

Honor-1616/1816

Genetic Analyzer User Guide

Nanjing Superyears Gene Technology Co., Ltd.

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Please read this User Guide carefully before installation and using the product.

Honor-1616/1816 Genetic Analyzer applies capillary electrophoresis technology to perform tests over the products of gene after PCR amplification which are dyed with different fluorescent colors accordingly. Since the size of each gene molecule in the product may vary, the electrophoretic mobility of molecules in high-voltage electric field is different. When the molecules are driven to the capillary detection window in accordance with their molecular sizes, these fluorescence-dyed molecules will be stimulated by the laser ejected from the window. Correspondingly, the fluorescent molecules will be detected one by one by the CCD camera detector in the detection window, and the stimulated fluorescence is separated by grating to distinguish the fluorescence of different colors representing different base information, and is synchronously imaged on a CCD camera. The analysis software will automatically transform different fluorescence into DNA information, and the analysis results can be output in various forms such as gel electrophoresis pattern and fluorescence peak map.

Please read this manual carefully before using the Honor-1616/1816 Genetic Analyzer. For questions about equipment maintenance services, please contact our Equipment Maintenance Department.

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Chapter I Safe Operating Requirements

1.1 Safety Convention

Honor-1616/1816 Genetic Analyzer adopts a variety of reliable protective measures to avoid accidental injuries and guarantees the safety of operators and maintenance staff under any circumstances. However, the following safety procedures must be followed throughout the installation, use and maintenance of the instrument.

(1) Nanjing Superyears Co., Ltd. assumes no liability for the damage of the instrument caused by the violation of the safe operating procedures mentioned in this guide.

(2) Instead of a replacement to the safe operating requirements of the laboratory users, the safe operating procedure is only a supplement to it. Only properly trained personnel are allowed to install and use the genetic analyzer.

(3) Only maintenance staffs are allowed to remove the cover plate or protective parts of the instrument during maintenance.

(4) Honor-1616/1816 Genetic Analyzer must work under specified operating voltage, and the voltage must be checked before using the instrument.

(5) Honor-1616/1816 Genetic Analyzers must be well grounded. Equipment sockets used at the installation site must be equipped with reliable grounding terminals.

(6) AC voltage regulators are recommended in areas where the city voltage fluctuation exceeds the specified requirements.

(7) Honor-1616/1816 Genetic Analyzer generates high-voltage output and high-intensity laser output during working. Use of the instrument is prohibited before reading and understanding this manual completely.

(8) Any improper modification may damage the genetic analyzer. No improper modification is allowed.






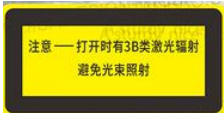


(9) Do not change any safety-related parts.

(10) Prevent any liquid from entering the power supply and laser parts of the Honor 1616/1816 Genetic Analyzer. If happens, turn off the device immediately.

1.2 Symbols and Safety Labels

Honor-1616/1816 Genetic Analyzer and associated documents use the following symbols and texts for security tips and warnings. The symbols may appear alone or with texts.

The meanings of symbols are as below:

Symbol or Text	Description
	Caution! Further operations should be done with care after checking the user guide.
	Caution! High voltage!
	Caution! Overheating and high temperature!
	Caution! Laser radiation!
	Caution! Class 1 radiation!
	Caution! Class 3B radiation! Avoid exposure to beam.
	Caution! Moving parts may hurt your hands.
	Caution! Biohazard.
Caution!	Indicate necessary operations such as correct instrument operation steps, accurate reagent use, etc. Failure to operate as required may


	result in improper operation of the instrument or incorrect analysis results.
Warning!	Indicate potential hazards, such as moving parts or heating parts. Failure to operate as required may result in instrument failure or user injuries.
Danger!	Indicate extreme dangers, such as high pressure leakage or laser radiation. Failure to operate as required may result in severe injuries or even death.


1.3 General Instrument Safety

1. Install and use the instrument strictly in accordance with the guide. Using the instrument in ways not specified by the institute may result in instrument failure or user injuries.
2. Contact the technical service engineer when installing or moving the instrument. After the instrument is installed, do not attempt to lift or move the instrument without the assistance of other people, lifters and normal lifting techniques. Improper lifting of the instrument may cause painful injury or permanent back injury. It may require two or more people to move or lift the instrument.
3. The operator must be trained by Nanjing Superyears Co., Ltd. before operation. The instrument operator ensures that he/she has received a description of the laboratory general and special safety indicators for the instrument, and reads and understands all applicable Material Safety Technical Data Sheets (MSDS).

1.4 Electrical Safety

Electrical appliances may use the following electrical symbols, which means:

Electrical Symbol	Description
	Indicate a terminal that accepts or supplies an alternating current or voltage

	<p>Indicate a terminal that may be connected to the signal ground (a reference position) of another instrument. This is not a protective grounding terminal.</p>
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The following contents include electrical safe operation, which must be read carefully and strictly followed by anyone operating this instrument:

1. The instrument should be installed and used under the conditions specified in the User Guide; otherwise the electrical safety protection parts may be damaged.
2. No operation is allowed when any of the instrument panel is open.
3. The capacitor inside the instrument may still have a residual high voltage when the power supply is disconnected. Do not open any part of the instrument except for those specified in the User Guide.
4. The instrument shall use proper cables, groundings and full-capacity sockets. The power supply should be connected correctly under the guidance of the technical service engineer.
5. Capillary array and lower polymer block are installed with high voltage terminals. In case of high voltage electric shock, touching is strictly prohibited under any circumstances.

1.5 Moving Parts Safety

Auto-sampler and polymer delivery module contain moving parts, which may cause extrusion or cutting during operation. Attention should be paid to the moving parts during operation, and hands should be kept away from running moving parts. Disconnect the power supply when maintaining the moving parts of the instrument.

1.6 Heating Parts Safety

Insulated oven is a heating part, which may cause scald. User Guide shall be strictly followed in operation, and the inner surface of the insulated oven shall not be touched casually.

1.7 Chemical Safety

1.7.1 Warning on Chemicals

Warning: chemical hazards - When handling any chemical, ask the manufacturer for the Material Safety Technical Data Sheet (MSDS) and comply with the relevant preventive measures.

Warning: chemical hazards - All chemicals in the instrument, including liquids in the pipes, are potentially hazardous. Check the chemicals used to be adopted in the instrument before replacing reagents or instrument parts. Proper protective clothing, protective glasses and gloves should be worn when operating the instrument.

1.7.2 About MSDS

The chemicals manufacturer shall provide the current Material Safety Technical Data Sheet (MSDS) of hazardous chemicals and shipment conditions to new customers. The manufacturer shall provide the updated MSDS when the first batch of hazardous chemicals is shipped to the customer.

MSDS includes the chemical safety information you need, i.e. information on safe storage, handling, transportation and disposal of chemicals. Every time you receive a newer MSDS of hazardous chemicals, make sure to replace the older MSDS in archive.

1.7.3 Chemicals Safety Guide

To minimize the risks of chemicals, please:

1. Read and understand the Material Safety Technical Data Sheets (MSDS) provided by the chemicals manufacturer before storing, handling or disposing the chemicals or hazardous materials.

2. Minimize exposure to chemicals. When handling chemicals, wear appropriate personal protective equipment, such as safety glasses, gloves or protective clothing. Please strictly follow the MSDS.

3. Minimize the inhalation of chemicals and ensure that chemicals are used in well-ventilated conditions such as in a fume cabinet.

4. Check the chemicals regularly for leakage or spillage, if any, please follow the manufacturer's recommended cleaning procedure in MSDS.

5. Comply with all national or regional laws and regulations related to storage, handling and disposal of chemicals.

1.7.4 Safety of Chemical Waste

1. Hazardous waste: refer to MSDS and relevant local regulations.

2. Chemical waste hazard: the waste generated by genetic Analyzer is potentially dangerous and may cause harm, disease or death.

3. In order to minimize the risk of chemical waste during your use of the instrument, please note the following:

(1) Read carefully and comprehend thoroughly of information about chemicals in waste containers in MSDS offered by manufacturer before storing, handling or disposing chemical waste.

(2) Prepare primary and secondary waste containers (primary containers store waste that is generated directly, secondary containers store waste that spills or leaks from primary containers). Make sure proper waste should be in their proper container and meet the local requirements on storage containers.

(3) Minimize exposure to chemicals. Wear appropriate personal protective equipment (e.g. protective glasses, gloves or protective clothing) when handling chemicals. In addition, keep the security guidelines provided by MSDS in mind.

(4) Dispose chemical waste in the fume cabinet.

(5) The emptied waste container should be sealed with appropriate lid.

(6) Disposal of contents in waste plates and bottles shall be conducted in accordance with laboratory rules and local environmental and healthy regulations.

1.7.5 Disposal of Chemical Waste

If potentially hazardous waste is generated during operation, you must:

(1) Describe the properties of waste generated by specific application processes, the reagents and substrates used in your laboratory.

(2) Ensure the health and safety of all personnel in your laboratory.

(3) Ensure the storage, handling, transportation and disposal of waste generated by the instrument are complied with local and national regulations.

Note: radioactive or biohazard materials must comply with specific operating

and handling restrictions.

1.8 Laser Safety

1.8.1 Classification of Lasers

The genetic analyzer uses semiconductor laser. Under normal working conditions, the laser is inside the equipment without exposure. According to the requirements of GB7247.1-2012, it can be classified under Class I Laser Product.

During the maintenance process, when the cover of laser part is removed, the maintenance personnel will be exposed to the laser, which can cause permanent eye damage. In this case, according to the requirements of GB7247.1-2012, this belongs to Class 3B Laser Product. This instrument has been tested in accordance with GB7247.1-2012 and the result shows consistency in the *GB7247.1-2012: Safety of Laser Products - Part 1: Equipment Classification, Requirements and User Guidance*.

1.8.2 Laser Safety

1. Ensure the safe operation of the laser device

(1) The instrument must be installed and maintained by technicians.

(2) When operating the instrument, all instrument panels must be installed in place on the instrument, and the laser safety symbols or laser safety protection parts shall not be removed. The instrument panels shall be installed without the presence of any detectable radiation. When operating the laser device, the operator may be exposed to excessive radiation from the laser device if any of the panels are removed (for example, stop the safety protection lock device during maintenance process).

(3) Except for maintenance personnel, it is not allowed to operate under any condition with any panel open, and it is not allowed to disconnect the safety protection lock device.

(4) Maintenance shall be carried out strictly in accordance with the SOP. Since the maintenance personnel may be exposed to Class 3B laser, protective glasses should be worn. Laser radiation warning should be posted at site entrance to prevent others from accidentally entering.

2. Other Laser Safety Information

(1) Danger of laser device: the laser device can burn fiber and cause permanent blindness, do remember not to stare at the laser beam. During maintenance, remove jewelry or other items that can reflect the laser into eyes while operation.

(2) When the cooling fan cannot cool the laser device, do not operate the laser device. Overheated laser device causes serious burns when contacting with skin.

1.9 Workstation Safety

The computer workstation is ergonomically optimized to reduce or prevent the effects of fatigue, pain and tension. Adjust your workstation to reduce the risk of musculoskeletal movements and repetitive movements:

(1) Choose tables and chairs that ensure your working posture is comfortable, and ensure sufficient operating range of the keyboard, monitor and mouse.

(2) The position of keyboard, mouse and monitor should ensure that the operator's body is in a comfortable position while working.

1.10 Safety and EMC Standards

The instrument is complied with the following standards and regulations:

- *Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements* (GB 4793.1-2007)
- *Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 9: Special Requirements for Automatic and Semi-Automatic Equipment for Analysis and Other Purposes in Laboratories* (GB 4793.9-2013)
- *Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Special Requirements for In Vitro Diagnostic (IVD) Medical Devices* (YY 0648-2008)
- *Electromagnetic Compatibility Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements* (GB/T 18268.1-2010)

- *Electromagnetic Compatibility Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 26: Special Requirements in In Vitro Diagnostic (IVD) Reagents* (GB/T18268.26-2010)
- *Safety of Laser Products - Part 1: Equipment Classification, Requirements and User Guidance* (GB 7247.1-2012)

Chapter II Product Summary and Features

2.1 Product Summary

Please read the User Guide before installing and using the product.

Product Name: Genetic Analyzer

Model Number: Honor-1616/1816

Main Power Supply Voltage: AC220V, 50Hz

Components: The genetic analyzer consists of capillary electrophoresis instrument, embedded software (V2.1) and external software (V2.0).

Scope of application: Used for analysis of DNA samples and detection of corresponding gene loci information in conjunction with dispensed reagents.

Contraindication: N/A

Applicable population: No special requirements, and can be applied to adults, children and newborns.

Honor-1616/1816 Genetic Analyzer applies capillary electrophoresis technology to perform tests over the PCR products which are labeled with different fluorescent dyes accordingly. Since the size of each PCR products may vary, the electrophoretic mobility of molecules in high-voltage electric field is different. When the molecules are driven to the capillary detection window in accordance with their molecular sizes, these fluorescence-dyed molecules will be stimulated by the laser ejected from the window. Correspondingly, the fluorescent molecules will be detected one by one by the CCD camera detector in the detection window, and the stimulated fluorescence is separated by grating to distinguish the fluorescence of different colors representing different base information, and is synchronously imaged on a CCD camera. The analysis software will automatically transform different fluorescence into DNA information, and the analysis results will be output in various forms such as gel electrophoresis pattern and fluorescence peak map.

This product should be operated by professionals to analyze DNA extracted from

human samples to detect genetic changes that may lead to diseases or susceptibility.

2.2 Product Features

2.2.1 Normal operating environment

This product is designed to be used in professional DNA testing laboratories and in conjunction with dispensed reagents. There are no special requirements for the operating environment which is consistent with the laboratory environment requirements. The operating conditions are as follows:

- 1) For indoor use;
- 2) Used by professional institutions;
- 3) Ambient temperature: 10°C ~ 30°C; temperature fluctuation during operation: $\pm 2^{\circ}\text{C}$;
- 4) Relative humidity range: 40% ~ 60% (No condensation);
- 5) Atmospheric pressure: 86 Kpa ~ 106 Kpa.

2.2.2 Product Classification

1. Electrical Safety

- 1) Rated voltage and frequency: 220V, 50Hz;
- 2) Rated power: 800VA;
- 3) Non-permanent installation equipment.

2. Environmental Conditions Classification

If classified by operating conditions, to be used in general environment is Group I which refers to the equipment is used in an environment with heating and ventilation.

If classified by transportation and circulation conditions, equipment easy to move is Group I refers to the equipment that allows for general vibration and shock during use.

Chapter III Accessories and Consumables

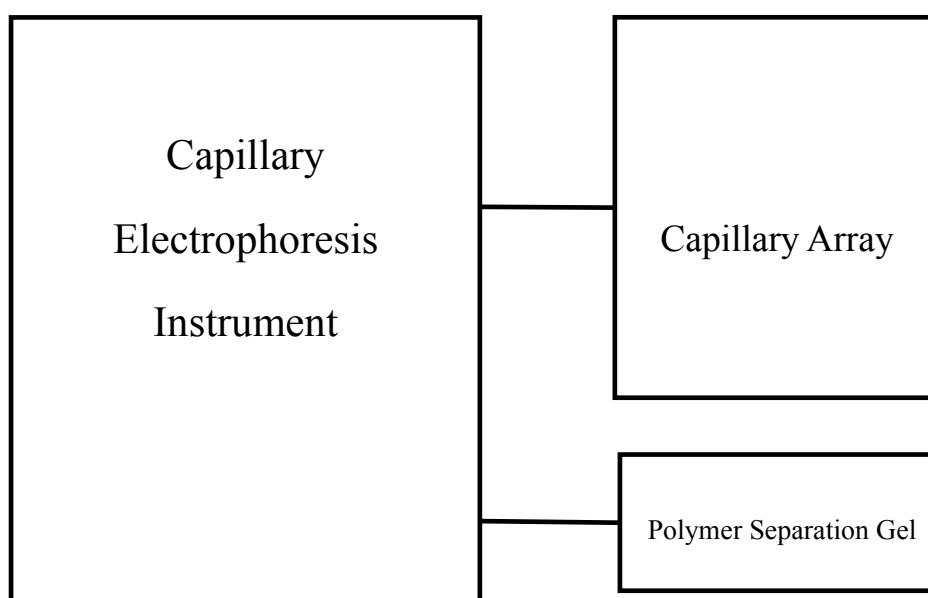
3.1 Packing Information

Product Packing List

No.	Specification	Quantity	Unit
1	Honor-1616/1816 Genetic Analyzer Host	1	set
2	Power Cord	1	piece
3	Internet Cable	1	piece
4	User Guide	1	unit
5	Buffer Tank	3	set
	Buffer Tank Sealing Pad		
6	96-Well Sample Tray Base	2	set
	Bracket		
	96-Well Sealing Pad		
7	Upper Polymer Block Drip Tray	1	set
8	Lower Polymer Block Drip Tray		

3.2 Instrument Structure

The layout of the instrument is shown as below:



Chapter IV Operation Guidance

4.1 Instrument Preparation

4.1.1 Start the System

- (1) Turn on UPS power supply to ensure that UPS is battery-powered and keep stable for 5 minutes;
- (2) Turn on the monitor and computer, and then log in the boot interface;
- (3) Check and ensure the door of heating furnace and instrument front door are closed;
- (4) Turn on the power switch of the instrument, the yellow light is on and the instrument is started.

4.1.2 Open Data Acquisition Software

Double click the keyboard shortcut of the data acquisition on the computer interface and enter the data acquisition software login interface of the genetic analyzer.

Enter username and password to log in the system as shown in Figure 1.



Figure 1. Data Acquisition Software Login Interface

During the login process, the instrument status will be displayed in the lower left corner of the interface. After receiving the inspection, the software welcome interface

will be displayed as shown in Figure 2.

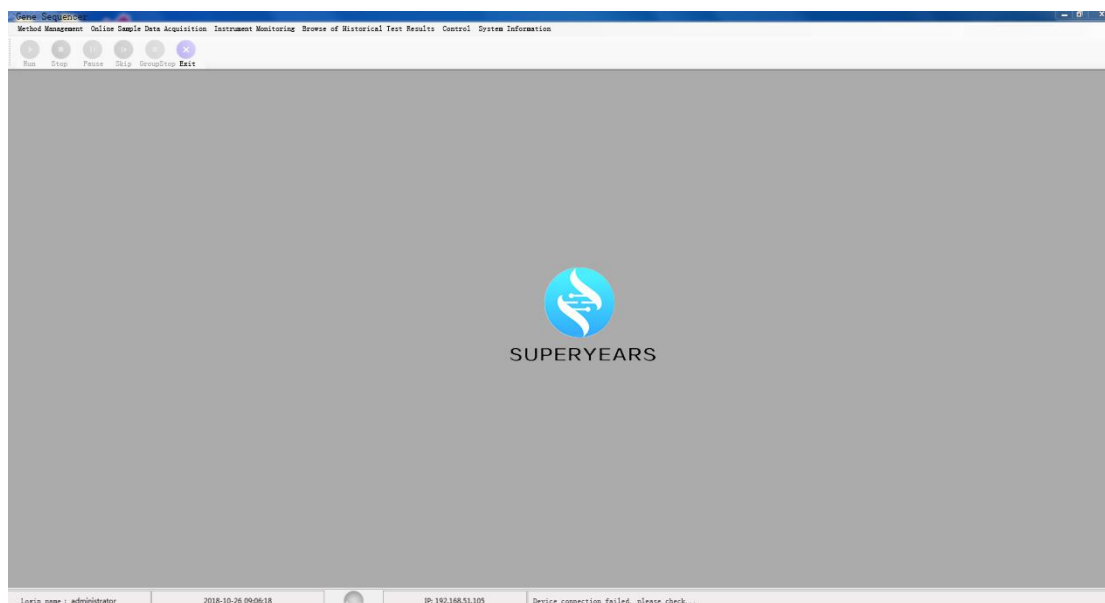


Figure 2. Data Acquisition Software Welcome Page

After successful login, the instrument starts self-checking. The instrument self-checking is completed until the green light is constantly on. If the instrument light is incorrectly displayed or the status displays “Error Message”, please check:

- (1) Check if the instrument power supply is connected, if not, turn on the instrument power supply.
- (2) Check if the instrument indicator light is green and constantly on. If not, please restart the software and wait for the instrument to complete self-checking.
- (3) Check if the connection line between the instrument and the computer workstation is loose, if so, please restart the software after checking.

4.1.3 Capillary Array Installation

The procedures for installing or replacing capillaries are as follows:

1. Confirm if the data acquisition software is in normal operation and the instrument indicator light is constantly green. Select the “Instrument Control” - “Maintenance Guide” - “Capillary Array Installation and Replacement Guide” in the software menu in turn, as shown in Figure 3.



Figure 3. Capillary Array Installation and Replacement Guide

2. Follow the instruction in the guide and select the processing method of capillary array according to the actual situation. “Remove the current capillary for reuse” or “Remove the current capillary and discard”, and then click the “Next” button, as shown in Figure 4.

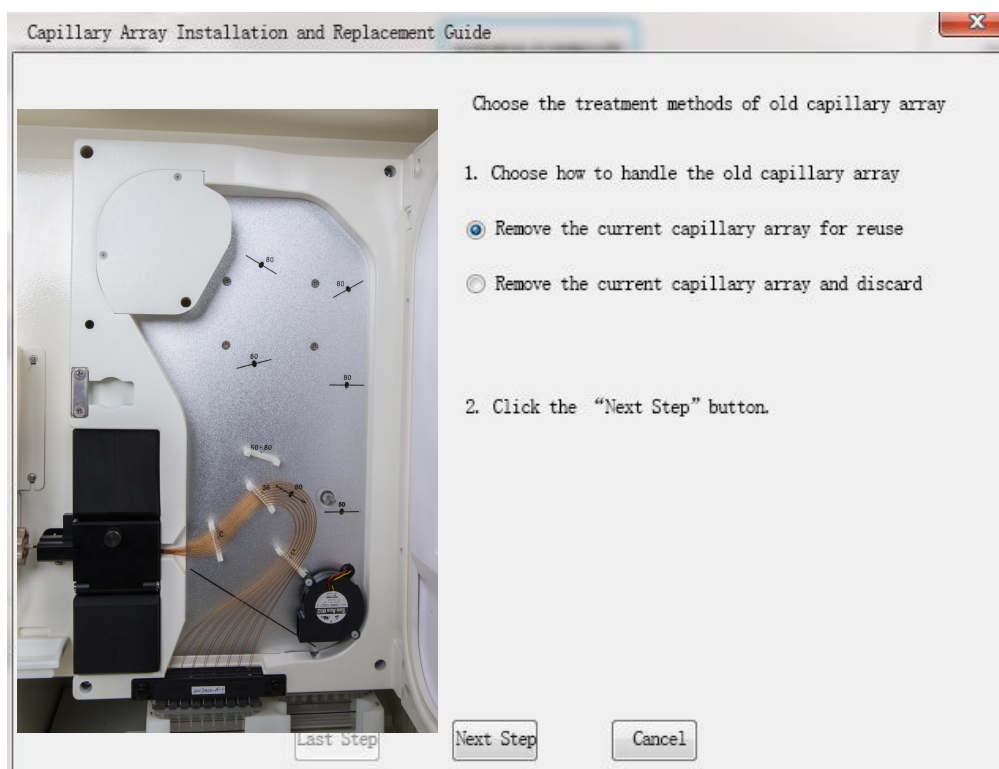


Figure 4. Capillary Array Installation and Replacement Guide

3. Remove the current capillary array according to the instruction in the guide.

The specific steps are as follows:

- (1) Press the “TRAY” button at the bottom of the panel. When the tray stops moving, the green indicator light of instrument changes from flashing to constantly on.
- (2) Open the front door of instrument, insulated oven door and the protective cover of detection window in turn.
- (3) Turn the knob of the cluster end of capillary array fixed on the upper polymer block anticlockwise, pull the upper polymer block outwards slightly, and gently pull the cluster end of the capillary array out of the upper polymer block.
- (4) Grasp the cluster end of capillary array with the left hand, take out the detection window of the capillary array with the right hand. Lift the left hand and pull out the rest of the fixing combs with the right hand.
- (5) After middle finger of the right hand holds the capillary array, the thumb and forefinger pull out the two buckles on two sides in turn, and then gently grasp the fixing buckle to pull out the capillary array injection end.
- (6) After removing the capillary array, hold the cluster end of the capillary array with the left hand. Remove the spindle sleeve and knob from the cluster end of capillary array and place the array in ultra-pure water for cleaning.
- (7) If this capillary array is needed to be reused, please take the sampling protection box out of the original packing box and fix it on the cluster end of the capillary array. Cover the protective cover of detection window, insert the cluster end into the protective bottle filled with buffer and tighten it. The last step is to place the capillary array in the original packing box and stored vertically. Otherwise, please discard the capillary array in accordance with relative laboratory regulations. As shown in Figure 5.

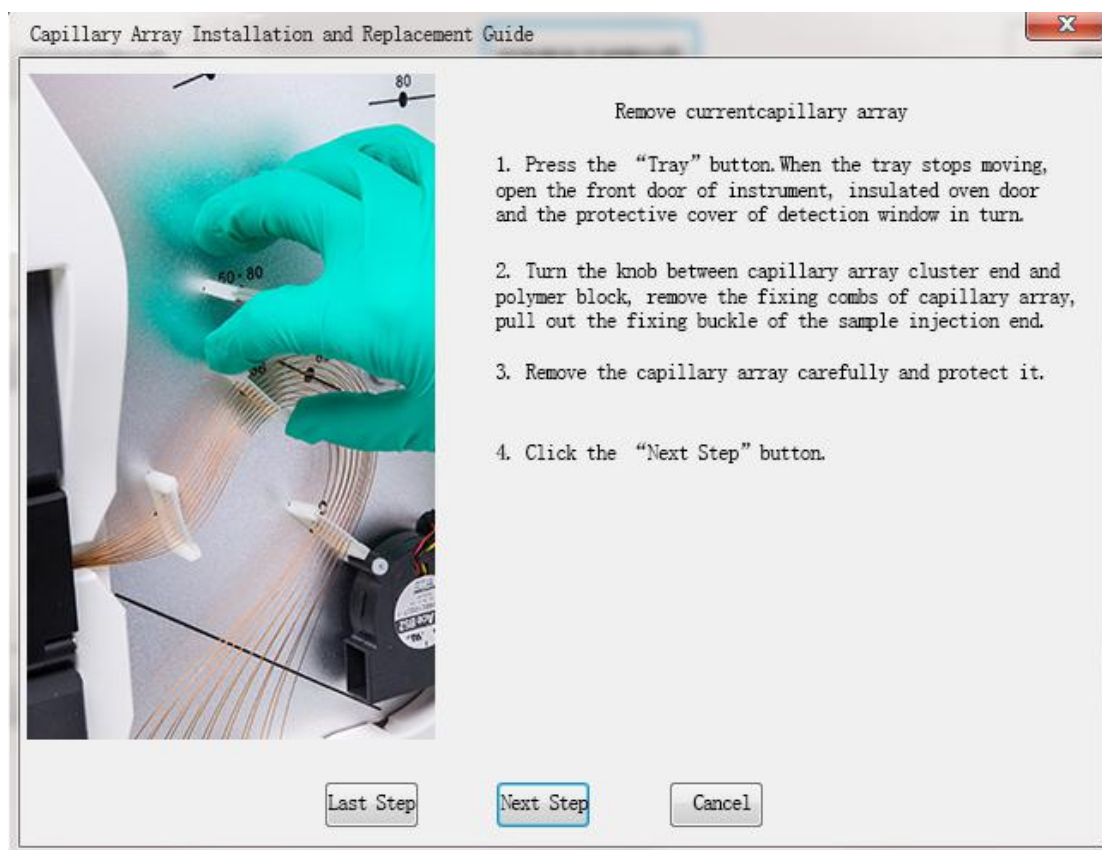


Figure 5. Removing Current Capillary Array

(8) Click the “Next” button on the interface of “Capillary Array Installation and Replacement Guide”.

4. Capillary Array Information Input

If select “Install a new set of capillary array”, enter the serial number and length of the capillary array. If you use used capillary array, select “Install a set of used capillary array” and select the serial number, length, the number of times of use and the installation time of the capillary array (the time of the last disassembly) in the drop down box as displayed on the page that is shown in Figure 6.

Capillary Array Installation and Replacement Guide

Input capillary array information

☒ Install a new set of capillary array Note: If the "Next Step" is not available, it indicates the serial number input has already existed in the system.

Serial number:

Length:

☐ Install an old set of capillary array

Select array:

Length:

Number of use:

Installation time:

Last Step Next Step Cancel

Figure 6. Capillary Array Installation Guide

5. Installation of capillary arrays, the specific steps are as follows:

(1) Take out the capillary array, remove the cluster end of the capillary array and the sampling protection box.

(2) Hold the cluster end of the capillary array with the left hand, carefully push the fixing buckle of the sampling end of the capillary array into the slot at the lower part of the insulated oven with the right hand, gently press with the middle finger, push the left buckle inside with the thumb first, then push the right buckle inside.

(3) Insert the fixing combs on capillary array into corresponding fixing slots. (Leave the last fixing comb near the cluster end of the capillary array).

(4) Install the cluster end button and spindle sleeve at the cluster end of the capillary array, bend the capillary array downward into an Ω shape, and insert the cluster end of the capillary array into the outlet hole of the upper polymer block.

(5) Adjust the detection window of capillary array to make it right in front of the detection window of the instrument.

(6) Push the upper polymer block back to its original position gently, carefully

push the capillary array detection window into the detection window of the instrument, and insert the last fixing comb near the cluster end of the capillary array.

(7) Gently tighten the knob of the cluster end to ensure no gel leakage.

(8) Cover the protective cover of the instrument detection window, tighten the fixing screw, check if all fixing combs are fixed well, and if the capillary bending is smooth.

(9) Close the door of the insulated oven and the front door of the instrument.

(10) Click the “Finish” button to complete the installation of capillary array, as shown in Figure 7.

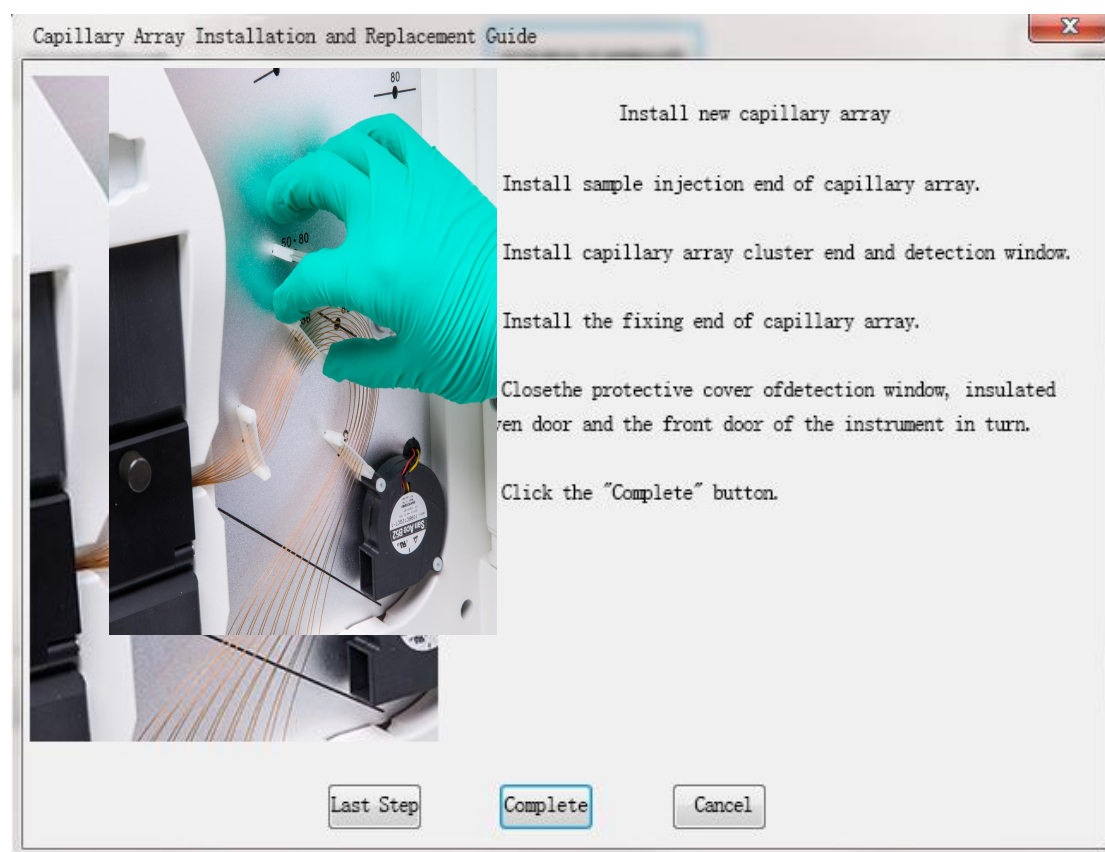


Figure 7. Installation of New Capillary Array

4.1.4 Calibration of Auto-Sampler

Calibration of auto-sampler is spatial positioning, which enables the injector to align precisely at the capillary array injection end.

Note: If the auto-sampler has not been calibrated for a long time, it is required to be calibrated before use.

The specific operations are as follows: Select "Instrument Monitoring" - "Guide

Maintenance" - "Auto-Sampler Calibration Guide" in the software menu in turn, and operate according to the software prompts:

(1) Press the "TRAY" button on the front panel of the instrument and wait for the green indicator light of the instrument to change from flashing to constantly on, and then the auto-sampler stops moving;

(2) Open the front door of the instrument and remove all sample trays and pools in the auto-sampler;

(3) Close the front door of the instrument. After the auto-sampler stops moving, click the "Initialization" button in the dialog box of "Auto-Sampler Calibration Guide";

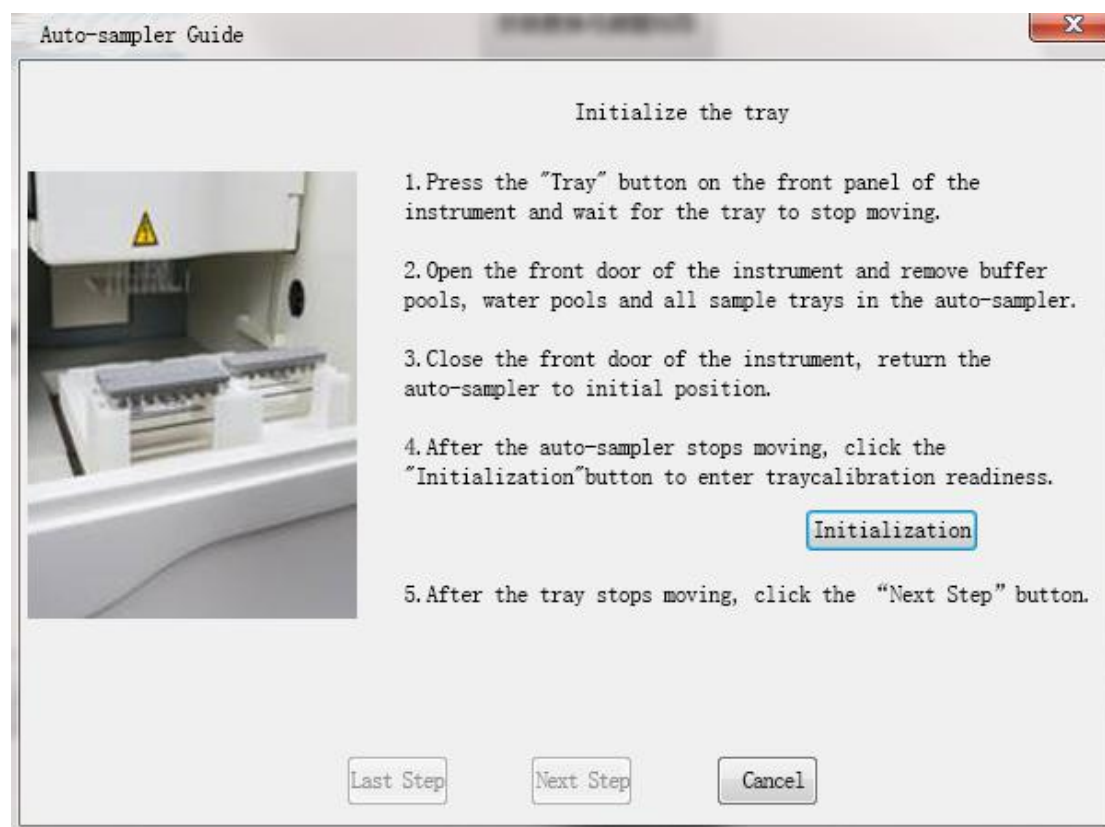


Figure 8. Calibration of Auto-Sampler

(4) After the auto-sampler stops moving, click "Next" button;

(5) Move the auto-sampler by software operation, make the eighth, or the fourth capillary array at the front row right aligned with the anchor point on the auto-sampler. If necessary, open the front door of the instrument to check the alignment degree after the auto-sampler stops moving;

(6) After completing the positioning, click the button "Set XY Calibration Value" in the dialog box of "Auto-Sampler Calibration Guide";

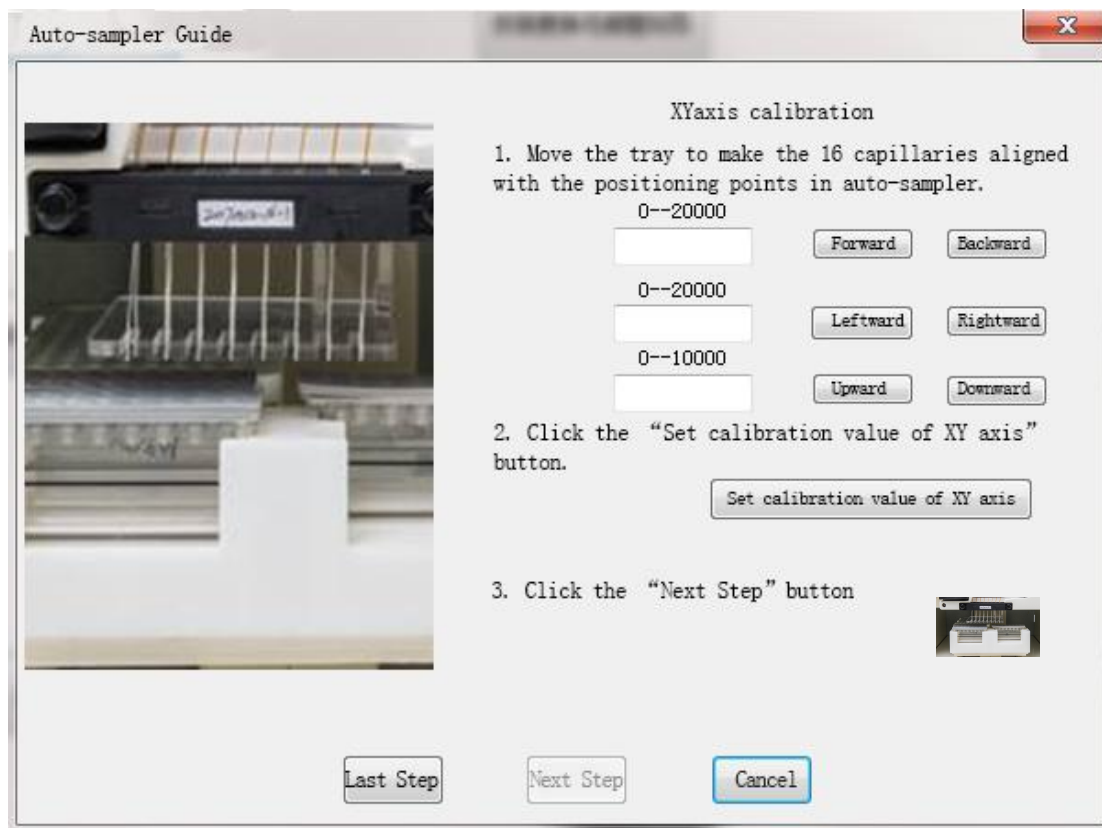


Figure 9. Calibration of Auto-Sampler

(7) Click the "Next" button;

(8) Press the "TRAY" button on the lower part of the front panel of the instrument;

(9) Wait the green indicator light of the instrument changes from flashing to constantly on. After the auto-sampler stops moving, open front door of the instrument and place an empty pool in the position of buffer pool;

(10) Close the front door of the instrument, click the "Initialization" button, and continue the automatic sample injection calibration;

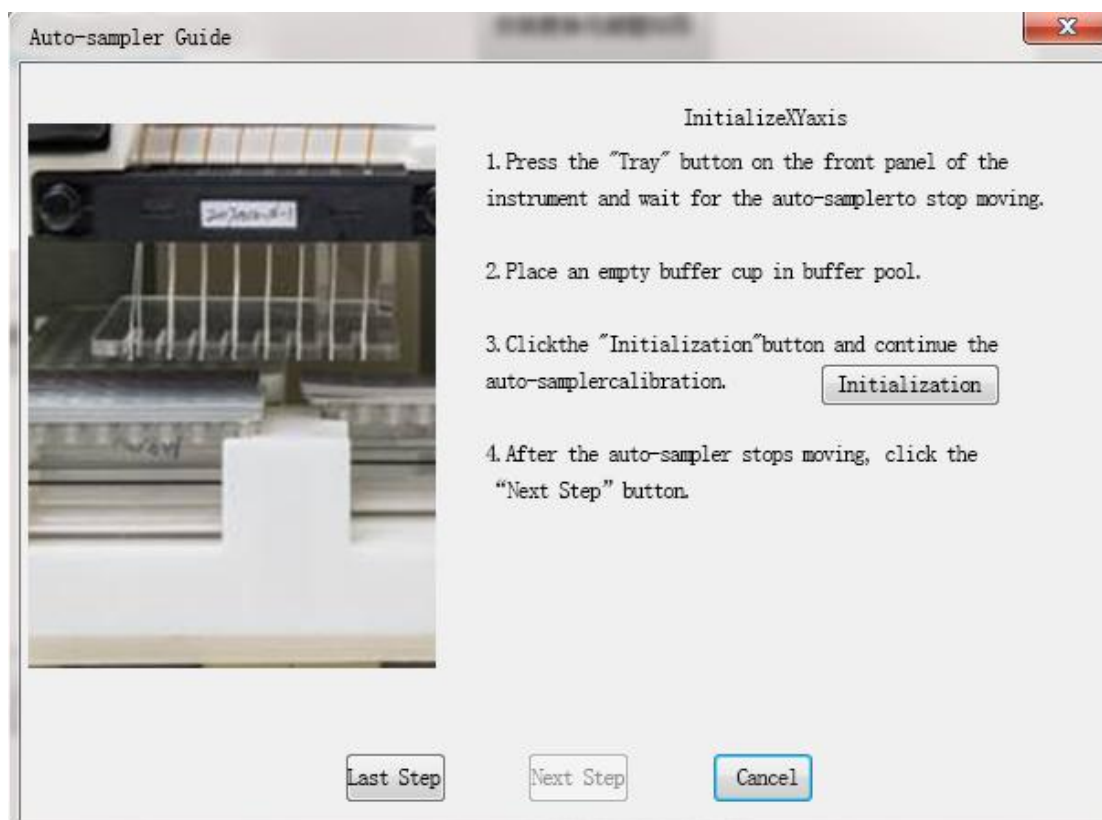


Figure 9. Calibration of Auto-Sampler

- (11) After the auto-sampler stops moving, click the "Next" button;
- (12) Move the auto-sampler up and down to make the pointed end of the capillary array (black rubber tip) parallel to the scale line of the buffer;

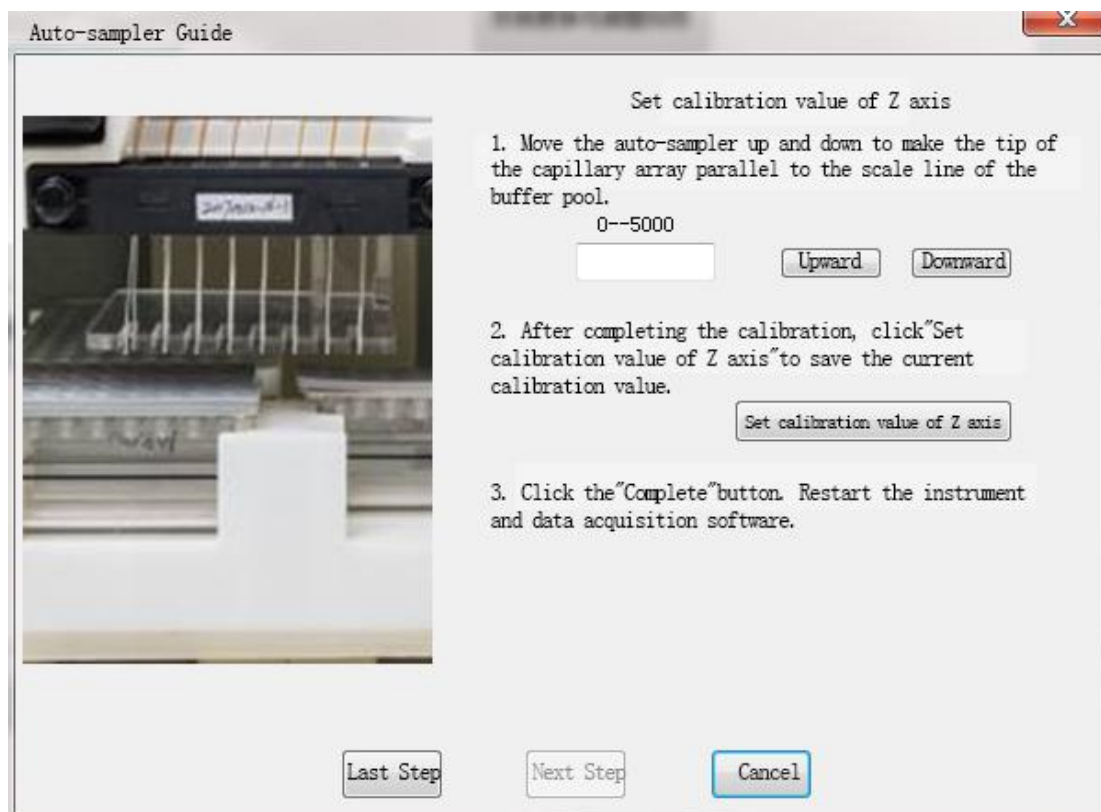


Figure 11. Calibration of Auto-Sampler

(13) After completing the calibration, click "Set Z Calibration Value" to save the current calibration value;

(14) Click the "Complete" button to finish auto-sampler calibration;

(15) Restart the instrument and data acquisition software.

4.1.5 Rinsing and Polymer Gel Replacement

1. Rinsing

After the auto-sampler calibration is completed, the gel pump needs rinsing. The specific operation steps are as follows:

Click "Instrument Monitor", "Maintenance Guide", "Rinsing and Gel Replacement Guide" in the software menu in turn, and operate according to the software prompts.

2. Polymer Gel Replacement

(1) Replacement of Different Polymer Gels

If the gel to be replaced is different from the gel type on the instrument, click "Instrument Monitoring", "Maintenance Guide", "Rinsing and Gel Replacement

Guide" in the software menu in turn to replace different kinds of polymer gels.

(2) Replacement of the Same Polymer Gel

If the gel to be replaced is the same as the gel type on the instrument, click "Instrument Monitoring", "Maintenance Guide", "Gel Supplement Guide" in the software menu in turn to replenish the same gel.

Note: If the original gel on the instrument doesn't put in use for a long time and crystallized, the gel injection pump bin should be washed first. The specific replacement steps are carried out according to "Rinsing and Gel Replacement Guide" in "Maintenance Guide" of the software.

4.1.6 Buffer Replacement

Click "Instrument Monitoring", "Maintenance Guide", "Buffer Injection and Replacement Guide" in the software menu in turn, and replace the buffer according to the guide. As shown in Figure 12.

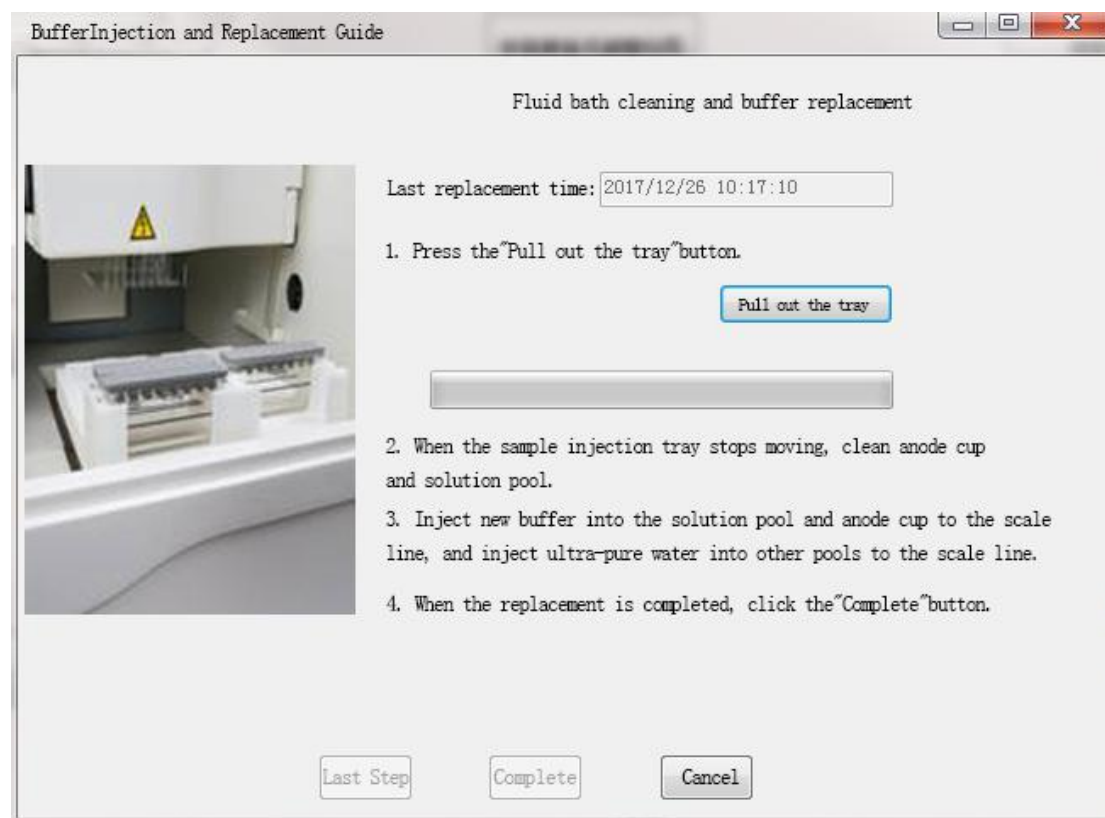


Figure 12. Buffer Replacement Guide

4.1.7 Automatic Bubble Removal

(1) Click "Instrument Monitoring" - "Maintenance Guide" - "Automatic Bubble

Removal Guide" in the software menu in turn;

(2) Remove the bubbles in the pump bin and pipeline according to the prompts of dialog box of "Automatic Bubble Removal Guide"; After confirming that all the bubbles have been removed, click the "Complete" button. As shown in Figure 13.

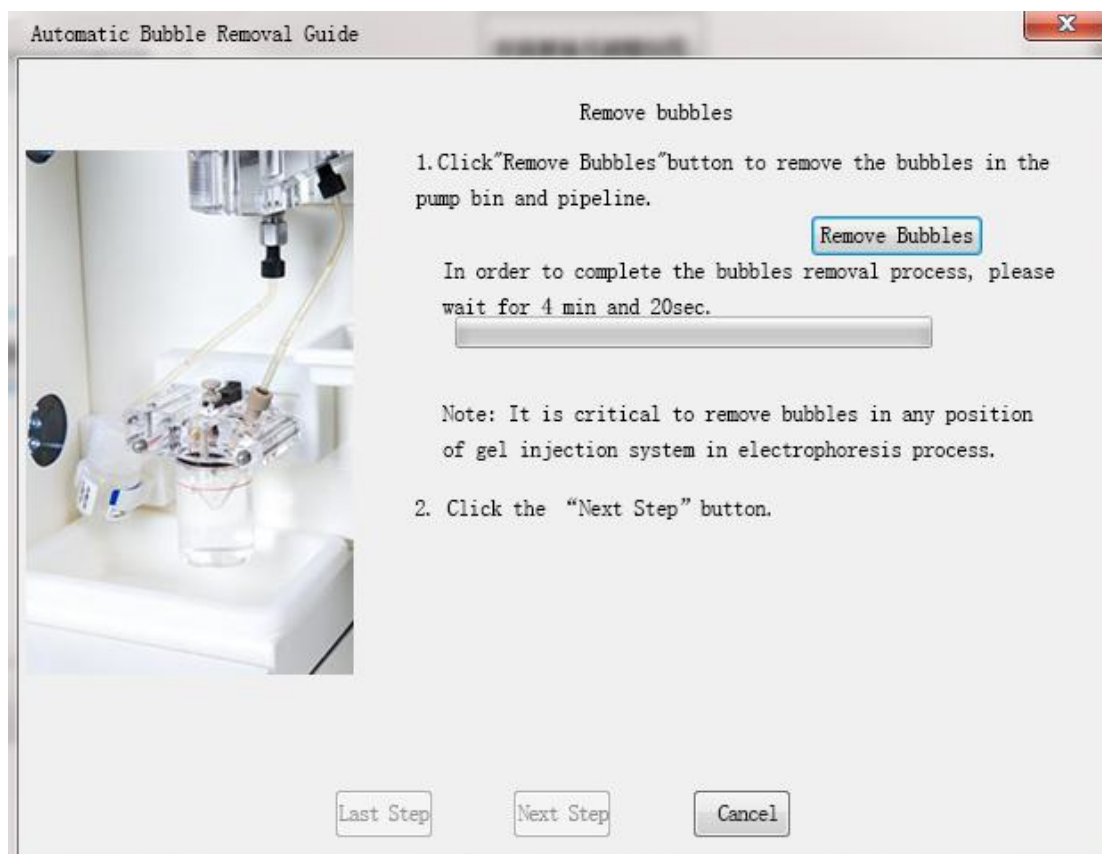


Figure 13. Automatic Bubble Removal

Note: If there are always bubbles in the pump bin or at the cluster end and can not be discharged, rewash the pump bin and continue to remove all the bubbles.

4.2 Spatial Calibration

4.2.1 Time to Carry Out Spatial Calibration

- (1) Installation or replacement of capillary arrays;
- (2) Removing or adjusting the position of capillary detection window;
- (3) After moving the instrument.

4.2.2 Create a Spatial Calibration File

(1) Select the "Method Management", "Space Calibration" in the menu of the software interface in turn. As shown in Figure 14.

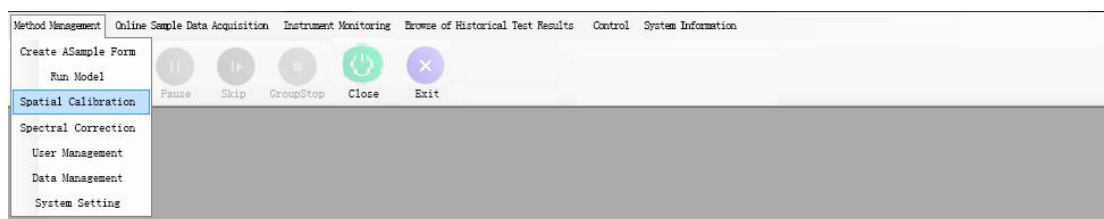


Figure 14. Spatial Calibration

(2) Choose the appropriate operation model in the "Operation Model" drop-down list of "Space Calibration Operation" at the lower left of the interface. If the capillary array contains fresh gel, no need to inject gel into the capillary, choose "No Spatial Fill". Otherwise, choose "Spatial Fill" to fill the capillary with fresh gel. As shown in Figure 15.

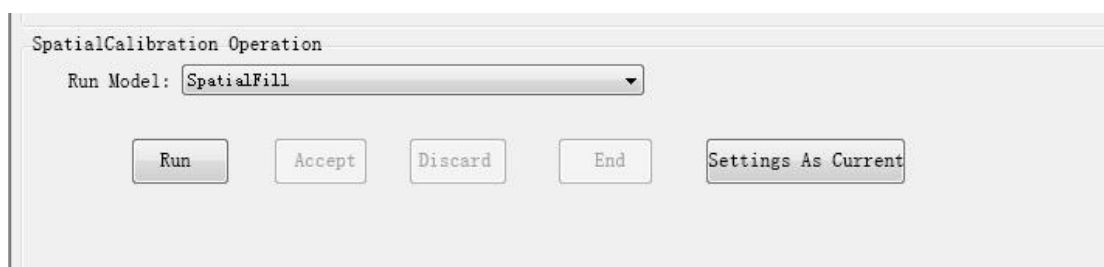


Figure 15. Spatial Calibration

(3) Click "Run" to start spatial calibration. The results of spatial calibration can be seen after the completion of spatial calibration as shown in Figure 16 below.

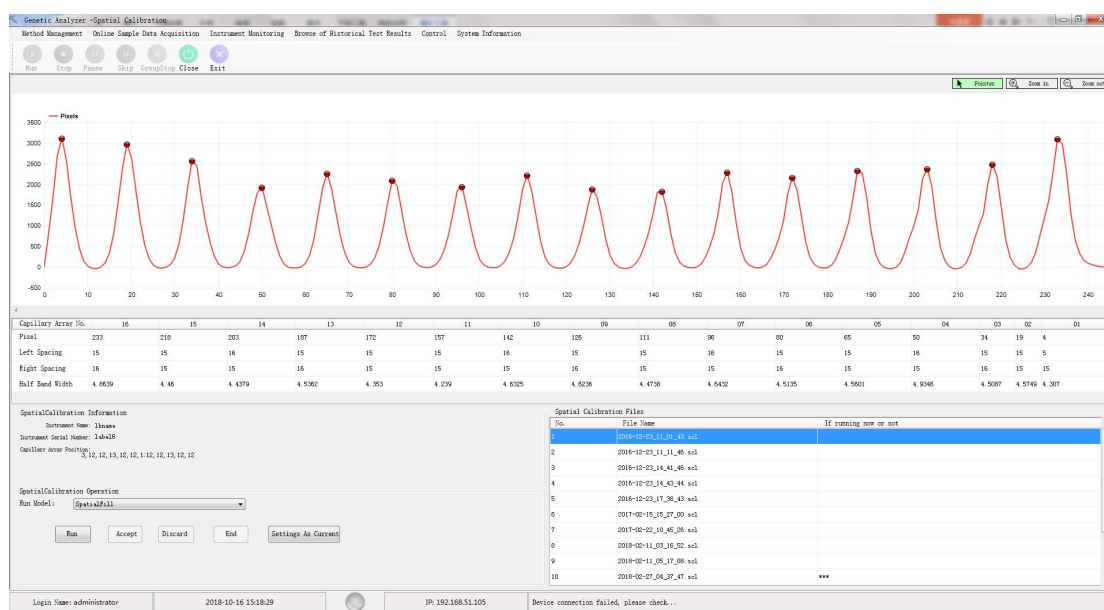


Figure 16. Spatial Calibration Diagram

(4) When checking the diagram, put mouse to the red spot of the peak to see the

height value of each peak; when the region of interest is selected, the spatial calibration diagram can be enlarged and the diagram can be reduced by clicking the "Zoom out" button.

4.2.3 Assessment of Spatial Calibration Results

(1) Check Spatial Calibration Files

The information of the spatial calibration file is displayed in the list of "Spatial Calibration Files" at the lower right of the interface, among which the spatial calibration file marked with "****" in the "Current or Not" menu is the spatial calibration file in use.

(2) Standards for Assessing Spatial Calibration Diagram

Peak Attribute	Qualification Standard
Height	All peaks have a similar height.
Red Dot	Each red dot marks one peak. There is no dislocated red dot.
Shape	Each capillary array has a single peak.
Distance	The distance between adjacent peaks is 13 ~ 16 pixels, and the theoretical distance between capillaries is 15 pixels.
Half Band Width	The half-band width of each peak should be between 2 and 5.8.

(3) Acceptance or Rejection of Spatial Calibration

If the space calibration passes, click "Accept" button in the "Spatial Calibration Operation Bar"; if the space calibration fails, click "End".

4.2.4 Spatial Calibration Failure

- (1) Re-operate spatial calibration;
- (2) Observe whether there are bubbles in the system and re-operate calibration after removing the bubbles;
- (3) Re-install capillary array detection window to carry out spatial calibration;
- (4) Remove the capillary array and clean the detection window of capillary array with methanol;
- (5) Put the capillary array back after the methanol dries and start spatial calibration;
- (6) If invalid, replace the capillary array.

4.3 Operation Model Setup

Before spectral calibration, fragment analysis and sequencing, parameters such as electrophoresis voltage, electrophoresis temperature and CCD data acquisition time can be set and changed manually. The specific operation methods are as follows:

4.3.1 Create a New Operation Model

(1) Click "Method Management", "Operation Model" in the software menu in turn. Click "Create a New Model" at the lower left corner of the page and the dialog box of creating a new operation model pops up. As shown in Figure 17.

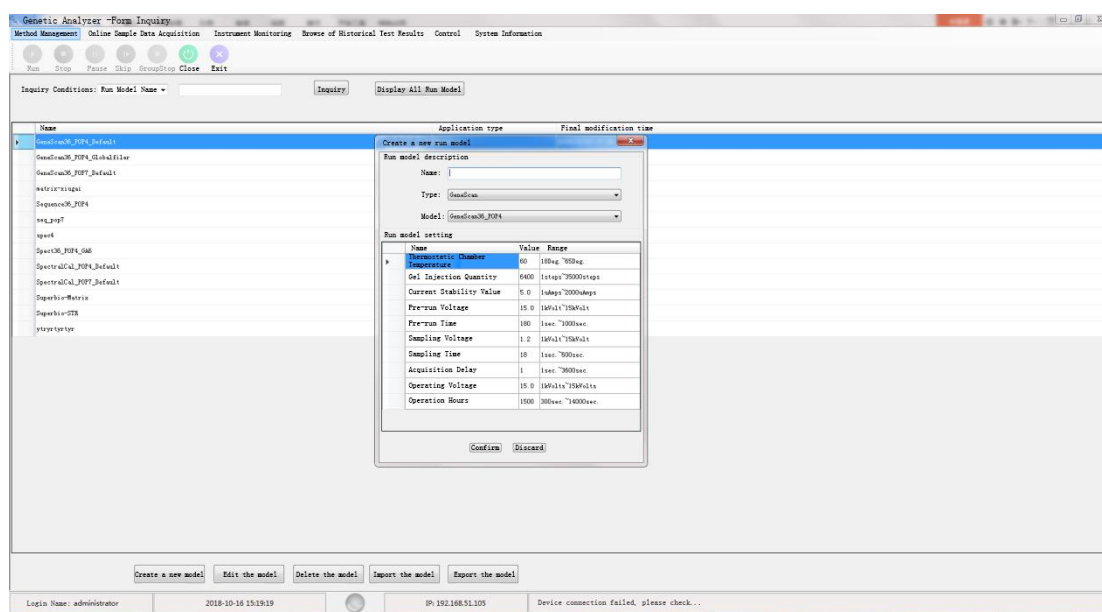


Figure 17. Create a New Operation Model

(2) Enter the name of the operation model and select the type of the operation model in the "Type" drop-down box. Choose from "Spectral Calibration", "Fragment Analysis" and "Sequencing Analysis". In the lower box of the module, choose the corresponding gel type model according to the different gel types. Set up the operation model according to the specific detection needs. The set values may vary according to different types of operation model. The other set values of different parameters should be in the range of the "Range" list.

(3) After editing, click the "Confirm" button to save the operation model, otherwise click the "Cancel" button to cancel the operation.

4.3.2 Edit Operation Models

- (1) Select the operation model to be edited at the operation interface.
- (2) Click "Edit" button at the lower left corner of the interface and the dialog box of editing running model pops up. Set the operation model according to the actual needs.
- (3) After editing, click the "Complete" button to edit, otherwise click the "Discard" button to cancel the operation.

4.3.3 Delete Operation Models

- (1) Select the operation model to be deleted at the operation interface.
- (2) Click the "Delete" button at the lower left corner of the interface and the dialog box pops up. Click the "Confirm" button to delete the operation model, otherwise click the "Discard" button to cancel the operation.

4.3.4 Import Operation Model

- (1) Click "Import" at the lower left corner of the interface of operation model.
- (2) Browse the operation model file in ".rmd" format that needs to be imported.
- (3) Select the operation model file and click "Open".

4.3.5 Export Operation Model

- (1) Select the operation model to be exported at the interface of operation model.
- (2) Click the "Export" button at the bottom left corner of the interface to display the dialog box of operation model file.
- (3) Browse the location of the file that needs to be exported.
- (4) Click "Save".

4.4 Spectral Calibration

4.4.1 When to do Spectral Calibration

- (1) When using a new combination of fluorescent dyes;
- (2) After the laser or CCD is adjusted or replaced;
- (3) The spectral resolution of original data or analytical data is reduced;
- (4) Changes in parameters (fluorescence type, capillary type and capillary length).

4.4.2 Preparations of Spectral Calibration Standard Product

- (1) Mix spectral calibration standard product with Hi-Di formamide and perform oscillation centrifugation according to the reagent kit manual.

- (2) After five minutes of denaturation at 95°C, perform ice bath for two minutes immediately and then perform oscillation centrifugation;
- (3) Add samples into the sample plate (add 10ul to 96-well plate, add 5ul to 384-well plate) and perform oscillation centrifugation;
- (4) Take out the sample from the centrifuge and confirm that all the samples have gone down to the bottom and there is no bubble.

4.4.3 Sample Tray Installation

- (1) Place sample tray on a clean horizontal surface, put the sealing pad on the sample tray, align the wells of the sealing pad with the wells of the sample tray, and press firmly on the sample tray. Then put the sample tray on the base. Fix the sample tray and base with the sample tray bracket. As shown in Figure 18.

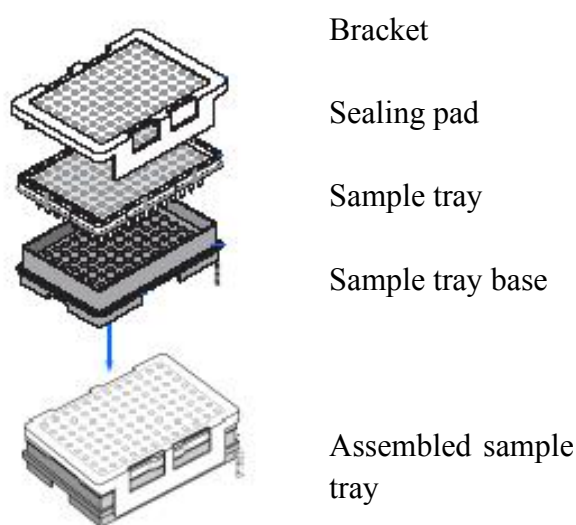


Figure 18. Assembly of Sample Tray

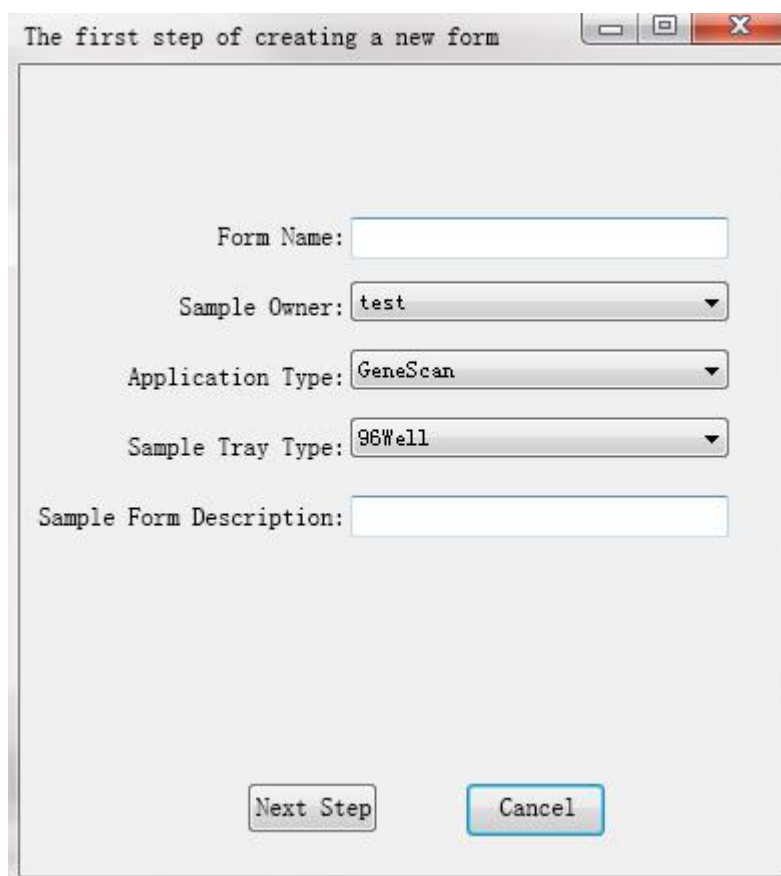
Note! The wells of sealing pad and sample tray must be aligned with each other, otherwise it will damage the capillary array!

- (2) Make sure that the front door of the instrument and insulated oven door are closed, press the "TRAY" on the instrument panel;
- (3) Waiting for the green indicator light of the instrument to change from flashing to constantly on, and the tray stops running;
- (4) Open the front door of the instrument, place the sample tray on the tray and confirm that the sample tray is placed horizontally on the tray;

(5) Close the front door of the instrument and wait for the green indicator light to change from flashing to constantly on. Place the tray back to standby position (insert capillary array sample injection end into buffer pool).

4.4.4 Create Spectral Calibration Files

(1) Click "Method Management", "Sample Formulation", "Create a New Form" in the software menu in turn and the dialog box of "Create a New Form" pops up. As shown in Figure 19.



The first step of creating a new form

Form Name:

Sample Owner:

Application Type:

Sample Tray Type:

Sample Form Description:

Next Step Cancel

Figure 19. Create a Spectral Calibration Form

(2) Enter the corresponding contents in items of the dialog box, the system sets the name inside the edit box of "Sample Owner" is the same with login system user name. Select "SpectralCal" in the "Application Type" drop-down box as shown in Figure 20.

The first step of creating a new form

Form Name:

Sample Owner:

Application Type:

Sample Tray Type:

Sample Form Description:

Figure 20. Create a Spectral Calibration Form

(3) Click "Next Step" and enter "Create a New Form Step 2" dialog box for sample input. Each row in the corresponding information form matches the sample information of well position respectively. Input sample name, dye set, operation model, and choose spectral calibration standard and Priority setting according to the well position of the sample. As shown in Figure 21.

The second step of creating a new form

Sample Form Name: Application Type: Operator: Sample Owner:

Tray Well	Sample Name	Dye Collection	Run Model	Spectral Calibration Standard	Priority Setting	Remark
A1						
B1						
C1						
D1						
E1						
F1						
G1						
H1						
A2						
B2						
C2						
D2						
E2						
F2						
G2						
H2						
A3						
B3						
C3						
D3						
E3						
F3						
G3						
H3						
A4						

Figure 21. Create a Spectral Calibration Form

Note: Specific parameters of the "Spectral Calibration Standard" file can be modified according to different reagent kits. Specific steps are as follows: Right-click "Mtxstd {Genscan-Set}", "Spectral Calibration Standard" and the "Modification Standard" dialog box to modify the number of dyes, the number of spectral blocks, the minimum mass number, conditional ranges, etc. pop up . As shown in Figure 22.

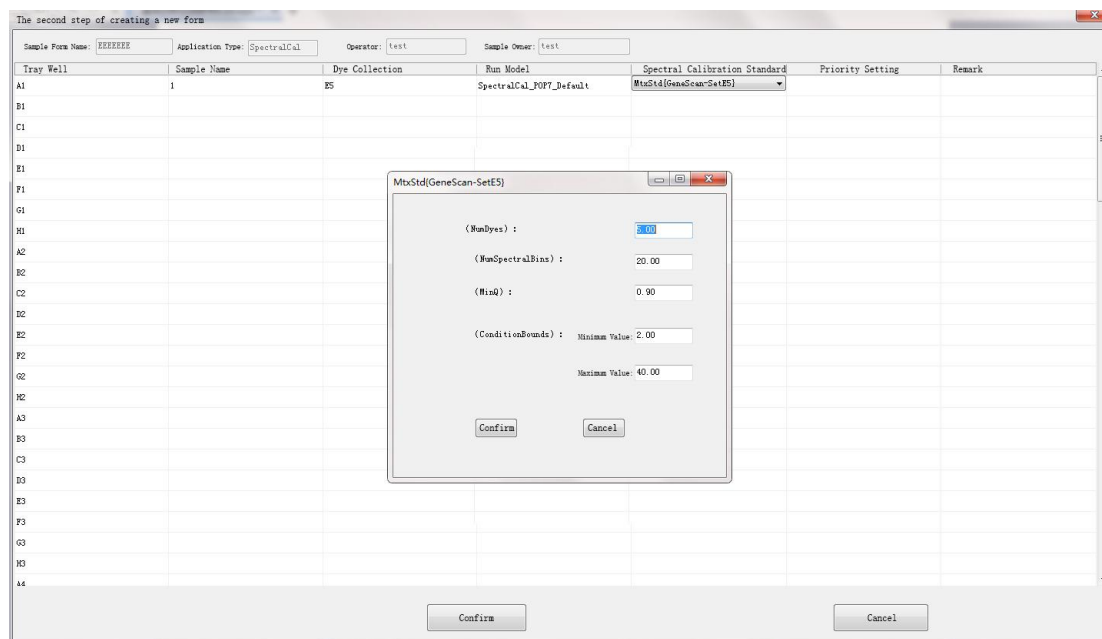


Figure 22. Modification of Spectral Calibration Standard

(4) Click the "OK" button, and the name of the new form and the corresponding information will be displayed in the column of "Unconnected Form". As shown in Figure 23.

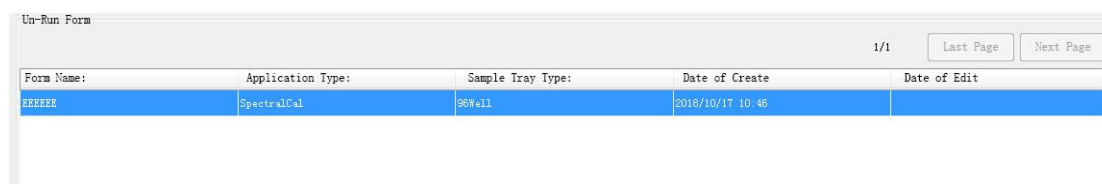


Figure 23. Unconnected Forms

4.4.5 Running of Spectrum Calibration File

(1) After selecting the form from the list, click the "Connect to A Tray" button or the "Connect to B Tray" button. The corresponding information of the form is displayed in the "Connected Form" list. The form connects to A tray is on the first line, and the form connects B tray is on the second line. The lower-right interface will display the

"Connected Form Information" column.

已链接的表单信息

名称: E5-96_1539744634

建立日期: 2018/10/17 10:50:33

修改日期:

建立者: test

应用类型: GeneScan

样品盘类型: 96Well

样品个数: 96

Figure 24. Connected Form Information

Note: The hole position edited with sample information in the connected form displays as green in the interface. After being connected, the name of the "Connect to A Tray" or (and) the "Connect to B Tray" button change to "Disconnect A Tray" and "Disconnect B Tray".

(2) Select connected form and click the "Run" button. After the test of the samples is completed, the dialog box "Spectral Calibration Result Display" pops up. As shown in Figure 25. Click the "Save Settings as Current" button to save the spectral calibration results, and click the "Discard" button to abandon.

4.4.6 Use Existing Spectral Calibration Files

(1) Click "Method Management", "Spectral Calibration" in the software menu in turn.

(2) The file with "****" marker is the currently running spectral calibration file in the column of "Spectral Calibration File" at the lower part of the software interface.

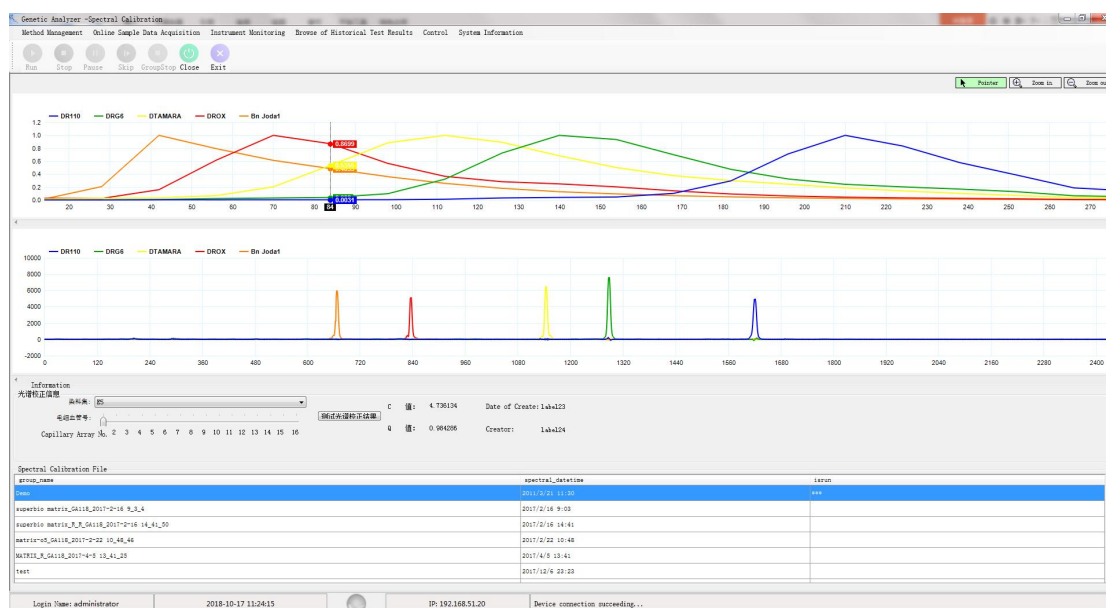


Figure 25. Spectral Calibration Diagram

(3) Double-click the chosen spectral calibration file and confirm "Settings as Current". Then, the operation is completed.

4.4.7 If spectral calibration fails, the following operations can be performed:

- (1) Redo the spectral calibration;
- (2) Reconfiguration of spectral calibration reagents and replacement of corresponding consumables;
- (3) Contact the after-sales service engineer.

4.5 Fragment Analysis (Sequencing)

4.5.1 Preparation of Sample

Prepare on-instrument samples according to the reagent kit manual.

4.5.2 Sample Tray Installation

Same as 4.4.3 sample tray installation.

4.5.3 Creation, Edit and Deletion of Sample Forms

1. Create a sample form

(1) Click "Method Management", "Sample Formulation", "Create a New Form" in the software menu in turn as shown in Figure 26.

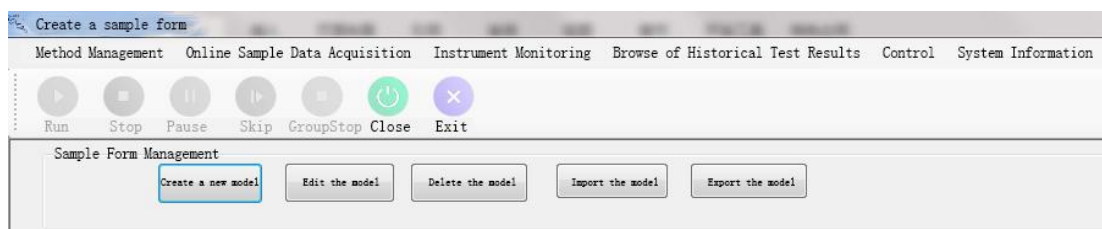


Figure 26. Creates a Sample Form

(2) Enter the contents of all items in the dialog box in turn, and select "GenScan" (or Sequence) in the "Application Type" column as shown in Figure 27.

Figure 27. Create a New Form

(3) Click "Next Step" and enter "Create a New Form Step 2" dialog box for sample input. Each row in the corresponding information form matches the sample information of well position respectively. Input sample name, dye set, operation model, and choose spectral calibration standard and priority setting.

(4) Click "OK" button to save the form information. The name of the new form and the corresponding information will be displayed in the column "Unconnected Forms".

2. Form Editing

Click "Method Management" , "Sample Formulation", "Form Editing" in the menu in turn and "Form Modification" dialog box pops up. Select the specific information to be modified, click "Save" to complete form editing. As shown in Figure 28.

The first step of editing the form

Form Name: E5-18-2_1539767237

Sample Owner: test

Application Type: GeneScan

Sample Tray Type: 96Well

Sample Form Description:

Next Step Cancel

Figure 28. Form Editing

Click "Next" and enter the "Edit Form Step 2" dialog box. Each line in the dialog box corresponds to the sample information in the corresponding hole of the sample tray. The sample name, dye set, operation model, spectral calibration standard and priority setting are input according to the pore position of the sample.

3. Import the Form

(1) Click "Method Management", "Sample Formulation", "Import the Form" in the menu in turn and the " Import the Sample Form" dialog box pops up, select the type of form to import "Import PLA File" or "Import Punching File". As shown in Figure 29.

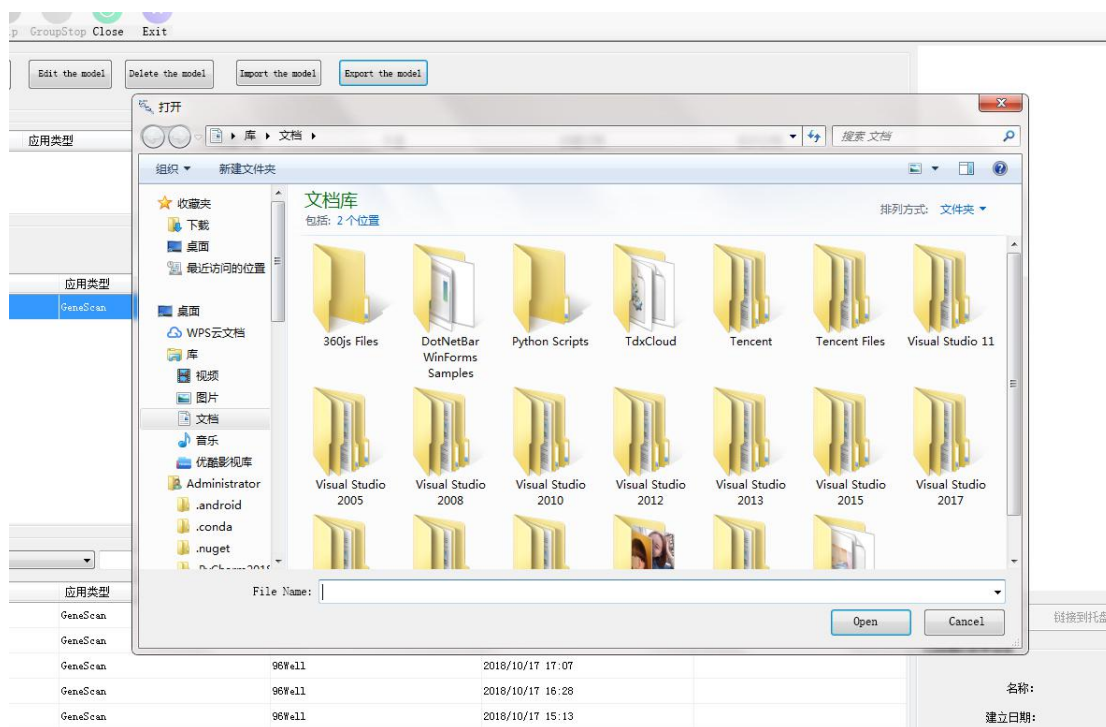


Figure 29. Import the Sample Form

(2) Browse the file location that needs to import. Select the file, click "Open" to display the path of sample form after import and the words "Sample Form Import Success" appear in the "Import the Sample Form" dialog box, and then click "Complete" to import the form.

4. Export the Form

(1) Select the form to be exported, click "Method Management", "Sample Formulation", "Export the Form" in the software menu and the dialog box of exporting standard file pops up.

(2) Browse the location of file that needs export and click "Save".

5. Delete the Form

(1) Select the form to be deleted, click "Method Management", "Sample Formulation", "Delete the Form" in the software menu and the dialog box of confirmation of deleting the form pops up.

(2) Click "Yes" to delete the form. Otherwise, click "No". As shown in Figure 30.

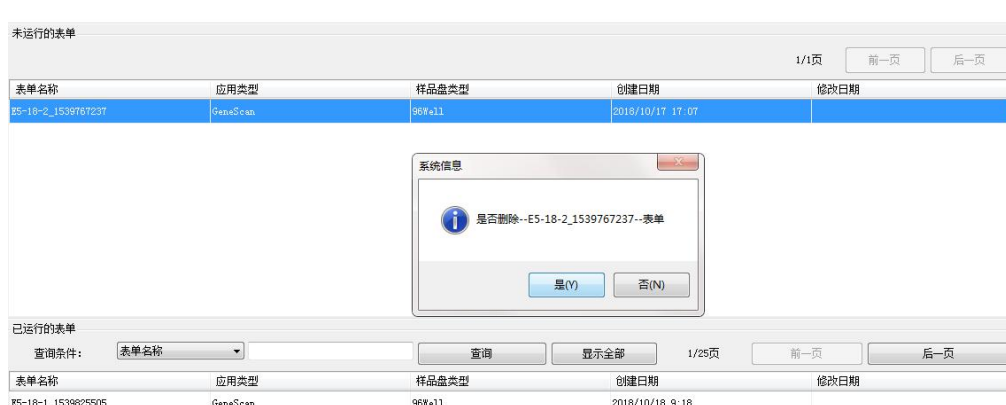


Figure 30. Prompts of Deleting the Form

4.5.4 Running of the Sample Form

(1) Connect Sample Form

After selecting the form in the un-running list, click "Connect to tray A" button or the "Connect to tray B" button, and the corresponding information of the form is displayed in the connected list.

The specific information of the form is displayed in the "Connected Form Information" column at the lower right corner of the interface. The well position edited with the sample information in the linked form shows blue on the interface. The name of "Connect to A Tray" button or (and) the "Connect to B Tray" button correspondingly changes to "Disconnect A Tray" and "Disconnect B Tray".

(2) Running the Sample Form




Select the connected form, click the "Run" button in the command toolbar, and the sample form starts to run automatically. The current running state of the instrument is displayed at the lower left corner of the software interface. When the current testing sample group (16 wells as a group) in the dial becomes red, it represents that the data of the sample operation group is being collected. During the operation of the sample group, the tray connection button became grey, indicating that the operation of disconnecting or connecting the tray is forbidden. After all sample groups of one tray finished, if another tray has connected to the form, another tray group would be automatically run.

Note: The form is editable during the process of current sample group operation. Modify the information of the sample group that has not yet been run, or adding new

sample groups. Specific steps: Select the form to be edited, click on "Form Editing" and the dialog box pop-up, click "Next Step", then edit the form according to the rules of sample formulation.

(3) Control the Running Form

Use the command bar at the top of the software window to control the running form

Click	Description
	Run: Start running.
	Stop: stop the current run and all other scheduled runs.
	Skip: Stop the current run and do other scheduled runs.

4.5.5 Stop Running

After the running is finished, the sample form automatically disconnects from the tray and move into the column of "Operation Forms". The test data of the sample after running will be stored in the folder specified by the system.

Note: Forms that have been run can also rerun. Specific steps: Select the pre-rerun form, right-click, select "Copy the Form", and then add the suffix "_copy" after the original form name in the pop-up dialog box of "Name of Sample Forms", and also can modify the form name and specific information according to actual needs.

4.6 Performance Monitoring

Through the data acquisition software, the running state of the instrument can be monitored and controlled. The specific operation is as follows:

4.6.1 Dial Monitoring

Click "Current Sample Data Acquisition", "Current Dial" in the menu of the software in turn, so users can monitor the information of the current running sample group. The window will display information such as "Current Sample Running Group Information", "Estimated Time of Current Sample Running Group", "Online Running State". As shown in Figure 31.

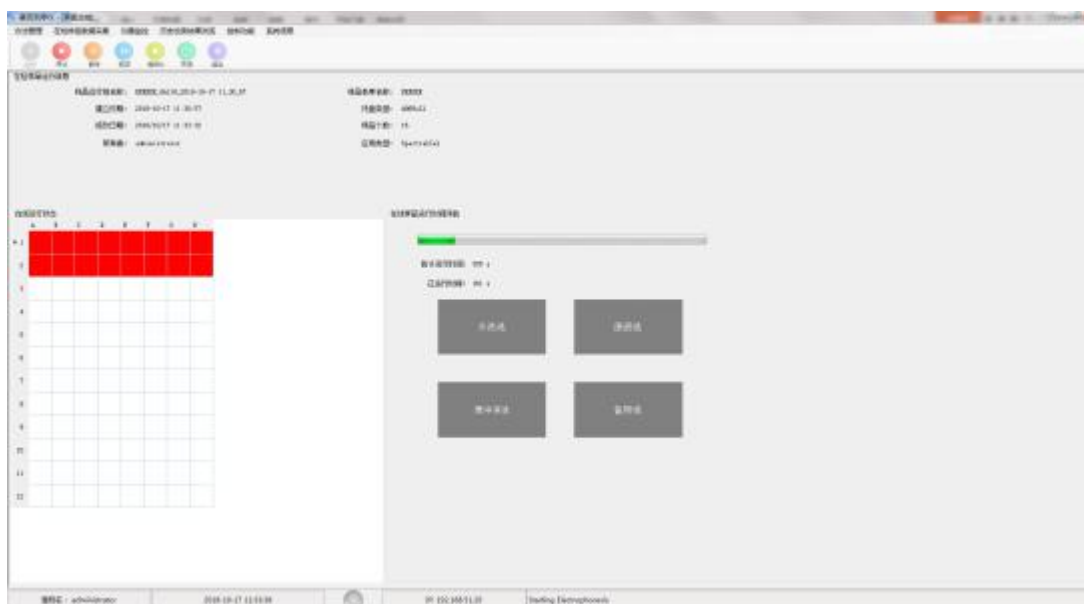


Figure 31. Dial Control

4.6.2 Electrophoresis Parameter Monitoring

Click "Current Sample Data Acquisition", "Electrophoresis Parameters" in the software menu in turn, so users can real-time monitor the parameters in the current electrophoresis process. As shown in Figure 32.



Figure 32. Monitoring of Electrophoresis Parameters

4.6.3 Records of Inspection Events

Click "Current Sample Data Acquisition", "Records of Inspection Events" in the software menu in turn, so users can know the events occurred during the running of the sample group, and the abnormal situation in the running process will be displayed

Click "Instrument Monitoring" , "Instrument Status" in the software menu in turn. The window will display the current serial number, gel number, name of the instrument, installation time, instrument type and the used times of capillary arrays in the "Instrument Status Overview" column. As shown in Figure 35.



Figure 35. Instrument Current Running Status

In the column of "State of Key Components", the operation parameters such as electrophoresis voltage, electrophoresis current, voltage set value, laser working time, laser power, pump position, oven temperature, laser temperature, detection window temperature and the state information of laser, high voltage power supply and insulated oven are displayed.

4.7 Historical Test Results Review

Click the sample running group to be browsed in the "Sample Run Group" and then information like the sample file name, the dial well position, etc. will display in column of "Sample Files of Sample Running Group" at the left of the interface. As shown in Figure 36.

Figure 37. Display of Fragment Analysis Map

In the window of "Base Map", drop down the "Select Channel" to select the dial wells and check the corresponding sequencing map and sequencing information, including base sequence and base mass numbers. As shown in Figure 38.



Figure 38. Base Map

4.8 Multi-Plate Operation

By following operations, a completed sample tray can be replaced during running operation or a new sample tray can be added to the unused sample tray tray.

- (1) Prepare the sample tray and create a sample form.
- (2) Click "Pause" button in the software command bar, and click "OK" in the pop-up dialog box.

Note: After clicking "Pause" button, the laser, optical valve and other equipment stop running except the insulated oven still works to keep the electrophoresis temperature. The electrophoresis voltage will be reduced to 0 KV and the current will be reduced to 0 A.

- (3) Press the "TRAY" button of the instrument panel to make the tray run to the left front. When the tray stops moving, the green indicator light of the instrument changes from flashing to constantly on. Open the front door of the instrument, remove the old sample tray, install a new sample tray; or directly install a new sample plate to an

unused sample tray.

(4) Close the front door of the instrument and wait for the green indicator light of the instrument changes from flashing to constantly on. The tray returns to its original position.

(5) Connect the running form to the corresponding sample tray.

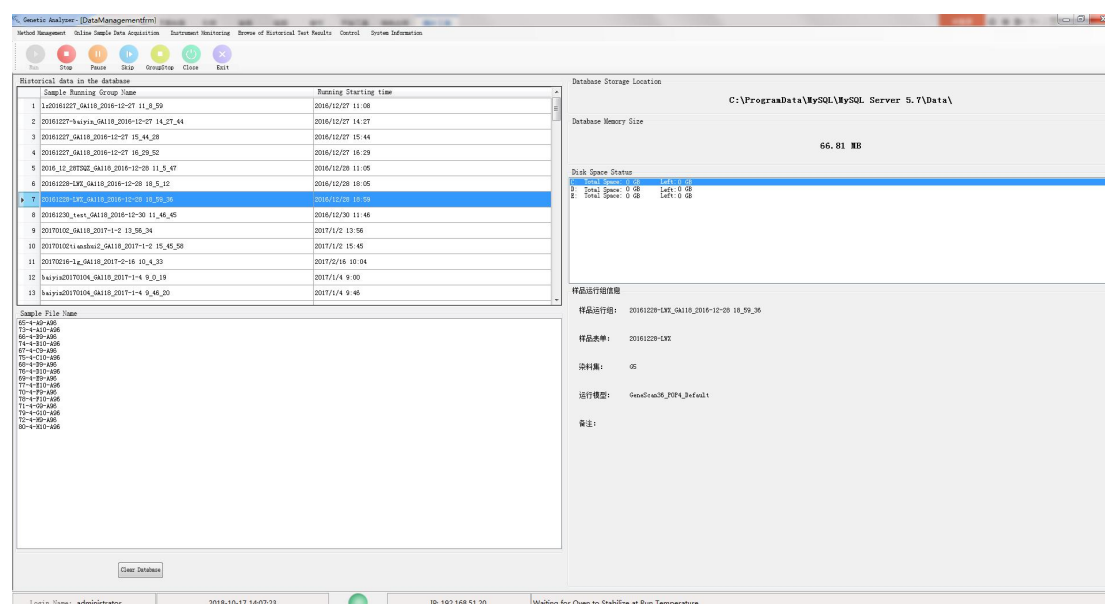
(6) Click "Continue" to run. After the current running sample form is completed, a new sample form continues to start running.

Note: In the process of setting up continuous running, the following issues need to be noted:

- ① When the instrument is suspended, only the sample tray can be installed or disassembled;
- ② It is better to create a sample form before suspending the instrument in order to improve the operating efficiency and shorten the suspension time.
- ③ After restarting, connect the new sample tray.

4.9 Database Management

Clicking "Method Management", "Database Management" in the software menu in turn, users can query the historical data, database type, database space status and corresponding sample operation group information of the database, and also can clean up the database. Figure 39.



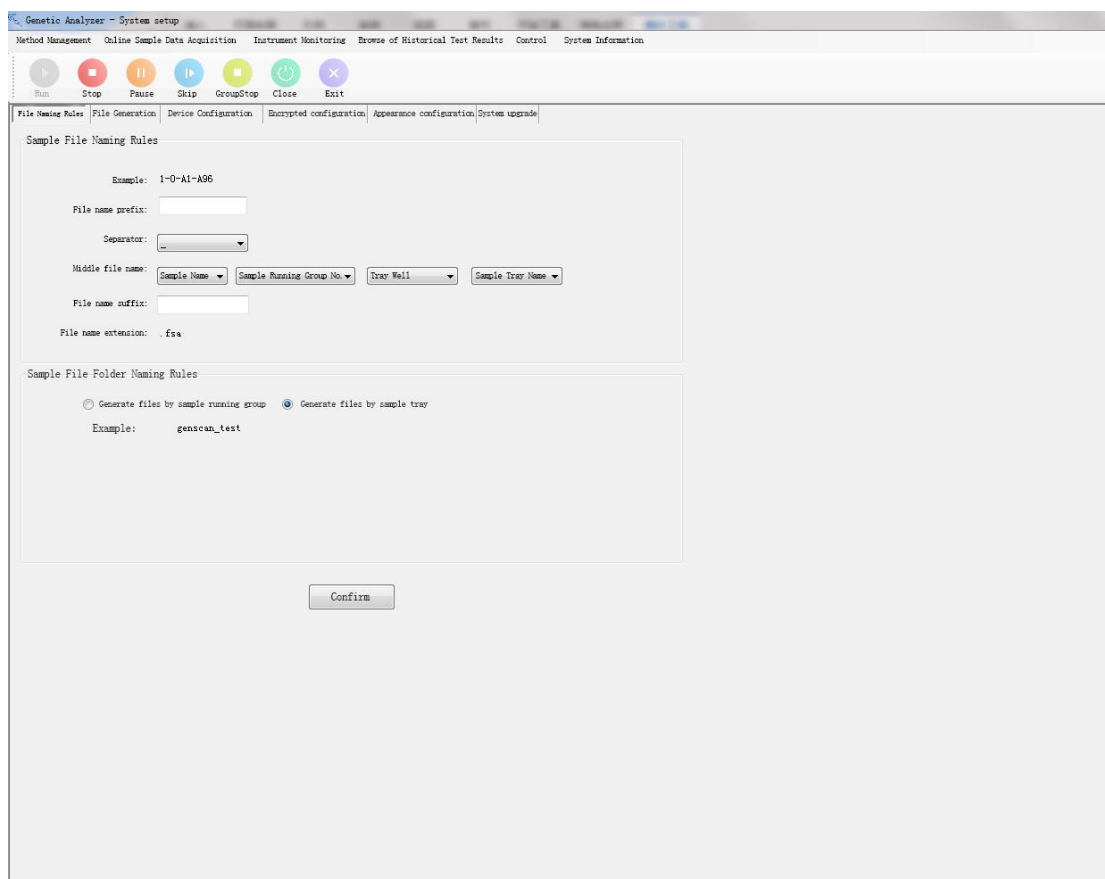


Figure 40 File Naming Rules

4.10.2 File Generation

Click "Method Management", "System Settings", "File Generation" in the software menu in turn which can set the file storage path, the information of file generation and the form of file generation. As shown in Figure 41.

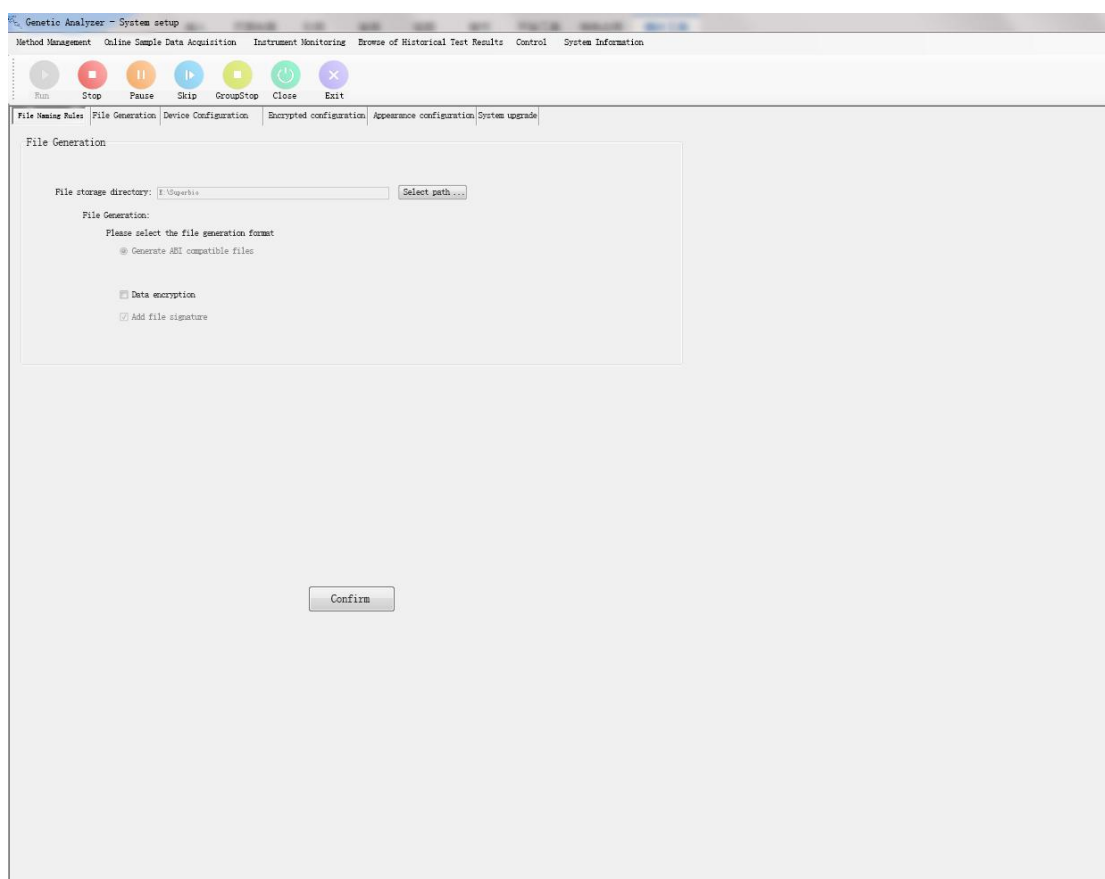


Figure 41. File Generation

4.10.3 Instrument Name

Click "Method Management", "System Settings", "Equipment Configuration" in the software menu in turn to query the relevant information of the instrument. Click "Edit" button to modify the information of the instrument, and click "OK" to save the modified contents. As shown in Figure 42.

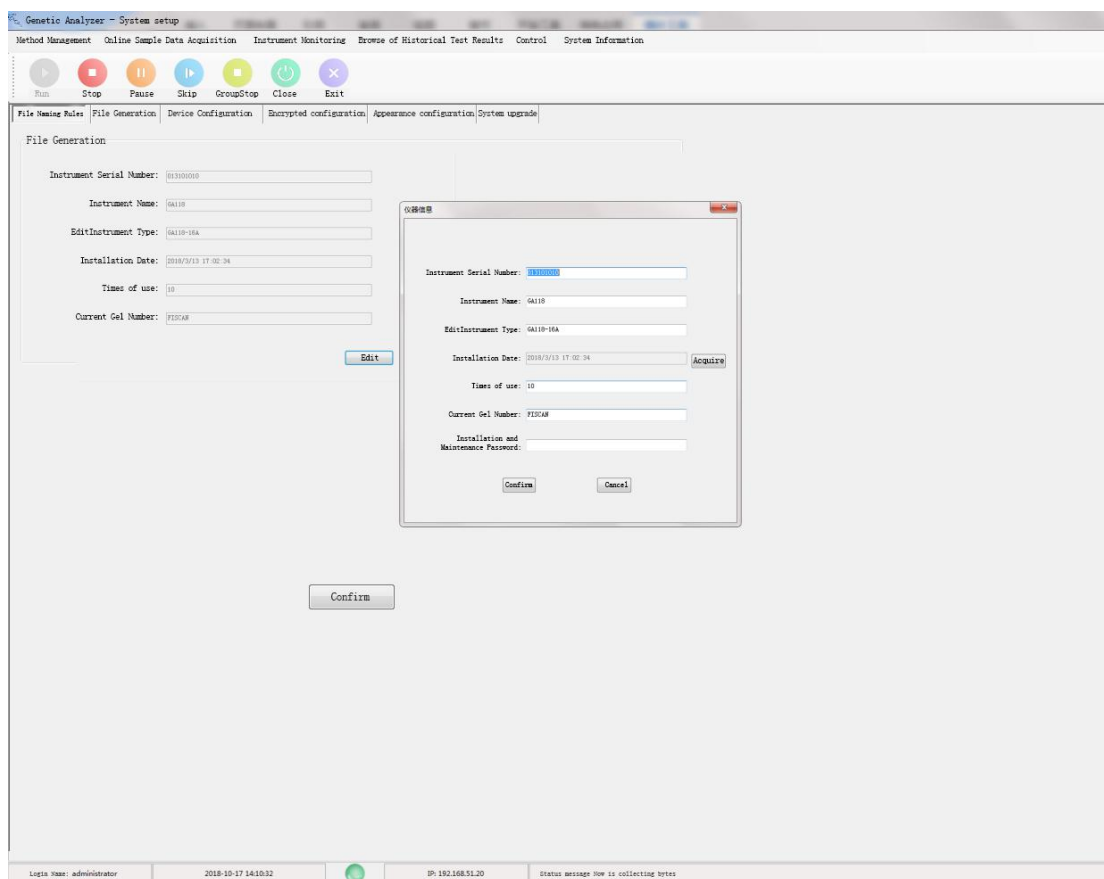


Figure 42. Instrument Name

4.11 User Management

User is classified into three levels: system manager, experimenter and general user. Managers can add or delete other users and set user's operation rights; experimenters and general users can only query the relevant information of user management; general users can also access the software and hardware maintenance operation interface of the instrument besides the rights of experimenters.

(1) Login the data acquisition software as an administrator, click "Method Management", "User Management" in the software menu in turn, and enter the "User Management Interface", as shown in Figure 43.

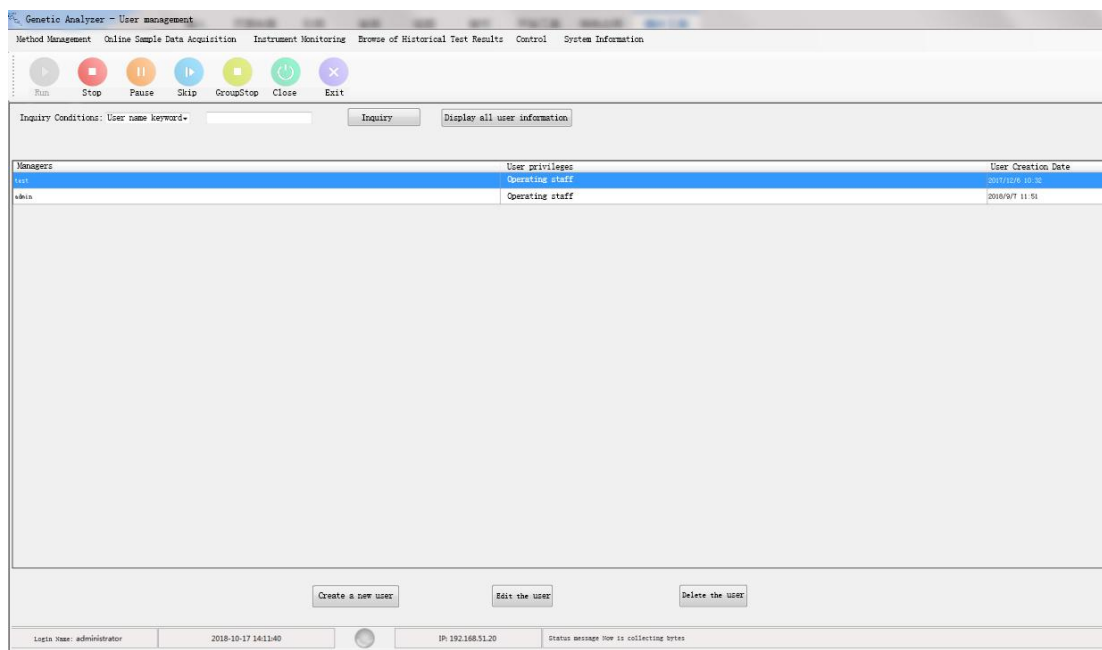


Figure 43. User Management for Managers

(2) Click "Create a New User" button at the lower left of the interface, enter the corresponding user code, user name, password and user rights in the pop-up dialog box, and click the "OK" button to add a new user, as shown in Figure 44.

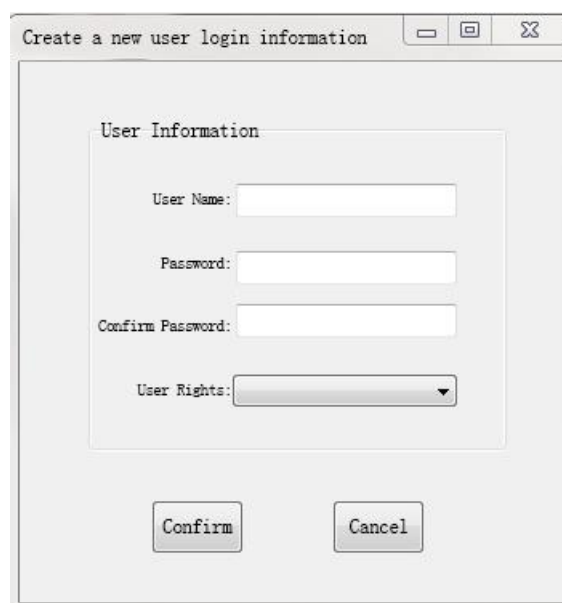


Figure 44. Create a New User

(3) On the "User Management" interface, click the user name which needs to be modified in the list, click "Edit the User" button in the lower left, modify the corresponding user name, password and user rights in the pop-up dialog box, and click "OK" button, then complete the modification, as shown in Figure 45.

The image shows a software window titled "Modify the user login information". Inside the window, there is a sub-section titled "User Information". This section contains four input fields: "User Name" (containing the text "test"), "Password", "Confirm Password", and "User Rights" (a dropdown menu currently showing "Operating staff"). Below these fields are two buttons: "Confirm" and "Cancel".

Figure 45. Edit the User

(4) On the "User Management" interface, click the user to be deleted from the list, click the "Delete the User" button at the lower left of the interface, and click the "OK" button in the pop-up dialog box to delete the selected user.

(5) Login the data acquisition software as experimenters or general users, click "Method Management", "User Management" in the software menu in turn which can check the relevant information of instrument users.

4.12 Manual Control

The instrument may need to be manually controlled during use. The specific operation steps are as follows:

(1) Click "Instrument Monitoring", "Manual Control" in the software menu in turn and the software interface pops up in which can be used to manually control electrophoresis, insulation furnace, laser, capillary gel injection, automatic sampling, etc.

(2) On the software interface, click the drop-down list of item names and select the name of the corresponding parts that need manual control, select commands in the "Task" drop-down list, and select the parameters or input the values according to the parameter information prompts. After confirming the correctness, click the "Execute" button to realize the corresponding control of the instrument.

4.13 Power-Off

- (1) Press the shut-down button at the upper right corner of the acquisition software and the dialog box of "Do you want to exit the program" pops up. Click the "Yes" button to close the main window;
- (2) Shut down;
- (3) Shut down the computer workstation;
- (4) Turn off the monitor;

Chapter V Warnings, Cautions and Notes

5.1 Cautions

(1) Under any circumstances, it is required to wait for the green indicator to stay continually on before pressing the “TRAY” button of the instrument, opening and closing doors, and performing software-related actions.

(2) Do not open the door when the instrument is running.

(3) When the Z-axis is too high during auto-sampler calibration, the protection mechanism will be triggered automatically and reset to zero. In this case, rise Z-axis again.

(4) If there is no special need, the Manual Control Interface is only used for rising the oven's temperature.

(5) Spectral calibration shall not be changed randomly in the process of fragment analysis.

(6) Clean the lower surface of the sealing mats with wet dust-free paper every three days, the capillary combs shall be cleaned at the same time.

(7) The black-and-white board and the sealing mats shall be placed evenly. Do not pull the mechanical arm by hand.

(8) Make sure the capillary is in the buffer before the end of every working day.

(9) Shut down the software and power off the computer before the end of every working day.

5.2 Potential Safety Hazards and Limitations

(1) Electric leakage of the host: if there is a host electric leakage, it may trigger the environmental leakage protection mechanism. The instrument with electric leakage is forbidden to be used, and the technical support department should be timely notified to test it till it passes the maintenance test before using again. Unauthorized use of malfunctioned instrument may cause electric shock to personnel who come into

contact with the product.

(2) Do not plug or unplug any live wire at any time. The instrument must be well-grounded.

(3) Frequent electric cut may seriously hamper the instrument's performance and reliability, lead to data loss or even instrument damage. Uninterruptible power supply (UPS) should be installed (this is optional depending on local user conditions, the company does not make mandatory requirements).

(4) Ensure that the power switch of the equipment is closed before switching on the power supply.

(5) The instrument shall use fuses with particular specifications.

(6) Read the User Guide carefully before use. Otherwise, the protection mechanism of the instrument may be damaged.

5.3 Response to Accidents

(1) Unable to start the host: failure with the "Start" button or wires.

(2) Red light flashing: restart.

5.4 Monitoring, Evaluating and Control Measures

(1) Check whether the insulation of the power cord is intact before use.

(2) Monitor whether the data displayed by the instrument is apparently abnormal.

If such situation occurs, please stop using the instrument, power off the instrument and report the instrument power failure to service staff in time.

5.5 Interference and Potential Hazards With Other Products During Use



Warning!

The user shall ensure the EMC environment of the instrument so that the

equipment can work normally.

The genetic analyzer conforms to the emission and anti-interference requirements stipulated by GB/T 18268.26:

(1) The instrument may cause radio interference at home, so protective measures should be taken.

(2) The EMC environment should be assessed before using the instrument.

(3) It is forbidden to use this instrument near a acute radiation source (such as non-shielded radio frequency source), otherwise it may interfere with the normal operation of the instrument.

(4) It is forbidden to use this equipment in a dry environment, especially in one with artificial materials (artificial fabrics, carpets, etc.), which may cause damaging electrostatic discharge and lead to incorrect testing result.

(5) If the equipment is not used as specified by the manufacturer, the protection mechanism of the instrument may be damaged.

5.6 Potential Adverse Events

N/A

5.7 Environmental Protection

The product belongs to the general medical device, the product itself will not produce environmental pollution during use. However, as the product and its accessories may cause pollution to the environment, it is recommended to use conventional disinfection treatment for the disposal of products after clinical use, and then destroy them according to the treatment of Waste Electrical and Electronic Equipment (WEEE).

Protective gloves and masks should be used during normal use and handling of potentially infectious materials (such as human samples or reagents) that may come into contact with the skin. Disposable accessories shall be treated as medical waste after use.

5.8 Installation and Assembling Instruction

5.8.1 Description of protective grounding

- A) Firmly hold the AC power cord when inserting or pulling it out of the socket;
- B) Do not insert or pull out the AC power cord plug with wet hands;
- C) Keep AC power cord away from heating equipment;
- D) If you do not use the instrument for a long time or damage it unintentionally, please power it off and pull out the power cord plug from the socket.

5.8.2 Ground bearing requirements

Ground bearing requirements: 140kg, the instrument should be placed on a platform with ground bearing capacity of at least this weight.

5.8.3 Weight of each major component

- (1) Optical module: 10Kg
- (2) Mechanical arm: 15Kg
- (3) Insulated oven: 6Kg
- (4) Polymer injection pump: 4Kg

5.8.4 Instructions on placement

- (1) There is a fan vent on the back of the instrument. Please place the instrument at least 10 ~ 15CM away from the wall and do not pile up things around.
- (2) Do not place the instrument in places with extreme temperature changes.
- (3) Do not place the instrument in a dusty place.
- (4) Do not place the instrument near electromagnetic equipment that generates magnetic field.
- (5) Do not place the instrument under direct sunlight.
- (6) Do not place the instrument in places where it is hard to disconnect and operate.
- (7) The instrument is well commissioned and placed by the technical support engineer. Do not move the instrument casually.

5.9 Warnings and Notes

5.9.1 General warnings

(1) Please read the User Guide carefully, understand the relevant matters needing attention and master the correct operation methods before proceeding with the operation.

(2) This product is a professional medical device. Untrained personnel are not allowed to use it.

(3) Please refer to Chapter VII for indications and contraindications of this instrument.

(4) Check whether the power supply is broken, the insulation layer cracked, scratched or other damage before use. Do not use if there is any damage.

5.9.2 Relevant warnings

(1) Wear dusty-free gloves when installing the capillary array and replacing the polymer, do not pull the capillary.

(2) Use the original packaging to store the used capillaries with the ends in the Cathode Buffer Container (CBC) and the vial respectively.

(3) Check whether there are bubbles in the polymer block and connection pipe every day when replacing it with a new one.

(4) Ensure good ventilation at the inlet and outlet at the bottom of the instrument, and clean the dust-free plate regularly.

Chapter VI Transportation and Storage

6.1 Transportation and Storage Conditions

(1) Shipment temperature: -40°C to $+55^{\circ}\text{C}$; relative humidity: no more than 80%; atmospheric pressure: 860hpa ~ 1060hpa; avoid direct sunlight, violent collision, rain and extrusion.

(2) Storage: the packaged products shall be stored at -40°C to $+55^{\circ}\text{C}$; relative humidity: no more than 80%; in a well-ventilated room free from corrosive substances.

Attention!

If the product is not used for a long time, it should be cleaned and placed in a dry and well-ventilated environment. It should be dust-proof and moisture-proof to prevent small animals from damaging the product.

6.2 Product Protection

(1) Please do not disassemble or modify the product casually, otherwise it may cause damage to the product.

(2) The product should not be exposed to the direct sunlight for a long time.

(3) Do not place the product in a dusty environment.

(4) Avoid extrusion, collision and falling-off.

(5) Shell and insulation layer of wires should be intact in case of electricity leakage.

Chapter VII Maintenance and Care

7.1 Use of Consumables and Accessories

(1) Polymer storage temperature is 2°C ~ 8°C, storage life is half a year, transport using ice bags to control temperature.

(2) Water: with electrical conductivity of 18.2 megohm

(3) Buffer: made by professional personnel

(4) Capillary: unused capillary should be stored in a dry place. Once used, both ends of the capillary should be immersed in water in case blockage of polymer residues inside.

7.2 Product Cleaning

(1) Dust accumulated on the surface of the product can be wiped and cleaned with dry flannelette.

(2) If there is any stain on the surface of the product, it can be cleaned with water or a mild cleaning agent for laboratory use.

(3) If there is any operational trace on the display screen, gently wipe it with wringing-out wet flannelette.

7.3 Services and Maintenance

(1) The product is a professional medical device, and the quality of the product conforms to relevant national standards. In order to ensure the security and effectiveness of the product, it is not recommended to disassemble, modify or repair the product casually.

(2) Due to the physical features of the product, the designed lifespan of the product does not mean that the lifespan of a certain device must exceed this time period. In case of any malfunction of the product, the manufacturer guarantees to undertake the maintenance work, and the materials and labor costs involved shall be implemented according to the terms regulated in the procurement contract.

(3) The inspection and replacement of all parts and components of the instrument must be conducted under the guidance of the maintenance engineer of the manufacturer. The original fuse protector used on the instrument is F10AL250V, which shall be replaced by the technical service engineer.

Table 2. Common Faults

Fault Description	Possible Reason	Solution
No signal	Fault in sample pre-treatment	Replace with a new sample.
	Bubbles in the sample plate	Centrifugation
Spectral Calibration Failure	Capillary blockage	Deliver polymer under the manual command, check whether there's fracture, inject the polymer again.
	Insufficient polymer in the capillary	Check whether there's fracture, inject the polymer again.
	Expired spectral correction samples	Check the quality guarantee period and storage conditions, and replace the samples with new batches if necessary.
Many other non-standard peaks	Expired polymer	Replace with a new polymer.
	Bubbles, especially in the polymer	Replace the polymer under Polymer-replacement Guidance; heat the polymer to room temperature before use; replace the expired polymer with a new one.
	Polymer contamination	Replace with a new sample.

7.4 Instrument Maintenance Instruction

7.4.1 The genetic analyzer should be disconnected during maintenance.

7.4.2 The consistency of the product should be kept in the maintenance process, and spare parts should not be replaced casually.

7.4.3 The protective covers which are allowed to contact laser exceeding radiation exposure limits ranging from Class 1 to Class 3B are 3569 mirror seat components, 3496 cover plate, 3498 mirror seat components, 3530 mirror seat components, 3512 mirror seat components, 3513 mirror seat components and base cover plate II.

7.4.4 When the instrument is out of service due to maintenance or treatment, take

down the capillary and encapsulate it with deionized water at both ends, then put it into a special packing box, and then take down the sample from the auto-sampler at the same time and store it in the refrigerator at -20°C. Watch out for hands stab by sample collection needles during transportation and maintenance.

7.4.5 If the equipment is out of use due to maintenance or treatment, please contact the after-sales service in time to avoid risks such as laser injury to eyes.

7.5 User Information

7.5.1 This product contains laser parts. It may cause eye injury if using optical instrument designed for remote observation (such as telescope and binoculars).

7.5.2 During maintenance, open the baffle (see Figure 46), and the laser emitted from the laser window is Class 3B Laser. Therefore, the maintenance personnel should wear protective glasses during maintenance. The wavelength is 505nm, the beam divergence angle is <1.2mrad, and the maximum power is 30mw.



Figure 46. Baffle

7.5.3 In addition to the introduction of this manual, the company also provides training in product use.

7.6 Daily Maintenance

Daily

Maintenance	Frequency
Make sure enough water and buffer in the container.	Before each operation
Confirm if the sample plate is correctly assembled. Note: the sealing mat must be aligned with the hole in the sample plate, otherwise the capillary will be damaged.	Before each operation
Confirm if the sample plate is firmly and smoothly fixed on the bracket.	Before each operation

Note: do not use bent sample plates.	
Replace the buffer and water in the container and confirm if the fringe of the container is dry.	Daily or before each operation
Check the gel pump, lower gel block connection pipe, gel tube and each passage. If there are bubbles inside, remove them with Bubble Remove Wizard.	Daily or before each operation
Check the sampling end of the capillary to confirm that it is not damaged.	Daily or before each operation
Check whether there's enough polymer in the bottle for the operation.	Daily or before each operation
Clean the surface of the instrument.	Daily
Check if there's polymer leakage in the bunch part of the capillary.	Daily
Check the amount of buffer in the Anode Buffer Container and make sure the overflow hole can flow freely and face the front of the instrument.	Daily

Weekly

Maintenance	Frequency
Change polymer via Polymer Change Wizard.	Weekly or if needed
Rinse the water seal ring.	Weekly or if needed

Monthly

Maintenance	Frequency
Run the Wash Wizard.	Monthly or if needed.

7.7 Lifespan of the Instrument

(1) The warranty period of the product is 2 years from the date of leaving the factory. Within 3 months after receiving and using the product, if the product is not working properly due to manufacturing quality problems, the company will repair or replace the product for clients free of charge. Regarding expired product or product

with non-responsible damages, maintenance fees will be charged in proportion to the situation of the product.

(2) The normal lifespan is 7 years.

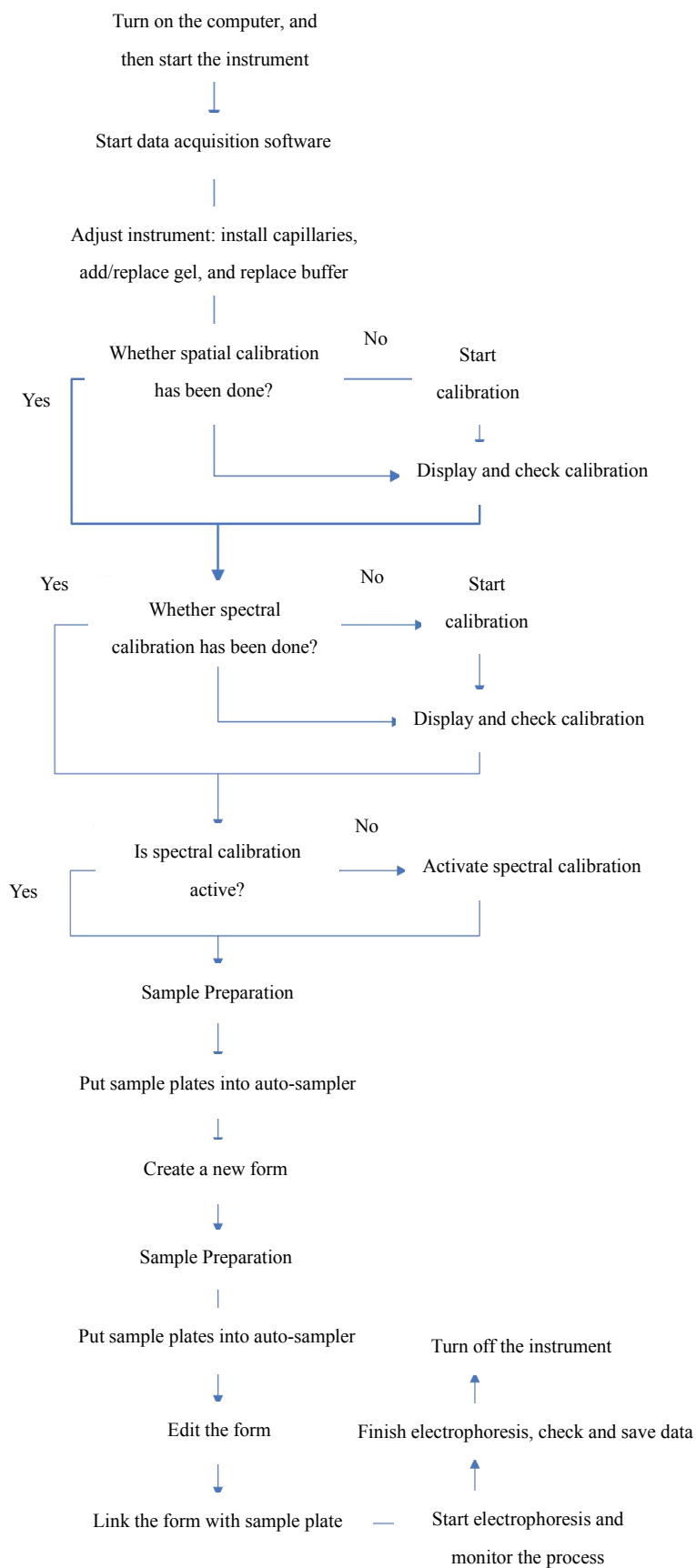
7.8 Compatible Reagents

Reagent types are classified by testing methods, which are mainly divided into capillary electrophoresis and fragment analysis. Among them, capillary electrophoresis uses B-raf Genetic Mutation Kit (NMPA Approval No. 20153401453), EGFR Genetic Mutation Kit (NMPA Approval No. 20153401131), etc. Fragment analysis uses CYP2C19 Genetic Testing Kit (NMPA Approval No. 20163400462), ALDH2 Genetic Testing Kit (NMPA Approval No. 20163400304), etc.

Annex 1 Basic Specification of the Instrument

1. Size: 812mm×610mm×532mm (L×W×H);
2. Weight: about 120 Kg;
3. Sampling method: auto-sampling, 96-well plates×2;
4. Polymer injection method: full-automatic;
5. Electrophoresis method: 16-channel capillary electrophoresis;
6. Electrophoresis conditions:
Electrophoresis temperature: 18°C ~ 65°C;
Electrophoresis voltage: 0KV ~ 15KV, tolerance:±2%.
7. Light excitation source: semi-conductor laser;
Dominant wavelength: 505nm;
Maximum output power: 30mW;
Beam-divergence angle: full angle <1.2rad;
Power supply: 220V AC, 50Hz, single-phase, 10A, 2200V.
8. Working Environment:
Temperature: 10°C ~ 30°C, tolerance: ±2°C;
Relative humidity: 40% ~ 60% (non-condensation);
Atmospheric pressure: 86k Pa ~ 106k Pa.

Annex 2 Overall Operation Workflow



Annex 3 Optional Parameters for Manual Control

Control Target	Task Name	Parameters
Control of Electrophoresis	Turn on/off power	On
		Off
	Set voltage value	Value between 1kV ~ 20kV
	Read voltage value	N/A
	Read current value	
	Set current value	Value between 10mA ~ 35mA
Control of insulated oven	Turn On/off insulated oven	On
		Off
	Set temperature	Value between 18°C ~ 65°C
	Read temperature	N/A
Control of Laser	Turn On/off laser valve	On
		Off
	Set Laser	On
		Off
	Set laser power value	Value between 1mW ~ 25mW
	Read laser power value	N/A
	Read set power value	N/A
	Read laser current value	N/A
Control of Polymer Injection	Reset polymer injection pump	N/A
	Turn On/off anode valve	On
		Off
	Set up the rising current and speed of polymer injection pump	2 numbers out of 1-1,000 with a blank space in between
	Set up the drop-out current and speed of polymer injection pump	2 numbers out of 1-1,000 with a blank space in between
	Set up the inhaling current and speed of polymer injection pump	2 numbers out of 1-1,000 with a blank space in between
Others	Check the version number of CCD Data Acquisition Board	N/A
	Check the version number of the Motion Control Board	N/A
	Check the version of CPU board	N/A
Control of	Reset auto-sampler	N/A

Auto-Sampler	Target the plate hole position	A: A1~H2 to A11~H12 B: A1~H2 to A11~H12
	Move auto-sampler	Buffer container
		Water wash container
		Back-up container
		Waste liquid container

Manufacturer: Nanjing Superyears Gene Technology Co., Ltd.

After-sales service provider: Nanjing Superyears Gene Technology Co., Ltd.

Registrant: Nanjing Superyears Gene Technology Co., Ltd.

Registration certificate number:

Production license number:

Technical requirement number:

Registered address: Room 1105, F11, Building 3-2B, No. 88 Pubin Avenue, Jiangpu Residential District, Pukou District, Nanjing, Jiangsu, China.

Production address: F11, Building 3-2B, No. 88 Pubin Avenue, Jiangpu Residential District, Pukou District, Nanjing, Jiangsu, China.

Tel: 4400-677-8378

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