

Lumilizer iA2000

Chemiluminescence Immunoassay Analyzer

User Manual

Bioartron Diagnostics Inc.



From Bioartron

Thank you for choosing **Lumilizer iA2000**, a Chemiluminescence Immunoassay Analyzer (the “**Analyzer**” or “**Instrument**”) proudly presented by **Bioartron Diagnostics Inc.** (“**Bioartron**”). Please read this user manual carefully for the instrument’s features and the instructions for its operational procedures before using. Please keep this manual for future reference.



This instrument is an in vitro diagnostic medical device (IVD) and it requires strict accordance with the operating instructions contained in this manual. Operators are required to participate in the relevant training organized by Bioartron before using the instrument.

About this manual

Disclaimer

Bioartron Diagnostics Inc. has made all efforts to ensure the information contained in this manual is correct and complete at the date of this issuance. Bioartron reserves the right to the modification of the product specifications and the right to change contents in this manual without prior notice as the technological and product development continues.

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Company Profile

Bioartron Diagnostics Inc., a Canadian leading IVD comprehensive solution provider who is dedicated to the development of world-class innovative bio-diagnostic technologies and to providing safer, quicker and more accurate testing solutions, is a biotech enterprise that integrates the total capabilities of R&D, manufacturing, marketing and technical supports for IVD instruments and reagents.

Bioartron's strong research and development force consists of a number of elite biotech professionals and the state-of-the-art R&D facilities. It also possesses a variety of intellectual property rights in the field of medical technologies. Over the past years, Bioartron has established a wide range of research strategic partnerships with many well-known global institutions.

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Chapter 1 Preface

Bioartron's Lumilizer iA2000 Chemiluminescence Immunoassay Analyzer, a fully automated in vitro diagnostics (IVD) analyzing instrument, is capable of conducting a variety of immunoassays for both qualitative and quantitative results. This analyzer includes its own interactive controlling interfaces to allow users to manage and operate tests and regular maintenance.

This manual contains detailed information of product label symbols, safety, intended use, system modules, operational and maintenance procedures.

Please follow the instructions in this manual to ensure safe operation of the system.




If the instrument is not used in the manners specified in the manual, the functions and safety features may be compromised.

Please keep this manual in a safe place.

This manual should be easy to access and ready for use.

Chapter 2 Symbols and Abbreviations

This manual uses the following symbols:

Symbols	
	<p>Attention!</p> <p>This symbol does not involve product safety, but it could affect the accuracy of the test results, the stability and the service life of the system.</p>
	<p>Warning!</p> <p>This symbol concerns product safety. Failure to follow the instructions may cause safety hazards.</p>
	<p>Biological hazards!</p> <p>This symbol is related to biological hazards. Failure to follow the instructions may cause environmental contamination or be harmful to the user's health.</p>

	Caution		Consult instructions for use
	<i>In vitro</i> diagnostic medical device		Temperature limit
	Manufacturer		Date of manufacture
	Protect from heat and radioactive sources		This way up
	Keep dry		Keep away from sunlight
	Fragile, handle with care		Do not roll
	Serial number		Do not stack
	CE Mark		Unique Device Identification
	Country of Manufacture		Model Number
	Importer		Distributor
	Authorized representative in the European Community / European Union		Biological risks




This manual uses the following abbreviations

Abbreviations	Definitions
Lumilizer iA2000	Lumilizer iA2000 Chemiluminescence Immunoassay Analyzer
the Manual	This User Manual
Bioartron	Bioartron Diagnostics Inc.

Chapter 3 Safety Information

3.1. Safety levels

This manual contains the information of the following three safety levels:

	Biological hazards
<p>Medical waste and possible biological hazards. Failure to follow the instructions may result in death, serious injury, or leakage of medical waste.</p>	
	Warning
<p>Indication of a potentially dangerous situation. Failure to follow the instructions may result in damages to the instrument which may lead to incorrect test results or injuries.</p>	
	Attention
<p>Notices regarding how to use the system properly, to ensure the accuracy of the test results, to avoid user's errors and to avoid the mitigation to the service life of the instrument.</p>	

3.2. Safety precaution information

The following precaution information is for the protection of the user's safety, the validity of the test results, and the proper use of the instrument. Users may suffer serious injuries if safety warning information is ignored.

3.2.1. Operator qualifications



Improper operation may lead to incorrect test results or damage to the instrument.

Operators should have relevant knowledge of clinical testing and should understand the principle of chemiluminescence immunoassay.

Operators are required to receive relative training from Bioartron before operating the instrument.

Operational guidelines and instructions in this manual regarding the system operation and regular maintenance should be followed.

If any operational malfunctions or any issues not contained in this manual occur, please contact Bioartron's customer service immediately and do not attempt to handle it without such consultation.

Please follow the requirements specified in Matrix 4.8 of the *Canadian Biosafety Standard (CBS)*, 2nd Edition to dispose of any waste liquid or used consumables from the instrument.

3.3. Installation and operational safety

3.3.1. Environmental conditions



Unqualified ambient humidity, temperature or cleanliness may lead to inaccurate test results or system damage

This product can only be used indoors.

3.3.2. Installation



Incorrect analysis results or analyzer damages due to improper installation

Please follow the installation instructions carefully. Please leave the installation work not described in the manual to professionally trained customer service engineers.

3.3.3. Handling and disposal



This instrument should be disinfected according to the requirements specified the *Canadian Biosafety Standard (CBS)*, 2nd Edition as it has direct contact with human blood.

This instrument is a potential medical hazard due to its direct contact with human blood. It should be strictly disinfected before being transferred, reused or disposed of. Special attentions should be paid to the disposal of this instrument. The disposal shall be conducted following the requirements specified in Matrix 4.8 of the *Canadian Biosafety Standard (CBS)*, 2nd Edition.

3.4. Operational safety

3.4.1. Electrical safety



General requirements

Please review the following safety notices to avoid injuries and to prevent damages to this instrument:

- To avoid potential hazards, standard operational procedures contained in this manual should be followed.
- The instrument is designed and tested to meet the IEC61010-1:2010 standards.
- The instrument is designed and tested to meet the requirements of electromagnetic compatibility of IEC61326-1:2012 and IEC61326-2-6:2012.
- Please read and follow all the safety items listed in this manual and closely follow the corresponding safety instructions and warnings in this manual.

Avoid electric shock, fire and injuries

- Unless otherwise specified in this manual, the operator should not remove any instrument cover or make contact with the power supply, circuits or wires inside the instrument when the power is on.
- Use only the power supply and cable specified for this instrument.
- Use the required power voltage. Before powering up, please make sure that the instrument is operating with the required power voltage specified in this manual.
- Instrument grounding. This instrument is grounded through the grounding conductor of the power cable. To avoid electric

shock, the grounding wire must be securely connected to the ground. Make sure the product is properly grounded before use.

- Do not operate the instrument if a malfunction is suspected. The operator should contact the designated service personnel for inspection.
- Keep the surface of the instrument clean and dry.
- The protective functions or the performance of the instrument may be compromised or failed if instructions in this manual are not followed.
- Do not use the instrument in a humid environment (ambient humidity greater than 70%).

3.4.2. Mechanical safety



Moving parts or mechanical movements could cause injuries

- The operator shall keep clear of all moving parts when the instrument is running, especially those critical parts which may have direct contact with samples or reagents, such as the sample needle, reagent needle and cleaning needle. Failure to do so may result in physical injury.
- When the instrument is running, the operator must not put fingers or any objects into the moving parts of the sample carousel, reaction carousel, reagent carousel, washing carousel or detection carousel, to avoid injuries or damage to the instrument.

- Unless otherwise specified in this manual, the operator should not remove any instrument covers, to avoid being cut by sharp parts inside the instrument.
- During the operation of the instrument, the transparent cover should be closed at all times.
- Operators should always wear gloves when using the instrument.

3.4.3. Power supply



Unstable power supply may cause instrument malfunctions or damages.

Unstable power supply voltage may cause damage to the instrument hardware, interruption of the operation, software failure, or data loss and etc.

3.4.4. Electromagnetic compatibility



- This instrument meets the emission and anti-interference requirements IEC61326-1:2012 and IEC61326-2-6:2012.
- This instrument is designed and tested under the standards of Class A device of IEC/CISPR 11:2010. In a domestic environment, this instrument may cause radio interference and protective measures may be required.
- This instrument is not allowed to be used next to strong radiation sources (such as RF sources without shields) which could interfere with its normal operation.

- the photoelectric detection devices in this instrument are very sensitive to electromagnetic interference. Please keep this instrument away from other electromagnetic devices or magnets.
- Manufacturer's statement and the user's statement regarding electromagnetic radiation:
 1. The manufacturer has the responsibility to provide to the customers/users the information of electromagnetic compatibility related to this instrument.
 2. The user has the responsibility to ensure this instrument is operated in a proper electromagnetic compatibility environment. An assessment of the electromagnetic compatibility environment is advised before using this instrument.

3.4.5. Replacing parts



The use of unauthorized or unqualified parts can cause instrument failure or detection errors

Please contact Bioartron customer service engineer when the instrument parts need replacement. Operators are not advised to conduct the replacement on their own or even with unauthorized parts. Unauthorized replacement will void the warranty of the instrument.

3.5. Safe handling of samples, reagents and waste

3.5.1. Sample pretreatment



Contaminated sample or incomplete stratification may lead to incorrect test results or needle clog.

- Samples should be centrifuged before testing to ensure no visible bubbles, blood clots or contaminants in the supernatant.
- Samples should not be exposed to air for extended period of time to avoid concentration errors caused by evaporation.
- To avoid sample spillage, please allow at least 10mm space in the sample vessel to full mark.

3.5.2. Use of reagents



Direct contact with reagents can be harmful to human body.

- The operator is required to wear gloves when handling the reagents to avoid direct contact.
- The reagents should be sealed and kept in the refrigerator for long use intervals to avoid any concentration error caused by evaporation.
- A small amount of reagents may remain in the used kits, cleaning treatment is required as per laboratory regulations.
- Please keep the substrates away from direct sunlight after opening.
- Substrates should be sealed and refrigerated after opening.

- Before placing the kit on the reagent carousel, please ensure that the bar code or label is clear to read with no condensation.

3.5.3. Treatment of liquid overflow



Bio-hazardous liquid contamination

- Contact with human samples may cause infection. All consumables and system components associated with human samples are potentially bio-hazardous.
- Liquid spillage on the surface or the inside of the instrument could cause instrument failure. Immediate sanitizing is required.
- If the sample makes contact with the skin, please wash and disinfect immediately, and consult a doctor.

3.5.4. Treatment of waste liquid and consumables



Waste liquid and consumables infections




- Direct contact with the waste liquid or disposables from the instrument could post risk of infection.
- When handling the waste liquid and consumables, protective measures are required, such as thick protective gloves, to avoid accidental cut and infection.
- The disposal of the waste liquids and consumables should follow the requirements specified in Matrix 4.8 of the *Canadian Biosafety Standard (CBS)*, 2nd Edition.

3.6. System safety symbols

For the safety of the operator and the stability and reliability of the instrument's operation, warning symbols are affixed to the relevant parts of the instrument. The specific positions and meanings are shown in the following table.

The safety symbols follow IEC60601 series standard.

If the symbol is damaged or unclear, please contact Bioartron customer service engineer for replacement.

	Attention This symbol indicates that there is safety matter related to operation. The user can find relevant information in this manual (within the specific chapter)
	Biological hazard warning This symbol indicates that there is a biological hazard in the vicinity and the user should follow the safety procedures for operation.
	Beware of electric shock This symbol indicates that there is a power supply in the vicinity and beware of the risk of electric shock.

Chapter 4 Instrument overview

4.1. The Instrument

Chemiluminescence Immunoassay Analyzer

4.2. Model

Lumilizer iA2000

4.3. Intended use

Bioartron's Lumilizer iA2000 Chemiluminescence Immunoassay Analyzer, a fully automated in vitro diagnostics (IVD) analyzing instrument, is capable of conducting a variety of immunoassays for both qualitative and quantitative results. This analyzer adopts the indirect chemiluminescence method based on AMPPD and alkaline phosphatase or horseradish peroxidase (HRP) catalyzed luminol and is used together with compatible detection reagents. It is clinically used for qualitative or quantitative detection of the analytes from human serum or plasma samples, including detection of myocardial markers, thyroid function, hypertension, tumor markers, novel coronavirus antibodies, and related items of infectious diseases.

The product is expected to be operated by personnel with basic knowledge of in vitro diagnostics after full training before operating the device.

The installation, maintenance and software upgrade of this product need to be completed by the Bioartron customer service engineer.

4.4. Product performance

4.4.1. Correctness and repeatability of sample loading

The minimum amount of device sample loading is 15 μ L and the maximum is

100 μ L; the minimum amount of reagent sample loading is 20 μ L and the maximum is 100 μ L.

Scope of correctness for sample loading at 15 μ L is: 13.5~16.5 μ L (10%), coefficient of variation (CV)% \leq 3.

Scope of correctness for sample loading at 20 μ L is: 18~22 μ L (5%), coefficient of variation (CV)% \leq 3.

Scope of correctness for sample loading at 100 μ L is: 95~105 μ L (5%), coefficient of variation (CV)% \leq 2.

4.4.2. Correctness and fluctuation of temperature control in the reaction zone

The temperature of the reaction zone should be within 37 $^{\circ}$ C \pm 0.5 $^{\circ}$ C, and the fluctuation should not exceed 0.5 $^{\circ}$ C.

4.4.3. Device noise

The background maximum luminous value (RLU) should be \leq 100.

4.4.4. Linearity of luminous value

In the range of not less than 3 luminous value orders, the linear correlation coefficient (r) should be \geq 0.99.

4.4.5. Repeatability of luminous value

Using the luminescent agent method, the coefficient of variation (CV) should be \leq 5%

4.4.6. Stability of luminous value

Using the luminescent agent method, the relative bias between the test results at the 4th hour and the 8th hour after the instrument is stably working and the test

results taken at the initial phase after the instrument is stably working should be not more than $\pm 10\%$.

4.4.7. Carryover rate

The carryover rate should be $\leq 10^{-5}$. For analyzers that can only report qualitative test results, test negative samples after testing high-concentration positive samples. The negative samples cannot be tested as positive.

4.5. Structural composition

The instrument consists of sample carousel module, reagent carousel module, sample arm and reagent arm module, reaction carousel module, loading module, transfer arm module, washing module, detection carousel module, substrate module, indicators and etc..

4.6. Contraindications

Not found yet.

4.7. Basic principles

Chemiluminescent immunoassay (CLIA) is to combine chemiluminescent substances with immunological reactions and use light reactions to express the concentration of the measured immune components, that is, the technology to combine high-sensitivity light reactions with specific immunological reactions.

Chemiluminescence immunoassay is a new analysis method that combines chemiluminescence analysis method, magnetic separation technology and enzyme immunoassay method. It takes advantage of the high sensitivity of the chemiluminescence analysis method, the rapid and easy automation of the magnetic separation method, and the extremely high specificity of the immunoassay method. It has broad application prospects in clinical immunoassays. Chemiluminescence immunoassay is a third-generation immunoassay technology. Because it has increased the level of ultramicro-

analysis by an order of magnitude, it has received much attention in clinical testing. It is not only widely used in clinical hepatitis, diabetes, infectious diseases, allergens, and anemia, etc., but also applied to non-clinical fields such as veterinary drugs, pesticide residues, stimulant detection, and environmental analysis. Effectively labeling chemiluminescent substances to antigens or antibodies is the key to the success of chemiluminescence immunoassay technology.

This system uses magnetic particles as a carrier in chemiluminescence immunoassay, by detecting emission strength of the analyte (antigen, antibody) catalyzing the substrate, to calculate the concentration of the analyte.

The principle of chemiluminescence immunoassay is as follows:

1. Make the antigen or antibody bind to the surface of a certain solid-phase carrier and maintain its immunological activity.
2. Connect the antigen or antibody with a certain enzyme to form an enzyme-labeled antigen or antibody. This enzyme-labeled antigen or antibody retains both its immune activity and enzyme activity.
3. After washing, add the luminescent substrate, the enzyme causes the luminescent substrate to emit light, and the number of photons is detected by special equipment, so as to calculate the concentration of unknown antigen or antibody.

Chapter 5 Product description

5.1. Instrument rating

Voltage: AC 100-240V

Frequency: 50/60Hz

Power: 1500VA

Use environment: indoor use, room temperature (10-30°C), humidity (30-70%Rh).

Air pressure: 85.0 kPa-106.0 kPa

Measurements: 1210 mm X 664 mm X 749 mm

(length) × (width) × (height)

Weight: 150 Kg

5.2. Connection and installation

1. Please ensure that the power outlet is grounded and has good connection.
2. The instrument should be placed on a flat and sturdy table with no obvious shaking. In case a universal wheeled table is used, please ensure that the wheels are locked before using the instrument.
3. The main control board is located at the back of the instrument. At least 50 cm of space (back and side) is recommended for heat dissipation and for engineers to examine the instrument when needed.
4. This instrument is a precision electronic instrument. Please keep it away from anything that may interfere with the normal operation of the instrument, such as direct sunlight, washing sinks, doorways, or places directly under air-conditioning.
5. Connect communication cable to the serial port of the computer and communication port. Secure the screws on both sides. As shown in Figure 5.2.1 and Figure 5.2.2:



Figure 5.2.1 Communication port



Figure 5.2.2 Communication port on computer

6. A built-in fuse is located under the power line switch. It fuses automatically when the current is overloaded, cuts off the power supply and protects the instrument. If there is a fault with the fuse, please replace the fuse after eliminating the fault. The fuse must be replaced according to rated characteristics.
7. Before the instrument is powered on, engineers and laboratory personnel shall ensure that the fixtures of the instrument are completely removed, and there are no other blockings in the range of the sampling needle, loading arm, transfer arm and cleaning carousel.
8. Clean the connecting pipelines. The washing pipeline shall be connected to the washing bucket and the waste pipeline shall be connected to the waste bucket, as shown in Figure. 5.2.3.



Figure 5.2.3 Pipeline connection

Note: A filter locates at the end of the washing pipeline. It requires regular check-up and replacement.

5.3. Validity period

The validity period for the instrument is 5 years under normal circumstances. Bioartron customer service engineer shall evaluate the remaining service life of the instrument through a thorough inspection to the instrument and provide an assessment report when the validity period ends. If the assessment determines that the instrument is no longer suitable to perform, it shall be immediately discarded. If the assessment determines otherwise, the instrument shall receive a full-scale service and examination before it continues to serve.

5.4. Computer precautions

1. Only the software provided by Bioartron should be used to avoid computer virus.
2. Do not change the date and time of the computer while the analyzer is running, otherwise it will affect the processing of error messages.
3. Only the user software and hardware protocol written by Bioartron for the analyzer can be used to control the instrument.

5.5. Carryover contamination prevention

Prevention of carryover contamination is important.

Carryover contamination could occur during the operation. The operator should adopt the following measures and steps to minimize the chance of carryover contamination:

1. Conduct daily check-ups and maintenance of the instrument. The operator should focus on regular maintenance of the sample loading system. The needle tips should be cleaned with 75% alcohol after the processing of each batch of samples. The operator shall not replace the needles on his own as Bioartron will not be responsible for any

problems derived from this matter.

2. If there is observation of increased carryover contamination after using for a period of time, please perform pipeline maintenance immediately.

It is a four-step service:

- i. Wash the pipeline 10 times with acidic solution;
- ii. Wash the pipeline 10 times with alkaline solution;
- iii. Wash with neutral solution, and
- iv. wash with distilled water.

The service shall be conducted under the guidance of a Bioartron engineer. Regular services are required every three months.

3. The operator should use the specialized neutral wash solution for the needles provided by Bioartron.

5.6. Accuracy deviation

The analyzer may have deviations in the accuracy of the test results. If a weak positive sample is identified immediately after a positive sample, it must be retested to verify the accuracy of the test result.

5.7. Warranty

Bioartron's warranty to this instrument includes free recoveries of any failures in the materials and performance quality of this instrument within 12 months after manufacturing date.

Any defects of the instrument discovered under proven normal operations which follow manufacturer's guidelines within warranty period shall be fixed or replaced by Bioartron or its authorized representatives free of charge.

Bioartron is not responsible for any accidents or any damages caused.

Bioartron's warranty to the accessories and consumables only valid on the quality of the materials when they are delivered and used.

Bioartron's warranty does not cover issues caused by the following:

1. Operation not following the instructions in this user manual.
2. The lack of regular and proper maintenance.
3. Unauthorized maintenance, repair or improvement of the instrument.
4. Unauthorized or unqualified parts used.
5. Unauthorized change of parts and components.
6. Return of the instrument without the original packaging from Bioartron.

Bioartron reserves the right to refuse to accept any products that are used along with microorganisms or radioactive materials or any other materials that are considered hazardous to Bioartron's employees. Such products should be properly disinfected and labeled.

5.8. Calibration

The instrument should be calibrated by Bioartron engineers after the initial setup. Regular calibrations should be conducted afterwards according to the time specified in the service agreement.

5.9. Packaging, transportation, and storage

5.9.1. Packaging

Product packaging should meet the following requirements:

1. The accessories and accompanying documents should be with the instrument, in separate packs.
2. The outer packaging should be strong enough to protect the instrument from mechanical and natural damages.
3. The accompanying documents should include this user manual and the packing list.
4. The outer packaging should be marked with labels specified in ISO 780:2015.

5.9.2. Transportation

Transportation should follow the requirements stipulated in the purchasing agreement.

5.9.3. Storage

The packed instrument should be stored at a well-ventilated environment of temperature ranging from -40°C to 55°C , the relative humidity not exceeding 80% and without corrosive gas.

Chapter 6 The instrument modules

6.1. Overall introduction

The instrument consists of sample carousel module, reagent carousel module, sample arm and reagent arm module, reaction carousel module, loading module, transfer arm module, washing module, substrates module, detection carousel module, and indicators, as shown in Figure 6.1.1:



Figure 6.1.1 Bioartron Lumilizer iA2000

6.2. The modules

6.2.1. Sample carousel module

The sample carousel is located on the left side of the instrument. There are 6 sample racks on the outer ring of the reagent carousel, each can hold up to 10 sample vessels. Sample types can be serum, plasma, calibrators and quality

controls. The applicable types of vessel include blood collection vessel, centrifugal vessel, micro cup and standard cup, as shown in Figure 6.2.1.

Note: the blood collection vessels should be fully inserted in the rack, otherwise it may collide with the instrument due to its height.



Figure 6.2.1 Sample rack and sample vessels

6.2.2. Reagent carousel module

The reagent carousel is located on the left side of the instrument. It consists of 18 groups of magnetic particle reagent bottle racks. Each reagent bottle rack has 2 reagent bottles and 1 magnetic particle bottle. The reagent bottle 1 (R1) is in the outer ring, and the reagent bottle 2 (R2) is in the middle. The magnetic particle bottle is in the inner ring. The reagent carousel has the cooling function to maintain the constant temperature generally at the level of 2-8° C, as shown in Figure 6.2.2.

Note:

- (1) The reagent carousel stops refrigerating after the instrument is powered off / the software is shut down. Hence, after the instrument is powered off, the reagent bottle should be removed, closed and kept in the refrigerator.
- (2) The reagent carousel cover should keep closed at all times except for necessary short intervals as refrigeration needs a relatively sealed environment.
- (3) Please load the reagents in the designated positions matching the set order in

the computer.

- (4) Please ensure that the reagent carousel cover is closed properly before the instrument operates in order to avoid needle collision by mistake.
- (5) The reagent carousel has a barcode scanning function. Please refer to 8.4.2 **Register reagent by barcode scanning** for details.
- (6) The reagent carousel cover has a monitoring function. Do not attempt to open the cover during the test. Opening the reagent carousel cover during the test may cause instrument malfunction.



Figure 6.2.2 Reagent carousel and reagent bottles

6.2.3. Sample arm and reagent arm module

The loading of the samples, reagents and magnetic particles are done through the loading needles on the sample arm and reagent arm. These collision-proof needles are equipped with clot detection function and liquid level detection function. Please see Figure 6.2.3,

Note:

- (1) Sample arm is a precision component, please do not block or leave any objects in the area when the instrument is in operation.
- (2) The needles require standardized service and maintenance after the operation to avoid clogs formed in the needles.
- (3) Please gently shake the magnetic particles bottle before loading.



Figure 6.2.3 Sample arm and reagent arm

6.2.4. Reaction carousel module

Reaction carousel is located at the centre of the instrument. It consists of 90 independent reaction vessel slots. The reaction carousel cover has 4 small circular openings for adding samples, adding reagents, loading reaction vessels and grabbing reaction vessels respectively. The reaction carousel provides a 37°C constant temperature incubation environment for sample and reagent reactions. The computer displays the reaction vessel incubation temperature in real time. Please see Figure 6.2.4.

Note:

- (1) After an emergency shut down, when the instrument reboots, any reaction vessels left in the reaction carousel will be automatically caught and disposed of during the initializing process.
- (2) Please ensure that the reaction carousel cover is closed properly before the instrument operates to avoid needle collision.



Figure 6.2.4 Reaction carousel

6.2.5. Loading module

The loading module is located at the centre of the instrument. It consists of a grabbing arm and 4 reaction vessel racks. The grabbing arm puts the reaction vessels into the reaction carousel. Each reaction vessel rack can hold up to 96 reaction vessels. Please see Figure 6.2.5.

Note:

- (1) Reaction vessel loading starts from the far-right position of the reaction vessel rack;
- (2) The instrument will automatically switch the reaction vessel racks in sequential order once the previous rack is done. After all racks are finished, an alert of empty consumables will appear. The computer will pause the action of loading samples.

In order to reload the consumables, please follow the below steps:

- Click **Start-up** in the function controls column
 - Click **Add Consumables**
 - Click **Add**. The consumables can be reloaded now.
 - After reloading, click **Finish adding**.
 - Set the serial number to 0 in the **Serial number mode**
 - Click **Start**, the operation will continue;
 - In the **Barcode mode**, set either the rack number or position number to 0, then click **Start**, the operation will continue.
- (3) If the grabbing arm fails to capture in one position, it will automatically jump to the next position;
 - (4) Note that the reaction vessel racks should be placed perfectly in position.

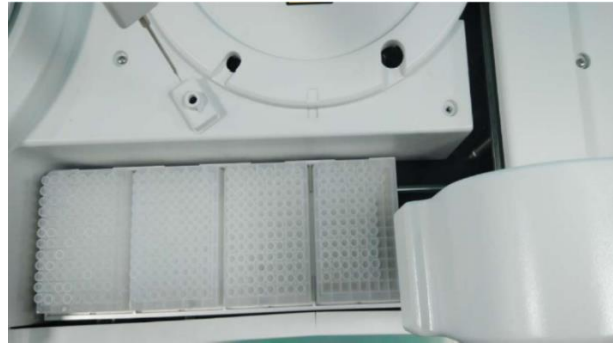


Figure 6.2.5 Loading module

6.2.6. Transfer arm module

The transfer arm places the reaction vessels into the washing carousel, reaction carousel and detection carousel. Please see Figure 6.2.6.



Figure 6.2.6 Transfer arm module

6.2.7. Washing module

The washing carousel consists of 4 sets of independent needles, including suction needle, injection needle, magnetic particle mixing and substrate needles. The substrate needle contains three channels: Substrates A, B and C for test items that require different substrates. Please see Figure 6.2.7.

Note:

- (1) Washing carousel requires regular maintenance;
- (2) Immediate service is required when crystallization is detected in washing needle.
- (3) Keep away from electromagnet.



Figure. 6.2.7 Washing carousel and substrate needle

6.2.8. Detection carousel module

The detection carousel consists of a rotation device and a detection device.
Please see Figure 6.2.8.1

Note:

- (1) Do not open the detection carousel;
- (2) Do not attempt to remove the reaction vessels when the detection carousel is in operation to avoid potential finger injuries.
- (3) Keep away from direct sunlight.



Figure.6.2.8.1 Detection carousel

The waste bucket is to collect the used reaction vessels and waste substrate. Please see Figure 6.2.8.2.



Figure 6.2.8.2 Waste bucket

Note:

- (1) The maximum capacity of the waste bucket is about 500 reaction vessels. Please empty the waste bucket frequently to avoid any potential failures or damages to the instrument;
- (2) Medical waste must be properly disposed of following the requirements specified in Matrix 4.8 of the *Canadian Biosafety Standard (CBS)*, 2nd Edition;

- (3) Waste buckets should be sanitized regularly.

6.2.9. Substrate module

The substrate module consists of 4 bottle slots for Substrates A, B, and C. Please see Figure 6.2.9,

Note:

- (1) Substrate bottles provided by Bioartron are required to ensure reliable test results;
- (2) Substrate bottles should be handled gently and the caps should be securely locked to prevent air suction which may lead to inaccurate test results.



Figure. 6.2.9 Substrate bottles

6.2.10. Pipeline module

The pipeline module consists of one wash buffer pipeline and two waste liquid pipelines. A filtering device is located in the wash buffer pipeline.

The wash buffer container, as shown in Figure 6.2.10.1, has a liquid level alarm function. When the wash buffer in the container is lower than the minimum level, an alarm will be triggered. Wash buffer should be refilled immediately upon alarm to avoid invalid test results. The liquid level sensor cable and the wash buffer pipeline should be properly connected to the instrument before use. A Bioartron Automatic Refiller, which will ensure the refilling of the pre-treated wash buffer when needed, is optional for purchase.

The waste liquid container, as shown in Figure 6.2.10.2, has a liquid level alarm function. When the waste liquid in the container is higher than the maximum

level, an alarm will be triggered. Waste liquid should be disposed of immediately to avoid overflow. The liquid level sensor cable and the two waste liquid pipelines should be properly connected to the instrument before use. The automatic drainage pump will drain the waste liquid regularly.



Figure. 6.2.10.1 Wash buffer container



Figure 6.2.10. 2 Waste liquid container

Note:

- (1) Regular replacement of the wash buffer filter is recommended on a monthly basis;
- (2) Please ensure no clog in the waste liquid pipelines after the waste liquid pipelines are connected.

6.2.11. Indicators

Three indicators are located at the front side of the instrument, as shown in Figure 6.2.11. The **Power** indicator turns **red** when the instrument is powered on;

the **Run** indicator turns **green** when the instrument is initializing, in maintenance status, or in operation status; the **Error** indicator turns **yellow** and is accompanied by an alarm when instrument failures occur.



Figure. 6.2.11 Indicators

Chapter 7 System requirements and software Installation

7.1. System requirements

1. Windows 7 SP1, 64-bit / Windows 10 or higher is required.
2. Microsoft Office 2010 or higher.
3. MySQL 5.7 64-bit or higher.

7.2. Software installation

1. Double-click to install the program and the installation wizard appears. Click **Next** to proceed to the next step. To exit please click **Cancel**.
2. Click **Browse** to confirm the installation location and click **Install**. To exit please click **Cancel**.
Note: Please use the default installation location.
3. After confirming the installation, a dialog box pops up, please check the **I agree to the license terms and conditions** box then click **Install**.
4. Operating environment set up is completed.
5. Click **Close** and then **Finish** to complete the installation of the Lumilizer iA2000 program.

Chapter 8 Software functions

8.1. Start up

Double-click the Lumilizer iA2000 program icon on the desktop, as shown in Figure 8.1.1, to start the program. The user login interface is shown in Figure 8.1.2:



Figure 8.1.1 Program icon



Figure. 8.1.2 User login

Note: Initial user name: **Admin**; initial password: **0000**

Please input the user's name and the password then click **Login** to initialize the program. The main interface will show after initializing.

8.2. The main interface

The main interface, as shown in Figure 8.2.1, will appear after the log-in:

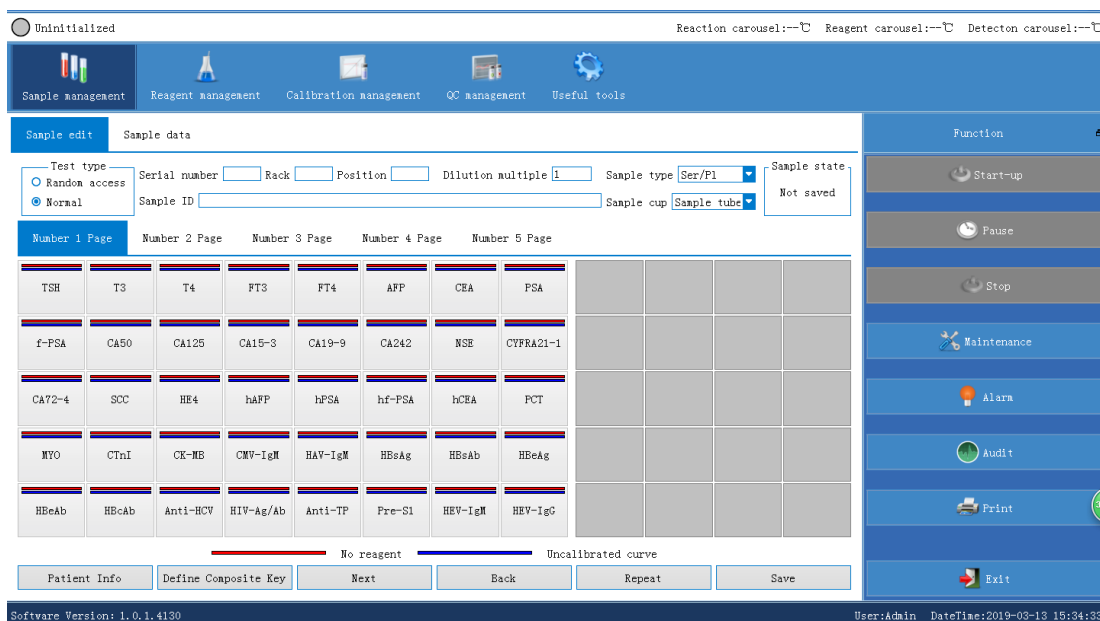


Figure 8.2.1 The main interface

The main interface includes the following sections:

- 1) Title bar
 - 2) Status
 - 3) Toolbar
 - 4) Function controls
 - 5) System info
 - 6) Main info display
1. Title bar

The title bar contains the company and product information and a **Help** button. Detailed info will show as Figure 8.2.2 after clicking **Help**:

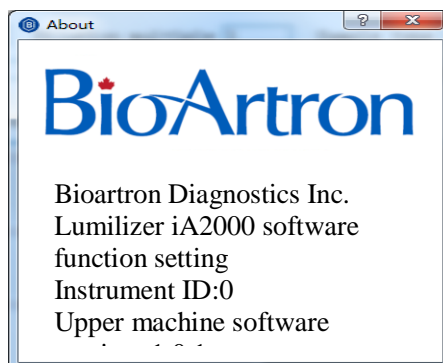


Figure. 8.2.2 Instrument related information

2. Status





The status section displays the current status and the real-time temperatures of the instrument.




- (1) The status is illustrated by indicators in various colours and the corresponding text. An example is shown in Figure 8.2.3:



Figure. 8.2.3 Ready status

Detailed description of all status is shown as below:

Status	Colours of the indicator	Description
Uninitialized		The instrument has not been initialized. No test and maintenance could be performed under this status until it is initialized.
Ready		The instrument is ready for operation now.
Run		The instrument is running (includes initializing, testing and in maintenance). The operator cannot enable other functions or override to operate the instrument now.
Pause	 In test (sample loading paused)	The instrument is in pause. The operator cannot enable other functions now.

Stop		The instrument stops running. No testing or maintenance can be enabled until initializing is finished.
Abnormal		Abnormal situations occur to the instrument. No testing or maintenance can be enabled until initializing is finished.
Sleep		The instrument is in sleep mode.

(2) The real-time temperatures include:

- Temperature of the reaction carousel
- Temperature of the reagent carousel
- Temperature of the detection carousel.

(3) If the temperature of the instrument is slightly over the limits, the colour of the text turns purple; if the temperature is significantly over the limits, the colour of the text turns red, and the alarm module will indicate that the temperature is abnormal.

3. Toolbar

The toolbar displays tool selections for the operator to switch between different interfaces, including **Sample management**, **Reagent management**, **Calibration management**, **QC management**, and **Useful tools**, as shown in Figure 8.2.4:



Figure. 8.2.4 Toolbar

4. Function controls

A list of the key function controls of the instrument is displayed, including **Start-up**, **Pause**, **Stop**, **Maintenance**, **Alarm**, **Monitoring**, **Print** and **Exit**, as shown in Figure 8.2.5:

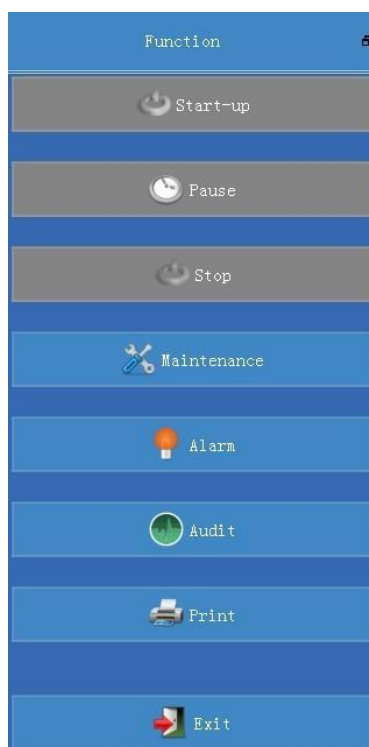


Figure. 8.2.5 Function controls

- **Start-up** is to start the test, including the replacement of the sample rack and the refill of the consumables.
- **Pause** is to pause the operation.
- **Maintenance** switches the interface to the maintenance procedures.
- **Alarm** is to view the messages of the alerts.
- **Monitoring** is for the real-time monitoring of the sample status.
- **Print** is to print out the sample information.
- **Stop** is to stop the testing. In case of any abnormal situation in the instrument, click **Stop** to terminate the operation.
- **Exit** is to exit the program.
 - ✧ Click **Exit**, a dialogue box will pop up, as shown in Figure 8.2.6.
 - ✧ Click **OK**, the shutdown progress will be enabled and the it will exit upon completion, as shown in Figure 8.2.7:



Figure. 8.2.6 Exit the system

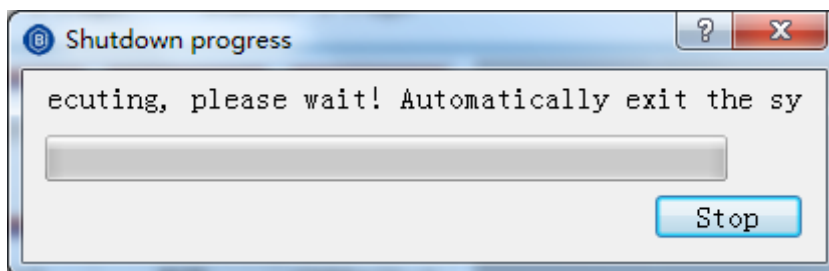


Figure. 8.2.7 Shutdown progress

5. System info

Information such as software version, user name and system time are displayed in this section.

6. Main info display

The operator can choose to view the key info of the test items in different pages.

8.3. Sample management

The sample management module is for the management and maintenance of sample information. It consists of sample editing section and sample data section.

The sample editing section handles the preservation of sample data, the repeated addition of sample items, the preservation of combination keys, the viewing of sample information, and the input of patient information.

The sample data section handles the search of sample data, the retesting of samples, the deletion of samples, the backup of sample information, the editing of test results, the editing of dilution multiple, the search of historical information, the recalculation of test results, the export of sample information and the uploading of sample data.

The functions of these two sections can be enabled in serial number mode and barcode mode, respectively.

8.3.1. Serial number mode

The serial number mode is the default mode of the system.

- Select **Sample edit** under **Sample management**. The serial number mode interface is shown in Figure 8.3.1.

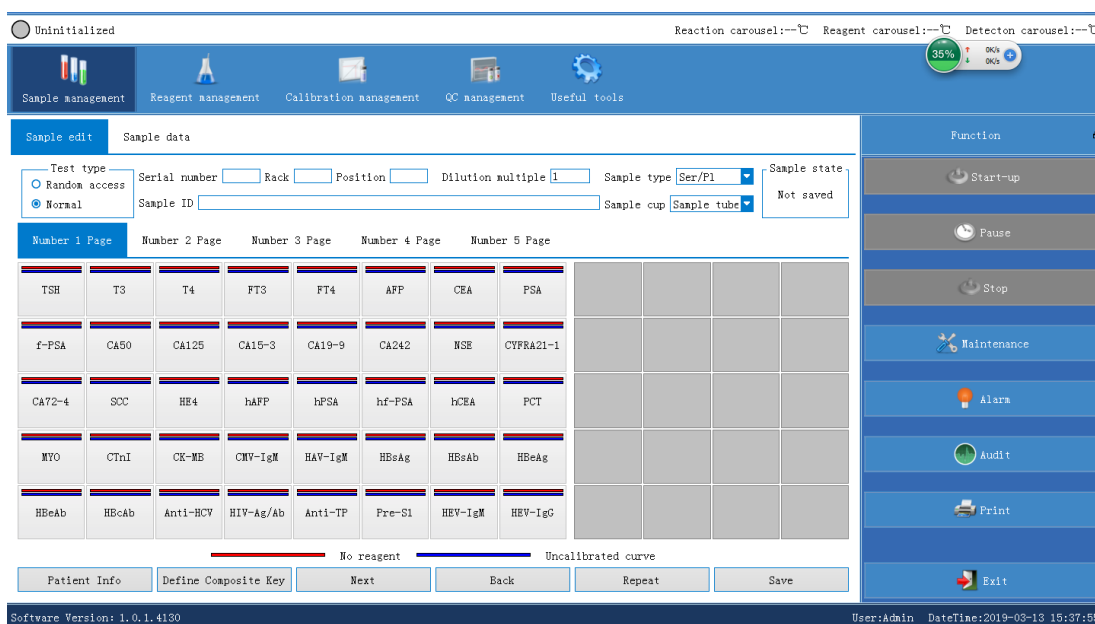



Fig. 8.3.1 Sample edit

- Select **Applications** under **Useful tools**. After the item is added, it will be displayed in the item list as shown in Figure 8.3.1.

A red bar in the item list indicates that the item has no reagents; 

A blue bar in the item list indicates that the item has no calibration curve. 

8.3.1.1. Save sample data

- Enter the proper serial number, rack number, position number in the interface of Figure 8.3.1

- Select the sample type, sample vessel type, and the test item
- Click **Save**. The serial number and position number in the interface are automatically incremented by 1.
- After save, the sample information is displayed in the sample data list of the **Sample data** interface. The sample data can be saved either as **Regular** or as **Emergency**, in the upper left part of Figure 8.3.1.

Note: The sample data type selected for the start-up item test will be the same as the sample data type selected for the sample editing.

8.3.1.2. Repeated adding of the same item for the same sample

- Click **Repeat** on the **Sample edit** interface, and the interface shown in Figure 8.3.2 will pop up.
- Click the items that require adding, enter the number to add, and click **Save** to exit the interface.
- The sample information is displayed in the sample data list of the sample data interface.

Note:

- (1) The sample type selected for the start-up item test is the same as the sample type selected for the sample editing;
- (2) The number of items to add is limited between 0-300 times.

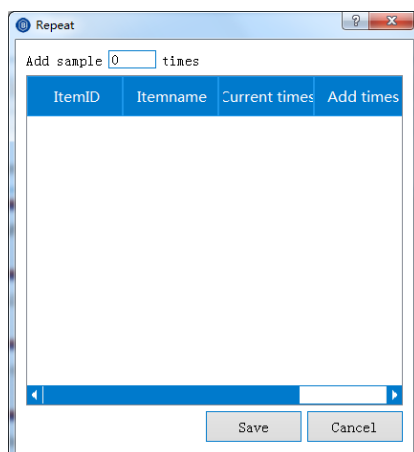


Figure. 8.3.2 Repeated sample addition

8.3.1.3. Repeated adding of the same item for different samples

As shown in Figure 8.3.2, Enter the number of samples to add, click **Save** to exit the interface. The sample information is displayed in the sample data list of the sample data interface.

Note:

- (1) The sample type selected for the start-up item test is the same as the sample type selected for the sample editing;
- (2) The number of sample to add is limited between 0-99 times.

8.3.1.4. Save combination key

Click **Define combination key** on the interface shown in Figure 8.3.1 to pop up the definition combination interface, as shown in Figure 8.3.3:

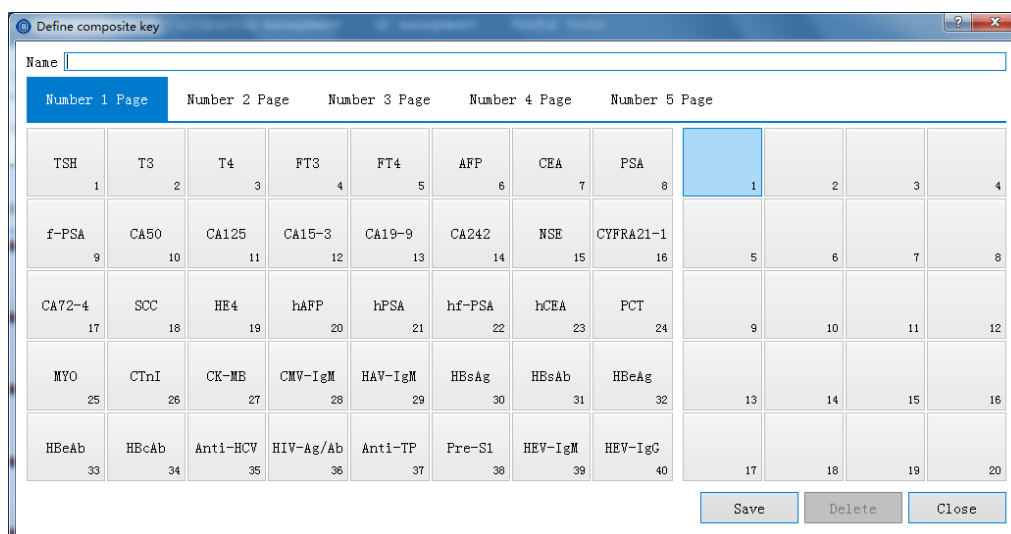


Figure. 8.3.3 Define combination key

Defining combination key includes the item list on the left and the key combination list on the right. Select a blank form from the list of key combinations, select the item to be combined from the item list, enter the combination name, and click **Save**. The key combination is also displayed in the corresponding position in the list of key combinations on the right side of the sample editing interface shown in Figure 8.3.1.

8.3.1.5. Check sample information

Click **Next** and **Back** on the interface shown in Figure 8.3.1 to view the saved samples info, or enter the serial number of the sample to be viewed in the serial number input box and press **Enter** on the keyboard.

8.3.1.6. Add patient information

- Click on **Patient info** in Figure 8.3.1, interface will pop up as shown in Figure 8.3.4.

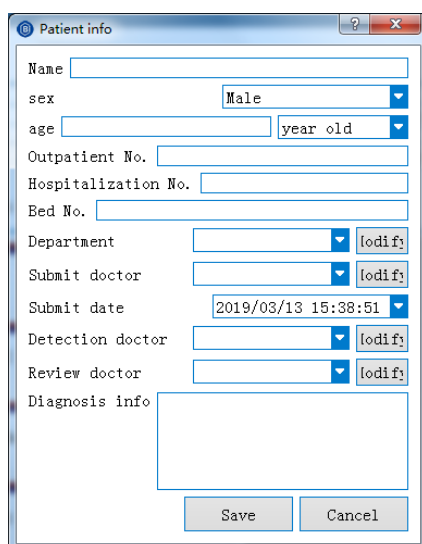


Figure. 8.3.4 Patient Information

- Enter the patient's name, age, sex (these three items are required), other information is optional.
- Click **Save** and then click **Save** in the interface of Figure 8.3.1. The patient information is now saved in the selected sample information.

To add information about the related departments, submitter, examiner or reviewer, please click **Modify** to input, as shown in Figure 8.3.5, 8.3.6, 8.3.7, and 8.3.8:

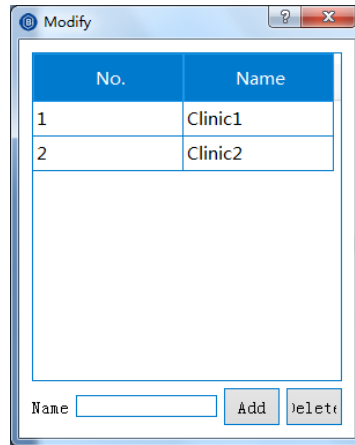


Figure. 8.3.5 Add department

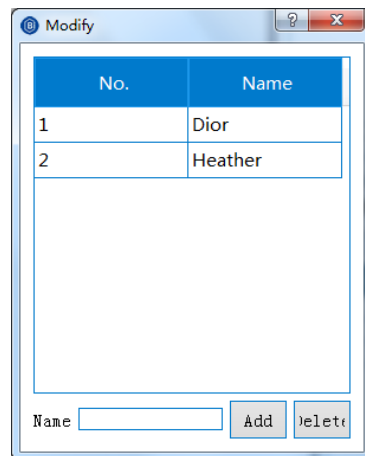


Figure. 8.3.6 Add submitter

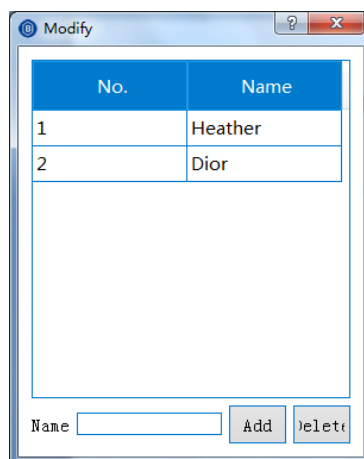


Figure. 8.3.7 Add examiner

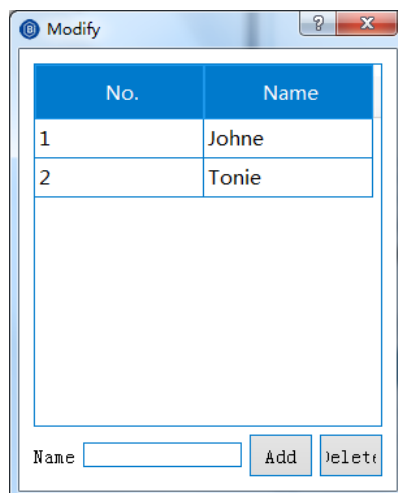


Figure. 8.3.8 Add reviewer

8.3.2. Barcode mode

Select **Sample edit** under **Sample management**. The barcode mode interface is shown as Figure 8.3.9. Please refer to 8.3.1 **Sample management** for details.

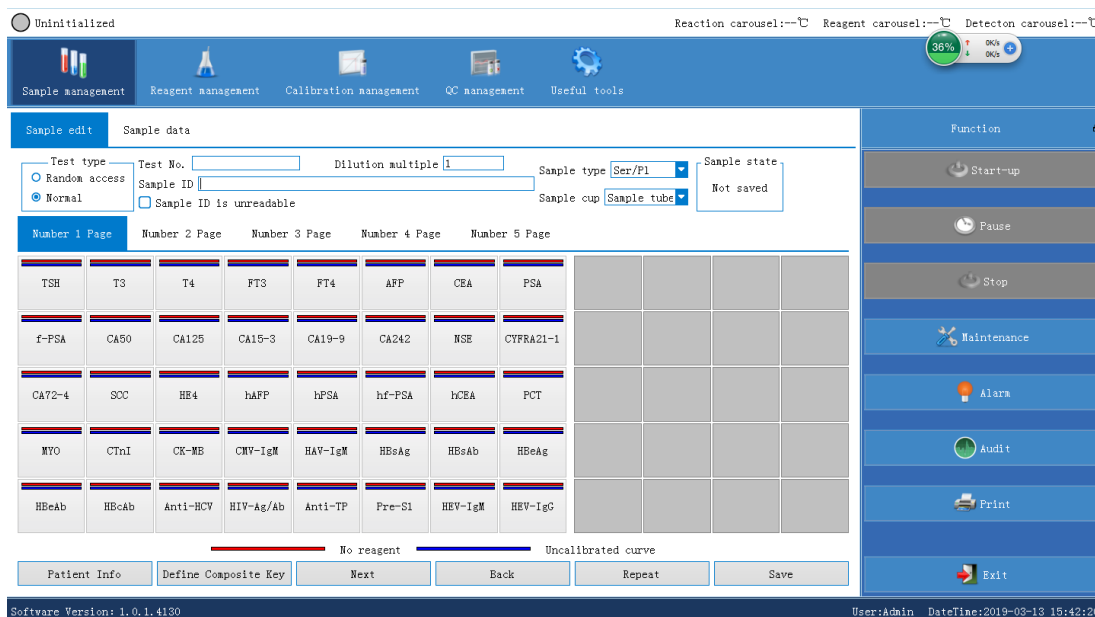


Figure 8.3.9 Sample edit

8.3.2.1. Save sample data

- Click **Sample ID** input box in the interface of Figure 8.3.9
- Scan the sample barcode information with the barcode scanner

- Select the sample type, sample vessel type, select the item to be processed, and save the sample data as either **Regular** or **Emergency**.

Note:

- (1) The sample ID should be unique;
- (2) If the sample barcode information cannot be scanned, check **Sample ID is not readable** and enter the rack number, position number and sample ID;
- (3) The sample type of the start-up item test selection is the same as the sample type selected by the sample editing.

8.3.2.2. Repeated adding of the same item for the same sample

- Click **Sample ID** input box on the interface of Figure 8.3.9
- Scan the sample barcode information that needs to be tested repeatedly with the barcode scanner
- Select the sample type, sample vessel type, select the item to be processed, and save the sample data as either **Regular** or **Emergency**
- Click **Repeat**, as the pop-up interface is as shown in Figure 8.3.10
- Click the items that require adding, enter the number to add, and click **Save** to exit the interface.
- The sample information is displayed in the sample data list of the sample data interface.

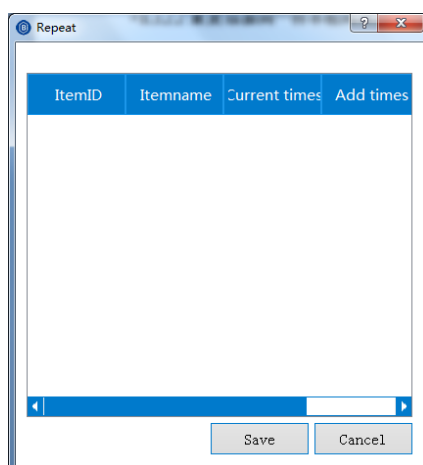


Figure. 8.3.10 Repeated addition of test items.

Notes are identical to that of 8.3.2.1.

For the use of the remaining functions in the **Barcode mode**, please refer to the similar functions in the **Serial number mode**.

8.3.3. Sample data

The sample data module mainly manages the sample information saved by the sample editing module.

Select **Sample data** under **Sample management**, as shown in Figure 8.3.11.

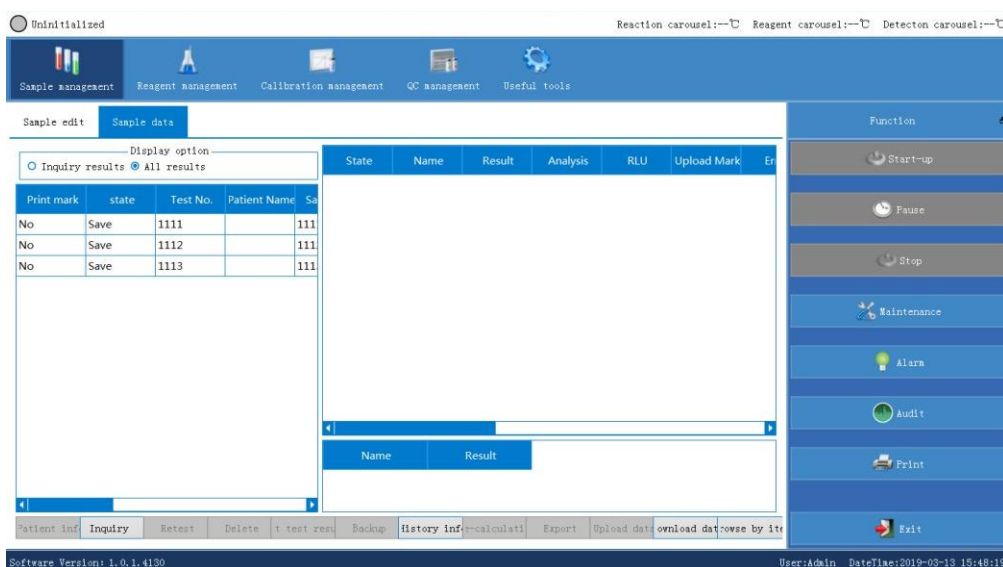


Figure. 8.3.11 Sample data

8.3.3.1. Search sample data

Figure 8.3.11 shows all sample data information by default in the sample data list.

- Click **Inquiry** on the interface of Figure 8.3.11.
- The search interface of serial number mode is shown in Figure 8.3.12. The operator can search by **Experimental Number**, **Sample ID**, **Registration Date**, **Diagnosis Type** or **Sample Type**.
- The search interface of **Barcode mode** is shown in Figure 8.3.13. The operator can search by **Sample ID**, **Registration Date**, **Diagnosis Type**

and **Sample Type**.

- Select the results for inquiry in Figure 8.3.11 interface, the sample data list will show the search results.

Figure. 8.3.12 Search with serial number mode

Figure. 8.3.13 Search with barcode mode

8.3.3.2. Delete sample/test items

- Select one or more samples in the sample data list in Figure 8.3.1
- Click **Delete**, or select the sample, select the item to be deleted in the test item list on the right side of the interface, click **Delete**, the system prompts a dialogue box to confirm the deletion, as shown in Figure 8.3.14
- Click **Yes**, the selected sample or item will be deleted.

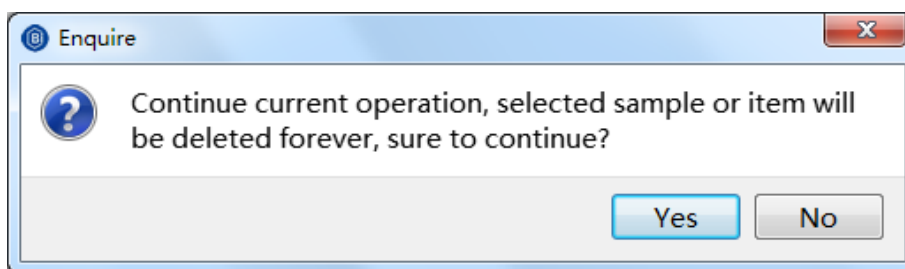


Figure. 8.3.14 Confirm deletion

8.3.3.3. Retest sample/test items

As shown in Figure 8.3.11, the tested samples/items on the sample data list can be retested.

- Select the sample or item to be retested, click **Retest**
- The status of the sample changes to **Save**, then the sample/item is good for retest.

8.3.3.4. Edit test results

- In the test item list in Figure 8.3.11, select the item to be edited
- Click **Edit test result**, and the edit test result dialog box will pop up, as shown in Figure 8.3.15
- Enter the number to edit and click **Save**. The edited result will be displayed on the test item list in Figure 8.3.11.

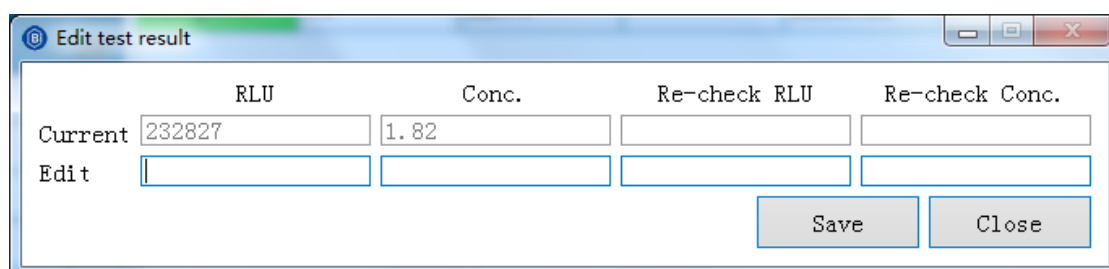


Figure 8.3.15 Edit test result

8.3.3.5. Sample backup

- Select the sample to be backed up in the sample data list of the interface shown in Figure 8.3.11
- Click **Backup**, the system prompts a dialogue box to confirm the backup, as shown in Figure 8.3.16
- Click **Yes**, the selected sample is no longer displayed in the sample data list. The backup is successful.

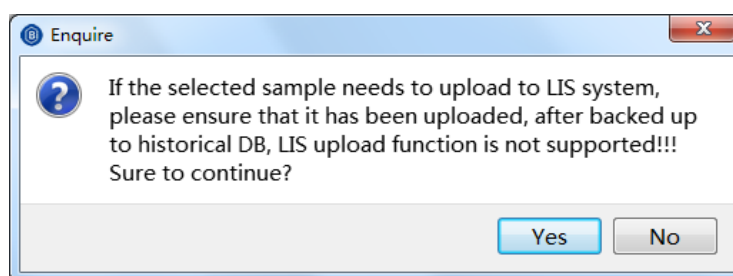


Figure 8.3.16 Confirm backup

8.3.3.6. Historical information

- Click **Sample history** in Figure 8.3.11 to display the historical information interface.
- Enter the search conditions and click **Inquiry**. The sample information that meets the conditions is displayed in the list on the left.

8.3.3.7. Export sample

- Select the sample or project to be exported in Figure 8.3.11
- Click **Export Sample/Export item**, and the export dialog box will pop up.
- Select the export location, fill in the export file name, and click **Save**.

8.3.3.8. Recalculation

- In Figure 8.3.11, select the item to be recalculated, determine the calibration curve of the recalculation of the item, set the curve as default in the **Calibration curve** interface under **Calibration management**
- Click **Recalculate**. The system prompts to confirm the recalculation
- Click **Yes**, the concentration result is calculated according to the selected calibration curve, and the calculation result replaces the original concentration value.

8.3.3.9. Data upload

Data upload includes manual upload and automatic upload. Both methods need to initiate LIS in the LIS server. The initiation of LIS needs configuration. For details of configuration, please see 8.7.1.1 **LIS settings**.

For the configuration of automatic upload, please refer to Step 2 of **LIS settings** in 8.7.1.1 (automatic upload and download).

For manual upload, please refer to the following procedures:

- 1) Upon the completion of the test, select the item to be uploaded, click **Upload**
- 2) the system prompts the confirmation of the upload, click **Yes**
 - a) If the upload is successful, the upload mark of the selected item in the test item list will mark as **Successful**.
 - b) If the upload fails, the system will prompt the message of upload failure and require another attempt.

Note: Only the tested items can be uploaded.

8.3.3.10. Browse by item

Click **Browse by item** in the **Sample data** interface to browse all tested items.

8.3.3.11. Data download

Click **Download data** in the **Sample data** interface to manually download tested items through LIS.

8.3.3.12. Edit dilution multiple

Select the items that require the dilution multiple editing in the test item list as shown in Figure 8.3.11 and click **Edit dilution multiple**, a dialogue box will pop up for the editing of the dilution multiple. Please input the required info and click **Save**. The dilution multiple after editing will show in the test item list in Figure 8.3.11.

8.4. Reagent management

The reagent management module manages the reagent information. This includes the addition of reagent information either by hand or by scan, the deletion of the reagent information, the viewing of reagent information, and the addition and deletion of the general material.

Select **Reagent management** to display the interface shown in Figure 8.4.1:

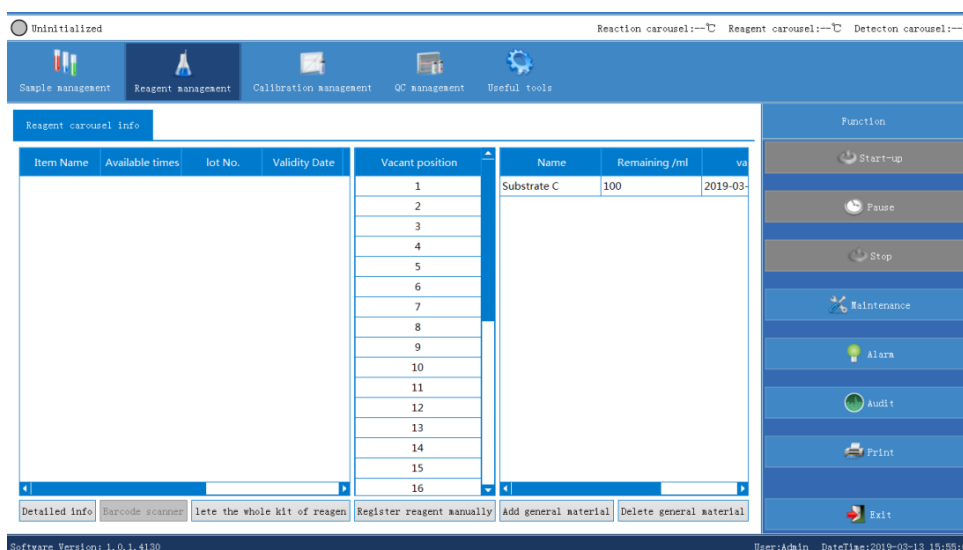


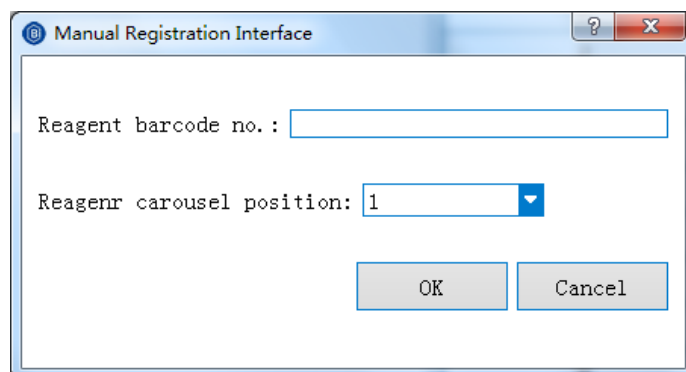
Figure 8.4.1 Reagent Management

- Red slots of **Available times** and **Remaining times** in Figure 8.4.1 mean no available reagent.

- Yellow slots mean only limited reagent remaining (1-29 times).
- White slots mean normal reagent status.
- Red slots in the Validity date column mean that the reagent has expired.
- Yellow slots mean that the validity after bottle opening has expired.
- White slots mean that the reagent is within validity.
- Red slots in the **Remaining/ml** column mean no available material.
- Yellow slots mean only limited material remaining (1-5ml).
- White slots mean normal material status.

8.4.1. Register reagents by hand

- Select **Register reagent manually** in Figure 8.4.1 to pop up the manual registration interface, as shown in Figure 8.4.2:



The image shows a software dialog box titled "Manual Registration Interface". It has a standard Windows-style title bar with a question mark icon and a close button. The main area contains two input fields. The first is labeled "Reagent barcode no. :" and is an empty text box. The second is labeled "Reagent carousel position:" and is a dropdown menu with "1" selected. At the bottom of the dialog are two buttons: "OK" and "Cancel".

Figure. 8.4.2 Manual registration

- Input the bar number with the bar code scanner, select the position of the reagent carousel
- Click **OK**, and the registered reagent information is shown in the **Reagent management** interface.

8.4.2. Register reagent by barcode scanning

- After the instrument is initialized, click **Scan barcode** in the **Reagent management** interface of Figure 8.4.1, a reagent barcode scanning dialog box will pop up as shown in Figure 8.4.3.
- Enter the starting and ending position, then click **Start**, the instrument starts to scan the reagent barcodes from the designated positions.
- The **Scanning complete** message will appear after the scanning is successful as shown in Figure 8.4.4. The reagent information is displayed in the reagent carousel information list.

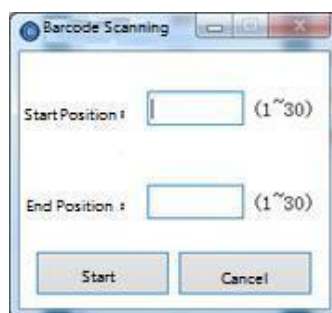


Figure. 8.4.3 Scan reagent barcode



Figure. 8.4.4 Reagent scanning completed

8.4.3. Inquire reagent details

- Select the reagent to inquire and click **Detailed info** in the **Reagent management** interface as shown in Figure 8.4.1, the reagent details will pop up. R1 of Anti-TP-G is used as an example, the reagent details are shown in Figure 8.4.5.

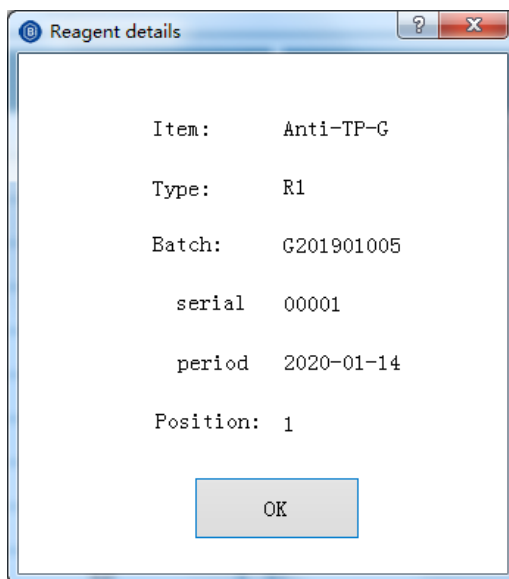


Figure. 8.4.5 Reagent details

8.4.4. Delete the whole kit of reagents

- Select the reagent to be deleted in the reagent carousel information list. The system allows to delete a single kit of reagents or multiple kits of reagents.
- Click **Delete whole kit of reagent** and the system will pop up the confirmation message, as shown in Figure 8.4.6
- Click **OK**, then the selected reagent info will be deleted.

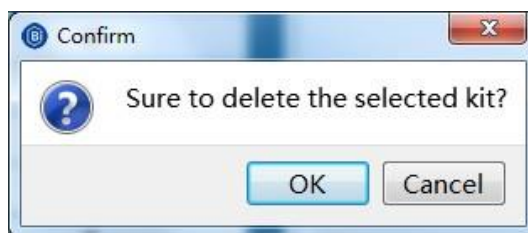


Figure. 8.4.6 Confirm deletion

8.4.5. Add general material

- Click **Add general material** in the **Reagent management** interface, as shown in Figure 8.4.1, to pop up the general material registration dialog box, as shown in Figure 8.4.7:

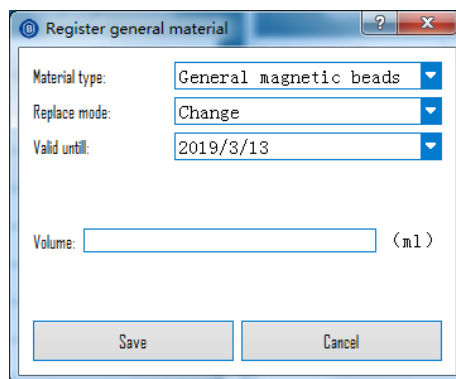


Figure. 8.4.7 General material registration

- Select **Material type**, **Replace mode**, and **Valid until**, fill in the required volume of the general material, and click **Save**. The registered general materials are displayed in the general material list.

Note:

- (1) The validity period shall not exceed the expiry date;
- (2) The maximum volume of substrate C shall not exceed 250 ml.

8.4.6. Delete general material

- Select the general material to be deleted in the general material list in the Reagent management interface.
- Click **Delete general material**, and the system will prompt the confirmation message for the deletion, as shown in Figure 8.4.8, click **OK** to delete the general material.

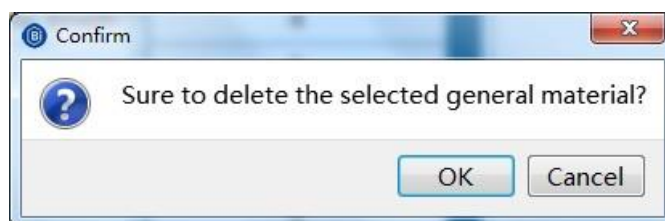


Figure. 8.4.8 Confirm deletion

Note: Register/delete reagents or add/delete general material during the test is not allowed.

8.5. Calibration management

The calibration management module mainly includes calibrator management, calibration status management and calibration curve management.

1. Calibrator management includes the addition (by scanning), the updating, the deletion and the activation of the calibrator;
2. Calibration status management includes calibration tracking, calibration info inquiry and the selection of the calibration type ;
3. Calibration curve management includes the addition, export, import, examining and deletion of the calibration curve.

8.5.1. Calibrator management

Select **Calibrator** under **Calibration management**, as shown in Figure 8.5.1. The item list is displayed on the left side, the calibrator list is displayed on the right, and the function buttons are at the bottom.

Select an item in the item list, the calibrator list will display all the calibrator information saved for the item.

Note: The text of the validity will be red if the calibrator expired.

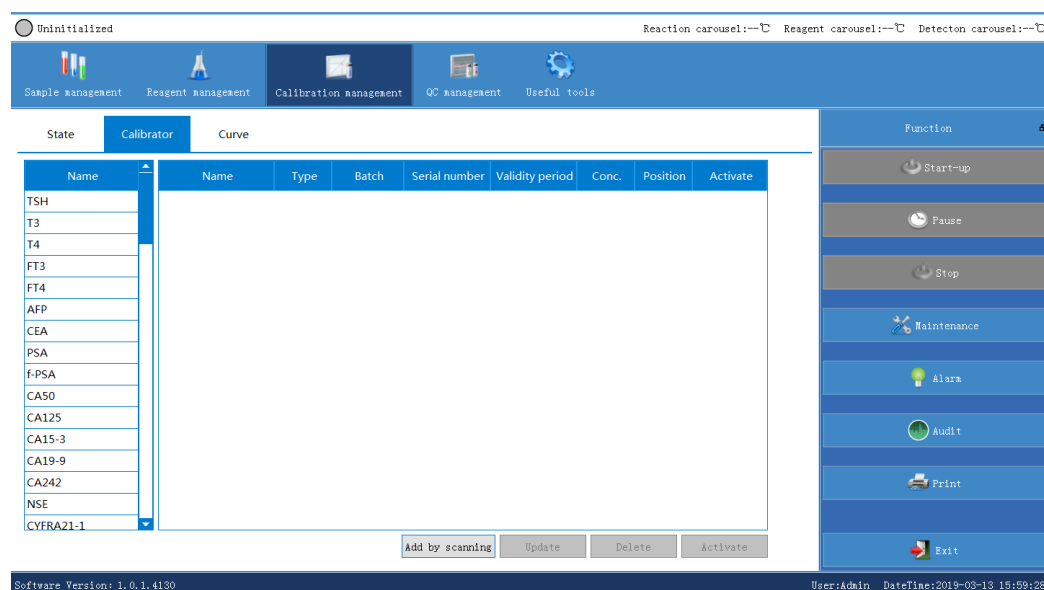


Figure. 8.5.1 Calibrator management

8.5.1.1. Add calibrator by barcode scanning

Click **Add by scanning** in the Calibrator management interface, as shown in Figure 8.5.1, a pop-up window will allow the calibrator addition by barcode scanning, as shown in Figure 8.5.2. Scan barcode to fill in barcode information and press **Enter** on the keyboard and select the rack number and position number for each calibrator and click **Save**. The added calibrator will be shown in the calibrator list and such calibration item will be displayed in the calibration status list as shown in Figure 8.5.6.

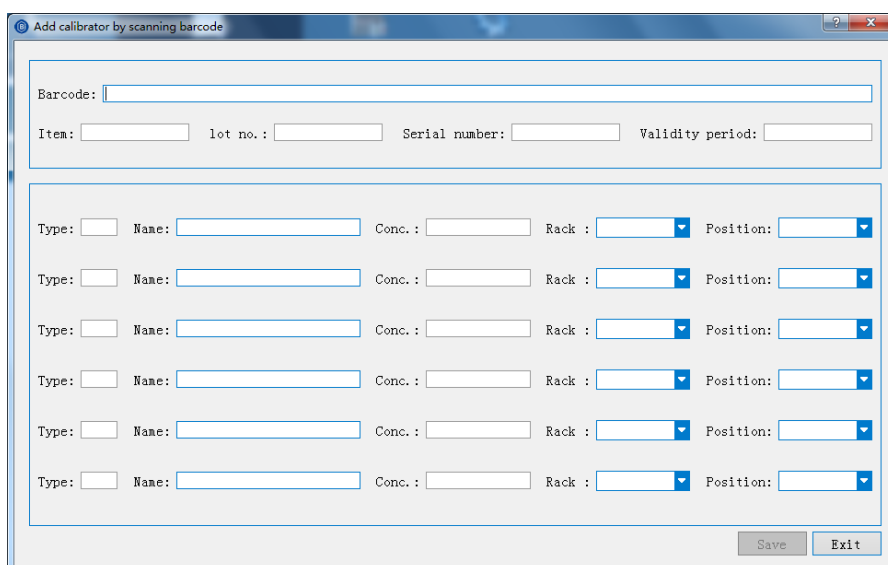
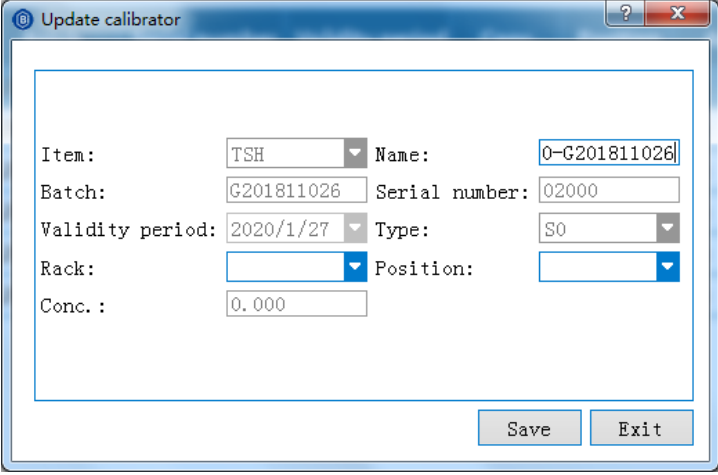


Figure. 8.5.2 Add calibrator by scanning

8.5.1.2. Update calibrator

- Select the calibrator to be updated in Figure 8.5.1 and click **Update**, the calibrator update interface will pop up as shown in Figure 8.5.3. The name, rack number and position number of the calibrator can be edited.
- Click **OK** after edition. The modified calibrator information will be displayed in the calibrator list.



Update calibrator

Item: TSH Name: 0-G201811026

Batch: G201811026 Serial number: 02000

Validity period: 2020/1/27 Type: S0

Rack: Position:

Conc. : 0.000

Save Exit

Figure. 8.5.3 Update calibrator

8.5.1.3. Delete calibrator

- Select the calibrator to be deleted in Figure 8.5.1 and click **Delete**. The confirmation to delete will pop up as shown in Figure 8.5.4.
- Click **OK**, the calibrator list will no longer show any info of such calibrator.

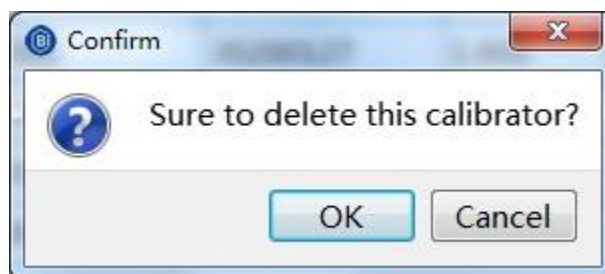


Figure. 8.5.4 Confirm calibrator deletion

Note: If the calibrator for the activation of the test item is deleted, All-point calibration or qualitative calibration cannot be performed on such item. Other calibrators must be activated.

8.5.1.4. Activate calibrator

The calibration test can only be performed after the calibrator is added and activated.

- Select the specific calibrator from the calibrator list and click **Activate**
- The **Activate** status will display **Yes**, as shown in Figure 8.5.5. This means the calibrator is successfully activated.

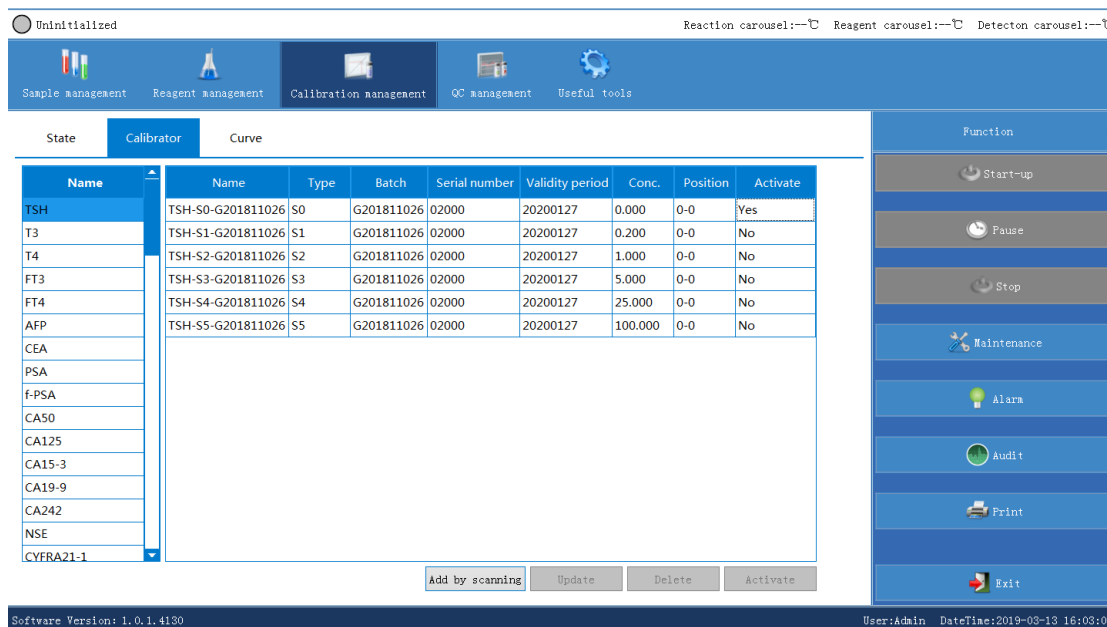


Figure. 8.5.5 Activate calibrator

Note: Only one calibrator can be activated for the same type of the same item.

8.5.2. Calibration status management

Select **Status** under **Calibration management**, as shown in Figure 8.5.6:

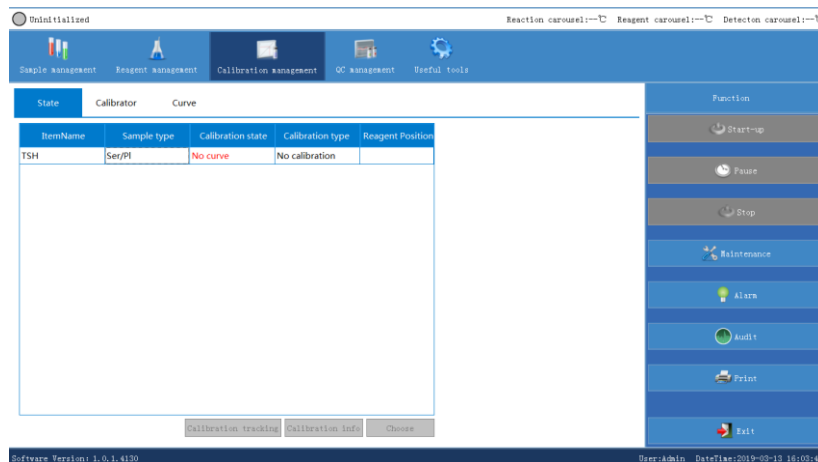


Figure. 8.5.6 Calibration status

- Red text under the calibration status means that the calibration curve

has expired;

- Yellow-green text means that the calibration curve is close to expiration
- Black text means that the calibration curve is normal.

The selection of the reagents for the calibration item can be either in the default reagent position or be set manually. Double-click the **Reagent Position** column and show the dropdown list of all reagents registered for this specific test item and then pick the desired reagent position.

8.5.2.1. Calibration tracking

Select the calibration item for tracking in the Calibration status interface as shown in Figure.8.5.6 and click **Calibration tracking**. The calibration test record window will pop up as shown in Figure.8.5.7

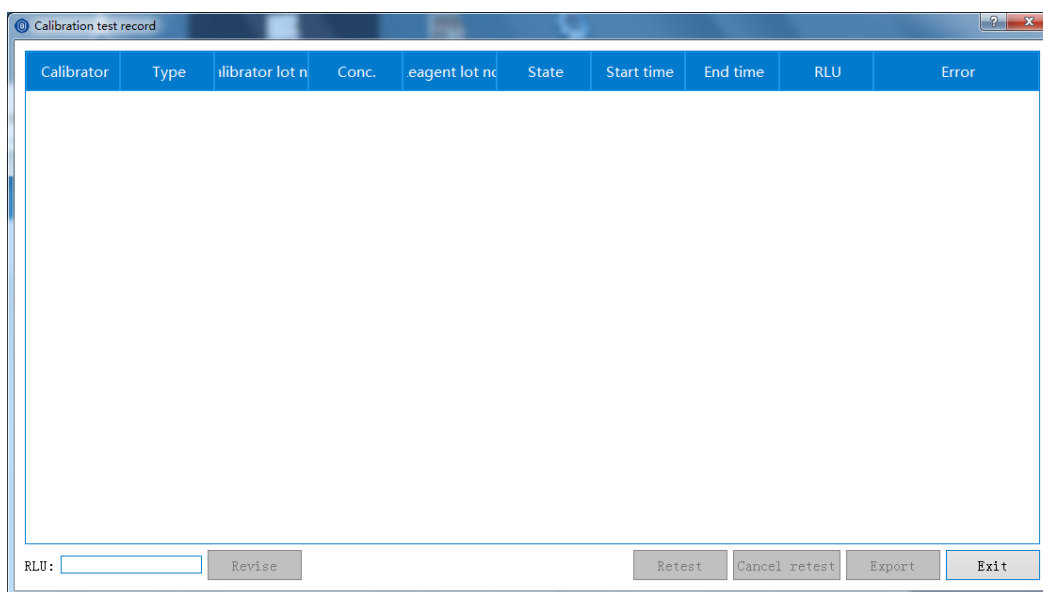


Figure. 8.5.7 Calibration tracking

In the calibration test record interface, the retest of the calibration item and the export of the test record can be set up.

Note:

- (1) Select the calibrator to be exported and click **Export**.
- (2) Select the location for export and fill in the file name then click **Save**. Exported file can be found at such location.

8.5.2.2. Calibration information

Choose the calibration item to be viewed in Figure 8.5.6 and click Calibration info. If the selected item is a quantitative item, the interface of the quantitative item calibration curve will pop up, as shown in Figure 8.5.8, the detailed information of the calibration curve will be available; if the selected item is a qualitative item, the detailed information of the qualitative analysis of such item will be available as shown in Figure 8.5.9.

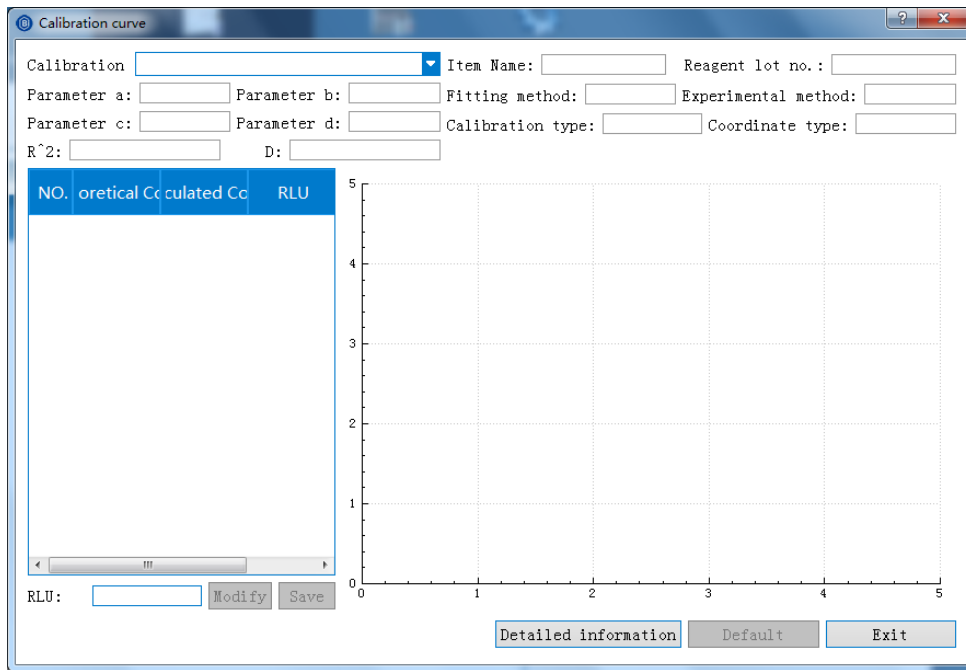


Figure 8.5.8 Calibration information

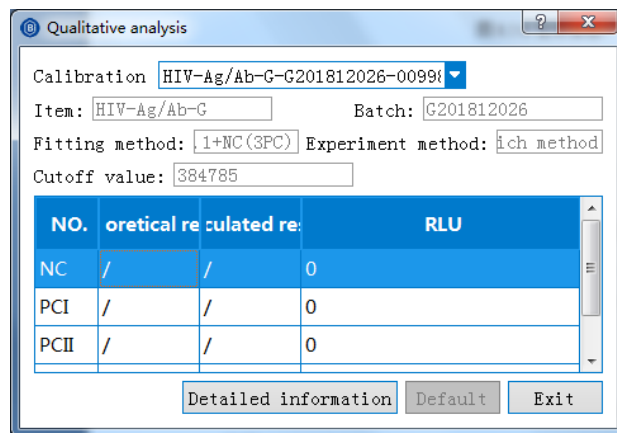


Figure 8.5.9 Qualitative analysis

8.5.2.3. Calibration types

The calibration types include all-point calibration, one-point calibration, two-point calibration, qualitative, retest, and no calibration.

- Select the calibration item under **Calibration status** as shown in Figure 8.5.6 and click **Choose**. The calibration type selection window pops up as shown in Figure 8.5.10
- Select the calibration type and click **OK**. The calibration type column will show the type as selected, as shown in Figure 8.5.11.

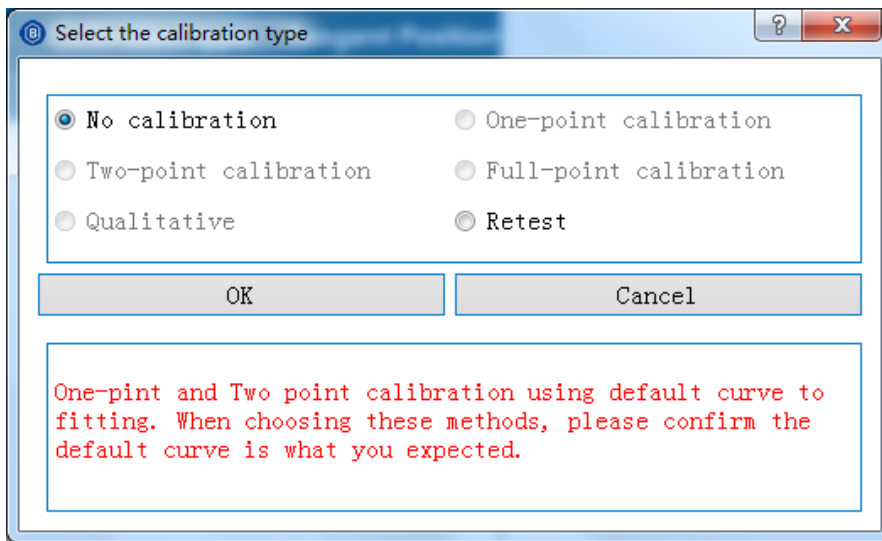


Figure 8.5.10 Select the calibration type

ItemName	Sample type	Calibration state	Calibration type	Reagent Position
TSH	Ser/Pl	Normal	No calibration	
HIV-Ag/Ab-G	Ser/Pl	Normal	No calibration	

Figure 8.5.11 Calibration type

Note:

- (1) All-point calibration is only available for selection when all 6 calibrators (S0-S5) have been added and activated;
- (2) One-point calibration or two-point calibration requires a calibration curve to perform the calibration test;

8.5.3. Calibration curve management

Select **Calibration curve** in the **Calibration management** interface, as shown in Figure 8.5.12., The list of items is displayed on the left, the list of calibration curves is on the right and the function buttons are at the bottom.

When an item is selected on the left, a list of all the calibration curves available for the item is displayed.

- Red text in the **Validity** column means that the calibration curve has expired;
- Yellow-green text means that the calibration curve is close to expiration;
- Black text means that the calibration curve is normal.

Uninitialized Reaction carousel:-- Reagent carousel:-- Detector carousel:--

Sample management Reagent management Calibration management QC management Useful tools

State Calibrator Curve Function

Name	Curve name	Item	Batch	Period of validity	Default	State
Anti-HCV	HIV-Ag/Ab-G-G2018120...	HIV-Ag/Ab-G	G201812026	20191229	Yes	valid

Sweep code addition Import Export examine Default Delete

Start-up Pause Stop Maintenance Alarm Audit Print Exit

Software Version: 1.0.1.4130 User:Admin DateTime:2019-03-13 16:08:49

Figure 8.5.12 Calibration curve management

8.5.3.1. Add calibration curve by barcode scanning

- Click **Scan to add** in the calibration curve management page code as shown in Figure 8.5.12, a window for adding calibration curve by scanning pops up as Figure 8.5.13.
- Scan the barcode to fill in the calibration curve info and press **Enter** on the keyboard. The name of the calibration curve can be changed at this

moment.

- Click **Save**, the added calibration curve is displayed in the calibration curve column and it is the default calibration curve.

Figure 8.5.13 Add calibration by scanning barcode

If a barcode is in error, the system will prompt a failure warning, as shown in Figure 8.5.14 :

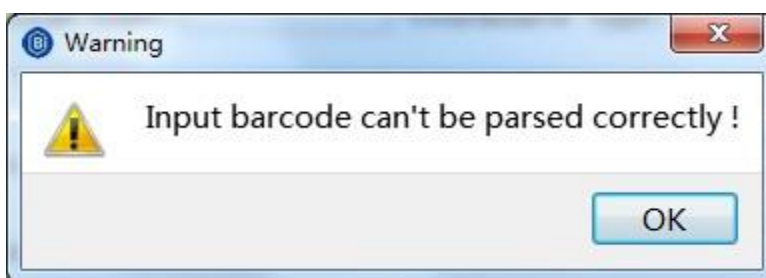


Figure 8.5.14 Barcode can't be parsed

8.5.3.2. Examine the calibration curve

- Select the calibration item in the list on the left side of the interface shown in Figure 8.5.12

- Select calibration curves to be checked
- Click **Examine**. The calibration curve interface will pop up as shown in Figure 8. 5.15 or Figure 8.5.16:

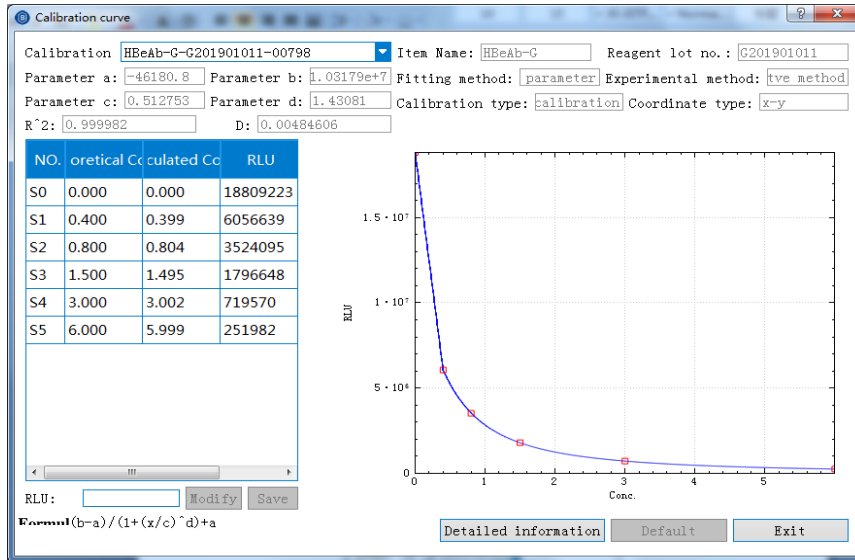


Figure 8.5.15 Calibration curve (Quantitative)

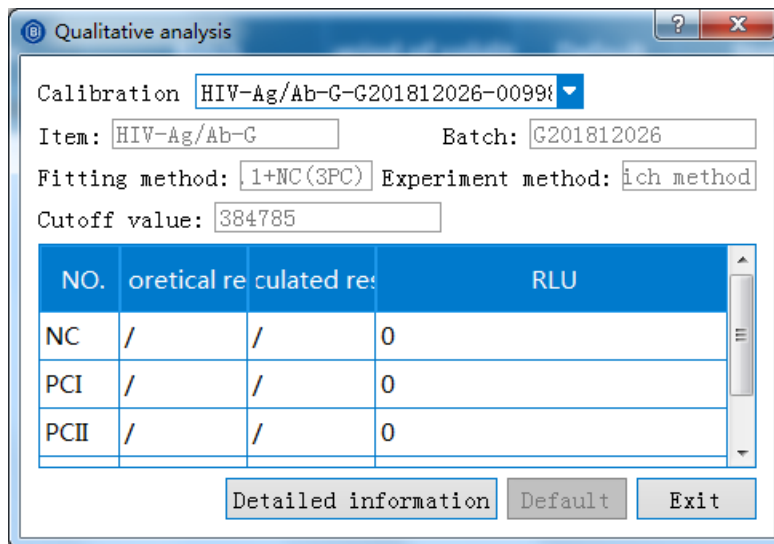


Figure 8.5.16 Qualitative analysis

- Detailed information of the calibration curve can be viewed as shown in Figure 8.5.15, and the RLU of the six points can be modified.
 - To modify the RLU, please select the specific point to be modified and enter the desired value, then click **Modify**. The system will

prompt a confirmation message for the modification as shown in fig 8.5.17

- Click **OK**, then click **Save** in the interface of Figure 8.5.15. The RLU is successfully modified.

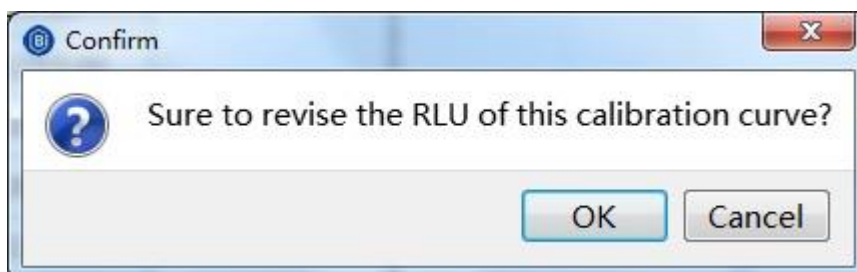


Figure 8.5.17 Confirm calibration curve modification

2. Click **Default** in the interfaces as shown in Figure 8.5.15 calibration curve (quantitative) or Figure 8.5.16 Qualitative analysis, the default calibration curve column will show **Yes** and the setting of default calibration curve is completed.
3. If the curve is generated from testing, the specific test record for that curve can be viewed.
 - Click **Detailed information** in the interfaces of Figure 8.5.17 or Figure 8.5.18, a calibration test record window will pop up as shown in Figure 8.5.7;
4. If the curve is generated by barcode scanning, when click **Detailed information**, the system will prompt a message that the calibration curve has no test record as shown in Figure 8.5.18:

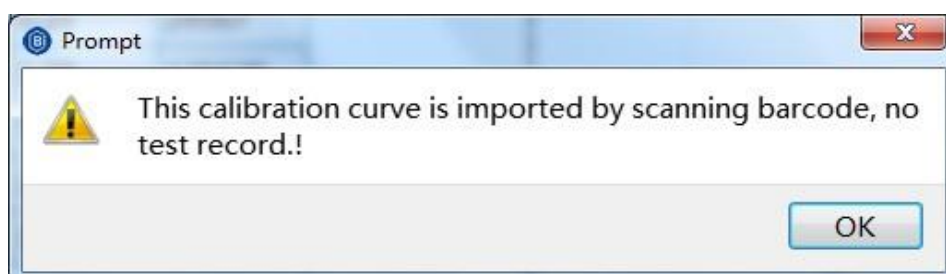


Figure 8.5.18 No test record found

8.5.3.3. Delete Calibration curve

- Select the curve to be deleted in the interface shown in Figure 8.5.12 and click **Delete**. The system will prompt to confirm the deletion.
- If the curve is a default calibration curve, it is not allowed to be deleted. If the curve is not a default calibration curve, it will be deleted and the list of calibration curves will no longer display the curve.

8.5.3.4. Set default calibration curve

- Select a calibration curve that is not set as the default curve in the calibration curve list in Figure 8.5.12, and click **Default**.
- A **Yes** will appear in the default column. Alternatively, a curve can be selected and click **Examine** in the calibration curve interface and follow the steps of Point 2 of 8.5.3.2. A default calibration curve can be set by both approaches.

Note: The latest qualified calibration curve generated through the calibration item test will automatically become the default calibration curve. The latest added qualified calibration curve either by barcode scanning or by hand will automatically become the default calibration curve too.

8.6. QC management

The QC management module mainly includes the management of QC products, QC status and QC data.

- The management of QCs includes the registration (by barcode scanning or by hand), the updating, the deletion and the activation of QCs.
- The management of QC status includes the test tracking of QC items and the setting of the number of QC test times;
- The management of QC data includes the management of QC chart data and the deletion, the display and the export of QC charts.

8.6.1. QCs management

QCs include three types of quality control: QCH, QCL, and external. The QCs registered by barcode scanning are under the types of QCH and QCL and those registered by hand are under the type of external.

Select **QC** under **QC management** as shown in Figure 8.6.1, the item list is on the left and the QCs list is on the right.

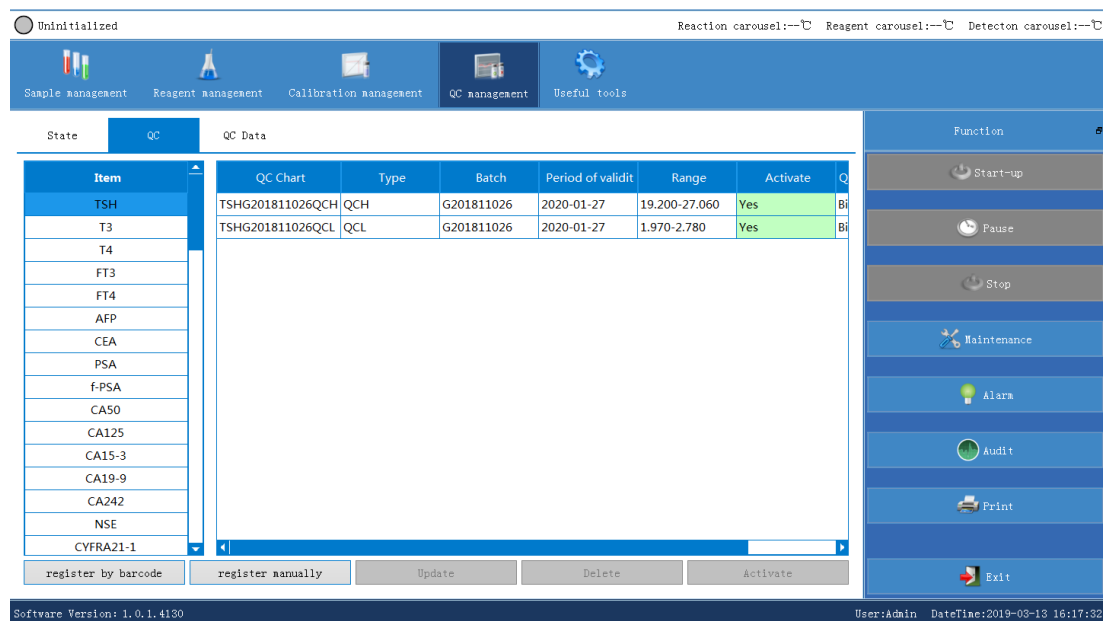


Figure 8.6.1 QCs management

8.6.1.1. QCs registration by barcode scanning/by hand

1. QCs registered by barcode canning

- Select the item in the QC item list shown in Figure 8.6.1 and click **Register by barcode**, a barcode registration window will pop up, as shown in Figure 8.6.2.
- Scan the barcode and press **Enter** on the keyboard then click **Save**. The registered QCs will be displayed in the QC list in Figure 8.6.1.

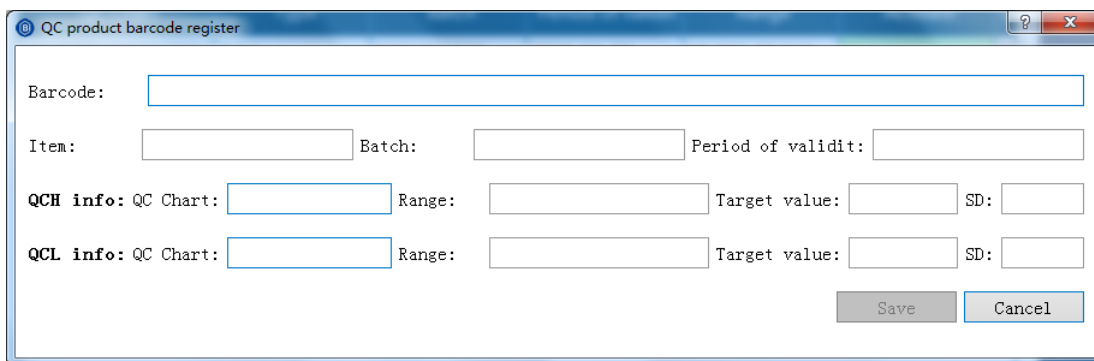


Figure 8.6.2 QCs barcode registration

Note: The same barcode cannot be registered repeatedly. If the barcode entered is in error, the system will notify a barcode error and no barcode parse.

2. QCs registered by hand

- Select the item in the QC item list shown in Figure 8.6.1 and click **Register manually**. A manual registration window will pop up as shown in Figure 8.6.3.
- Input the information such as the manufacturer of the QCs, target value of the QCs, QCs type, the name of the QC chart, SD value, production batch number, selection rule and expiration date then click **Save**. The registered QCs will be displayed in the QC list in Figure 8.6.1.

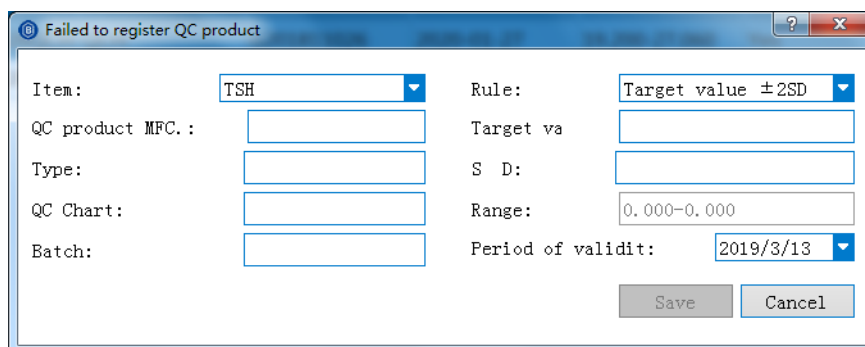


Figure 8.6.3 QCs manual registration

8.6.1.2. Update QCs

- Select the item in the QC item list as shown in Figure 8.6.1 and click **Update**, a QC product update window will pop up as shown in Figure

8.6.4.

- Modify the target value, the name of the QC chart, SD value, production batch number, selection rule and expiration date then click **Save**. The modified QCs info is displayed in the QCs list in Figure 8.6.1.

Figure 8.6.4 Update QCs

Item name:	TSH	Rule:	Target value ±3SI
QC product MFC.:	Bioscience	Target value:	23.130
QC type:	QCH	S D:	1.310
QC chart:	TSHG201811026QCH	Range:	19.200-27.060
Batch:	G201811026	Period of validity:	2020/1/27

Save Cancel

8.6.1.3. Delete QCs

- Select the item in the QC item list as shown in Figure 8.6.1 and click **Delete**. A confirmation window will pop up to confirm the deletion of the selected QCs, as shown in Figure 8.6.5.
- Click **Delete** and the deleted QCs information is no longer displayed in the list in Figure 8.6.1.

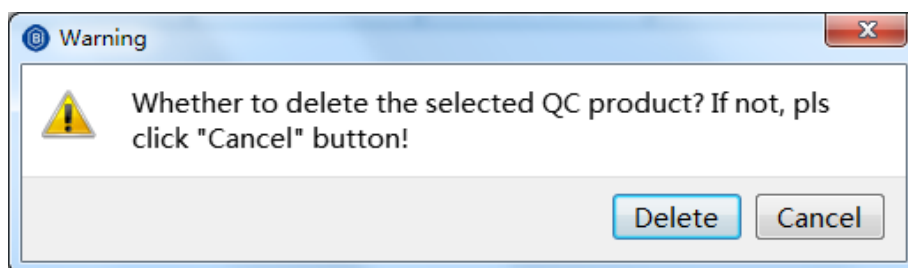


Figure 8.6.5 Confirm to delete selected QCs

8.6.1.4. Activate QCs

- Select the item in the QC item list as shown in Figure 8.6.1 and click **Activate**, a **Yes** will be shown in the **Activate column** of the list and the background color will change from white to light green, as shown in Figure 8.6.6.

- The activated QC product will be displayed in the **QC status** interface and the **QC data** interface.

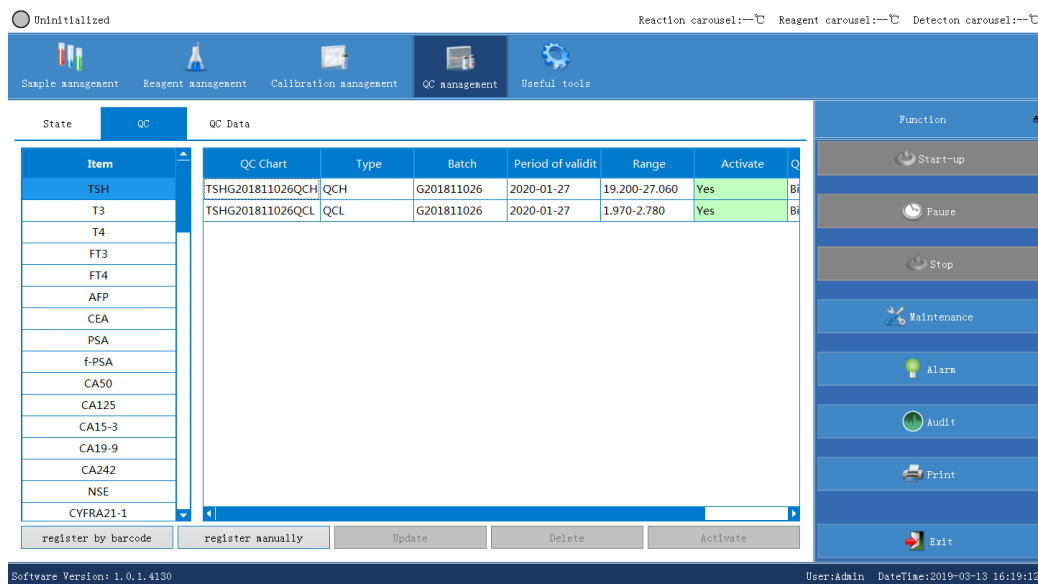


Figure 8.6.6 Activate QCs

Note: Only one QC can be activated for the same type of the same item.

8.6.2. QC status management

QC status management includes the test tracking of QC items and the setting of the number of QC items

- Select **Status** under **QC management** interface, as shown in Figure 8.6.7, the default reagent position can be selected for the QC item or it can be set up manually.
- Double-click the reagent position in the figure below and select the reagent position.

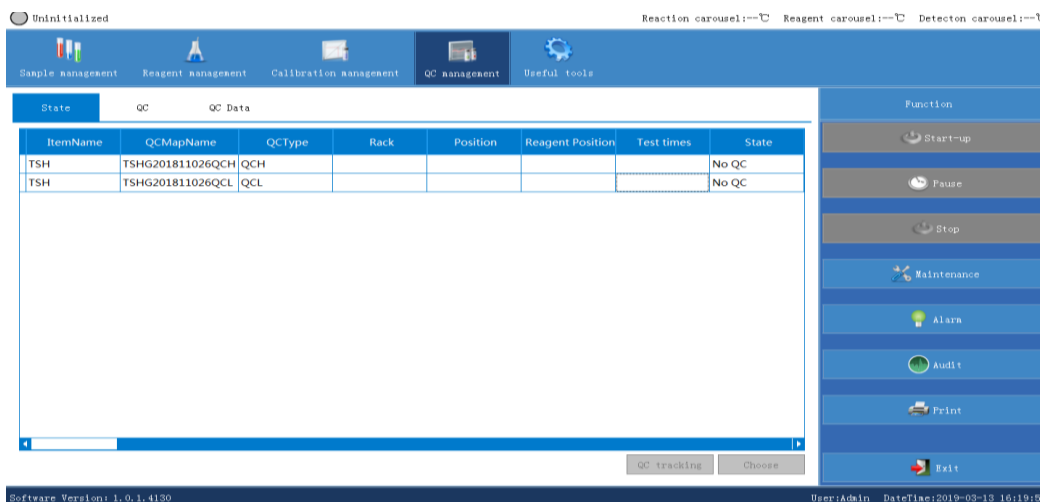


Figure 8.6.7 QC status management

8.6.2.1. QC tracking

Select the QC item in the **QC status** interface as shown in Figure 8.6.7 and click **QC tracking**, a QC tracking window will pop up, as shown in Figure 8.6.8:

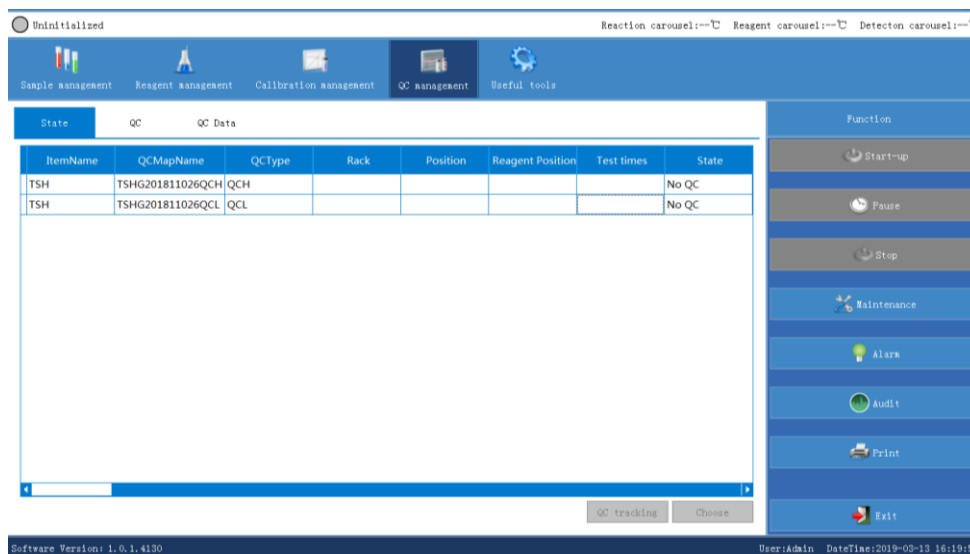


Figure 8.6.8 QC tracking

8.6.2.2. Set QC test times

- Select the QC item in the **QC status** interface as shown in Figure 8.6.7 and double-click the rack number and position number of this item.
- A drop-down list will appear, as shown in Figure 8.6.9.

- Select the position of this QC product and click to choose. The QC test times setting interface will pop up as shown in Figure 8.6.10.
- Set the QC test times and click **OK**. In the **Status** column, the background color changes from white to light green, and the set test times will be shown in the **Test times** column as shown in Figure 8.6.9:

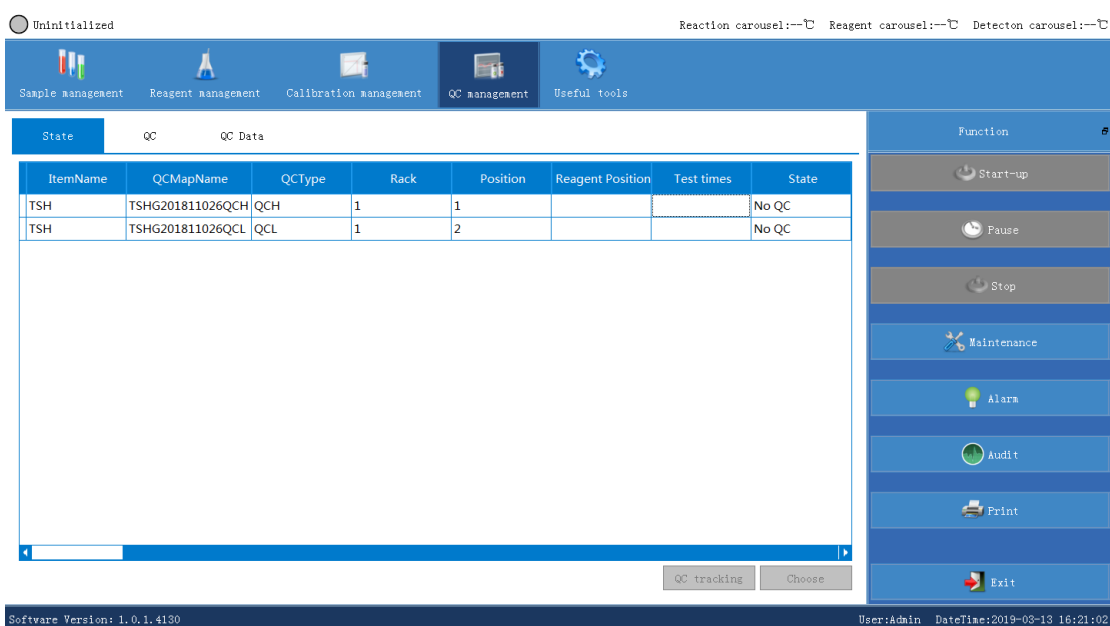


Figure 8.6.9 Set QC position

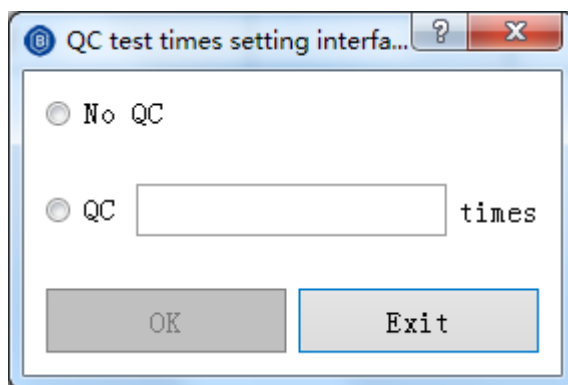


Figure 8.6.10 Set QC test times

8.6.3. QC data

QC data management mainly includes the addition, deletion, modification and recalculation of the QC chart data as well as the display, viewing, export and deletion of the QC chart.

Select **QC data** under the **QC management** interface as shown in Figure 8.6.11. The QC item list is on the left, the QC data list is on the right and the function buttons are at the bottom.

Item	QC chart	QC Type	Time	product M	target value	Unit	SD	QC ra
TSH	TSHG201811026QCH	QCH	2019-03-13 16:17:30	Bioartron	23.130	µIU/mL	1.310	19.200-
T3	TSHG201811026QCL	QCL	2019-03-13 16:17:30	Bioartron	2.375	µIU/mL	0.135	1.970-2

Figure 8.6.11 QC data

8.6.3.1. QC chart data management

QC chart data management includes the addition, deletion, modification, recalculation, detail display, export and upload of the QC chart data.

- Select the item in the QC item list shown in Figure 8.6.11;
- Select the QC item in the QC data list;
- Select the QC data in the QC data list;
- Click **QC chart data management** and the interface will pop up, as shown in Fig 8.6.12:

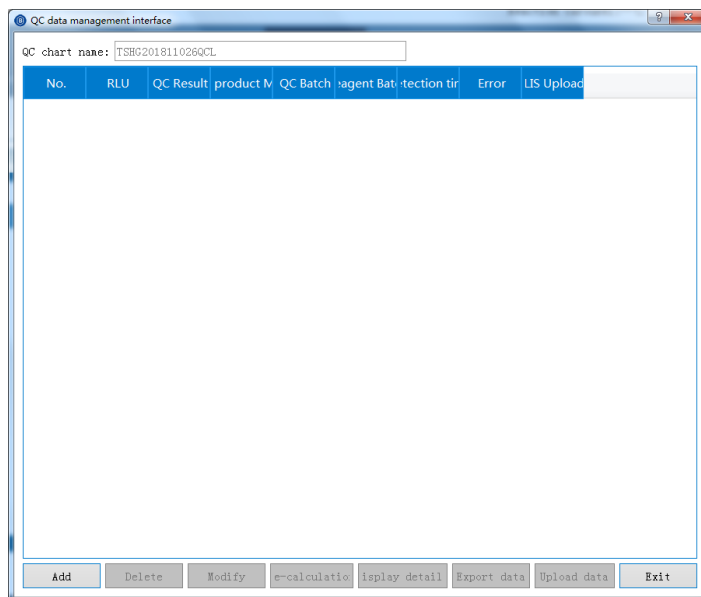


Figure 8.6.12 QC data management

1. Add QC data by hand

- Click **Add** and the **QC data addition** interface will pop up, as shown in Figure 8.6.13.
- Select QC time and enter RLU value and QC result and click **Save**.

The added data will be saved in the **QC data management** interface as shown in Figure 8.6.12.

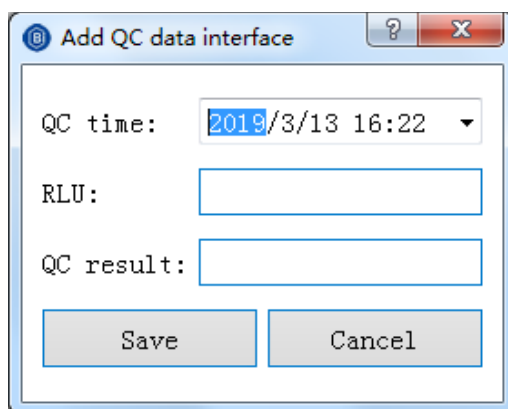


Figure 8.6.13 Add QC data

2. Delete QC chart data

- Select a set of QC data in the **QC data management** interface in

Figure 8.6.12 and click **Delete**. A confirmation of deletion will pop up.

- Click **Delete** and the specific set of QC data will no longer appear.

3. Modify QC chart data

- Select a set of QC data in the **QC data management** interface in Figure 8.6.12 and click **Modify**
- the **Update QC data** interface will pop up, as shown in Figure 8.6.14.
- Modify the QC time, the RLU value and QC result then click **Save** to complete modification.

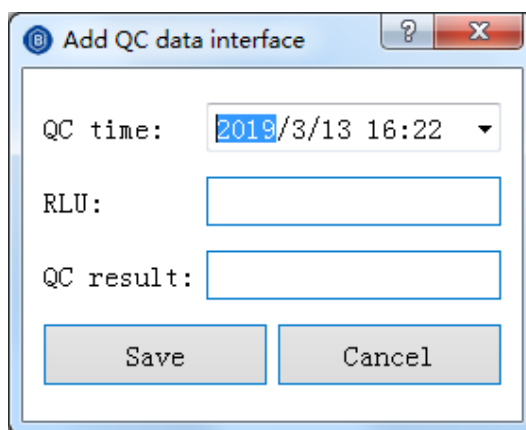


Figure 8.6.14 Modify QC data

4. Recalculate QC chart data

- Select a set of QC data in the **QC data management** interface in Figure 8.6.12 and click **Recalculation**.
- The result of recalculation will be displayed in the QC result column. Please ensure that the selected QC item has a default calibration curve before recalculating the QC results. If the QC item has no calibration curve, the recalculation failure alert will appear in the error column when clicking **Recalculation**.

5. Exit the QC data interface

Click **Exit** in the **QC data management** interface to exit the page.

8.6.3.2. Display QC chart

- Select the **QC chart data** tab in Figure 8.6.11, click **QC chart display** as shown in Figure 8.6.15. The details of each point are available for viewing when clicking on the point.
- Click **Move Up**, **Move Down**, **Move Left** or **Move Right** to adjust the size of the interface.
- Click **Prev.** or **Next** to view different pages when a large number of points are available.
- Click **Initial** to view the original chart and click **Print** to print out the chart.

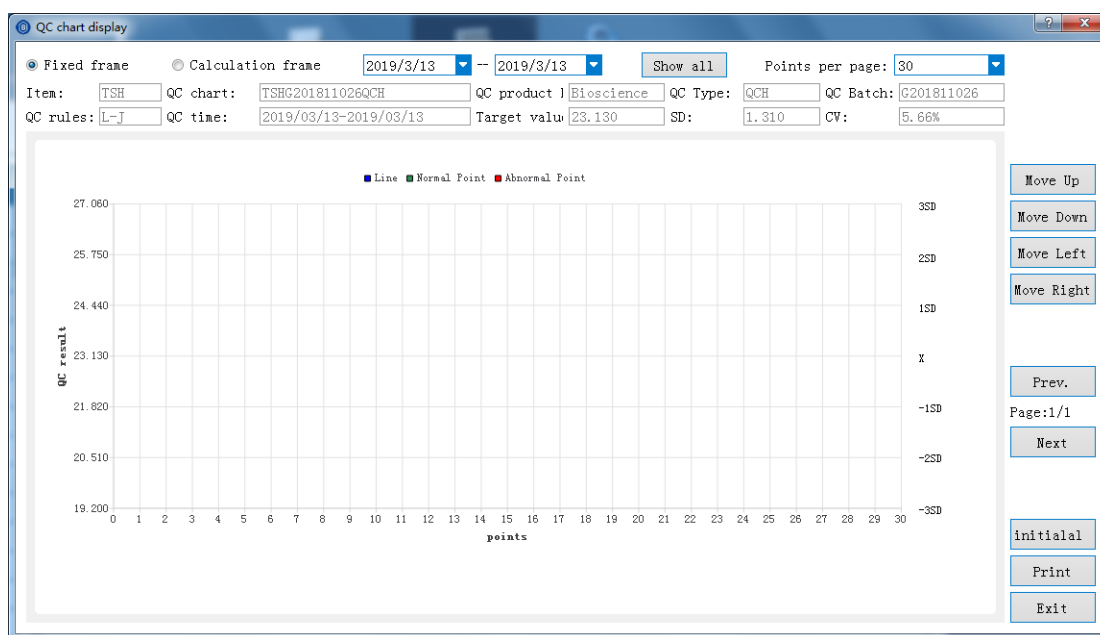
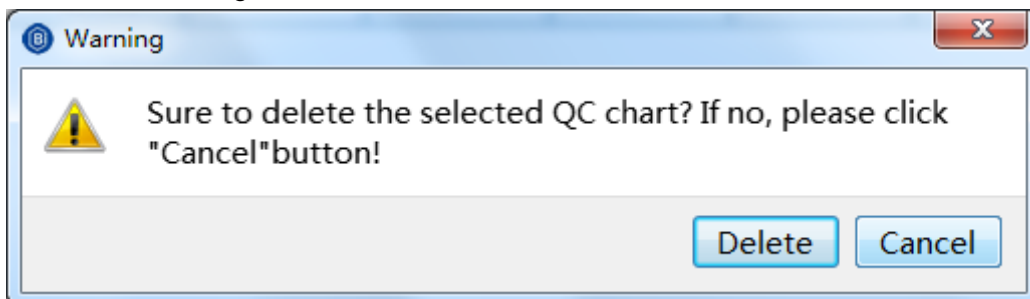


Figure 8.6.15 Display QC chart

8.6.3.3. Delete QC Chart

- Select the QC chart data in Figure 8.6.11 and click **Delete QC chart**. A confirmation to delete the QC chart will appear as shown in Figure 8.6.16.
- Click **Delete** and the QC chart data will be deleted from the QC chart list.

Figure 8.6.16 Confirmation to delete QC chart



8.7. Useful tools

The useful tools mainly include the configuration of system parameters, the setting of the parameters of test items, the editing of the calculation items and the maintenance functions of the instrument.

8.7.1. System

The system module mainly includes LIS settings, logs queries, authorization of user permissions, serial number setting and system settings.

Select **System** under **Useful tools**. For the administrator, the system interface will be shown as Figure 8.7.1; for other users, the system interface will be shown as Figure 8.7.2:

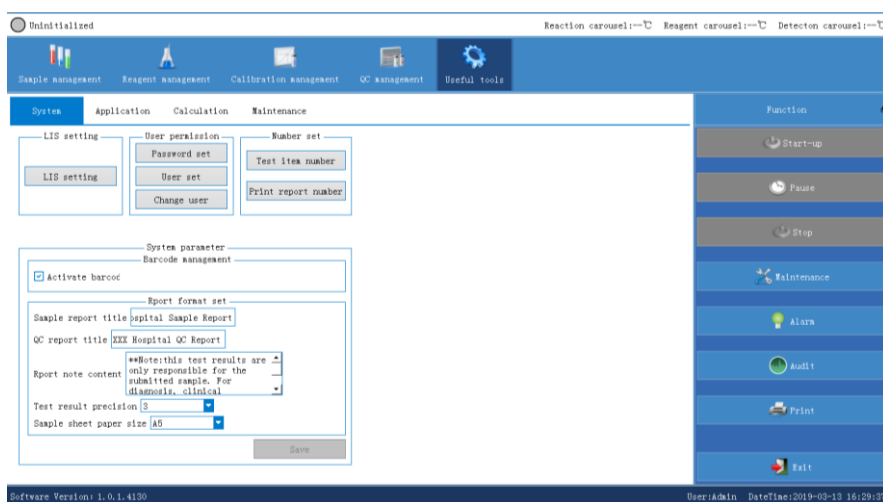


Figure. 8.7.1 System Settings (Administrator)

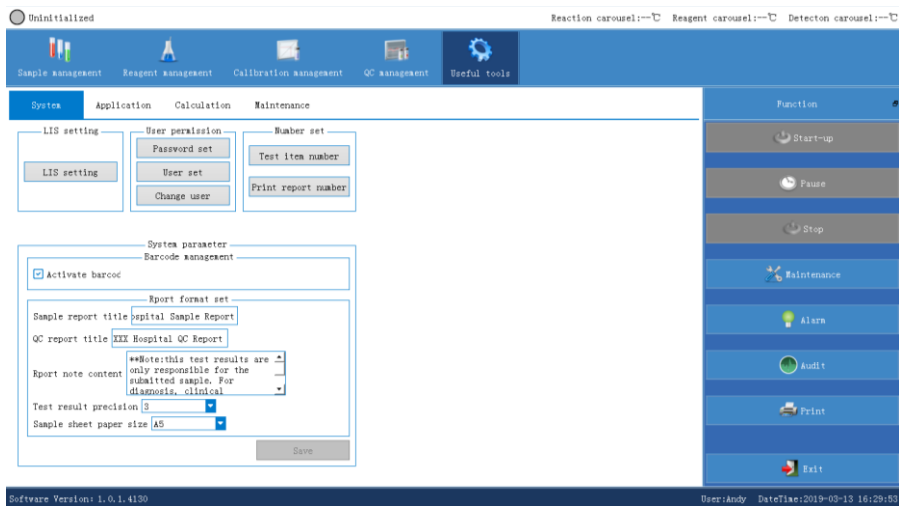


Figure. 8.7.2 System Settings (Users)

8.7.1.1. LIS settings

The LIS communication module includes the following:

1. Set up to activate LIS
2. Set up to activate automatic uploading, downloading and QC results uploading.

1. Activate LIS

- Select **System** tab under **Useful tools** and click **LIS settings**. The LIS setting window will appear, as shown in Figure 8.7.3.
- Check **Activate Communication LIS** and set the port and IP address of LIS server then click **Save** and exit. LIS connection is complete.

Note: The LIS server must be powered on before initiating the LIS communication.

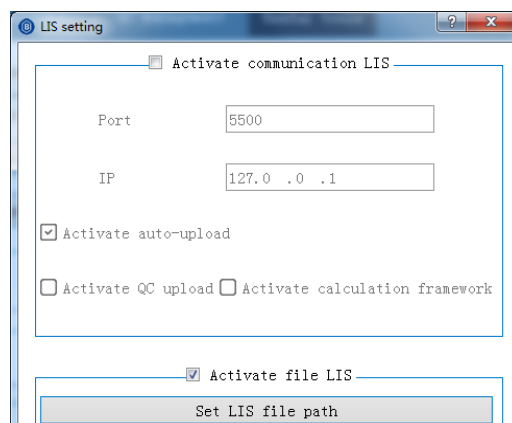


Figure. 8.7.3 LIS setting

After a successful LIS connection, please set the sample management module to the barcode mode.

- Click **Start-up** of the function controls and set the rack number and position number in the pop-up interface then click **Sample carousel scan**.
- After the scanning, please set the rack number and position number then Click **Start**. The downloaded item information will appear in the sample data list and the test will start.

2. Automatic uploading and downloading

- In the **LIS settings** interface as shown in Figure 8.7.3, check the boxes of **Activate auto-uploading**, **Activate auto-downloading** and **Activate QC results uploading** then click **Save**.
- The sample info will be downloaded automatically when the sample carousel is scanned under the **Barcode mode**; the tested results will be uploaded automatically in the **Sample data** interface as shown in Figure 8.3.11 and marked as successful in the **Upload mark** column.

Note: The LIS server must be powered on before initiating the LIS communication.

8.7.1.2. Logs queries

This module mainly records the operations performed by the user in each module.

- Select the **System** tab under **Useful tools** and click **Logs**. A system log will pop up.
- Enter the search conditions and click **Inquire**, the related log info will show in the logs.

8.7.1.3. User permissions

1. Password setting

- Select the **System** tab under **Useful tools** and click **Password Setting** to pop up the Change Password dialog box, as shown in Figure 8.7.5.
- Set the new password and click **Confirm**. The new login password will be in effect.

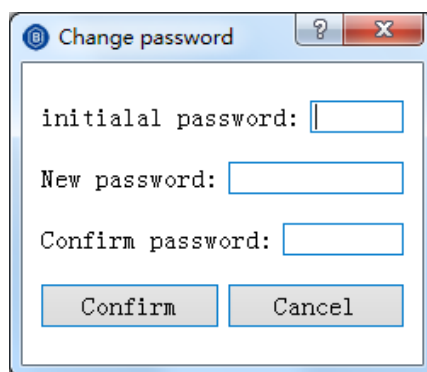


Figure. 8.7.5 Password setting

2. User settings (for administrator only)

User settings include adding users and deleting users. Click **User settings** under **System** interface, as shown in Figure 8.7.6.

- To add new user:
 - Enter user name, password and confirm password;
 - Click **Add**.
- To delete user:
 - Select the user for deletion in the user name list on the left and click **Delete**. A confirmation to delete will pop up as shown in Figure 8.7.7;
 - Click **OK** to delete the selected user.

Note: Administrator cannot be deleted.

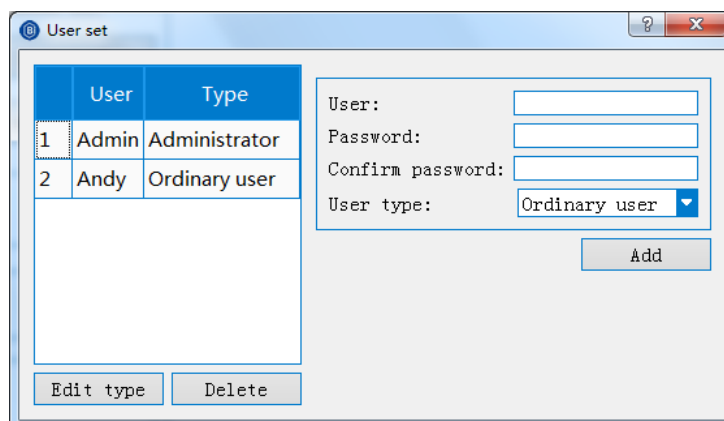


Figure. 8.7.6 User settings

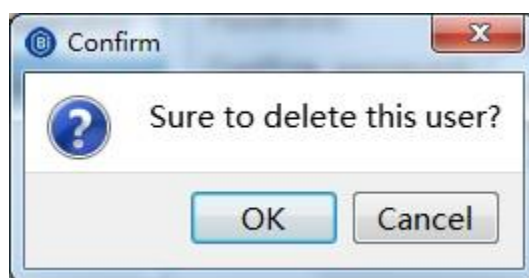


Figure. 8.7.7 Confirm to delete user

3. Change user

Click **Change User** under the **System** interface to pop up the user login interface as shown in Figure 8.1.2. Enter the username and password, and switch between different users without exiting the system.

Note: This function is disabled when the system is in testing or the sample loading is in pause.

8.7.1.4. Serial number setting

1. Setting serial number for test items

- Select **System** tab under **Useful tools** and click **Test item number** to pop up the serial number dialog box, as shown in Figure 8.7.8. The order of the test items initially follows the item number sequence from small to large.

Note: The initial test numbers are all 1.

- Rearrange the order of the test items by selecting each item and clicking **Up** or **Down** or double-clicking the item information to adjust the order.
- Click **Save** when the order is set. The test items will be listed as adjusted and the test numbers will be in sequential order of 1, 2, 3... now.

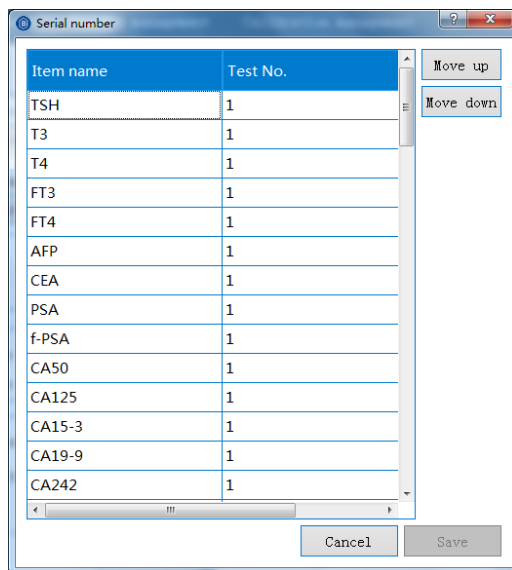


Figure. 8.7.8 Serial number for test items

2. Setting report printing order

- Select **System** under **Useful tools** interface and click **Print report number**.
- Rearrange the order of the printing items by selecting each item and clicking **Up** or **Down** or double-clicking the item information to adjust the order.
- Click **Save** when the order is set. The printing items will be listed as adjusted and the numbers will be in sequential order of 1, 2, 3... now.

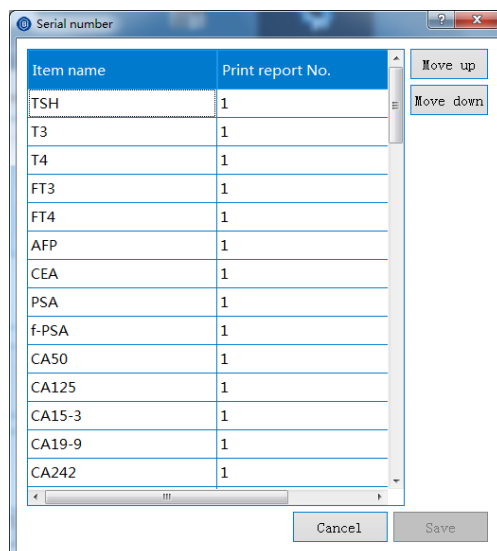


Figure 8.7.9 Setting the report printing order

8.7.1.5. System settings

1. Settings for the barcode mode

Check the **Barcode scanner** box in **System** tab and click **Save**. The barcode mode is enabled. Note that when switching between barcode mode and serial number mode, no sample information should remain in the sample data list in Figure 8.3.11, otherwise the switch will fail.

2. Settings for the report titles

Set the report formats in **System** tab and click **Save**.

8.7.2. Applications

The application module mainly includes the interfaces of Item list, Analysis, Calibration, and Range.

- The Item list interface is for adding and deleting items;
- The Analysis interface is for the setting of test item parameters and procedures;
- The Calibration interface is for the setting of the calibration item parameters;

- The Range interface is for the setting of the printing parameters.

8.7.3. Calculation

The calculation module is to add formulas and to calculate medically meaningful results based on the test results generated from the formula-related test items. This module includes the functions of adding and deleting calculation items.

Select **Calculation** tab under **Useful tools** as shown in Figure 8.7.10.

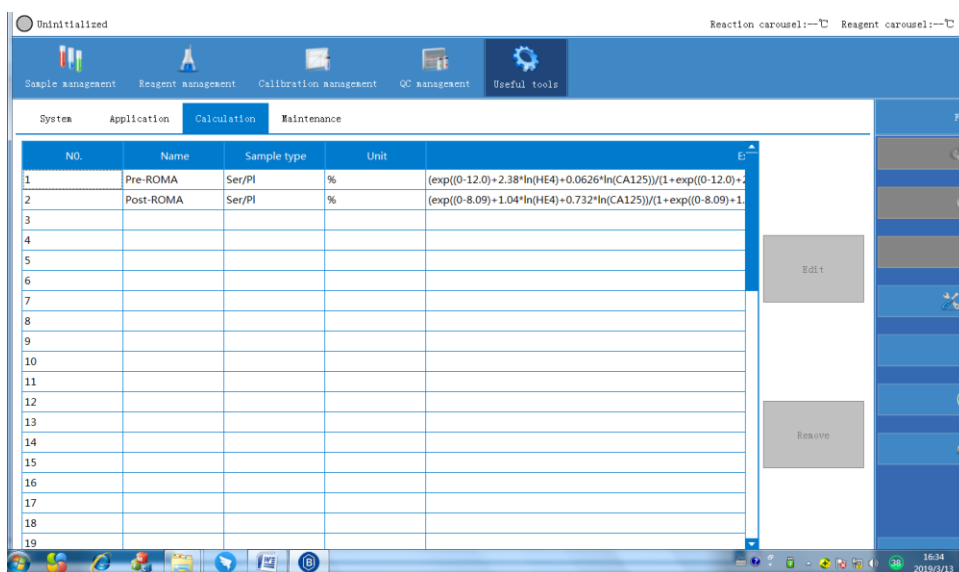


Figure 8.7.10 Calculation

1. Add calculation items

- Select a blank line and click **Edit** to bring up the calculation item dialog box, as shown in Figure 8.7.11.
- Enter the name, unit, select the sample type and edit the expression then click **Save**. The added calculation item will appear in the calculation item list.

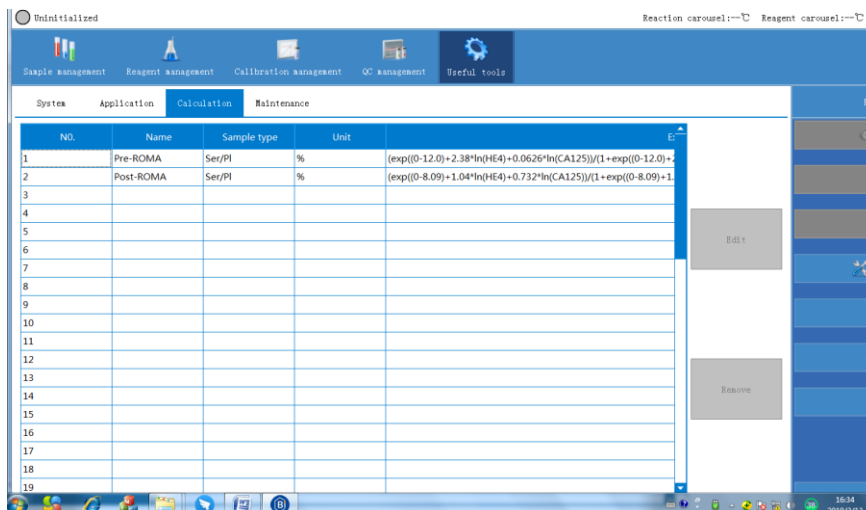


Figure. 8.7.11 Edit calculation item

2. Delete calculation items

- In the **Calculation** page, select the calculation formula to be deleted and click **Remove**. The selected calculation formula will be deleted.
- After the relevant test is completed, the result will be calculated (according to the formula) and appeared in the lower right corner of the data management, as shown in Figure 8.7.12.

Name	Result
PPI	91.7477
PPII	82.9689

Figure. 8.7.12 Calculation formula results

Note: Only when the relevant item has a calibration curve will there be a result for the calculation formula.

8.7.4. Maintenance functions

Maintenance functions include **One-button startup**, **One-button shutdown**, **System reset**, **Startup cleaning**, **Weekly maintenance – Deep cleaning**, **One-button empty**, **One-button fill-up**, **Shutdown cleaning**, **Shutdown**, **Sleep**, **Wakeup**, **Substrate preparation**, **Substrate test**, **Start buffer pool fill-up** and **Stop buffer pool fill-up**.

Note: Only **One-button startup** and **System reset** functions can be performed under the uninitialized status. All other functions can only be performed when the system is ready.

Select **Maintenance** tab under **Useful tools** or click **Maintenance** on the function controls column shown in Figure 8.7.13.

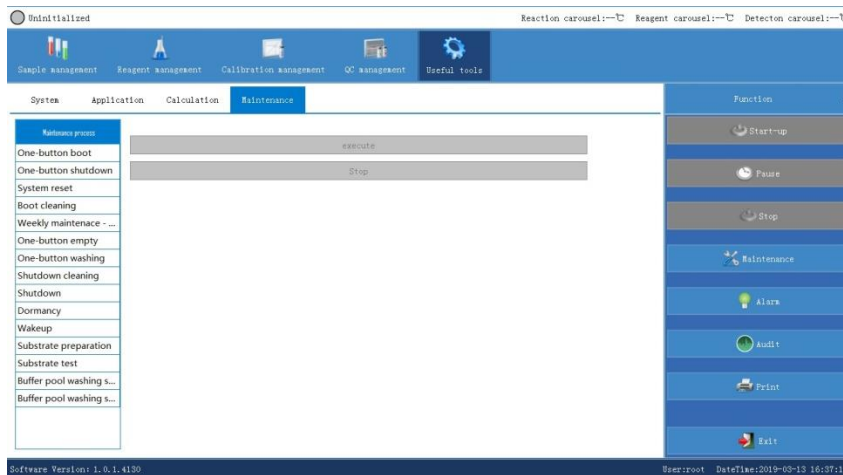


Figure 8.7.13 Maintenance

8.7.4.1. One-button startup

One-button startup includes both system reset and startup cleaning functions.

- Select **One-button startup** and the **Execute** button will be clickable.
- Click **Execute**, the instrument will perform the system reset action, followed by the startup cleaning action. During the system reset process, the status of the instrument is **Initializing**. During the startup cleaning process, the status of the instrument changes to **In maintenance**.

When the instrument is in maintenance status, the **Stop** button is clickable and the progress bar is at the bottom of the maintenance process interface, as shown in Figure 8.7.14:

Executing, please wait! 20% completed



Figure.8.7.14 In maintenance

- The progress bar will indicate when the execution is completed, as shown in Figure 8.7.15. The status of the instrument then changes to **Ready** and other maintenance functions are available for use.
- If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

Execution completed !



Figure.8.7.15 Execution completed

Execution failed !



Figure.8.7.16 Execution failed

8.7.4.2. One-button shutdown

One-button shutdown includes both shutdown cleaning and shutdown functions.

- Select **One-button shutdown** and the **Execute** button will be clickable.
- Click **Execute**, the instrument will perform the system reset action followed by the shutdown cleaning action, and finally the shutdown action.

During the actions, the instrument is in maintenance status. The **Stop** button is clickable and the progress bar is at the bottom of the maintenance process interface.

- The progress bar will indicate when the execution is completed, as shown in Figure 8.7.15. The status of the instrument then changes to **Uninitialized**.
- If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

8.7.4.3. System reset

Select **System reset** and the **Execute** button is clickable, as shown in Figure 8.7.17.

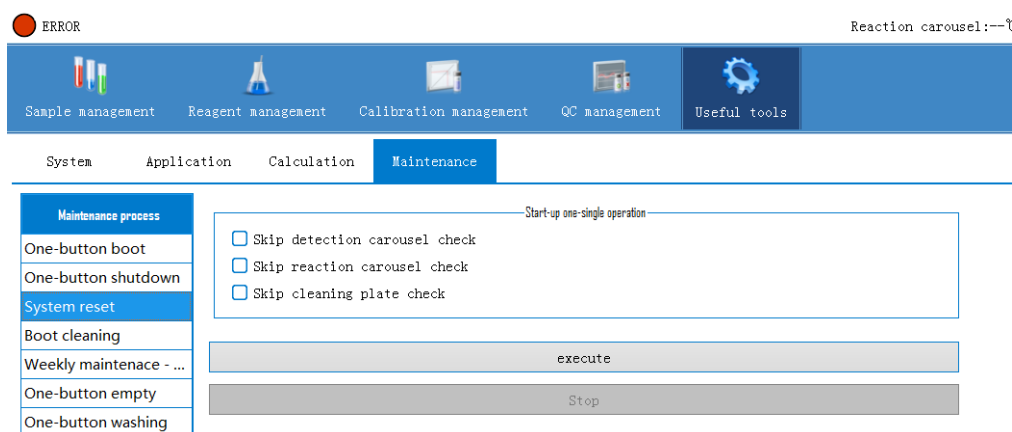


Figure. 8.7.17 System reset

- Click **Execute** and the vessel drop-off actions will be triggered in the three locations shown above. If no vessels in any of these three locations, please check **Skip** and the drop-off action will not be triggered at that particular location.
- The system reset starts after clicking **Execute**. The instrument is in the status of initializing. The **Stop** button is clickable at this time.
- The progress bar will indicate when the execution is completed, as shown in Figure 8.7.15. The status of the instrument then changes to **Ready**. Other maintenance functions are now available for use.
- If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

8.7.4.4. Startup cleaning

Select **Startup cleaning**, as shown in Figure 8.7.18:

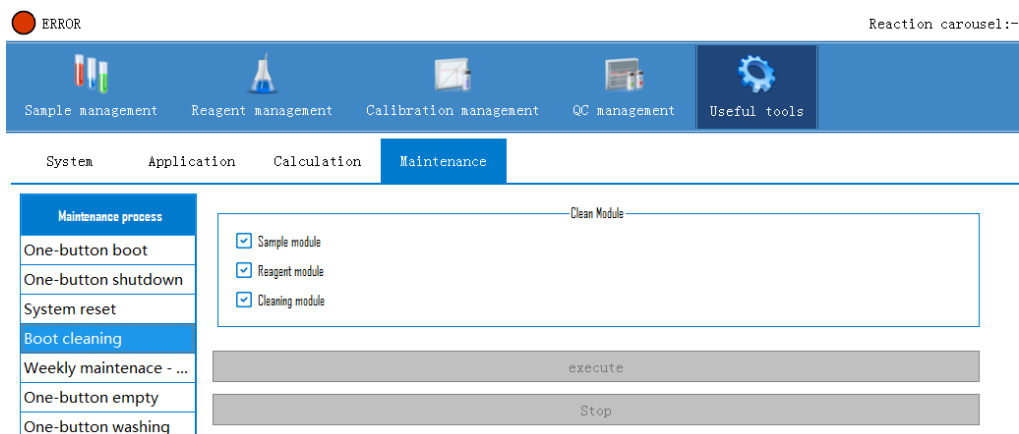


Figure. 8.7.18 Startup cleaning

Modules to be cleaned shall be selected before action.

- The **Sample module** cleaning requires to insert a sample vessel containing alcohol to the 1-1 position of the sample carousel. This is for the cleaning of the sample needle (sample size 3-4 mL).
- The **Reagent module** cleaning requires to insert a reagent kit containing alcohol to the No. 1 position of the outer ring of the reagent carousel. This is for the cleaning of the reagent needle (reagent amount 8-10 mL).
- The **Washing module** cleaning requires to have at least four vessels remained on the loading platform (starting from the next place where the vessels were removed last).
- Click **Execute** when the preparations are finished. The status of the instrument changes to **In maintenance**. The progress bar will show at the bottom.
- The progress bar will indicate when the execution is completed, as shown in Figure 8.7.15, The status of the instrument then changes to **Ready**.
- If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

8.7.4.5. Weekly maintenance— Deep cleaning

The Weekly-maintenance deep-cleaning interface is identical to the startup cleaning interface.

Modules to be cleaned shall be selected before action.

- The **Sample module** cleaning requires to insert a sample vessel containing enhanced cleaning solution or alcohol to the 1-1 position of the sample carousel. This is for the cleaning of the sample needle (sample size 3-4 mL).
- The **Reagent module** cleaning requires to insert a reagent kit containing enhanced cleaning solution or alcohol to the No. 1 position of the outer ring of the reagent carousel. This is for the cleaning of the reagent needle (reagent amount 8-10 mL).
- The **Washing module** cleaning requires to have at least four vessels remained on the loading platform (starting from the next place where the vessels were removed last).
- Click **Execute** when the preparations are finished. The status of the instrument changes to **In maintenance**. The progress bar will show at the bottom.
- The progress bar will indicate when the execution is completed, as shown in Figure 8.7.15. The status of the instrument then changes to **Ready**.
- If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

8.7.4.6. One-button empty

One-button empty function is applicable to situations such as transportation, the replacing of wash buffer, or long-time idling (such as holidays).

The one-button empty interface is identical to the startup cleaning interface.

- Before the action, the modules shall be completely empty, and the

substrate bottles and the pipelines connecting to the wash buffer container shall be removed.

- The **Washing module** cleaning requires to have at least four vessels remained on the loading platform (starting from the next place where the vessels were removed last).
- Click **Execute** when the preparations are finished. The system will prompt a message to remove the wash buffer pipelines and the substrate bottles.
- Click **OK** and the status of the instrument changes to **In maintenance**.
- The progress bar will indicate when the execution is completed, as shown in Figure 8.7.15. The status of the instrument then changes to **Uninitialized**.
- If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

8.7.4.7. One-button fill-up

One-button fill-up is applicable to situations such as the installation of the instrument, the replacing of wash buffer, or pipeline flushing after long-time idling (such as holidays).

The one-button fill-up interface is identical to the startup cleaning interface.

Modules to be filled up shall be selected before action.

- The **Washing module** fill-up requires to have at least four vessels remained on the loading platform (starting from the next place where the vessels were removed last).
- Click **Execute** when the preparations are finished. The status of the instrument changes to **In maintenance**.
- When the pipeline flushing is done, the progress bar at the bottom indicates that the execution is completed, as shown in Figure 8.7.15. The status of the instrument then changes to **Ready**.

- If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

8.7.4.8. Shutdown cleaning

Before implementing shutdown cleaning, the following actions are essential:

1. Insert a sample vessel containing alcohol to the 1-1 position of the sample carousel. This is for the cleaning of the sample needle (sample size 3-4 mL).
 2. Insert a reagent kit containing alcohol to the No. 1 position of the outer ring of the reagent carousel. This is for the cleaning of the reagent needle (reagent amount 8-10 mL).
 3. At least four vessels shall be on the loading platform (starting from the next place where the vessels were removed last).
- Click **Execute** when the preparations are finished. The status of the instrument changes to **In maintenance**
 - The progress bar will indicate when the execution is completed, as shown in Figure 8.7.15. The status of the instrument then changes to **Ready**.
 - If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

8.7.4.9. Shutdown

Select **Shutdown** and click **Execute**. The system will be in the shutdown process and the status changes to **Shutting down**.

- The progress bar will indicate when the execution is completed, as shown in Figure 8.7.15. The status of the instrument then changes to **Uninitialized**.

- If the process is incomplete, the progress bar indicates that the execution has failed, as shown in Figure 8.7.16. The status of the instrument then changes to **Stop**.

8.7.4.10. Sleep and Wakeup

Sleep

- Select **Sleep** and click **Execute**. The system will enter into the status of **In maintenance** and then change to **Sleep** mode after the process is finished. At this moment, only the **Execute** button in the **Wakeup** tab is clickable in the entire maintenance process interface.
- In **Sleep** mode, only the temperature control and alarm functions of the reagent carousel are in working status. The reaction carousel and the detection carousel cease to operate in this mode.

Wakeup

- Select **Wakeup** and click **Execute**. The system will enter into the status of **In maintenance** and then change to **Uninitialized** after the process is finished.
- At this moment, only the **Execute** buttons for **One-button startup** and **System reset** tabs are clickable.

8.7.4.11. Substrate preparation

Select **Substrate preparation** as shown in Figure 8.7.20:

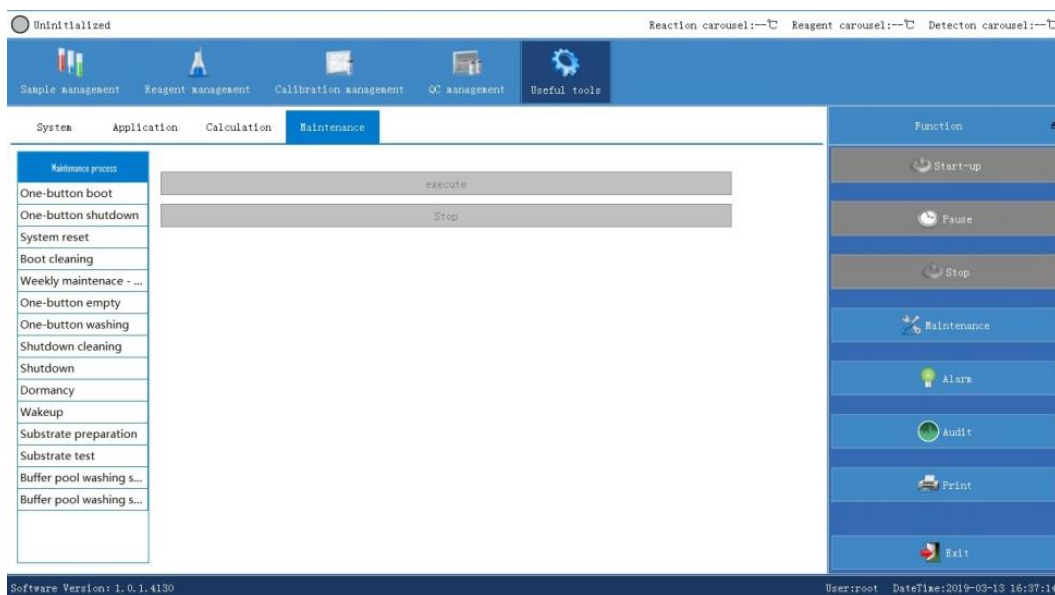


Figure. 8.7.20 Substrate preparation

Substrate preparation is for the fill-up of the substrate pipelines.

- Substrate type must be selected when executing the substrate preparation;
- the fill-up volume of **Substrates A & B** and the **Buffer** shall be multiples of 100 and the fill-up volume of **Substrates C** shall be multiples of 200.

If the distilled water is selected as the fill-up fluid, please replace the corresponding substrates with distilled water and checked the relative substrate type in the interface.

- Click **Execute** and the status of the instrument changes to **In maintenance**. The flushing of the substrate needle starts.
- The progress bar will indicate when the execution is completed. The status of the instrument then changes to **Ready**.

8.7.4.12. Substrate test

Select **Substrate test**, as shown in Figure 8.7.21:

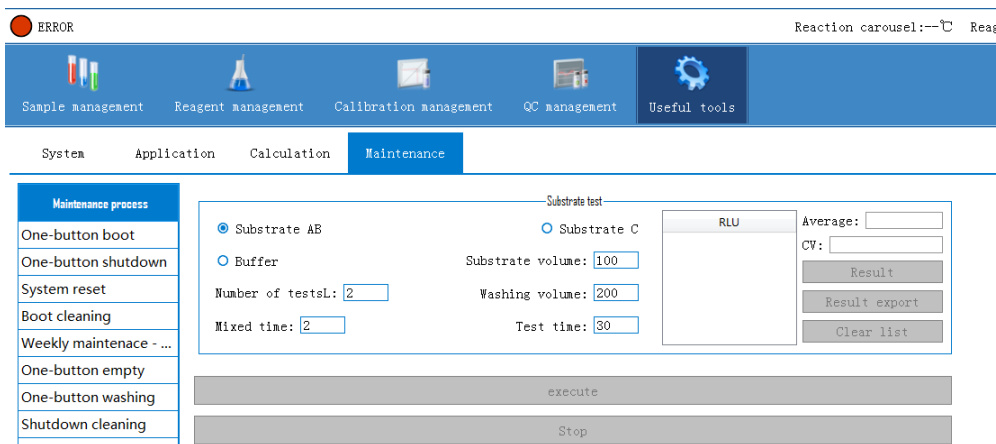


Figure. 8.7.21 Substrate test

- The volume of substrate and the fill-up volume shall be multiples of 100;
- the test time shall only be either 5 or 30 seconds;
- At least four vessels shall be on the loading platform (starting from the next place where the vessels were removed last) before the substrate test starts.
- Click **Execute** after filling in the substrate test information in the interface. The status of the instrument changes to **In maintenance**.
- The progress bar at the bottom will indicate when the execution is completed. The result is displayed in the list of RLU. The status of the instrument then changes to **Ready**.
- Click **Result** upon the completion of the test and the average value and CV will be calculated.
- Click **Result Export** to export the results to an excel spreadsheet.

8.7.4.13. Start buffer pool fill-up

This function is to initiate the automatic fill-up of the buffer pool.

- Select **Start buffer pool fill-up** and click **Execute**. A dialog box will pop up, as shown in Figure 8.7.22.
- Click **OK** and the system will start the buffer pool fill-up process.

- After the fill-up is done, the status of the instrument then changes to **Ready**.

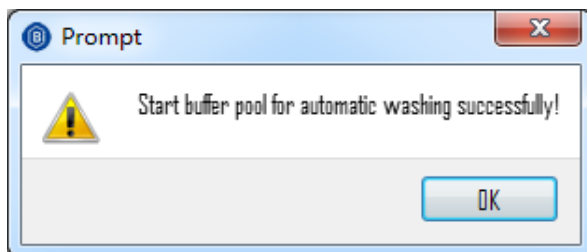


Figure.8.7.22 Start buffer pool fill-up

8.7.4.14. Stop buffer pool fill-up

This function is to stop the automatic fill-up action of the buffer pool.

- Select **Stop buffer pool fill-up** and click **Execute**. A dialog box will pop up, as shown in Figure 8.7.23.
- Click **OK** and the system will stop the buffer pool fill-up process.
- The status of the instrument then changes to **Ready**.

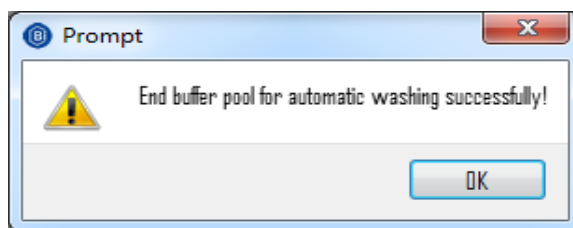


Figure. 8.7.23 Stop buffer pool fill-up

8.8. Function controls

Function controls include the start, pause and stop of the test, the addition of consumables/sample racks replacement, maintenance, alarm, print, monitoring and exit.

8.8.1. Function controls of the test

1. Start item test

- Click **Start** to start the item test. This includes the regular/emergency sample test, the calibration item test and the QC item test.
- The status of the instrument then changes to **Testing**. Please refer to 8.9 Test control for details.

2. Pause item test

- Click **Pause** to pause the item test. At this moment, consumables can be added and the sample racks can be replaced.
- The status of the instrument changes to **Testing (sample loading paused)** when **Pause** is clicked.

3. Stop item testing

- Click **Stop** to stop the ongoing test. When errors occur during tests, please click **Stop** to prevent damages to the instrument.
- The status of the instrument then changes to **Stop**.

8.8.2. Adding consumables/sample racks replacement

- When the consumables in the loading platform run out during the tests, the system will pop up a warning message that the consumables container is empty.
- The status of the instrument then changes to **Sample loading paused**.
- Select **Start-up** and click **Add** in the pop-up window, as shown in Figure 8.8.1.
- After the adding the consumables, please click **Finish adding**, as shown in Figure 8.8.2.
- Set the serial number to 0 under the **Serial number mode** and click **Start** in the **Start-up** tab, and the test continues.

- Set one of the rack number position numbers to 0 under the **Barcode mode** and click **Start**, and the test continues.

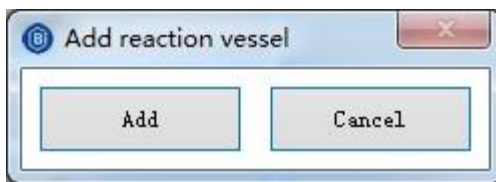


Figure. 8.8.1 Adding reaction vessels

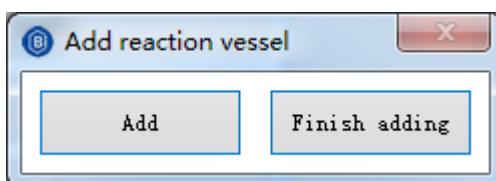


Figure. 8.8.2 Finish adding reaction vessels

- In case the sample racks need replacement during the tests, please click **Pause** in the function controls column and the status of the instrument changes to **Sample loading paused**.
- Click **Start** and click **Replace sample rack** in the pop-up window, as shown in Figure 8.8.3.
- Select the sample rack to be replaced.
- After the replacement, please click **Finish**, as shown in Figure 8.8.4.
- Continue the test by following the above start-up steps.

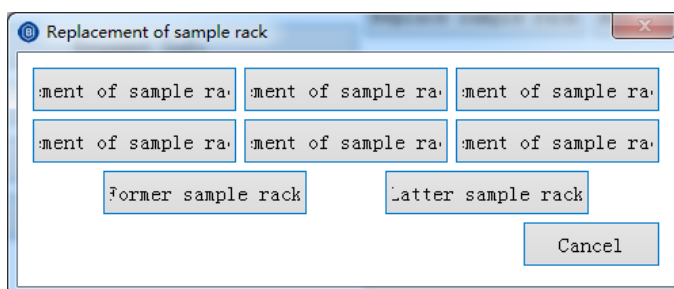


Figure. 8.8.3 Replacing the sample racks

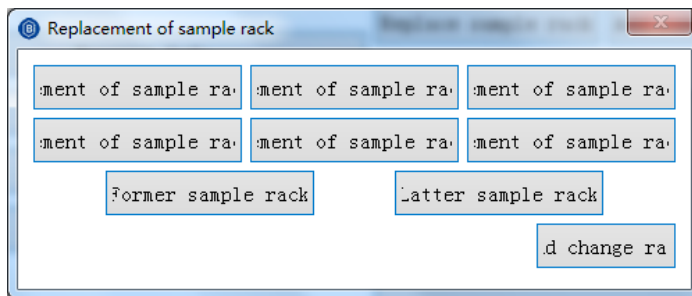


Figure. 8.8.4 Finish the replacement of the sample racks

8.8.3. Maintenance

Please refer to 8.7.4 **Maintenance functions** for details.

8.8.4. Alarm

The **Alarm** section will show all details of the alarm, such as error codes, levels of the alarm, triggered time, the alarm description, reasons for the alarm, notices for the alarm and solutions.

- Click **Alarm** in the function controls column to pop up the alarm window, as shown in Figure 8.8.5:

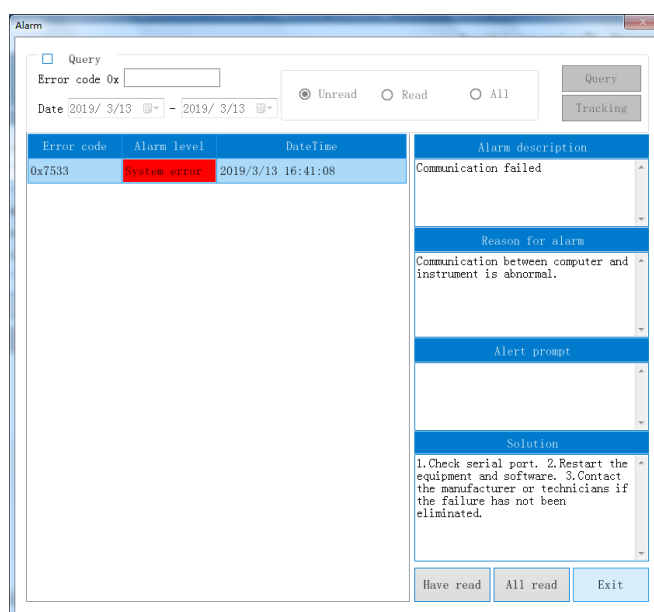


Figure.8.8.5 Alarm

Different colours are used to identify different levels of alarm as follows:

- Red means critical errors
- Yellow means alerts or notices
- White means normal records.

1. Inquire about the current alarm details

- When the test error occurs, the buzzer will sound.
- Click **Alarm** in the function controls column and check the alarm details.
- After reading the alarm messages, please click **Read** or **All read** and then click **Exit** to quit the alarm interface. The alarm will stop sounding.

2. Inquire about the specific alarm information

- Select **Inquiry mode** in the alarm interface, as shown in Figure 8.8.5.
- Fill in the error code or triggered date as needed, select **All** or other options listed and click **Inquire**.

3. List of error codes

Error Codes	Levels of Alarm	Description	Reasons for Alarm	Solutions
0x0001	Warning	loading arm placing reaction vessels failure	1. No vessel in the current position of the consumable container 2. External intervention 3. Loading arm system error 4. Reaction carousel error	1. Check consumable container 2. Eliminate external intervention 3. Check and confirm, no negative effects on normal operation.
0x0002	Warning	Consumable container empty	1. No vessel in the current position of the consumable container 2. External intervention 3. Loading arm system error 4. Reaction carousel error	1. Check consumable container 2. Eliminate external intervention 3. Reboot instrument/system after test 4. If error persists, contact Bioartron
0x0003	Warning	Conflicts in reaction vessels placing by the loading arm	1. Existing vessel in the loading position of the reaction carousel 2. Reaction carousel error	Check and confirm, no negative effects on normal operation.
0x0004	General error	Continuous conflicts in reaction vessel placing by the loading arm	1. Existing vessel in the loading position of the reaction carousel 2. Reaction carousel error	1. Check if there is existing vessel in the relative position of the reaction carousel after test 2. Reboot instrument/system 3. If error persists, contact Bioartron
0x07D1	Alarm	Insufficient	1. Improper reagent position	1. Check and confirm, no negative

		reagent	<ol style="list-style-type: none"> 2. Reagent bottle cap still on 3. Improper position of reagent carousel cover 4. Insufficient reagent amount 5. Liquid level detector error 6. Reagent carousel error 	<p>effects on normal operation.</p> <ol style="list-style-type: none"> 2. Double-check the test item is advised.
0x07D2	Alarm	Continuous insufficient reagent	<ol style="list-style-type: none"> 1. Improper reagent position 2. Reagent bottle cap still on 3. Improper position of reagent carousel cover 4. Insufficient reagent amount 5. Liquid level detector error 6. Reagent carousel error 	<ol style="list-style-type: none"> 1. Check reagent position and remaining amount 2. Check reagent bottle cap and reagent carousel cover 3. Reboot instrument/system 4. If error persists, contact Bioartron
0x07D3	Alarm	Insufficient magnetic particles	<ol style="list-style-type: none"> 1. Improper magnetic particles position 2. Magnetic particles bottle cap still on 3. Improper position of magnetic particles carousel cover 4. Insufficient magnetic particles amount 5. Liquid level detector error 6. Magnetic particles carousel error 	<ol style="list-style-type: none"> 1. Check and confirm, no negative effects on normal operation. 2. Double-check the test item is advised.
0x07D4	Alarm	Continuous insufficient magnetic particles	<ol style="list-style-type: none"> 1. Improper magnetic particles position 2. Magnetic particles bottle cap still on 3. Improper position of magnetic particles carousel cover 4. Insufficient magnetic particles amount 5. Liquid level detector error 6. Magnetic particles carousel error 	<ol style="list-style-type: none"> 1. Check magnetic particles position and remaining amount after test 2. Check magnetic particles bottle cap and carousel cover 3. Reboot instrument/system 4. If error persists, contact Bioartron
0x07D6	Alarm	Insufficient reagent amount	Insufficient reagent remaining amount counts in the system (software)	<ol style="list-style-type: none"> 1. Edit or add reagent amount in the system (software) and save the unsaved test items again. 2. Check and confirm, no negative effects on normal operation.
0x03E9	Alarm	Insufficient sample amount	<ol style="list-style-type: none"> 1. Improper selection of sample vessel type 2. Sample vessel cover still on 3. Improper sample vessel position 4. Insufficient remaining sample amount 5. Sample carousel error 6. Liquid level detector error 	<ol style="list-style-type: none"> 1. Check and confirm, no negative effects on normal operation. 2. Pause sample loading and examine this sample info 3. Retest this item
0x03EA	Alarm	Continuous insufficient sample amount	<ol style="list-style-type: none"> 1. Improper selection of sample vessel type 2. Sample vessel cover still on 3. Improper sample vessel position 4. Insufficient remaining sample 	<ol style="list-style-type: none"> 1. Check sample vessel type 2. Check sample vessel cover, position and remaining amount 3. Reboot instrument/system 4. If error persists, contact Bioartron

			amount 5. Sample carousel error 6. Liquid level detector error	
0x0BBE	General error	transfer arm capturing vessels failure in washing carousel	1. External intervention 2. Washing carousel error 3. Transfer arm error	1. Reboot instrument/system after test. 2. If error persists, contact Bioartron
0x7533	Critical error	Communication failure	Communication error between computer and instrument	1. Check connecting ports 2. Reboot instrument/system 3. If error persists, contact Bioartron
0x7919	Alarm	LIS connection failure	1. LIS server not on 2. LAN connection error 3. System firewall still on 4. System and LIS server not in the same network	1. Check LIS server power 2. Check LAN connection 3. Check system firewall 4. Check if system and LIS server are in the same network 5. Reboot instrument/system 6. If error persists, contact Bioartron
0x791A	Alarm	LIS result upload failure	1. LIS server not on 2. LAN connection error 3. System firewall still on 4. System and LIS server not in the same network	1. Check LIS server power 2. Check LAN connection 3. Check system firewall 4. Check if system and LIS server are in the same network 5. Reboot instrument/system 6. If error persists, contact Bioartron
0x0FA1	Alarm	Insufficient substrate amount	Insufficient substrate remaining amount counts in the system (software)	1. Edit or add substrate amount in the system (software) and save the unsaved test items again 2. Check and confirm, no negative effects on the normal operation
0x7534	Critical error	Continuous over time limits	1. External intervention 2. Instrument actions not finished as planned 3. Communication error in the connecting ports	1. Eliminate external intervention 2. Check connection ports 3. Reboot instrument/system 4. If error persists, contact Bioartron

8.8.5. Print

This function is for the printing of the test reports.

8.9. Test control

8.9.1. Sample testing

Sample testing has two modes: **Serial number mode** and **Barcode mode**.

8.9.1.1. Serial number mode

1. Register the reagent information of the item. Please refer to 8.4 **Reagent management** for details.
2. Save the sample information of the item. Please refer to 8.3.1 **Serial number mode** for details.
3. Start the test.
 - Click **Start-up** in the function controls column to pop up the start-up conditions interface, as shown in Figure 8.9.1.
 - Select the type of test: **Regular** or **Emergency**.
Note: the system default type is **Regular**.
 - Fill in the starting serial number and click **Start**
 - The status of the samples will change from **Saved** to **To be tested** in the sample data interface
 - If the serial number does not exist, the system will pop up warning of start-up failure, as shown in Figure 8.9.2:

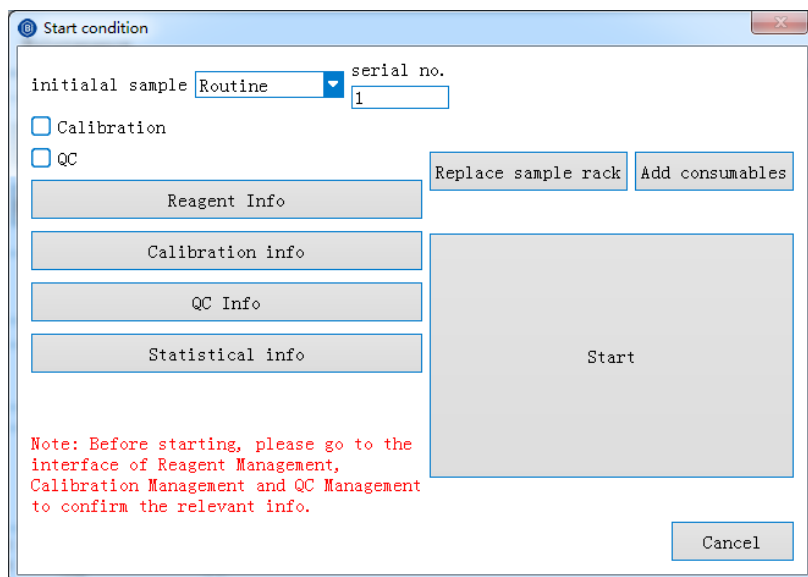


Figure. 8.9.1 Start-up conditions (serial number mode)

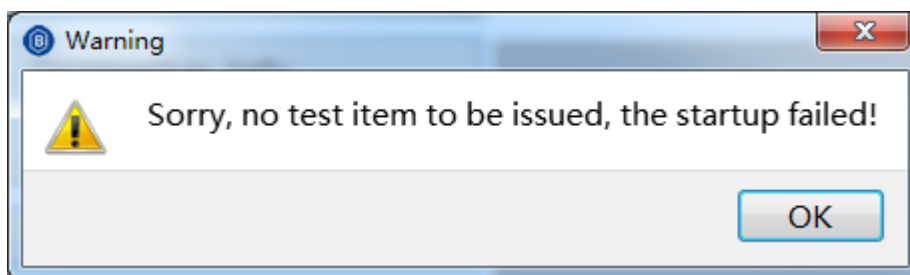


Figure. 8.9.2 Start-up failure

8.9.1.2. Barcode mode

1. Register the reagent information of the item. Please refer to 8.4 **Reagent management** for details.
2. Save the sample information of the item. Please refer to 8.3.2 **Barcode mode** for details.
3. Start the test.
 - Click **Start-up** in the function controls column to pop up the start-up conditions interface, as shown in Figure 8.9.3.
 - Fill in the sample rack number and position number and click **Sample carousel scan**.
 - Barcode scanning will start from the selected position.
 - The system will indicate when the barcode scanning is done.

- Click **OK** and the status of the samples will change from **Saved** to **To be tested** in the sample data interface.

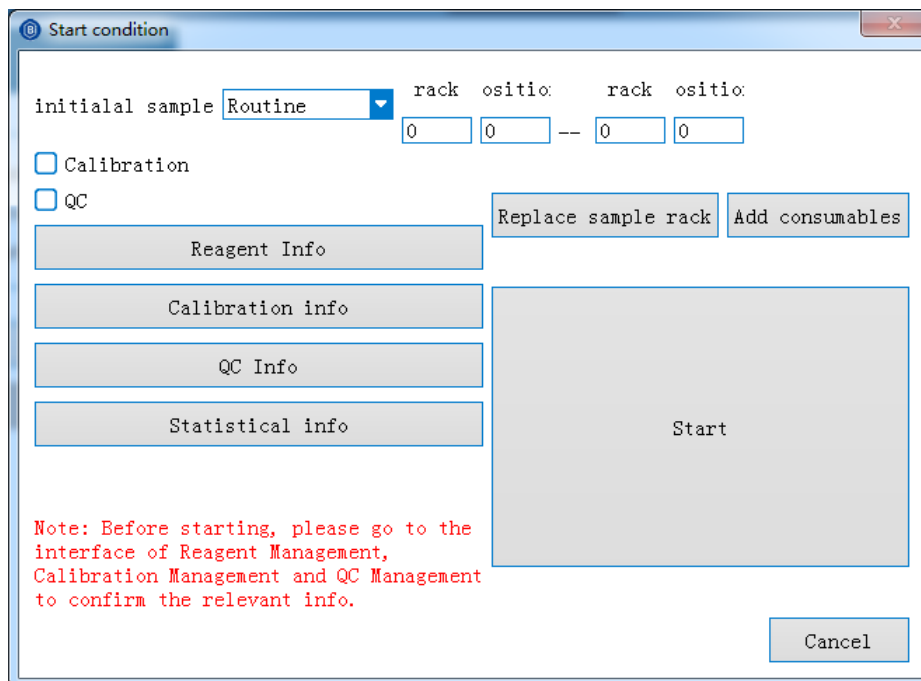


Figure. 8.9.3 Star-tup conditions (barcode mode)

8.9.2. Calibration item test

8.9.2.1. All-point calibration

1. Register the reagent information of the item. Please refer to 8.4 **Reagent management** for details.
2. Add calibrator S0-S5, a total of 6 calibrators for the item in the calibrator interface.

Please refer to 8.5.1 **Calibrator management** for details.

3. Activate calibrator S0-S5. Please refer to 8.5.1.4 **Activate calibrator** for details.
4. Select items that need to add calibrators, as shown in Figure 8.5.6
5. Select calibration type and click **Choose**
6. Select **All-point calibration** and click **OK**. The **Calibration type** column will show **All-point calibration**.

7. If the item requires any specific reagent, double-click the reagent position of the corresponding calibration item to select the designated reagent.
8. Click **Start-up** in the function controls column and select **Calibration** in the pop-up window.
9. Click **Start** to start the all-point calibration item test.

8.9.2.2. One-point / two-point calibration

1. Select **Calibrator** tab under **Calibration management** and add a calibrator for one-point or two-point calibration;
2. Activate the calibrator;
3. Select **Status** tab under **Calibration management** and select the calibration type: one-point calibration or two-point calibration;
4. Start the test. Details are similar to that of the all-point calibration.

Note: One-point or two-point calibration item must have a calibration curve to perform the calibration test;

8.9.2.3. Qualitative item

Details of the qualitative item test are similar to that of the all-point calibration.

8.9.3. QC item Test

1. Register the reagent information of the item. Please refer to 8.4 **Reagent management** for details.
2. Add the quality controls' information. Please refer to 8.6.1 **Quality control management** for details.
3. Activate quality controls. Please refer to 8.6.1.4 **Activate QC** for details

4. Set the rack number, position number and number of tests of the QC item in the QC status interface. Please refer to 8.6.2.2 **Setting the QC test times** for details.
5. Start the test. Click **Start-up** in the function controls column and select **QC** in the pop-up window, then click **Start** to start the QC item test.

8.9.4. Additional test item

Additional tests include additional sample test, additional calibration test and additional QC test.

Additional sample test is used as an example:

1. Save the sample information of the item. Please refer to 8.3.1 **Serial number mode** for details.
2. Start the test.
 - Click **Start-up** in the function controls column to pop up the **Start-up conditions** interface, as shown in Figure 8.9.1.
 - Select the test type: **Regular** or **Emergency**. The system default type is **Regular**.
 - Fill in the starting serial number of the additional sample and click **Start**. The status sample in the **Sample data** interface will change from **Saved** to **To be tested**.

If the additional test item is **Emergency** type, it will be tested at the beginning of next cycle;

if the additional test item is **Regular** type, it will be tested following the previous round of test items.