锐拓仪器
RAYTOR INSTRUMENTS

Raytor RT612-ST Dissolution System Operation Manual

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STATEMENT

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Attention!

Please operate the equipment according to the instructions in the operation manual.

Read the operation manual carefully before use, especially the Safety Instructions and Equipment Maintenance.
This operation manual will use the following signs to warn or prompt for additional concerns. Please read them carefully.

Warning Sign

Attention

This sign is used to remind you of possible safety risks or experimental failure risks during use. **Violating or ignoring the warning content may result in the failure of the experiment, abnormal results, loss of data, and even injury of personnel.**

Informatory Sign

Suggestion

This sign is used to remind you of the matters you need to pay attention to in the process of using, and make relevant suggestions. Following the suggestions can better maintain the performance of the equipment, and achieve more stable and reliable experimental results and better compliance.

Contents

1. Safety Instructions

Attention:

Before using or installing this equipment, please read Chapter 1 Safety Instructions carefully.

1. Safety Instructions

The Raytor dissolution apparatus has stable performance and high automation. The related technology design can effectively ensure the safety of users in the use process. Therefore, users should operate the dissolution apparatus in accordance with the way specified in these instructions, in order to ensure the safety of personnel and maintain the stability of the equipment. Any operation not in accordance with the instructions or unauthorized modification of the equipment may weaken the safety protection function of the equipment or lead to instability of the performance of the equipment.

- The power supply requirement of this equipment is: AV 220V ± 10%, 50Hz. Please use three-hole socket with grounding connection and enough rated load. In order to avoid possible overload risk, it is not recommended to share the same socket with other high-power equipment. Using the wrong voltage, the socket without grounding function or overload, which may lead to unsafe situations such as electric shock, equipment damage and so on.

- It is strictly forbidden to disassemble the equipment when the equipment is connected to the power supply. When the equipment is connected to the power supply, the internal electronic circuits and components of the instrument may have dangerous voltage, contacting these internal components may cause the danger of electric shock. If disassembly and maintenance are required, please contact Raytor maintenance engineer to provide professional and safe maintenance services.
- This equipment has the function of dry burning protection of heater. However, in order to further ensure safety, it is strongly recommended to confirm that there is enough water in the water bath before opening the heating function.
- This equipment is designed for the separation of water and electricity, and has the function of leakage protection, which can effectively prevent the electric shock risk caused by leakage. However, in order to further ensure safety, attention should be paid to avoid spilling on power supply and circuit components when adding purified water and dissolution medium. If water leakage is found, cut off the power supply immediately, and contact the Raytor maintenance engineer to deal with it.
- When cleaning the dissolution apparatus, please avoid water entering into the dosing motor. It is very likely that the automatic synchronous dosing function of the dosing motor will be abnormal, or even the components will be damaged.

- Do not lengthen, shorten or alter the pipe of the sampling system without authorization. Any unauthorized modification of the pipe of the sampling system may cause abnormal sampling or other unforeseen experimental risks.
- Before installation and use, read the operation manual carefully, and understand the functional information of each component and the matters needing attention, so as to use the Raytor dissolution apparatus safely and efficiently.
- It is suggested that the equipment should be verified regularly to ensure the safety and stability of the equipment.

2. Overview of Dissolution System

Brief Introduction of Raytor RT612-ST Automatic Sampling Dissolution System

Raytor RT612-ST Automatic Sampling Dissolution System is the latest 12-Cup Automatic Sampling Dissolution System launched by Raytor Instruments in combination with the latest United States Pharmacopoeia, Chinese Pharmacopoeia and customer needs. It is a dissolution apparatus that fully meets data integrity and audit tracking. It is equipped with LCD touch panel display and has a straight interface, easy to operate, stable performance, high degree of automation.

RT612-ST Dissolution System has the following characteristics

- The mechanical performance parameters of the instrument fully meet the relevant requirements of the Chinese Guidelines for Mechanical Verification of Drug Dissolution Apparatus and the United States FDA DPA-LOP.002, ASTM E2503-07, USP Toolkit.

- The medium temperature sensor is non-resident, which can flexibly monitor the temperature of dissolution medium.

- The operating system uses account password to login, which meets the requirements of computer system regulations.

- The innovative collar incorporated onto the dissolution vessel, clamping the center position automatically by rotating 30 degrees. The center position has good reproducibility.

- Patent design of common shaft for paddle and basket, it is not necessary to reset the height after switching method, and it is convenient to use and clean.

- Automatic synchronous dosing device, eliminate the time difference of dosing, and the point of dosing can be audit tracked.

- Dissolution methods can be created, stored or edited to facilitate direct invocation, with no upper limit on the number of methods.

- Experimental reports will be automatically generated and saved independent for each dissolution experiment. Temperature and rotation rate charts are presented intuitively, and the experimental records can be exported as PDF documents.

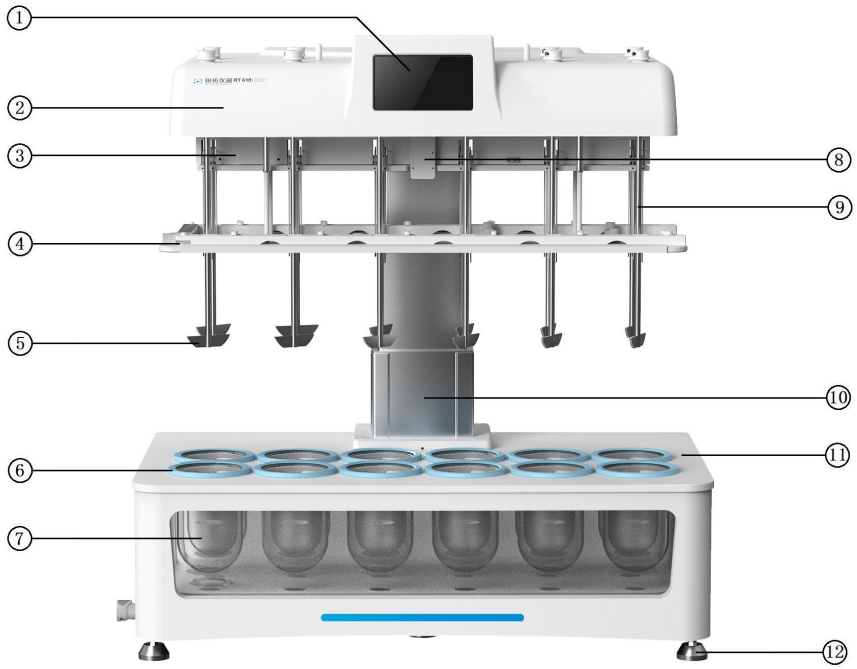
- Modification of testing parameters and other operations will be recorded automatically and in real time by the system, which fully meets the regulation requirements of audit track.

- Sampling pipe automatic cleaning, automatic emptying, automatic purging function.

- Secondary online filtering function is available.

3. Hardware Composition and Performance Parameters of Dissolution System

3.1 Hardware Composition of RT612 Dissolution Apparatus

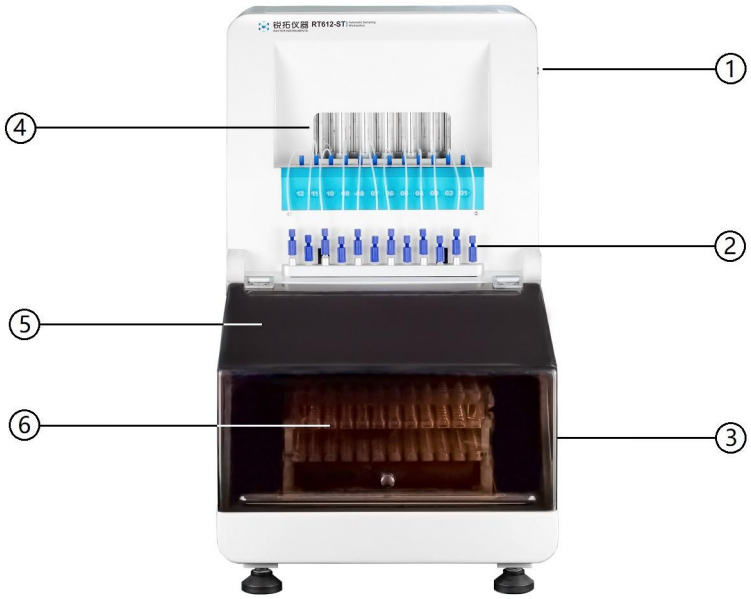


1. Touch Screen: Human-Computer Interactive Interface
2. Lifting Head
3. Sampling Frame
4. Integrated Dissolution Vessel Cover
5. Dissolution Stirring Element
6. Dissolution Vessel
7. Water Bath
8. Vessel Cover Clasp
9. Sampling Needle &Temperature Probe
10. Lifting Column
11. Dissolution Vessel Installation Platform
12. Dissolution Apparatus Support Foot

3.2 Parameters of RT612 Dissolution Apparatus

Item		Parameters
Size	Dissolution Vessel Number	12
	Length × Width	~ 92cm × 56cm
	Height (Fully Raised)	~ 96cm
	Weight (No Load)	~ 110kg
Power Supply		AV 220V±10%, 50Hz
Rotation Speed	Setting Range	20-250 RPM
	Resolution	0.01 RPM
	Steady Speed Error	≤±0.3 RPM
Temperature	Temp. Accuracy	≤± 0.2℃
	Resolution	0.01 ℃
Mechanical Parameters	Level	＜ 0.5°
	Vessel Verticality	90° ± 0.5°
	Shaft Verticality	90° ± 0.5°
	Centering Deviation	＜ ± 2.0 mm
	Depth Positioning Deviation	＜ ± 1.0 mm
	Shaft Wobble	＜ ± 1.0 mm
	Basket Wobble	＜ ± 1.0 mm

3.3 Hardware Composition of RT612-ST Automatic Sampling Workstation



1. Light Switch of Injection Pump Observation Window (above the left right side of the equipment)

2. Sampling Pipe-Sample Injection Needle Connection

3. Connecting Signal Indicator (below the left side of the equipment)

4. Injection Pump Observation Window

5. Hood

6. Test Tube Holder

3.4 Parameters of RT612-ST Automatic Sampling Workstation

Item		Parameters
Size & Specification	Length × Width	~ 40cm × 70cm
	Height	~ 70cm
	Weight (No Load)	~ 45kg
	Sampling Pipe Number	12
	Holes in Test Tube Holder	12 × 15
Sampling Parameters	Maximum Settable Sample Number	20
	Sampling Range	1 ~ 20ml
	Minimum Sampling Interval	2 minutes
	Maximum Working Time	720 hours
	Sampling Precision	≤±1%
	Sampling Pump	Piston Injection Pump or Plunger Pump

4. Installation of Dissolution Apparatus

4.1 Installation Area Preparation

（1）According to the weight information of the equipment in **Chapter 3**, select a flat lab table with enough load.

Attention:

If the load-bearing capacity of the lab table is insufficient, there will be obvious shaking., which will lead to abnormal results of equipment performance verification and experiment. When the load-bearing capacity of the lab table is seriously insufficient, it is very likely that the lab table will collapse or the equipment will collapse, resulting in equipment damage or personnel injury.

（2）According to the equipment size information in **Chapter 3**, confirm that there is enough installation space for the lab table. When the dissolution lifting head is completely elevated, the space above it should be at least 30 cm high. The back and side of the equipment should have a width of about 10 cm.

（3）Normally, the automatic sampling workstation should be placed on the right side of the dissolution apparatus. If it needs to be adjusted to the left side of the dissolution apparatus, it will involve the problem of pipe rearrangement. So please contact Raytor first for technical support.

（4）The power supply requirement of this equipment is: AV 220V + 10%, 50Hz. Make sure the voltage of installation environment meets the requirement.

Attention:

Please use a three-hole socket with enough rated load and grounding connection.

（5）Avoid direct sunlight on equipment to avoid sample photodegradation. If the dissolution sample is particularly sensitive to the light source, it is prone to photodegradation even under the normal light source in the laboratory. It is suggested to use a light-shielded dissolution vessel and a light-shielded dissolution vessel cover. Raytor Instruments and its local contracted agents provide relevant accessories.

（6）It is suggested to monitor the daily temperature and humidity in the operating environment of the equipment to ensure that the dissolution experiment is carried out in a controllable environment.

Reference Range for Environmental Temperature Monitoring: 25 ±5℃

Reference Range for Environmental Humidity Monitoring: ≤80%

(Users can adjust appropriately according to their actual needs)

4.2 Unpacking

Attention:

Read Chapter 4.2 in detail and completely before unpacking, fully understand the possible safety risks in the process of unpacking and the handling measures in case of abnormal situations.

Please arrange for sufficient personnel to move the wooden cases and the equipment. If there are insufficient relocation personnel, injuries may occur. It is forbidden to drop wooden cases or equipment from a certain height or let them fall freely. As this operation will most likely damage the equipment components, resulting in abnormal functions of the equipment, and even unexpected safety risks.

（1）Before unpacking, please make sure the appearance of the wooden case is intact and there is no obvious damage. If it is found that the wooden case is obviously damaged or has been opened artificially before reaching the user, please contact the Sales Officer of this equipment to coordinate the treatment immediately.

（2）Use a hexagonal wrench to unscrew the fixing screw of the top cover of the wooden case and remove the top cover.

（3）Use the hexagonal wrench to unscrew the fixed screw of the side cover of the wooden case and remove the side cover.

（4）Make sure that the appearance of the equipment in the wooden case is complete and undamaged. If it is found that the equipment is obviously damaged, please contact the Sales Officer of this equipment to coordinate the treatment immediately.

（5）Remove the equipment and accessories from the wooden case, and check again that they are not damaged during transportation.

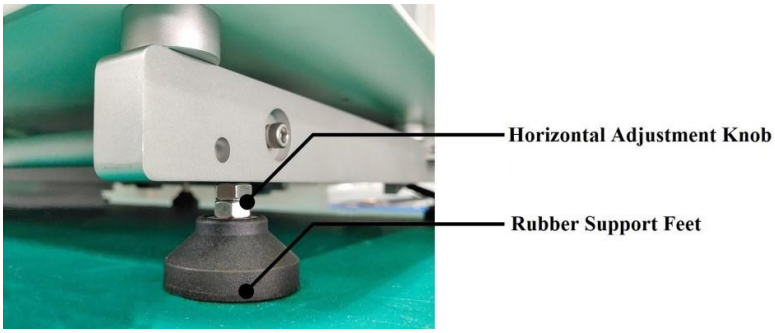
（6）According to the information of **Attachment 1 " Configuration List "**, check whether the number of equipment and related accessories is complete. If you find that the types or quantities of accessories do not match the list, please contact the Sales Officer of this equipment to coordinate the processing immediately.

4.3 Installation of Dissolution Apparatus

4.3.1 Horizontal Adjustment of Dissolution Apparatus

（1）Place the RT612-ST Dissolution System on a flat and firm lab table.

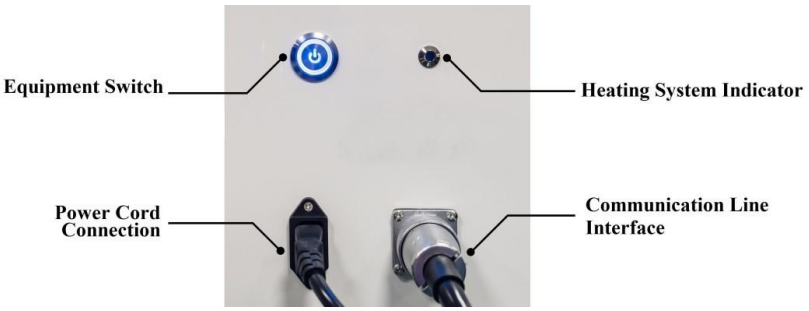
（2）The base of RT612-ST Dissolution System has six rubber support feet, which can provide good support and seismic effect. At the same time, the level of dissolution apparatus can be adjusted by rotating the horizontal adjustment knob on the supporting foot with a hexagonal wrench.



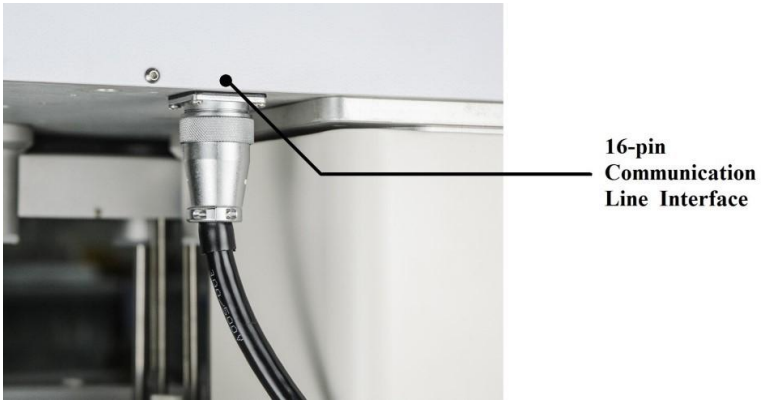
（3）When adjusting the horizontal state, rotate and suspend the two supporting feet in the middle of the base. Then adjust the horizontal adjustment knob of the four supporting feet on the bottom side until the dissolution apparatus is in the horizontal state. Finally, the rotate the middle two supporting feet to connect the table to ensure that the dissolution apparatus is in a stable horizontal state.

4.3.2 Line Connection

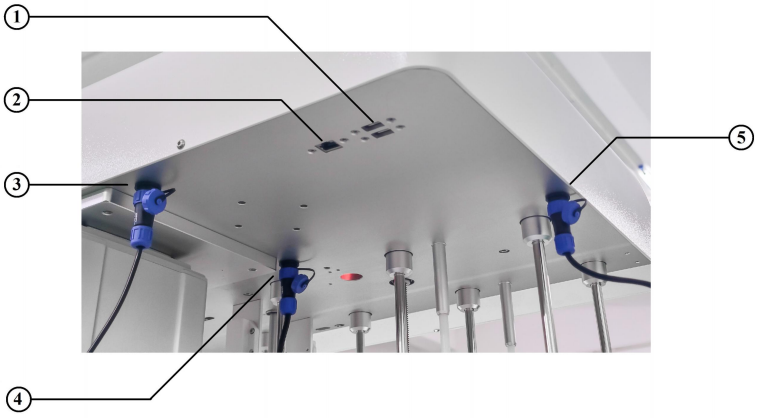
（1）Respectively connect the power cord and 16-pin data communication line to the power cord connection and data communication line connection on the right side of the dissolution apparatus.



（2）Connect the other port of the 16-pin data communication line to the corresponding communication line interface at the bottom of the lifting head of the dissolution apparatus.



（3）



1. USB interface

2. RJ-45 network interface

3. Communication interface for water bath temperature probe

4. Communication interface for vessel temperature probe

5. Communication interface for synchronous dosing motor

4.3.3 Add Water in the Water Bath

（1）Control the lifting head rise to an appropriate height.

（2）According to the water level indicator line (without vessels installed) on the water bath, add water into the water bath until the water level reaches the height of the indicator line.

Attention:

If the water level inside the water bath does not reach the indicator line, the water bath heating effect may be not good, thus affecting the temperature uniformity of the medium in the dissolution vessel.

If the water level inside the water bath exceeds the indicator line, the excess water will overflow when the dissolution vessel is installed. If the water overflows to the power supply, it may cause short circuit of the equipment and even electric shock of the personnel.

Suggestion:

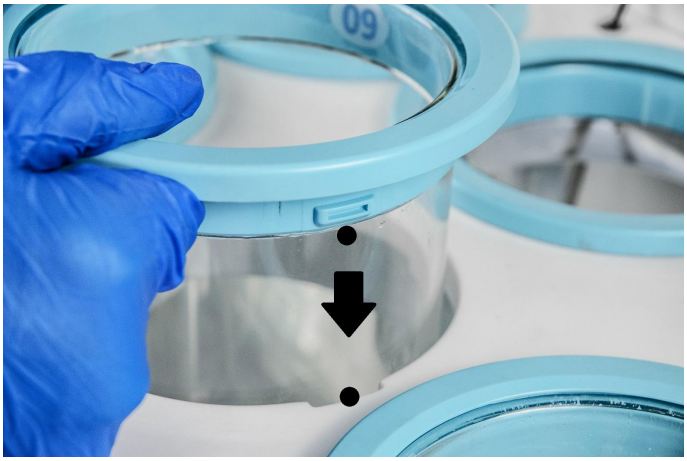
It is suggested to use purified water to minimize scale formation and bacteria, fungi and algae growth in water bath.

It is suggested to replace water in the water bath at least weekly to ensure that the water bath is in a clean and controllable state.

4.3.4 Installation of Dissolution Vessel

（1）Each dissolution vessel of Raytor Dissolution Apparatus has its corresponding number. When installing, please select the vessel corresponding to the same number according to the rotating shaft serial number.

（2）There are three buckles on the rim of Raytor dissolution vessel. First, confirm that the number label of the vessel is facing outward, and then align the three buckles of the vessle with the three concave positions of the vessel holes.



（3）Gently put the vessel in; rotate clockwise 30 degrees, and the vessel will be automatically fastened.

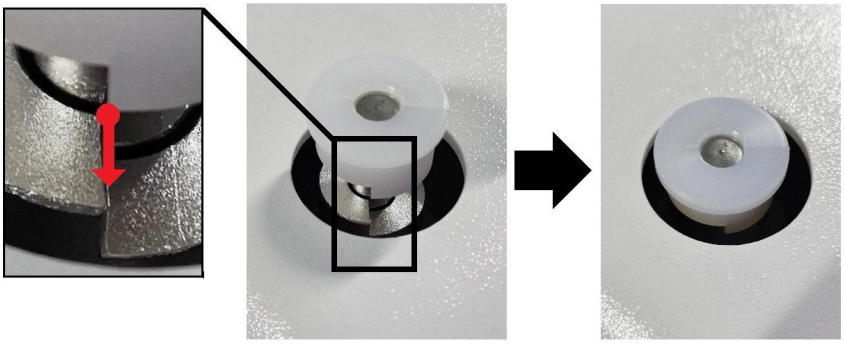
（4）Under the fastening condition, the number label of the vessel should be uniformly facing out.

Attention:

In daily use, please install the vessel corresponding to the same number according to the rotating shaft serial number. This is because the Mechanical Qualification of Raytor Dissolution Apparatus is carried out in the corresponding order. If the vessel is not installed according to its number, the compliance of its mechanical properties will not be guaranteed, which may affect the experimental results.

4.3.5 Installation of Rotating Shaft

（1）Confirm that the base rotating shaft has been installed in place.



（2）Install paddle shafts/basket shafts in numbering order.

Attention:

In daily use, please install the paddle shafts, basket shafts and basket in numbering order. This is because the Mechanical Qualification of Raytor Dissolution Apparatus is carried out in this corresponding order. If it is not installed according to its number, the compliance of its mechanical properties will not be guaranteed, which may affect the experimental results.

Attention:

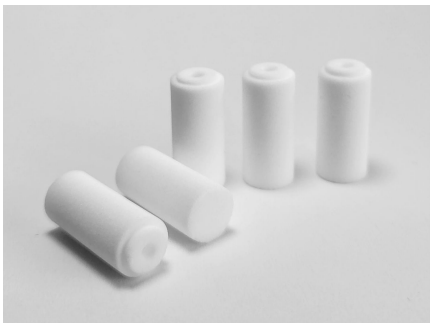
In daily use, do not loosen the fixed clutch of the rotating shaft at will.

When the fixed clutch of the rotating shaft is loosened, the position of the rotating shaft will be offset and the position adjustment needs to be carried out again.

Raytor Dissolution Apparatus has the patent design of common shaft for paddle and basket. **After adjusting and fixing the position of the shaft, it is not necessary to adjust its position after replacing the paddle shaft/basket shaft.**

4.3.6 Installation of Columnar Filter Element

（1）Install the columnar filter element at the front end of the sampling needle to realize the of on-line filtering function when sampling. **Installation of columnar filter element can effectively prevent pipe and valve blockage in automatic sampling workstation.**



（2）Gently insert the lower end of the sampling needle into the installation hole of the columnar filter element. The light rotary columnar filter element ensures that it is firmly installed.

Attention:

Long needle is for sampling, short needle is for replenishment.

Attention:

Please select a columnar filter element matching the outside diameter of the sampling needle. If the filter element does not match the outside diameter of the sampling needle, it is very likely that the filter element will fall off the sampling needle during the dissolution test. Raytor Instruments and its local contractors provide matching high-quality columnar filters.

Suggestion:

Avoid reusing columnar filters. Reuse of the filter element will retain the sample from the previous experiment, which may affect the results of the next dissolution test. It is suggested to replace the columnar filter element after each experiment.

4.3.7 Installation of Mini Vessel Dissolution Method Accessories

Raytor mini vessel dissolution method accessories include: paddle for mini vessel dissolution method, mini dissolution vessel and mini dissolution vessel fixing part.

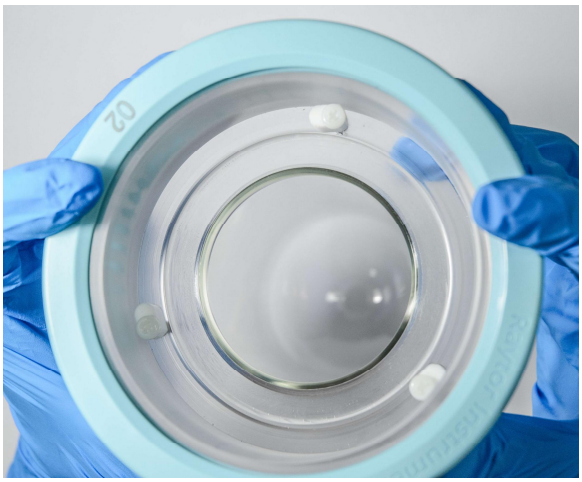
Paddle for Mini Vessel Dissolution Method:

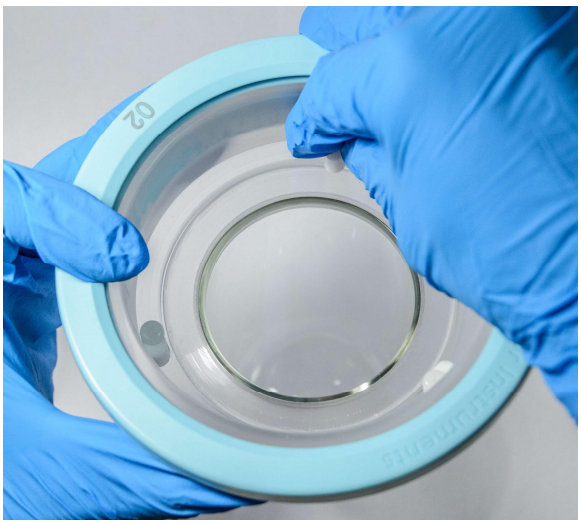
Mini Dissolution Vessel

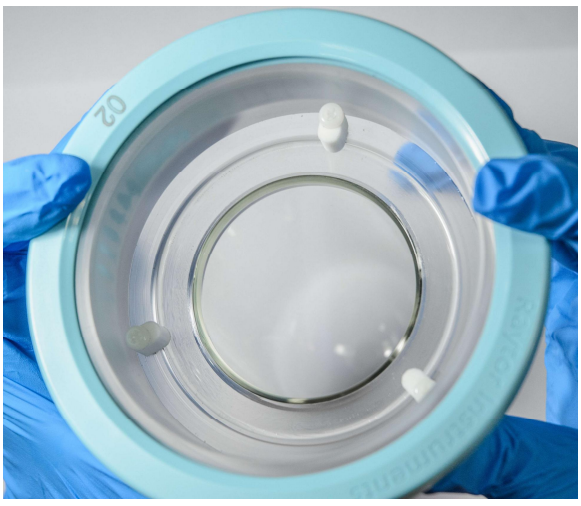
Mini Dissolution Vessel Fixing Part

（1）Put the mini dissolution vessel into the fixing part.

（2）Rotate the 3 fixing buckles on the fixing parts and fasten them to the dissolving vessel.







（3）Install the installed and fixed dissolution vessel and the fixing part on the dissolution vessel installation platform: align the three convex buckles of the fixing part with the three concave positions of the hole position, and gently put into the fixing part with mine dissolution vessel; rotate 30° clockwise, and the fixing part will automatically fasten the dissolution vessel installation platform.

4.4 Installation of Automatic Sampling Workstation

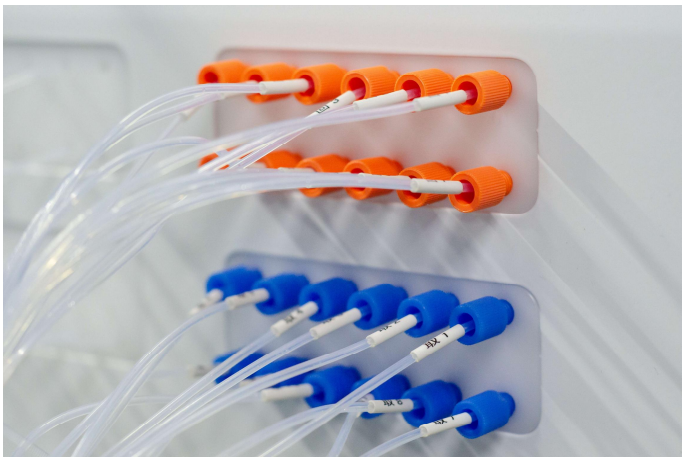
4.4.1 Line Connection

（1）Connect the communication line of the automatic sampling workstation to the specified interface of the bottom plate of the lifting head of the dissolution apparatus.

（2）Connect the other end of the communication line to the designated connection port on the left side of the automatic sampler workstation, and connect the power line at the same time.

4.4.2 Pipe Connection

（1）Install the sampling pipe (IN) and loop (OUT) at the corresponding pipe interface of the automatic sampling workstation according to the serial number of the sampling pipe.



Attention:

When connecting pipe, be sure to connect them in accordance with the sequence of pipe number, and distinguish between **sampling pipe (IN)** and **loops (OUT)**. Any connecting action which does not in accordance with the sequence of pipe number or does not distinguish between pipe types will lead to sampling disorder.

Suggestion:

In order to avoid the possible residue in the pipe affecting the experimental results, it is suggested that after the first installation or replacement of the new pipe, clean the pipeline about 10 times with a certain concentration of hydrochloric acid solution (e.g. 0.1 mol/L). After that, clean the pipe about 5 times with water.

For setting up the relevant automatic cleaning procedures, please refer to the relevant automatic cleaning settings Chapter of this operation manual.

4.4.3 Installation of Test Tube Rack and Waste Liquid Tank

（1）Move the tray out from the automatic sampling workstation at an appropriate distance.

（2）Install the waste liquid tank in the designated groove of the automatic sampling workstation.

（3）Align four circular holes on the bottom of the test tube rack with four cylindrical protrusions on tray of the automatic sampling workstation, and let the side printed with "Raytor Instruments" facing outwards, then lower test tube rack the gently and vertically. Move back the tray and complete the installation.

Attention:

The outer diameter of the glass test tube should match the hole of the test tube rack. If the outer diameter of the glass tube is obviously smaller than that of the tube rack’s hole, the tube may be dislocated during the sampling process, resulting in the injection needle not aligned with the tube, and the dissolution solution will not be injected into the designated tube.

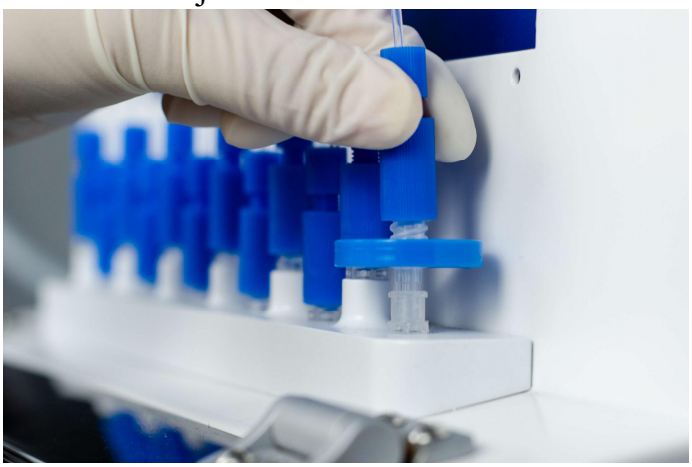
4.4.4 Installation of Secondary On-Line Filters

（1）Install the filter at the connection of injection needle and sampling pipe can realize the function of on-line filtering when sampling.

（2）Before installing the on-line filter, unscrew the sampling pipe and injection needle at the connection interface.

（3）Install the filters.

（4）Connect the injection needle.

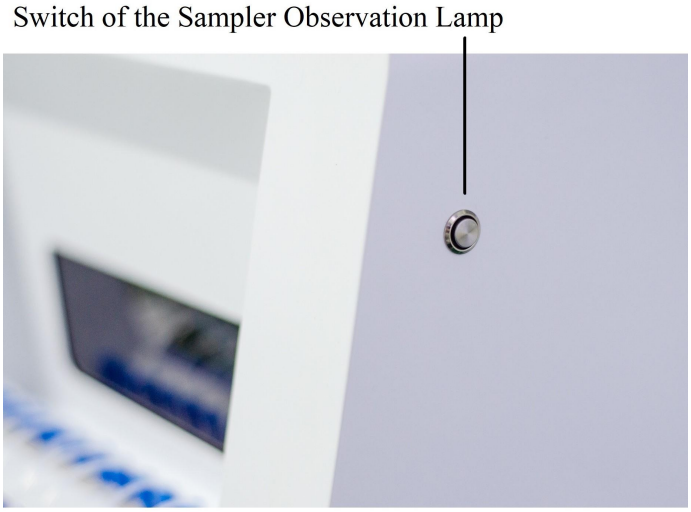


Attention:

Make sure the filter is fully saturated. Unsaturated filters may adsorb samples, resulting in a low sample dissolution rate.

4.4.5 Observation Lamp of Sampler

By pressing the key switch on the upper right side of the automatic sampling workstation, the switch of the sampler observation lamp can be controlled.



5. Dissolution Operating System

5.1 Starting up

（1）Press the Equipment Switch Button on the right side of the dissolution apparatus for about 3 seconds, and the light of the power button will turn blue, indicating that the equipment has been turned on normally.

（2）Dissolution lifting head and other parts will be reset and perform self-check action, the lifting head will slowly rise to the top, and enter standby state, the screen shows the landing interface.
The signal indicator lights on the left side of the automatic sampling workstation will turn on when the connection is normal.

5.2 Login Interface

The operating system of Raytor Dissolution System has the function of account login protection. Users need to input user name and correct password. After clicking on the button of Login, the users can login to the operating system.

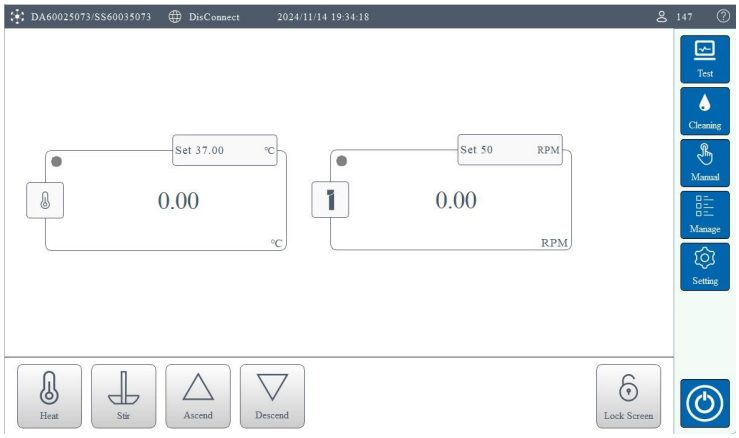
Under the login interface, if the dissolution system needs to be turned off, press the power switch of the dissolution system for several seconds, and the blue light of the switch button will be turned off.

Attention:

The system will stop running completely at 10 seconds after shutdown, and the power cord can be unplugged at this time. Otherwise, there may occur an error alarm when the next starting-up.

5.3 Main Interface of Dissolution System

After successful login, users will enter the main interface of Dissolution System. The main interface will display the temperature and rotational speed of the dissolution system. The authorized operation functions of the user will be displayed in the sidebar on the right side of the main interface.



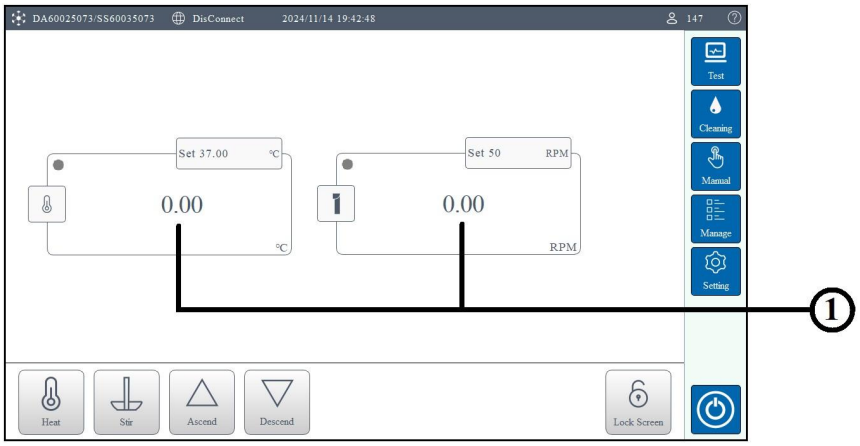
5.3.1 Information Bar

The information bar located at the top of the main interface of the Dissolution System, displays the basic information of the equipment, which is in turn: the number of the equipment, the date and the user name.

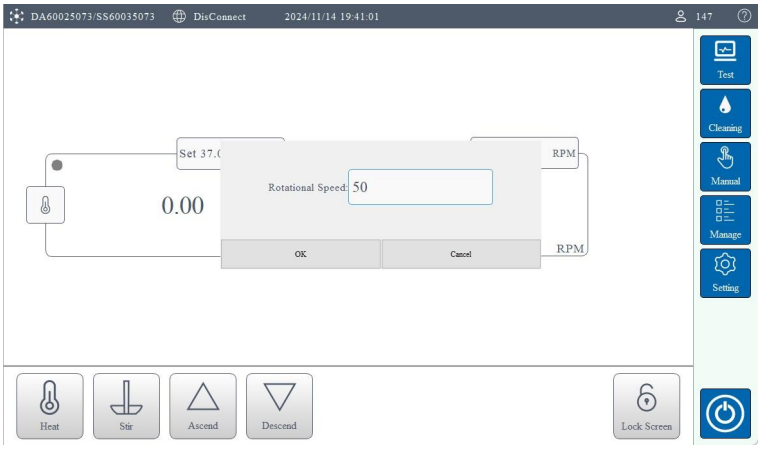
5.3.2 Convenient Setting

Quickly set the heating temperature and the rotational speed on the main interface by following these steps:

（1）Click on the real-time temperature or the rotational speed of the dissolution system ① on the main interface, and a setting input box will pop up on the interface.



（2）Enter the desired value and click OK.



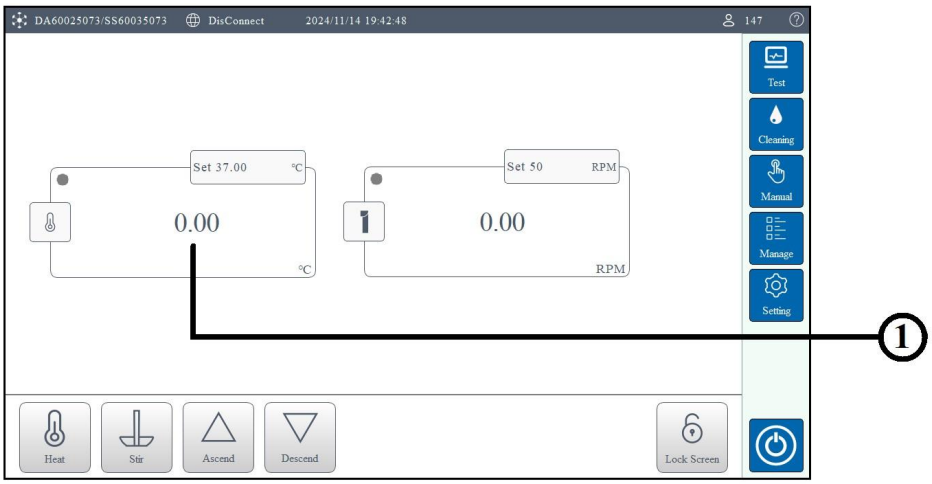
（3）Click on the manual control button in the bottom left corner of the interface to control the dissolution system to perform related operation.

No.	Button	Function Instruction
1		Start or stop the water bath heating.
2		Start or stop the stirring element.
3		Ascend the lifting platform.
4		Descend the lifting platform.

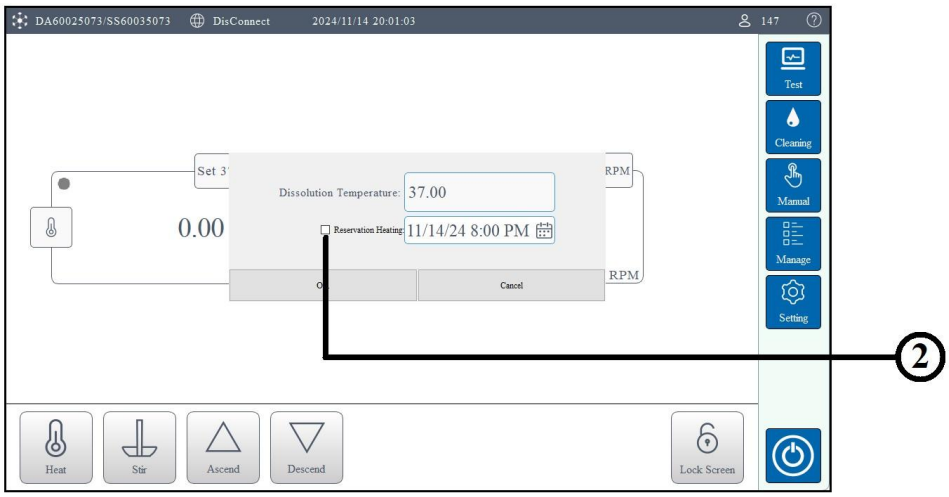
5.3.3 Reservation Heating

This dissolution system provides a reservation heating function, and users can reserve the dissolution system to start heating at a specified time.

（1） Click on the real-time temperature of the dissolution ① on the main interface, the temperature setting input box will pop up.



（2） In the reservation heating input box, enter the start time of the reservation heating and click to confirm the reservation heating ②. Then click OK button. The system will start the dissolution heating according to the set temperature at the reservation time.


DA60025073/SS60035073
DisConnect
2024/11/14 20:01:03
147
Test
Cleaning
Manual
Manage
Setting
Set 3
0.00
RPM
Dissolution Temperature:
37.00
Reservation Heating
11/14/24 8:00 PM
Cancel
RPM
Heat
Stir
Ascend
Descend
Lock Screen
2

5.3.4 Operation Button

The operation button function in sidebar of the main interface is described in the following table. The user can enter the sub-page of the corresponding function by clicking on the relevant function operation key, and perform further experimental operations.

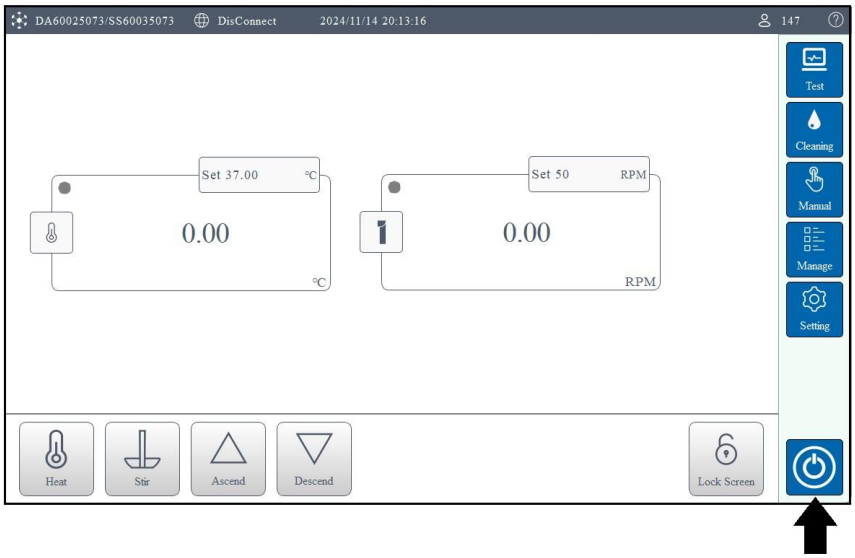
No.	Button	Function Instruction
1		Set up experimental methods, run sequences of multiple batches automatic dissolution experiment, and view experimental running records.
2		Perform automatic cleaning of the system and check the current cleaning status.
3		Manually control the operation of key components in the dissolution systems.
4		User management and role management. Time calibration and calibration of critical system components.
5		Software system settings and password strength settings.

5.3.5 Shutdown/Logout Button

The Shutdown/Logout Button is located in the bottom right corner of the main interface. Click the Shutdown/Logout Button, the logoff and shutdown options will pop up, and the corresponding options can be clicked to execute the shutdown or logoff.

Shutdown: Shut down the operating system.

Logout: Log out of the current account, but the operating system will not be shut down.

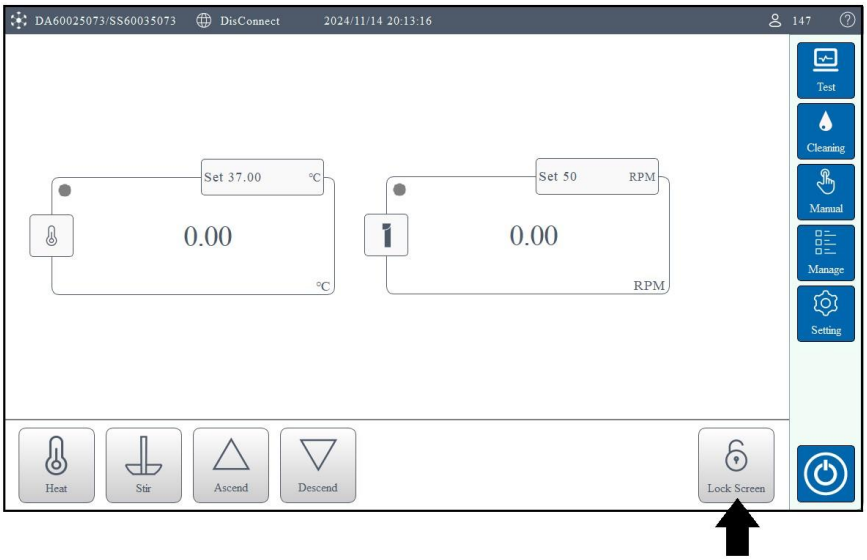


Attention:

The system will stop running completely at 10 seconds after shutdown, and the power line can be unplugged at this time. Otherwise, there may occur an error alarm when the next starting-up.

5.3.6 Lock Screen Button

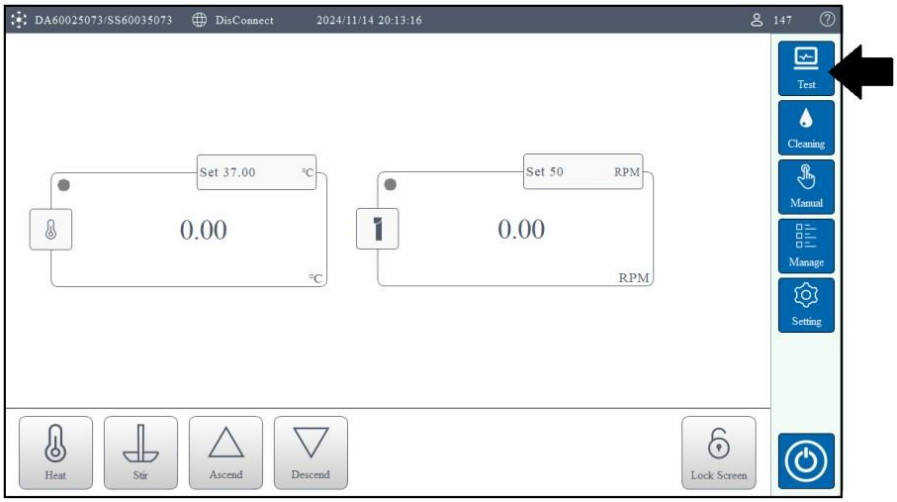
The Lock Screen button is located in the bottom right corner of the main interface. Click the Lock Screen button to enter the screen lock state. In the screen lock state, it will be impossible to control the dissolution system through the screen, thus avoiding the occurrence of personnel mis-operation during the operation of the dissolution system.



To unlock the screen, enter the current user's login password and click the Unlock button.

5.4 Automatic Dissolution Experiment

On the main interface of the dissolution system, click the Experiment button in the sidebar to enter the interface of batch automatic dissolution experiment.

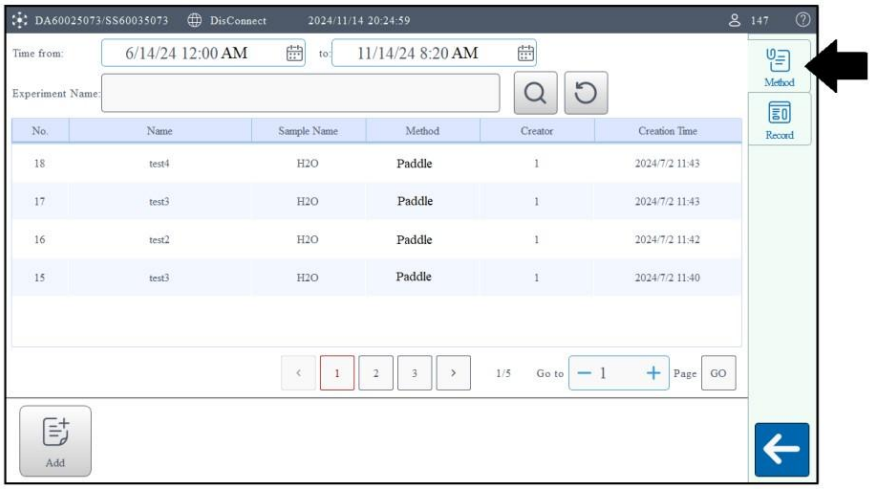


In this interface, users can click on the function buttons in the sidebar to switch between different functional interfaces.

No.	Button	Function Instruction
1		View the list of experimental methods, set up the dissolution experiment method.
2		View the dissolution experiment records.
3		Return to the previous page.

5.4.1 Experiment Method List

In the experimental interface, click the Method button in the sidebar to enter the experimental method list interface. In this interface, users can view a list of established experimental methods.



To find a specific experimental method, you can select the creation time range of the experimental method you want to find in the search function block at the top of the interface, or directly enter the method name. Then click the Search Button to search for methods.

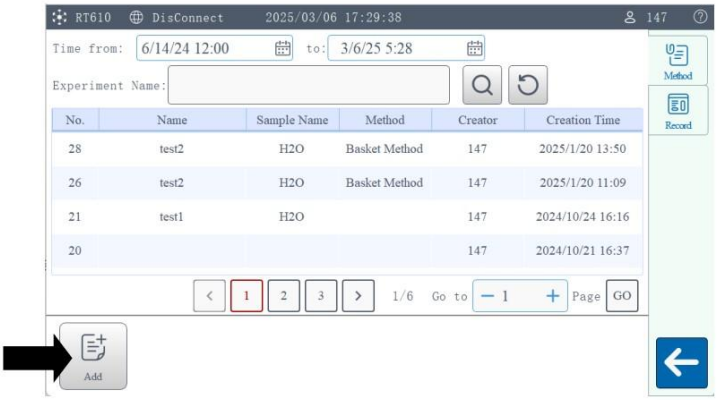
No.	Button	Function Instruction
1		Search Button. Click to search for methods.
2		Clear Button. Click to clear the current search content.

5.4.2 Experiment Method Setting

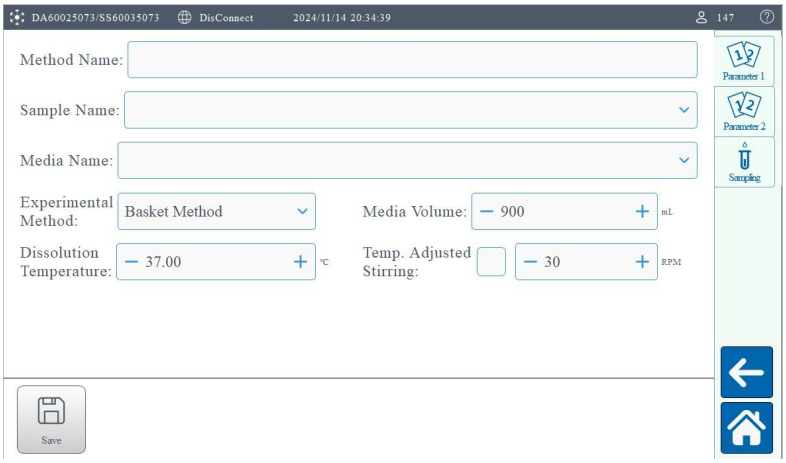
In the experimental method list interface users can add dissolution experimental methods or modify existing dissolution experimental methods

（1）Add Dissolution Method

Click the Add button in the bottom left corner of the interface to enter the dissolution method creation interface.

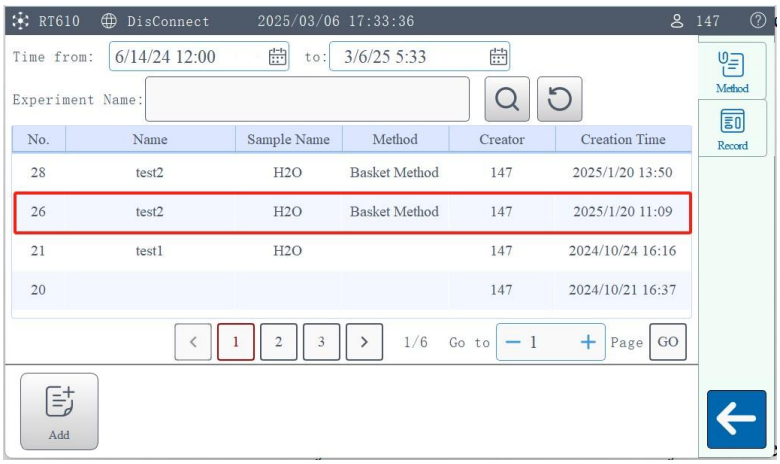


After completing the dissolution method settings on this interface, click the Save button to save this method.

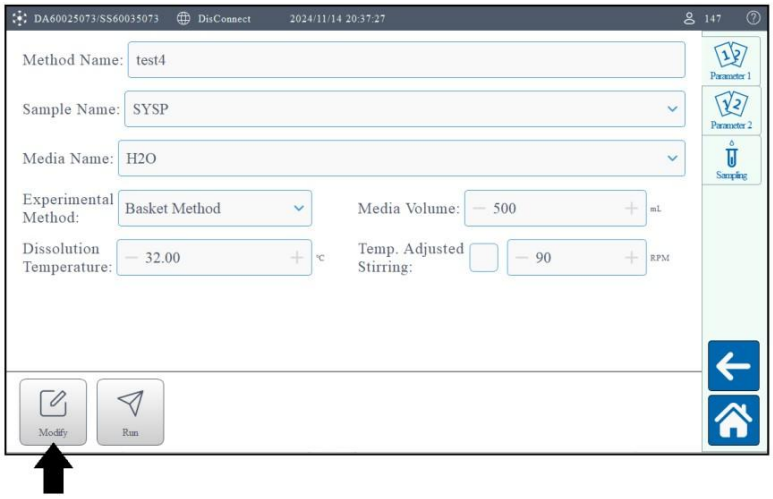


（2）View & Modify Dissolution Method

Click on the name of the experimental method in the list of experimental methods to view the set parameters of the dissolution method.



Click the Modify button on this interface to modify the current dissolution method.



After completing the parameter modification in the method modification interface, save the requirements according to the specific method. Click the Save button or the Save As button to save the modified dissolution method.

No.	Button	Function Instruction
1		Replace the old method with the current modified new method. The old methods will be hidden, but will not be deleted from the database.
2		Add a new method based on the currently modified parameters. The old method will not be hidden and can still be called in the method list.

5.4.3 Experimental Method Parameters

In the experimental method setting interface, the instructions for setting experimental parameters are as follows:

Method Parameter Interface

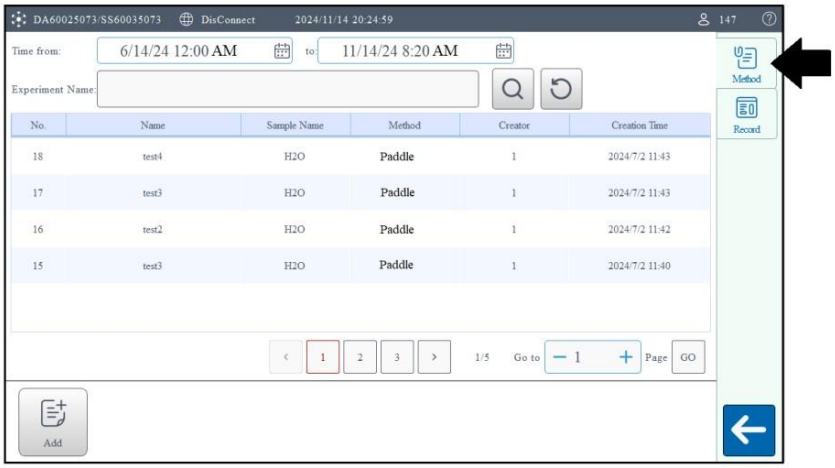
Setting Items	Instruction	
Method Name	Enter the name of this dissolution method.	
Sample Name	Enter the sample name or select a sample name that has already been entered from the drop-down box.	
Media Name	Enter the media name or select a media that has already been entered from the drop-down box.	
Dissolution Method	Select the dissolution method from the drop-down menu.	The system will calculate and determine the location of sampling needle based on the set dissolution method and media volume.
Media Volume	Set the media volume.	
Dissolution Temperature	Set the temperature for the dissolution experiment.	
Temperature-Adjusted Stirring	When the temperature-adjusted stirring function is enabled, the stirring function will be activated during the preheating of the dissolution medium.	

Method Parameter Interface (Cont.)

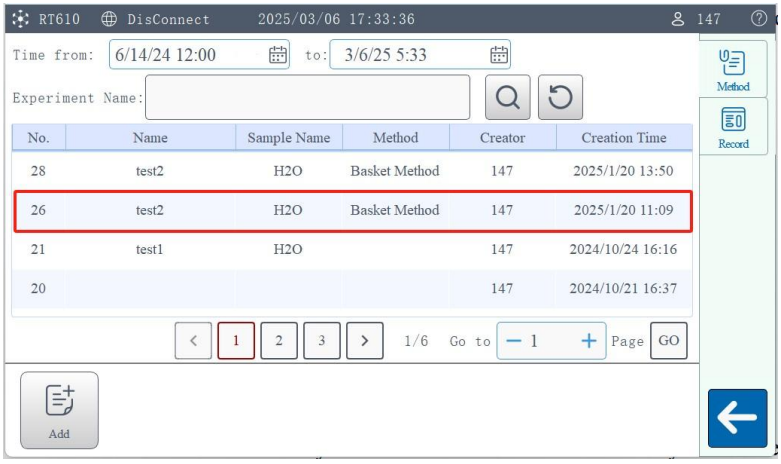
Setting Items	Instruction
Stirring Speed	Set the rotational speed of the stirring element during the dissolution experiment.
Ultimate Speed	After the sampling is completed, the system will continue stirring at the set ultimate speed according to the duration, and it will perform once sampling after the end of the ultimate duration.
Ultimate Duration	When the duration is set to 0, the system will not execute the ultimate speed.
Rinse Volume	Volume of rinsing the sampling pipe before formal sampling,
Sampling Volume	Volume of solution injected into the sampling container=Sampling volume - Initial filtrate volume
Initial Filtrate Volume	When the initial filtrate volume is set to 0, the instrument will not perform the action of discarding the initial filtrate.
Replenishment Volume	Set the volume of blank media to be replenished after sampling is completed.
Sampling Sequence	The equipment will perform sampling at the set sampling time after the dissolution experiment starts according to the sampling sequence.

5.4.4 Perform Automatic Dissolution Experiment

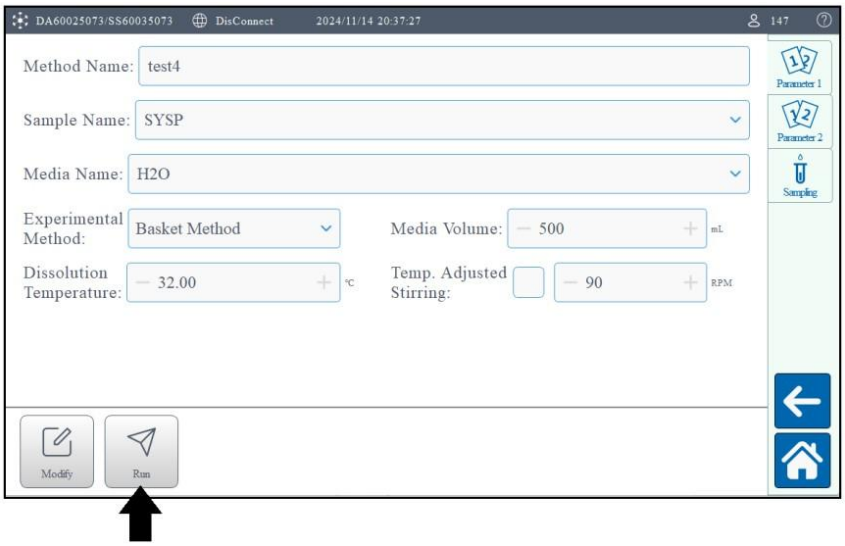
In the experimental interface, click the Method button in the sidebar to enter the experimental method list interface.



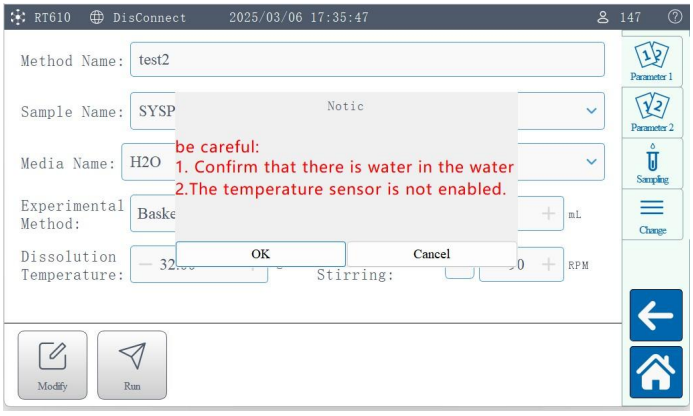
（1）In the dissolution method list interface, click to select the dissolution method that needs to be run.



（3）After clicking to select the dissolution method that needs to be run, it will enter the detailed experimental parameter interface of the dissolution method. Confirm that the parameters are correct, click the Run button at the bottom left of the interface.

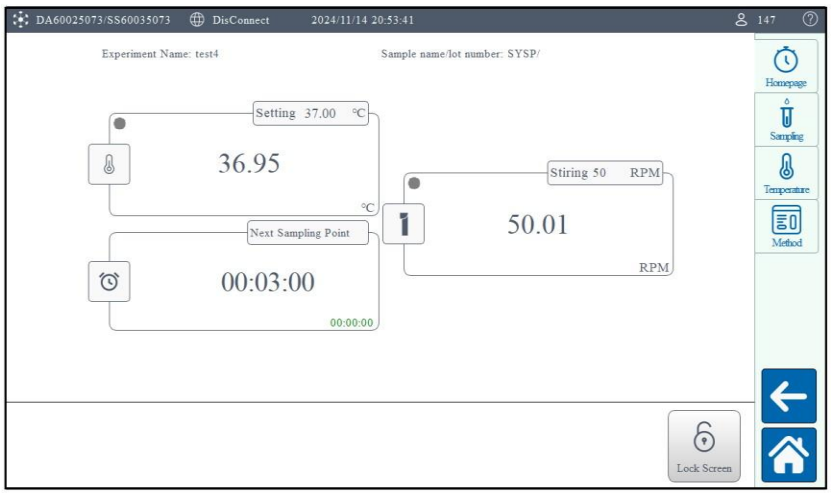


（4）The system will pop up a prompt window. Enter the sample lot number in the Sample Lot No. input box, click the OK button, and start the automatic dissolution experiment.



5.4.5 Experimental Operation Monitoring

In the experimental operation interface, click the Run button to enter the experimental operation monitoring interface. In this interface, users can view the current running status of the experiment.



No.	Button	Function Instruction
1		View the running status of the dissolution experiment currently in progress.
2		View the completion status of the sampling sequence.
3		View the temperature of each dissolution vessels.
4		View the parameters of current dissolution experiment method.

Terminate Experiment

Click the Back Button or Home Button in the bottom right corner of the interface, and a pop-up window will appear saying "Confirm terminate the experiment". Click the OK button to terminate the experiment and exit.

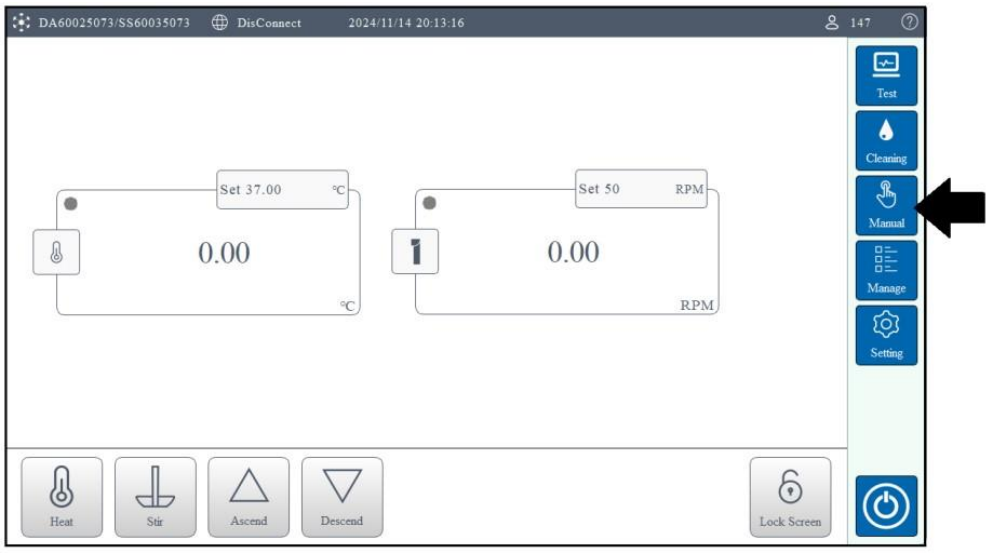
No.	Button	Function Instruction
1		**Return Button:** Terminate this experimental and return to the previous page (experimental operation interface).
2		**Home Button:** Terminate this experimental and return to the homepage.

Suggestion:

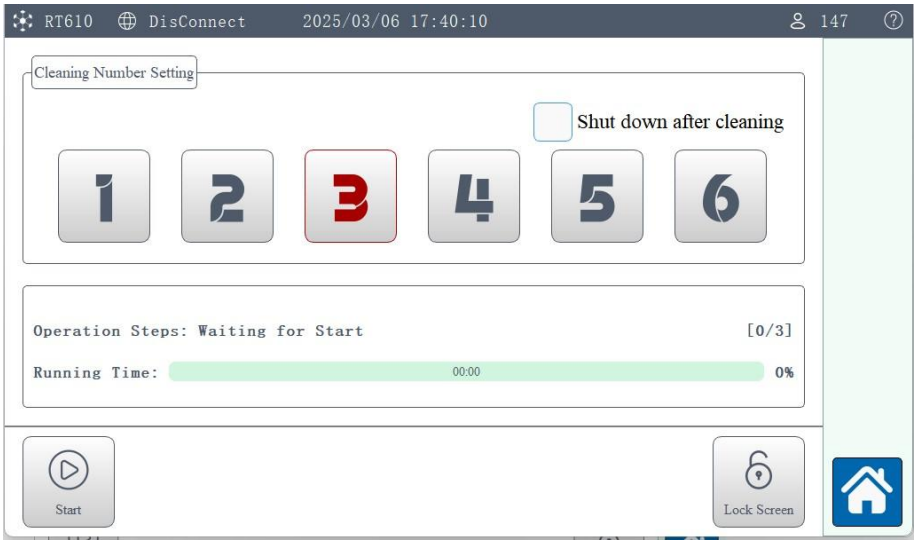
Be circumspect to abort the experiment. If it is not necessary, it is not recommended to forcibly abort the experiment sequence. Reneging the experiment will lead to incomplete experiment records.

5.5 Automatic Cleaning

On the main interface of the dissolution system, click the Cleaning button in the sidebar to enter the interface of automatic cleaning.



Confirm that all filters have been removed, click on the OK Button and enter the Automatic Cleaning Interface.



（1）Immerse the end of the replenishment pipe of the automatic sampling workstation in sufficient cleaning agent.

(2) Select the frequency of automatic cleaning.

- One-time automatic cleaning refers to a complete cleaning of all pipe, sampling needles, replenishment needles and injection needles by using the cleaning agent.
- If you select Shutdown After Cleaning, the dissolution system will be shut down after automatic cleaning is completed.

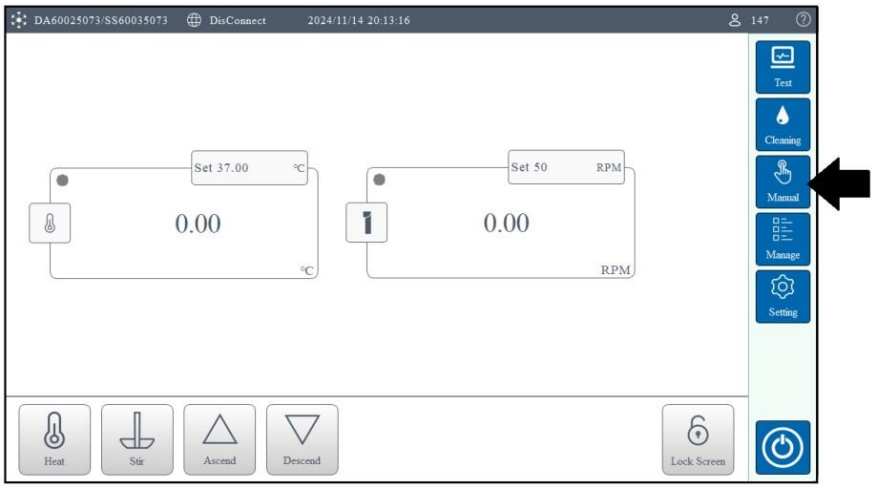
Attention:

If all 12 channels need to be cleaned automatically, 360ml detergent is needed for one cleaning time. Please prepare enough cleaning agent according to the selected cleaning times.

(3) Click the Start button, and the dissolution system will start automatic cleaning.

5.6 Manual Control

On the main interface of the dissolution system, click the Manual Control button in the sidebar to enter the manual control interface.

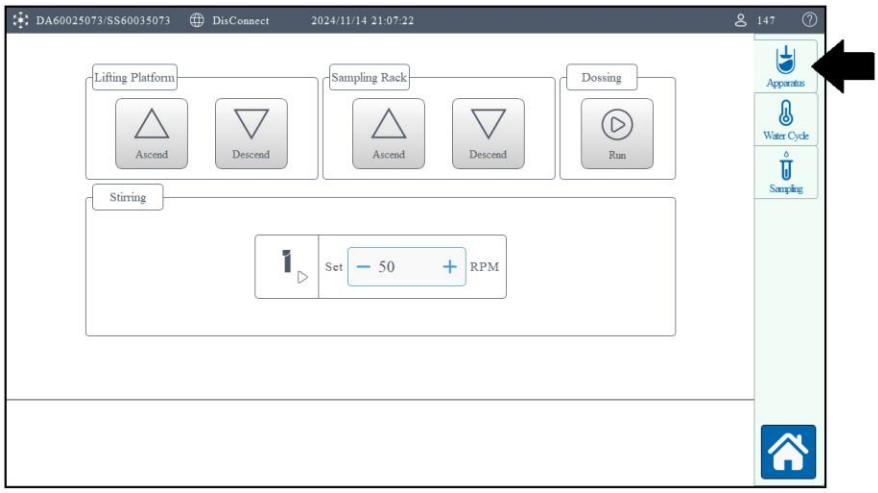


In the manual control interface, users can click on the function buttons in the sidebar to switch between different functional interfaces.

No.	Button	Function Instruction
1		Manual control the lifting platform, sampling rack, dossing and stirring of the dissolution apparatus.
2		Manually control the water circulation heating and monitor the temperature inside each vessel.
3		Manually control the sampling system.

5.6.1 Manual Control of Dissolution Apparatus

In the manual control interface, click the Apparatus button in the sidebar, to enter the manual control interface of the dissolution apparatus. Users can manually control the operation of key components of the dissolution apparatus.

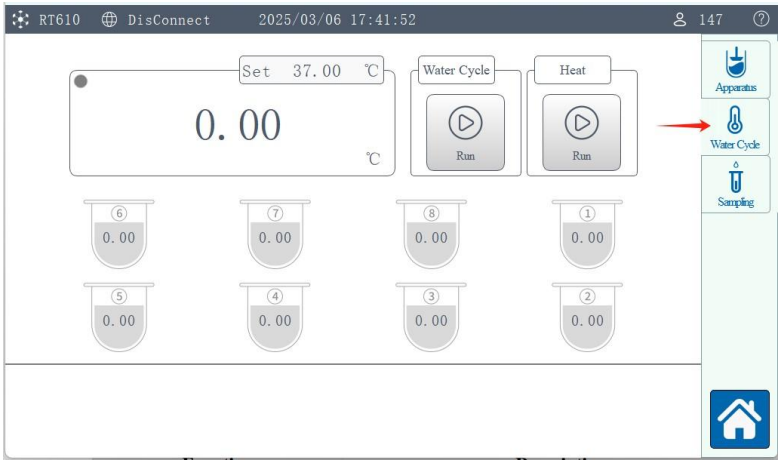


Function	Description
Lifting Platform	Click the Ascend or Descend button to control the lifting platform to rise or fall.
Sampling Rack	Click the Ascend or Descend button to control the sampling rack to rise or fall.
Dossing	Click the Run button, and the instrument will perform an automatic sample dosing action.

Function	Description
Stirring	 Set the rotational speed of the stirring element.
	 Click button 1 to control the rotation or pause of the stirring element.

5.6.2 Manual Control of Water Bath Cycle and Heating

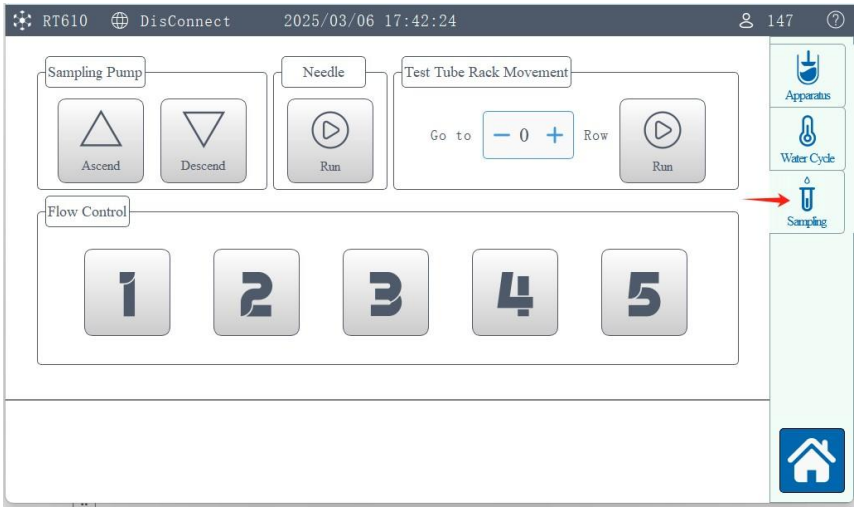
In the manual control interface, click the Water Cycle button in the sidebar, to enter the manual control interface of the water bath cycle and heating. Users can manually control the water bath cycle and heating function.



Function	Description
Temperature Setting & Monitoring	et the heating temperature of the water bath. Monitor the temperature of water bath and each vessel.
Water Cycle	Only start the circulating water pump, but do not start the heating.
Heat	Simultaneously start the circulating water pump and heating.

5.6.3 Manual Control of Automatic Sampling System

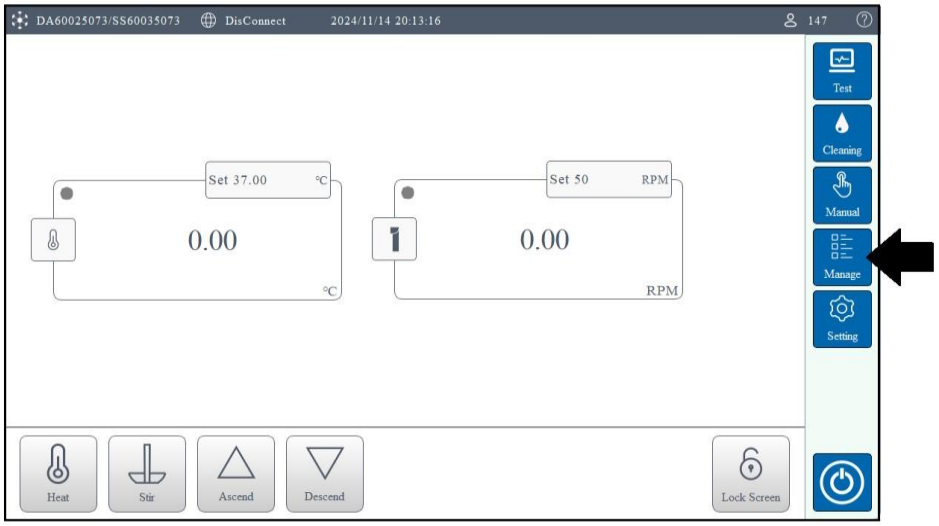
In the manual control interface, click the Sampling button in the sidebar, to enter the automatic sampling system manual control interface.



Function	Description
Sampling Pump	Click the Ascend or Descend button to control the sampling pump to extract or output.
Injection Needle	Click the Ascend or Descend button to control the injection needle to rise or fall.
Test Tube Movement	Set and control the test tube to move to the designated position.
Valve Control	Control the opening and closing of different types of valves within the pipe system.

5.7 Management

On the main interface of the dissolution system, click the Management button in the sidebar to enter the management interface.

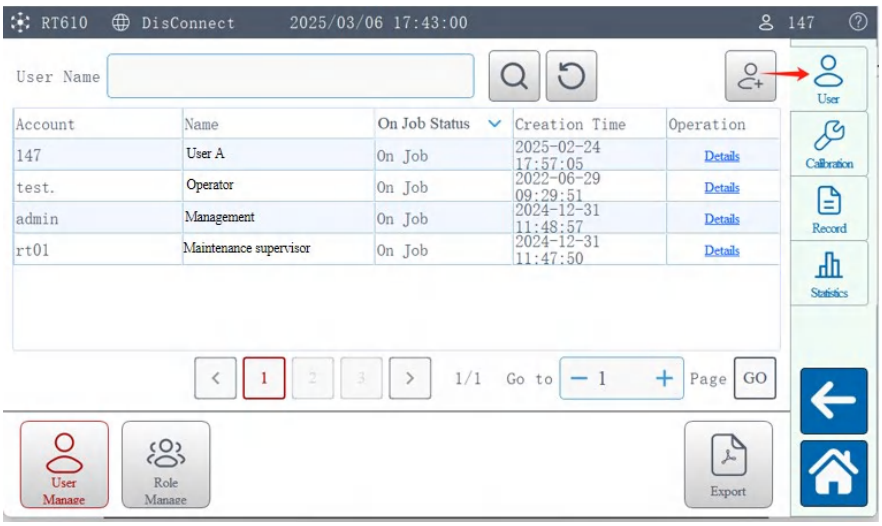


In the management interface, users can click on the function buttons in the sidebar to switch between different functional interfaces.

No.	Button	Function Instruction
1		Enter the user interface to perform user management, role management, and permission settings.
2		Enter the calibration interface to perform the calibration of temperature sensor, sampling location and system time.
3		Enter the record interface to view login records, operation records, cleaning records, time calibration records, and software update records.
4		Enter the statistics interface to view login statistics and experimental statistics.

5.7.1 User

In the management interface, click the User button in the sidebar, to enter the user interface.



At the bottom of the user management interface, users can click different function buttons to switch between different function interfaces.

No.	Button	Function Instruction
1		User management can be performed: creating new users, modifying user information, and viewing user lists.
2		Role management can be performed: creating new roles, modifying role information and permissions, and viewing role lists.

Word Interpretation

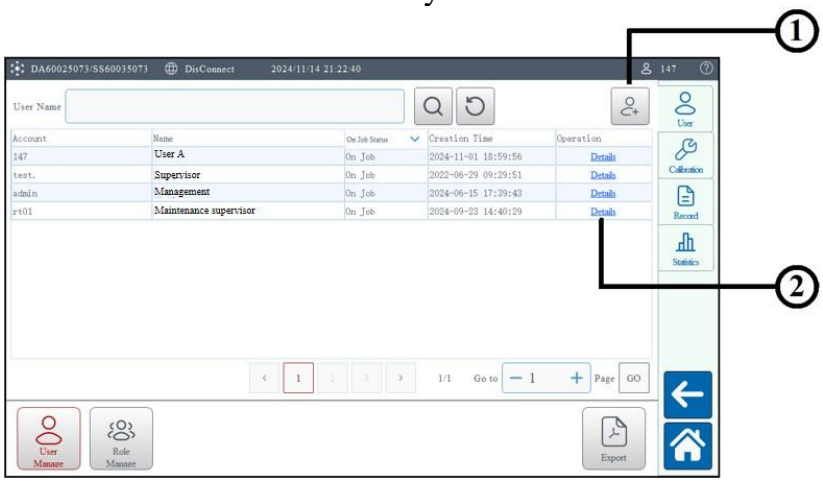
Word	Interpretation
User	User is an independent single individual of the operation system. It has a user account and identified by the user name.
Role	also known as user groups, are used to distinguish user groups with different permissions. Users in the same role have the same permissions.
Permission Level	Used to define the level of permission that a role has. The smaller the number of permission levels, the higher the permissions they have.

Suggestion:

Please cautiously assign the account management permission. In order to reduce the risk of experimental violation, it is not recommended to assign the account management permission to the ordinary operators. It is recommended to assign account management to system administrators or designated responsible persons.

5.7.1.1 User Management

At the bottom of the user interface, click the User Management button to enter the user management interface. This interface will display a list of all current users of the system.



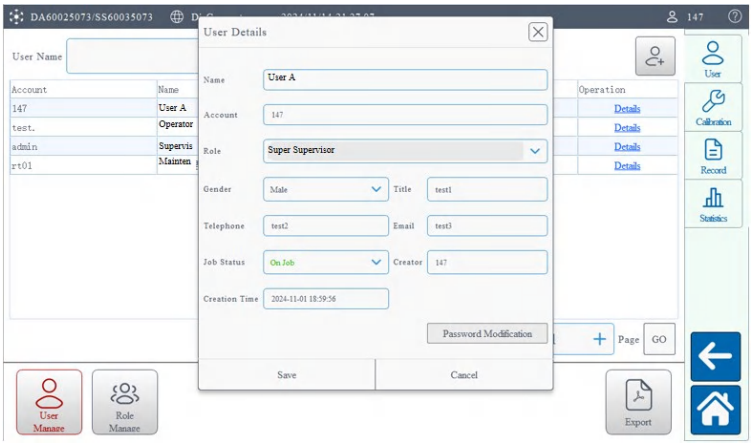
① Create User

Click Button ①, and the system will pop up an create user window. According to the window requirements, enter the user's information and login password.

② View & Modify User Information

Click on Details ② in the user list, and the system will pop up a window for user detail information.

If you need to modify user information, click the Edit Information button on the window, and the window will transition to user information edition mode.



If you need to change the password, click the Change Password button. The interface will pop up a password modification window. After the user completes the password input, click the Save button to complete the password modification.

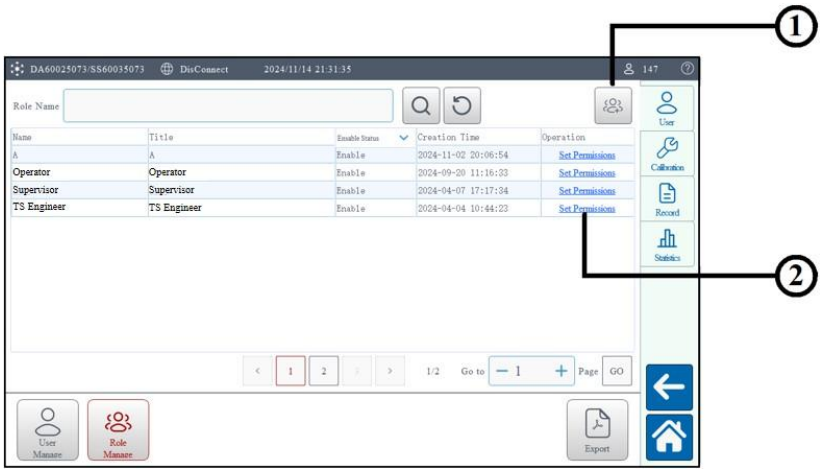
Suggestion:

In order to meet the relevant regulations of data integrity and computerized system, the operation system of Raytor Dissolution System does not provide the function of deleting accounts.

If there is a user quitting, select the content of the User Status as "Quit" in user information modify window.

5.7.1.2 Role Management

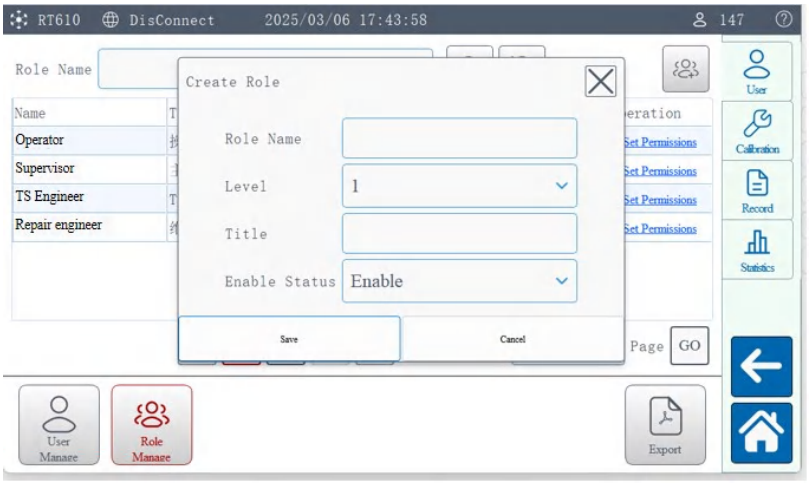
At the bottom of the user interface, click the Role Management button to enter the role management interface. This interface will display a list of all current roles of the system.



① Create Role

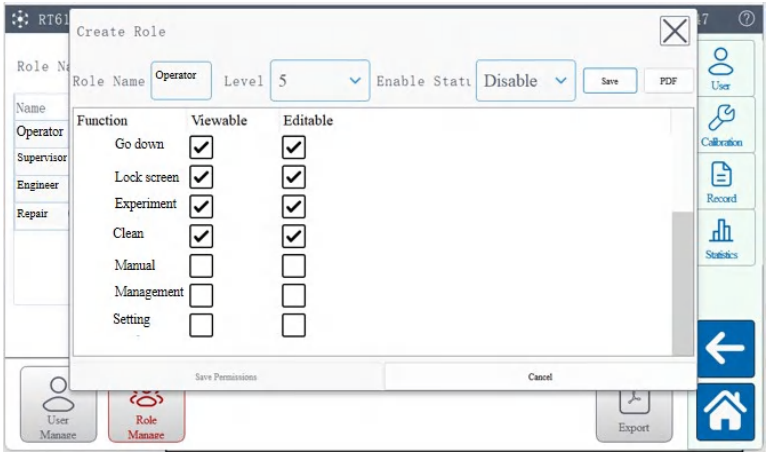
Click Button ①, and the system will pop up an create role window. According to the window requirements, enter the role's information and permission level.

Permission Level: Used to define the level of permission that a role has. The smaller the number of permission levels, the higher the permissions they have.



② View & Modify Role Setting

Click on Set Permission ② in the role list, and the system will pop up a window for detailed role settings. In this window, you can set and modify the information and permissions of roles.



Click the Save Information button to save the modified role information, such as role name, level, and enabled status.

Click the Save Permission button to save the modified role permissions.

Click the PDF button to export the current role's permission list in PDF format.

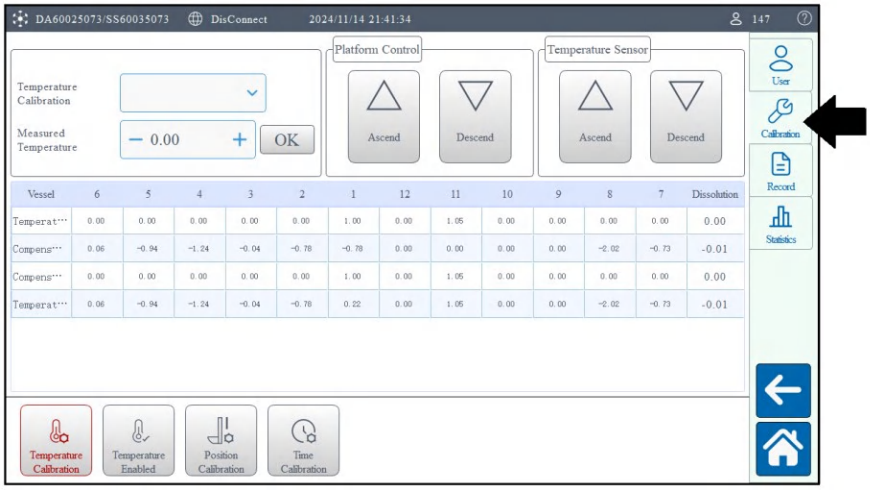
Suggestion:

In order to meet the relevant regulations of data integrity and computerized system, the operation system of Raytor Dissolution System does not provide the function of deleting roles.

If you want to deactivate a role, you can change its enabled status to 'not enabled'.

5.7.2 Calibration

In the management interface, click the Calibration button in the sidebar to enter the calibration interface.

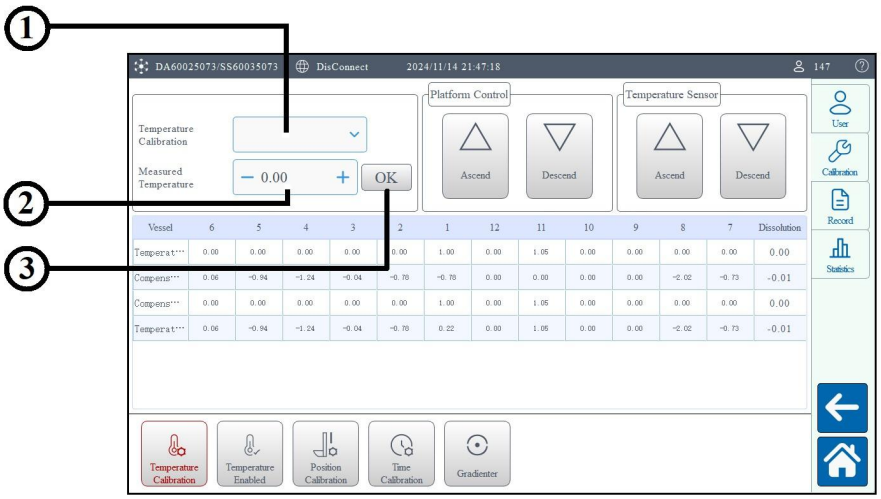


In this interface, users can click on the function buttons in the sidebar to switch between different functional interfaces.

No.	Button	Function Instruction
1		Calibrate temperature probe of the water bath and the vessel.
2		Enable or disable the temperature sensor.
3		Calibrate the sampling positioning of the sampling needle.
4		Calibrate the system time.

5.7.2.1 Temperature Calibration

At the bottom of the calibration interface click the Temperature Calibration button to enter the temperature calibration interface.



① In the drop down box of Temperature Calibration, select the sensor which needs to be calibrated.

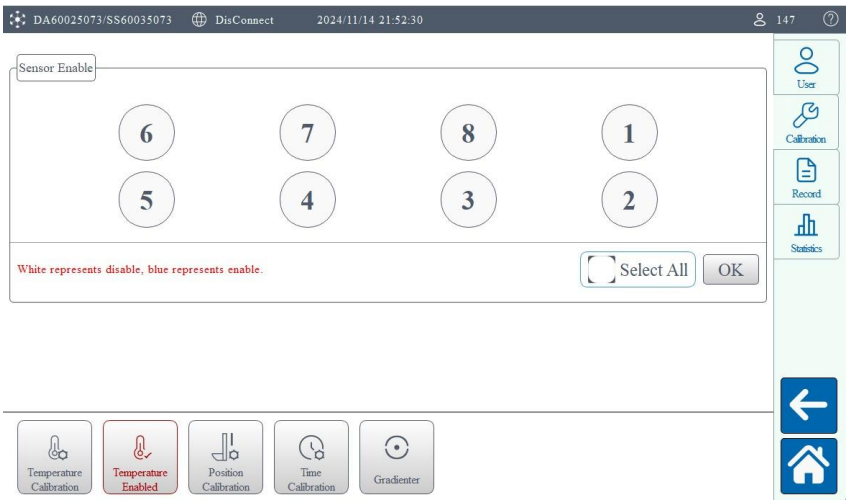
Place the temperature probe of the standard thermometer close to the temperature probe to be calibrated. Adjust the position of the temperature probe by clicking the up and down buttons of the Platform Conrol and Temperature Sensor.

② In the Measured Temperature field, enter the reading value of the standard thermometer.

③ Click the OK button to complete the corresponding temperature sensor calibration.

5.7.2.2 Temperature Enable

At the bottom of the calibration interface click the Temperature Enable button to enter the temperature enable interface.

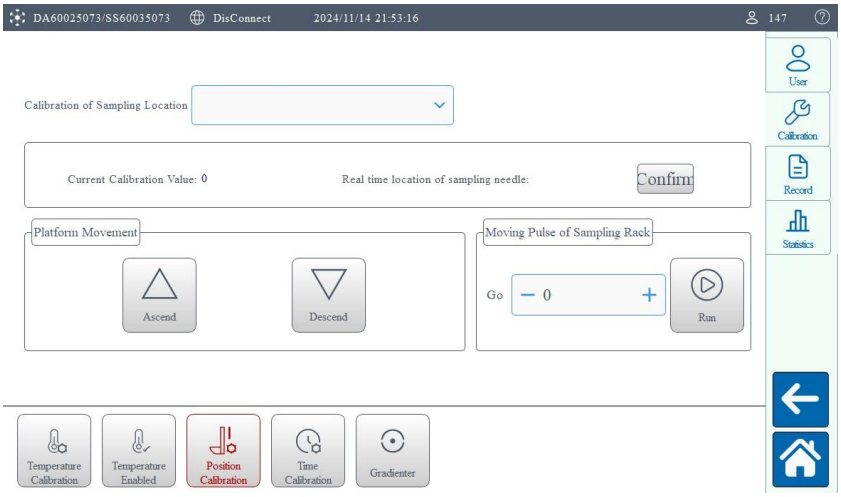


Click the button in the temperature enable field to set whether the corresponding temperature sensor reading will participate in the automatic experiment start judgment.

During the execution of automatic experiments, the instrument will only prompt for dosing when the measurement value of the temperature probe with temperature enabled meets the set requirements.

5.7.2.3 Sampling Needle Calibration

At the bottom of the calibration interface of the dissolution apparatus, click the Sampling Location button to enter the sampling needle location calibration interface. This interface is used to calibrate the position of the sampling needle by the Raytor Engineer.

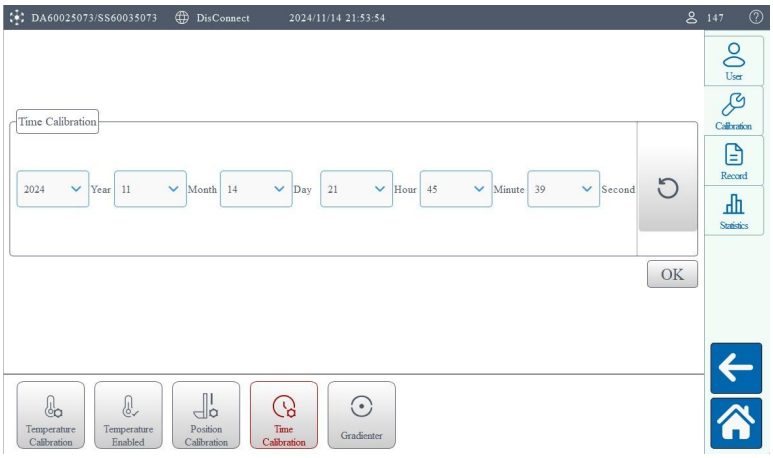


Attention:

Each Raytor Dissolution System has been completed the position calibration of the sampling needle before leaving the factory. **Please do not change the position calibration parameters of the sampling needle at will**. The modification of position calibration parameters may lead to inaccurate positioning of sampling needles.

5.7.2.4 Time Calibration

At the bottom of the calibration interface, click the Time Calibration button to enter the time calibration interface.



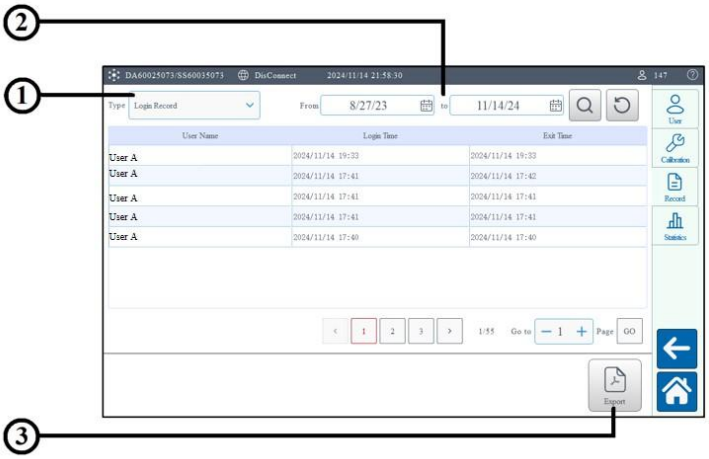
In the Time Calibration field, enter the standard time required for calibration, click the OK button, and complete the system time calibration.

Attention:

Please cautiously assign the time calibration permissin. In order to avoid forgery of experimental data, do not assign the time calibration permissin to ordinary users.

5.7.3 Record

In the management interface, click the Record button in the sidebar, to enter the user interface.



① In the Type drop-down selection box, select the record type you want to view. The relevant record list will be automatically displayed on the interface.

② To search for records within a specific time range, you can select the time range in the search function block at the top of the interface. Then click the Search button to search for methods.

No.	Button	Function Instruction
1		Search Button. Click to search for record.
2		Clear Button. Click to clear the current search content.

③ Click the Export button to export the searchable record list in PDF format to a designated location on the computer or USB flash disk.

5.7.4 Statistics

In the management interface, click the Statistics button in the sidebar, to enter the statistics interface.

At the bottom of the user management interface, users can click different function buttons to switch between different function interfaces.

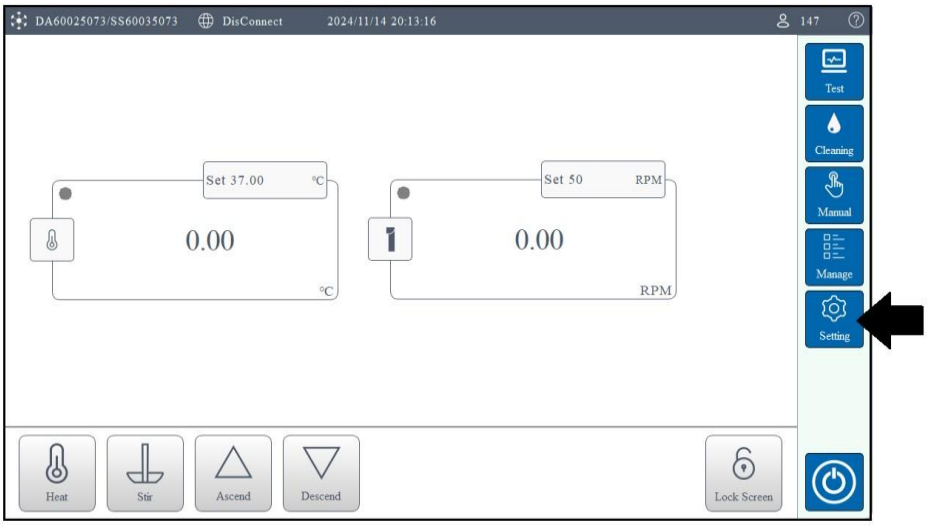
No.	Button	Function Instruction
1		Check the number of user operations performed correctly or incorrectly.
2		Analyze the trend of the number of experiments.

Suggestion：

If statistical analysis finds that the number of false logins in a month is unusually high, it is suggested to confirm the cause of this abnormal situation and avoid repeated attempts by a user to login the system with the wrong password.

5.8 Setting

On the main interface of the dissolution system, click the Setting button in the sidebar to enter the setting interface.

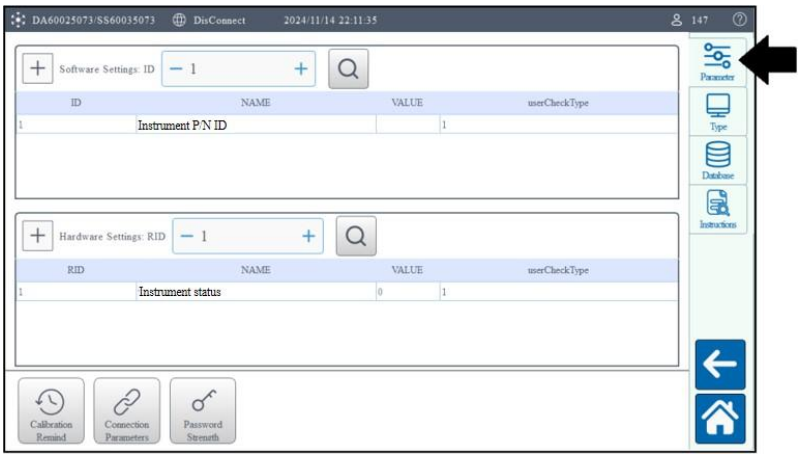


In setting interface, users can click on the function buttons in the sidebar to switch between different functional interfaces.

No.	Button	Function Instruction
1		System parameter setting, reservation calibration prompt setting, connection parameter setting, password strength setting.
2		Set the equipment type base on the dissolution system configuration.
3		View the database, perform backup, restore, or restore to factory state of the database.
4		View the instruction manual and relevant technical materials

5.8.1 Parameter Setting

In the setting interface, click the Parameter button in the sidebar, to enter the parameter setting interface.



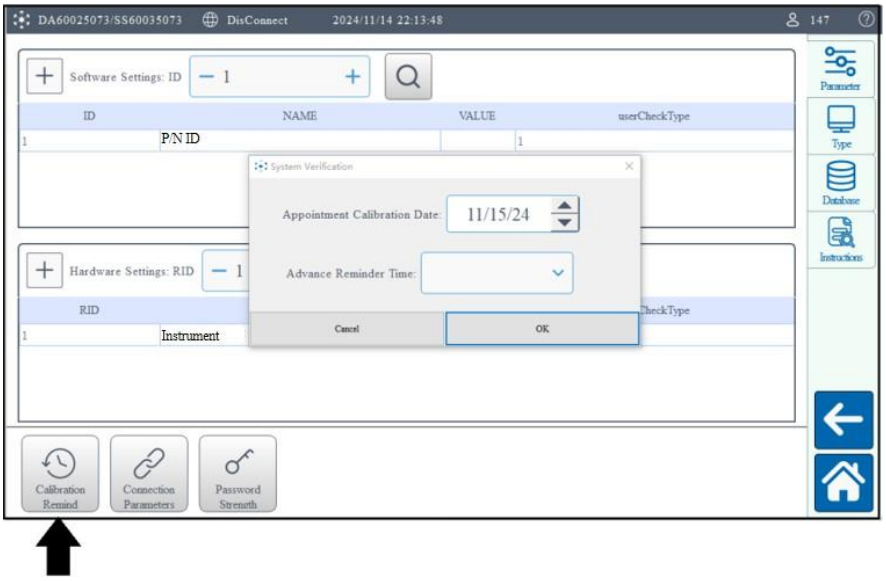
In this interface, users can set default system parameters for automatic backup, automatic operation, and automatic cleaning.

Suggestion:

In order to reduce the risk of experimental violation, it is not recommended to assign this permission to the ordinary operators. It is recommended to assign to system administrators or designated responsible persons.

5.8.1.1 Calibration Remind

At the bottom of the parameter setting interface, click the Calibration Remind button, and the interface will pop up the dissolution system calibration remind setting box.

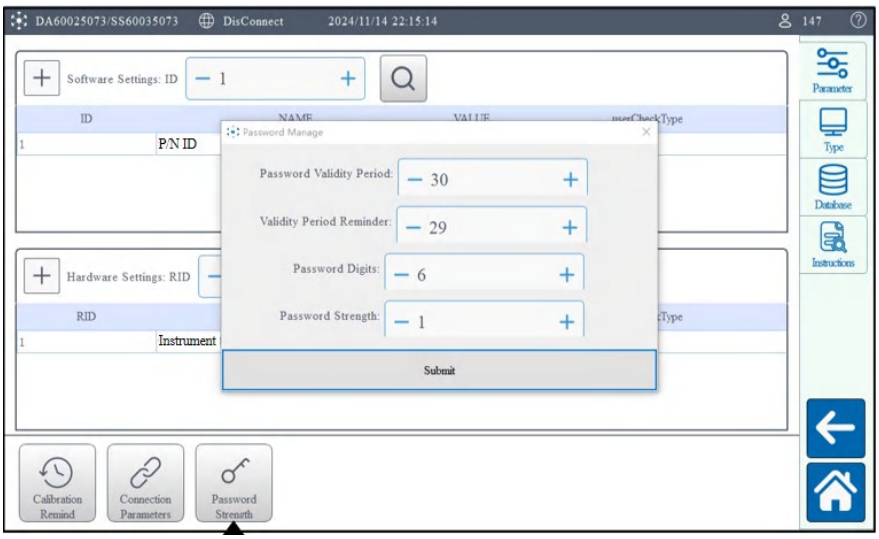


In the input box for the Calibration Due Date, enter the calibration expiration date of the dissolution system. In the input box for the Advance Remind Time, enter how many days in advance would you like to be reminded of the calibration due date.

The system will notify users in advance through pop ups that the dissolution system is about to reach the calibration deadline.

5.8.1.2 Password Strength

Strength button, and the interface will pop up the Password Strength setting box.



Password Validity Period (Unit: Day)

The password validity period is set within the range of 0 to 365 days. After creating or changing a password, when the set expiration date is reached, the system will require the user to change the password.

When set to 0, the system defaults to passwords without any expiration date restrictions and does not require password changes when the expiration date is reached.

Validity Period Remind (Unit: Day)

The validity period remind is set within the range of 0 to 365 days. The system will remind users to change their password according to the set validity period remind time before the password expires.

Password Length

The range of password length is set from 1 to 50. When users create or modify passwords, the password length must not be less than the set number of password characters.

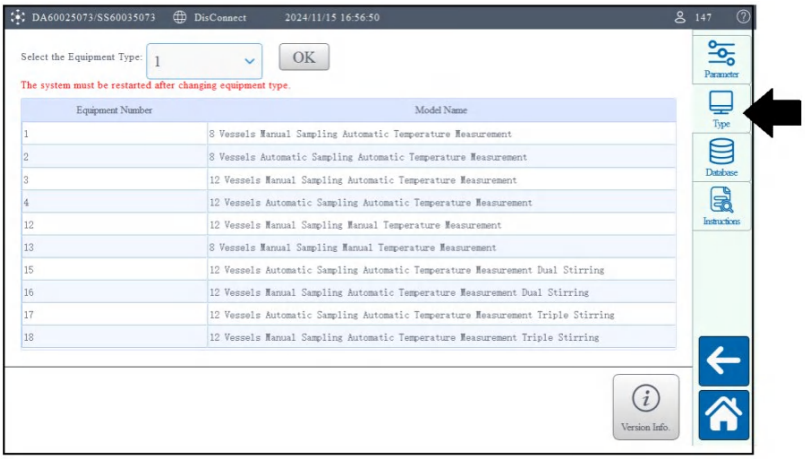
Password Strength

The password strength setting range is 1-3. The password strength requirements represented by different numbers are as follows:

NO.	Strength	Instruction
1	Weak	There is no mandatory requirement for password content, it can contain numbers, uppercase or lowercase letters.
2	Media	The password content must contain both numbers and English letters.
3	Strong	The password content must contain numbers and uppercase and lowercase letters.

5.8.2 Equipment Type

In the setting interface, click the Type button in the sidebar, to enter the equipment type setting interface.



Select the required equipment type code in the Equipment Type drop down box (see the table below for the type number corresponding to different equipment models).

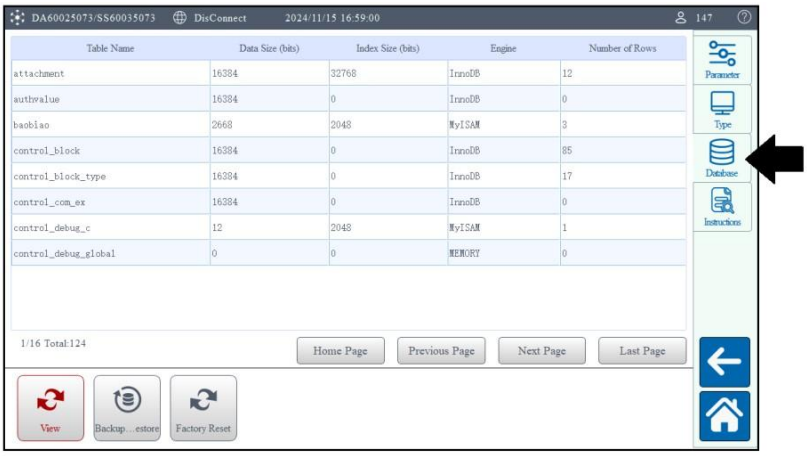
Click OK button. The system will prompt that the modification is successful. Please restart the dissolution system before use.

Attention:

If you need to modify the equipment type of mini vessel method, please be sure to raise the sampling needle bracket to the top in the manual control interface before modification. To avoid collision between sampling needles and mini vessel method accessories.

5.8.3 Database

In the setting interface, click the Database button in the sidebar, to enter the database setting interface.

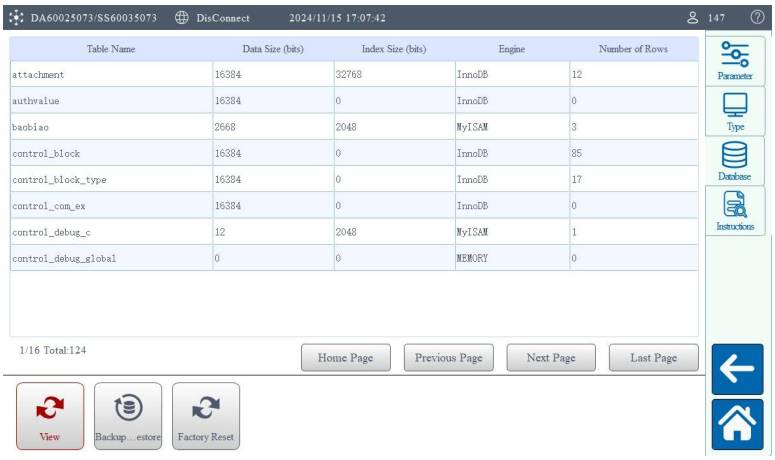


You can click the function buttons at the bottom of the interface to switch between different function interfaces.

No.	Button	Function Instruction
1		View database parameters.
2		Perform database backup and restore.
3		Restore the database to its factory state.

5.8.3.1 View Parameters

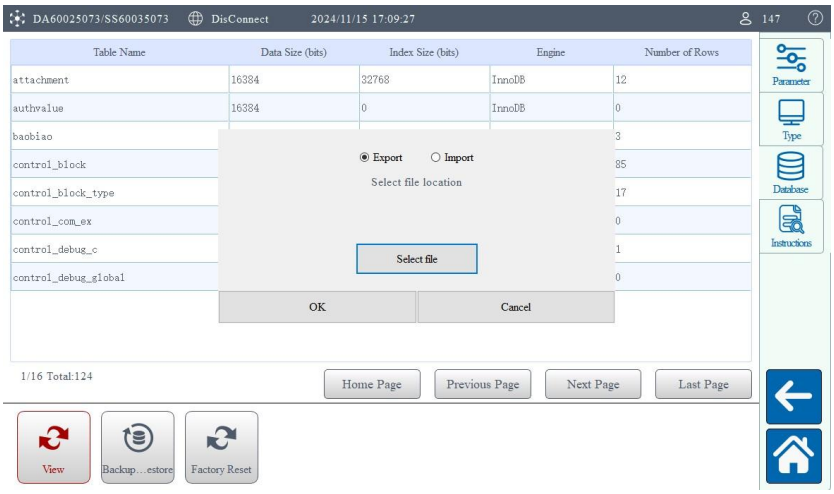
At the bottom of the database interface, click the View button, you can enter the database parameter viewing interface.



The parameter information of the current database can be viewed on this interface.

5.8.3.2 Backup & Restore

At the bottom of the database interface, the interface will pop up a window for database backup and restore.



Database Backup

（1）Click on the Export in the window.

（2）Click the Select File button and select which folder to export the database to.

（3）Click the OK button to complete the database export.

Database Restore

（1）Click on the Import in the window.

（2）Click the Select File button and select which database file to import into this system.

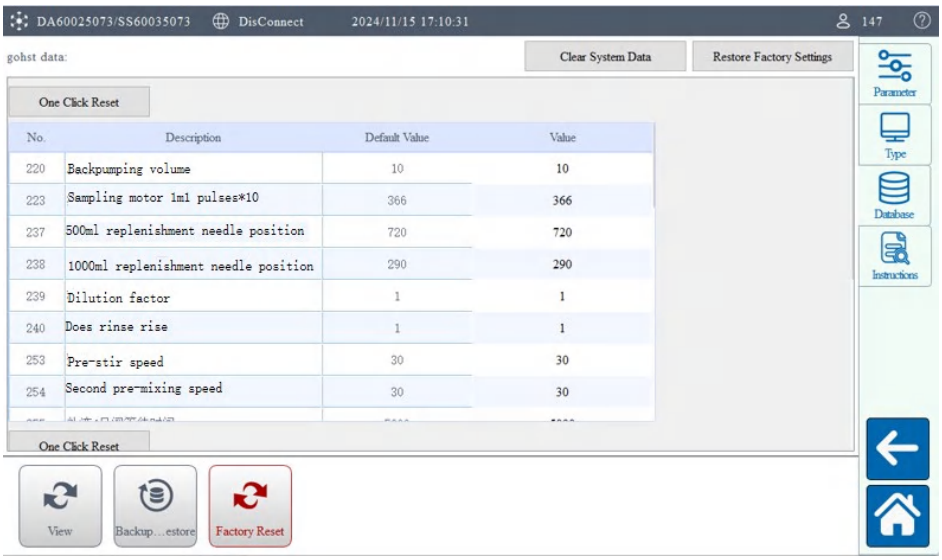
（3）Click the OK button to complete the database import, this system will restore to the database under the specified file.

Attention:

Before performing database restoration, please carefully confirm the correctness and integrity of the database to avoid causing database anomalies.

5.8.3.3 Factory Reset

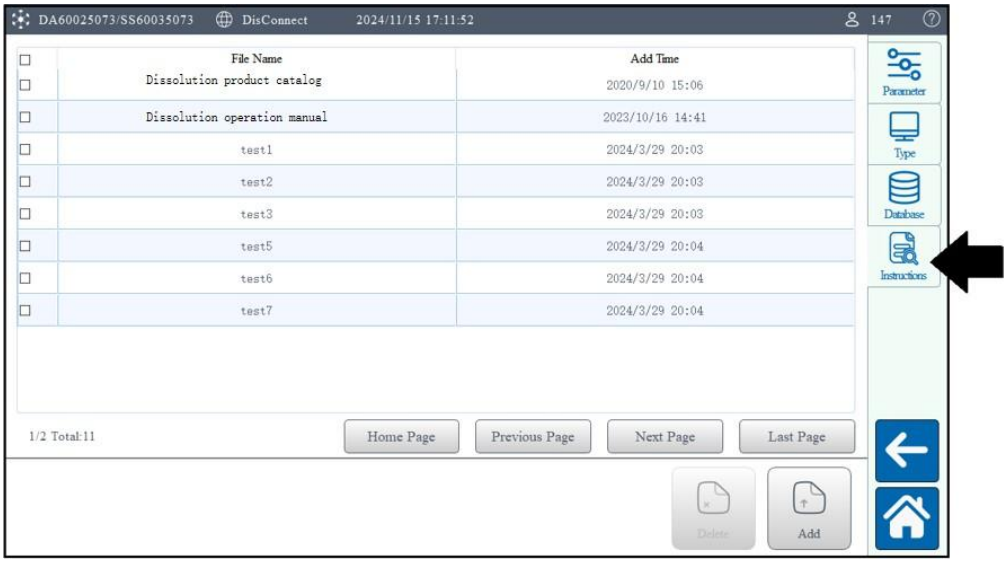
At the bottom of the database interface, click the Factory Reset button to enter the factory reset interface.



Click the Factory Reset button on this interface to restore all database parameters to their factory settings. Or individually click on the Restore button in different parameter fields to restore the parameters of different system components to their factory state.

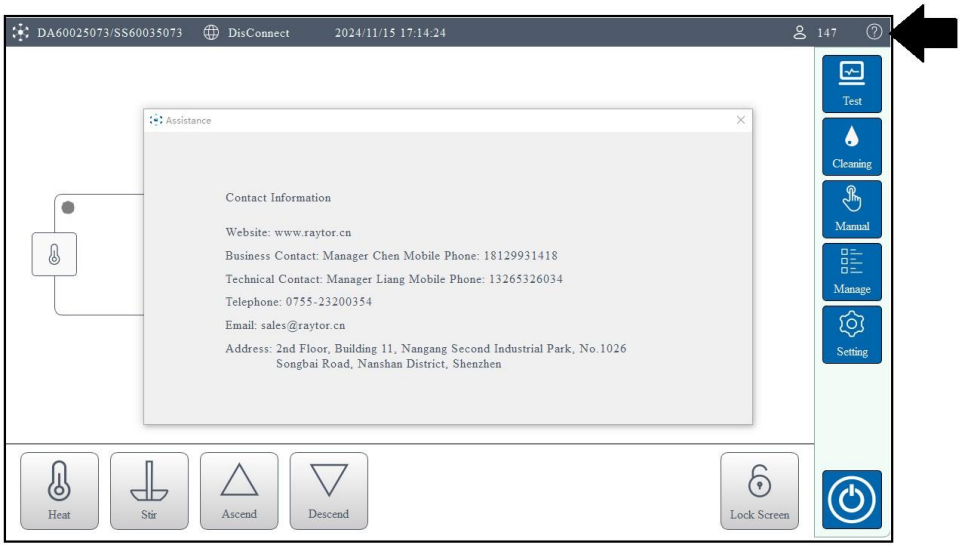
5.8.4 Instruction

In the setting interface, click the Instruction button in the sidebar, to enter the instruction interface. Users can view the instrument manual and other technical information on this interface.



5.9 Contact Information

In any interface, clicking the button in the upper right corner of the interface will pop up a contact information window. This window will show the contact information of the Raytor Instruments. If there are any technical problems in machinery, method, application, calibration or verification, you can contact us for technical support.



6. Guidelines for Dissolution Experiment

This chapter provides a quick and simple guide for users to carry out dissolution experiments. Users can refer to this guide and design a dissolution experiment process that meets their own needs according to the actual use.

6.1 Preparation before Experiment

（1） Starting up

Press the blue power switch on the right side of the dissolution apparatus for 3 seconds to start the equipment. Each part of the equipment will be self-checked and reset.

（2） Login

Enter account, password in login interface and login system. S

（3） Cleaning Automatic Sampling Pipe

When the automatic sampling workstation is unused for a long time or when necessary, clean all the pipe before the experiment to ensure that the pipe is clean and free of blockage when sampling.

（4） Add Water

Fill the water bath with water to the indicator line.

（5） Install Dissolution Vessel

According to the number of dissolving vessels, install dissolving vessel, rotate and fix them.

（6） Add Medium

According to the experimental requirements, fill the dissolution vessel with medium of specified volume.

Suggestion：

Medium should be degassed properly. In addition, when adding medium into the dissolution vessel, it is suggested to add slowly along the wall of the vessel to reduce the generation of bubbles.

（7） Water Bath Heating

In the Main Interface, descend the sampling platform and lifting head. Set the water bath temperature and start the heater and circulating pump.

（8） Paddle Installation

If paddle apparatus is needed, the paddles can be installed in turn according to the serial number.

（9） Waste Liquid Tank Installation

Install the waste liquid tank for the automatic sampling workstation and confirm that the waste liquid in the waste liquid tank has been cleared.

（10）Test Tube Rack Installation

Install the test tube rack for the automatic sampling workstation and place a sufficient number of clean test tubes on the test tube rack.

（11）Secondary Filters Installation

Install secondary on-line filters at the automatic sampling workstation.

（12）Columnar Filter Element Installation

Install the columnar filter element that meets the requirements at the front end of the sampling needle.

6.2 Establishment and Invocation of Dissolution Method

（1）Method Establishment

According to the test method requirements, laboratory supervisor establish the dissolution method in the Experimental Method Interface (if the relevant method has already existed in the system, it is not necessary to establish it again).

（2）Method Invocation

Operator clicks the Experiment Button under the main interface, and enters the Experimental Method List Interface, select the experimental method in the method list, and click it to enters the Experimental Method Parameters Interface, click Run button, fill in the lot number of the sample, and click the OK Button, the equipment will perform the automatic dissolution experiment.

6.3 Automatic Dissolution Experiment Process

（1）The lifting head and sampling platform will automatically descend, and the dissolution vessel cover covers each dissolution vessel.

（2）When the temperature of the medium reaches the experimental requirement, the system will prompt that put the sample into the dosing area.

Paddle Apparatus:

Put the sample into the automatic dosing tank. Click OK to confirm, the system starts automatic synchronous dosing device, to perform automatic synchronous dosing.

Basket Apparatus:

The lifting head rises automatically. Put the sample into the basket, and install the rotating shaft and basket. After installation, Click OK to confirm, the lifting head will decline again, and the baskets will enter the medium.

（5）After completing the dosage, the dissolution apparatus will automatically start the dissolution experiment and waits for sampling.

（6）One minute before the sampling point, the system buzzed and the sampling needle will decline into the sampling position of the dissolution vessel.

（7）The automatic sampling workstation will perform automatic sampling at the sampling time.

（8）When the experiment is completed, the rotating shaft stops rotating and the water bath remains constant temperature.

（9）Take the sample from the automatic sampling workstation for next analysis.

7. Equipment Maintenance

7.1 Regular Maintenance

7.1.1 Maintenance after Each Experiment

（1） Cleaning the Dissolution Vessel

Pour the dissolution medium into the waste liquid recycling container, and clean the dissolving vessel with water and dry by airing.

- It is recommended to use soft material to clean the dissolution cup. Hard materials or even wire brushes are not recommended, to avoid scratching or damage to the vessel.
- Avoid collisions between dissolving vessel or collision with hard objects, so as to avoid breakage of dissolving vessel.

（2） Clean the Dissolution Vessel Installation Platform

Use soft cloth to clean the dissolution vessel installation platform, to keep it clean and dry.

- Do not use hard materials or even wire brushes, to avoid scratches or damage.
- Do not use corrosive detergents. If cleaning agents must be used, make sure that they are as mild as possible and compatible with hydrocarbons.

（3） Cleaning the Dissolution Stirring Elements

Rinse the stirring elements (shaft, paddle/basket) with clean water, wipe and dry them with soft towel or soft paper towel after rinsing.

- When using corrosive medium (e.g. hydrochloric acid solution) to perform the experiment, please clean the stirring element immediately after each use.
- Use soft material to clean stirring elements. Do not use hard materials or even wire brushes, to avoid scratches or damage.
- Do not use corrosive detergents. If cleaning agents must be used, make sure they are as mild as possible and compatible with hydrocarbons and stainless steel.
- Avoid using high temperature to dry the stirring elements as far as possible. High temperature may damage the anti-corrosion coating of stirring elements.
- Please try to avoid collision between stirring elements, avoid random storage of stirring elements in drawers, in order to avoid scratches, notches, loss or deformation of components. It is a good maintenance way to use the airing bracket matched by Raytor Instruments to dry and store stirring elements.

（4） Cleaning the Temperature Probe, Sampling/Replenishment Needle

Clean the temperature probe and the outer wall of the sampling needle and replenishment needle with clean water, and dry them with soft towel or soft paper towel.

- When using corrosive medium (e.g. hydrochloric acid solution) to perform the experiment, please clean the temperature probe，sampling needle and replenishment needle immediately after each use.
- Do not use hard materials or even wire brushes, to avoid scratches or damage.
- Do not use corrosive detergents. If cleaning agents must be used, make sure they are as mild as possible and compatible with stainless steel.

（5） Cleaning the Dissolution Vessel Cover

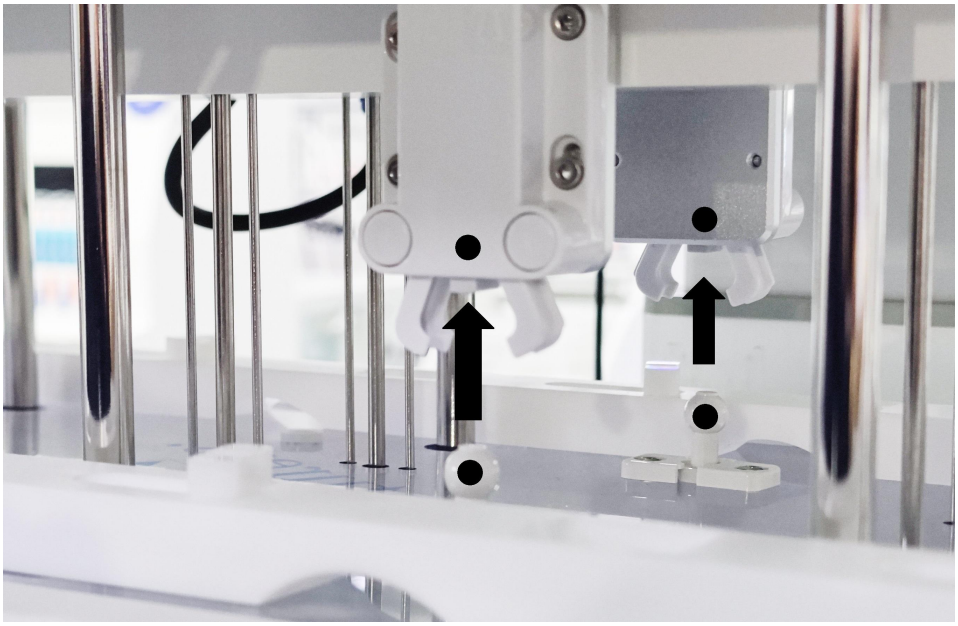
Use a soft cloth to clean and vessel cover, keeping it clean and dry.

- Do not use hard materials or even wire brushes, to avoid scratches or damage.
- Do not use corrosive detergents. If cleaning agents must be used, make sure they are as mild as possible and compatible with polycarbonate (PC).
- Please make sure that there is no sample powder residue in the dossing trough.

（6） Cleaning the Base Shaft

Lift the integrated vessel cover with both hands, to let the cover fixed with the clasp at the bottom of the lifting head. Use soft towel to clean the outer wall of the base shaft.

- When using corrosive medium (e.g. hydrochloric acid solution) to perform the experiment, please clean t base shaft immediately after each use.
- Do not use hard materials or even wire brushes, to avoid scratches or damage.
- Do not use corrosive detergents. If cleaning agents must be used, make sure they are as mild as possible and compatible with stainless steel.



（7） Cleaning the Automatic Sampler Pipe

Raytor Automatic Sampling Workstation has the function of automatic cleaning of sampling pipe. Users can set up automatic cleaning procedures.

Attention:

Before performing the automatic cleaning, make sure that the replenishment line on the side of the automatic sampling workstation has been put into a sufficient volume of cleaning agent.

Suggestion:

For general soluble samples, purified water at 40~50℃ is a good cleaning agent for the pipe The residual samples in the pipe can be effectively removed by a certain number of cleaning times.

For insoluble samples, appropriate cleaning agent, such as acid/alkali solutions with appropriate pH values, can be use. Please use surfactant cautiously as cleaning agent. If the surfactant in the pipe is not removed completely, it may have a great impact on the results of the subsequent dissolution test. The user should have appropriate experiments to prove that the subsequent cleaning steps can remove the surfactant completely.

Special cleaning agent should be compatible with Teflon.

Whatever cleaning agent is used, even for general soluble samples, the validity of the cleaning procedure should be verified to ensure that the corresponding cleaning procedure can remove the residues of the samples tested last time and has no effect on the results of the next experiment.

（8） Clean up the Waste Liquid in the Waste Liquid Tank

Remove the waste liquid tank from the automatic sampling workstation, and pour the waste liquid into the corresponding recycling container. Wash the waste tank and dry by airing.

Regularly clean the bottom of the waste liquid tank of the automatic sampling station and, if liquid is left, clean it in a timely manner to avoid possible risks of corrosion.

7.1.2 Weekly Maintenance

It is suggested to drain the water in the water bath every week, clean the inner wall of the water bath with soft materials, and check whether there are scales, algae accumulation and leakage in the water bath.

Confirm that cleaning agent and algaecides are compatible with polycarbonate (PC).

7.1.3 Semi-Annual / Annual Maintenance

It is suggested to perform the safety confirmation of leakage switch, the mechanical performance qualification of the equipment, the accuracy verification of Automatic Sampling Workstation and the performance qualification of equipment by using dissolution standard tablets every six months. Ensure that the performance of the equipment is still in good condition.

Raytor Instruments can provide customers with mechanical performance qualification, accuracy qualification of Automatic Sampling Workstation and performance qualification of dissolution standard tablets in accordance with Pharmacopoeia regulations. If necessary, contact Raytor Instruments for further technical support.

7.1.4 Two-Year Maintenance

It is recommended to appoint Raytor engineers or local agents authorized by Raytor to perform equipment status diagnosis every two years, confirm that the performance of the internal mechanical parts of the instrument is normal, and maintain them properly to ensure the equipment can continue to operate well.

7.2 Maintenance of Equipment Components

7.2.1 Dissolution Vessel

（1）After each use, please clean the dissolved vessel carefully. When cleaning the dissolution vessel, be sure to refer to **Chapter 7.1.1 (1)**.

（2）Do not let the dissolving vessel undergo sudden cooling and sudden heating. Do not pour a large amount of hot water into the dissolution vessel in the case of room temperature water bath. These behaviors are likely to lead to the breakdown of the dissolution vessel.

（3）If cracks are found in the dissolution vessel, please replace it in time.

7.2.2 Water Bath

（1）Do not pour a large amount of high temperature hot water into the empty water bath quickly, especially at low room temperatures, which may lead to the rupture of the water bath.

（2）It is recommended to change and clean the water bath once a week, and confirm whether there is leakage (see **Chapter 7.1.2**).

（3）It is recommended to add purified water to the water bath to minimize scale formation and bacteria, mould and algae growth.

7.2.3 Dissolution Stirring Element (Paddle/Basket)

（1）After each use, please carefully clean the stirring elements. For the cleaning and placement of stirring elements, be sure to refer to **Chapter 7.1.1 (2)**.

（2）Do not polish the surface of the stirring element, which will destroy the anti-corrosion layer on the surface of the stirring element.

（3）Do not let the stirring elements fall from high places, which is likely to cause damage.

（4）Do not over-extrude the dissolution basket, which is likely to lead to the deformation of the basket.

（5）Please regularly check the appearance of the stirring elements and replace the damaged or deformed dissolution components.

7.2.4 Sampling Needle/ Replenishment Needle

（1）After each use, please clean the sampling needle/ replenishment needle carefully. When cleaning, please refer to **Chapter 7.1.1 (4)**.

（2）Do not bend the sampling needle/replenishment needle.

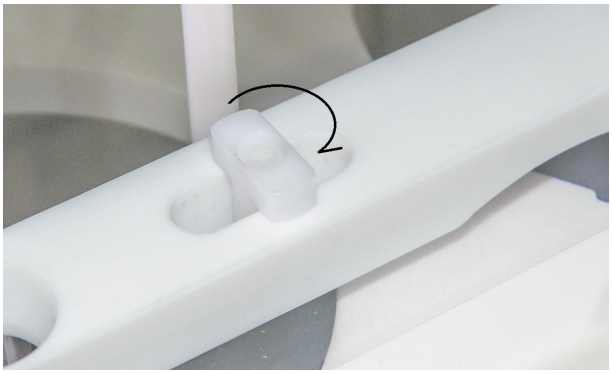
（3）Do not polish the surface of the sampling needle/ replenishment needle, which will destroy the anti-corrosion layer on the surface.

（4）Using the columnar filter can effectively prevent the blockage of sampling needle and pipe.

7.2.5 Dissolution Vessel Cover

（1）After each use, please carefully clean the dissolving vessel cover. When cleaning the vessel cover, please refer to **Chapter 7.1.1 (5)**.

（2）If it is necessary to clean the automatic dosing trough, each screw of the dosing strip module can be transferred to the position of the corresponding hole in the module, and the whole dosing strip module can be removed and cleaned.



7.2.6 Automatic Sampling Workstation

（1）After each use, carefully clean the pipe of the automatic sampling workstation and remove the waste liquid from the waste liquid tank.

（2）The use of columnar filter can effectively prevent the valve and pipe blockage of the automatic sampling workstation.

（3）If the automatic sampling workstation may not be used for a long time, it is recommended to use 95% alcohol to flush the pipe several times after the pipe is cleaned in normal procedure. The residual water in the pipe can be taken out, which can effectively prevent the breeding of microorganisms in the pipe.

Before reusing, the pipe should be cleaned again according to the procedure.

（4）Perform regular inspection of automatic sampling pipe and valve operation.

8. Revision History

The revision history of the of Raytor RT612-ST Dissolution System Operation Manual is as follows:

Document Version	Effective Date	Revised Summary
DS-D101-2502001	2025.02.26	1. New documentation.

Attachment

锐拓仪器
RAYTOR INSTRUMENTS

Equipment Qualification Certificate

Raytor Instruments Co., Ltd. declares that: RT612-ST Dissolution System,

Serial number_____, has been completed the production and assembly in Raytor Instruments,
The performance of this equipment meets the current regulations and standards of China and the United States.

Raytor Instruments Co., Ltd

Year Month Date

Raytor Instruments, CO., LTD.
Address: Second Floor, Building 11, Nangang Second Industrial Park, No. 1026, Xilishongbai Road, Nanshan District, Shenzhen
Tel: +86 (20) 31608901; Email: Sales@raytor.cn; Web: https://www.raytor.com/

锐拓仪器
RAYTOR INSTRUMENTS

Product Warranty

Product Name: Raytor Dissolution System

Product Model: _____

Serial Number: _____

Delivery Date: _____

Under the premise of normal and correct use of the product, the quality problems arising from the material or manufacturing of the product within one year from the date of installation of the client will be repaired or replaced by Raytor Instruments.

The warranty period for replacement of spare parts after the warranty period is 90 days. During the warranty period, the warranty period of all replacement parts will automatically terminate after the warranty period of the whole instrument. Service beyond poor maintenance will be charged according to the charging standard.

Unless otherwise specified, the limited quality assurance period for refurbished parts or accessories is 90 days, and the specific installation is carried out by the authorized person of Raytor Instruments. If the customer installs it himself, only the relevant parts are guaranteed for 90 days.

Raytor Instruments, CO., LTD.
Address: Second Floor, Building 11, Nangang Second Industrial Park, No. 1026, Xilishongbai Road, Nanshan District, Shenzhen
Tel: +86 (20) 31608901; Email: Sales@raytor.cn; Web: https://www.raytor.com/

锐拓仪器
RAYTOR INSTRUMENTS

From the date of the equipment shipment, due to unexpected events, transportation, user negligence, improper operation, not strictly following the instructions given by technical experts through the telephone for operation and other incorrect use of the equipment caused by failure and damage, the relevant maintenance costs are all borne by users.

During the warranty period, the adverse phenomena need to be notified to Raytor Instruments. Raytor Instruments Experts can make remote diagnosis and guide the solution or on-site inspection and maintenance services.

When necessary, the materials or parts identified as faulty should be returned to Raytor Instruments, which will bear the related express charges.

Raytor Instruments is not responsible for any special circumstances and consequent damage. Except for the provisions of this paragraph, Raytor Instruments shall not provide any express or implied warranties, including any warranties of marketability, suitability or otherwise.

Raytor Instruments Co., Ltd

Year Month Date

Raytor Instruments, CO., LTD.
Address: Second Floor, Building 11, Nangang Second Industrial Park, No. 1026, Xilishongbai Road, Nanshan District, Shenzhen
Tel: +86 (20) 31608901; Email: Sales@raytor.cn; Web: https://www.raytor.com/

锐拓仪器
RAYTOR INSTRUMENTS

Equipment Installation and Acceptance Report

Customer Name			
Product Name		**Model**	
Serial Number		**Arrival Time**	
Equipment Installation and Acceptance Result			
Acceptance Item	**Conclusion**		
Appearance	**Pass☐**	**Fail☐**	
Software System	**Pass☐**	**Fail☐**	
Physical Calibration	**Pass☐**	**Fail☐**	
Performance	**Pass☐**	**Fail☐**	
Overall Conclusion:	**Pass☐**	**Fail☐**	
Remarks:			
Engineer/ Date		**Customer/ Date**	

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锐拓仪器
RAYTOR INSTRUMENTS

Equipment Installation and Acceptance Report

Customer Name			
Product Name		**Model**	
Serial Number		**Arrival Time**	
Equipment Installation and Acceptance Result			
Acceptance Item	**Conclusion**		
Appearance	**Pass☐**	**Fail☐**	
Software System	**Pass☐**	**Fail☐**	
Physical Calibration	**Pass☐**	**Fail☐**	
Performance	**Pass☐**	**Fail☐**	
Overall Conclusion:	**Pass☐**	**Fail☐**	
Remarks:			
Engineer/ Date		**Customer/ Date**	

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