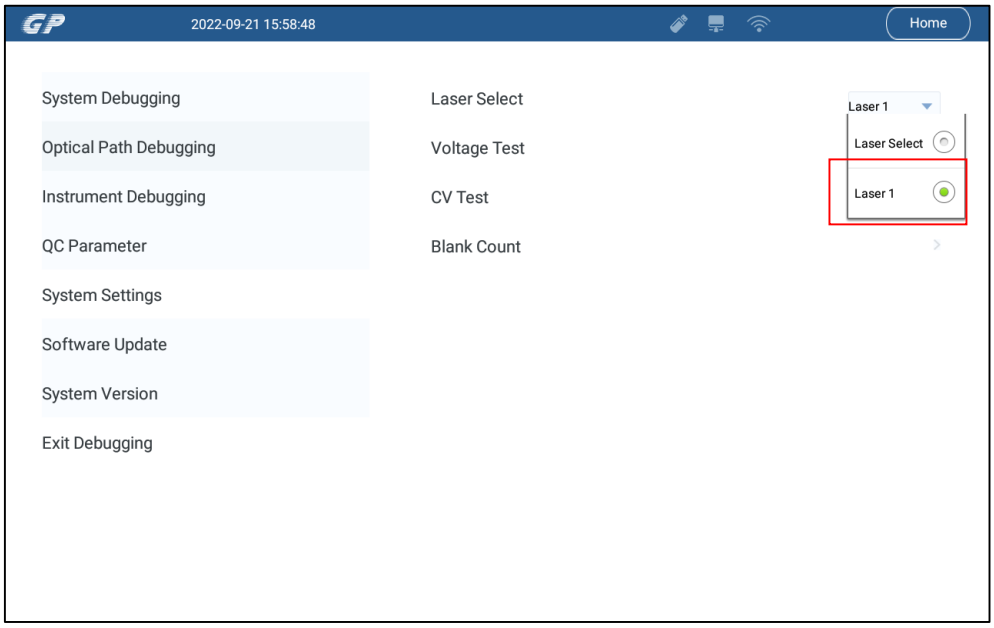


Fig. 7-7 Laser select

3. Click Voltage Test.

4. Insert a set of standard cards with different voltages into the instrument, click Test, and record the tested values displayed on the screen.
5. T Lines variance: the value tested ≤ value ± 4% measured by the standard instrument.
6. Background value variance: the value tested ≤ value ± 5% measured by the standard instrument.

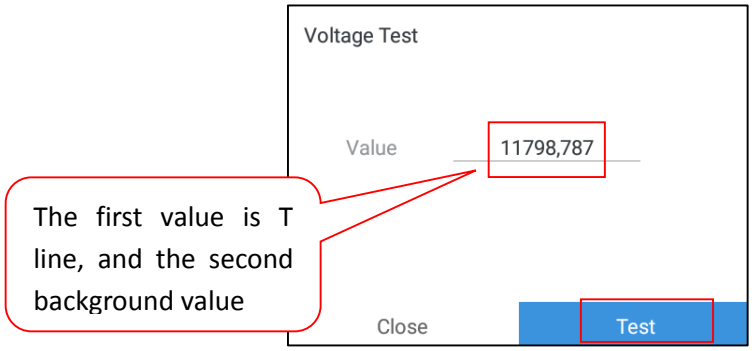


Fig. 7-8 Voltage Test

T Line Voltage Range	T Lines Variance	Background Values Variance
30±10mv	± 4%	± 5%
65±15mv	± 4%	± 5%
100±30mv	± 4%	± 5%
400±60mv	± 4%	± 5%
750±150mv	± 4%	± 5%
1400±300mv	± 4%	± 5%
3500±500mv	± 4%	± 5%
6000±1000mv	± 4%	± 5%
10000±2000mv	± 4%	± 5%
15000±3000mv	± 4%	± 5%

7.2.4 CV Test

Follow the steps below to perform repetitive test:

1. Click Maintenance - Optical Path Debugging, and select Laser 1 of Laser Select.
2. Click CV Test.

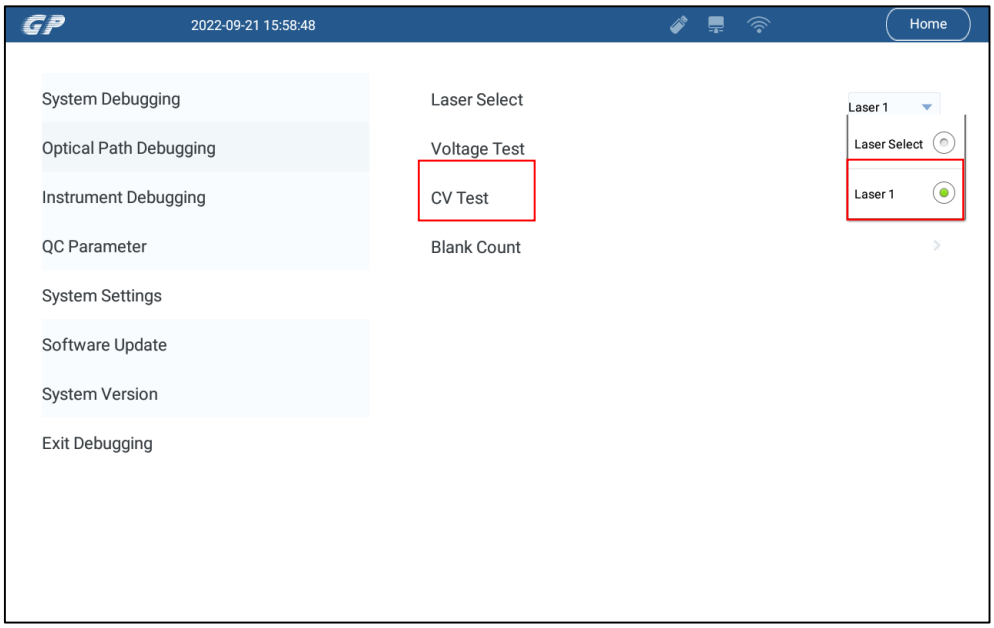


Fig. 7-9 Optical Path Debugging

3. Insert a card with voltage between 25-35mv, click Test, and the CV value is required to be ≤2%.
4. Insert a card with voltage between 70-90mv, click Test, and the CV value is required to be ≤2%.
5. Insert a card with voltage between 600-900mv, click Test, and the CV value is required to be ≤1%.
6. Insert a card with voltage between 13000-15000mv, click Test, and the CV value is required to be ≤1%.

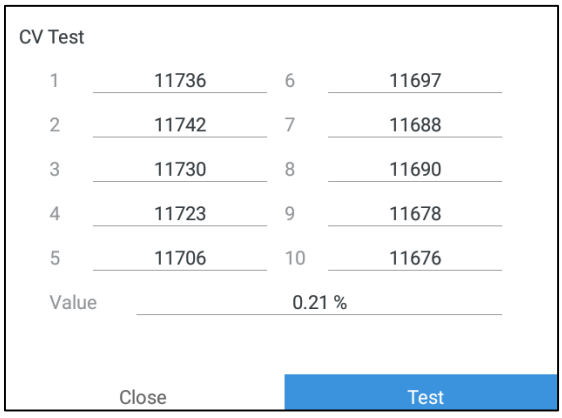


Fig. 7-10 CV Test

7.2.5 Sub Optical Path Sampling Point Adjust

Follow the steps below to adjust the sub optical path sampling point:

1. Click Maintenance - Instrument Debugging.
2. Click Sub Optical Path Sampling Point Adjust.

3. Insert the step-count card of the sub optical path, and click Get. If the current barcode sampling point position is not the default value of 10500, click Reset to restore the default value.

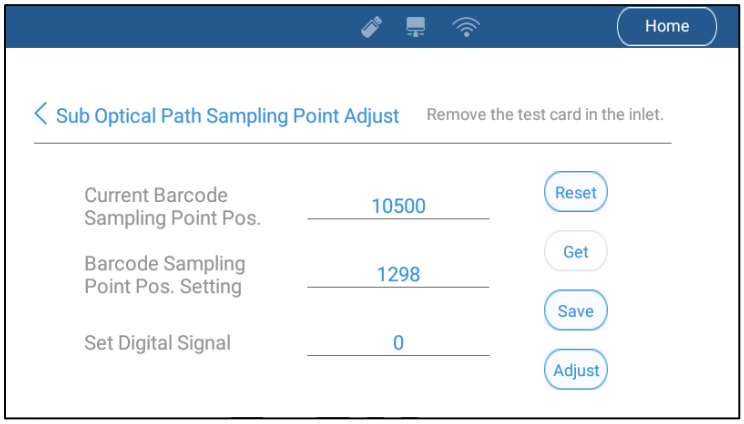


Fig. 7-11 Sub optical path sampling point adjust 1

4. The test value of the barcode sampling point position should be within 800±10. If not, enter 800, click Save and Get until the standard is met.

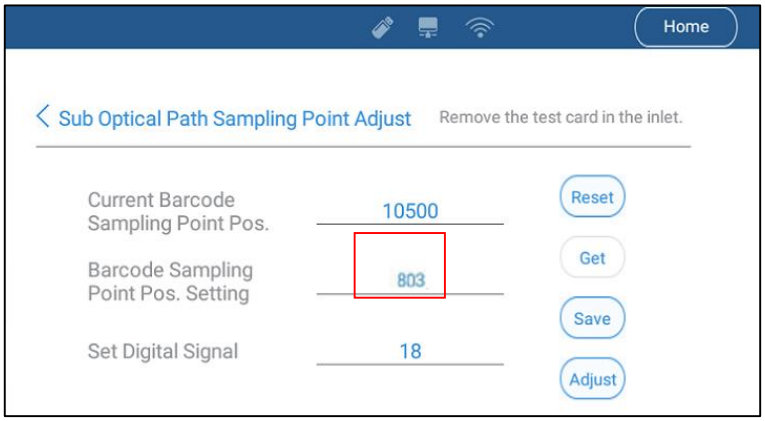


Fig. 7-12 Sub optical path sampling point adjust 2

5. After setting the value of the barcode sampling point position, check whether reference value P meets 1800 < P < 2300, the value of L1-L7 is in the specified range (1. 50 - 178; 2. 178 - 293; 3. > 293) and the difference between L4-L7 is within ± 20. If the requirements are not satisfied, adjust Set Digital Signal. Please note that the digital signal range should be between 1-64.

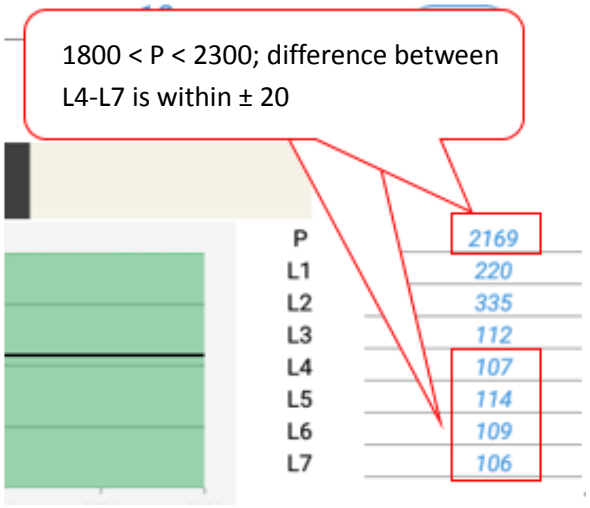


Fig. 7-13

7.3 Position Debugging

7.3.1 Card-in Position Adjustment

Follow the steps below to adjust the card-in position:

1. Click Maintenance -Instrument Debugging.
2. Click Instrument Debugging - Card-in pos. adjust, and the Card-in pos. adjust dialog box pops up.

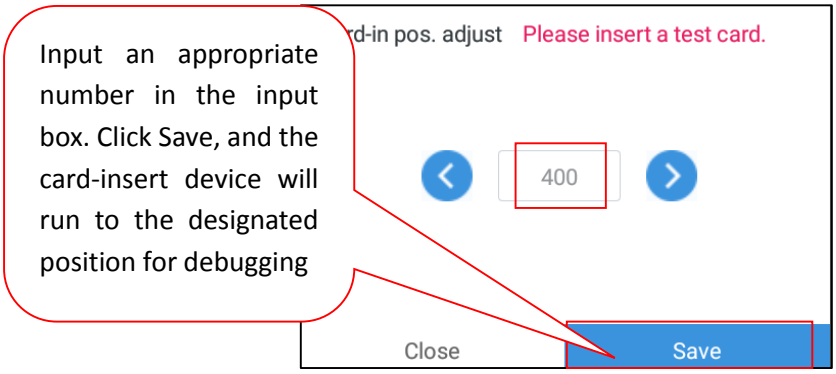


Fig. 7-14 Card-in Position Adjustment

3. Enter the corresponding steps and click Save. You can increase steps to adjust the hook of the card-grabbing device till the hook is right at the inner edge of card entrance.
4. Insert a test card. If the test card can be inserted successfully and smoothly without strange noise, take out the card and click Close.

Fig. 7-15 Card-in position adjust

7.3.2 Card-discarding Position Adjustment

Follow the steps below to adjust the Y axis card position:

1. Click Maintenance -Instrument Debugging.
2. Click Y axis card pos. adjust to prompt the dialogue box.

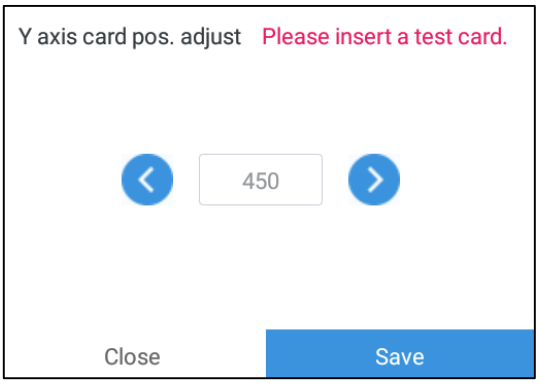


Fig. 7-16 Y axis card pos. adjust

3. Insert a test card at the card entrance, and click Save. The X/Y axis arm starts running. When the test card starts moving, observe if the card end overlaps with the internal line on the card-pushing block of the card-discarding device as shown in the figure below. If not, adjust the Y axis card position until it overlaps.

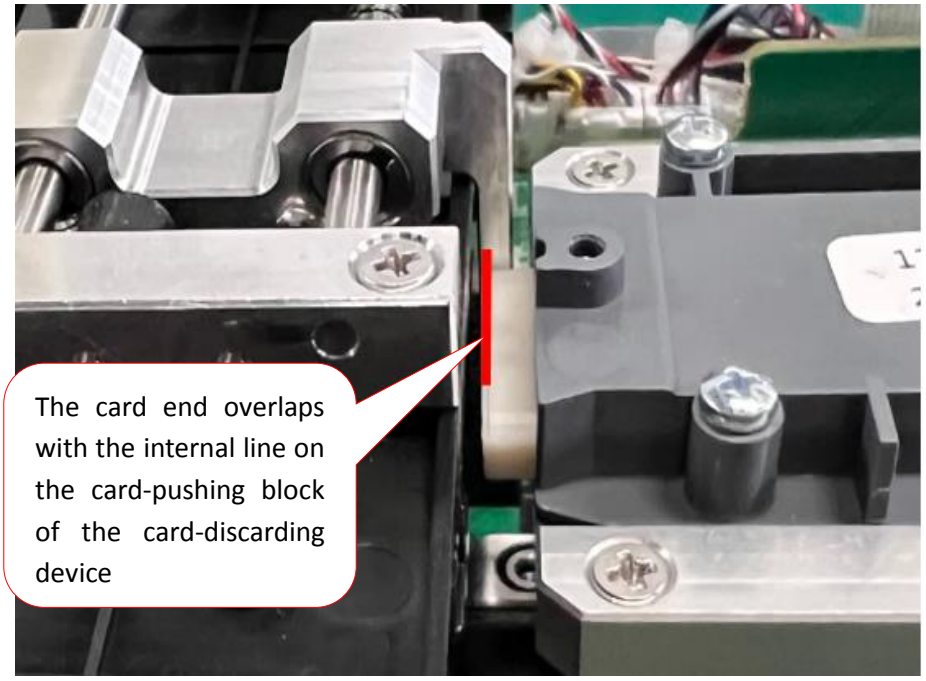


Fig. 7-17

4. After the position is well adjusted. Reduce the steps in the input box by 50 and click Save (e.g. if the steps are 700 when the position is adjusted, the final steps will be 650).

Follow the steps below to adjust the X axis card position:

1. Click Maintenance - Instrument Debugging.
2. Click X axis card pos. adjust to prompt the dialogue box.
3. Insert a test card at the card entrance, enter an appropriate number and click Save. The X/Y axis arm starts running. When it stops, observe if the microswitch is triggered and the switch signal light is lit up. If not, click OK to reset the position.

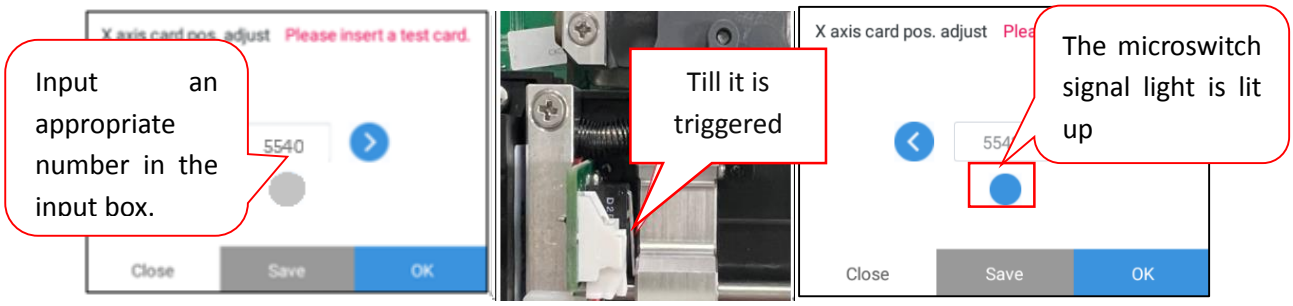


Fig. 7-18

4. Re-insert the test card. Keep increasing the step and then clicking Save until the microswitch light is lit up. Click OK. Click Close after the X/Y axis arm resets.
5. If there is strange noise, decrease the steps to stop it and ensure the microswitch is triggered.

7.3.3 Card-out Position Adjustment

Follow the steps below to adjust the X axis card-out position:

1. Click Maintenance -Instrument Debugging.
2. Click X axis card-out pos. adjust to prompt the dialogue box.
3. Enter a number and Click Save, and then the X/Y axis arm stars running. When it stops, check if card-pushing device groove is aligned with the incubator left groove. If it is not, adjust the X axis card out position until the two grooves are aligned. Click Save.

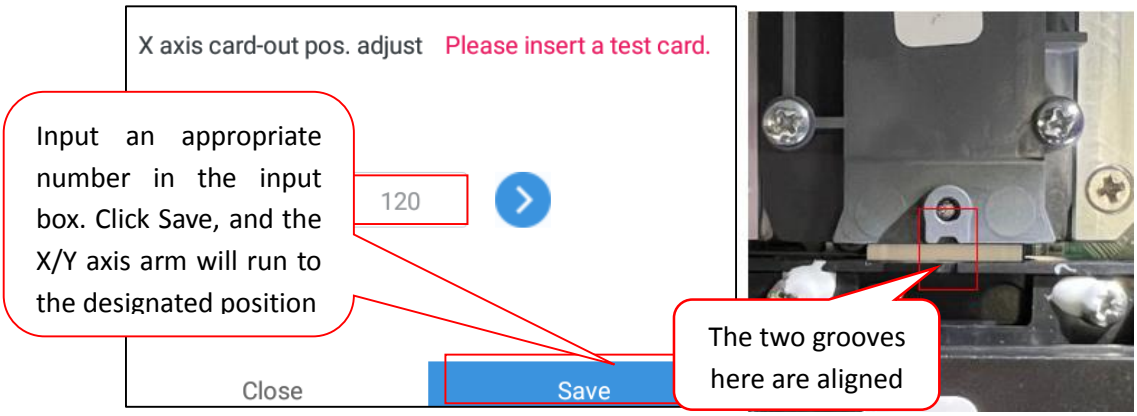


Fig. 7-19

Follow the steps follow to adjust the Y axis card out position:

1. Click Maintenance -Instrument Debugging.
2. Click Y axis card-out pos. adjust to prompt the dialogue box.
3. Enter a number and click Save. The X/Y axis arm starts running. When it stops, observe if the card-out optocoupler signal light is lit up. If not, click OK to reset the position.
4. Re-insert the test card. Keep increasing the step and then clicking Save until the light is lit up. Click OK. Click Close after the X/Y axis arm resets.
5. If there is strange noise, decrease the steps to stop it and ensure the light is on.

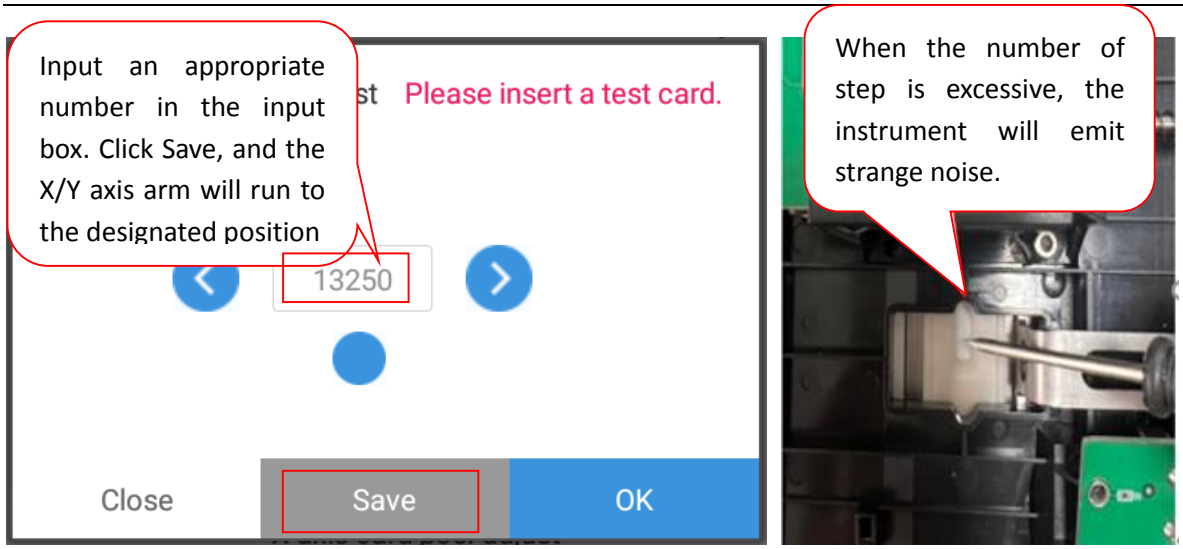


Fig. 7-20

7.4 Temperature Control Coefficient Adjust

Take the following steps to adjust incubation temperature control coefficient:

1. Click Maintenance -Instrument Debugging.
2. Click Temperature control coefficient adjust.
3. Insert to the end the thermometer into the second channel from left to right.
4. Enter thermometer temperature in the upper Temp input box. Click Calibrate. After two to three minutes, click Get Temp. Check if the tested and thermometer temperature is the same. Or, calibrate it repeatedly until the temperature tested ≤ thermometer temperature ±0.3℃.

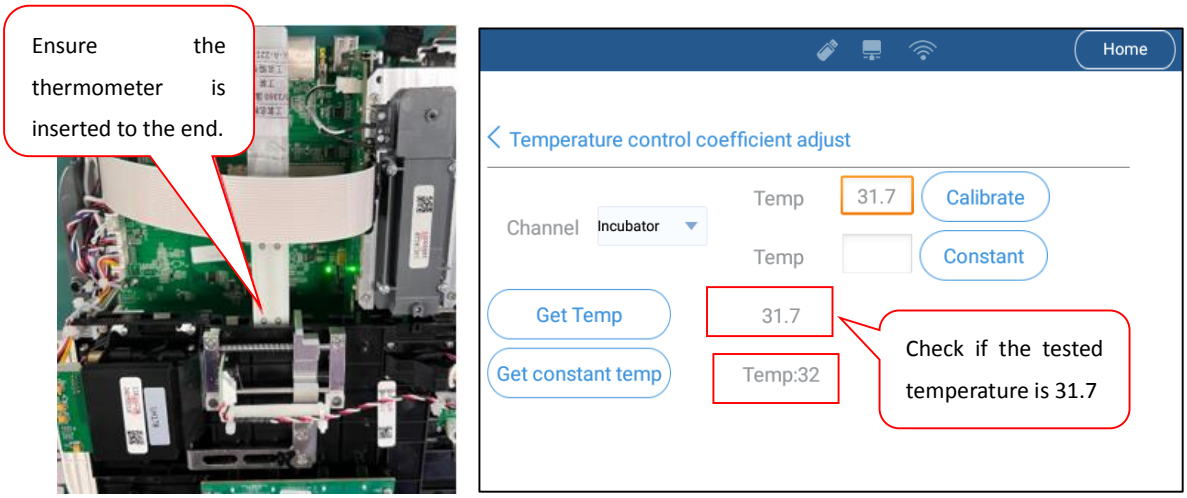


Fig. 7-21

Chapter 8 Instrument Maintenance

8.1 Regular Maintenance

Regular instrument maintenance is necessary to ensure the normal operation of the system. In order to keep the optimal performance of the system and ensure a good and safe operation, the maintenance personnel need to assist users to formulate a regular maintenance plan for the instrument and carry out the plan strictly. The maintenance interval is assumed to be approximately 100 sample tests per day. Based on the number of samples analyzed every day and environment conditions, the interval of the maintenance can be adjusted accordingly.

8.2 Daily Maintenance

1) Materials needed: dust-free cloth, 75% ethanol

2) Operations

Clean the instrument

- Spray the 75% ethanol on the dust-free cloth, and then use the cloth to wipe the surface of the instrument and the display screen;
- Empty the wasted card container.

Check power cables

- Check if the power cable or switch is damaged or if there is electric leakage;
- Check if there is obstacle at the card entrance.

8.3 Weekly Maintenance

Every week, check and maintain the instrument in a comprehensive way, especially for the ones not in use for over two days.

1) Materials needed: dust-free cloth, 75% ethanol

2) Operations

Clean the instrument

- Wipe the card entrance;
- Wipe the instrument with cloth;
- Empty the wasted card container.

Check power cables

- Check if the power cable or switch is damaged or if there is electric leakage;

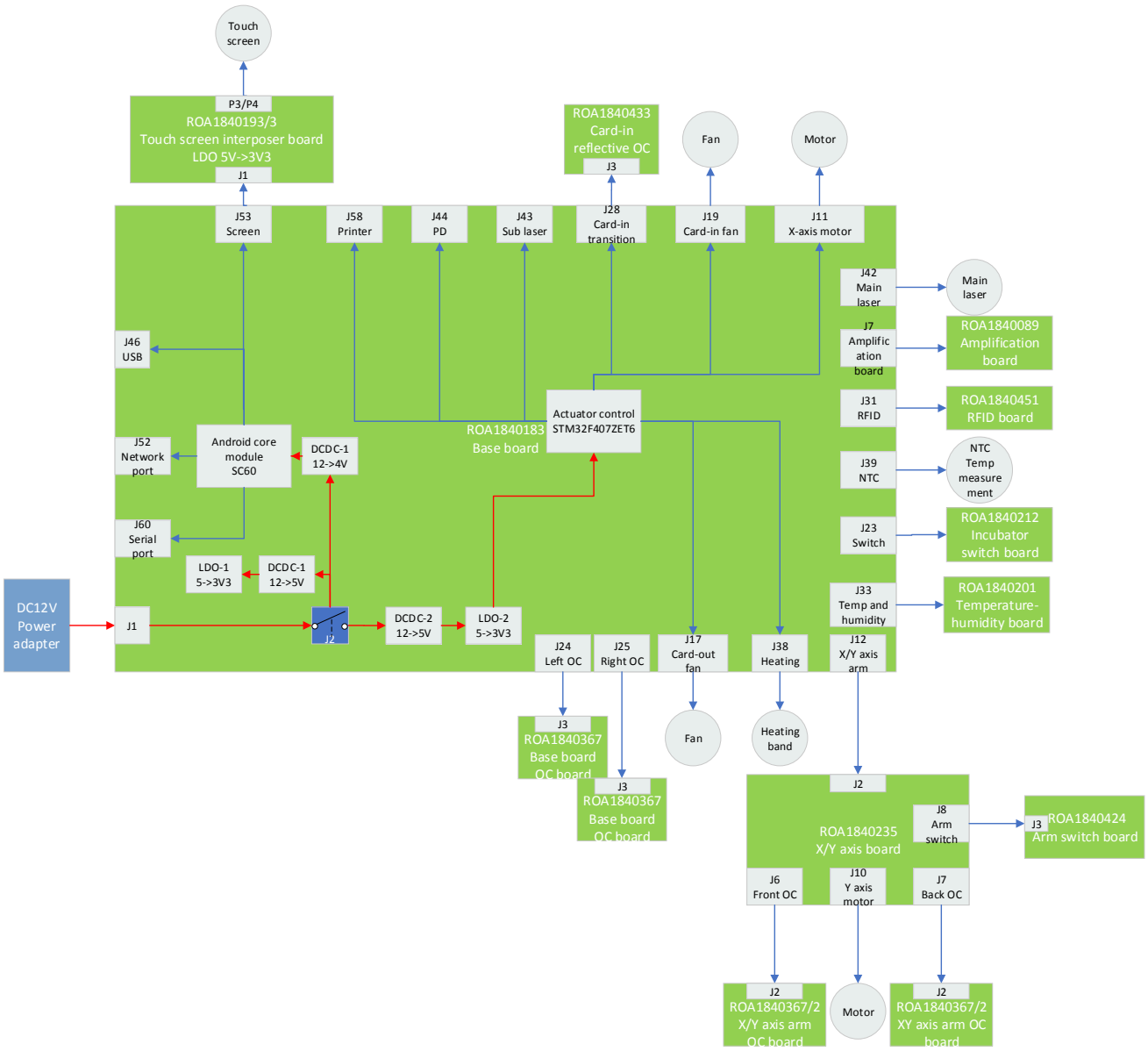
- Check if there is obstacle at the card entrance.

Appendix

Abbreviations

Abbreviation	Definition
HIS	Hospital information system
HL7	Health level seven
IP	Internet protocol
IVD	In vitro diagnostic
LIS	Laboratory information system
LAN	Local area network
POCT	Point of care testing
SD	Standard deviation
UPS	Uninterruptible power supply
WLAN	Wireless LAN
PD	Photosensitive diode

Circuit Schematic Diagram 2



Amendment Record

Version	New/Revised Content	Writer (Reviser)/Date
01	Finishing writing this service manual	Xu Xuemin, Tang Haitang 17 Oct. 2022
02		