

EXC200 Installation Guide

1. Installation procedure

1.1 Pre-installation preparation

Installation tool:

- Allen wrench
- Scissor
- Cross screwdriver
- Fixing belt (4x150mm 10 strips)
- Gloves
- Pincer plier
- Straight screwdriver

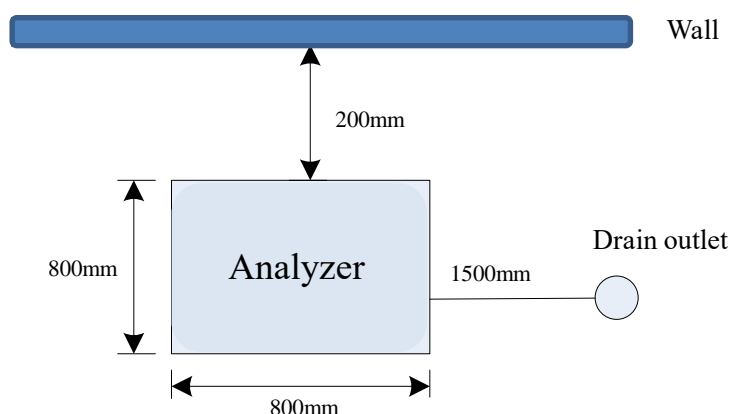
1.2 Environment requirements

1.2.1 Operating conditions

- Ambient temperature range: 10°C ~ 30°C
- Relative humidity range: 30% ~ 85%, no condensation
- Atmospheric pressure range: 70.0 kPa ~ 106.0 kPa
- Stay away from magnetic interference
- Avoid direct exposure to strong light
- Good grounding environment
- The installation table or ground should be flat (Slope < 1/200)
- Altitude: < 3000 meters
- Pollution rated degree: Level 2
- Indoor use only
- The installation table should bear a weight of at least about 100kg
- Good ventilate
- Dust-free environment
- Be away from heating and windy outlet
- No corrosive and flammable gas
- No vibration on the table (or ground)
- No loud noise and power interference
- If room temperature out of requirements, air conditioners needed

1.2.2 Space requirement

Please install the instrument as space requirement of below figure:



1.2.3 Power and grounding

- AC 100-240V, 50/60HZ, Good Grounding (Grounding resistance $< 10\text{m}\Omega$)
- Power input: $\leq 500\text{VA}$
- Please grounding power supply correctly. Incorrect grounding may cause electric shock, hardware damage, and instrument failure

1.3 Water supply requirements

■ General requirements

- Water quality should meet the requirements of **CLSI Grade II water**; resistance is greater than $1\text{M}\Omega \cdot \text{CM}$, the silicate content is less than 0.1mg/L ;
- Water supply: not less than 5L/h ;
- Temperature: Water temperature $5\text{--}32^\circ\text{C}$.

■ Water supply method

- Built-in water inlet pump: Supply instrument water via water inlet pump, **external water source cannot be under pressure**.
- Water supply tank cannot exceed the height of water inlet of analyzer, and the length of water pipe should not exceed 1.5 meters.

1.4 Drainage requirements

■ General requirements

- The waste tube should place without bending or protrusion
- The waste liquid discharge cannot be blocked

■ Waste discharge method

- **Connect waste tank:** The waste tank must lower than instrument placed level, ensured the

waste tank cap is lower than waste outlet of the instrument.

- **Connect the waste tube:** The distance between waste tank port and instrument discharge port should not exceed 1.5 meters, the waste tube shall not be laid flat on the same level as the drainage outlet of instrument.



Biosafety risk

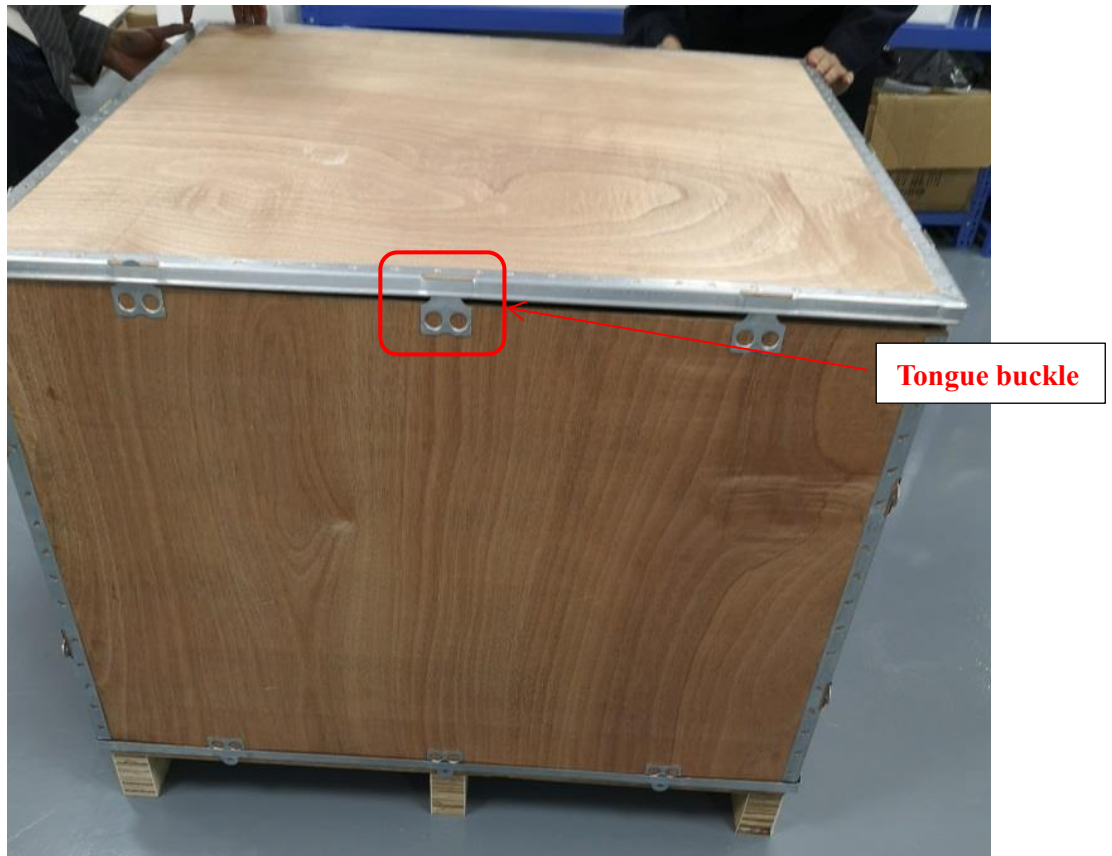
Please dispose the waste liquid according to local discharge standards

1.5 Instrument installation

1.5.1 Unpacking Check

1. Check all the packing cases before unpacking, **include: 1 tank case, 1 concentrated detergent case, 1 instrument wooden case** (Note: There are 3 accessory packages in the wooden case).
2. All the instrument packages had passed strict inspection by Zybion company before transportation. After you receive the instrument, please check the items carefully as below before opening the box:
 - 1) If outer packing has inverted or deformation, if tilting prevention label turn red or not.
 - 2) If outer packing has obvious marks of wet water or not.
 - 3) If the outer packaging is obviously impacted or not.
 - 4) If the package has been opened or not.
 - 5) Check appearance of all devices carefully, to see if have cracks, bruises or deformation or not.

If find any abnormal sign please take photo or video of it, then contact assigned engineer of Zybion.



1.5.2 Unpacking

1. Push the wooden box to a suitable position, ensure there is enough space to open it. And ensure there is enough space for two people to lift out the instrument.
2. Wear protective gloves, disassemble the tongue buckle (by a vise) which connecting upper cover & side plate. Remove the upper cover of the wooden box, then remove the front side panel—left side panel—rear side panel—right side panel, remove fixing tape. Take out all foam and accessory box.

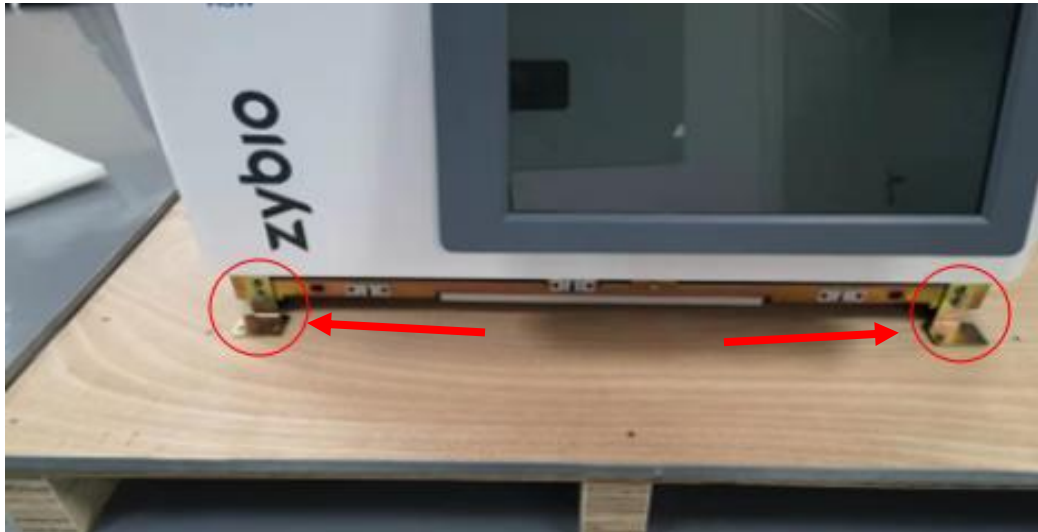


Figure of After remove box cover

3. Remove instrument PE bag, take out desiccant, remove trim strip from instrument front case.



4. Remove fixing bracket, unscrew **M8×35** Allen screws of four fixing brackets (at the bottom) by **M8 Allen wrench**. Then unscrew **2 M4×10** Allen screws on the side of the fixing bracket by **M4 Allen wrench**, then take out the fixing bracket.



5. Carry and placing the instrument on work table gently, pay attention to safety.
6. Install back the front trim strip to the front panel of instrument. Then take out the rear trim strip from foam, install it by **M3×8** cushion screw (which place in accessories box #3).



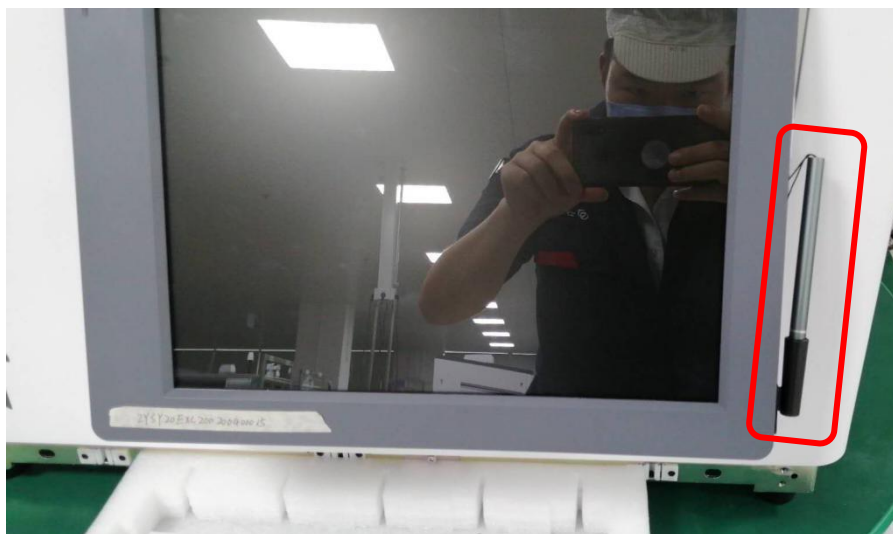
7. Take out the capacitive touch pen from accessory **box# 3** and stick the pen holder on the right side of monitor, then place the capacitive touch pen in the pen holder. **Figure shown as below:**



Stick pen holder

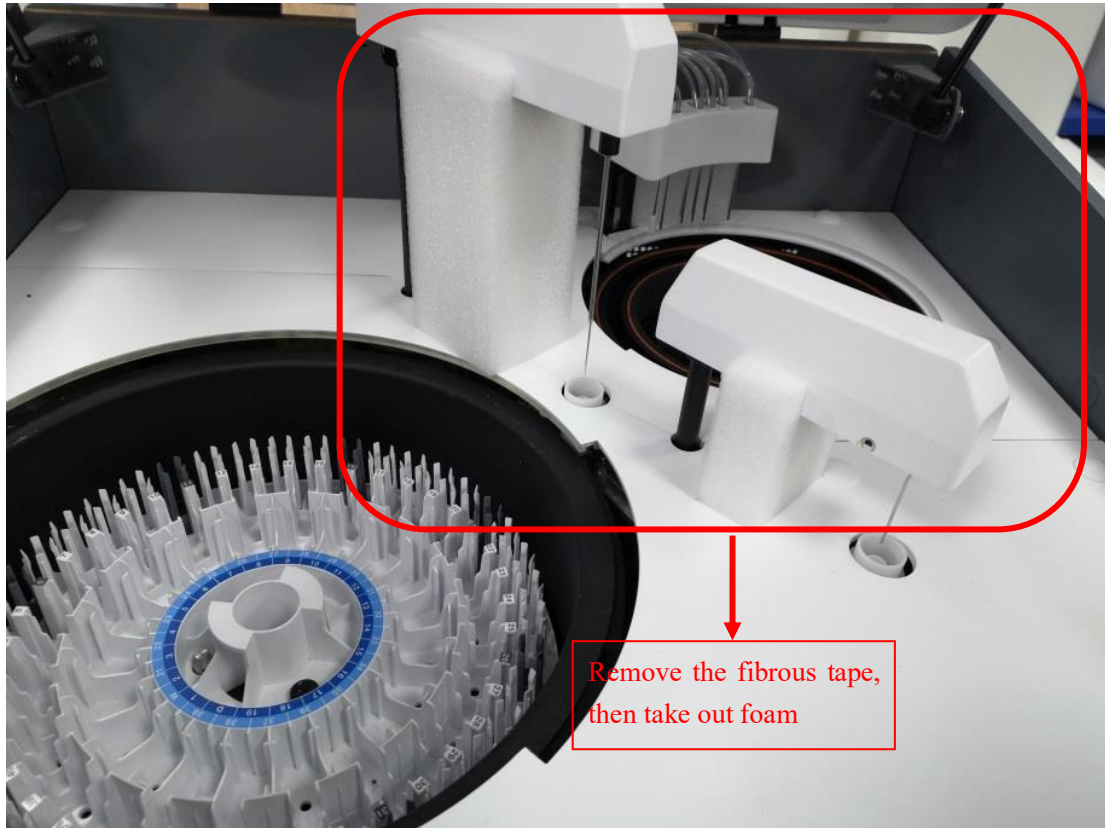


Capacitive touch pen



1.5.3 Protective film dismantle.

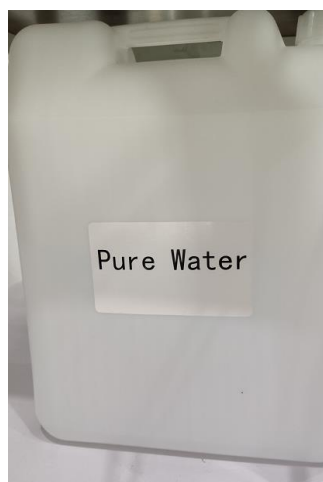
1. Open the upper cover of instrument, remove the adhesive tape & the protective foam of needle module & Stirring rod gently (Stirring rod come first).



1.6 Whole machine connection

Pipeline connection on the left of the instrument is shown in the figure as below:

1. Take out the purified water tank from waste tank packing box, take out **C043** and **C046** labeled pipeline from Accessory **box #3**; and take out purified water tank floater assembly from Accessory **box #2**;

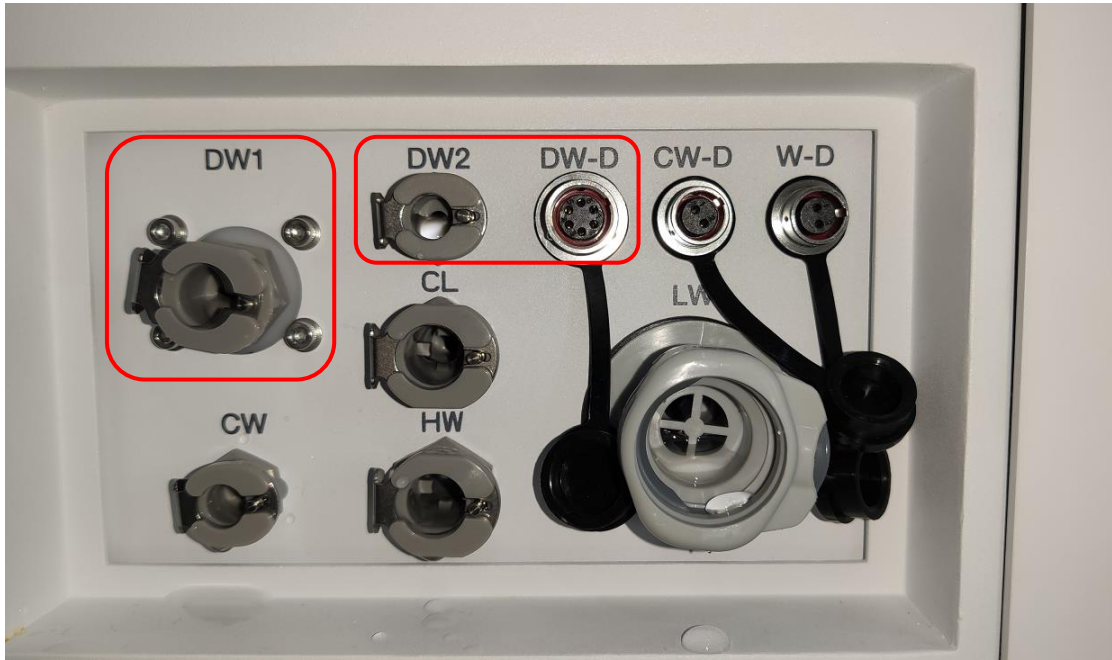


Purified water tank

Tube of purified water

Inlet float sensor

2. Fill the purified tank with purified water, place it under analyzer. **Note:** The purified water tank can't place on the table of analyzer; insert **C043** labeled tube into "**DW1**" connector of analyzer, insert **C046** labeled tube into "**DW2**" connector of analyzer. Connect the other end of these two tubes to purified water tank cap according to diameter size, then tighten the cap of purified water tank, insert the float sensor to "**DW - D**" connector.





3. Take out waste tank from waste packing box, and take out **C051**, **C053**, **C055** labeled tube from Accessory **box #3**. Take out the waste tank float assembly from Accessory **box #2**;



Waste tank



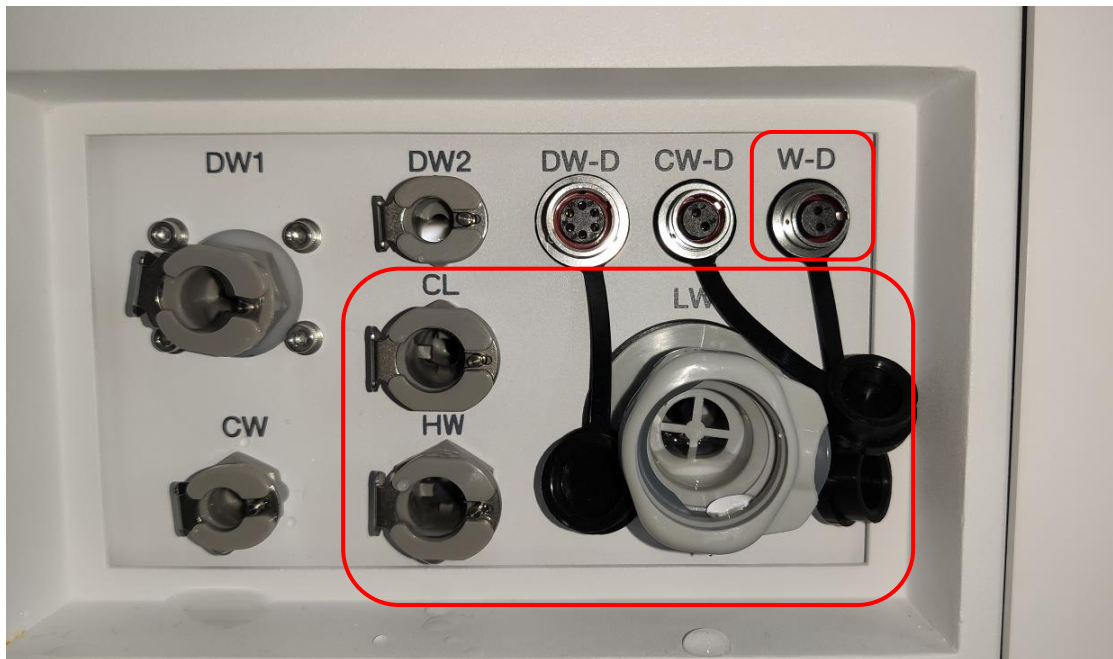
Waste Tube



Waste float sensor

4. Connect **C051** labeled waste tube to "LW" quick-plug connector, connect **C053** labeled waste tube to "HW" quick-plug connector, connect **C055** labeled waste tube to "CL"

quick-plug connector.



5. **Drain Waste Method 1:** If there is a sewage outlet for waste liquid, connect the waste liquid drain pipe to the corresponding joint on the side of the instrument, and insert the other end of the waste liquid pipe directly into the sewage outlet for waste liquid (length of the pipeline shall be cut according to the distance);

Drain Waste Method 2: If there is no sewage outlet for waste liquid, tighten liquid float assembly on the waste tank, connect float sensor cable to **W-D connector**, and insert other end of those three waste liquid pipe to waste tank accordance with pipeline diameter respectively (length of the pipeline shall be cut according to the distance, pipe C051 can't be bent directly or in u-shaped bending, otherwise it will lead to liquid seal, then cause waste liquid flow backward).



6. Take out concentrated detergent from cleaning packing box, take out **C048** labeled pipe from Accessory **box #3**; take out its float sensor assembly from Accessory **box #2**



Cleaning floater assembly

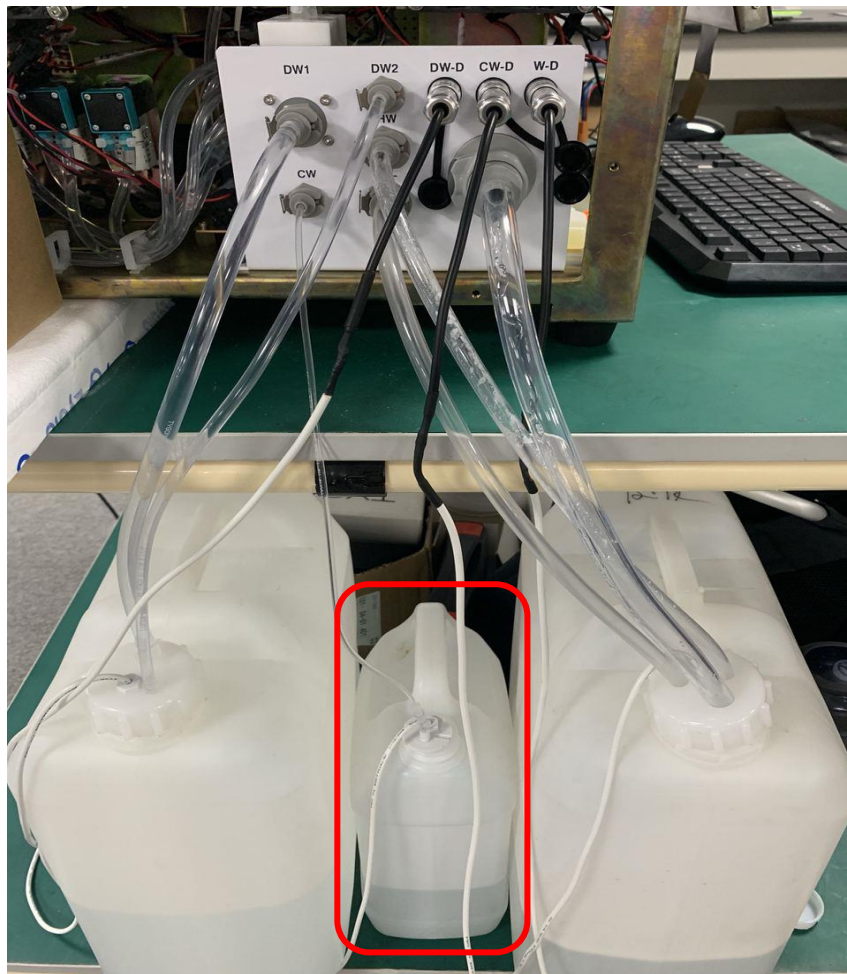
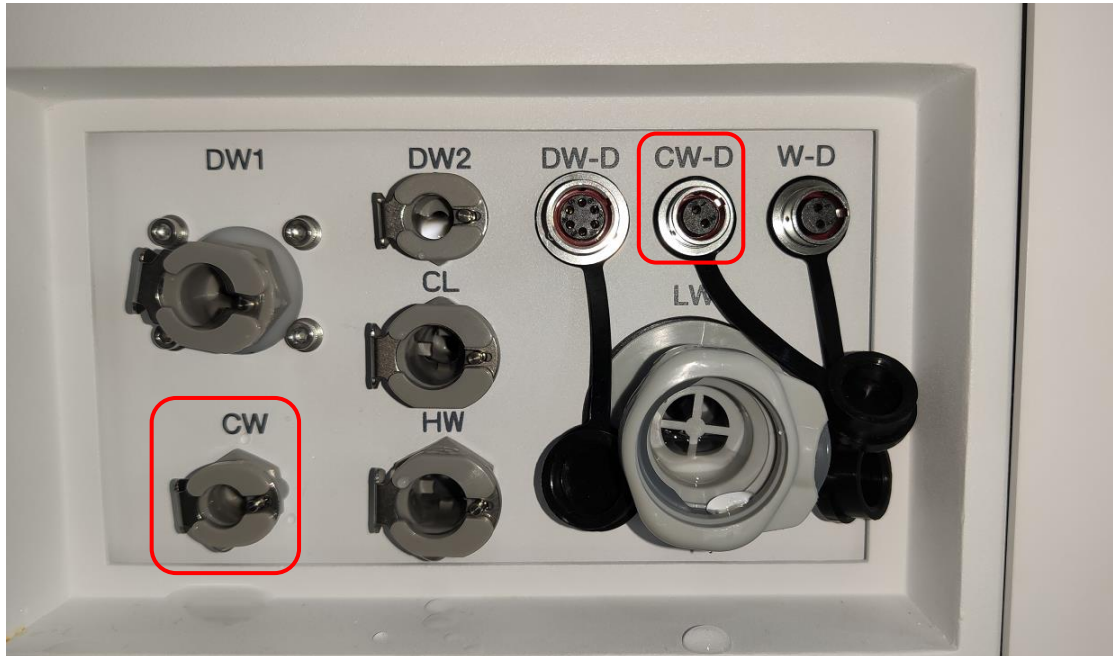


Concentrated detergent inlet pipe



Concentrated detergent

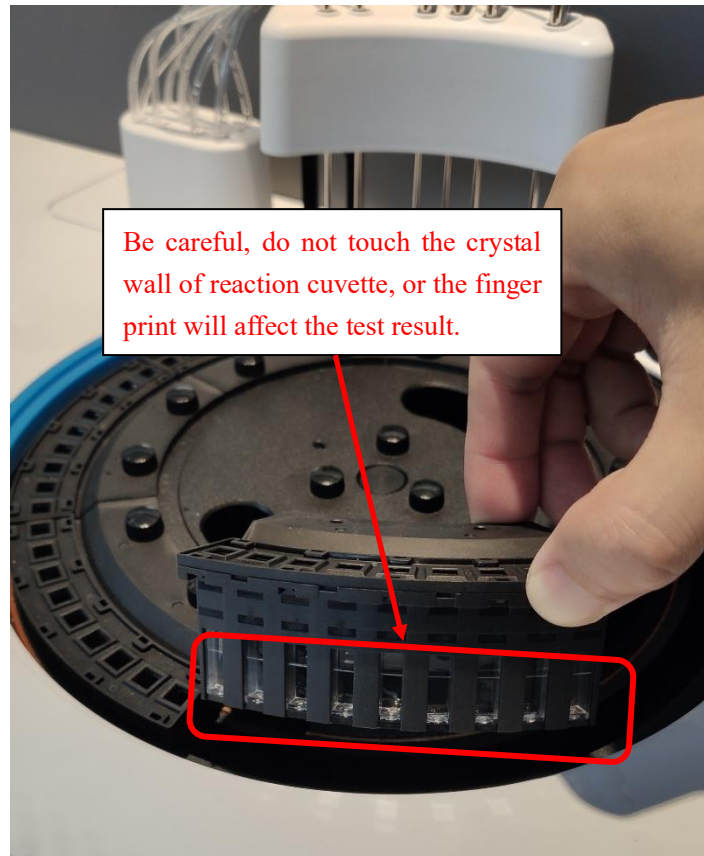
7. Connect the float sensor and pipeline to the "**CW-D**" connector and "**CW**" quick-plug connector on left side of the instrument, screw the Concentrated detergent float sensor into the bottle.



8. Pipeline connection:

Label	Signification	Function
DW1	Distilled water	Distilled water inlet, supply distilled water For instrument
DW2	Distilled water	Connected to distilled water suction tube, flow back distilled water automatically
CW	Concentrated detergent	Connect to concentrated detergent tube, supply Concentrated detergent
HW	High concentration waste	Drain waste for reaction cuvette
CL	Condense water	Drain condense water for reagent disk
LW	Low concentration waste	Drain waste for wash pool
DW-D	Distilled water float sensor	Distilled water level detection
CW-D	Concentrated detergent float sensor	Concentrated detergent level detection
W-D	Waste liquid float sensor	Waste liquid level detection

9. Take out 7 sets of reaction cup assembly from the accessory bag (1 extra set for backup),
Be careful, do not touch crystal of the reaction cup; Press the reaction cup assembly on
the reaction plate body, and then fix the reaction cup assembly on the reaction tray
main unit with 14 thumbscrews, picture as following.

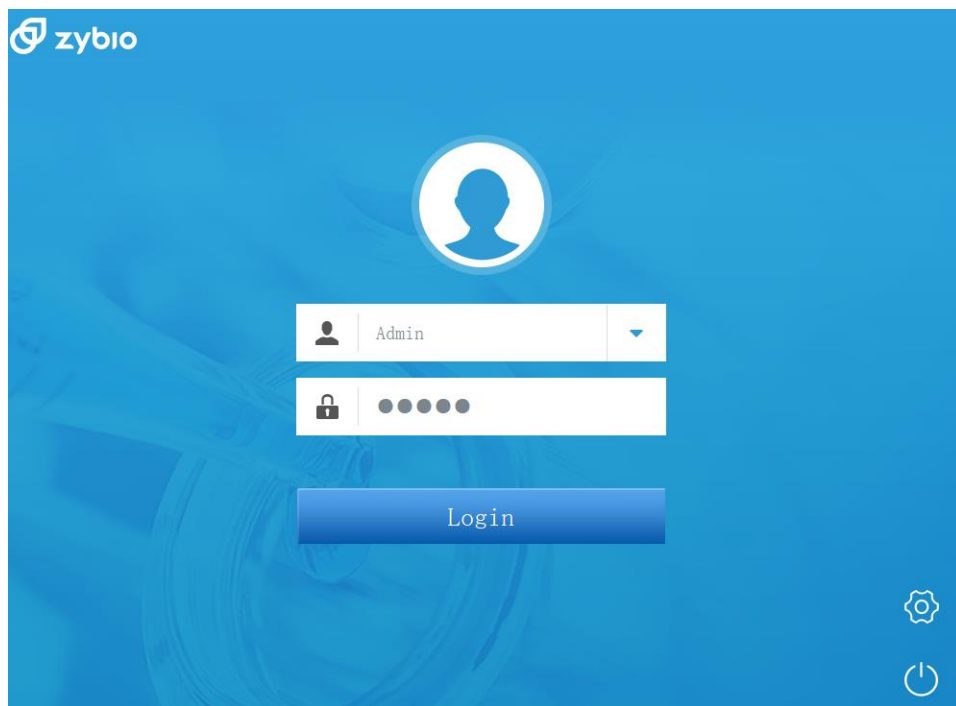


10. Take out the power cord from accessory **box # 3**, connect to biochemical analyzer.

2. Whole unit test

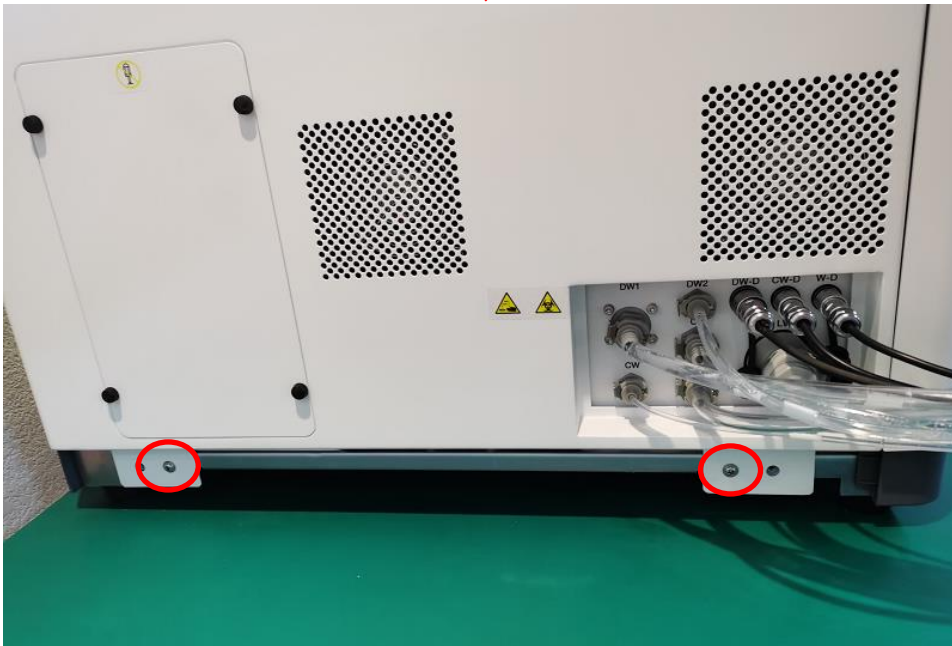
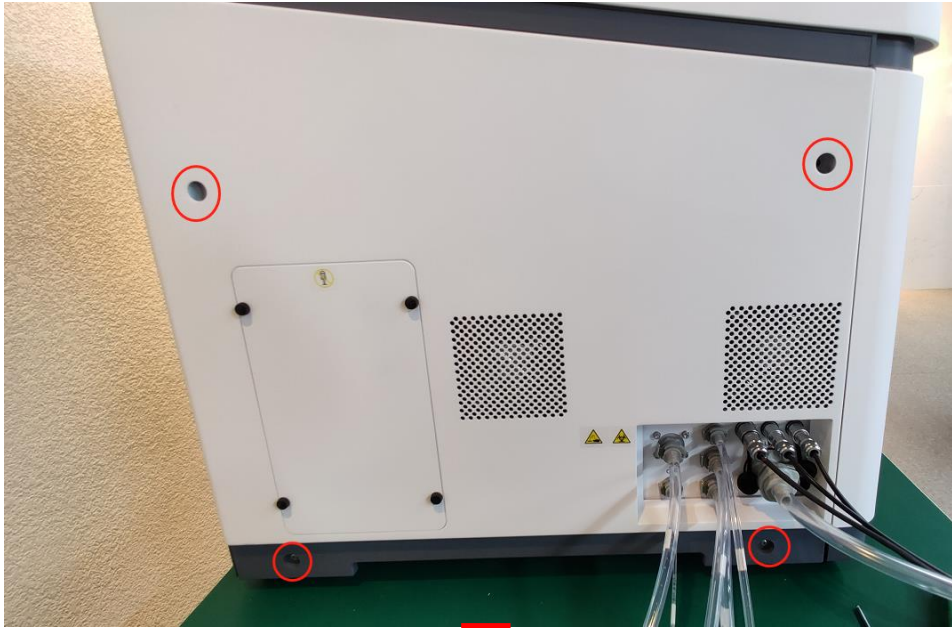
2.1 Bootup initialization

1. Before starting up, confirm that purified water tank and concentrated detergent tank are full, then waste liquid tank is empty.
2. After confirmation, turn on the main power switch on the right-side panel of instrument, then turn on the analysis switch on the front panel, and waiting around 45 seconds;
3. Log in with authority: **Admin**, password: **zybio**, wait several minutes for initialization.



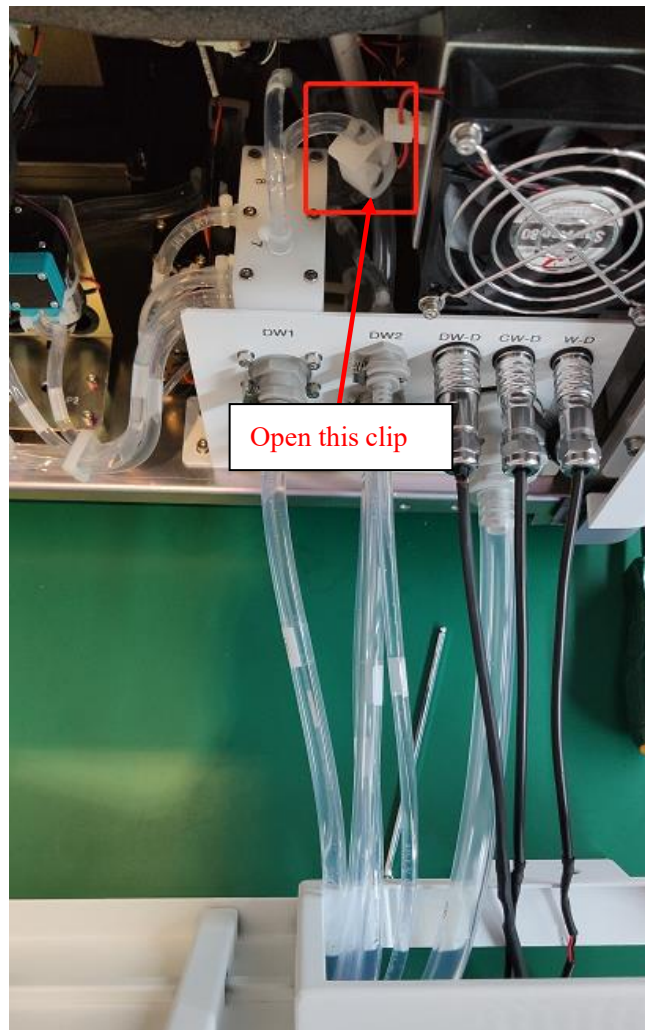
2.2 Exclude bubble and hydraulics priming

1. After log in, first please disassemble the left-side panel by removing 6 screws at these 4 positions in the following picture.

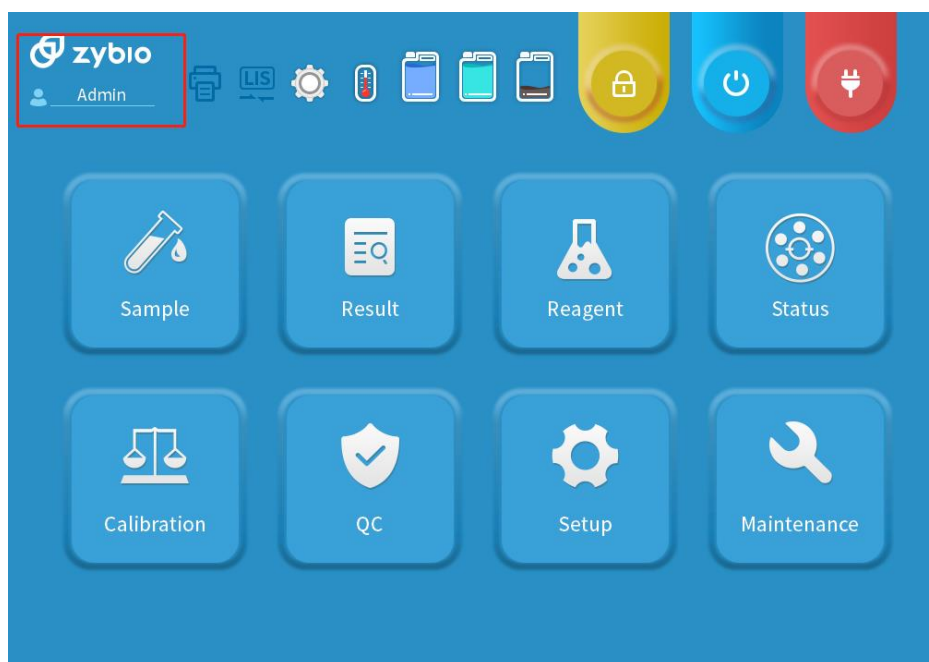


2. No need to unplug the pipeline on the left side panel, just open left-side panel to make your hand can reach and open the clip on the **C011** pipeline. Please see the figure as below:

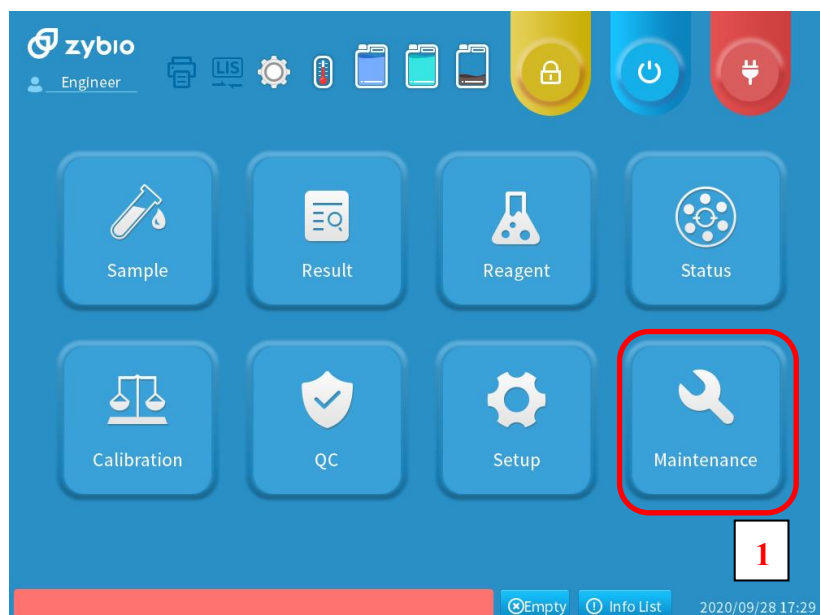


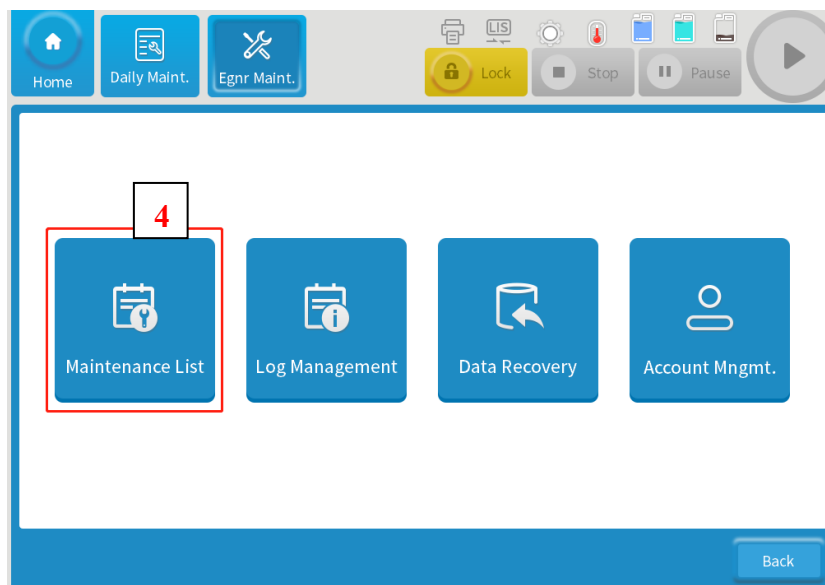
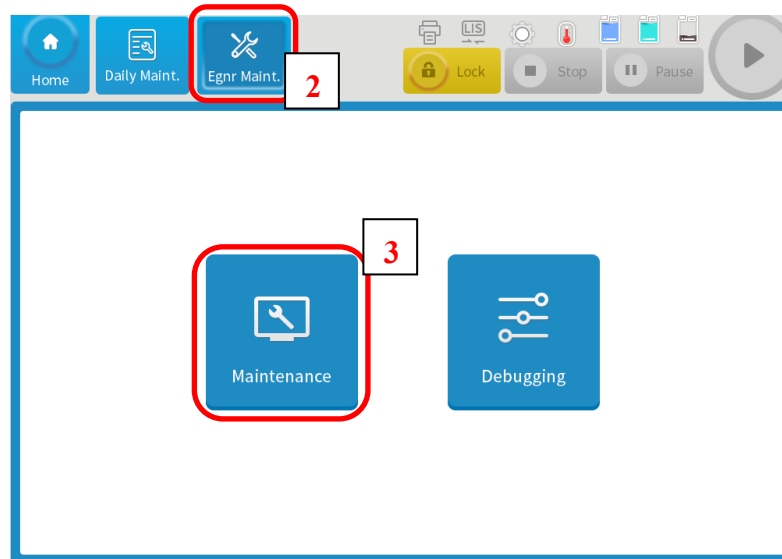


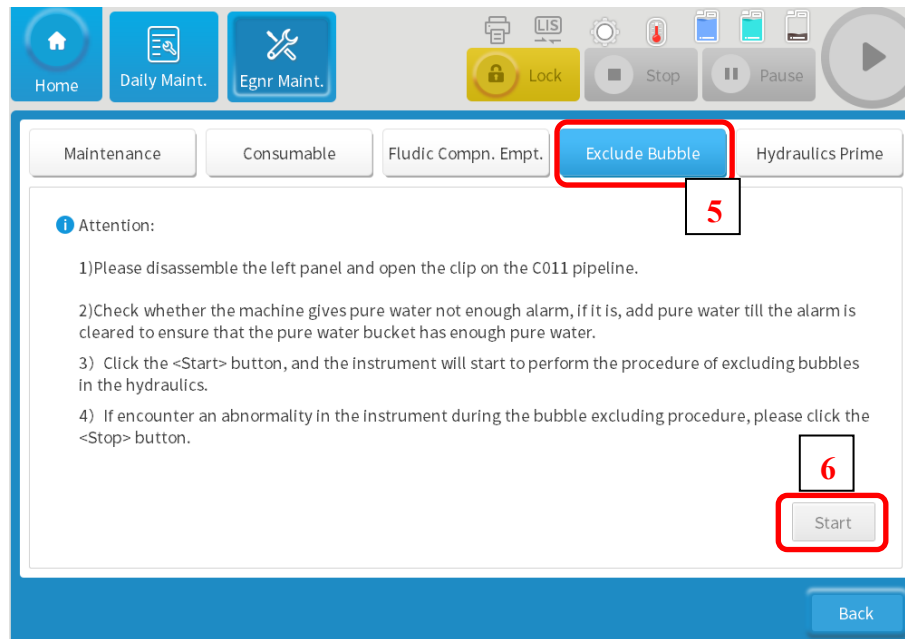
3. After open the clip on the **C011** pipeline, back to screen, click the upper left part to switch to engineer authority with user name: **Engineer**, password: **zybio888**.



4. Go to **[Maintenance]→[Engineer Maintenance]→[Maintenance]→[Maintenance List]→[Exclude Bubble]**, ensure purified water tank remaining sufficient water, and then click **[Start]** to proceed the bubble excluding procedure.

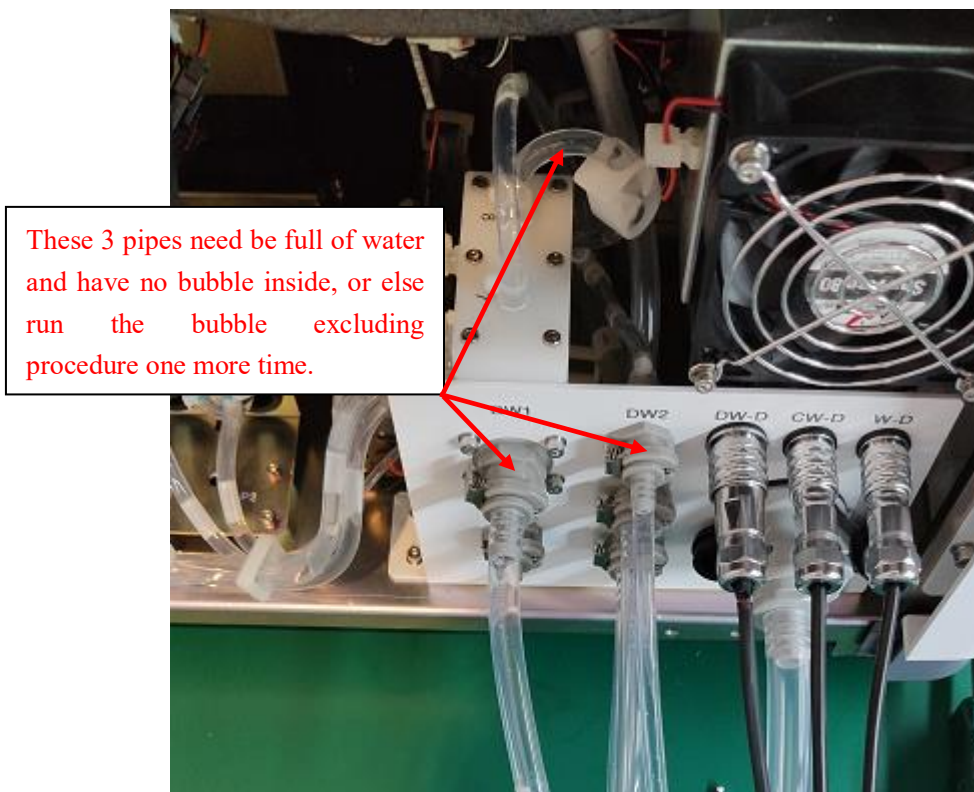




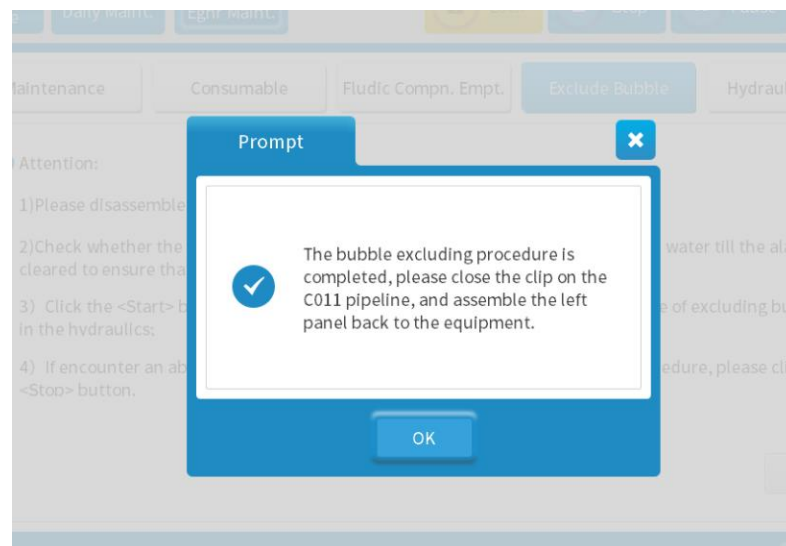
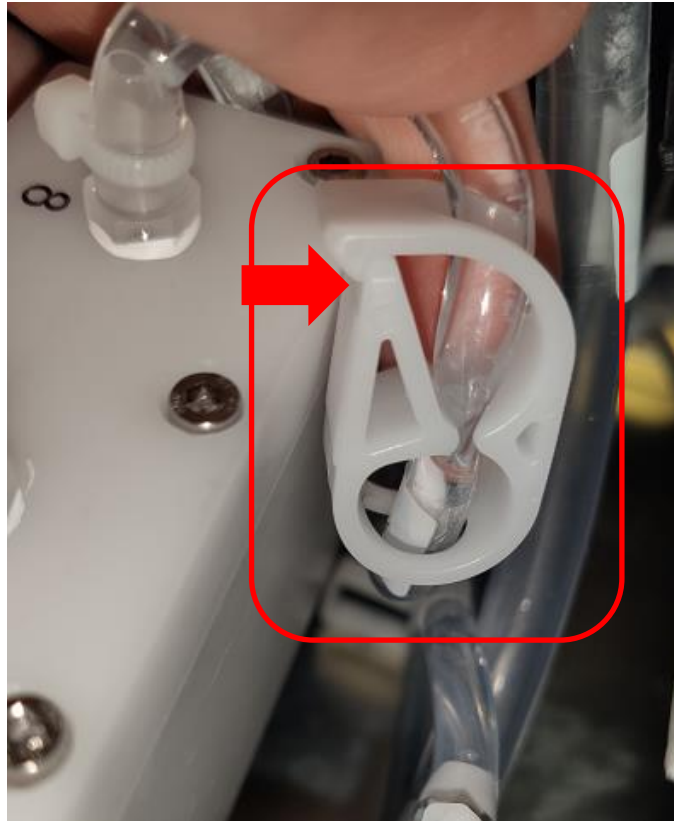


5. After confirm the clip is opened, click **[OK]** to start procedure, and wait the next prompt pop up on the screen.

After the next prompt pop on the screen, please check if the pipe connect to **DW1** port & the pipe connect to **DW2** port & the pipe related to the clip are all full of water and no bubble. If there is bubble, please check if any of these 3 pipes is loose or cracked, run the bubble excluding procedure one more time.



6. After checking, follow the prompt to close the clip on the **C011** pipeline, and click OK.



7. After bubble excluding and close the clip on the **C011** pipeline, assemble back the left-side panel.
8. Please disassemble the wash station and put the cleaning needles to a beaker or clean container which capacity no less than **250ML**, please refer to the following picture. In the next procedure, all the needles of wash station will dispense water continuously.

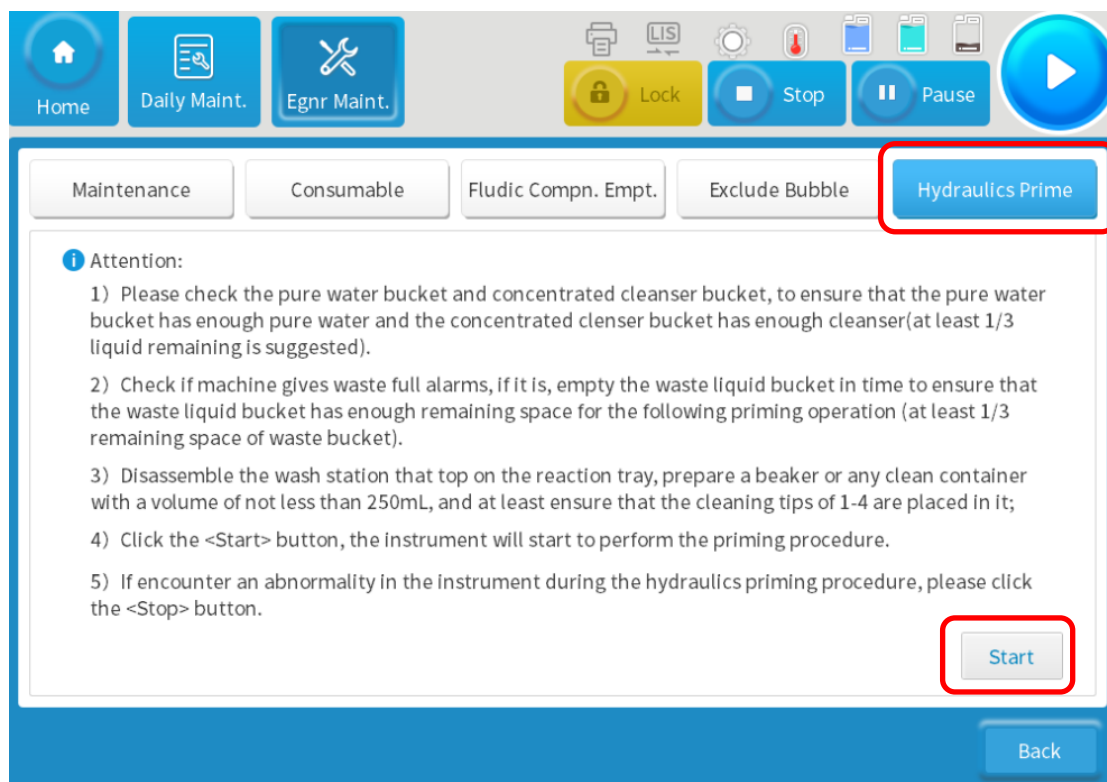


9. Click Hydraulics prime:

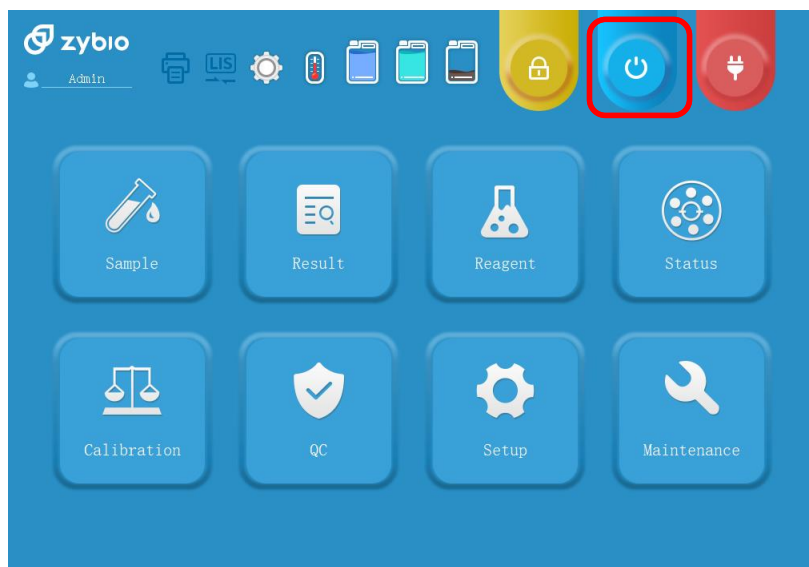
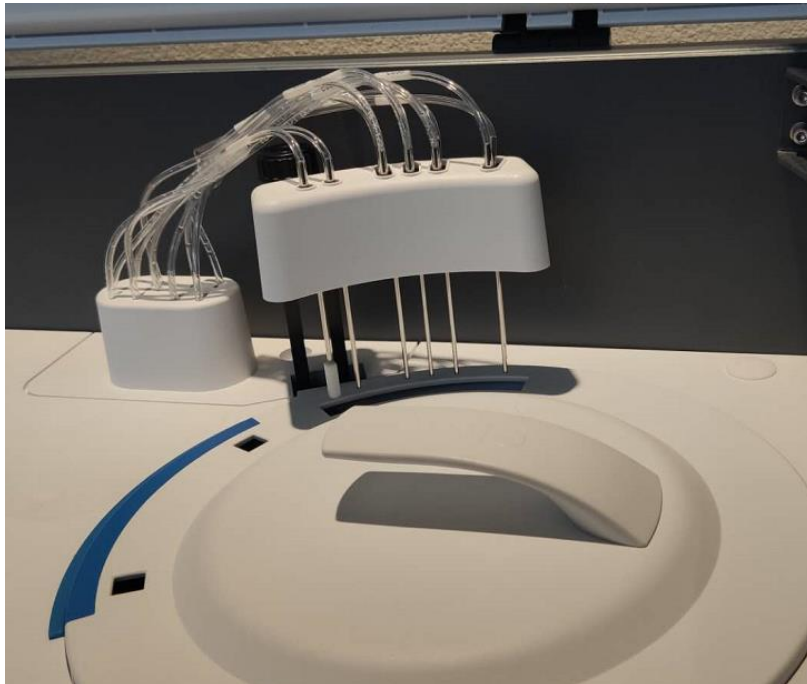
Ensure the purified water and concentrated detergent sufficient, $\geq 1/3$ remaining.

Ensure the waste tank has enough cubage for the following priming procedure.

After checking, click [start] and confirm [OK] to wait 2 minutes till next prompt pop up on the screen.

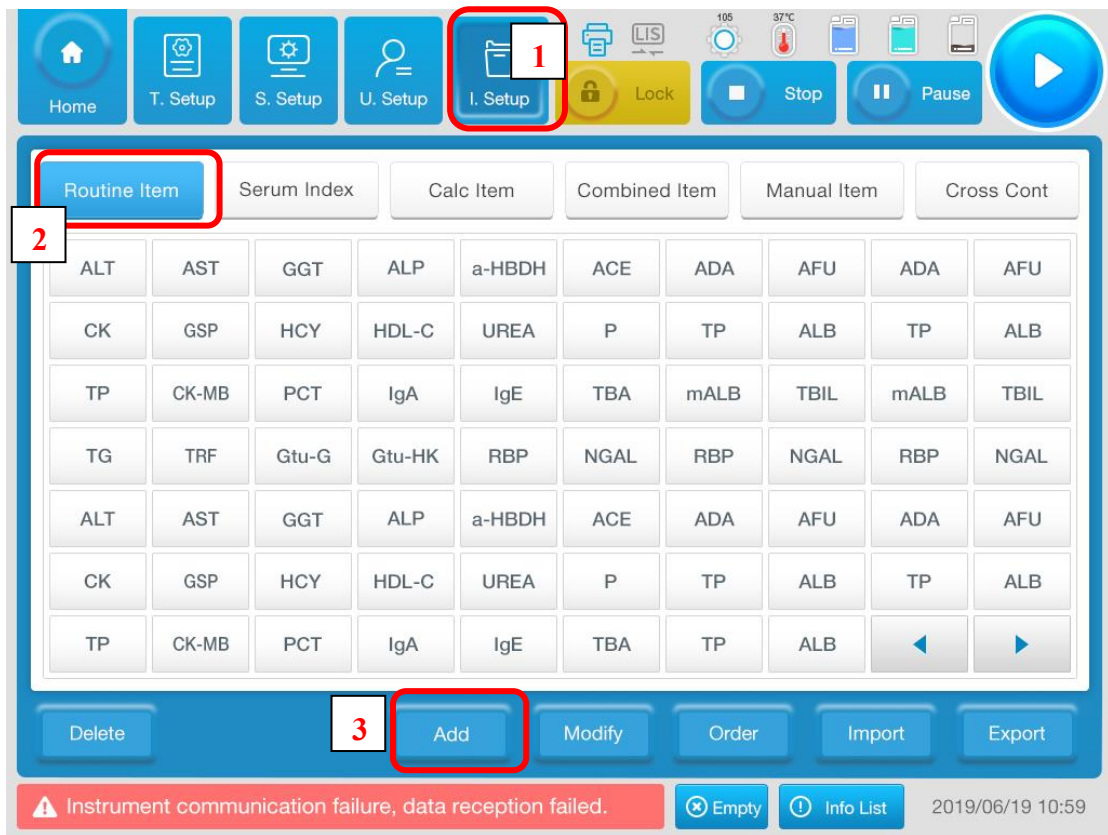
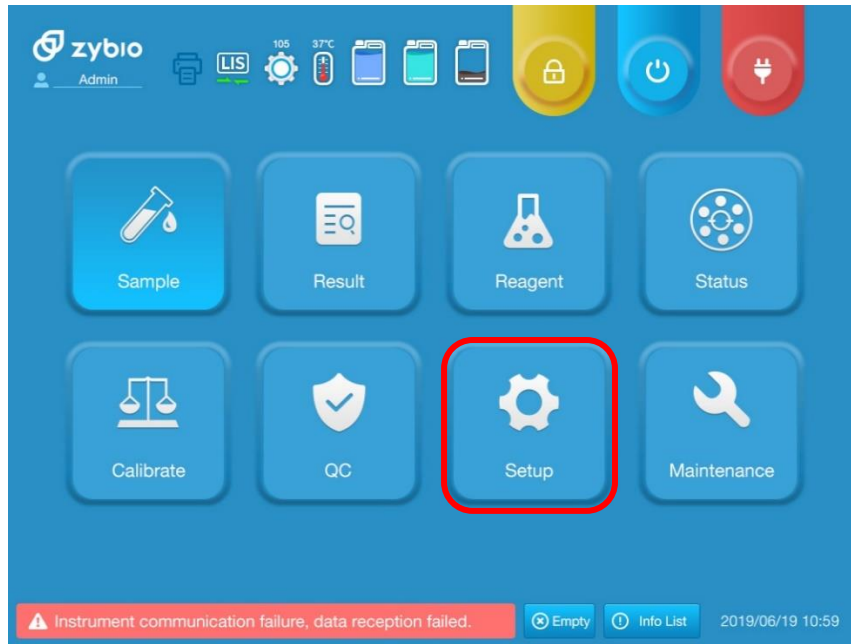


10. After Hydraulics priming, please assemble back the wash station. Turn off the machine and restart the machine again under **Admin** authority.



2.3 Item parameter setup

As the following picture, enter main interface and select **Setup** => **Item setup** => **Routine Item** => **Add**, then input item parameter according to reagent specification, click Save. Specific steps as following:



Add Routine Item

Ite Abb FN/Ite

SAM TYP ☒ Serum ☐ Plasma ☐ Urine ☐ CSF ☐ Others Rea O-V SL Day

Test M R. Direc R Unit

R ACC Dom WL Sub-WL

S Vol μL R1 Vol μL R2 Vol μL

Bl. Time - React T - CF k b

RR - [More](#) Range/CV - [More](#)

[Cancel](#) [M. Para](#) [Save](#) [Close](#)

Notice:

1) Blank time:

single reagent: recommend 7-9

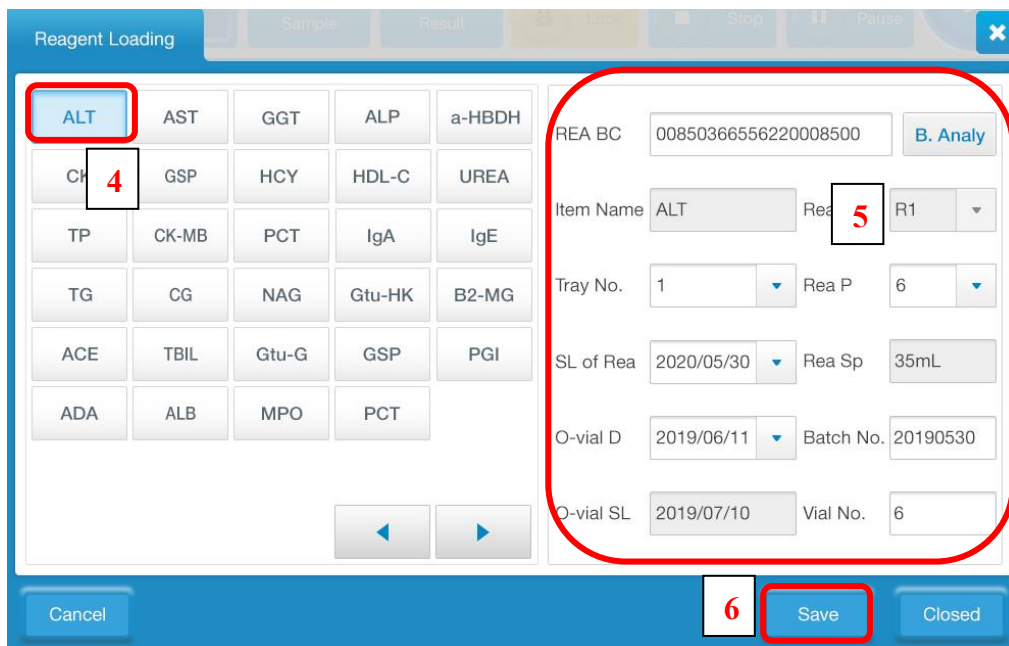
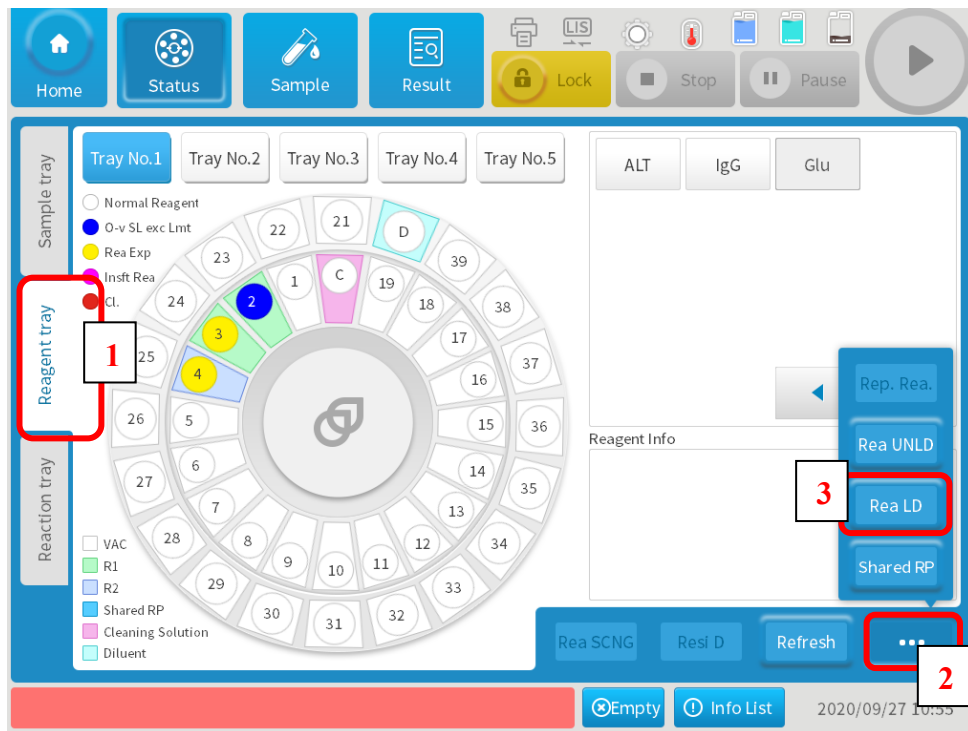
dual reagent: recommend 20-22

2) K value: recommend empty

3) b value: recommend empty

2.4 Reagent position setup

1. Enter main interface of upper computer, select **[State] => [Reagent tray]**, place the corresponding reagents(item) in selected position of reagent tray. Operation procedure as following steps:
 - 1) Select reagent of being about to loaded: For example, ALT; Click [...] in reagent tray interface, select **[load reagent]**, and select **[ALT]**, select the reagent for R1 or R2, fill out information of the reagent.

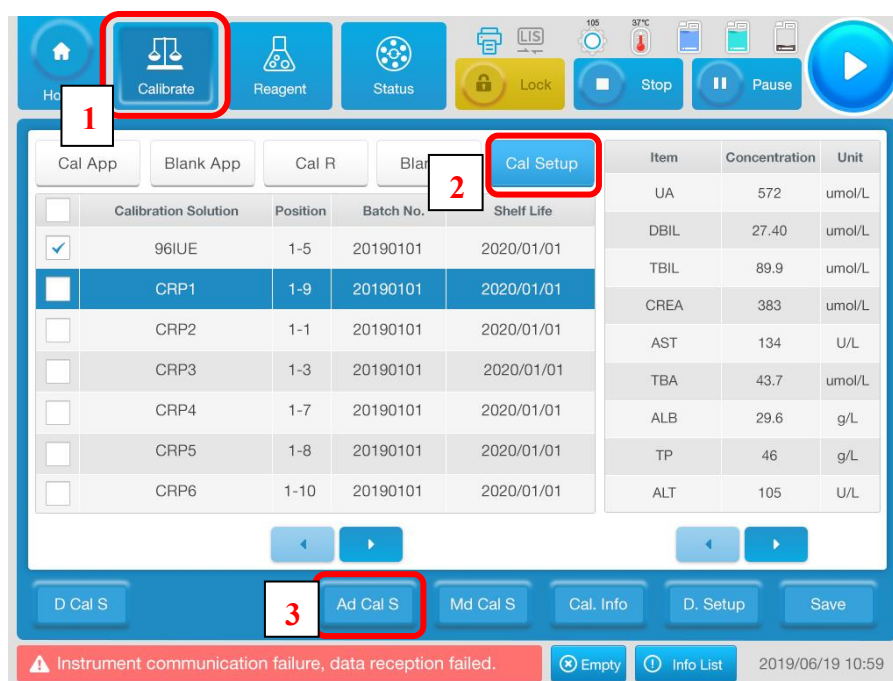


- 2) Reagent Barcode: Can keep blank, without input;
- 3) Item Name: Automatic synchronization, unchangeable;
- 4) Reagent Type: "R1" or "R2";
- 5) Reagent Position: Select the position on Reagent/sample tray;
- 6) Reagent Specification: Synchronizes with the reagent position, no need to changes;
- 7) Shelf life of Reagent: according to reagent validity period;
- 8) Opening date: automatic synchronization, unchangeable;

- 9) Opening shelf life: Automatic synchronization, unchangeable;
 - 10) Lot. number: According to reagent Lot number;
 - 11) Vial number: Can keep blank, without input.
2. Then click **[Save]** to complete R1 reagent loading. If loading double-reagent item, then load the R2 in the same way as R1 loading;
 3. Place corresponding reagent in the set position of reagent-sample tray, place probe cleanser and distilled water in C and D position respectively, and place purified water in the 40th position in outer circle, ensure these three positions are always non-empty.

2.5 Calibration

1. Enter main interface of upper computer, click **[Calibrate]** => **[Cal Setup]** => **[Ad Cal S]** .



2. Input calibrate name, Lot number, valid date, position, and associated test items of calibrator, then click **[Save]**.

Add Calibration Solution

Calibrator: 96IUE

Batch No.: 20190101

Shelf Life: ▼

Position: 1-6 SEL Pos.

As. Test: UA,DBIL,TBIL,HCY... SEL Item

Cancel Save Closed

- Set the calibrator concentration according to the calibrator specification (concentration parameter), and then click **[Save]**.

Home Calibrate Reagent Status Lock Stop Pause

Cal App Blank App Cal R Blank R Cal Setup

Calibration Solution	Position	Batch No.	Shelf Life	Item	Concentration	Unit
<input type="checkbox"/>				UA	572	umol/L
<input checked="" type="checkbox"/>	96IUE	1-5	20190101	DBIL	27.40	umol/L
<input type="checkbox"/>	CRP1	1-9	20190101	TBIL	89.9	umol/L
<input type="checkbox"/>	CRP2	1-1	20190101	CREA	383	umol/L
<input type="checkbox"/>	CRP3	1-3	20190101	AST	134	U/L
<input type="checkbox"/>	CRP4	1-7	20190101	TBA	43.7	umol/L
<input type="checkbox"/>	CRP5	1-8	20190101	ALB	29.6	g/L
<input type="checkbox"/>	CRP6	1-10	20190101	TP	46	g/L
<input type="checkbox"/>				ALT	105	U/L

D Cal S Ad Cal S Md Cal S Cal. Info D. Setup Save

Instrument communication failure, data reception failed. Empty Info List 2019/06/19 10:59

- In **[Calibration Information]** interface, set basic calibration information according to the characteristics of item or requirement of customer, then click **[Save]** to finish.

The main calibration interface features a top navigation bar with icons for Home, Calibration, Reagent, Status, Lock, Stop, and Pause. Below this, there are tabs for 'Cal App', 'Blank App', 'Cal R', 'Blank R', and 'Cal Setting'. The 'Cal Setting' tab is active, displaying a table of calibrators:

Calibrator	Position	Batch No.	Shelf Life
ALT	1-1	20200728	2021/01/28
IgG	1-7	20200703	2020/08/30

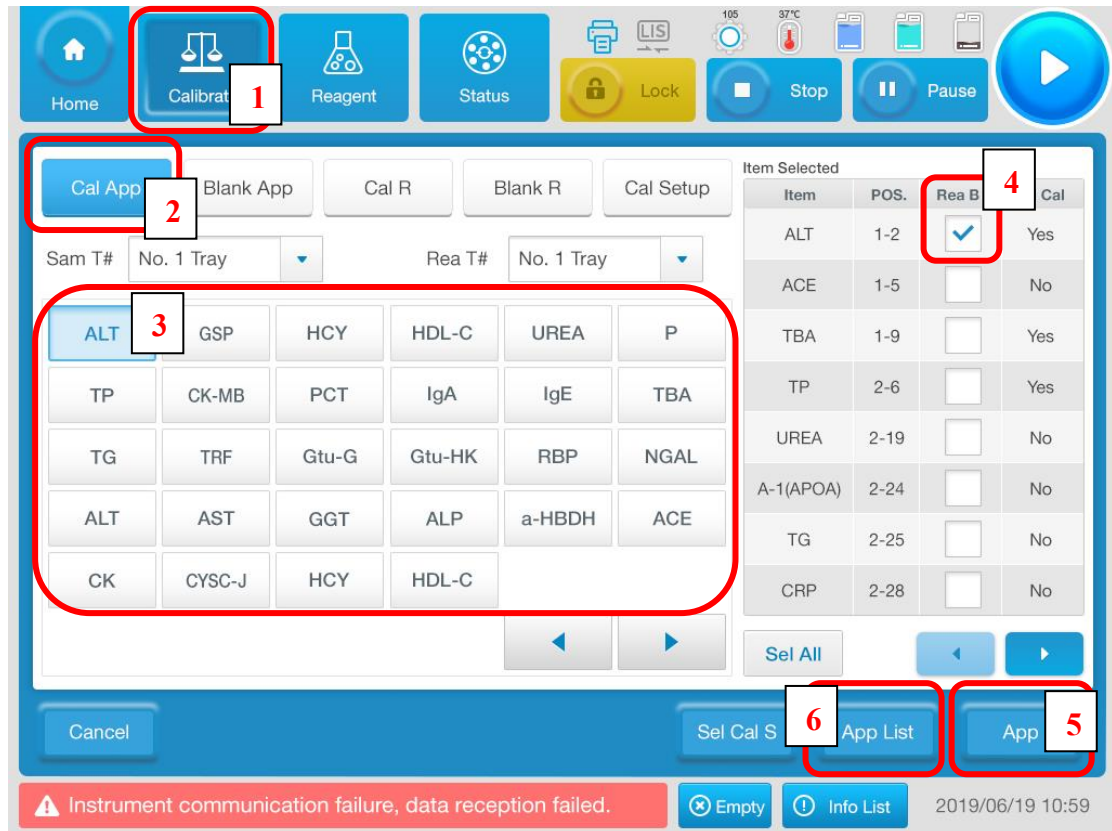
At the bottom of the interface, there are buttons for 'D Cal', 'Ad Cal', 'Md Cal', 'Cal. Info' (highlighted with a red box), 'D. Setup', and 'Save'.

The 'Calibration Information' dialog box is shown, with the 'ALT' item selected. The settings are as follows:

- Item: ALT
- Cal Rule: Linear
- K-f value: [empty] R0: [empty]
- Cal Rep: 1
- VP of Cal Para: 30 Day
- ☐ BAT CNG CAL
- ☐ Reagent Blank

At the bottom of the dialog, there are buttons for 'Cancel', 'Test Info', 'Save' (highlighted with a red box), and 'Close'.

- After set calibration, switch to **[Calibration Application]** interface and select calibrating item, click **[blank]**, and then click **[App]**. When finish the application, view Application checklist in application list interface. (Note: Reagent blank test can be applied separately in the **[Blank Application]** interface).



6. Place purified water in the sample position #40, place the calibration reagent in the position which has been set, ensure corresponding reagent volume are sufficient, click **[Start]** button to run the test.
7. Finish test running, click **[Cal R]** to enter the calibration results research interface to check calibration results, select relevant date, item then click **[C. Curve]** to check the calibration curve.

Home Calibrate Reagent Status Lock Stop Pause

Cal App Blank App **Cal R** Blank R Cal Setup Default Results All Results

	Item	Cal Stat	Calibration Rule	Calibration Time	Batch No.	P. exp.date	Vial No.	Mark
<input checked="" type="checkbox"/>	GSP	Failed	Linear calibration	2019/01/01 11:30:00	20190101	2019/02/01		
<input type="checkbox"/>	HCY	Expired	Logistic-Log4P	2019/01/01 11:30:00	20190101	2019/02/01		
<input type="checkbox"/>	HDL-C	APP.	Logistic-Log5P	2019/01/01 11:30:00	20190101	2019/02/01		
<input type="checkbox"/>	IgA	Delayed	Exponential5P	2019/01/01 11:30:00	20190101	2019/02/01		
<input type="checkbox"/>	IgE	Success.	Polynomial5P	2019/01/01 11:30:00	20190101	2019/02/01		
<input type="checkbox"/>	mALB	Success.	Spline	2019/01/01 11:30:00	20190101	2019/02/01		
<input type="checkbox"/>	NGAL	Success.	K-factor method	2019/01/01 11:30:00	20190101	2019/02/01		

Query **C. Curve** Rea Info Delayed Print LIS Send

Instrument communication failure, data reception failed. Empty Info List 2019/06/19 10:59

2.6 QC

1. Click [QC]=> [QC Setup] => [Ad QC S] on the main interface.

Home **QC** Status Lock Stop Pause

QC App **QC Setup** L-J Curve TwinPlot Curve QC Data QC Summary

QC Solution	Batch No.	POS.	S T	Shelf Life	Item	M	SD
QC Solution 1	20190101	1-1	Serum	2020/01/01	UA	340	20
QC Solution 2	20190101	1-2	Serum	2020/01/01	CHOL	3.92	0.3
QC Solution 3	20190101	1-3	Serum	2020/01/01	DBIL	16.4	1.5

D QC S **Ad QC S** Md QC S QC Rules Save

Instrument communication failure, data reception failed. Empty Info List 2019/06/19 10:59

2. Input QC data according to QC instruction, select position and relative item, click **[Save]** to finish.

QC App

QC Solution

QC Solution

QC Solution

QC Solution

QC

Landau Quality ...

Batch No.

20190101

Sample Type

Serum

Shelf Life

2020/01/01

Position

1-6

SEL Pos.

As. Test

UA,CHOL,DBIL...

SEL Item

Cancel

Save

Closed

Instrument communication failure, data reception failed.

Empty

Info List

2019/06/19 10:59

3. Set mean value and standard deviation of QC (for which include item and methodology in detailed) according to the packing insert of QC, then click **[Save]** to finish setting.

QC App

QC Retup

L-J Curve

TwinPlot Curve

QC Data

QC Summary

QC Solution	Batch No.	POS.	S T	Shelf Life	Item	M	SD
QC Solution 1	20190101	1-1	Serum	2020/01/01	UA	340	20
QC Solution 2	20190101	1-2	Serum	2020/01/01	CHOL	3.92	0.3
QC Solution 3	20190101	1-3	Serum	2020/01/01	DBIL	16.4	1.5

D QC S

Ad QC S

Md QC S

QC Rules

Save

Instrument communication failure, data reception failed.

Empty

Info List

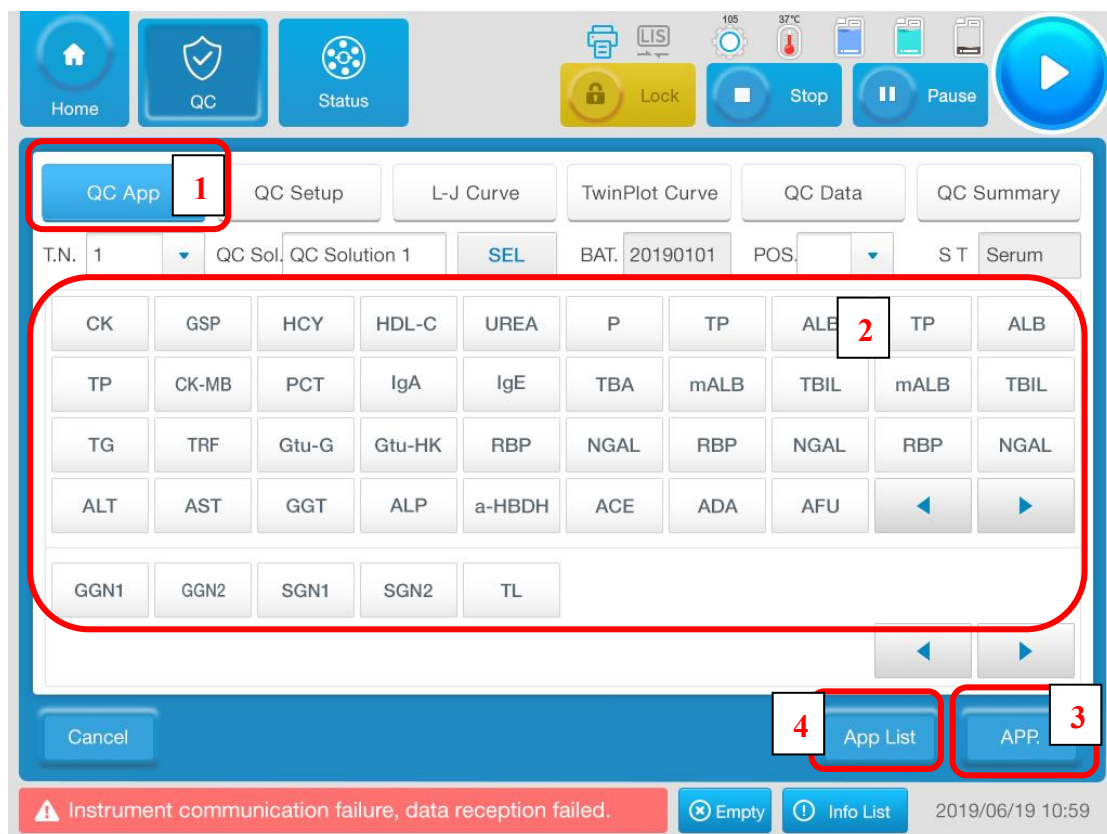
2019/06/19 10:59

4. Click **[QC Rules]**, choose item name, select "**1_s**" and "**1_{3s}**", then click **[Save]**.

The screenshot shows the QC App interface. At the top, there are buttons for Home, QC, and Status. Below these are buttons for Lock, Stop, Pause, and a play button. The main area has tabs for QC App, QC Retup, L-J Curve, TwinPlot Curve, QC Data, and QC Summary. The QC Data tab is active, showing a table with columns for QC Solution, Batch No., POS., S T, Shelf Life, Item, M, and SD. The table contains three rows of data. At the bottom, there are buttons for D QC S, Ad QC S, Md QC S, QC Rules (highlighted with a red box), and Save. A status bar at the bottom indicates 'Instrument communication failure, data reception failed.' and shows the date and time as 2019/06/19 10:59.

The screenshot shows the 'Quality Control Rules' dialog box. It has a grid of buttons for various items: UA, ST, GGT, ALP, a-HBDH, CK, GSP, HCY, HDL-C, UREA, TP, CK-MB, PCT, IgA, IgE, TG, CG, NAG, Gtu-HK, B2-MG, ACE, TBIL, Gtu-G, GSP, PGI, ADA, ALB, MPO, PCT, RBP, AFU, TRF, NGAL, Gtu-HK, GSP, and AFU. The 'UA' button is highlighted with a red box and labeled '1'. To the right, there is a 'Multi-rule QC' section with checkboxes for 1s, 13s, 2s, 4s, and 10s. The 1s and 13s checkboxes are checked and highlighted with a red box and labeled '2'. Below this is a 'Joint QC' section with checkboxes for QC (X) and QC (Y), each with a 'SEL' button. At the bottom, there are buttons for Cancel, Save (highlighted with a red box and labeled '3'), and Closed. A status bar at the bottom indicates 'Instrument communication failure, data reception failed.' and shows the date and time as 2019/06/19 10:59.

5. Click **[QC App]**, choose item name, and then click **[App]** to apply this item. And can view the application list by click **[APP List]** button.

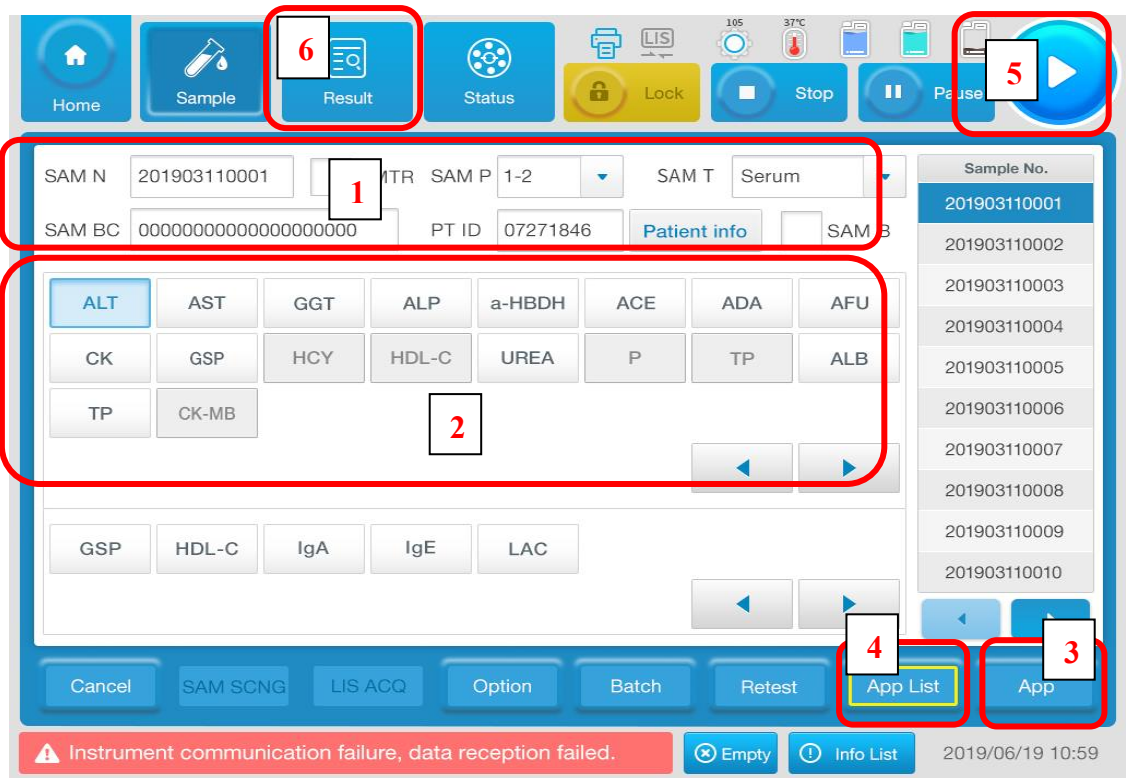


6. Place QC reagent in set position, and ensure sufficient volume for corresponding reagent, then click **[Start]** button to run QC test.
7. Finish QC test running, click **[QC]** in main interface=> **[L-J Curve]** to check the QC curve.

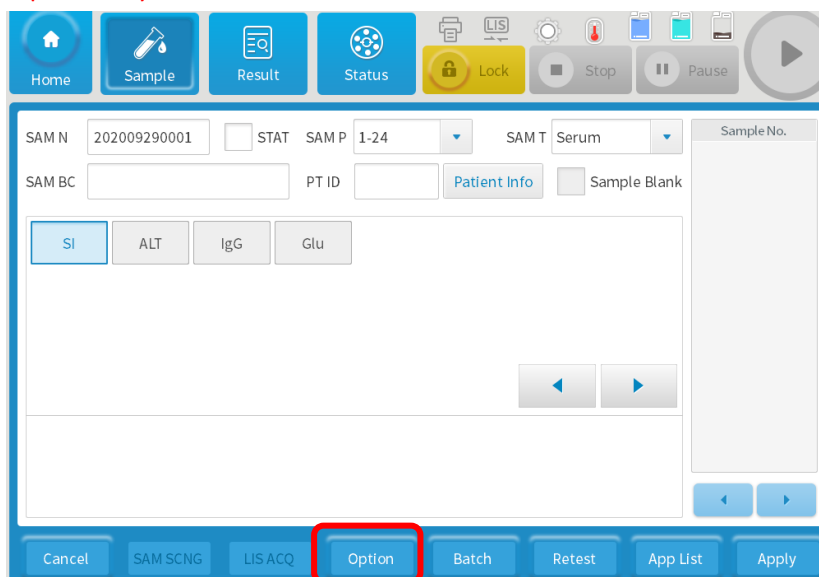


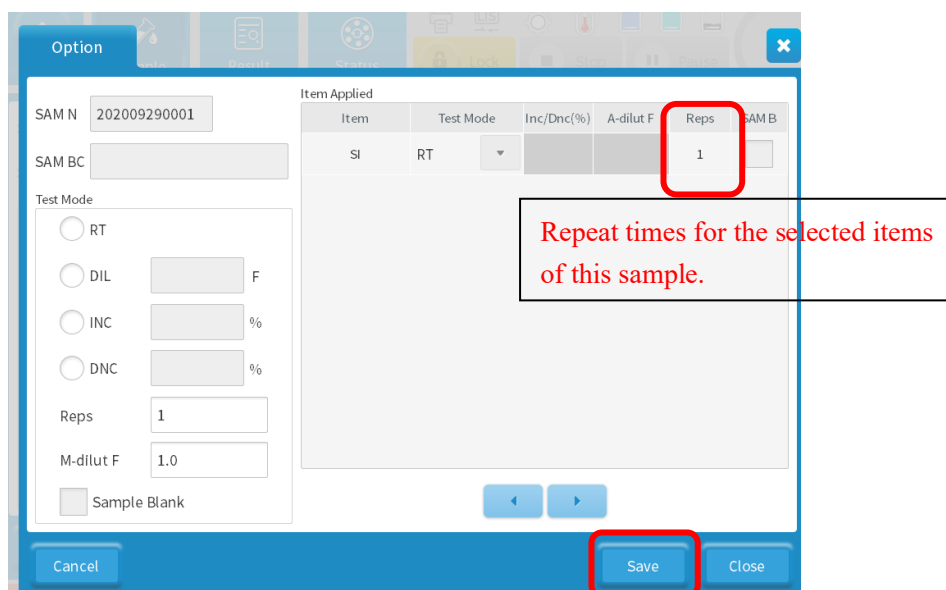
2.7 Sample Test

1. Enter **[Sample]** interface, input the patient information, select testing item, apply the items for this sample, confirm item name and relevant reagent position are well set, check the sample apply list, click **[Start]** button to run sample test.
2. Finish sample test, view the results in **[Result]** interface.



3. Tips: click option could select how many times repeat for this test, it can help check the repeatability for this item.





4. **Tips:** Calibration, QC, sample test can be applied together, then run together in one batch.

2.7 Exit Software

When shutdown the machine, ensure that analyzer is not in the process of testing.

Note:

1. Shutdown the machine by normal shutdown, analyzer will process complete cleaning procedure to shutdown.

Shutdown by emergency shutdown, the machine will not process the cleaning procedure, not recommended.

2. After exit operating software, turn off the main switch, then take all the reagent back to refrigerator. If want to keep reagents on board in the analyzer, please keep the main switch on meanwhile.

