Automated Clinical Analyzer

BIOLIS30i

Operator's Manual

Ver.1.00

TOKYO BOEKI MEDISYS INC.

Original Instructions

Contact Address for System Trouble

We appreciate your adoption of our Automated Clinical Analyzer.
This system is produced under the severe quality control and production management.
But if the system has any trouble, please contact one of our offices without hesitation.
In case of trouble, we would like to ask you to let us know the following information, which may make us rapid action.

- Serial No.
- Installation date
- System Software Version
- Status of the trouble including estimated cause of the trouble

Also if you have any question regarding analyzer function, or if you want to have technical training information, please contact one of our offices .

Manufactured by Tokyo Boeki Medisys Inc.

1-14-21, Higashitoyoda, Hino-shi, Tokyo 191-0052, Japan
Tel: (81)-42-587-7777

EC REP **MT Promedt Consulting GmbH**
Altenhofstr.80, D-66386 St. Ingbert, Germany

Caution

・This analyzer system may cause unpredictable accident or injury, it if is improperly installed or improperly operated. Therefore, please follow the instruction of operation manual strictly.

・Please read the 【Safety caution】 certainly, in advance. You should not do the following action, without our approval beforehand.

・Modification for the analyzer

Addition of an attachment, supplied from the other maker than us.

・Self-repair or parts replacement

Self-adjustment of the points, assigned as qualified service engineer only.

・If you conflict the above, you may loose our assurance and maintenance agreement does not cover the trouble.

・For the safety operation of the analyzer, it is necessary to do daily maintenance by yourself, but also the inspection of the whole analyzer by a qualified service engineer, is necessary at the time of consumable replacement or at the time of proper interval to keep smooth operation.

・For the accident or the trouble, without above inspection, we are not responsible.

・After analyzer installation has finished, if position movement, transfer, resale or abolition is necessary, please let us know. If the above action has done without presence of qualified engineer, we will not responsible for the accident or trouble after that.

・The maintenance function parts, which are necessary to keep analyzer function, will be stored for 7 years after the sales date. If you want to have these parts over 7 years, please consult to us within storage period.

・The contents of this operation manual and software specification may change without notice.

・If you find any defects or mistakes in this manual, please let us know.

Original Instructions

Registered trademark

【Windows】is a registered trademark of Microsoft USA.

CSA Standard

This product meets the requirements of CSA.

"This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements"

Before the software installation, which is supplied from TOKYO BOEKI MEDISYS INC (TMS), please read the following Software license agreement carefully. Software installation to a computer is considered your agreement to the all items of Software license agreement. If you find any objection, please let us know before installation.

Software license agreement

The purpose of this Software license agreement is to establish mutual agreement between customer and TMS on license of the software which belongs to TMS.

1 The right to use

The word Software license agreement means the privilege to use the supplied software from TMS.

2 License

2.1 TMS permits to the customer a privilege to use the software, supplied by TMS, under the condition of Software license agreement, antimonopoly and non-transferring basis.

Note A privilege to use the consented software, means that the privilege to install the supplied software on a computer, having recommended operating system, and run the software on the computer.

2.2 All the privileges which are not included in Software license agreement are reserved by TMS.

2.3 Any customer cannot do the following action such as: let a third party use the consented software, disclose, takeout to the other countries by means of setting the re-use rights and other methods.

3 Copyright

3.1 Copyright, trademark right, and intellectual property right related with consented software and operation manual belong to TMS.

3.2 Any customer cannot do the following action, such as transfer, sublease, disclosure, related to the consented software and operation manual, without written permission of TMS in beforehand. No customer can set security interest.

3.3 Any customer cannot do the following action, such as partial collection, modification, reverse engineering, reverse compile, reverse assemble for the consented software. If a customer did the above and any trouble occurred on the analyzer, based on the modification, TMS has no responsibility.

4 Reproduction prohibition

Any customer cannot copy the consented software, even though partly.

5 Guarantee and responsibility limit

5.1 TMS does not guarantee, no defect on consented software, and also we do not guarantee that our analyzer system fits customer's special needs, or useful for the needs.

5.2 TMS has no responsibility on the loss of customer or the third party, caused by the usage of consented software or related action. Also we have no responsibility on the claims of a customer caused by the third party.

6 Forbidden items

Customer should not do the following action intentionally.

6.1 Transmitting harmful computer program, such as virus, to TMS or the third party.

6.2 The action violating the law and regulation.

6.3 The action inducing or promoting criminal acts and leading to criminal acts.

6.4 The action infringing copyright, trademark right, portrait right and other right and profit of the third party.

6.5 The action of slander TMS or the third party and the action staining honor.

6.6 The action of publish or transmitting false information or information leading to misunderstanding.

6.7 The action contrary to other public order and morals.

6.8 Other than the above items, any action which disturbs operation of TMS.

7 Effective period

7.1 This contract is active from the date of agreement, and active till failure of the contract, by the procedure explained at the next article.

7.2 In spite of the above, the third article is active after the failure of the contract.

8 Cancellation of the agreement

8.1 If the customer violates this agreement, TMS can notice the cancellation of

this agreement without any notification. Other than that, TMS can demand on the loss, caused by the violation.

8.2 The customer can cancel this agreement by the abandonment of the consented software.

9 The action after the agreement has over

When this agreement is cancelled based on the article 8, customer should abandon the consented software and notify to TMS.

10 Conference

10.1 Regarding the subjects which are not covered by the agreement, customer and TMS will discuss and reach to the conclusion by the basis of principle of good health.

10.2 If you have any question regarding the agreement, please contact to TMS by a document.

Contents

Preface

Introduction

This Automated Clinical Analyzer is an IVD medical equipment for indoor use and is based on the colorimetric and turbidimetric measurement.
Its main application is expected to be colorimetric measurement, clinical chemistry testing, immuno-serological testing, hematological testing and urine testing in hospitals, clinical laboratories and other research laboratories.

This operation manual is composed of the following contents.

1. Expression of Warning and Notice

In this manual, the items you have to be careful for safety are indicated by the following levels.

Classification of display

⚠ Caution : If ignored, the accident may cause personal injury or heavy damage on the instrument.

⚠ Warning : If ignored, the accident may lead to death or heavy injury.

Note : Pay attention, additional explanation.

Description of the mark


: Biohazard.
There is the risk of your being infected.
In case of treating samples that may be hazardous or infectious, wear rubber gloves not to touch directly.
Any spills on the skin should be washed off with a great volume of water and sterilized.
And consult a physician if necessary.
Also any spills on the system should be wiped off and sterilized at once.


: This mark means electric shock if touched.


: This mark means laser light leakage. Do not see by naked eye.


: This mark means high temperature. Keep out from burn.


: This mark means do not touch with wet hand.


: This mark means electric ground is necessary.


: This mark means to protect eye, wear protective goggle.


: This mark means do not touch with naked hand.

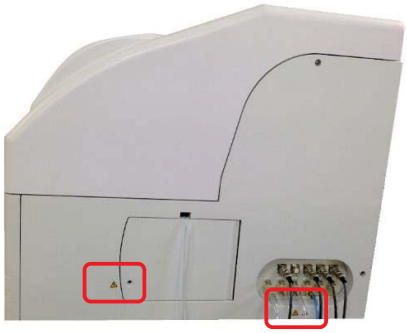
Explanation of caution and warning seal

The following seal are stuck on the analyzer body as warning.
If this mark is attached to the analyzer, read the corresponding caution of the operation manual. Never remove these seals for safety protection.

1) Warning label of top cover

Revolution, vertical movement hazard
Some units rotate and move up and down.
Location: top cover

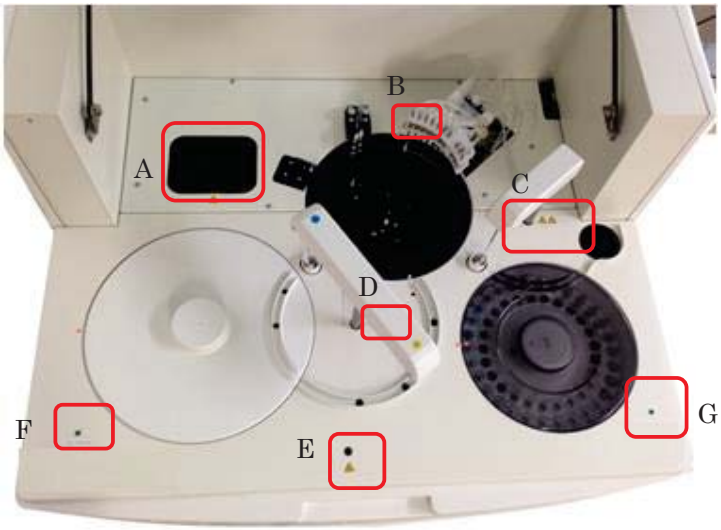
2) Right side cover ; ISE unit, Water supply/drain panel



Revolution, vertical movement hazard
Some units rotate and move up and down.

Biohazard
If you operate the dangerous parts, please wear glove.

3) Upper panel warning label



A: Lamp house

High temperature hazard
Scald by high temperature
If you operate the parts, turn off the main breaker of the machine and disconnect the cable.
Location : Lamp house (Lamp)

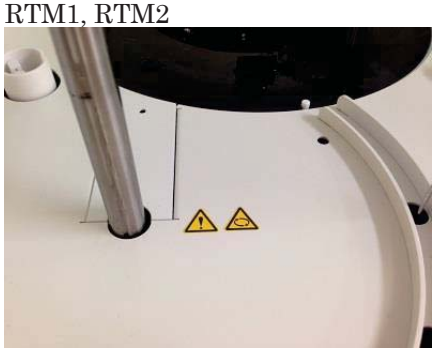
B: CWS

Revolution, vertical movement hazard
Some units rotate and move up and down.

C: STM

Revolution, vertical movement hazard
Some units rotate and move up and down.
Location: STM, STM for ISE

D: RTM1, RTM2



Revolution, vertical movement hazard
Some units rotate and move up and down.
Location: RTM1, RTM2

E: Body

Biohazard
If you operate the dangerous parts, please wear glove.
Location : Sample tray, Reagent tray

F: Reagent tray

Injury hazard
Never open this cover while analyzer is in operation.
Only Access cover when green tray replace light is on.

G: Sample tray

Injury hazard
Never open this cover while analyzer is in operation.
Only Access cover when green tray replace light is on.

2. Safety Caution ・Caution in Operation

⚠ Warning

1) Electric shock prevention

When electrically charged, never open rear cover nor covers of both sides. It may cause electrical shock.

2) Usage

Mainly used for clinical chemistry electrolyte tests and immuno-serological test of water soluble samples.
The system may not be proper to use for the purpose other than the above.

⚠ Caution

1) Moving parts while operation

(1) Do not touch sample pipette, reagent pipette nor washing mechanism in operating.
(2) During the measurement, the analyzer will stop immediately if the unit is not correct position under own check program.
(3) Two tray replace lamps are on the analyzer. When the tray replace lamp is off, do not touch the sample and reagent tray. You might be injured.

2) Light from light source／Bar code reader LED class 1


Do not look at light source by naked eyes.
It might hurt your eyes.
Wearing safety goggles for ultra violet is recommended.

3) Sample handling

(1) Do not touch infectious or dangerous samples directly.
If the system is contaminated, please wipe out at once.
(2) Please make sure that no insoluble matter, such as fibrin, is in sample. It may give improper results.

4) Waste liquid treatment

(1) Waste liquid should be treated properly under the related regulation. It may cause pollution problem.
(2) About the concentration of poisonous chemicals in a reagent, please ask the reagent maker.

5) Accuracy of measured data

During the operation, please check the system condition by measuring control samples.
Inaccurate test results may lead wrong diagnosis and improper patient treatment.

6) Inflammable substance

Do not use inflammable substance around the system. It might cause fire or explosion.

7) Warning mark

When warning or caution mark peeled off, contact our serviceman to replace by a new one.

8) Specified manner

If the system is used in a manner not specified by the manufacturer, the protection provided by the system may be impaired

9) Power plug

(1) Do not plug or unplug with the wet hands. It might cause electric shock.
(2) Do not pull the cord when unplugging. It might cause electric shock.

10) Protective grounding

Use a 3-pin-plug whose ground terminal will be connected first and be sure that the earth resistance of terminal is less than 100 ohm. It avoids electric shock.

11) Installed and used in environmental conditions

Please observe the conditions listed in the Operation manual.

12) Moving or Rejection

When not using the system for a long period, or when moving or rejecting the system, remove biohazards.

13) Limited operator

(1) The operation of system should be controlled by a person who had training of an organization authorized by the distributor.
(2) If used for clinical testing, the operation should be controlled by a medical doctor or a medical technologist.

14) Operation and maintenance

(1) During the operation and maintenance, please follow the instruction and never touch the points besides designated.

15) Treatment on reagents and others

(1) Reaction cuvette, sample cup and waste liquid line are not sufficiently tolerant to organic solvents. Do not use solvents.

(2) Do not use sticky substance on sample probe, reagent probe nor reaction cuvette.

(3) Handling the reagents, which is supplied by reagent makers, please keep the caution from the reagent maker.

16) Top cover

(1) Take care not to have your fingers pinched, when opening or closing the top cover. You might be hurt.

(2) Do not put anything on the top cover. Liquid spilt into the air hole might cause a malfunction.

17) Piping

In installation of the system and in feeding liquid or drainage, take care not to bend or break piping.

18) Washing solution

Do not use other washing solution than the certified one for the system. It might cause a malfunction.

19) Static electricity

Do not put a thing charged with static electricity on the system, nor touch with hands charged with static electricity. It could cause a malfunction of the system.

20) Emergency

For emergency stop, turn off main breaker at the left side panel.

21) WEEE directives

(1) Do not throw away this instrument with wastes. This instrument has to be thrown away as medical waste. Strictly follow laws and regulations of your country when discarding the instrument.

(2) When discarding the instrument, please contact Tokyo Boeki Medisys Ltd. or our distributor in your country.

(3) Please cooperate with recycling to follow a global environment.

(4) The trash box mark in the right means the WEEE directives.

3. Warranty

1) Warranty period

Twelve months after the installation date or fourteen months from shipment date from Japan, whichever comes earlier.

2) Warranty and remedy

- We warrant that, during the warranty period, the analyzer operates in accordance with our standard technical specifications (failure to operate is called as “Defect”).
- When a Defect is found and your written claim fully describing the details of the same is accepted by the end of the warranty period, we will, at our expense and sole option, provide either of the following remedies:

(a) to supply and ship replacement parts on a FCA basis that are deemed necessary for repair of the analyzer; or

(b) to repair and ship back the analyzer on a FCA basis, when the analyzer is brought to the designated place at your expense.

-The above warranty and remedy are exclusive and in lieu of any other warranties and remedies, whether in contract, tort or otherwise.

We will in no event held liable for consequential, incidental or special damages such as loss of revenue, data and information, even if we have been notified or aware of the possibility of such damages.

3) Warranty and remedy

- We will not be responsible for any defect or nonconformance, including all losses, costs and damages incidental to them, when any one or more of the following applies. In this section, the word “analyzer” includes its consumables and spare parts.

1. Unauthorized removal, displacement or transportation of the analyzer after installation of the same;
2. Use of the analyzer under improper installation;
3. Unauthorized disassembly, modification or repair of than analyzer;
4. A damage or nonconformance caused by a natural disaster such as fires, earthquakes and lightning;
5. When the computer used with the analyzer is installed with any unauthorized program or is connected to any unauthorized network (including the Internet);
6. Inappropriate storage or maintenance of the analyzer;
7. Incorrect operation of the analyzer;
8. Use of the analyzer under improper operating conditions (including use under the atmosphere containing corrosive gas)
9. Use of unauthorized consumables or spare parts for the analyzer;
10. Normal wear and tear of the analyzer;
11. Incompatibility of the analyzer with other products (including that with

reagents);

12. A defect or nonconformance that you found or could have found at the time of receipt of the analyzer such as loss of or apparent damage to the analyzer and that you failed to promptly notify to us in writing;
13. Minor defect or nonconformance that does not affect operation, function and performance of the analyzer; and
    Any other defect or nonconformance that is not attributable to us.

- The warrantees of consumables and spare parts of the analyzer are to be accordance with its manufacturer's warranty.

- In case any defect or nonconformance is found in the analyzer, both you and we will, at its own costs respectively, cooperate to promptly determine the cause of the same, whereby you will, upon our request, provide us with information in writing that is necessary to verify such cause.

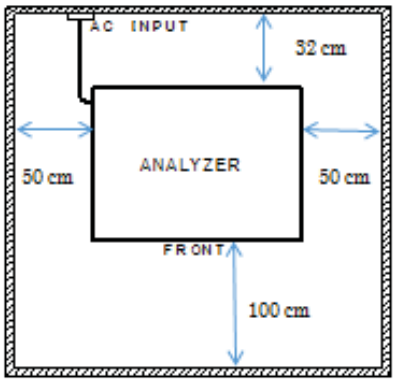
- If we perform any remedy for a defect or nonconformance of the analyzer, such as repair and replacement of the analyzer and payment of compensation money (including offer of price discount), and subsequently it is found that any one of the events contained in the foregoing (3) applies and that we are not responsible for such defect or nonconformance, then you will, within fourteen days after receipt of our invoice, reimburse us with all the costs we have incurred associated with the remedy (including costs associated with the investigation and dispatch of our personnel) and refund the full amount of the compensation money we have paid to you. Delay in reimbursement or refund is subject to the five percent monthly compound overdue interest or the maximum interest permitted by applicable laws from the due date till paid in full.

4. Storage and Transportation Requirements

1) Indoor.
2) No direct sunlight.
3) No dust.
4) Ambient temperature should be 1 ~ 45 Celsius degrees.
5) Ambient humidity should be 10 ~ 85% (no condensation).
6) No dropping.
7) No throwing down.
8) No upper load.
9) Transport condition is marked on the box. Follow the written instruction on a label.
10) Transportation and the movement of the equipment should be done by a trained service engineer.

5. Usage environment

1) No dust, good ventilation.
2) No direct sun light.
3) The gradient of the table should be less than 5mm/m.
4) The table should be able to support over 100kgf/m^2
5) Room temperature range is 15～30℃, and deviation during test is ±2℃.
6) Room humidity should be 45 ~ 80 %, and no condensation.
7) Small vibration
8) Voltage : AC100V／115V／220V／230V (± 10%)
9) Install away from high frequency electromagnetic wave emitting equipment (such as centrifuge, electric discharge), preferably not in the same room.
10) Earth resistance of ground terminal should be less than 100 ohm.
11) Power supply capacity should be over 600VA.
12) No Multi-outlet extension code.
13) Please do not use the power supply cord except the following rating ;
    Rating In AC 100V/115V ... 125V 7A or more
    In AC 220V/230V ... 250V 3.5A or more
14) Outlet that insert to securely back.
15) The system should be installed at altitude less than 2000 meters.
16) Keep the space around the system for taking out the power cord in an emergency, for good ventilation and for maintenance, as the following. Also keep the space of at least 100 cm over the system. (At the minimum)



6. Installation and Servicing

1) Installation
   Installation and checking of deliveries or transport condition will be performed by our serviceman.
   Prepare a receptacle with earth terminal (3 terminals) and be sure the earth resistance of terminal is less than 100 ohm.
   When moving the system, consult our serviceman.
2) Servicing
   Come in contact with us about servicing.

7. Cleaning and disinfection procedure

When you do the maintenance operation, wear protective globes, mask and glasses to avoid the infection.
Wipe out the panels by dry cloth or soaked in diluted neutral detergent.
Do not use organic solvent such as Thinner or Benzene which will affect the paint and shape.

- Disinfection
  Wipe out the biohazard area (sample probe) by 70% ethanol. Clean up by de-ionized water after disinfection. If you use ethanol for sterilization, be careful not to burn. Keep away fire source.

8. Position of the nameplate

The position of the table is as follows.

Chapter 1
Specifications and structure of the System

1.1. General Specifications

Item		Contents
Method		Discrete, Single line random access, multi-tests analysis
Test items on board		36 items (24 items Option)+ ISE 3 items
Throughput		270 tests/hr. ・MAX 450tests/hr. (in case of loading ISE) ・90 test/hr. (HbA1c Item Only)
Analysis method		End point method, Rate method ISE
Calibration curve		Linear, Factor, Non-linear (Logit-log, Spline, Exponential, Polynomial)
Reaction time		About 10 min. (1st react. about 5 min+ 2nd react. about 5 min.)
Sample	Tray mode	Software tray
	Tray kind	Patient sample tray : Tray No. 1 - 50 Calibration tray : C1 – C6 QC sample tray : Q1 – Q3
	Contents of test	Serum, Plasma, Blood cell ,Urine, Dialysate, CSF (ISE not available for CFS and Blood cell)
	Container	Sample cup, Primary tube (5mL, 7mL, 10mL)
	Sampler	Patient sample : 1 -30 (Outside)
		Standard sample, Blank sample : 1 - 45
		ISE standard (for serum sample) : 2 ISE standard (for urine sample) : 2 ISE standard (for dialysis) : 1
		QC sample : ➢ Patient sample tray, Calibration tray (Inside) ; 31 - 45 ➢ QC sample tray; 1 - 45
		Washing : 3
		ISE washing :1
	Dispensation volume	2.0 – 25 μL (0.1 μL steps)
	Dilution ratio	0.5,6,10,20,30,40,50,60,70,80,90,100 times (When dilution ratio is set 0.5, the sample volume is used two times. Set the sample volume less than 12.5uL and the total reaction volume less than 400uL.)

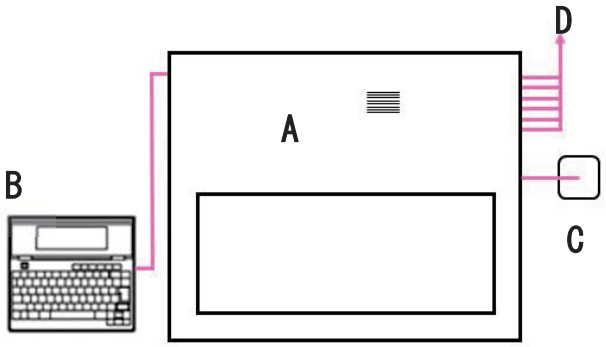
Item		Contents
Reagent	Dispensation volume	R1 ;140-300 μL (1μL steps) R2 ;20 -260 μL (1μL steps)
	Number of bottles on board	R1,R2 ;36position (Option R1,R2 ; 24 position)
	Storage	Reagents are cooled at 5 – 15 Celsius degrees. The reagent cooling becomes room temperature minus 13℃ when the room temperature is over 25℃
	Bottle volume	36 item ; Single R1;40mL,Double R1; 25mL, R2;13mL (24item;Single R1 60mL, Double R1;40mL,R2;20mL)
Mixing method		2 rooms air pressure mixing (without a stirrer)
Reaction tray	Temperature control	Direct block heating
	Reaction temperature	37 plus-minus 0.1Celsius degrees
	Reaction cuvette	Material : Plastics
		Optical path length : 8 mm
		Number of cuvette : 60 pieces (semi-disposable)
		Reaction volume : 140 – 400 micro-liter
Spectro-photometer	Optical absorption	Cuvette direct measurement
	Wavelengths	Fixed 13wavelengths ➢ 340,380,405,450,480,505,546,570,600,660,700,750, 800nm
	Light detector	Silicon photo-diode
	Wavelength accuracy	Plus-minus 1.5nm
	Linearity range	0 - 2.5 Abs.
	Light source	Halogen lamp
User interface	Calculation between item	Calculation based on user's formula Correlation factor
	Monitor function	Reaction curve monitor Data review Run-monitor
	Quality control	Westgard algorithms Within day, day to day
	Data storage capacity	Based on the PC specification
System interface		Instrument→PC : LAN(TCP/IP) PC→LIS : LAN (TCP/IP) (HL7 Ver2.5standard)

Item		Contents
Equipment Class		Class Ⅰ
Over voltage Category		Category Ⅱ
Pollution Degree		Pollution Degree 2
Power supply		AC100V/115V/ 220V/230 V plus-minus 10 %
Frequency		50/60 Hz
Electric consumption		600 VA
Grounding		Resistive less than 100 ohm
Ambient temperature		15 – 30 Celsius degrees (During operation Plus-minus 2 Celsius degrees/hour)
Ambient humidity		45 – 80% (No condensation)
Water consumption		About 3.8L/hour
Dimension (system)		800 (W) ×670 (D) ×555 (H) mm
Weight		Approx. 95kg
ISE	Electrodes	Na, K, Cl and Reference electrode.
	Sample volume : Measurement	60 micro-liter for Serum ,Plasma and Dialysis 120 micro-liter for diluted urine (Use sextuple diluted sample by urine diluent)
	Analysis time	45 seconds for serum and dialysis 37 seconds for diluted Urine sample
	Reagents	Serum ; Calibrator (A ,B) Urine ; Calibrator 1 for urine, Calibrator 2 for urine Dialysis; Dialysis calibrator D
	Sample volume : Calibration	120 micro-liter for Serum, Plasma and Dialysis 240 micro-liter for diluted urine

1.2. Structure of the System

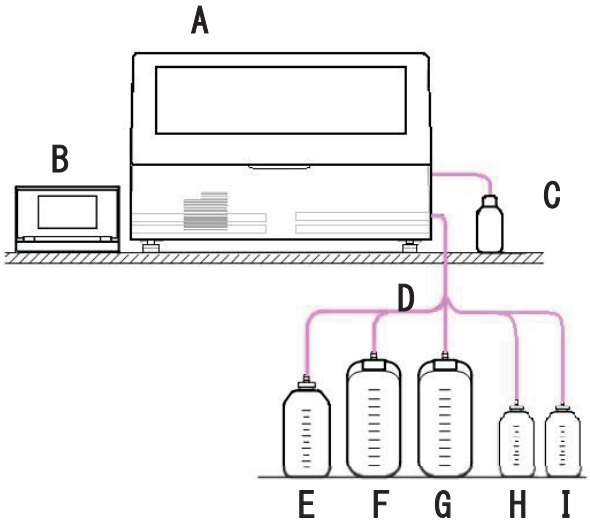
The instrument is consisted with sampler (sample tray), sampling mechanism, reagent tray, reagent transfer mechanism, reaction tray (with reaction cell), mixing unit, reaction cell washing station and spectrophotometer.

1.2.1. Over All Structure



A : Instrument
B : Personal computer
C : ISE drainage reservoir
D : Tanks

＜Top view＞



A : Instrument
B : Personal computer
C : ISE drainage reservoir

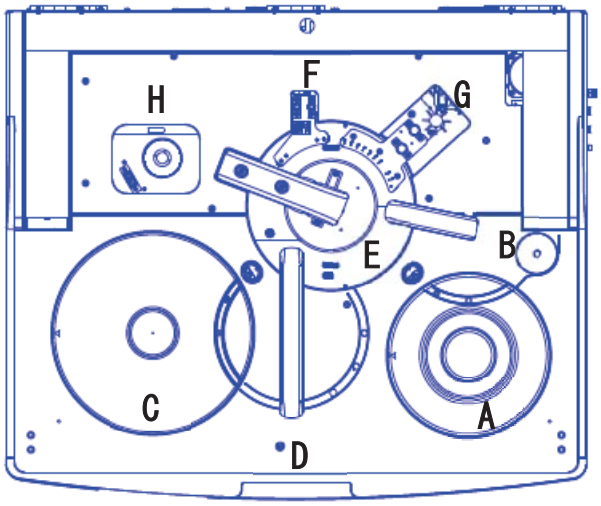
D : Tanks
E : Separate collection reservoir
F : Drainage reservoir
G : Water reservoir
H,I : Cleaning solution reservoir
・Alkaline detergent
・Acidic detergent

＜System front view＞

*Both Acidic and Alkaline Cleaning Solution Reservoirs must be set the same level of the instrument or below the instrument.

*Separate Collection Reservoir, Drainage Reservoir and Water Reservoir must be set below the instrument level

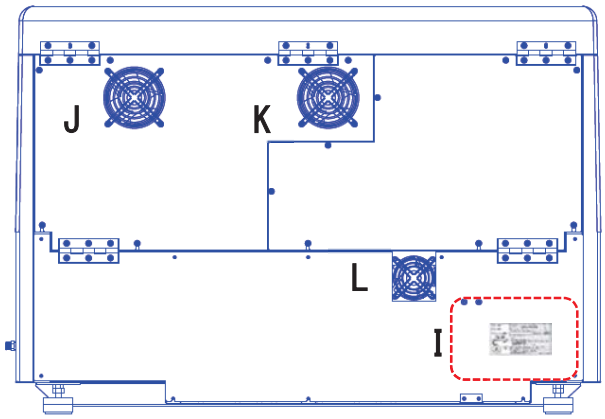
1.2.2. Plan of the System Section



A : Sample tray
B : Sample probe
C : Reagent tray
D : Reagent probe
E : Reaction tray
F : Mixing
G : Cuvette washing station
H : Lamp house

The plan when the top cover is removed

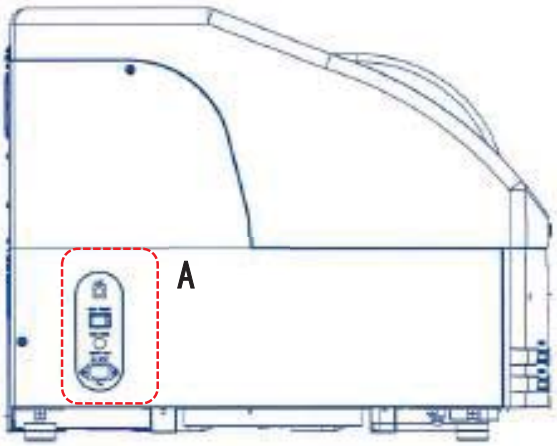
1.2.3. Rear view



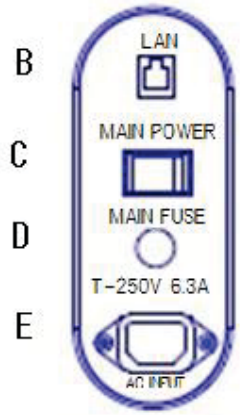
I : Nameplate
J,K,L : Fan

Rear view

1.2.4. Left Side Elevation of the System



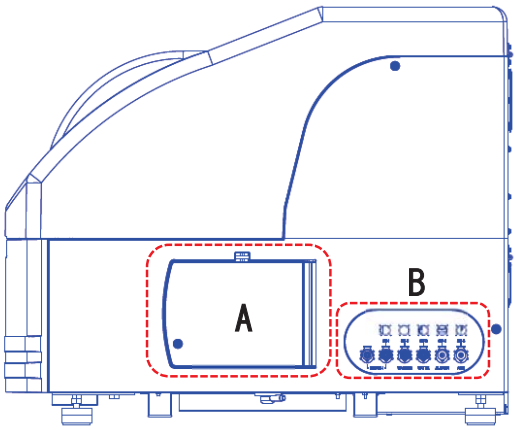
Left Side



A. Main power switch

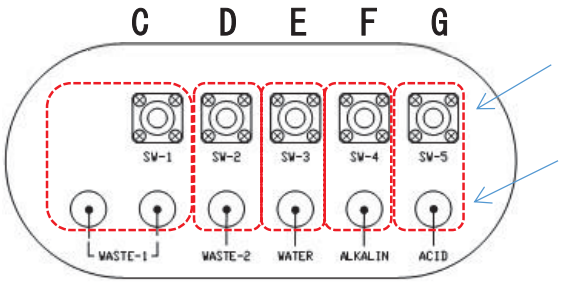
A:Main power switch panel
B:LAN
Connect to the PC
C: Main power switch
I ON
The reagent cooler is working
○ OFF
All the functions stop
D:Main Fuse
Time lag fuse (AC250V 6.3A)
C: AC power supply

1.2.5. Right Side Elevation of the System



Right Side

A:ISE module (Inside the door)
B:Water supply/drain panel



Water supply/drain panel

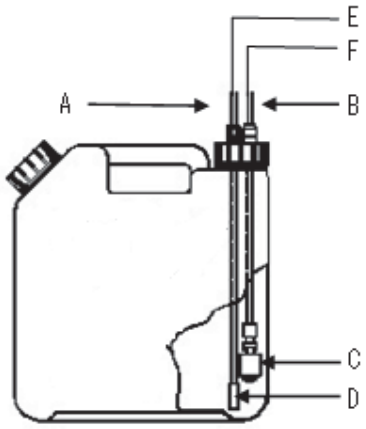
B: Water supply/drain panel
Upper : Cable line (SW-1 ～ 5)
Connect each sensor cables
Lower : Piping line
Connect each tubes

C : Drainage reservoir
SW-1, WASTE-1
D : Separate collection reservoir (option)
SW-2, WASTE-2
E : Water reservoir
SW-3, WATER
F : Alkaline cleaning solution reservoir
SW-4, ALKALIN
G : Acidic cleaning solution reservoir
SW-5, ASID

1.2.6. Reservoirs

- Separate Collection Reservoir, Drainage Reservoir and Water Reservoir must be set below the instrument level.
- Both Acidic and Alkaline Cleaning Solution Reservoirs must be set the same level of the instrument or below the instrument.

1. Water Supply Reservoir (10L)

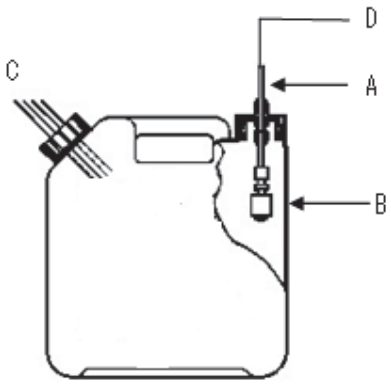


Water Supply Reservoir

A : Tube (blue)
B : Cable
C : Float switch
D : Filter
E : To water supply/drain panel, "WATER"
F : To water supply/ drain panel, "SW-3"

1) Please use ion-exchange water. (Electric conductivity < 1 micro S/cm)
2) Pure water line filter has to be replaced periodically.
3) If residual amount is less than a certain amount, an alarm is given.

2. Drainage reservoir (10L)

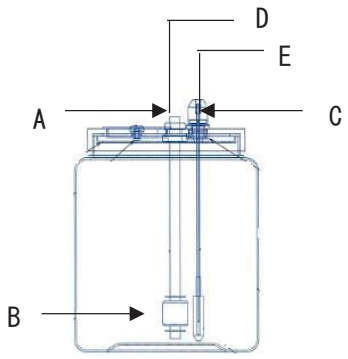


Drainage reservoir

A : Cable
B : Float switch
C : To water suppl/drain panel, "WASTE-1"(2 ports)
D : To water supply]/drain panel, "SW-1"

1) If the content exceeds a certain level, an alarm is given.

3. Alkaline and Acidic Cleaning Sol. Reservoir (3L)

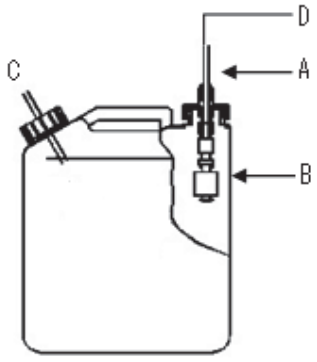


A : Cable
B : Float switch
C : Tube (thin)
D : To water supply/drain panel
"ALKALIN" or "ACID"
E : To water supply/drain panel
"ALKALIN-"SW - 4"
"ACID "SW - 5"

Alkaline Cleaning Sol. Reservoir
Acidic Cleaning Sol. Reservoir

1) Please use exclusive dilute alkaline cleaning solution (or acid cleaning solution.)
2) Filter has to be replaced periodically.
3) If residual amount is less than a certain amount, an alarm is given.

4. Separate Collection Reservoir (5L)



A : Cable
B : Float switch
C : To water supply/drain panel,
"WASTE-2"
D : To water supply/drain panel,
"SW-2"

Separate Collection Reservoir

1) If residual amount is less than a certain amount, an alarm is given.

1.2.7. Personal computer

By the personal computer to be used, it depends on the placement of each terminal.
The personal computer instruction manual well we read, should be connected with the device.
In addition, the handling on the PC alone, please refer to the PC instruction manual for operations.
To find out actual ports to be used, please refer to the operation manual of your PC.
* Please use the PC that complies with IEC60950.

・PC specification (Recommendation)

Model	All in one PC
OS	Windows 10 64bit
CPU	Intel Core i5/i7
Memory	8GB
Chip set	Not specified
Storage	500GB Hard disk
Video chip	Not specified
Video ram	Not specified
Display	Display resolution WXGAtt (1600x900) above Multi touch compatible
Speaker	Yes
LAN	Wired

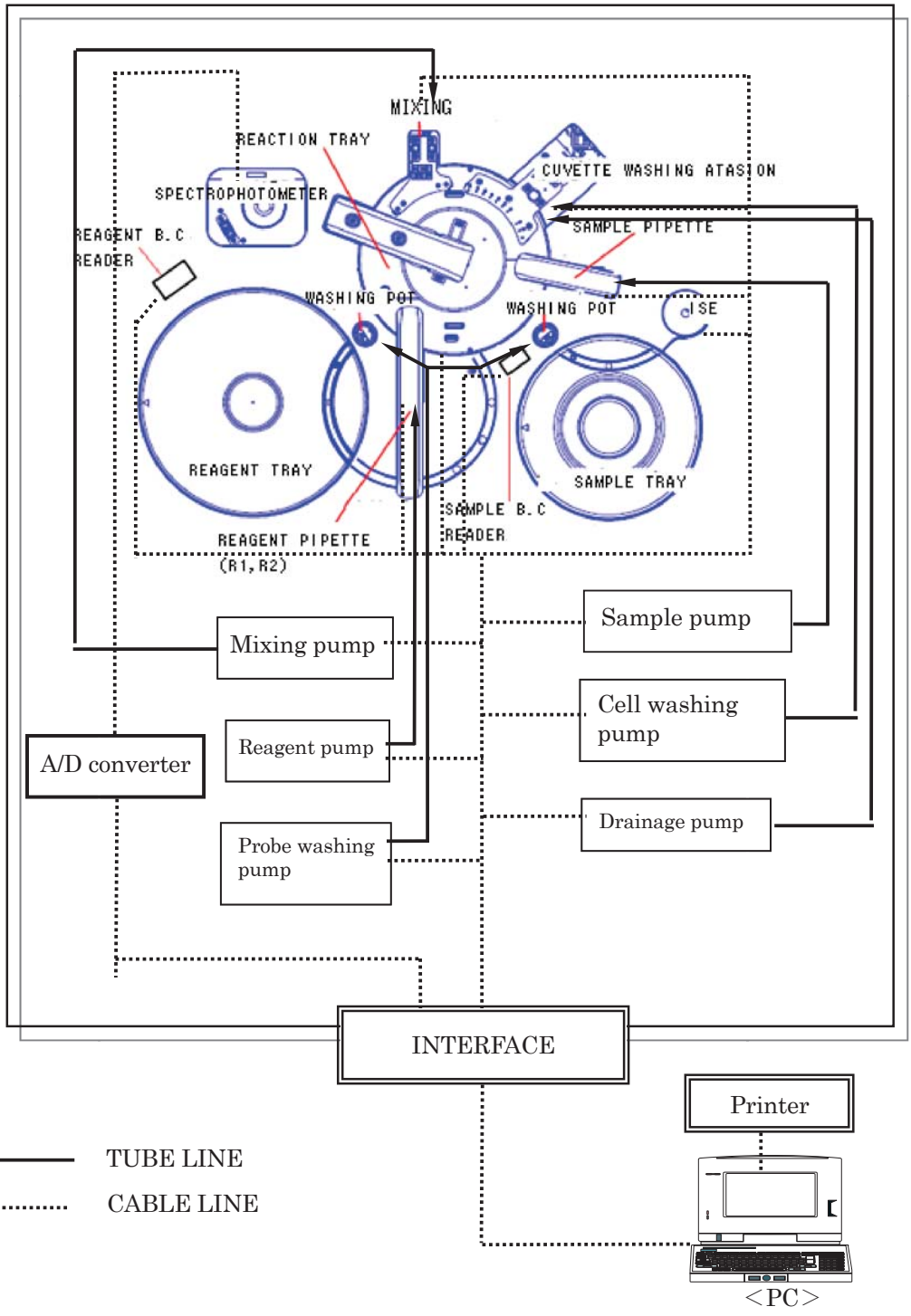
・LAN cable specification (Recommendation)

Standard	CAT5e (Category 5e) above

Chapter 2 Functions and principles

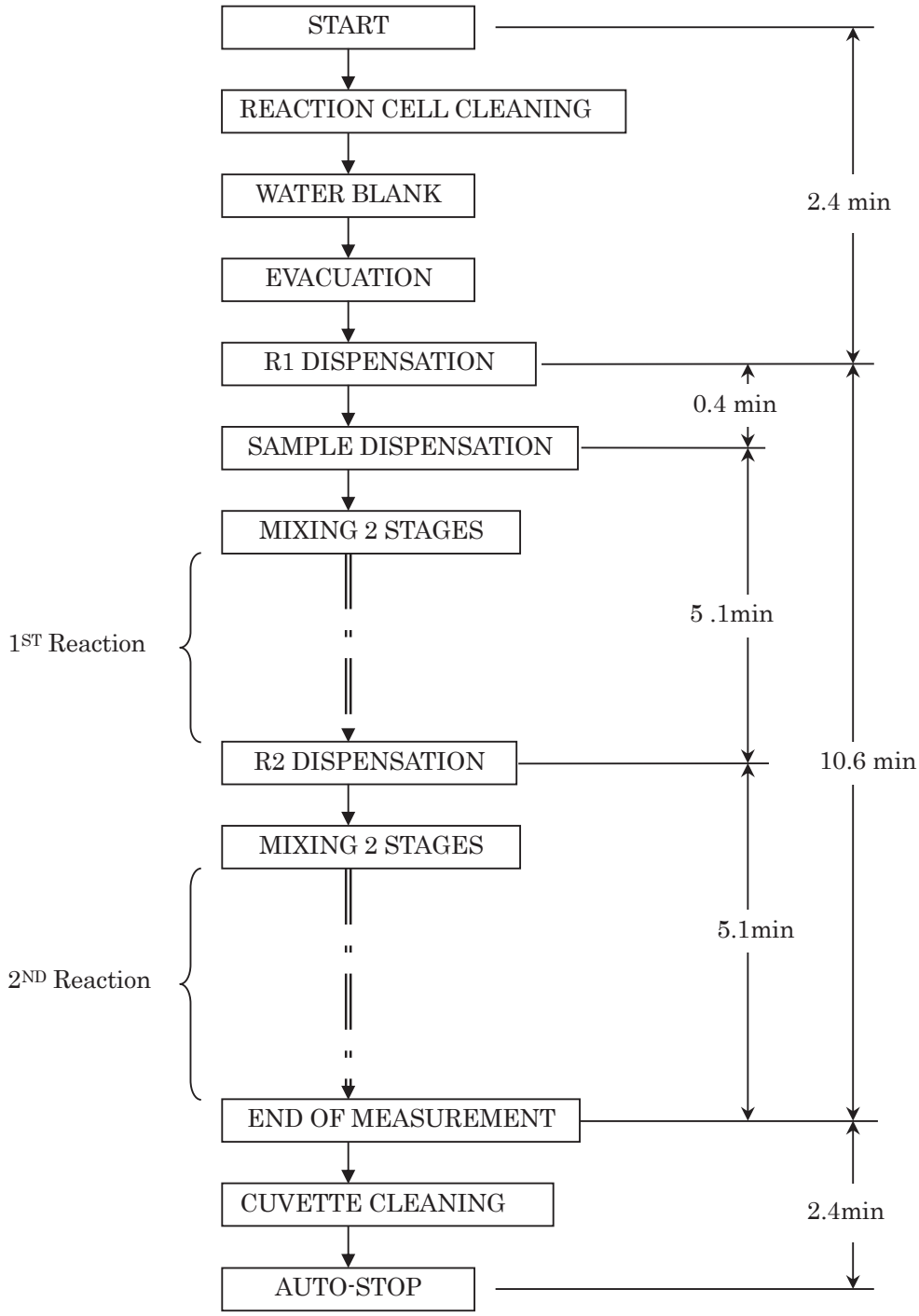
2.1 System overview

2.1.1 System structure



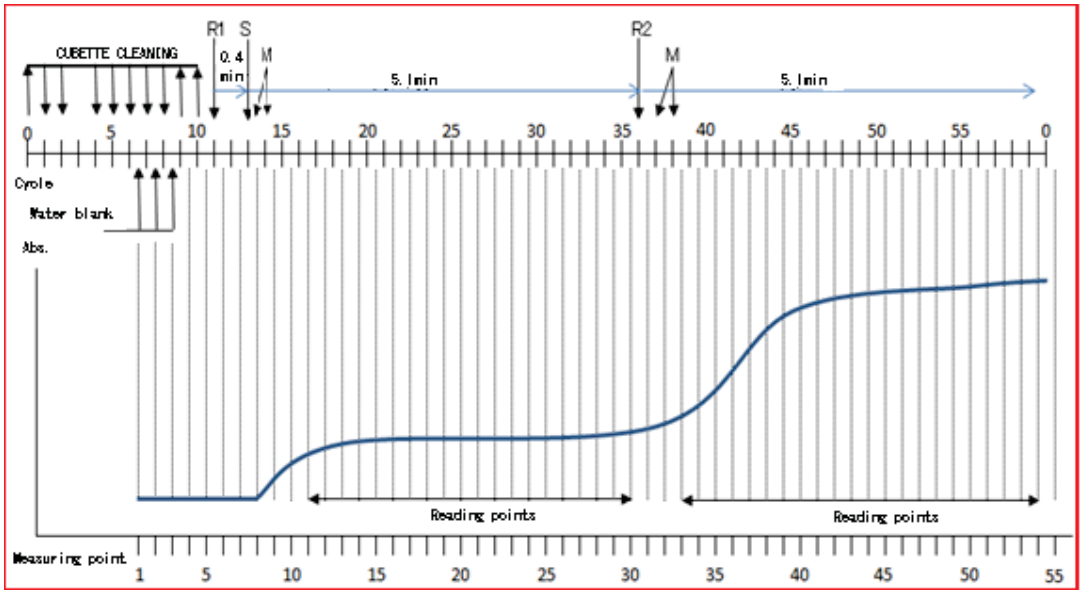
2.2 Principle of measurement

2.2.1 Analysis flow chart



2.2.2 Analysis process and optical measurement point

1) Analysis process



Measuring point19,37＝8sec、54＝24sec、Other=13sec

＜Explanation＞

S : Sample dispensation
R1 : R1 dispensation
R2 : R2 dispensation
M : Mixing

2) Optical Measurement Point

Cycle after start	Function	Optical measurement
6, 7, 8	Water blank measurement	1, 2 ,3
11	R1 dispensation	6
13	Sample dispensation	8
13, 14	Mixing (R1 + sample)	8,9
36	R2 dispensation	31
37, 38	Mixing (R2 + reaction solution)	32, 33
60	Reaction drainage aspiration	55

* For 1st regent only system, there is not R2 dispensation.

2.2.3 Principle of measurement and flow

1) Measurement principle
   - The optical absorption is measured every one cycle.
   - When the reaction tray rotates and the reaction cell passes the optical measurement position, light absorption data are measured.

2) Measurement flow

(1) When the start button is clicked, the cuvette washing unit starts cleaning from the start cuvette.
   - Water blank is measured during cuvette cleaning.
   - These data are the basis of optical absorption (Absorption = 0) to the following optical absorption measurement.

(2) The reagent tray rotates and transports the reagent bottle to the reagent aspiration position.

(3) The R1 probe moves to the aspiration position, above the reagent bottle, then moves down to aspirate the reagent.

(4) The R1 probe goes up and moves to R1 dispensation position and waits for the cuvette coming to the dispensation position.

(5) The reaction tray rotates and moves to R1 dispensation position.

(6) R1 probe goes down into the reaction cell and dispenses the reagent.

(7) The R1 probe goes up and moves to the probe washing pot and both inside and outside are washed by de-ionized water there.

(8) The sample tray rotates and moves to sampling position.

(9) The sample probe goes to sample position and move down to aspirate the sample.

(10) The sample probe moves above reaction cells.

(11) The reaction tray rotates and the R1 dispensed cell moves to sample dispensation position.

(12) Sample probe goes down into the reaction cell and dispenses the sample.

(13) The sample probe moves to the probe washing pot and both inside and outside are washed with de-ionized water.

(14) The reaction tray rotates and the reaction cell of R1 and sample moves to mixing position.

(15) The R1 and sample are mixed by air pressure of mixing unit.
   - This mixing is repeated in the next cycle, two times in total.

(16) After 5 minutes of sample dispensation, the reaction tray rotates and the reaction cell of R1 and sample moves to R2 dispensation position.

(17) R2 is dispensed by R2 probe, which has the same function as R1 probe.

(18) The R2 probe goes up and moves to the probe washing pot and both inside and outside are washed by de-ionized water there.

(19) The reaction tray rotates and the reaction cell (R1, sample, R2) moves to mixing position.

(20) The R1, sample and R2 are mixed by air pressure of mixing unit.

- This mixing is repeated in the next cycle, two times in total.
- No mixing from (16) – (20) is done when using mono-reagent.

(21) After 10 minutes of sample dispensation, the reaction liquid in the reaction cell is aspirated out and ends the measurement.

- The measurement result is displayed in result screen.

(22) The used reaction cell is washed by reaction cell washing unit and stop the movement automatically.

- When continue the measurement, start the analysis from (1)

2.2.4 ISE (Option) Principal of measurement and flow

1) Principle of measurement

- Ion selective electrode method (Direct method)

2) Measurement flow

- When measuring the calibration, perform the calibrator aspiration and dispensation twice. The electro-motive force (mV) of second time result is adopted.
- When measurement the urine, use urine diluted with the urine diluent by six times.

(1) Cal-1 in the electrode unit is discharged.

(2) The sample tray rotates and moves to sampling position (sample cup or primary tube).

(3) The sample probe goes to sample position and move down to aspirate the sample.

(4) Sample probe goes up and move to sample pot position.

(5) Sample probe dispenses the sample into the sample pot.

(6) The sample probe moves to the probe washing pot and both inside and outside are washed with washing solution.

- When measuring the urine, the sample aspiration and dispensation repeats twice.

(7) Sample is down to the electrode unit position. Electro-motive force os sample is read.

(8) Sample in the electrodes unit is discharged.

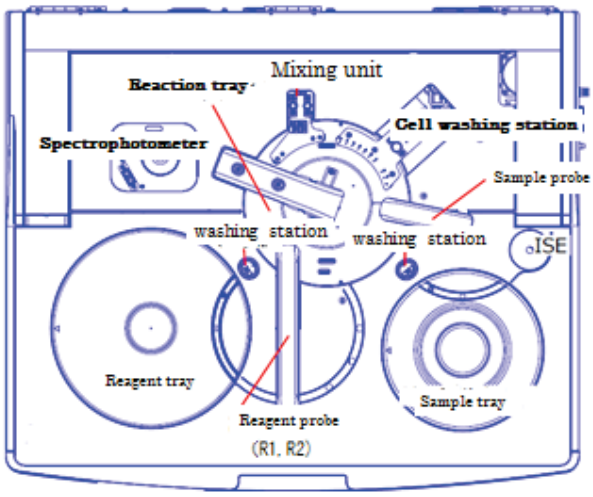
(9) The sample pot and the electrode unit are washed with Cal-1.

(10) The electro-motive force of Cal-1 in the electrode unit is read.

2.3 Units and functions

2.3.1 Plane of the main units

The system is composed sampler, sample transfer mechanism, reagent tray, reagent transfer mechanism, reaction tray, mixing units, cell washing unit, spectrophotometer and so on.



2.3.2 Sample tray

A sample tray holds cups and tubes.
Sampler rotates a sample tray and transfers samples to the sampling position.

2.3.3 Sampling transfer mechanism

Sample probe aspirates the designated volume of a sample from a sample cup/tube and STM carries sample probe to the cuvette position and the sample is dispensed into a reaction cuvette.

- The sample probe has a level sensor.

Sample probe is filled with washing water till tip.
When aspirating sample, the probe aspirate a small amount of air, and then aspirates a little excess amount of sample, and dispenses designated volume.

2.3.4 Reagent tray

When power is ON, these bottles are kept cooled.
Reagent tray holds reagent, diluent and cleaning solution bottles and transfers them to the aspiration position.

2.3.5 Reagent transfer mechanism

Reagent probe aspirates the designated volume of reagent from a reagent bottle and RTM carries the reagent probe to the cuvette position and the reagent is dispensed into a reaction cuvette.

There are two reagent probes. R1 probe (for the 1st reagent) is at the washing pot side and R2 probe (for the 2nd reagent) is at the opposite side, when initialized.

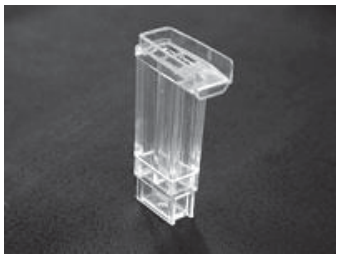
- Reagent probe has a level sensor.

A reagent pump is commonly used for R1 and R2.

Reagent probe is filled with washing water till tip.

When aspirating reagent, the probe aspirate a small amount of air, and then aspirates a little excess amount of reagent, and dispenses designated volume.

2.3.6 Reaction tray and reaction cell



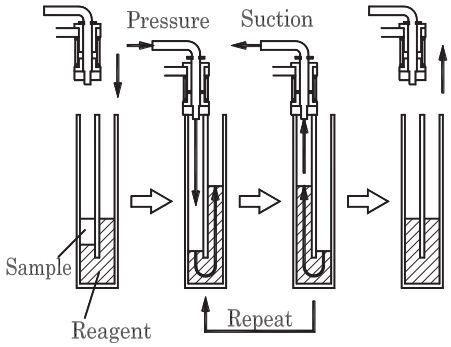
Reaction cuvette

Holds reaction cells at 37Celsius degrees, and lets sample and reagent react. Reaction cells are optical cells to measure light absorption.

Reaction cell direct optical measurement

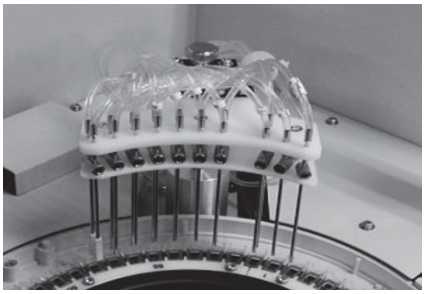
2.3.7 Mixing unit

By applying reciprocal air pressure at one opening end of a cuvette, the reaction liquid moves up and down, which causes good mixing.



Principle of mixing

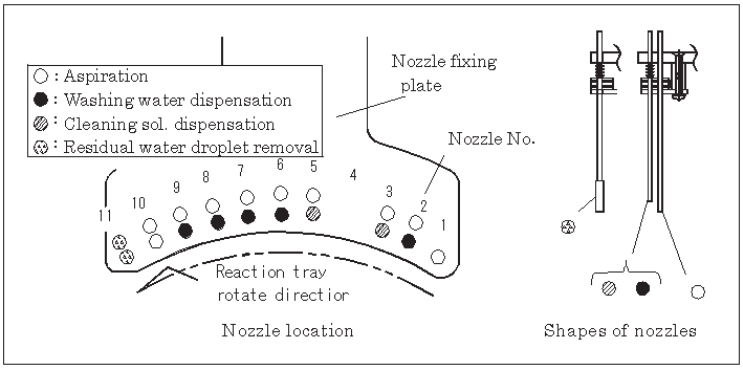
2.3.8 Cell washing station



Reaction cell washing mechanism

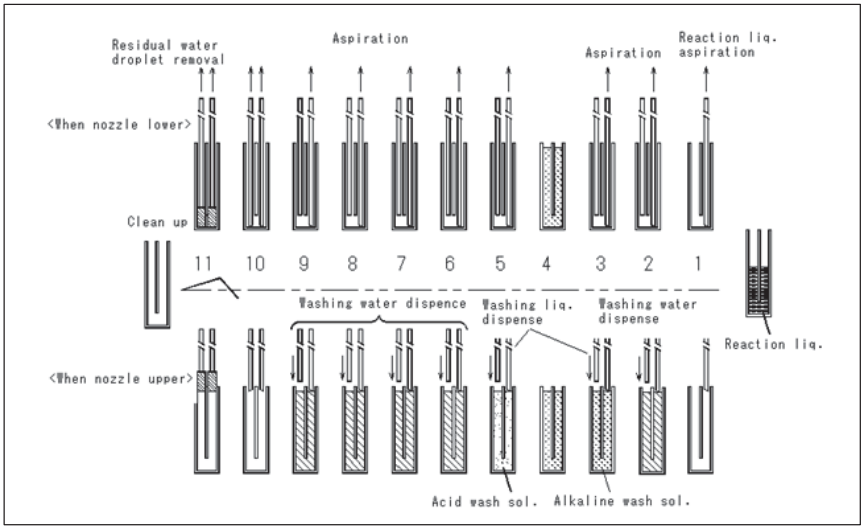
Perform reaction cell washing before start the measurement. The reaction drainage after the test is removed and the cell is washed with cleaning solution. The washing solutions are pre-heated.

1) Washing nozzle location



- For reaction drainage aspiration ---------1 nozzle (Nozzle No.1 ○)
- For cleaning sol. Aspiration ----------7 nozzles (Nozzles No.2,3,5~9 ○)
- For pure water aspiration ----------2 nozzles (Nozzle No.10 ○)
- For residual water droplet removal -----2 nozzles (Nozzle No.11 ⊛)
- For cleaning solution dispensation-------2 nozzles (Nozzles No.3, 5 ▨)
- For pure water dispensation ----------5 nozzles (Nozzles No.2, 6 ~ 9●)

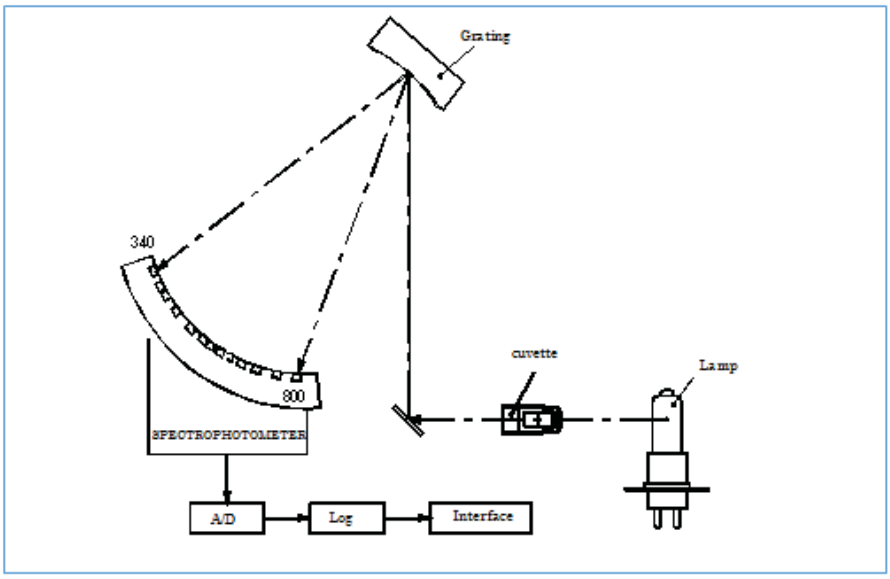
2) Cell washing process



2.3.9 Spectrophotometer and measurement method

Measures optical absorption of 13 wavelengths of pure water and reaction liquid in cuvettes while the reaction tray rotating.

1) General view of optical system



2) Measurement method

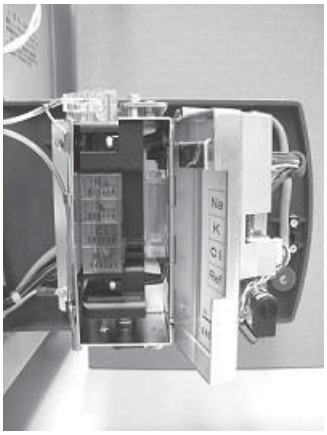
(1) White light emitted from the light source lamp is converged to a light beam.
(2) The light goes through the reaction cuvette.
(3) Then leads to a concave grating, so called the rear diffraction spectrophotometry.
(4) After the diffraction, light energy is measured by 13 individual photo detectors in each designed wavelength.
(5) For the monochromatic measurement, the output of one detector is taken out of 13, and for the bi-chromatic measurement, two outputs are taken.
(6) These output voltages are converted into digital data and logarithmic transformed, which is linearly corresponds with concentration.

3) Measurement characteristic

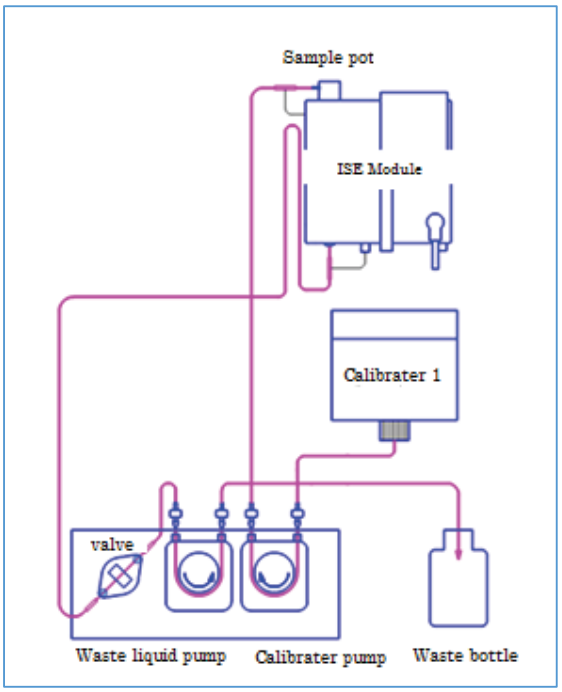
When the reaction tray rotates and the reaction cell passes the optical measurement position, light absorption data are measured. The optical absorptions are measured all the cycle.

2.3.10 ISE Module (Option)

ISE module is used for measurement of ion concentration (Na+, K+, Cl+) in the sample.



ISE Module



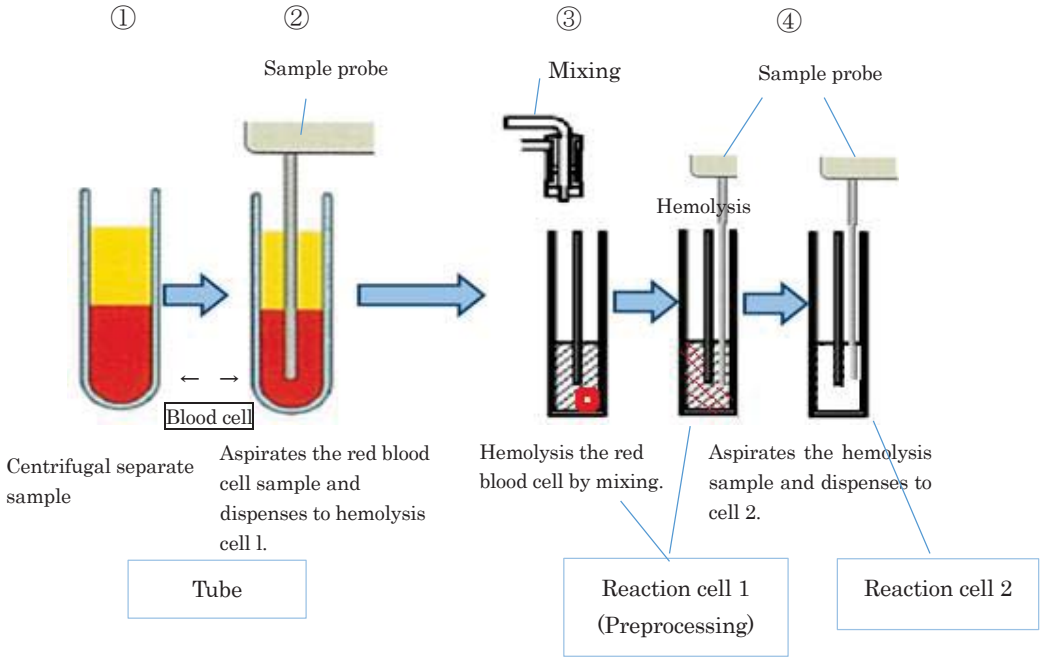
ISE piping diagram

2.3.11 HbA1c Sample preparation

HbA1c sample preparation(Hemolysis) is performed automatically.

HbA1c sample preparation flow (Hemolysis)

① Set the centrifugalized tube on the sample tray. (Fig ①)
② Aspirates the red blood cell sample from the blood cell layer by sample probe. (Fig. ②)
③ Reaction cell 1 (Sample preparation cell)
Dispense the lysing solution and blood cell sample. Prepare the hemolysis sample by mixing. (Fig. ③)
④ Reaction cell 2
After reagent dispensation to reaction cell 2, aspirate the hemolysis sample from reaction cell 1 and dispenses.
Continue the measurement.(Fig. ④)

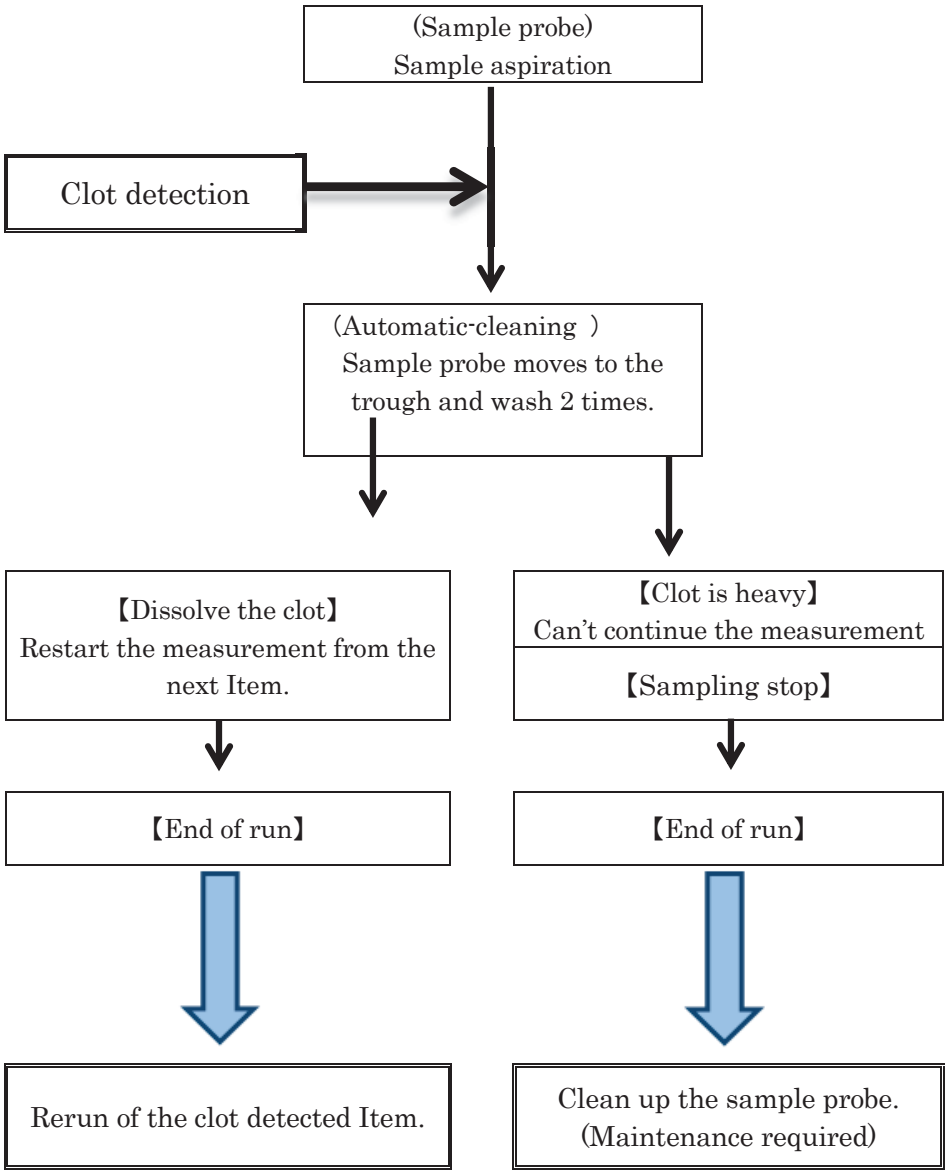


HbA1c sample preparation flow

2.3.12 Sample clot detection

When the sample probe detects the clot by fibrin, perform the washing automatically. The error flag “c” is attached to related result.

Solution flow after clot detection



Refer to Chapter 5, Maintenance.

2.3.13 Probe crash detection

When the probe detects the clash, the movement stops immediately to protecting the probe.

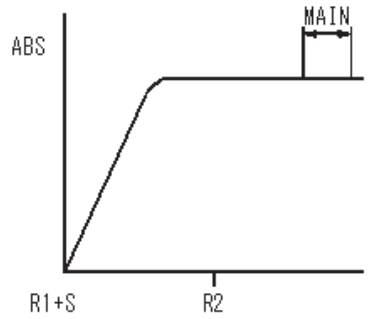
The probe crash detection is effect when the probe is down.
The probe movement stops by liquid level error instead of crash error in next case.

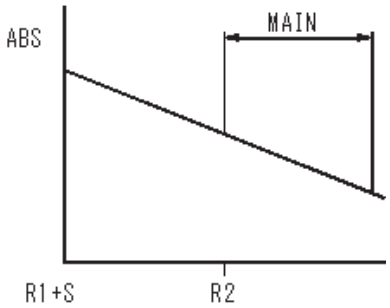
- When the crashed thing includes water or water drop attach on the surface. Confirm the crash, and remove it. Rerun the measurement.

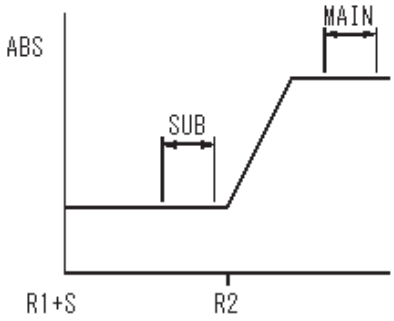
2.4 Analysis type

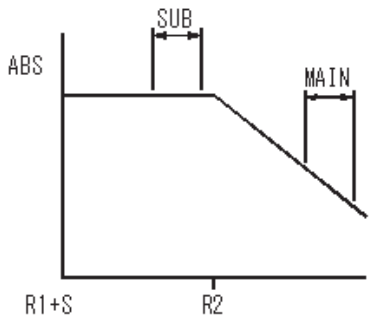
2.4.1 Kinds of analysis types

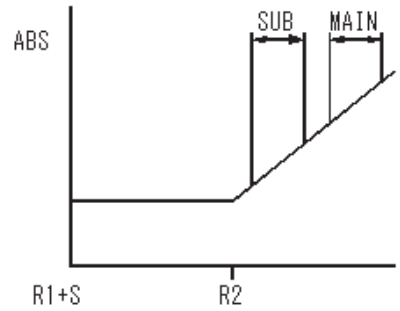
End assay	Rate assay
One point end assay	One point rate assay
Two points end assay 1	Two points rate assay 1
Two points end assay 2	Two points rate assay 2

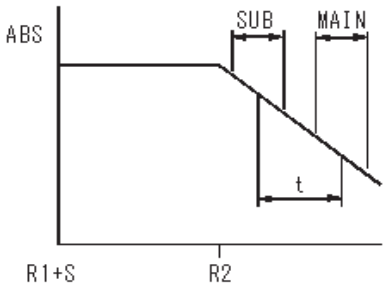
<table>
<tr>
<td> 

Measure the optical absorbance at the fixed time.</td>
<td> 

Concentration or activity is calculated from the rate of absorption change.</td>
</tr>
<tr>
<td>One point end assay</td>
<td>One point rate assay</td>
</tr>
<tr>
<td> 

Calculate the absorbance difference of the two different intervals, sub- and main-intervals.</td>
<td> 

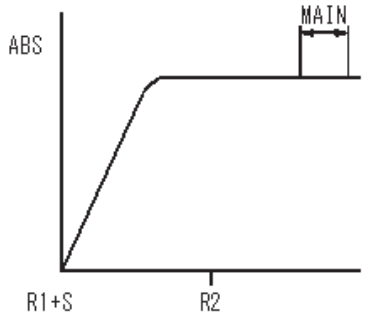
Calculate the absorbance rate of two different intervals, sub-interval and main-interval, and calculate concentration or activity from the difference between these two rates.</td>
</tr>
<tr>
<td>Two points end assay 1</td>
<td>Two points rate assay 1</td>
</tr>
<tr>
<td> 

Calculate the absorbance difference of the two different intervals, sub- and main-intervals.</td>
<td> 

Calculate the absorbance rate of two different intervals, sub-interval and main-interval, and calculate concentration or activity from the difference between these two rates.</td>
</tr>
<tr>
<td>Two points end assay 2</td>
<td>Two points rate assay 2</td>
</tr>
</table>

2.4.2 One point end assay

Measure the optical absorbance at the fixed time after mixing the reagent and the sample.



One point end assay

S : Sample dispensation
R1 : 1st reagent dispensation
R2 : 2ndreagent dispensation
R1+S : 1st reagent + Sample
ABS : Optical absorbance
MAIN : Main-measurement interval

1) Optical measurement points input

MAIN: 11 ≦ START ≦ END ≦ 54

2) Optical absorbance calculation for unknown sample

$$Ax = \frac{(\Sigma A_{L1} - (R \times \Sigma A_{L2}))}{N}$$

Ax : Absorbance of unknown sample
AL1 : Absorbance of main-wavelength
AL2 : Absorbance of sub-wavelength
N : Number of measurement points
R : Bi-chromatic factor (Default= 1)

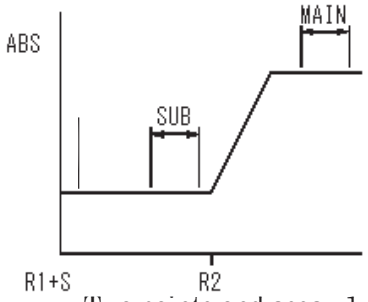
3) Concentration calculation

$$Cx = \frac{(Ax - Ab)}{(As - Ab)} \times Cs$$

Cx : Concentration of unknown sample
Ax : Absorbance of unknown sample
Ab : Absorbance of reagent blank
As : Absorbance of standard sample
Cs : Concentration of standard Sample

2.4.3 Two points end assay 1

Calculate the absorbance difference of the two different intervals, sub- and main-intervals.



Two points end assay 1

S : Sample dispensation
R1 : 1st reagent dispensation
R2 : 2nd reagent dispensation
R1+S : 1st reagent + Sample
ABS : Optical absorbance
MAIN : Main-measurement interval
SUB : Sub-measurement interval

1) Optical measurement points input

MAIN : 34 ≦ START ≦ END ≦ 54
SUB : 11 ≦ START ≦ END ≦ 30

2) Optical absorbance calculation

$$Ax = \left[\frac{(\Sigma A_{L1} - (R \times \Sigma A_{L2}))}{N} \right]_{MAIN} - K \times \left[\frac{(\Sigma A_{L1} - (R \times \Sigma A_{L2}))}{n} \right]_{SUB}$$

Ax : Absorbance of unknown sample
AL1 : Absorbance of main-wavelength
AL2 : Absorbance of sub-wavelength
N : Number of measurement points of main-interval
n : Number of measurement points of sub-interval
R : Bi-chromatic factor (default = 1)
K : Volume correction factor (Calculated automatically)
MAIN: Main-interval
SUB : Sub-interval

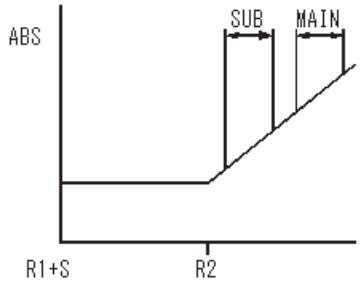
3) Concentration calculation

$$Cx = \frac{(Ax - AsL)}{(AsH - AsL)} \times (CsH\# - CsL\#) + CsL\#$$

Cx : Concentration of unknown sample
Ax : Absorbance of unknown sample
Ab : Absorbance of reagent blank sample
AsH : Absorbance of high value standard sample
AsL : Absorbance of low value standard sample
(When standard sample is one, Ab above is used in calculation.)
CsH# : Concentration of high value standard sample
CsL# : Concentration of low value standard sample

2.4.4 Two points end assay 2

Calculate the absorbance difference of two different intervals, sub- and main-intervals.



S : Sample dispensation
R1 : 1st reagent dispensation
R2 : 2nd reagent dispensation
R1+S : 1st reagent + Sample
ABS : Optical absorbance
MAIN : Main-measurement interval
SUB : Sub-measurement interval

Two points end assay 2

1) Optical measurement points input
MAIN :SUB≦START≦END≦ 54
SUB :34≦START≦END≦START

2) Optical absorbance calculation

$$Ax = \left[\frac{(\Sigma A_{L1} - (R \times \Sigma A_{L2}))}{N} \right]_{MAIN} - K \times \left[\frac{(\Sigma A_{L1} - (R \times \Sigma A_{L2}))}{n} \right]_{SUB}$$

Ax : Absorbance of unknown sample
AL1 : Absorbance of main-wavelength
AL2 : Absorbance of sub-wavelength
N : Number of measurement points of main-interval
n : Number of measurement points of sub-interval
R : Bi-chromatic factor (default = 1)
K : Volume correction factor (Calculated automatically)
MAIN : Main-interval
SUB : Sub-interval

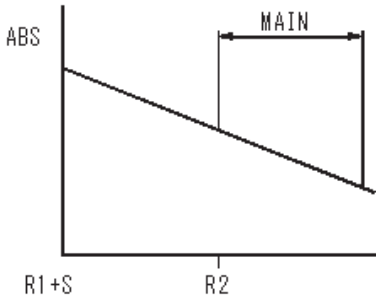
3) Concentration calculation

$$Cx = \left(\frac{(Ax - AsL)}{(AsH - AsL)} \right) \times (CsH\# - CsL\#) + CsL\#$$

Cx : Concentration of unknown sample
Ax : Absorbance of unknown sample
Ab : Absorbance of reagent blank sample
AsH : Absorbance of high value standard sample
AsL : Absorbance of low value standard sample
(When standard sample is one, Ab above is used in calculation.)
CsH# : Concentration of high value standard sample
CsL# : Concentration of low value standard sample

2.4.5 One point rate assay

Concentration or activity is calculated from the rate of absorption change.



S : Sample dispensation
R1 : 1st reagent dispensation
R2 : 2nd reagent dispensation
R1+S : 1st reagent + Sample
ABS : Optical absorbance
MAIN: Main-measurement interval

One point rate assay

1) Optical measurement points input
MAIN: 11≦START< END≦54

2) Optical absorbance calculation

$$\Delta Ax = (\Delta A_{L1} - \Delta A_{L2}) / min$$

ΔAx : Absorbance rate of unknown sample
ΔAL1 : Absorbance rate of unknown sample in main-wavelength
ΔAL2 : Absorbance rate of unknown sample in sub-wavelength

Absorbance rate is calculated by the least squares method in the given interval, and the rate is expressed by the absorption change per minute.

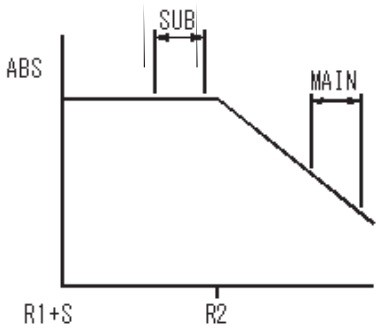
3) Concentration calculation

$$Cx = (\Delta Ax - \Delta Ab) \times F$$

Cx : Concentration of unknown sample
ΔAx : Absorption rate of unknown sample
ΔAb : Absorption rate of reagent blank
F : Factor

2.4.6 Two points rate assay 1

Calculate the absorbance rate of two different intervals, sub-interval and main-interval, and calculate concentration or activity from the difference between these two rates.



Two points rate assay 1

S : Sample dispensation
R1 : 1st reagent dispensation
R2 : 2nd reagent dispensation
R1+S : 1st reagent + Sample
ABS : Optical absorbance
MAIN : Main-measurement interval
SUB : Sub-measurement interval

1) Optical measurement points input
Main : 34 ≦ START ≦ END ≦ 54
SUB : 11 ≦ START ≦ END ≦ 30

2) Optical absorbance calculation

$$\Delta Ax = \left[\frac{(\Delta A_{L1} - \Delta A_{L2})}{\min} \right]_{MAIN} - K \times \left[\frac{(\Delta A_{L1} - \Delta A_{L2})}{\min} \right]_{SUB}$$

Absorbance rate is calculated by the least squares method in the given interval, and the rate is expressed by the absorption change per minute.

ΔAx : Absorbance rate of unknown sample
ΔAL1 : Absorbance rate of unknown sample in main-wavelength
ΔAL2 : Absorbance rate of unknown sample in sub-wavelength
K : Blank correction factor (Need to input factor value manually)
MAIN : Main-interval
SUB : Sub-interval

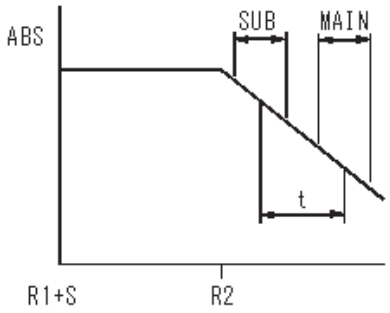
3) Concentration calculation

$$Cx = (\Delta Ax - \Delta Ab) \times F$$

Cx : Concentration of unknown sample
ΔAx : Absorption rate of unknown sample
ΔAb : Absorption rate of reagent blank
F : Factor

2.4.7 Two points rate assay 2

Calculate the absorbance rate of two different intervals, sub-interval and main-interval, and calculate concentration or activity from the difference between these two rates.



S : Sample dispensation
R1 : 1st reagent dispensation
R2 : 2nd reagent dispensation
R1+S : 1st reagent + Sample
ABS : Optical absorbance
MAIN : Main-measurement interval
SUB : Sub-measurement interval
t : time

Two points rate assay 2

1) Optical measurement points input
MAIN : SUB≦ START ≦ END ≦ 54
SUB : 34 ≦ START ≦ END ≦ MAIN

2) Optical absorbance calculation

$$\Delta Ax = \left(\frac{(\Delta A_{L1} - \Delta A_{L2})}{\min} \right)_{MAIN} - K \times \left(\frac{(\Delta A_{L1} - \Delta A_{L2})}{\min} \right)_{SUB}$$

Absorbance rate is calculated by the least squares method in the given interval, and the rate is expressed by the absorption change per minute.

ΔAx : Absorbance rate of unknown sample
ΔAL1 : Absorbance rate of unknown sample in main-wavelength
ΔAL2 : Absorbance rate of unknown sample in sub-wavelength
K : Blank correction factor (Need to input factor value manually)
MAIN : Main-interval
SUB : Sub-interval

3) Concentration calculation

$$Cx = (\Delta Ax - \Delta Ab) \times F$$

Cx : Concentration of unknown sample
ΔAx : Absorption rate of unknown sample
ΔAb : Absorption rate of reagent blank
F : Factor

2.5 Kinds of calibrations

- Linear 1 (Two points linear)
- Linear 2 (Multi-points linear)
- Factor
- Non-linear
  1) Logit 1 2) Logit 2 3) Spline
  4) Exponential 5) Polynomial

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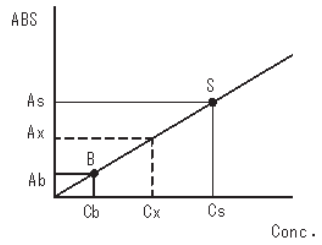
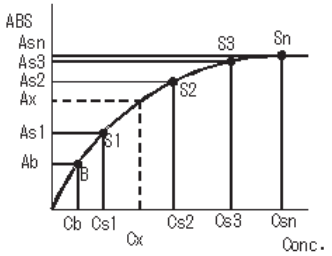
<tr><td> 
</td><td> 
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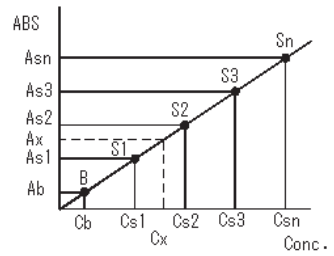
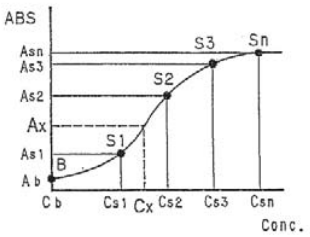
<tr><td> 
</td><td> 
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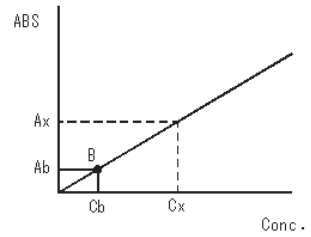
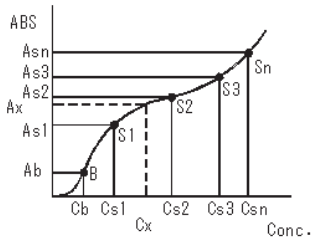
<tr><td>Linear 2 (Multi-points linear) · Linear2</td><td>Spline</td></tr>
<tr><td> 
</td><td> 
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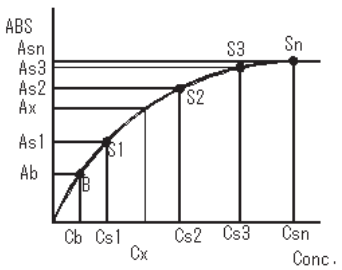
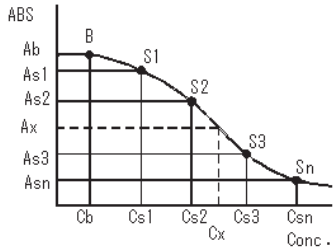
<tr><td> 
</td><td> 
</td></tr>
<tr><td>Logit 1</td><td>Polynomial</td></tr>
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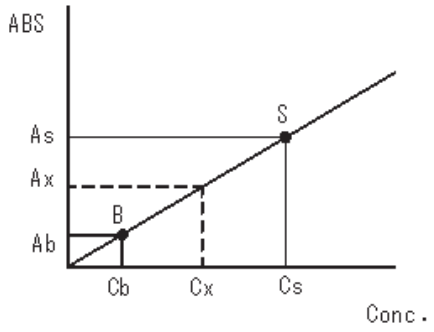
2.5.1 Linear 1 (Two points linear)

One standard sample and a blank sample make a linear calibration line. The "Linear 1 calibration" is applicable.



Linear 1 (Two Points Linear)

ABS : Optical absorbance
Conc. : Concentration
B : Reagent blank
Ab : Absorbance of reagent blank
Cb : Concentration of reagent blank
Ax : Absorbance of unknown sample
Cx : Concentration of unknown sample
S : Standard sample
As : Absorbance of standard sample
Cs : Concentration of standard sample

1) Standard sample concentration input

Blank : Input concentration of blank or lowest concentration of the standard sample.

Standard 1 : Input standard sample concentration

2) Concentration calculation of end point assay

$$Cx = \frac{(Ax - Ab)}{(As - Ab)} \times Cs$$

Cx : Concentration of unknown sample
Ax : Absorbance of unknown sample
Ab : Absorbance of reagent blank
As : Absorbance of standard sample
Cs : Concentration of standard sample

3) Concentration calculation of rate assay

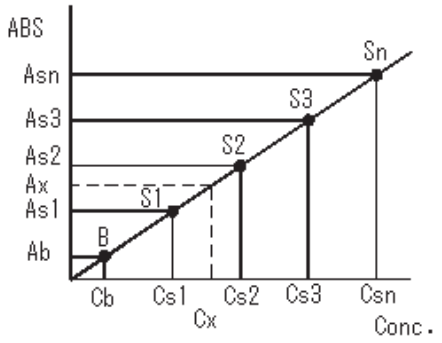
$$Cx = \frac{(\Delta Ax - \Delta Ab)}{(\Delta As - \Delta Ab)} \times Cs$$

Cx : Concentration of unknown sample
ΔAx: Absorbance rate of unknown sample
ΔAb: Absorbance rate of reagent blank
ΔAs: Absorbance rate of standard sample
Cs : Concentration of standard sample

2.5.2 Linear 2 (Multi-points linear)

Multiple standard samples (2-6) and a blank sample make a linear calibration line.

The "Linear 2 calibration" is applicable.



Linear 2 (Multi-points Linear)

ABS : Absorbance
Conc. : Concentration
B : Reagent blank
Ab : Absorbance of reagent blank
Cb : Concentration of reagent blank
Ax : Absorbance of unknown sample
Cx : Concentration of unknown sample
S1-Sn : Standard sample

1) Standard sample concentration input

Blank : Input the blank or lowest sample concentration.
Standard 1～8 : Input the standard sample concentration.
Inputting of maximum 8 standards is possible.

2) Concentration calculation of end point assay

Cx : Concentration of unknown sample
Ax : Absorbance of unknown sample
Ab : Absorbance of reagent blank
As# : Absorbance of standard sample#
Cs# : Concentration of standard sample#

(1) $Ax \leqq As1$

$$Cx=(Ax-Ab)\times\frac{(Cs1-0)}{(As1-Ab)}$$

(2) $As1 \leqq Ax \leqq As2$

$$Cx=(Ax-As1)\times\frac{(Cs2-Cs1)}{(As2-As1)}+Cs1$$

(3) $As2 \leqq Ax \leqq As3$

$$Cx=(Ax-As2)\times\frac{(Cs3-Cs2)}{(As3-As2)}+Cs2$$

(4) As3 ≦ Ax ≦ As4

$$Cx=(Ax-As3)\times\frac{(Cs4-Cs3)}{(As4-As3)}+Cs3$$

(5) As4 ≦ Ax ≦ As5

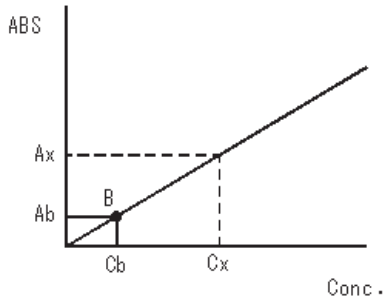
$$Cx=(Ax-As4)\times\frac{(Cs5-Cs4)}{(As5-As4)}+Cs4$$

(6) As5 ≦ Ax ≦ As6

$$Cx=(Ax-As5)\times\frac{(Cs6-Cs5)}{(As6-As5)}+Cs5$$

2.5.3 Factor

A blank sample and a given factor make a linear calibration line.



Factor

ABS : Optical absorbance
Conc. : Concentration
B : Reagent blank
Ab : Absorbance of reagent blank
Cb : Concentration of reagent blank
Ax : Absorbance of unknown sample
Cx : Concentration of unknown sample

1) Factor input

Input the value in factor box.

2) Concentration calculation of end point assay

$$Cx = (Ax - Ab) \times F$$

Cx : Concentration of unknown sample
Ax : Absorbance of unknown sample
Ab : Absorbance of reagent blank
F : Factor

3) Concentration calculation of rate assay

$$Cx = (\Delta Ax - \Delta Ab) \times F$$

Cx : Concentration of unknown sample
ΔAx : Absorbance rate of unknown sample
ΔAb : Absorbance rate of reagent blank
F : Factor

4) Factor calculation

$$F = \frac{Tv}{Sv} \times \frac{1}{L} \times \frac{1}{(\varepsilon 1 - \varepsilon 2)} \times 10^6$$

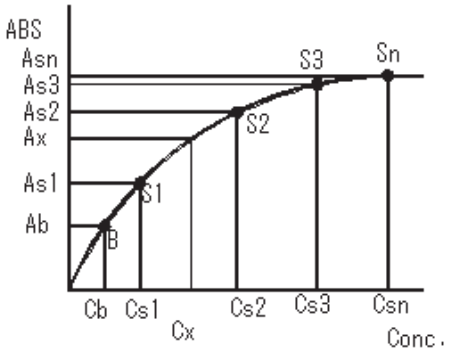
Tv : Total volume (micro-liter)=Sample volume x Dilution ratio+Reagent volume
Sv : Sample volume (micro-liter)
L : Optical length (default=10 mm)
The measured optical absorption data are converted to 10 mm optical lengths by system software.
ε 1 : Substrate molar light absorption coefficient (1/mol.cm) at main wavelength.
ε 2 : Substrate molar light absorption coefficient (1/mol.cm) at sub-wavelength.

2.5.4 Non-linear

This logic makes the approximate curve using 2-6 standard samples including a blank sample, as a calibration curve. There are the following five types.

4-1. Logit 1

This logic is used for the calibration curve in which the absorbance converges to the increase of concentration.



Logit 1

ABS : Absorbance
Conc. : Concentration
B : Reagent blank
Ab : Absorbance of reagent blank
Cb : Concentration of reagent blank
Ax : Absorbance of unknown sample
Cx : Concentration of unknown sample
S1-Sn : Standard sample
A1-An : Absorbance of standard sample
C1-Cn : Concentration of standard sample

1) Standard sample concentration input

Blank : Input the blank or lowest sample concentration.
Standard 1～8 : Input the standard sample concentration.
Maximum 8 standards are possible.

2) Concentration calculation

$$Cx = (C + Cb)$$

$$Ax = Ab + \frac{K}{(1 + \exp(-a - b \times \ln C))}$$

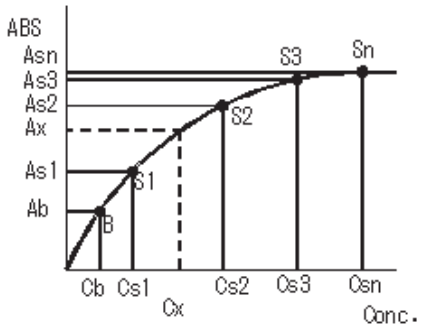
$$C = \exp\left(\frac{1}{b}\left(\ln\left(\frac{Ax - Ab}{K - (Ax - Ab)}\right) - a\right)\right)$$

Cx : Concentration of unknown sample
Ax : Absorbance or absorbance rate of unknown sample
Cb : Concentration of reagent blank
Ab : Absorbance or absorbance rate of reagent blank
K, a, b : Constants (Calculated automatically)

When Cx is being ∞, close to Ax=K+Ab.
When K ＞0 and ≦ Cb, C=0.
When K ＜0 and Ax ≧ Cb, C=0.

4-2. Logit 2

This logic is used for the calibration curve in which the absorbance converges to the increase of concentration.
As this logic uses more parameters than logit.log 1, better approximation may be expected.



Logit 2

ABS : Absorbance
Conc. : Concentration
B : Reagent blank
Ab : Absorbance of reagent blank
Cb : Concentration of reagent blank
Ax : Absorbance of unknown sample
Cx : Concentration of unknown sample
S1-Sn : Standard sample
A1-An : Absorbance of standard sample
C1-Cn : Concentration of standard sample

1) Standard sample concentration input

Blank : Input the blank or lowest sample concentration.
Standard 1～8 : Input the standard sample concentration.
Maximum 8 standards are possible.
Two standard samples are essential

2) Concentration calculation

$$Cx = (C + Cb)$$

Cx : Concentration of unknown sample
Ax : Absorbance or absorbance rate of reagent blank
Cb : Concentration of reagent blank
Ab : Absorbance or absorbance rate of reagent blank
K, a, b, c : Constants (Calculated automatically)

$$Ax = Ab + \frac{K}{(1 + \exp(-a - b \times \ln C - c \times C))}$$

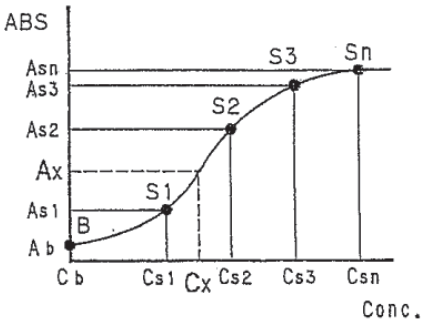
$$0 = a + b \times \ln C + c \times C - \ln\left[\frac{(Ax - Ab)}{(K - (Ax - Ab))}\right]$$

Calculate C by Newton approximation method

When Cx is being ∞, close to Ax=K+Ab.
When K ＞0 and ≦ Cb, C=0.
When K ＜0 and Ax ≧ Cb, C=0.

4-3. Spline

Connect absorption data of #I to #I+1 standard samples (I = 1 - n), taking into the account of the data of #I-1 and #I+2 and adjust to make a smooth calibration curve.



Spline

ABS : Absorbance
Conc. : Concentration
B : Reagent blank
Ab : Absorbance of reagent blank
Cb : Concentration of reagent blank
Ax : Absorbance of unknown sample
Cx : Concentration of unknown
S1-Sn: Standard sample
A1-An: Absorbance of standard sample
C1-Cn: Concentration of standard sample

1) Standard sample concentration input

Blank : Input the blank or lowest sample concentration.
Standard 1～8 : Input the standard sample concentration.
Maximum 8 standards are possible.
Two standard samples are essential

2) Concentration calculation

$$Cx = (C + Cb)$$

Cx : Concentration of unknown sample
Ax : Absorbance or absorbance rate of unknown sample
Cb : Concentration of reagent blank
Ab : Absorbance or absorbance rate of reagent blank

$$Ax = a(I) + b(I) \cdot (C - C(J)) + c(I) \cdot (Cx - C(J))^2 + d(I) \cdot (C - C(J))^3$$

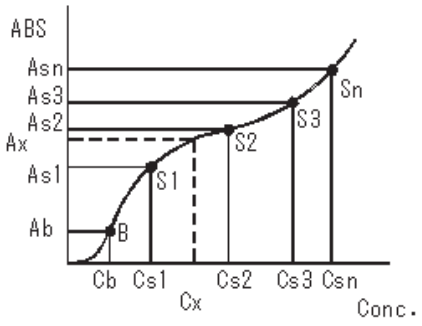
a(I),b(I),c(I),d(I): Constants (Calculated automatically)
I=1～N
Calculate C by Newton approximation method

$$f(C - C(J)) = a(I) + b(I) \cdot (C - C(J)) + c(I) \cdot (C - C(J))^2 + d(I) \cdot (C - C(J))^3 - Ax$$

Increasing type a(1) ≦ a(N) and a(1) ≧ Ax then C=C1
Decreasing type a(1) ≧ a(N) and a(1) ≦ Ax then C=C1

4-4. Exponential

For being different from 4-1,4-2,4-3 above, this logic is used for the calibration curve in which the absorbance diverges to the increase of concentration.



Exponential

ABS : Absorbance
Conc. : Concentration
B : Reagent blank
Ab : Absorbance of reagent blank
Cb : Concentration of reagent blank
Ax : Absorbance of unknown sample
Cx : Concentration of unknown sample
S1-Sn : Standard sample
A1-An: Absorbance of standard sample
C1-Cn: Concentration of standard sample

1) Standard sample concentration input

Blank : Input the blank or lowest sample concentration.
Standard 1～8 : Input the standard sample concentration.
Maximum 8 standards are possible.
One standard sample is essential

2) Concentration calculation

$$Cx = (C + Cb)$$

Cx : Concentration of unknown sample
Ax : Absorbance or absorbance rate of unknown sample
Ab : Absorbance or absorbance rate of reagent blank

$$Ax = Ab + K \cdot \exp(a \cdot (\ln C) + b \cdot (\ln C)^2 + c \cdot (\ln C)^3)$$

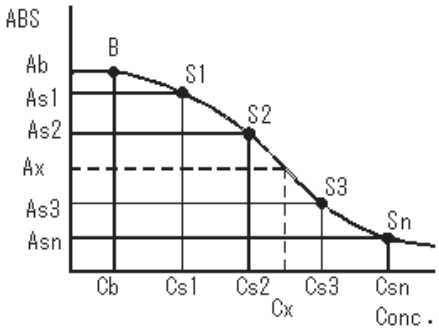
K,a,b,c : Constants (Calculated automatically)
Calculate C by Newton approximation method

$$a \cdot (\ln C) + b \cdot (\ln C)^2 + c \cdot (\ln C)^3 - \ln\left(\frac{Ax - Ab}{K}\right) = 0$$

When $K > 0$ and $Ax \leqq Ab$, $C = 0$

4-5. Polynomial

This calibration curve is used for the case which optical absorbance decreases as concentration increases.



Polynomial

ABS : Absorbance
Conc. : Concentration
B : Reagent blank
Ab : Absorbance of reagent blank
Cb : Concentration of reagent blank
Ax : Absorbance of unknown sample
Cx : Concentration of unknown sample
S1-Sn : Standard sample
A1-An : Absorbance of standard sample
C1-Cn : Concentration of standard sample.

1) Standard sample concentration input

Blank : Input the blank or lowest sample concentration.
Standard 1～8 : Input the standard sample concentration.
Maximum 8 standards are possible.
One standard sample is essential

2) Concentration calculation

$$Cx = (C + Cb)$$

Cx : Concentration of unknown sample
Ax : Absorbance or absorbance rate of unknown sample
Cb : Concentration of reagent blank
Ab : Absorbance or absorbance rate of reagent blank

$$C = K + (a \times Ax) + (b \times Ax^2) + (c \times Ax^3)$$

K,a,b,c : Constants (Calculated automatically)

2.6 ISE Module (Option)

ISE (ion selective electrode) measures electro-motive force (mV), induced by ion concentration in the sample.

Four kinds of electrodes are used for the system.

Na electrode : Sensitive only for Na ion in the sample.
K electrode : Sensitive only for K ion in the sample.
Cl electrode : Sensitive only for Cl ion in the sample.
Reference electrode : No ion selectivity

2.6.1 ISE Calibration

1) Two points calibration (Calibration measurement)
Two points calibration is done every morning, before the system starts to operate.
Calibrator-1(Cal-1) and Calibrator-2 (Cal-2) are measured and the slope, ion concentration versus mV, is calculated for each item.

- If the slope is out of the standard range, below, the electrode should be replaced. If the slope of all electrodes is out of range, reference electrode should be checked.
  Please refer to Chapter 6 Alarm.

	Slope range (mV/)		Range (mmol/L)	
	Serum	Urine	Serum	Urine
Na	30.37-73.40	30.37-73.44	100-200	10-400
K	29.45-69.46	29.46-69.46	1-10	1-200
Cl	21.01-68.71	21.01-68.71	70-200	30-400

2) One point calibration (Patient sample measurement)
One point calibration is done for each test.
For each test, both sample mV and Calibrator-1(Cal-1) mV are measured, and correlate the measurement condition.

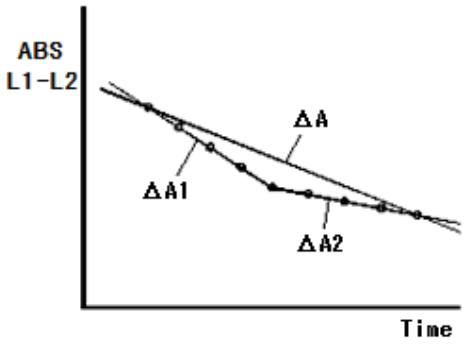
2.6.2 ISE Concentration calculation

$$Cx = Ca * 10^{[(Ex - Ea) / S]}$$

Cx : Concentration of unknown sample
Ca : Concentration of Cal-1
Ex : Electromotive force of unknown sample
Ea : Electromotive force of Cal-1
S : Slope, measured by two points calibration.

2.7 Linearity check

To determine if a curve is linear, a linearity check will be calculated after each rate assay.
The “L” flag appears when that check exceeds the preset value.



L1 : Main wavelength
L2 : Sub wavelength
ΔA1 : The slope of measuring range 1
ΔA2 : The slope of measuring range 2
ΔA : The slope of the total curve

Linearity check

1) Parameter setting
Input the Linear Check(%) in Item parameter screen (above zero).

2) Calculation Formula

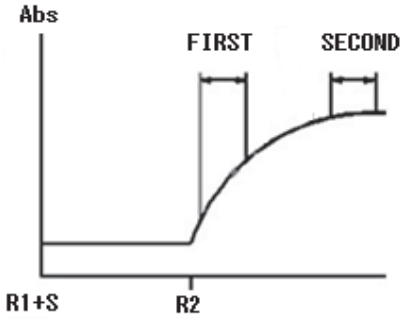
$$\text{Linearity check}(\%) = (\Delta A1 - \Delta A2) / \Delta A \times 100\%$$

ΔA1 The slope of the first half of the curve (using a least-squares method.)
ΔA2 The slope of the second half of the curve (using a least-squares method.)
ΔA The slope of the range of measuring A (using a least-squares method.)

2.8 Prozone check

This function checks if there is a Prozone phenomenon in immunoassay. Based on the registered parameter, this function checks the curvature of reaction diagram up to 2 zones, and if Prozone is detected, puts the data message flag "P" on the printout data.

- Prozone phenomenon : The high conc. result shows lower result cause of the special immunological reaction.



Prozone check

S : Sample dispensation
R1+S : 1st reagent+Sample
R2 : 2nd reagent dispensation
ABS : Optical absorbance
FIRST : Interval(1)
SECOND : Interval(2)
Use main wavelength

1) Prozone check value setting.
   Input the Prozone check conditions in Item parameter setting column.
   (1) First interval- Start, End : Starting and ending test points of basic test interval.
   Second interval-Start, End: Starting and Ending test points of second interval.
   Input range is 34 – 54 point.
   (2) Limit value: Input the comparison limit value(%).
   (3) High, Low: Select the check high or low.

2) No Prozone check condition setting.
   Input the no Prozone check condition (minimum Abs. of average, minimum slope value) in Item parameter Prozone setting column.
   (1) Minimum Abs. average value: Input the first interval value.
   (2) Minimum slope value: Input the first interval value(⊿OD/min).

   - No Prozone check is done if the average or slope value exceeds the input value.
   - No Prozone check is done if no input the check value or the slope value of the first interval is below zero.

3) Calculation formula
   The second check value ΔOD2／ΔOD1＊100(%)
   Δ OD1 The gradient in the first interval
   Δ OD2 The gradient in the second interval
   (using a least-squares method.)

2.9 Serum information (L-H-I)

The Lipemia, Hemoglobin and bilirubin which included in serum sample is influenced the result.
The serum information measures the Lipemia, Hemoglobin, Bilirubin (L-H-I), and judges the level of it.
The serum information result makes the judgement based on the information results.
Affect the measurement result. Lipemia(L)·Hemolysis(H)·Bilirubin(I).

1) Serum information check method

Lipemia(L)

Measures the two wavelengths in the wavelength rang of visible light. (No effect of hemolysis and bilirubin)

Hemoglobin (Hemolysis · H)

Measures the two wavelengths in the medium wavelength region (No effect of bilirubin). And measure the two wavelengths in the long wavelength region.

Bilirubin (Icteric · I)

Measure the two wavelengths in the short wavelength region. And measure two wavelengths of medium and long-wavelength region.

2) Measurement preparation and method

The serum information Item (L-H-I) is fixed in the program. Prepare the saline bottle to measure the serum information. (Bottle condition and setting)

*Order entry and measurement is same as other Items. Please refer to Chapter 3 Operation for details.

Item setting and result	Operation
Item parameter setting	The serum information is set as default.(L-H-I) ➢ Condition setting of concentration result transforms to qualitative result.
Reagent setting(Position)	① The reagent bottle position set in reagent screen for Item [L-H-I]. ② Set the saline bottle on the reagent tray.
Calibration	No necessary
Order entry	Order by selection of [L-H-I].
Measurement	Use saline as a reagent.
Result	Display value in results column, and judgement of＋－ is shown in qualitative column by the Item parameter setting. ➢ L : Lipemia, H: Hemoglobin, I:Bilirubon ➢ If there is a decision the difference between serum information by visual, please adjust by changing the decision value.

2.10 Carryover avoidance

As sample probe, reagent probes and reaction cells contact with different kinds liquid and sometimes built-in cleaning process is not sufficient.
It may cause carryover. To avoid these kinds of carryover, it is possible to do special cleaning by carryover protection function.

2.10.1 Kinds of carryover avoidances

1. Reagent probe cleaning

   After the aspiration of proceeding reagent, analyzer aspirates cleaning solution instead of reagent and dispenses into empty cell and washed.

2. Sample probe cleaning

   After the aspiration of proceeding sample, sample probe aspirates cleaning solution instead of sample and dispenses into empty cell.

   There are 3 kinds of sample probe cleaning, between Items, samples and sample kinds. One kind of sample probe washing registration is possible.

3. Reaction cell cleaning

   A reaction cell used for registered reagent is not used for test at the next cycle. Reagent probe dispenses cleaning solution into the cell and washed.

2.11 Automatic start-up, shut down and automatic maintenance

By the combination of automatic start-up, shut down and maintenance, shorten the performance time when start-up and shut down the analyzer.

2.11.1 Automatic start-up and shut down

By using the auto-start and shut down setting, analyzer power switch is

ON or OFF automatically at the time, which is set by the timer for weekly day.

2.11.2 Automatic maintenance

By the setting of automatic maintenance, perform the maintenance before and after system power OFF or ON automatically. The function is able to set by the timer for weekly day.

Chapter 3

Explanation of each screen and operating condition

3.1 Software program installation

The analyzer is used exclusive software program. Please install the program by attached CD.

3.1.1 PC specification

- Refer to Chapter 1, 1.2.7. PC (LAN cable) for PC specification.

3.1.2 Install CD information

- Install the database and system program by install CDs.

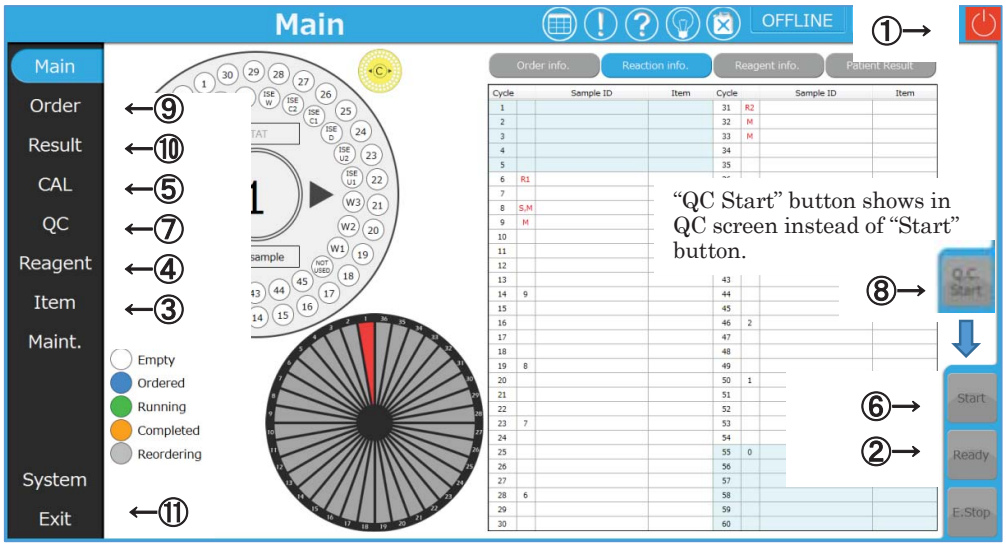
3.1.3 Installation procedure

1) Insert the CD to PC driver.
2) Installation starts automatically.
3) Continue the installation under the “Wizard”.
   If some dialog box appeared cause of the Windows security, ensure “YES”.
4) Select the installation language.
5) Click “Install” button.
6) Proceed by clicking “Next” and “Agree” buttons.
7) Input analyzer serial number, select default language and analyzer name.
8) Click “Next” button.
9) Click “Install” button.
10) Click “Finish” button. The installation completed.

- In case of version up: Install the version up CD.
  The uninstallation is unnecessary.

3.2 Routine operation flow

- Routine operation (from start up to shutdown) follows the procedure steps.
- The operation flow includes unnecessary settings on each time. Please operate according to the requirement.



Main screen

Step	Button & Screen	Operation
1	—	Start-up inspection.
2	① Icon (Analyzer system switch)	Start up the analyzer ➢ Turns on the PC power switch, and start up the system program. Turns on the analyzer main switch and system switch.
3	② Ready	Analyzer initialization
4	③ Item	Setting of Item parameters (Item name, wavelength, sample volume and reagent volume)
5	④ Reagent	Setting of reagent position.
6	—	Set the reagent bottle on the reagent tray.
7	⑤ CAL	Setting of calibration (Calibrator position, concentration).
8	⑤ CAL	Order entry of calibration sample.
9	⑥ Start	Set the calibration blank and standard sample on the sample tray. Start the calibration measurement.
10	⑤ CAL	Confirmation of calibration results.
11	⑦ QC	Setting of QC sample measurement (Control setting)
12	⑦ QC	Order entry of QC sample.
13	⑧ QC Start	Set the QC sample on the sample tray. Start the QC sample measurement.

Step	Button & Screen	Operation
14	⑦ QC	Confirmation of QC sample results.
15	⑨ Order	Order entry of patient sample.
16	⑥ Start	Set the patient sample on the sample tray. Start the patient sample measurement.
17	⑩ Result	Confirmation of patient sample results.
18	—	Shutdown inspection and analyzer maintenance.
19	①  Icon (Analyzer system switch)	Shutdown the analyzer. ➢ Turns off the system switch, and close the system program. Turns off the PC switch and analyzer main switch.

3.2.1 Start-up inspection

- Confirmation of the following points before starting the analyzer. Perform the reagent refill or other requirement.

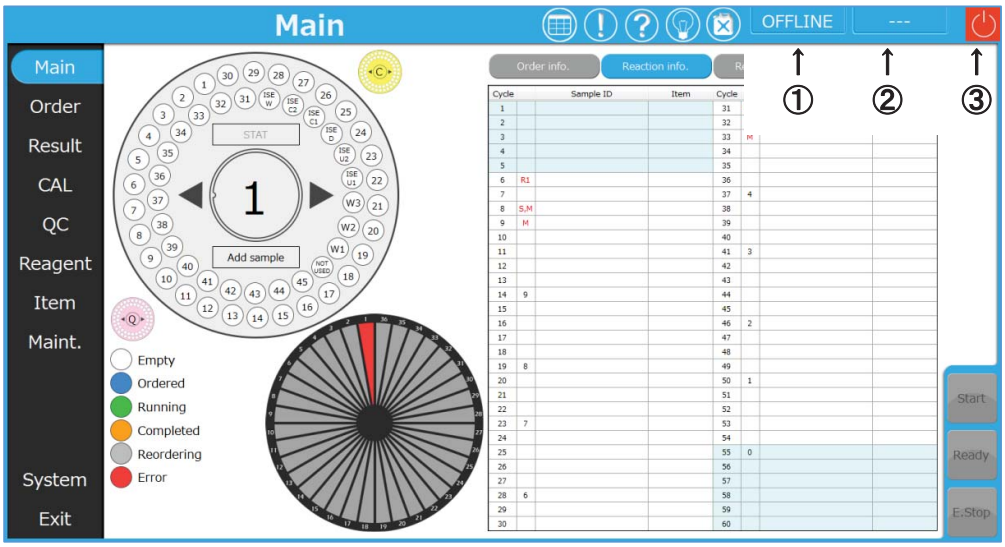
Step	Inspection
1	No obstruction for analyzer movement (Sample probe and Reagent probes)?
2	Confirmation of water supply. ➢ Is de-ionized water enough in the water reservoir? ➢ Open the water supply line on the water purification system?
3	Confirmation of cleaning solution reservoir. ➢ Are the Alkaline and Acid cleaning solutions enough in the cleaning solution reservoir?
4	Confirmation of drainage reservoir. ➢ Are the waste tank and separate waste tank empty?
5	Confirmation of residual reagent. ➢ Are the reagents enough?

- When analyzer is attached the ISE unit, add the following inspection.

6	Is the ISE Calibrator 1 enough?
7	Is the ISE drainage tank empty?

3.2.2 Start-up (Analyzer power switch ON)

➢ Start up the analyzer. Analyzer stand-by after power on follows the procedure steps.
Analyzer "stand-by" means? : The reaction tray temperature reaches 37 Celsius degrees.



Main screen

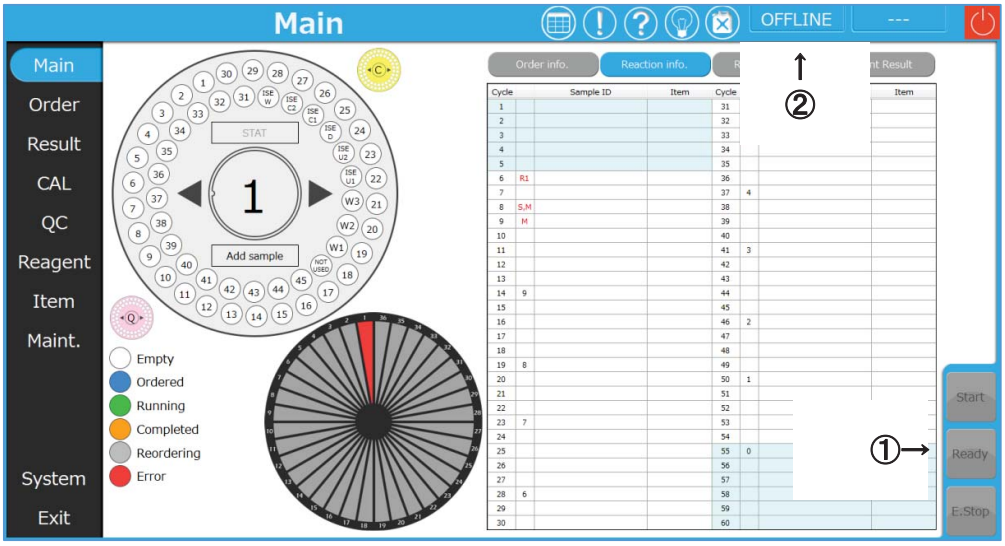
Step	Button & Screen	Operation & Display
1	—	Turns on the analyzer main switch. ➢ The main switch is left rear side on the analyzer.
2	—	Turns on the PC power switch.
3	(PC screen)	Confirmation of Main screen.
4	① Status monitor	➢ Indicates [OFF LINE].
5	② Temperature control monitor	➢ Indicates [---].
6	③ Icon (Analyzer system switch)	Click power switch ON/OFF Icon. ➢ Turns on the Analyzer system switch.
7	—	Starts the connection between the PC and analyzer. ➢ Confirmation of popup screen message. [Connecting] →[Program Downloading] →[Parameter Downloading]
8	—	The connection between the PC and analyzer completes.
9	① Status monitor	➢ Indicates [IDLE].
10	② Temperature control monitor	➢ Indicates [WARM-UP].
11	—	Wait until the reaction temperature reaches 37 Celsius degrees
12	② Temperature control monitor	➢ Indicates [OK].
13	—	The analyzer stays stand-by.

3.2.3 Analyzer initialization (Ready)

➢ Initialize (Ready) the analyzer. For analyzer stand-by (Ready), follows the procedure steps.

Analyzer initialization means? : All the analyzer units move to home position (start position).

Analyzer stand-by (Ready) means? : All the analyzer units stay at home position (start position).

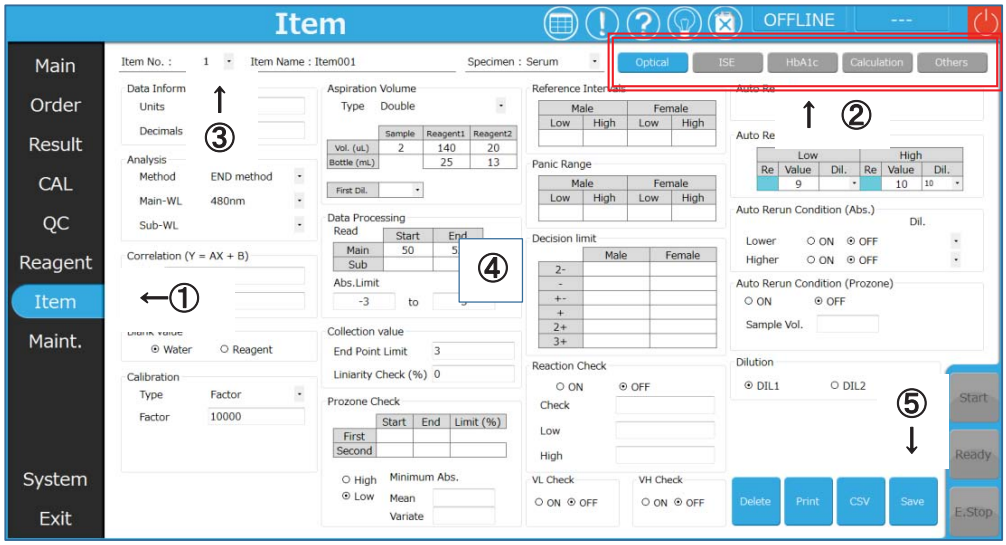


Main screen

Step	Button & Screen	Operation & Display
1	① Ready	Click "Ready" button.
2	—	Analyzer starts the initialization. ➢ All of the analyzer units move to home position (Start position).
3	② Status monitor	➢ When the analyzer is initializing, indicates [INIT].
4	—	Analyzer initialization completes.
5	② Status monitor	➢ Indicates [READY] after initialization.
6	—	Analyzer status stays stand-by (Ready). ➢ All of the analyzer units stay at home position (Start position).

3.2.4 Measurement condition (Item parameter) setting

- For measurement setting (Item parameter) follows the procedure steps.
- Please refer to Chapter 4, 4.6 Item screen of the other Item screen (except Optical screen).

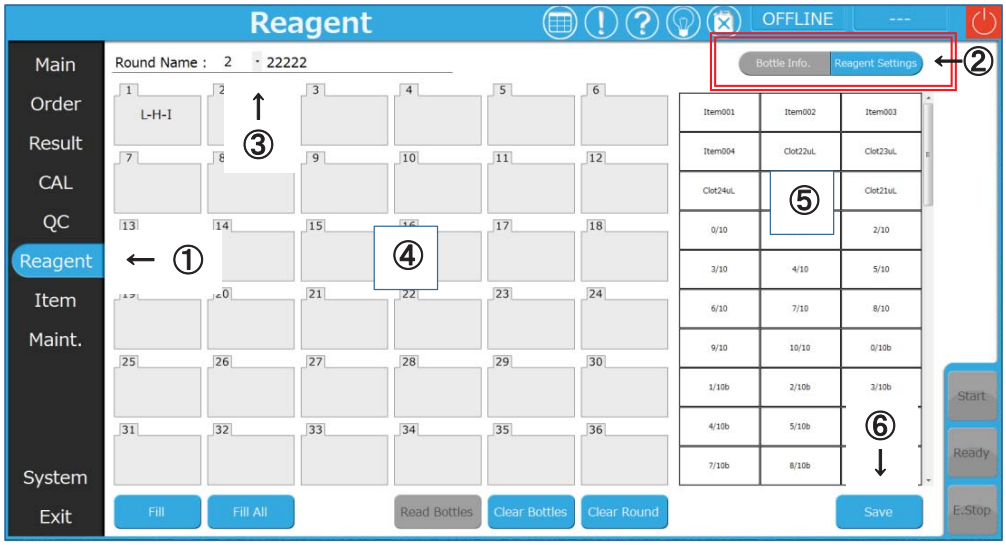


Item screen – Optical Item screen

Step	Button & Screen	Operation & Display
1	① Item	Click "Item" button.
2	(PC screen)	Item screen is shown.
3	② Optical Item ISE (Na,K,CL) HbA1c Calculation Item Other	Select the measurement Item button.
4	(PC screen)	Selected Item screen is shown.
5	③ Item No.____▼	Select Item number.
6	④ (Input measurement conditions)	Select or Input the measurement parameter. ➢ In case of optical screen, following selection and inputting are essential. ・Item name ・Specimen ・Data Information ・Analysis ・Correlation ・Blank value ・Calibration ・Aspiration volume ・Data process ・K factor
7	⑤ Save	Measurement settings are stored.

3.2.5 Reagent bottle position setting

- When using the reagent barcode, please refer to "Reagent barcode manual".
- Please refer to Chapter 4, 4.6 Reagent screen for details.
- Reagent bottle setting in "Reagent Setting" screen follows the procedure steps.

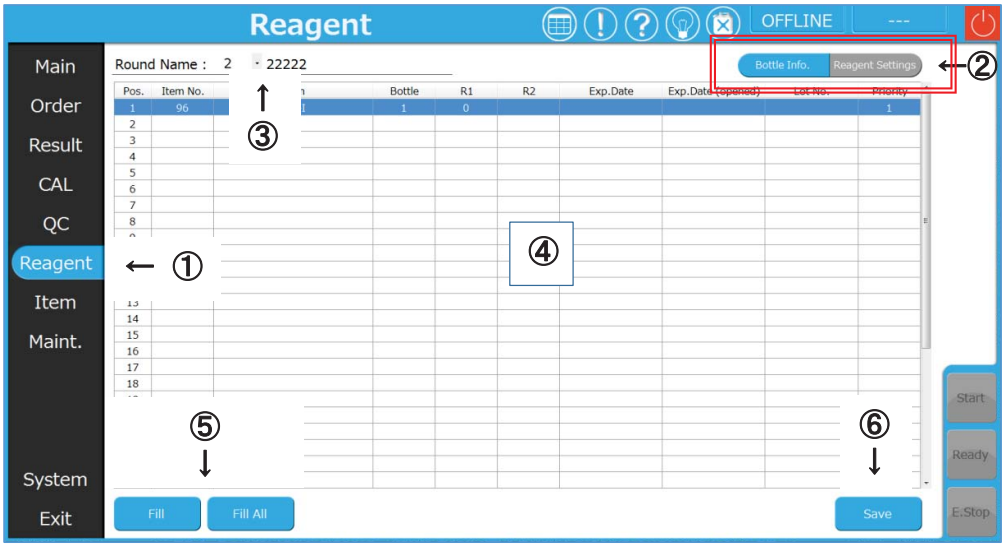


Reagent screen - Reagent Setting screen

Step	Button & Screen	Operation & Display
1	① Reagent	Click "Reagent" button.
2	(PC screen)	Reagent screen is shown.
3	② Reagent setting	Click "Reagent Settings" button.
4	(PC screen)	"Reagent Settings" screen is shown.
5	③ Round name : ▼ (Round name)	Setting of "Reagent round". ➢ Click ▼ button, and select the round number. Input "Round name".
6	④ (1 ～ 36) ⑤ (Item name)	Setting of reagent bottle position. ➢ ④ Select bottle position number from 1～36. (Back color of selected column turns to blue) ➢ ⑤ Select the Item name from right side list.
7	④ (1～36)	Confirm the bottle position. ➢ Display the Item name at lower part for each 1～36 bottle positions.
8	⑥ Save	Bottle settings are stored.

3.2.6 Reagent bottle setting

- Please refer to Chapter 4, 4.6 Reagent screen for details.
- Reagent bottle setting in “Bottle Info” screen follows the procedure steps.

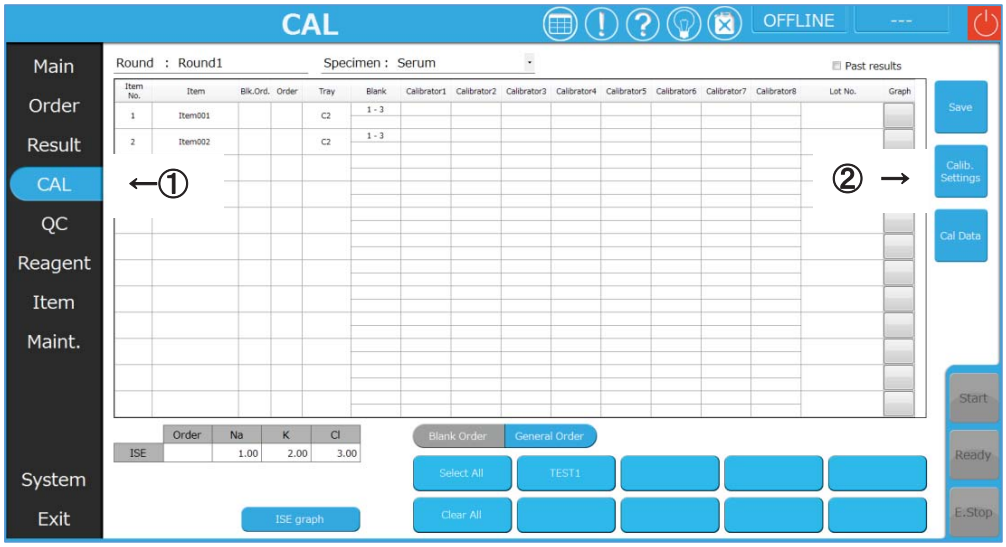


Reagent screen – Bottle Info screen

Step	Button & Screen	Operation & Display
1	① Reagent	Click “Reagent” button.
2	(PC screen)	Reagent screen is shown.
3	② Bottle Info.	Click “Bottle Info” button.
4	(PC screen)	Bottle Info screen is shown.
5	③ Round name : ▼ (Round name)	Select “Reagent round”. ➢ Select the bottle setting round.
6	④ (1～36)	Confirmation of the reagent bottle position and setting. ➢ Reagent tray, position and Item name etc..
7	—	Set the reagent bottle which is confirmed in step 6.
8	⑤ Fill Fill All	Set the reagent remaining. Reagent remain is updated automatically by calculation of measurement condition. Fill=Residual test number are renewed automatically. ・Click Fill after Item selection. Fill All=All reagents are renewed automatically. ➢ In case of “Level sensor” setting, reagent remain is updated by reagent probe movement.
9	⑥ Save	Reagent bottle setting (Reagent residual volume) is stored.

3.2.7 Calibration setting (Standard sample position, concentration)

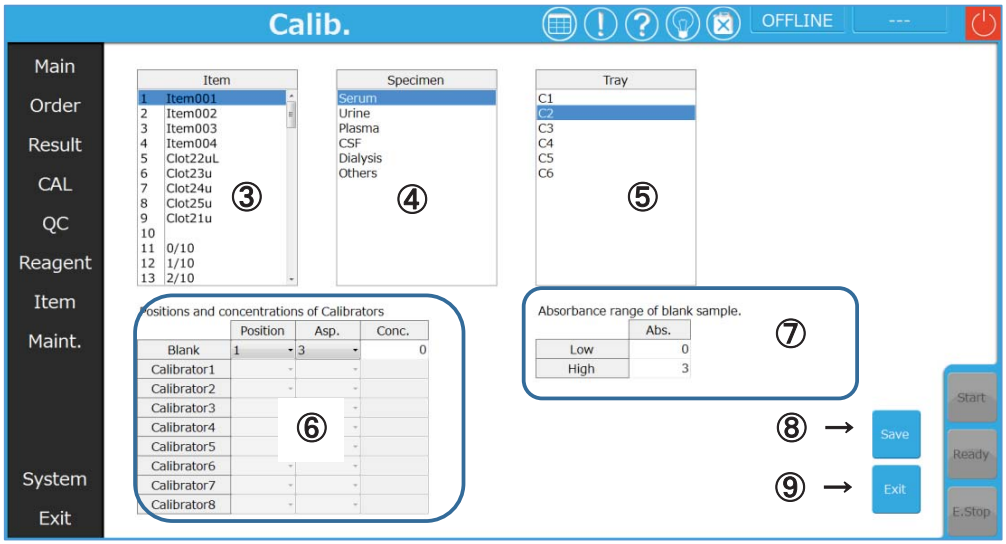
- Input calibration measurement condition (Standard sample position, concentration) in "CAL -Calib . Settings" screen.
- Setting of the ISE Items are unnecessary. Tray and standard positions are fixed.



CAL screen

- Display of Calibration setting screen follows 1-4 steps.

Step	Button & Screen	Operation & Display
1	① CAL	Click "CAL" button.
2	(PC screen)	CAL screen is shown.
3	② Calib. settings	Click "Calib. settings" button.
4	(PC screen)	CAL-Calib. settings screen is shown.



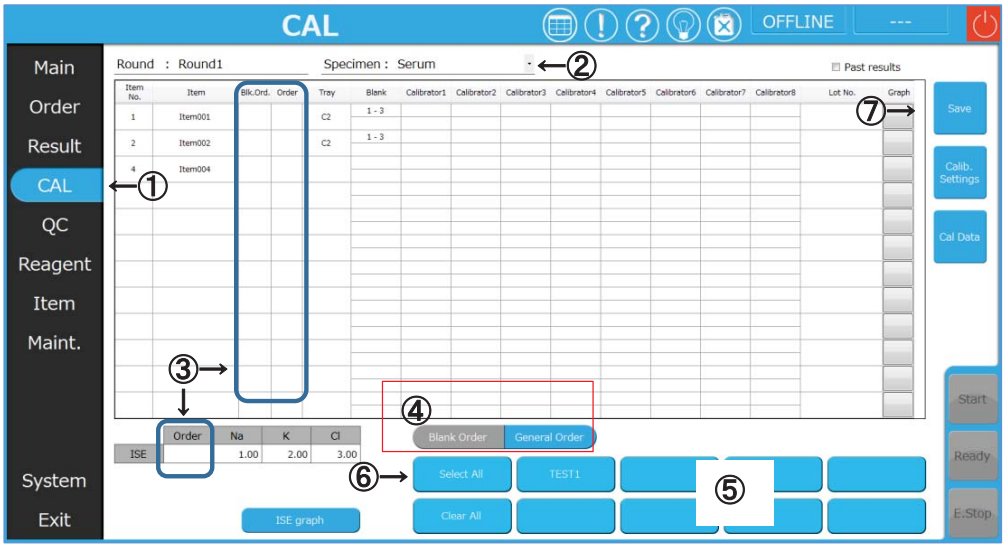
CAL-Calib. Settings screen

➢ Setting of Calibration measurement in Calib. Settings screen follows the procedure steps.

Step	Button & Screen	Operation & Display
5	③ Item name	Select “Item name”.
6	④ Specimen: ▼	Select “Specimen”.
7	⑤ Tray	Select using calibration tray for measurement. ➢ ISE calibration tray is fixed to C1.
8	⑥ In ☐ box ➢ Position ➢ Asp. ➢ Conc.	Setting of calibrator position and concentration. ➢ ISE calibrator positions are fixed. Setting of calibration measurement. ➢ Select position of “Blank” and “Standard sample” ➢ Select repetition number. ➢ Input concentration of blank and standard sample.
9	⑦ In ☐ box ➢ Lower limit Abs. ➢ Upper limit Abs.	Setting of calibration blank sample Abs. range. ➢ Input lower limit Abs. for blank sample. ➢ Input upper limit Abs. for blank sample. When blank sample is out of range, error displays. No check if the setting is zero.
10	⑧ Save	Calibration setting is stored.
11	⑨ Exit	Close the Calib. Settings screen and return to CAL screen.

3.2.8 Calibration order entry

➢ Calibration order entry in "CAL" screen follows the procedure steps.

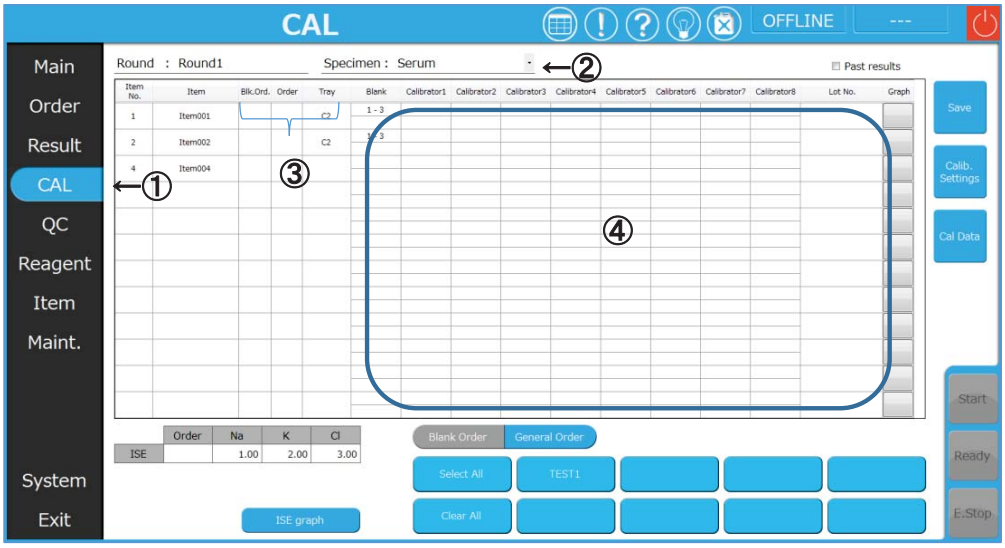


CAL screen

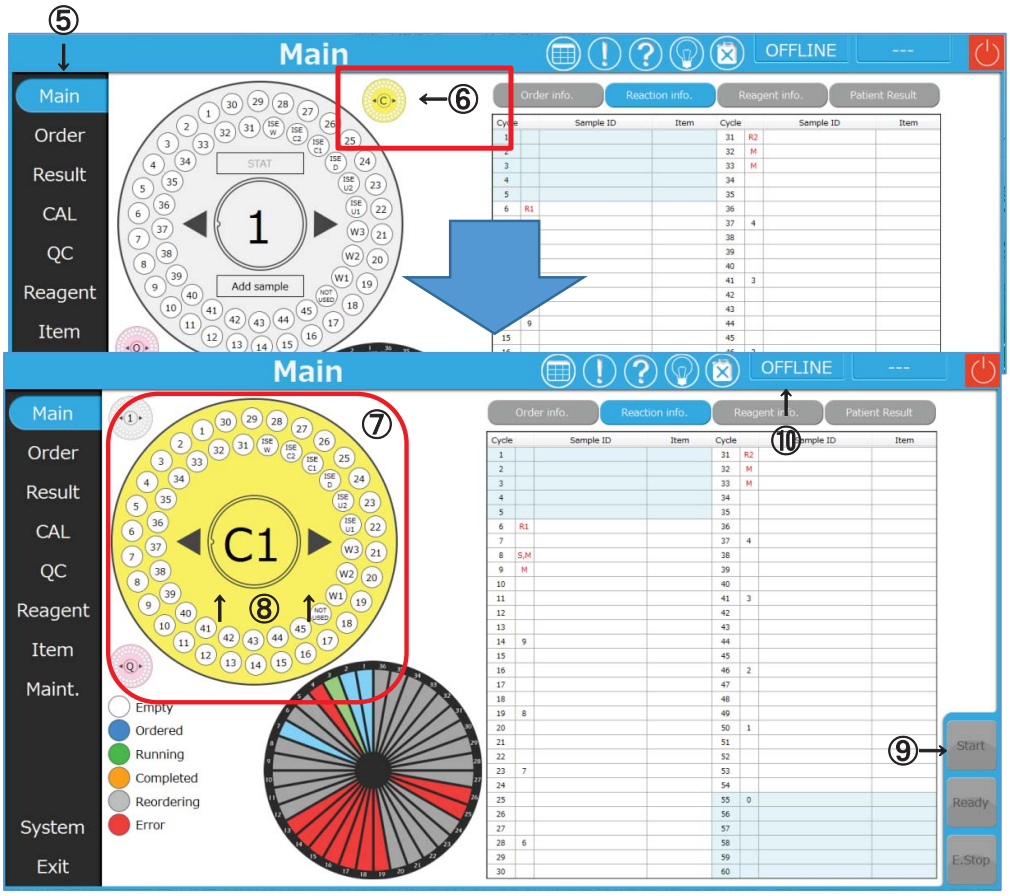
Step	Button & Screen	Operation & Display
1	① CAL	Click "CAL" button.
2	(PC screen)	CAL screen is shown.
3	② Specimen : ▼	Select "Specimen".
4		Order entry of calibration by Item selection. ➢ Order status turns to blue for blank order or dark blue for general calibration.
	③ Blank order ☐ Order ☐	Check the box ☑ for each Item. ➢ Blank Order=Order entry of blank sample only. ➢ Order = Order entry of blank and standard sample.
	④ Blank order ☐ Order ☐	Click Blank Order or Order button, and select "Profile name" or Select All. ➢ Blank Order=Order entry of blank sample only. ➢ Order = Order entry of blank and standard sample.
	⑤ In ☐ box (Profile name)	Select profile Items.
	⑥ Select All	Select all the displayed Items.
5	⑦ Save	Calibration order entry is stored.

3.2.9 Calibration sample setting (Blank, Standard) and measurement

➢ Calibration blank and standard sample setting and measurement follows the procedure steps. For ISE item, refer to Chapter 3, 3.2.10 ISE calibration sample setting and measurement.



CAL screen



Main screen —CAL tray selection

Step	Button & Screen	Operation & Display
1	① CAL	Click "CAL" button.
2	(PC screen)	CAL screen is shown.
3	② Specimen: ▼	Select "Specimen".
4	③ ➢ Blank order/Order ④ ➢ Tray In ▭ box Upper parts Position-repetition	Confirmation of calibration order entry. ➢ Order status turns to dark blue for blank and standard sample or blue for blank sample in Item box ☑. ➢ Tray number. ➢ Measurement position and repetition number upper parts from Blank to Standard 8 positions. Left side of hyphen shows measurement position. Right side of hyphen shows repetition number.
5	⑤ Main	Click "Main" button.
6	(PC screen)	Main screen is shown.
7	⑥ CAL tray Icon (Yellow)	Click "CAL " tray Icon.
8	⑦ CAL tray Icon (Yellow)	CAL tray screen is expanded.
9	⑧ CAL tray Icon (Yellow)	Select tray number which selected in step 3 by clicking ◄ or ► button.
10	—	➢ Back color of ordered sample turns to blue in tray position. Set the blank and standard sample which confirmed in step 4 on the tray.
11	⑨ Start	Click "Start" button.
12	—	Starts the calibration measurement.
13	⑩ Analyzer status monitor	When the analyzer is running→ Indicates [RUN] After sampling stop →Indicates [S.STOP]
14		After calibration completed→ Indicates [END]

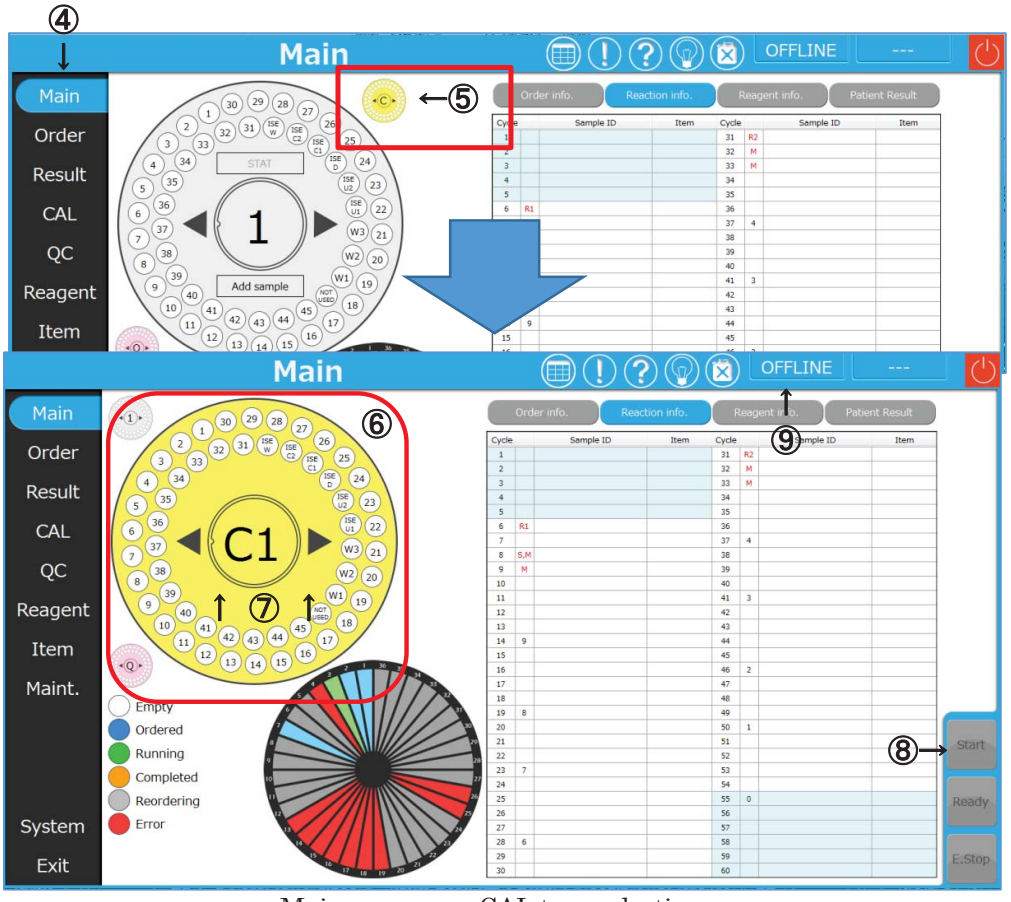
Note:

- When calibrate the different specimen, please order and save for each specimen.
  All of the ordered specimen perform the calibration measurement.
- When using the Item No.106 of HbA1c, please order both of Item No. 107 and 108 for calibration measurement.

3.2.10 ISE Calibration sample setting and measurement

- ISE calibration for plasma sample is unnecessary.　Serum sample calibration is used.
- ISE calibration sample setting and measurement follows the procedure steps.

CAL screen

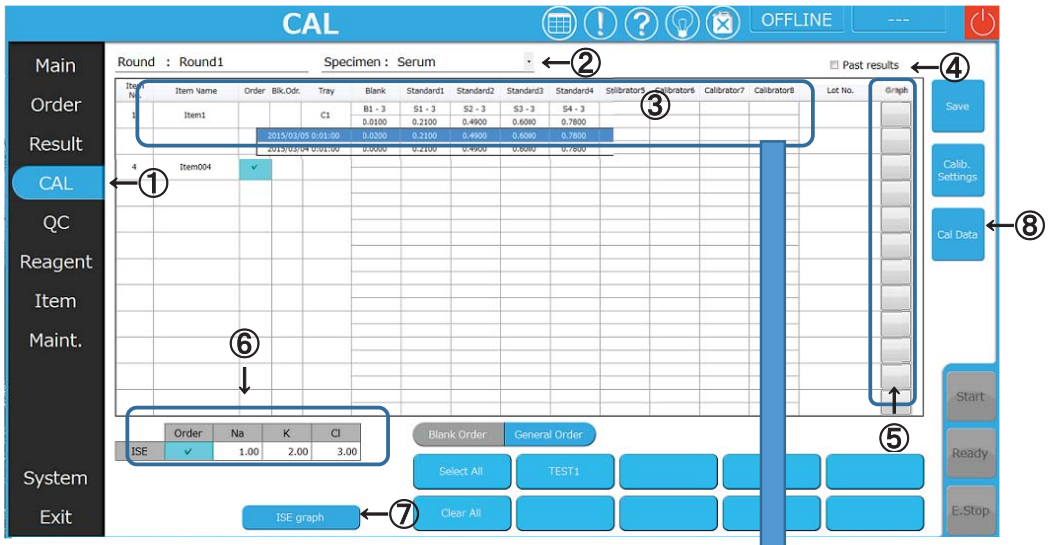


Main screen　－CAL tray selection

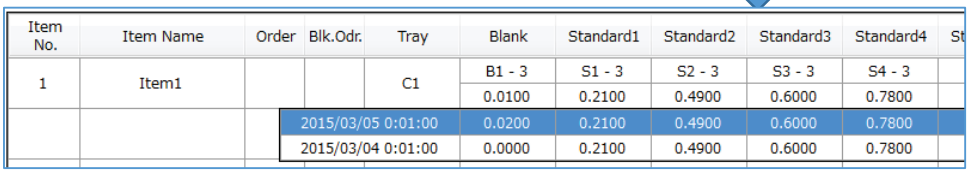
Step	Button & Screen	Operation & Display
1	① CAL	Click "CAL" button.
2	(PC screen)	CAL screen is shown.
3	② Specimen: ▼	Select "Specimen".
4	③ In ☐ box	Confirmation of calibration order entry. ➢ Order status turns to blue.
5	④ Main	Click "Main" button.
6	(PC screen)	Main screen is shown.
7	⑤ CAL tray Icon (Yellow)	Click "CAL " tray Icon.
8	⑥ CAL tray Icon (Yellow)	CAL tray screen is expanded.
9	⑦ CAL tray Icon (Yellow)	Select tray number C1 by clicking ◄ or ► button.
10	—	Set the Calibrator cup (250uL) on the tray. ➢ Back color of ordered sample turns to blue in tray position. ISE calibration positions are fixed in program. ISE C1= (for serum) Calibrator A ISE C2=(for serum) Calibrator B ISE U1=(for urine) Urine calibrator 1. ISE U2 = (for urine) Urine calibrator 2 ISE D = (for dialysis) Dialysis calibrator
11	⑧ Start	Click "Start" button.
12	—	Starts the calibration measurement.
13	⑨ Analyzer status monitor	When the analyzer is running→ Indicates [RUN] After sampling stop→ Indicates [S.STOP]
14		After calibration completed→ Indicates [END]

3.2.11 Calibration result confirmation

- Confirmation of Calibration result in CAL screen.
- Please refer to Chapter 4, 4.4 CAL screen for details.



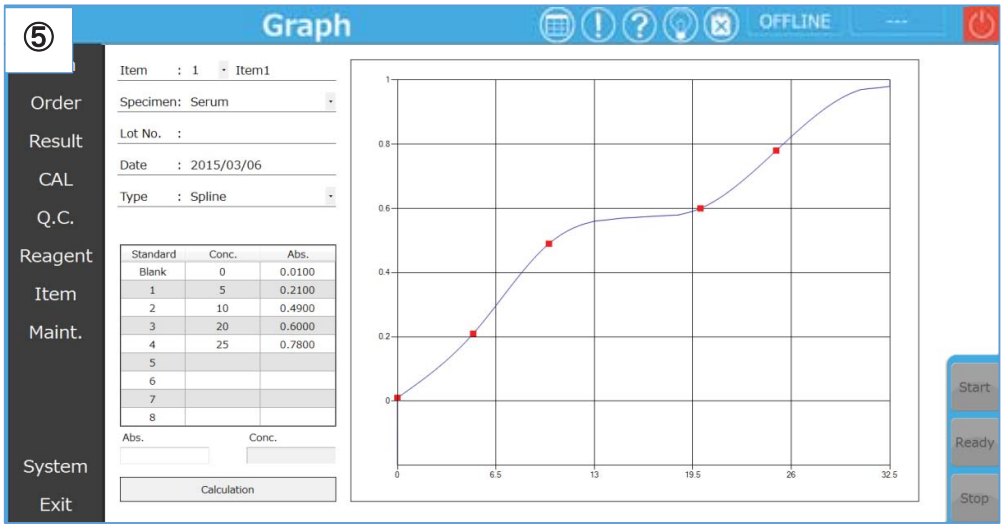
CAL screen



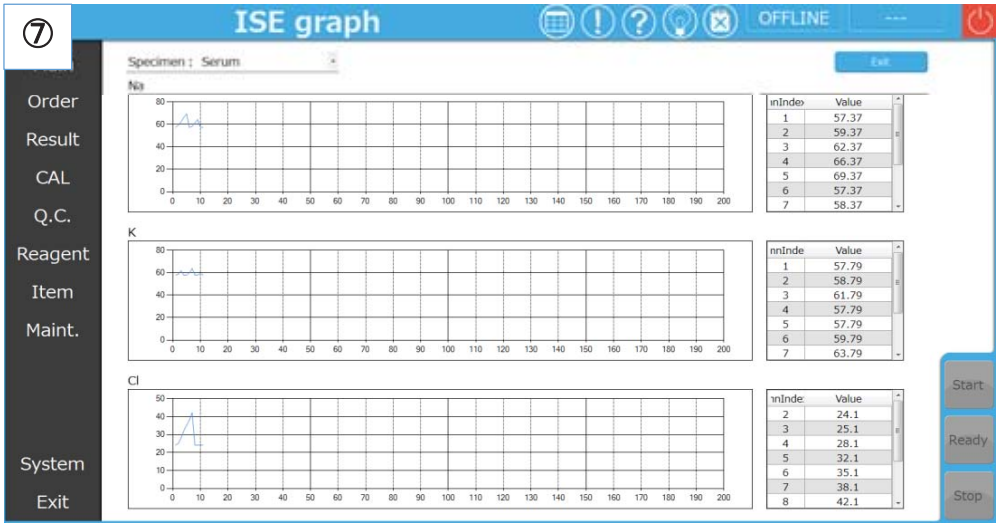
CAL screen — Display of former Calibration results

Step	Button & Screen	Operation & Display
1	① CAL	Click "CAL" button.
2	(PC screen)	CAL screen is shown.
3	② Specimen: ▼	Select "Specimen".
3	③ In ☐ box	Confirmation of calibration result. Absorbance results ➢ The Absorbance value displays lower part from Blank to Standard 1-8.
3	④ ☐Old Data	Former results ➢ Check the Old data box □, select the Item name.
3	⑤ Graph	Display result graph ➢ Display graph screen of selected Item.
3	⑥ In ☐ box ⑦ ISE graph	ISE results ➢ Display of latest results. ➢ Display of graph or list of former results.
3	⑧ Cal Data	Display of calibration result for details. ➢ When ISE calibration result is out of graph, the calibration is an error. Need to try re-calibration measurement.

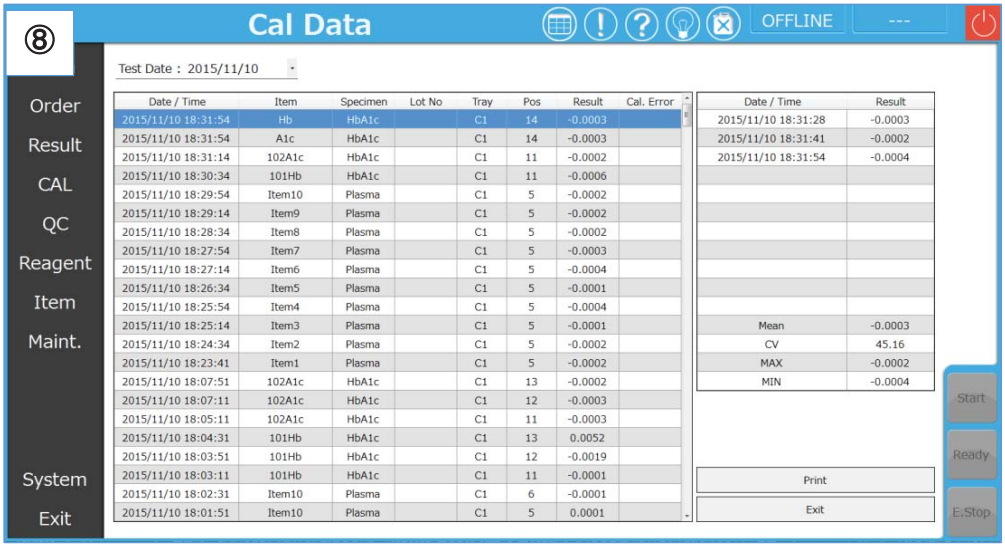
➢ Please refer to Chapter 4, 4.4 CAL screen for calibration graph and results.



CAL screen—Graph screen



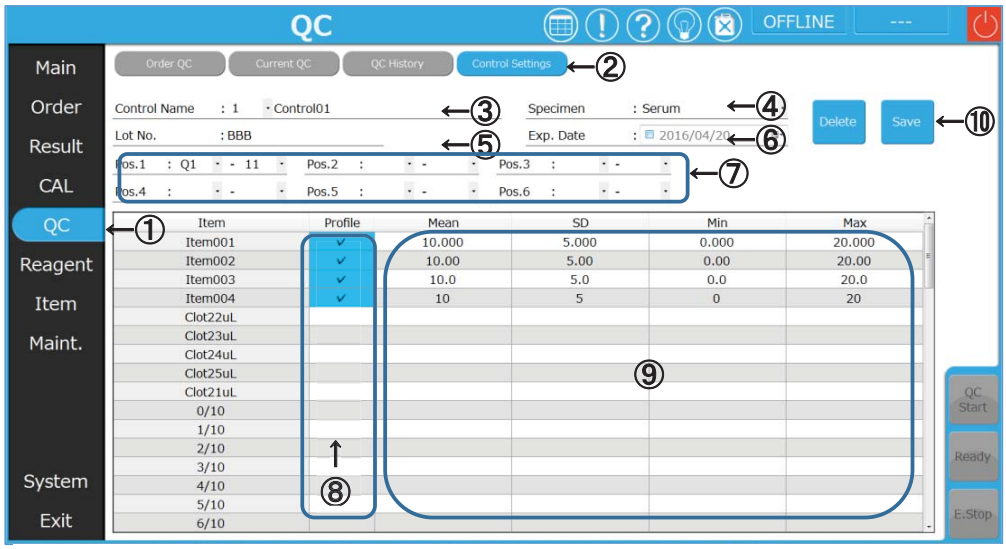
CAL screen—ISE Graph screen (When result is out of range, the graph is not displayed.)



CAL screen—Cal Data screen

3.2.12 QC measurement condition setting (Control setting)

- Setting of QC measurement (QC sample name, measurement position, mean) follows the procedure steps.
- Please refer to Chapter 4, 4.5 QC screen for details.

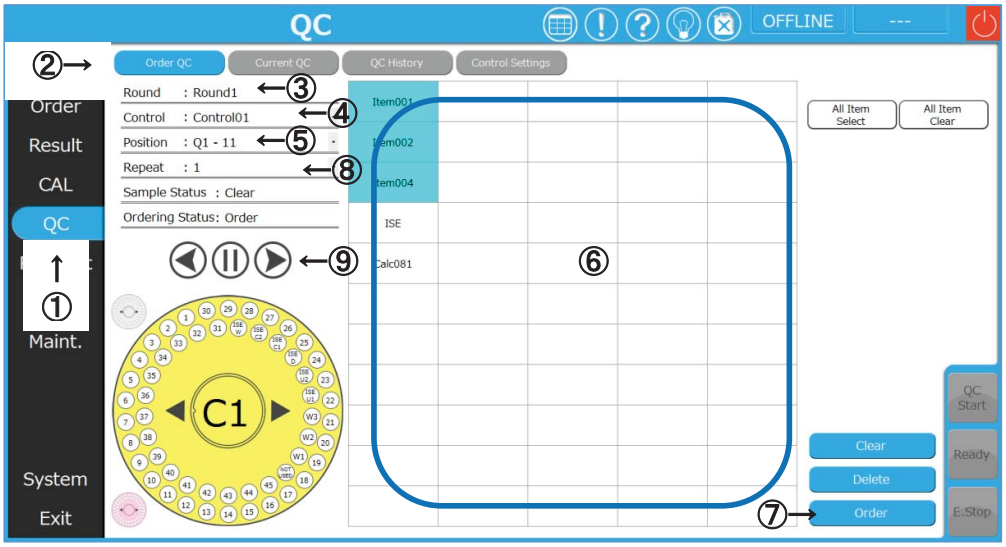


QC screen—Controls Settings screen

Step	Button & Screen	Operation & Display
1	① QC	Click "QC" button.
2	(PC screen)	QC screen is shown.
3	② Control settings	Click "Control Settings" button.
4	(PC screen)	Control settings screen is shown.
5	③ Control name:___▼	Select Item number and input control name.
6		Setting or input of QC measurement.
	④ Specimen: ▼	Select "Specimen".
	⑤ Lot No.	Input Lot number of QC sample.
	⑥ Exp. date:☐ _ _▼	Check the box ☑ when input the expire date. Select QC sample expire date in calendar date.
	⑦ Pos.1 : ▼ - ▼ ～ Pos.6 : ▼ - ▼	Select QC sample tray and position. ➢ Left side of hyphen shows sample tray. Right side of hyphen shows sample position.
	⑧ Profile☐	Setting of QC sample profile. ➢ Check the box ☑ to setting the QC profile order. (Ordered sample turns to blue.)
	⑨ Mean, SD, Min, Max	Input control values (Mean, SD, Max and Min). ➢ Min and MAX±2SD are calculated automatically.
7	⑩ Delete Save	QC sample setting (profile) is deleted. QC sample setting is stored.

3.2.13 QC sample order entry

➢ Order entry of QC sample in "Order QC" screen follows the procedure steps.

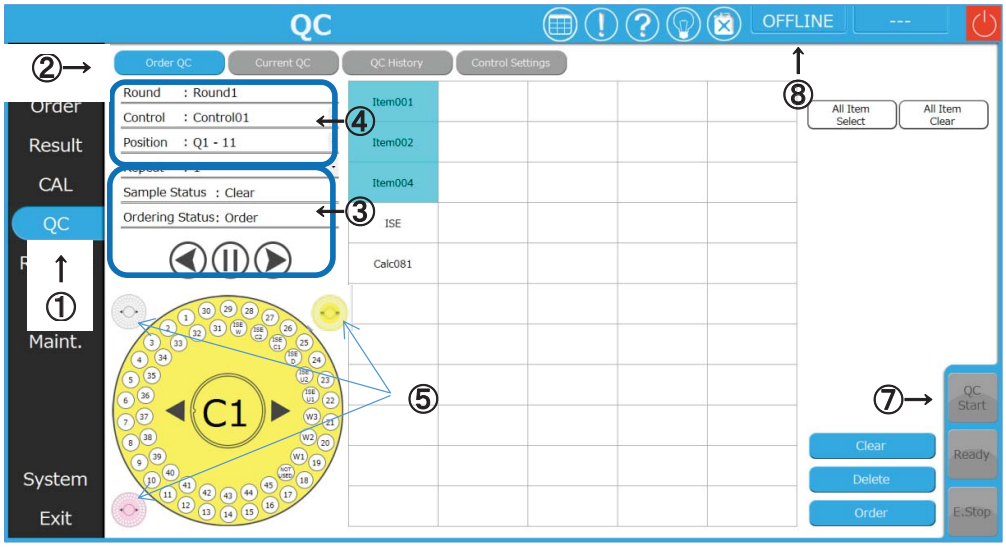


QC screen— Order QC screen

Step	Button & Screen	Operation & Display
1	① QC	Click "QC" button.
2	(PC screen)	QC screen is shown.
3	② Order QC	Click "Order QC" button.
4	(PC screen)	Order QC screen is shown.
5		Select QC sample measurement Item.
	③ Control: ▼	Select QC sample name.
	④ Position : ▼	Select measurement position (Sample tray— sample position).
	⑤ #of Asp: ▼	Select repetition number.
	⑥ In ☐ box (Item name)	Confirmation of order entry. ➢ Profile setting Items are ordered automatically. ➢ Back color of ordered Item turns to blue.
6	⑦ Order	Order entry of QC sample measurement. ➢ After order entry, display next "Order QC" screen automatically.
	➢ When continue the order, follows the step 5 to 6.	
7	⑧ Sample states : _____	Confirmation of QC sample order entry Display the "Order".
	⑨ ◀ ▶	When order the multiple QC samples, confirm the order by clicking ◀ or ▶ button.

3.2.14 QC sample setting and measurement

➢ QC sample setting on the sample tray and measurement follows the procedure steps



QC screen— Order QC screen

Step	Button & Screen	Operation & Display
1	① QC	Click "QC" button.
2	(PC screen))	QC screen is shown.
3	② Order QC	Click "Order QC" button.
4	(PC screen)	Order QC screen is shown.
5	③ In ☐ box Sample state : ____ ④ In ☐ box Control : ____▼ Position : ____▼ #of Asp : ____▼	Confirmation of QC sample order entry. ➢ Display "Order". ➢ Confirm of all the order entry by clicking ◄ or ► button. ➢ QC sample name. ➢ Measurement position. Left side of hyphen shows sample tray. Right side of hyphen shows sample position. ➢ Repetition number.
6	⑤ Tray Icon	Select tray Icon which confirmed in step 5. Patient tray=Gray Calibration tray=Yellow QC sample tray=Pink

Step	Button & Screen	Operation & Display
7	⑥ Tray Icon ◄ ►	Select tray number which confirmed in step 5 by clicking ◄ or ► button. Patient tray=1~50 Calibration tray=C1~C6 QC sample tray=Q1~Q3
8	—	➢ Back color of ordered sample turns to blue in tray position. Set the QC sample which confirmed in step 5 on the tray.
9	⑦ QC Start	Click "QC Start" button.
10	—	Starts the QC sample measurement.
11	⑧ Analyzer status monitor	When the analyzer is running→ Indicates [RUN] After sampling stop→ Indicates [S.STOP]
12		After QC sample measurement completed→ Indicates [END]

3.2.15 QC sample result confirmation

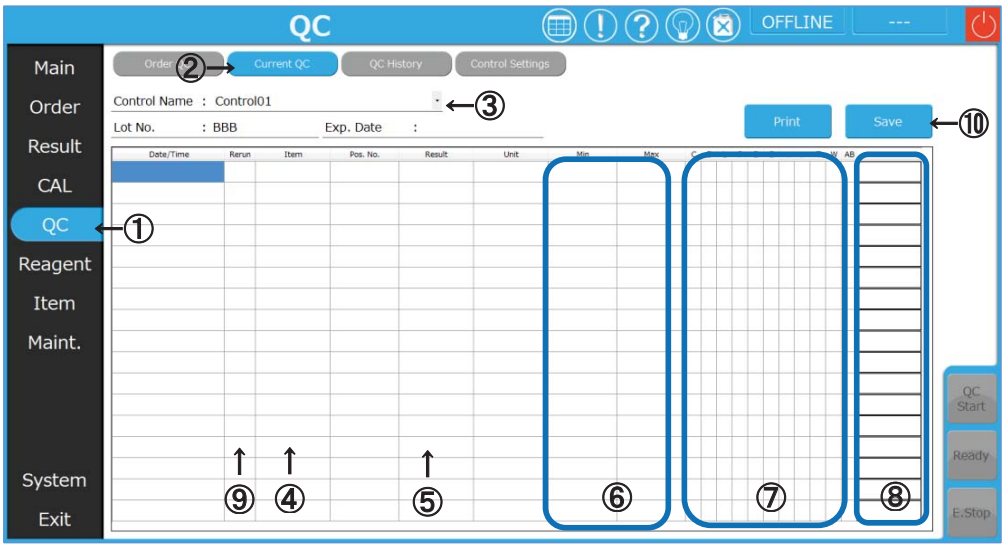
QC sample results are shown in next screens.

- Current QC screen : Latest QC measurement result list is shown.
- QC History screen : QC measurement result graph and list are shown for each Items.

When QC result is out of range or error occurred, confirm the reagent and QC sample. Rerun or recalibration is required if necessary.

1. Current QC screen

- Latest QC measurement result is shown. QC result is reflected to the QC History.
- Rerun order of QC sample is possible in this screen.



QC screen-Current QC screen

- Confirmation of QC result in “Current QC screen” follows the procedure 1 to 7steps
- Rerun order of QC sample follows the procedure 8– 9 steps.

Step	Button & Screen	Operation & Display
1	① QC	Click “QC” button.
2	(PC screen)	QC screen is shown.
3	② Current QC	Click “Current QC” button.
4	(PC screen)	Current QC screen is shown.
5	③ Control name: ____▼	Select QC sample name.
6	④ Item ⑤ Result ⑥ Min, Max ⑦ (Error flag)C ～AB	Confirmation of QC result Item name Result value Result value which is within ±2SD. ➢ When result is out of ±2SD, back color turns to red. Confirm no error within run. ➢ When error occurred, related box turns to red.

➢ Please refer to Chapter 6 for details.

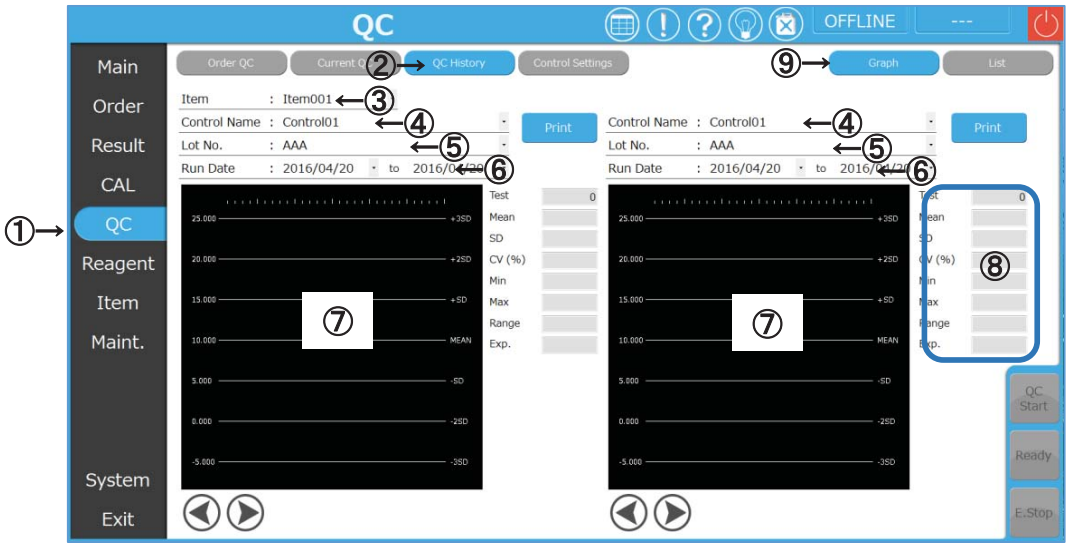
Step	Button & Screen	Operation & Display
7	⑧ (Approve)	The Approved result is reflected to QC History.

➢ Rerun order procedure of QC sample

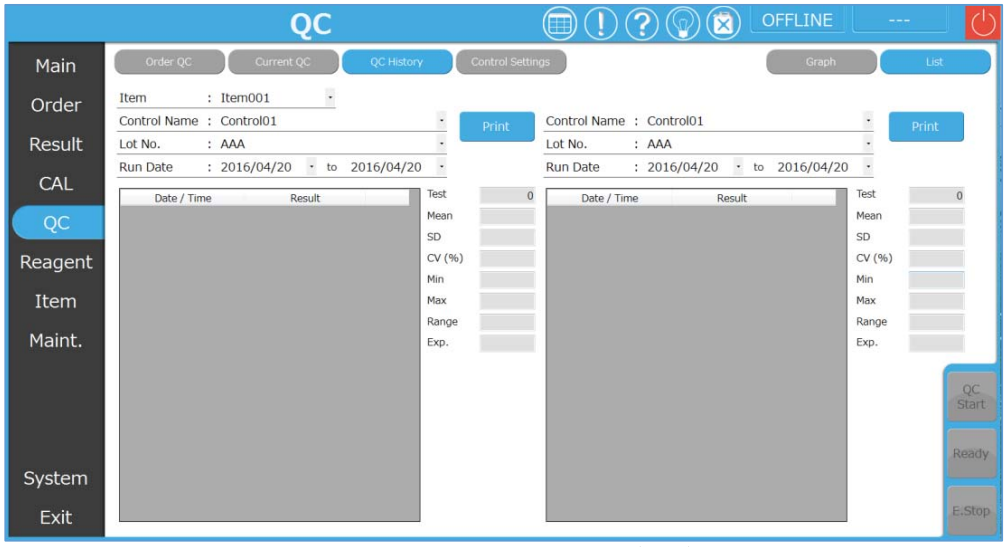
Step	Button & screen	Operation & Display
	➢ When the QC result is out of range or error occurred, perform the reagent and QC sample check include expire date. Rerun or Recalibration is required if necessary.	
8	⑨ Rerun	Select the Item for rerun order. ➢ The ordered Item turns to blue.
9	⑩ Save	QC sample order and rerun order are registered. ➢ Rerun measurement of QC sample is same procedure as patient sample. Please refer to Chapter 3, 3,2,14 Patient sample setting and measurement.

2. QC History screen

- QC results are shown by graph or list.
  Two QC sample results are able to display for one Item.



QC screen- QC History screen (Graph)



QC History screen (List)

Step	Button & Screen	Operation & Display
1	① QC	Click “QC” button.
2	(PC screen))	QC screen is shown.
3	② QC History	Click “QC History” button.
4	(PC screen)	QC History screen is shown.
5	③ Item name: ____▼	Select Item name.
6	④ Control name: ____▼	Select QC sample name.

Step	Button & Screen	Operation & Display
7	⑤ Lot No.:____▼	Select QC sample Lot number.
8	⑥ Run date: ____▼	Select date.
9	⑦ In ☐ box	Display of the QC history graph or list.
10	⑧ In ☐ box	Display of the statistical results for each sample.
11	⑨ Graph or List	Select the graph or list.

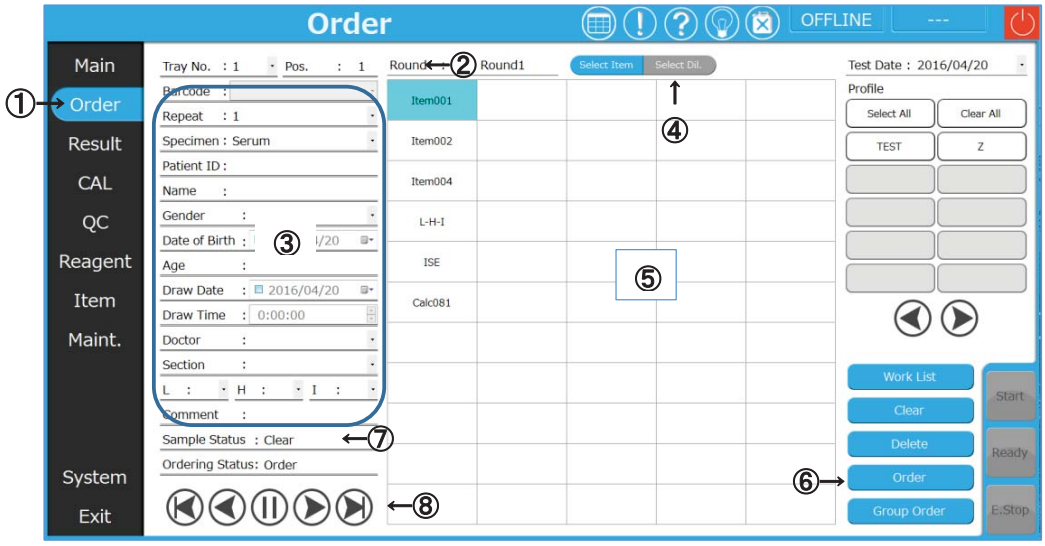
- If the QC result is unstable which suspected systematic error or random error, the analyzer needs to movement check and total maintenance include reagents and sample.
- When the graph display, Westgard check mark is attached at upper part. Please refer to Chapter 4, 4.5.4 QC History screen for details.

3.2.16 Patient sample order entry

The order entry of patient sample in “Order “ screen.

When position mode is selected, order entry of patient sample in “Order” screen follows the procedure steps.

➢ When barcode mode is selected, please refer to Chapter4, 4.2 Order screen. (Patient sample order)



Order screen

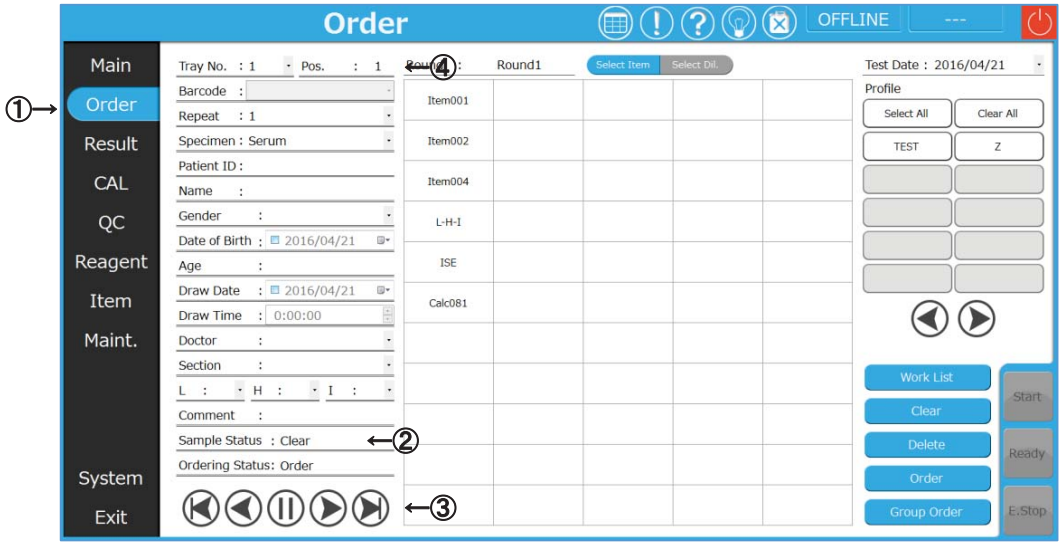
Step	Button & Screen	Operation & Display
1	① Order	Click “Order” button.
2	— (PC screen)	Order screen is shown.
3		Select measurement and sample information.
	② Tray No.: ____▼ Pos.:____▼	Select sample tray. (Essential) Select sample position number. (Essential) ➢ Select by ◄ or ► buttons.
	③ #of Asp: ____▼	Select repetition number. (Essential)
	Specimen:____▼	Select specimen. (Essential)
	Patient ID	Input patient ID
	Name Gender: ____▼ Date of birth Age	(Patient ID input is necessary.)
	Draw date: ____▼	Select blood correcting date.
	Draw time: ____▼	Select blood correcting time.
	Doctor : ____▼ Section : ____▼	(Patient ID input is necessary.)
	L/H/I	Select serum information.
	Comment	Input comment.

Step	Button & Screen	Operation & Display
4	④ Item selection Dilution selection	Click "Item select" button. ➢ When sample dilution is required, select dilution button and dilution ratio.
5	⑤ (Item name)	Select Item name. ➢ Back color of selected Item turns to blue. ➢ When sample dilution selected, display the dilution ratio under the Item name.
6	⑥ Order	Displayed order entry screen is registered. ➢ Next order screen is shown automatically after clicking of order entry button. ➢ When you continue the patient order, follow the procedure 3 - 6 steps.
7	⑦ Sample state : ⑧ ◂ ▸	Confirmation of patient sample order entry ➢ Display the "Order". ➢ All the order entry by clicking ◂ or ▸ button.

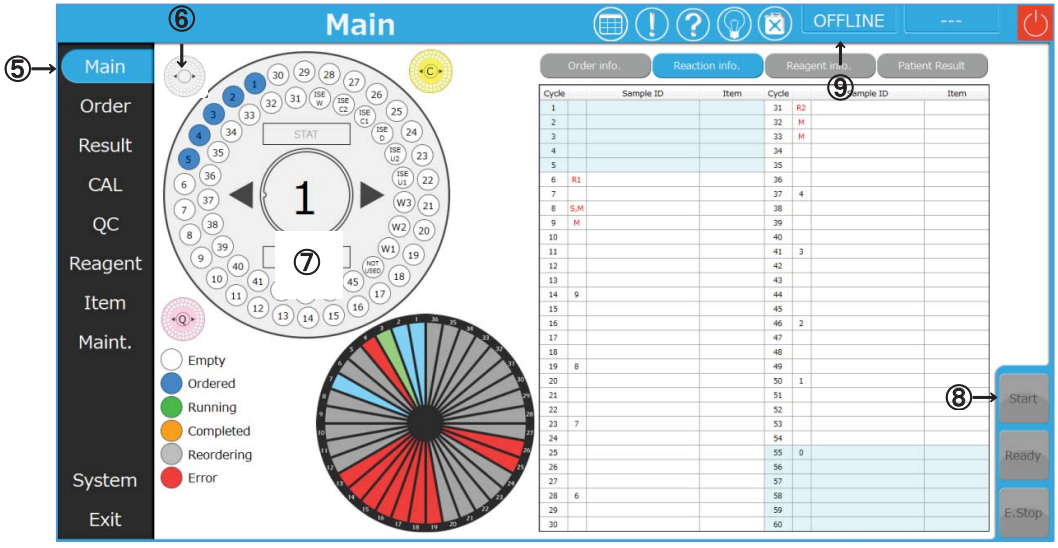
➢ Please refer to Chapter 4, 4.2 "Order screen" for profile order and group order.

3.2.17 Patient sample setting and measurement

- Patient sample order confirmation in “Order” screen before sample setting on the tray follows the procedure 1-4 steps.
- Sample setting on the tray and measurement start follow the procedure 5-13 steps.



Order screen



Main screen – Patient sample tray selection

Step	Button & Screen	Operation & Display
1	① Order	Click “Order” button.
2	(PC screen))	Order screen is shown.
3	② Sample state : ③ ◄ ►	Select “Order” status screen. Select screen by clicking ◄ or ► button.

Step	Button & Screen	Operation & Display
4	④ Tray: _____▼ Position :	Confirmation of patient sample order (Position) ➢ Confirm the tray number and measurement position.
5	⑤ Main	Click "Main" button.
6	(PC screen)	Main screen is shown.
7	⑥ Tray Icon	Select "Patient tray (Gray) Icon".
8	⑦ Tray Icon	Select tray number which checked in step 4 by clicking ◄ or ► button.
9	—	Confirmation of order status on the tray. ➢ Back color of ordered position turns to blue. When the analyzer is running ＝Green Measurement completed＝Orange
10	—	Set the patient sample which confirmed in step 4 on the sample tray.
11	⑧ Start	Starts the measurement.
12	⑨ Analyzer status monitor	When the analyzer is running→ Indicates [RUN] After sampling stop→ Indicates [S.STOP]
13		After patient sample measurement completed→ Indicates [END]

Note:

- Please be careful when dilution ratio is set 0.5, the sample is used two times volume.
- For ISE Items
  1) When measuring the urine sample, need to make six times dilution sample by exclusive dilution solution manually. The analyzer can't make a urine dilution sample automatically.
  2) When using the plasma sample, blood collection tube of Heparin Lithium is recommended for anticoagulant.

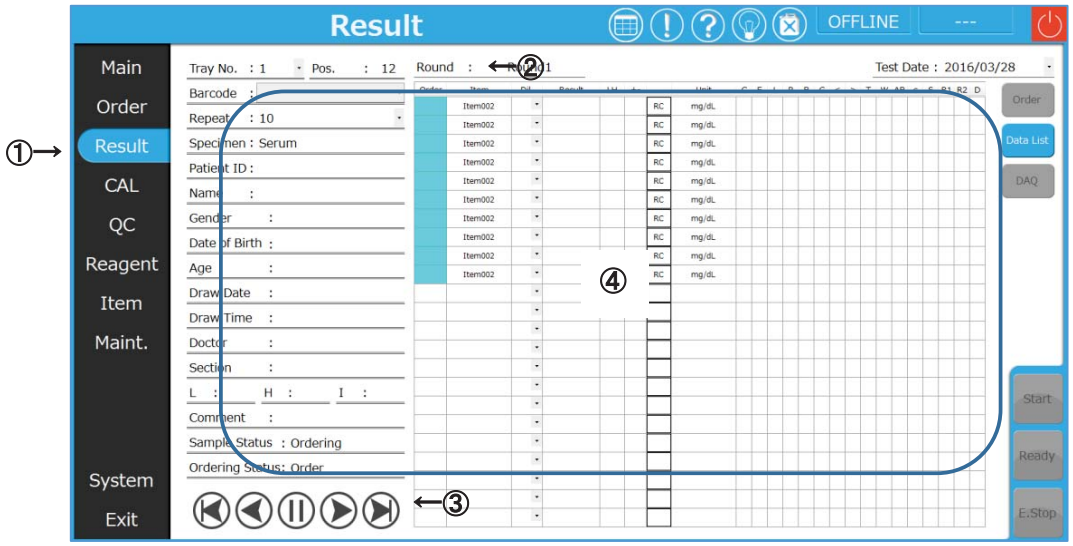
3.2.18 Patient result confirmation

Patient sample results are shown in next 4 screens.

- Result screen : Patient results are shown for each sample.
- Result Log screen : Result list is shown.
- Patient Result screen : Results of measurement day are shown for each sample.
- Data List screen : Display of results, patient history and print out of patient report. When using the data list (Patient report), patient ID input in order screen is necessary.

1. Result screen

- Display of each patient result.
- Please refer to Chapter 4, 4.3 Result screen.



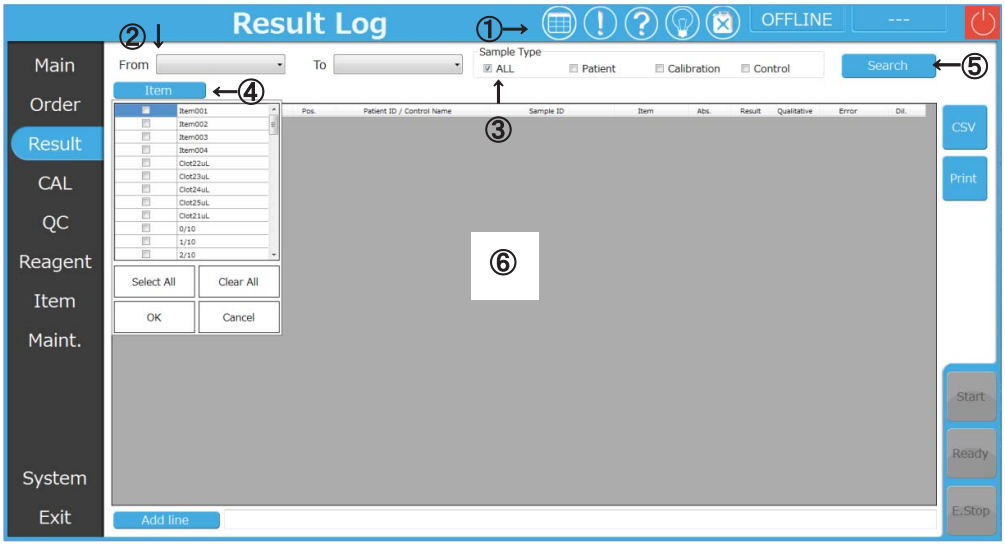
Result screen

Step	Button & Screen	Operation & Display
1	① Result	Click "Result" button.
2	(PC screen))	Result screen is shown.
3	② Tray_▼ Position ▼ ③ ◀ ▶	Select tray number and position number. Select the screen by clicking ◀ or ▶ button.
4	④ Item Result RC □C～D	Confirmation of patient result Item name. Result value. Reaction monitor screen displays for selected Item. No error within run. ➢ When error occurred, related box turns to red.

- Please refer to Chapter 6 .

2. Result Log screen

- Display of Result Log list (Within last 3 months).
- Please refer to Chapter 4, 4.1 Main screen 1.Result log screen.



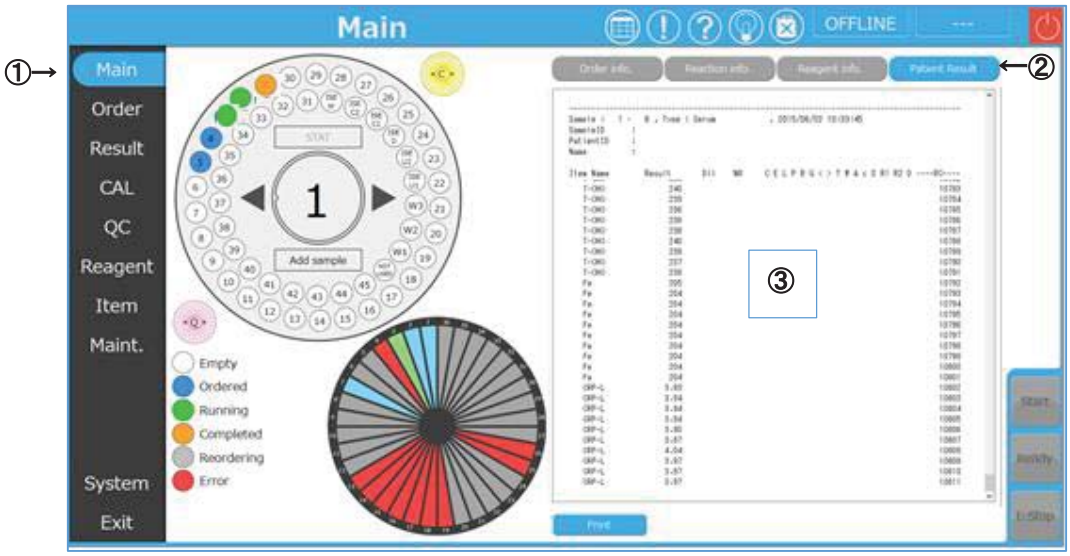
Result Log screen

Step	Button & Screen	Operation & Display
1	① Icon	Click Icon.
2	(PC screen)	Result Log screen is shown.
3	② From____▼ to____▼	Select the date.
4	③ Specimen: _____▼	Select "Specimen".
5	④ Item	When you display by Item, check the box ☑ of Item.
6	⑤ Search	Click "Search" button.
7	⑥ (Result display) Item Result Error ・・・	Confirmation of result Item name. Result value. No error within run. ➢ When error occurred, the error code is shown.

- Please refer to Chapter 6 .

3. Patient Result screen

- Results of measurement day display by each sample order.
- Please refer to Chapter 4, 4.1 Main screen14. Result screen.

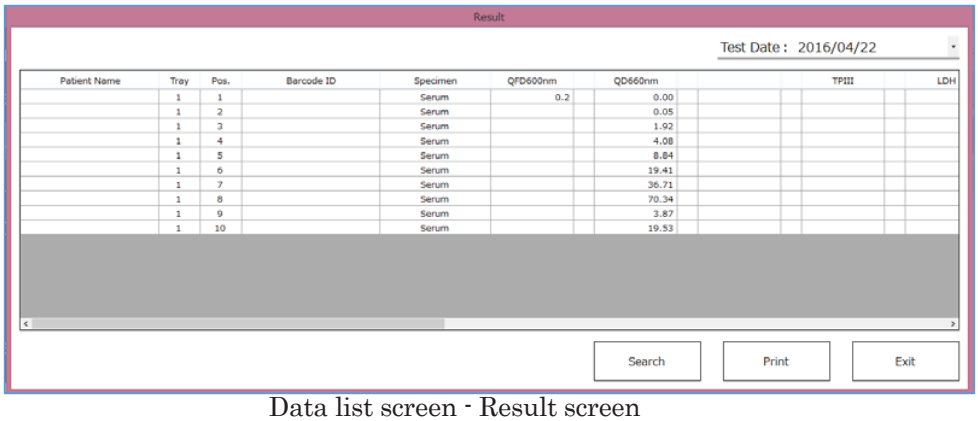


Main screen –Patient Result screen

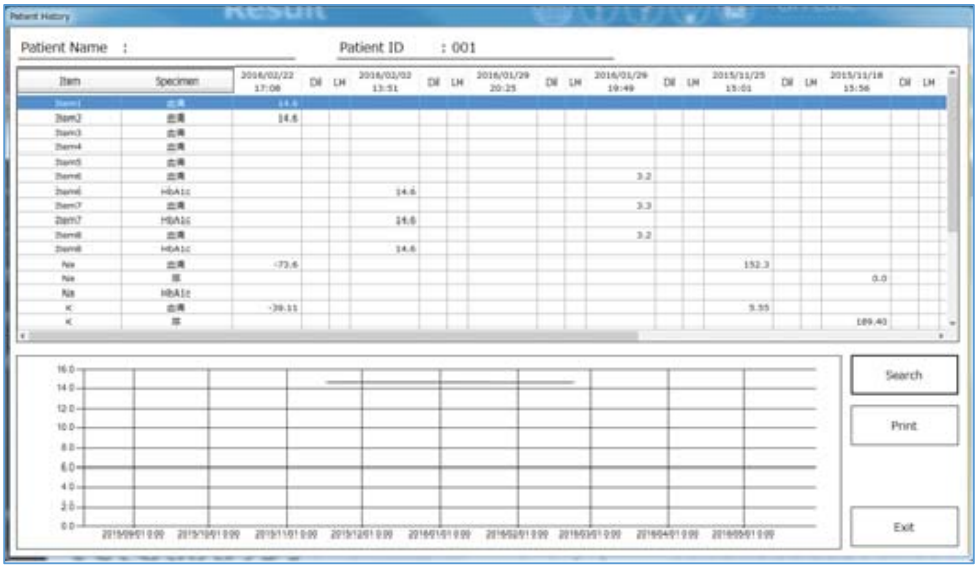
Step	Button & Screen		Operation & Display
1	①	Main	Click “Main” button.
2		(PC screen)	Main screen is shown.
3	②	Patient result	Click “Patient result” button.
4		(PC screen)	Patient result screen is shown.
	③	(Result display) Item Result Error ・・・	Confirmation of the measurement result Item name. Result value. No error within run. ➢ When error occurred, “*”(asterisk) is shown in related column.

4. Data List screen

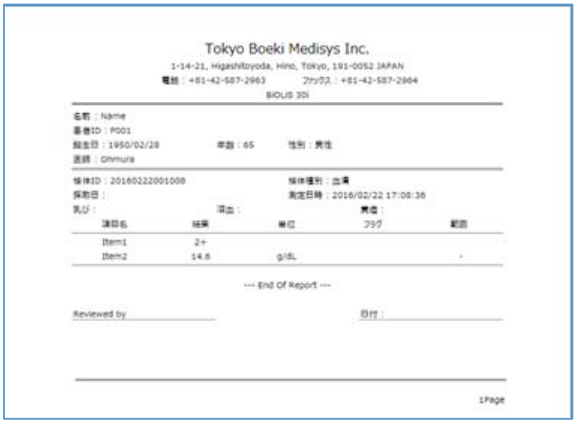
- When using the Data List (Patient report), the patient ID input in order screen is necessary.
- Display of Results, Patient History and print out the Single Report.
- Please refer to Chapter 4, 4.3.1 Data List screen.



Data list screen - Result screen



Data list screen - Patient History screen



Data list screen – Printing of Single Report

3.2.19 Inspection and maintenance at the end of operation

➢ Please perform the following check and maintenance at the end of operation.

1. Caution

➢ Please read and secure the "Preface" in operation manual for "Safety caution- Caution in operation".

When you do the maintenance operation, wear protective globes, mask and glasses to avoid the infection.

2. Inspection and maintenance

➢ Please refer to Chapter 5 Maintenance.

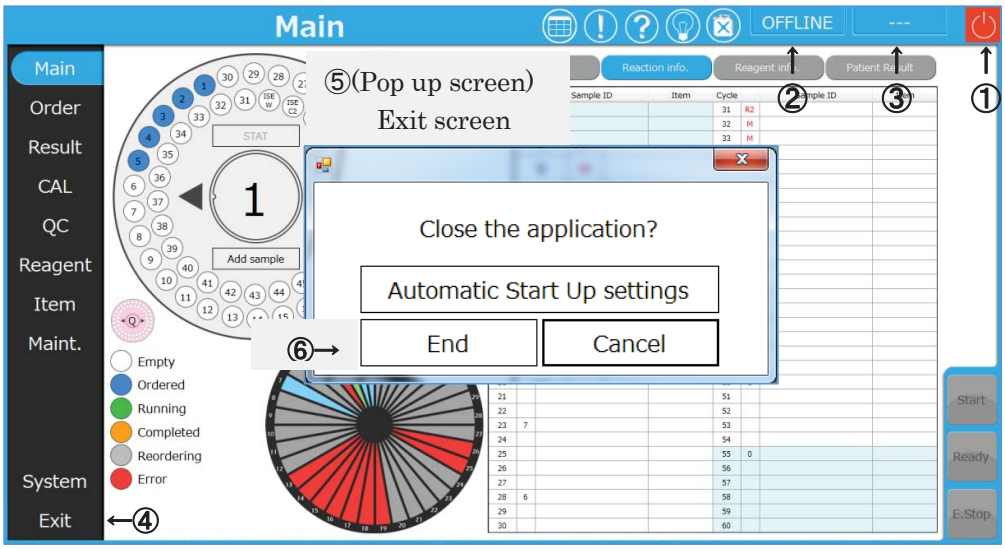
Step	Operation
1	Cleaning of cabinet and reaction cell cover. ➢ Remove the sample on the sample tray. ➢ Wipe the spilled sample and reagent.
2	Cleaning of sample and reagent probes.
3	Empty the drainage reservoir. ➢ When you discard the waste, follow the instruction of related law.

➢ When analyzer is attached the ISE unit, add the following inspections and maintenance.

4	Cleaning of ISE sample pot.
5	Perform the ISE Wash.
6	Empty the ISE drainage tank. ➢ When you discard the ISE waste, follow the instruction of related law.
7	Check the residual Calibrator 1. ➢ Replace the Calibrator 1 if necessary.

3.2.20 Shutdown

➢ Please refer to Chapter 4, 4.10 "Exit" screen when perform the shutdown for automatic start up and after automatic maintenance.



Main screen

Step	Button & Screen	Operation & Display
1	① Icon	Click system power switch Icon. ➢ Analyzer system power turns off. The Icon is inactive when running the analyzer.
2	② Analyzer status monitor	➢ Confirmation of the indication [OFF LINE].
3	③ Temperature control monitor	➢ Confirmation of the indication [---].
4	④ Exit	Click "Exit" button.
5	⑤ (PC screen)	Popup dialog "Exit" screen is shown.
6	⑥ End	Select "End".
7	—	Turn off the system program.
8	—	Turn off the PC power switch.
9	—	Turn off the analyzer main power switch. ➢ The main power switch is left rear side.

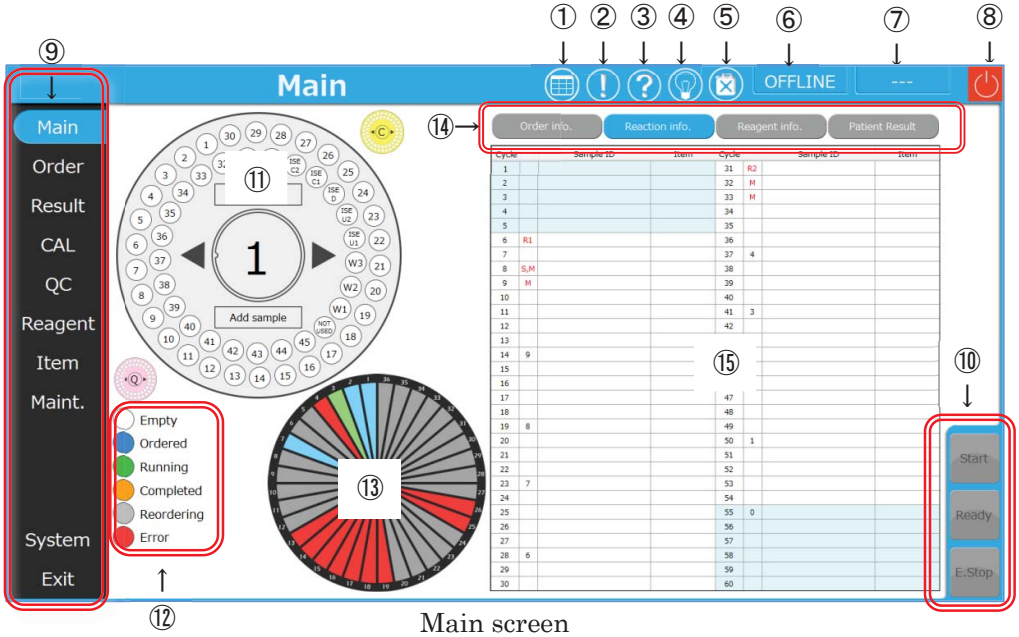
Chapter 4

Explanation of each screen and operating condition

4.1 Main screen

The following informations are shown in Main screen.

4.1.1 The content of Main screen



Main screen

① : Result log screen is open.
② : Error list screen is open.
③ : Help screen is open.
④ : When lamp is ON, turns to yellow.
Display of remain time of lamp life.
⑤ : When tank error occurred, turns to red.

Displays of the analyzer status monitor.

⑥[Analyzer status monitor] : Indicates the analyzer status.
⑦[Temperature control status monitor] : Indicates the reaction tray temperature control status.
⑧ : System power switch.

⑨ Condition setting and operation button.

Main	: Main screen
Order	: Patient sample order entry screen
Result	: Test result screen
CAL	: Calibration menu screen
QC	: QC menu screen
Reagent	: Reagent information screen
Item	: Item parameter screen
Maint.	: Maintenance menu screen

System : System menu screen
Exit : Ending operation screen

⑩ Operation control button

Start : Test starting button, both for patient sample and Calibration sample
QC Start : Test starting button, for QC sample in QC screen.
Ready : Analyzer initializing
E.Stop : Emergency stop

⑪ Sample tray character display

Expanded tray is shown at the center for each tray selection.
The number (1, Q1, C1) at the center of display is tray number.

- QC tray can be selected "ON" in System parameter.

Color	Tray kind
Gray	Patient sample tray
Yellow	Calibration sample tray
Pink	QC sample tray

When patient sample tray is set, the following information are shown.

STAT : Select when set the STAT sample.
STAT sample setting position screen is shown, when analyzer is under operation.
Add sample : Select when set the additional sample.
Analyzer stops sampling, for additional sample testing.

⑫ Testing status monitor (Information table)

: Each sample position on sample tray is colored, depending on the analysis stage.

State	Color	Analysis stage
Empty	White	No sample order
Ordered	Blue	Waiting
Running	Green	Test is running.
Completed	Orange	Test has finished
Reordering	Gray	Rerun is ordered
Error	Red	Test has failed

⑬ Reagent tray monitor

Reagent bottle residual volume range is shown by color.
The number at the display is bottle position number.

Color	Reagent residual status
Gray	No reagent bottle setting
Blue	Above alarm level
Red	Below test stop level
Yellow	Below alarm level
Green	Effective date or effective date after open is expired.

⑭ Test status information request button
Screen changes by clicking each buttons.

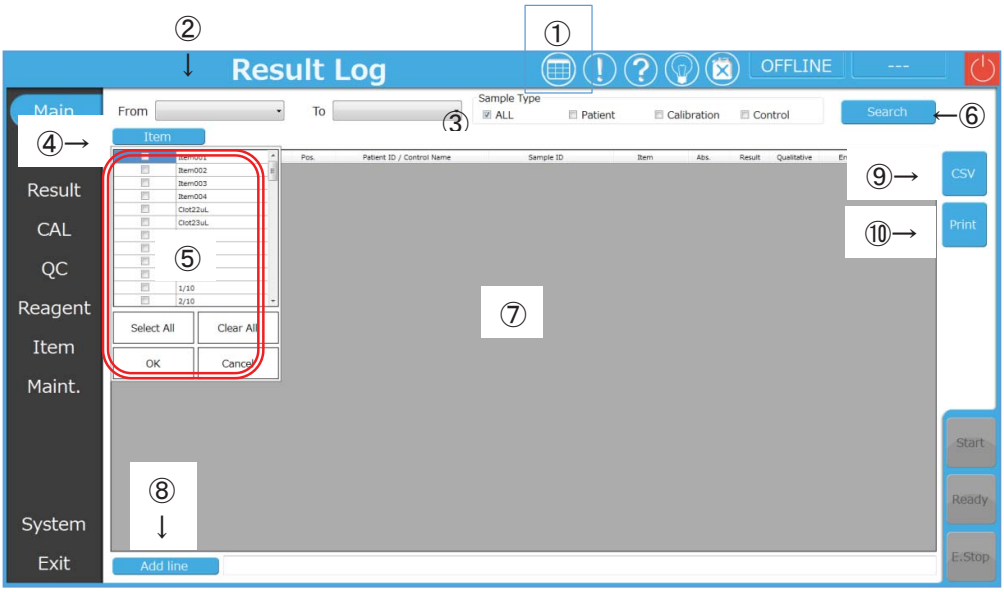
Order info.	: Order entry status
Reaction info.	: Test status
Reagent info.	: Reagent information
Patient Result	: The test results of each sample.

⑮ Detailed information screen display
When you choose one of the buttons of ⑭, detailed information are shown.

1. Result Log screen

- Result Log Icon displays at the upper part in operation screen. Result log screen is able to open when analyzer is under operation.
- Display the result log list of running date. The list is shown by selected date, specimen and Item. The result log designated range in the list export to CSV file or external printer.

① Clicking button, result log screen opens.

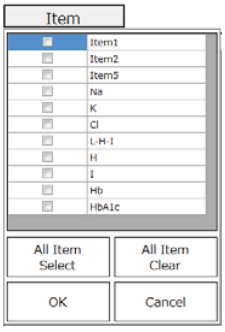


Result log screen

② From ____▼ to ____▼ : Select the starting day and final day of interest.

③ Sample Type : Select sample type of interest.
☐ALL ☐Patient ☐Calibration ☐Control

④ Item : Open ⑤ Item list screen.
⑤ Item selection list : Result is able display by Item.



☐Item name	To select individual test item, input a check mark into desired check box.
All Item Select	Select all items, shown in the table.
All Item Clear	To clear all registered items.
OK	To register the contents of the table.
Cancel	Item selection screen is closed.

⑥ Search : Click search button, test results are shown in ⑦area.

⑦ Display of the result and information.

	Contents
Date /Time	Tested date and time
RC No.	Reaction monitor number
Pos.	Tray number - Position number
PatientID/ Control Name	Patient ID/ QC samle name
Sample ID	Displays ID by selected mode. ➢ Position mode ; Sample ID ➢ Barcode mode ; Sample barcode ID
Item	Item name
Abs.	Optical absorbance
Result	Test result
Qualitative	The result of qualitative judgement. ➢ Registration of qualitative judgement condition is necessary in Item parameter.
Error	Error code ➢ Refer to Chapter 6, Alarm function.
Dil.	Dilution ratio

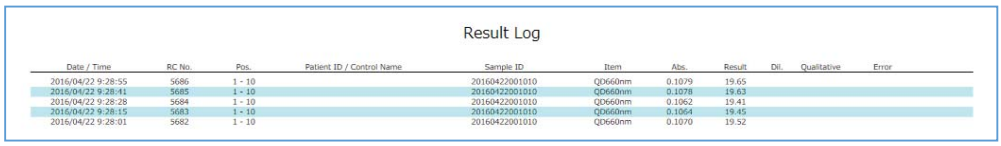
⑧ Add line : "Add line" box is used for test result export to CSV file or external printer.

Export and Printout range setting.

- Input Log number (Left end number)
- Select the lines (Turns to blue), and click Add line button.
  (In case of mutiple line selection)
  Insert conma between the lines.
  (In case of continues range selection)Insert hyphn between the numbers.

⑨ CSV : The result log designated in ⑧Add line is export to CSV file.

⑩ Print (external printer)
: The result log designated in ⑧Add line are printed out by external printer.

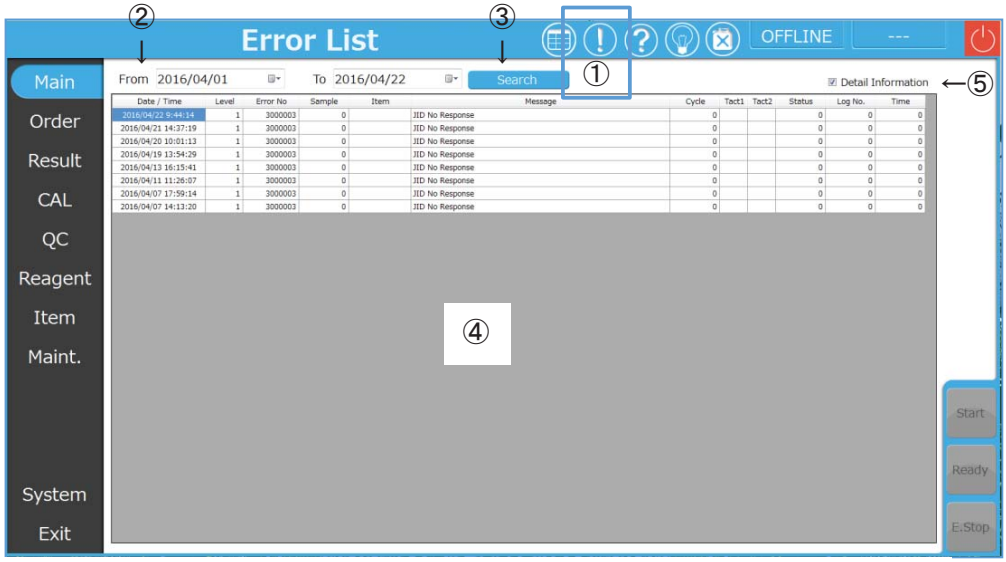

Result Log

Date / Time	RC No.	Pos.	Patient ID / Control Name	Sample ID	Item	Abs.	Result	Dil.	Qualitative	Error
2016/04/22 9:28:55	5686	1 - 10		20160422001010	QD660nm	0.1079	19.65			
2016/04/22 9:28:41	5685	1 - 10		20160422001010	QD660nm	0.1078	19.63			
2016/04/22 9:28:28	5684	1 - 10		20160422001010	QD660nm	0.1062	19.41			
2016/04/22 9:28:15	5683	1 - 10		20160422001010	QD660nm	0.1064	19.45			
2016/04/22 9:28:01	5682	1 - 10		20160422001010	QD660nm	0.1070	19.52			

2. Error list screen

- Error list Icon displays at the upper part in operation screen. Error list screen is able to open when analyzer is under operation.
- Display the error list of the day. The list is able to show by selected date.

① Clicking button, Error list screen opens.



Error list screen

② From ____▼ to____▼ : Select the starting day and final day of interest.
③ Search : Click Search button, Error list is shown in ④ area.
④ Display of the error code and information.

	Contents
Date /Time	Date and time when error occurred.
Level	Error level (1-3) is shown. [1]: Emereny stop error or screen error (When error occurred, screen changes automatically) [2]: Sampling stop (Tank error, clot error) [3]: Warning error
Error No	Error number
Sample	Sample number
Item	Item name
Message	Content of the error

⑤ ☐Detail information : Check the box ☐for error information display.

	Contents
Cycle, Tact1・2, Status, Log No., Time	Please tell the number when inquiring about the error.

3. Help screen 

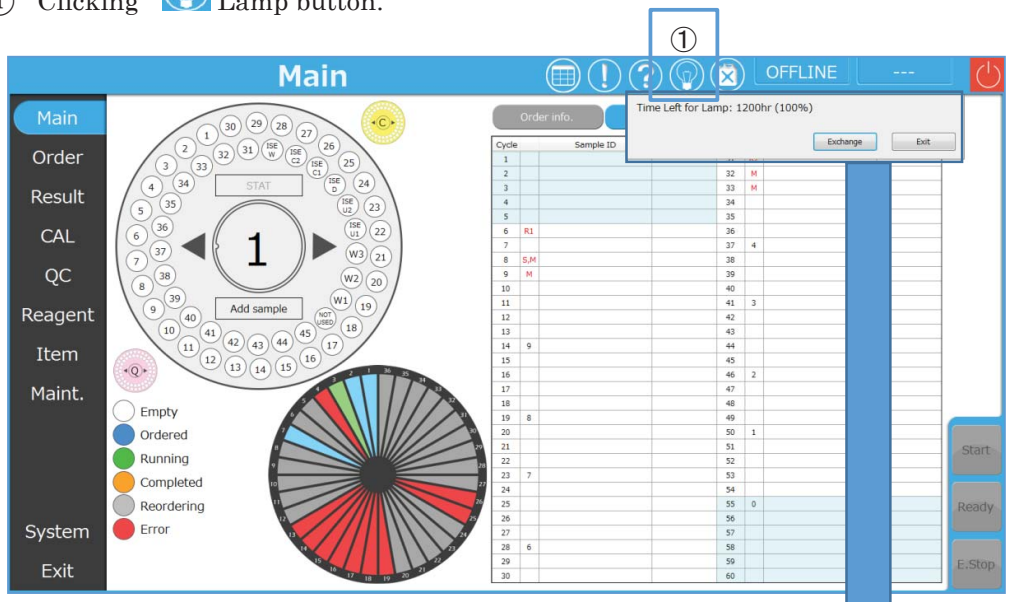
- Help screen Icon displays at the upper part in operation screen. Help screen is able to open when analyzer is under operation.

① Clicking  button, Help screen opens.

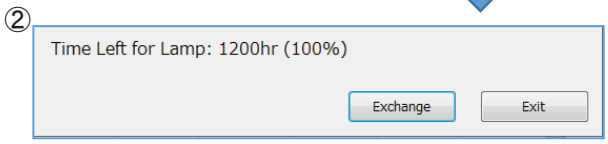
4. Lamp screen

➢ Lamp Icon displays at upper part in operation screen. Lamp screen is able to open when analyzer is under operation.

① Clicking Lamp button.



Main screen



Lamp screen

② Lamp screen opens.

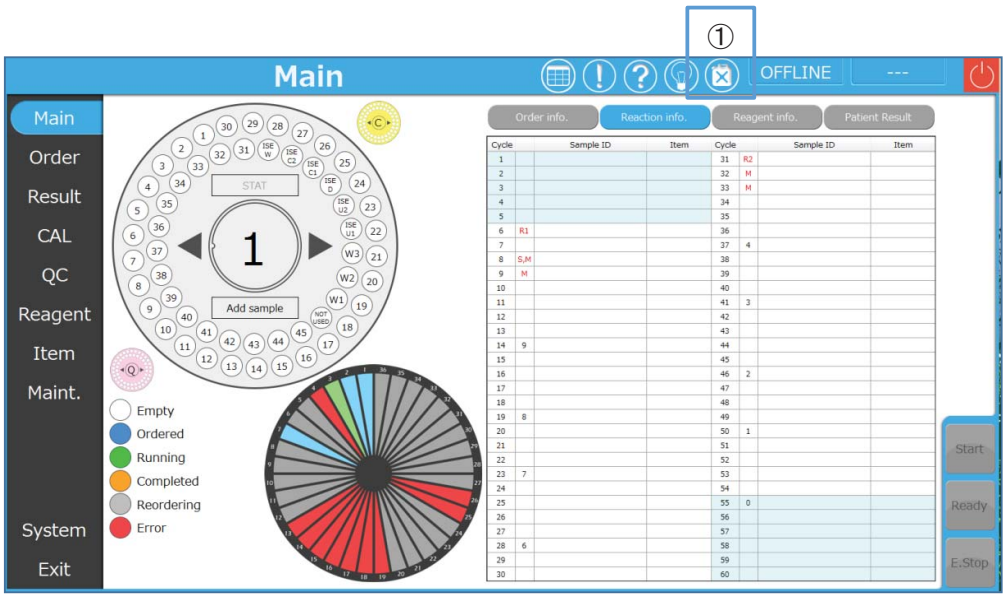
	Contents
Time Left for Lamp	Display of remain time of lamp life. (Maximun 1200 hours)
Exchange	Select when changing the lamp Reset the remaining time.
Exit	Close the lamp screen.

5. Tank error screen

- Tank Icon displays at the upper part in operation screen. Tank creen is able to open when analyzer is undr operation.

① When tank error occurred, tank Icon turns to red. (supply water, drainage, detergent and separate drainage tanks)

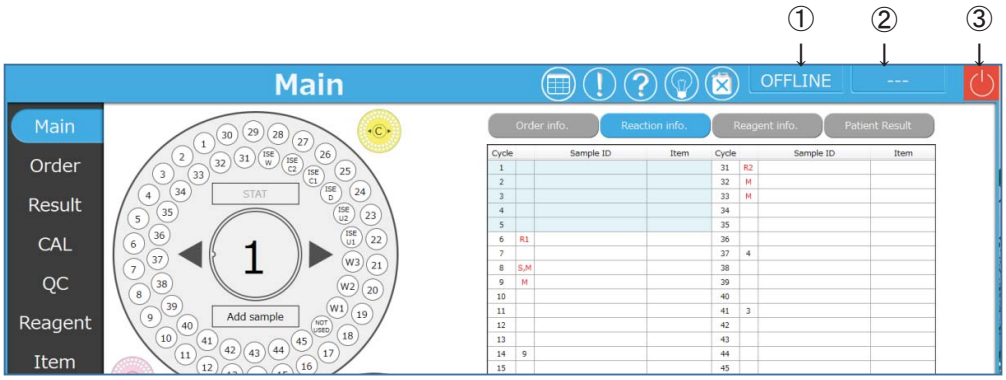
- When tank error solved, the Icon turns to blue.



Main screen

6. Analyzer status monitor, temperature control status monitor and System power switch

➢ Analyzer status monitor, temperature control status monitor and system power switch button display at the upper part in operation screen.



Main screen

① [Analyzer status monitor] : The analyzer status is shown.

Notation	Analyzer status
OFF LINE	PC is not connected with analyzer.
IDLE	PC is connected with analyzer.
READY	Analyzer is ready to start testing. (All the units move to start position)
INIT	Under Initialization operation.
RUN	Analyzer is running tests.
S.STOP	Sampling stop
END	Analyzer has finished all tests.
CLOT	Sampling nozzle is clogged. (Keep clog
BARCODE	Reagent barcode reading operation is going.
GAIN	Auto-gain action is going.
MAINTE	Maintenance action is going.
CRS	CRS test is going.

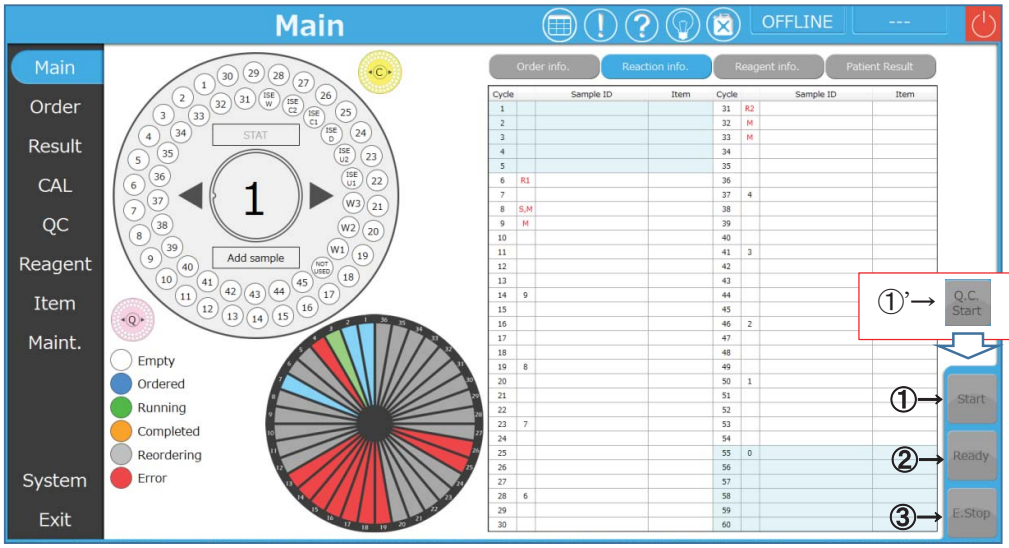
② [Temperature control status monitor] : The reaction tray temperature control status is shown.

Notation	Status
---	No temperature control
WARM UP	After the temperature control starting, the reaction tray temperature does not reach 37℃ ±0.1℃
OK	Under the temperature control, the reaction tray temperature is 37℃ ±0.1℃
NG	Under the temperature control, the reaction tray temperature is out of 37℃±0.1℃ after [OK] status.

③ Icon : The Icon is system power switch.
Clicking this button, system power switch is turned ON or OFF.

7. Operation control button. (Start, QC start, Ready, Stop)

- Operation control buttons (Start, QC start, Ready, Stop) display at the right lower part in operation screen.
- The button changes to inactive depending on the analyzer status. The color turns to gray.



Main screen

① Start : Test starts.

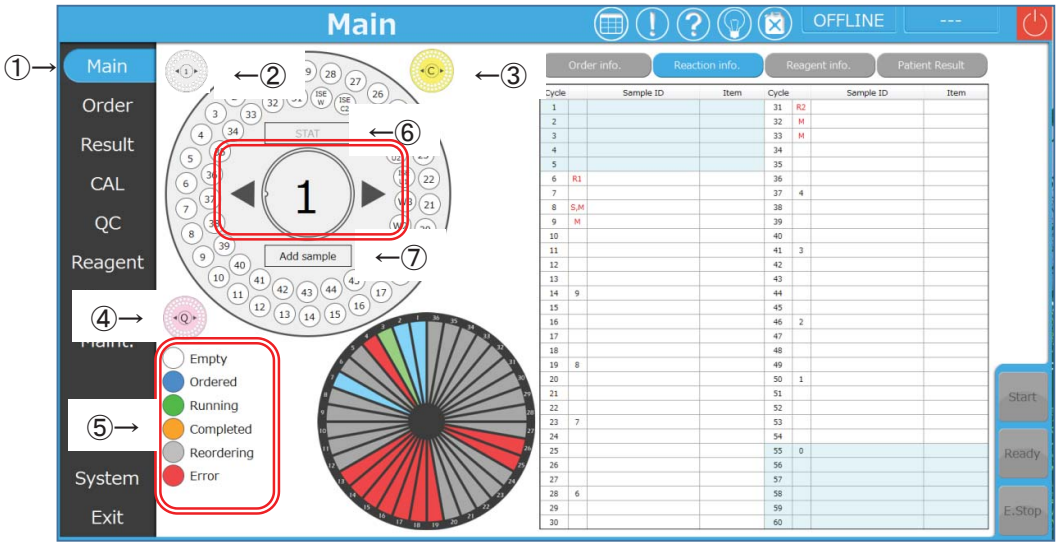
①' QCStart : When analyzer is QC testing mode, Start button is replaced by this button. QC sample tests start.

② Ready : Analyzer initialization starts.

③ E.Stop : All the analysis operation stops.

8. Sample tray monitor screen

➢ Sample order status is shown by tray Icon in main screen.



Main screen

➢ The selected tray is shown on a central area. The order status displays by the color.

➢ The number in Icon shows tray number. The tray number is changed by ◀▶ keys.

➢ ④QC tray can be selected "ON" in System parameter.

① Main button : Main screen is shown.

②～④ Tray Icons

		Color	Analysis	Usable tray number
②	Patient sample tray	Gray	Patient sample measurement	1 ～ 50
③	Calibration tray	Yellow	Calibration measurement	C1 ～ C6
④	QC sample tray	Pink	QC sample measurement	Q1 ～ Q3

⑤ The order entry status

Color	Order status	
White	Empty	No sample order
Blue	Ordered	Waiting
Green	Running	Test is running.
Orange	Completed	Test has finished
Gray	Reordering	Rerun is ordered
Red	Error	Test has failed

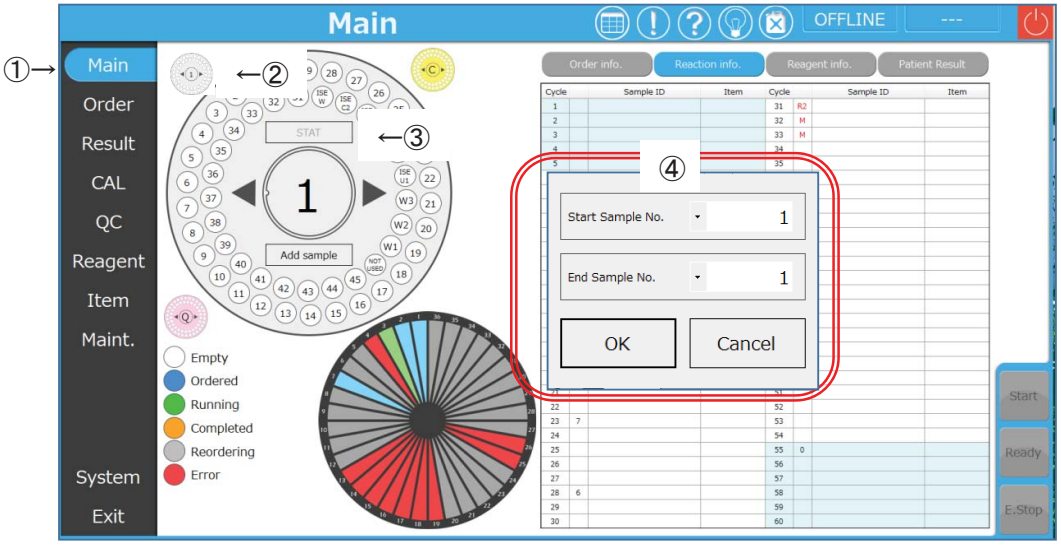
➢ When patient tray is set, the following buttons are shown.

⑥ Stat : Select for Stat sample.
・The Stat sample position screen is shown under operation.

⑦ Add Sample : Select for additional sample under operation.
・The sampling stops after clicking the button.

9. STAT button

- Clicking “STAT” button, STAT sample measurement is possible.
- STAT button displays when patient tray is selected in main screen.
- STAT button is able to use when analyzer is under operation.
- STAT sample is performed cut in between the measuring sample.



Main screen- STAT sample position setting screen

① Main button : Main screen is shown.
② Patient tray Icon : Patient tray displays in center part.

③ Stat button : Select when stat sample order.
④Pop-up screen for STAT sample test position designation screen appears.

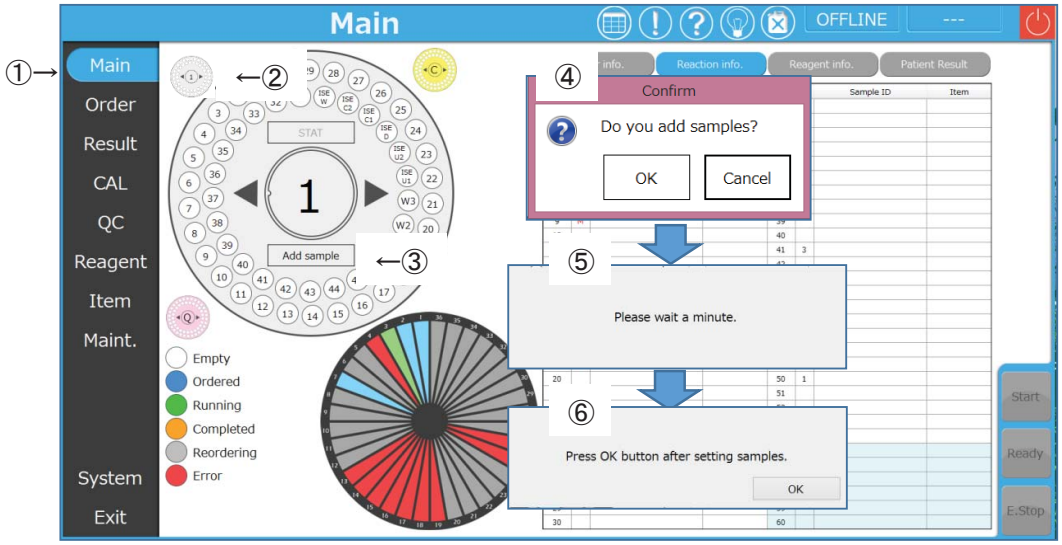
Pop-up screen

④ Stat sample position designation screen : Set the stat sample position.

Start Sample No.	Input stat sample start number.
End Sample No.	Input stat sample end number.
OK	Stat sample measurement starts.
Cancel	Close stat sample position designation screen.

10. Add sample

- Clicking "Add sample" button under operation (sampling), the sampling stops.
- Add button displays when patient tray is selected in main screen.



Main screen

① Main button : Main screen is shown.

② Patient tray Icon : Patient tray displays in center area.

③ Add sample button : Select when required additional sample test
④Pop-up screen appears.

Pop-up screen

④ Do you add sample? : Clicking of OK when add the sample.
- ⑤Pop-up screen appears.

: Clicking of Cancel when cancel the sample addition.
- Close the Pop-up screen, and analyzer continues operation.

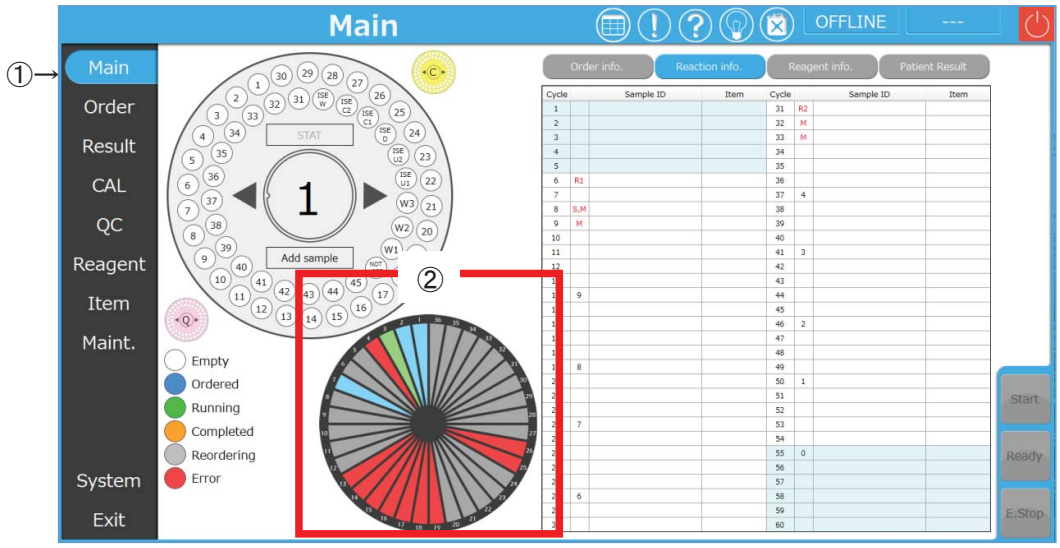
⑤ Please wait a minute? : Sampling stops.

⑥ Press OK button after setting samples.
- Set add sample on the sample tray.

OK : Clicking OK, and restart the sampling.

11. Reagent tray monitor screen

➢ Reagnet tray information displays in main screen.



Main screen

① Main button : Main screen is shown.

② Reagent tray Icon : Reagent residual volume is shown by color.

➢ The number in Icon is shown bottle position number.

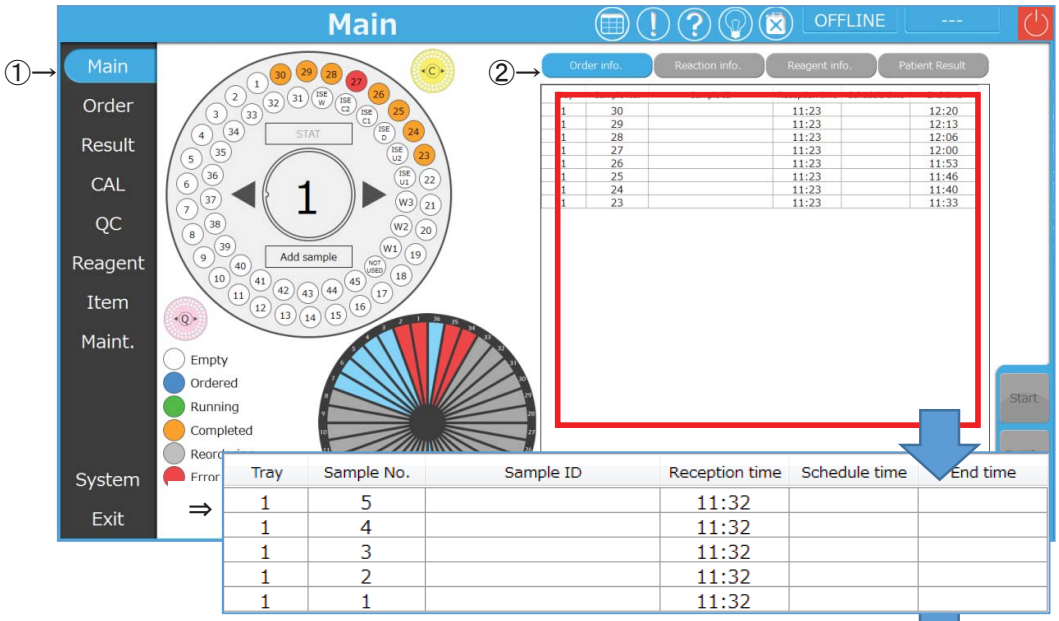
Color and status

Color	Reagent residual status
Gray	No reagent bottle setting
Blue	Above alarm level
Red	Below test stop level
Yellow	Below alarm level
Green	Effective date or effective date after open is expired.

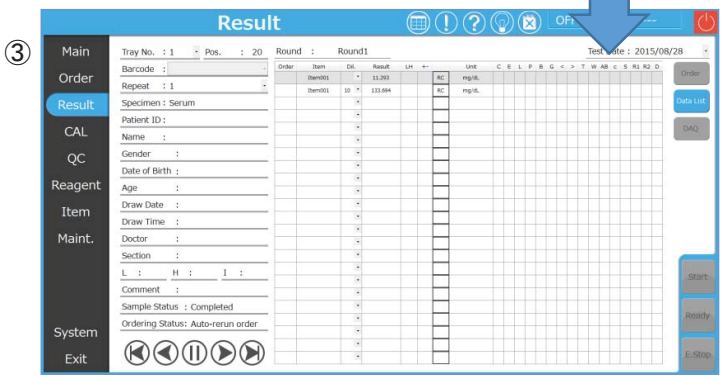
➢ Alarm level and test stop level are set in syste screen. Refer to Chapter 4, 4.9.6 System setting.

12. Order information screen

- Order information list displays.
- Clicking "Order info." button in main screen, displays "Order info." screen.



Select order entry status line in order info. screen.



Result screen

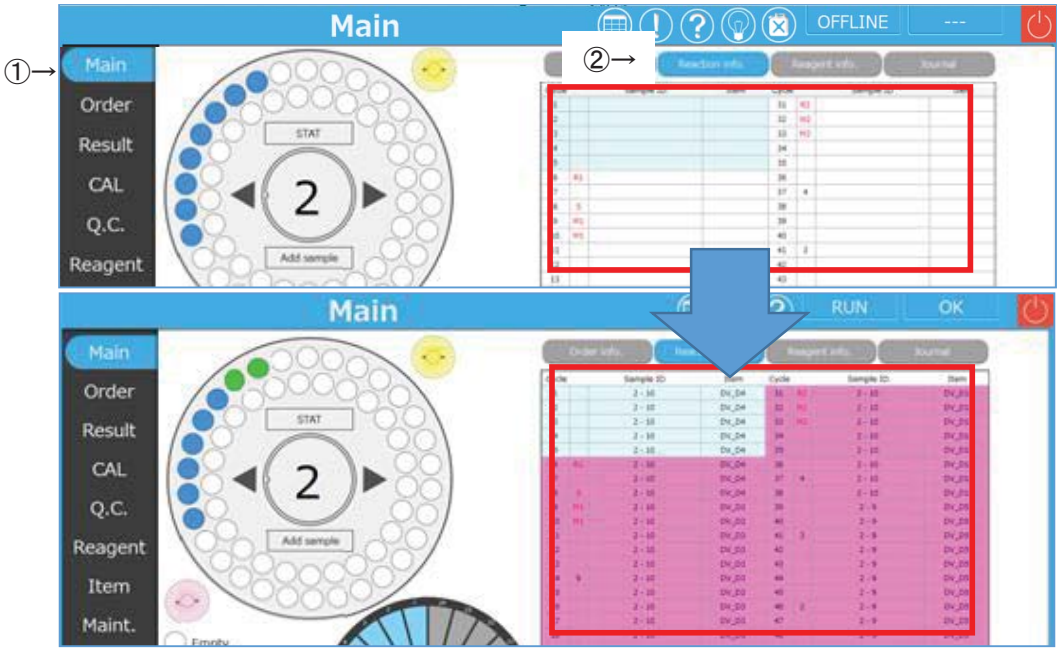
① Main button : Main screen is shown.
② Order info. button : Order entry status is shown.

	Contents
Tray	Sample Tray number
Sample No.	Sample position number
Sample ID	Displays ID by selected mode. ・Position mode ; Sample ID ・Barcode mode ; Sample barcode ID
Receipt time	Receipt time
Schedule time	Forecast of test ending
End time	Time of test has finished.

③ Select order entry status line and double click it, screen changes to result screen, corresponding to the test item.

13. Reaction information screen

- Real reaction information displays.
- Clicking “Reaction info.” button in main screen, displays “Reaction info.” screen.



Under operation — Reaction info.screen

③ Main button : Main screen is shown.
④ Reaction info. : Real time display of test status

Back color display

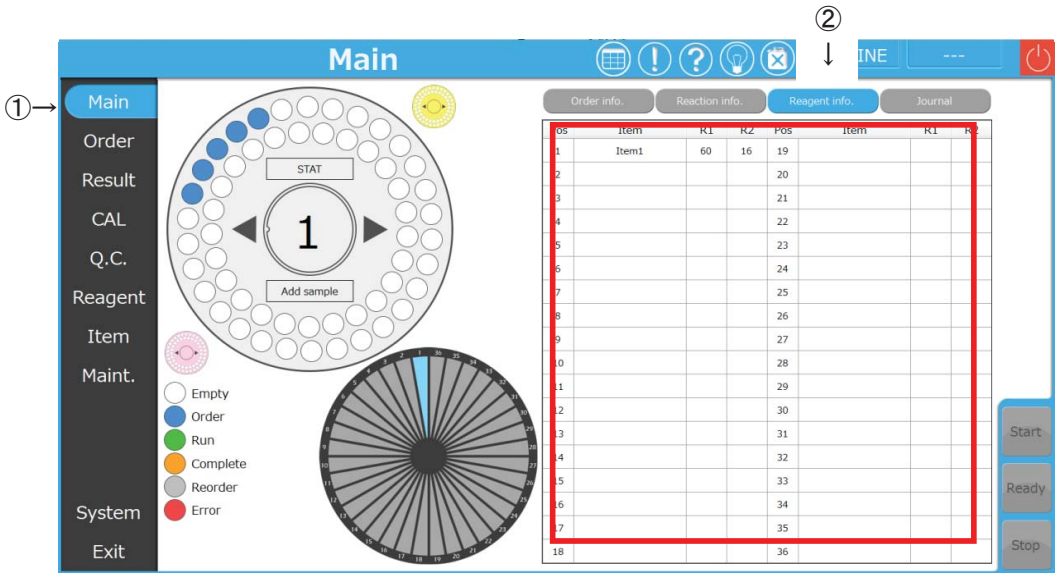
Back color	Contents
Blue	Single reagent or ISE Item (Other Item)
Pink	Double reagent Item

Characters display

	Contents
Cycle(1~60)	Light intensity measurement point number
R1	R1 reagent dispensing point
S, M	Sample dispensing and mixing point
(Cycle 9)M	Mixing point (R1 + Sample)
R2	R2 reagent dispensing point
(Cycle 32, 33) M	Mixing point (R1+Sample + R2)
Number (0-9)	Waiting time till test complete.
Sample ID	Sample position, barcode number or patient ID ➢ Set Run monitor dsipaly in System Parameter screen.
Item	Test Item

14. Reagent information screen

- Reagent information list (Item name, residual reagent) is shown.
- Clicking "Reagent info." button in main screen, displays "Reagent info." screen.



Main screen

① Main button : Main screen is shown.
② Reagent info. button : Residual reagent test number display.
Back color changes depending on reagent residual volume level.

Back color display :

Back color	Reagent residual volume
White	Enough reagent volume
Red	Below test stop level
Yellow	Below alarm level
Green	Effective date or effective date after open is expired.

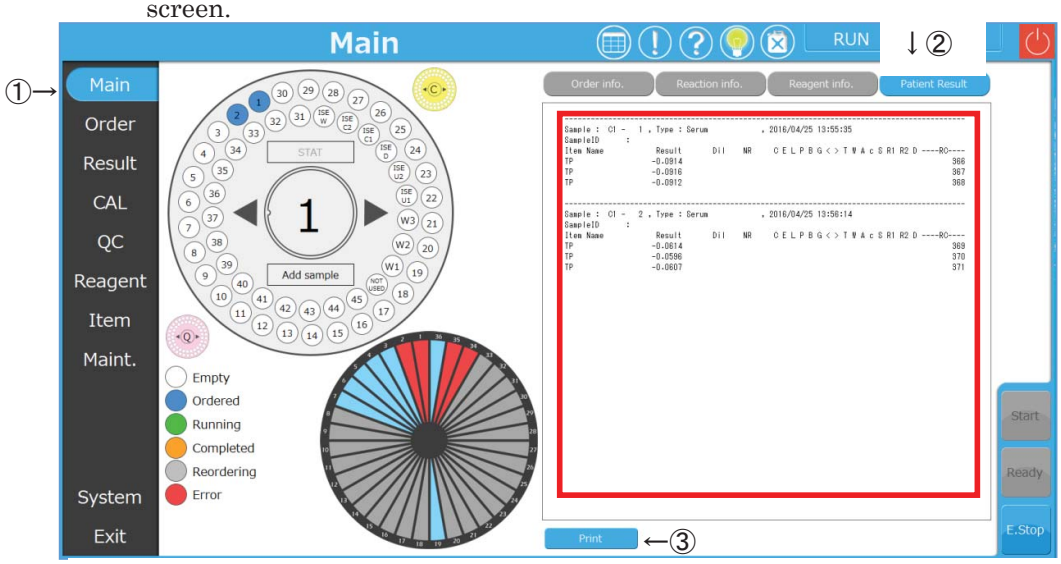
- Alarm level and test stop level are set in system screen.
Please refer Chapter 4, 4.9.6 System setting.

Characters display:

	Contents
Pos	Reagent tary and bottle position
Item	Item name
R1	R1 reagent residual test number
R2	R2 reagent residual test number

15. Patient result screen

- Results of measurement day display by each sample order.
- Clicking Patient result button in main screen, displays patient result screen.



Main screen — Pstient Result screen

① Main button : Main screen is shown.
② Patient Result button : Patient results of the day are shown by each sample order.

	Contents
Sample : -	Sample tray number – sample position number
Type :	Sample kind
Date/Time	Date and time (Format depends on PC)
Sample ID	Displays ID by selected mode. ・Position mode ; Sample ID ・Barcode mode ; Sample barcode ID
Patient ID	Patient ID (Only for patient sample)
Name	Patient name (for patient sample) QC sample name (for QC sample measurement)
Item Name	Item name
Result	Test results
Dil	Dilution ratio ※For no dilution sample, blank.
NR	Error flag (Low,High,PL,PH)
C,E,L,P～ R1,R2,D	When error occurred, "*"(asterisk) is shown in related column.
----RC----	Reaction monitor number

- Please refer to Chapter 6 Alarm function.

③ Print (external printer) : Test results are printed out by external printer.

- Printout range is designated by drag.

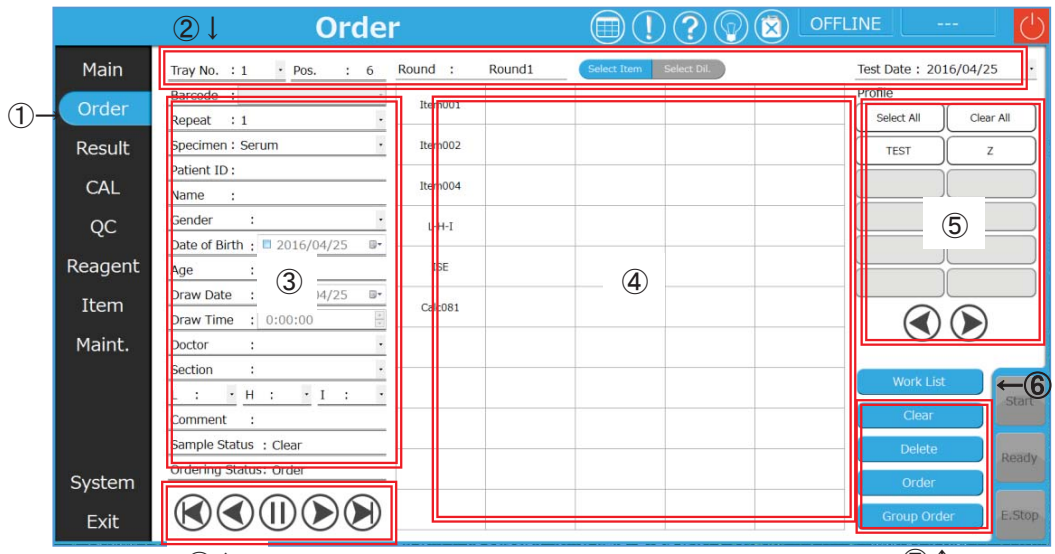
```
Sample :   1 -  23 , Type : 血清              , 2016/04/18 11:27:34
SampleID     :
PatientID    :
Name         :

Item Name          Result      Dil    NR     C E L P B G < > T W A c S R1 R2 D ----RC----
Na                   32.1                   <00000>                                    0
K                    0.52                   <00000>                                    0
Cl                   23.5                   <00000>                                    0
```

4.2 Order (Patient sample order entry) screen

This screen is used for order entry of patient samples.

- There are two kinds of order entry screen, one is used for position mode and the other is used for barcode * mode. The sample mode can be selected in System screen. Default mode is Position mode.
- Order entry operation is possible during test operation, but order modification or test cancellation for the sample, which is under test stage, is impossible.
- Order entry status is shown in Work list of this screen.

4.2.1 The contents of Order screen



Order screen

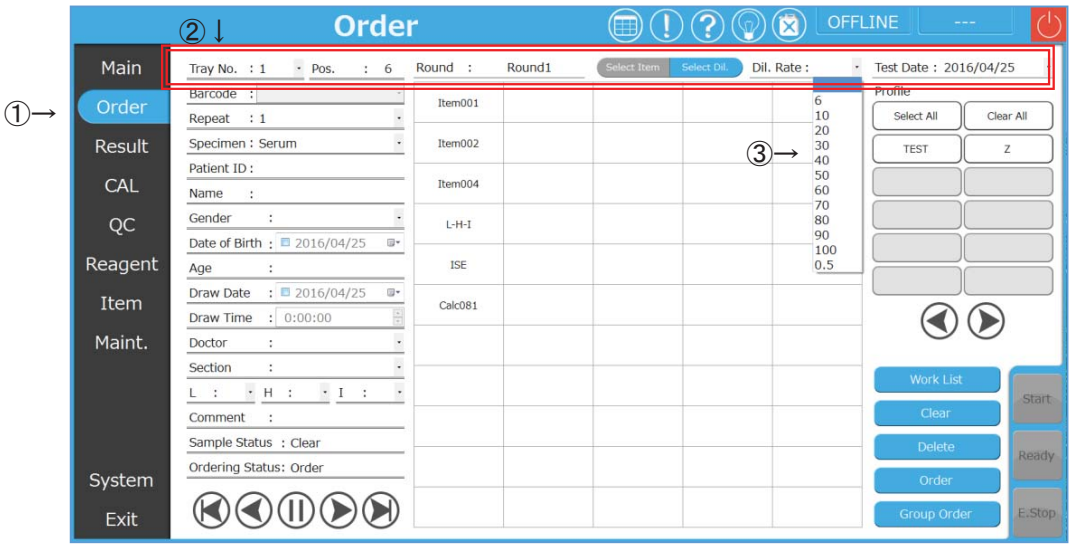
① Order button : Order screen is shown.

The following items are used in order screen.

② Test condition (tray, position number) input and display
③ Sample information (Patient information) input and display
④ Test item display and selection
⑤ Profile list display and selection
⑥ Work list and order status display button
⑦ Order entry button
- "Goup order" button is cannot used when sample mode is barcode mode.

⑧ Order entry page switching button.

1. Test condition input and display



Order screen

① Order button : Order screen is shown.

② Test conditions (tray, position number) input and display.
Input and display of test conditions are different depending on the sample mode. The sample mode can be selected in System screen. Default mode is Position mode.

➢ Position mode Order screen

	Display contents, input condition, contents of the selection		
Tray	Sample tray number selection	Select a number 1– 50	Input is essential.
Pos.	Sample position number input	Input a position number 1～30	Input is essential.
Round	The contents of display are different by the display contents of [Sample state]. ➢ In case of [Clear], Round name, selected in Reagent screen, is shown. ➢ Other than [Clear], the [Round name], at the time of order entry, is sown.		
Select Item	This function is selected for ordinary order entry.		
Select Dil.	This function is selected when order entry with sample dilution.		
Test date	Test date displays ➢ Former date selection is possible. ➢ Confirmation of order entry for past date is possible.	Default date is today.	Input is essential.

- Barcode mode order screen
  Display of sample barcode contents, and input or read by barcode reader automatically.

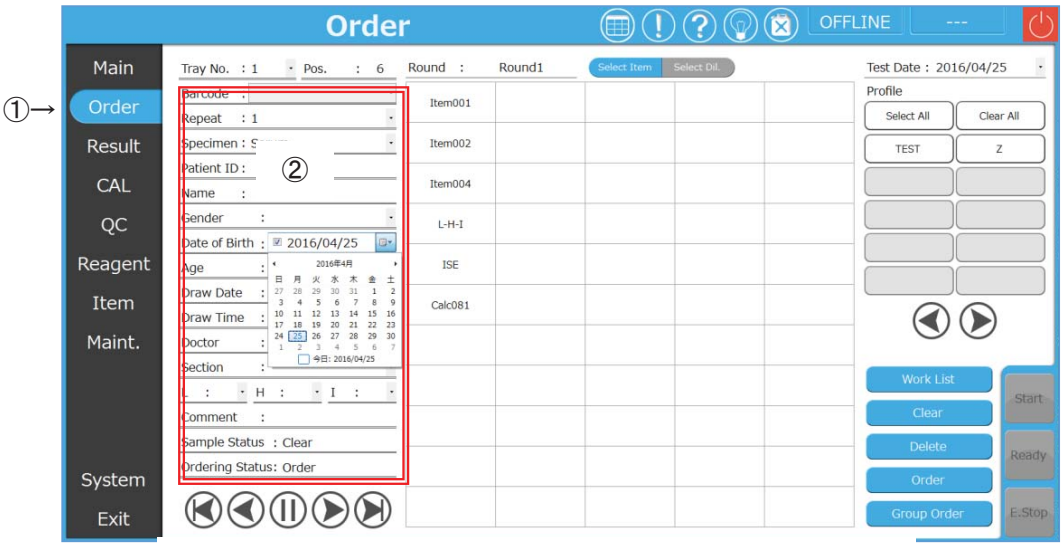
	Display contents, input condition, contents of the selection		
Tray	Fixed as tray number 1. Cannot be changed.		
Pos.	No input is acceptable.		
Round	Display contents are different depending on the display contents of [Sample state]. ➢ In case of [Clear], Round name, selected in Reagent screen, is shown. ➢ In case of the other than [Clear], Round name, selected in order entry is shown.		
Select Item	This function is selected for ordinary order entry.		
Select Dil.	This function is selected when order entry with sample dilution.		
Test date	Test date displays ➢ Former date selection is possible. ➢ Confirmation of order entry for past date is possible.	Default date is today.	Input is essential.

③ Dilution rate setting
- Dil Rate displays after clicking the Select Dil button.
- This section is common for Position mode and Barcode mode.

	Display contents, input condition, contents of the selection	
Dil.	Select dilution ratio.	Select one out of 0.5 6, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100.

Note:
- Please be careful when dilution ratio is set 0.5, the sample is used two times volume.

2. Sample information (Patient information) input and display



Order screen

① Order button : Order screen is shown.

② Sample information (Patient information) input and display.
Input and display of test conditions are different depending on the sample mode. The sample mode can be selected in System screen. Default mode is Position mode.

➢ Position mode Order screen

	Display contents, input condition		
Barcode▼	No input is possible.		
# of Asp▼	Select sampling repetition number.	Select 1 – 10	Default is 1
Specimen▼	Sample kind selection	Serum Urine Plasma CSF Dialysis Other HbA1c(Wholeblood) HbA1c(Primary tube) HbA1c(Hemolyzed)	Default is Serum
Patient ID	Patient ID input ➢ When using of result screen data list (patient report), input is necessary.		Less than 20 letters

➢ To input Name – Age, Patient ID input is necessary.		
Name	Input patient name.	Less than 30 characters
Gender▼	Select gender.	Select one out of Male, Female and unknown.

	Display contents, input condition	
Date of birth	Input the date of birth, by input a check mark into a box or select the date out of the calendar by clicking ☑ mark.	
Age	Displayed automatically.	
Draw date	Input the date by input a check mark into a box or select the date out of the calendar by clicking ☑ mark.	Default is today.
Draw time	Input draw time, or select draw time. ➢ Draw date input is necessary before time input	
➢ Patient ID input is necessary before Doctor – Section input.		
Doctor ▼	Select Doctor name ➢ Doctor name registration is done in Tools screen.	
Section ▼	Select Section ➢ Section registration is done in Tools screen.	
Lipemic/ Hemolysis/ Icteric	Serum information selection. ➢ Select one out of 2-, -, +-, 2+, 3+, 4+.	
Comment	Input comment	Less than 30 characters
Sample state	Sample state displays	Clear (No order entry) Order Run Complete Error (Error has detected)
Order state	Display of order entry status	Order (First test) Re-run order Auto-rerun order

➢ Barcode mode order screen

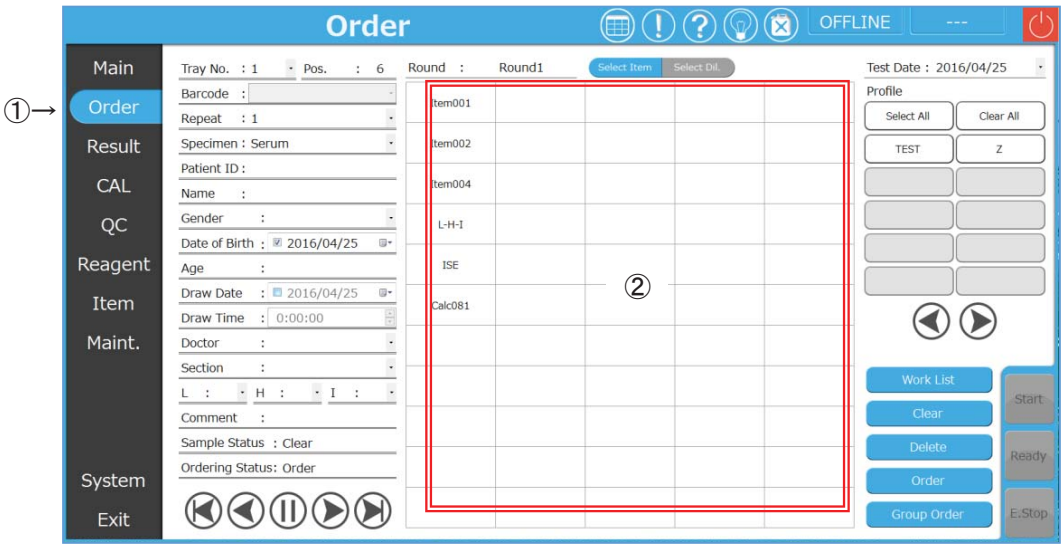
➢ Input or read sample barcode information contents and displays it

	Display contents, input condition		
Barcode ▼	Input or display a sample barcode character string.		Less than 20 characters
# of Asp ▼	Select sampling repetition number.	Select 1 – 10	Default is 1
Specimen ▼	Select sample kind or displays barcode information. Serum Urine Plasma CSF Dialysis Other HbA1c(Wholeblood) HbA1c(Primary tube) HbA1c(Hemolyzed)		Default is Serum

	Display contents, input condition	
Patient ID	Patient ID input or displays of barcode information. ➢ When using of result screen data list (patient report), input is necessary.	Less than 20 letters
➢ To input Name – Age, Patient ID input is necessary.		
Name	Input patient name or display of barcode information..	Less than 30 characters
Gender▼	Select gender or display of barcode information.	Select one out of Male, Female and unknown.
Date of birth	Input the date of birth, by input a check mark into a box or select the date out of the calendar by clicking ☑ mark.	
Age	Displayed automatically.	
Draw Date	Input the date by input a check mark into a box or select the date out of the calendar by clicking ☑ mark.	Default is today.
Draw time	Input draw time, or select draw time. ➢ Draw date input is necessary before time input	
➢ Patient ID input is necessary before Doctor – Section input.		
Doctor▼	Select Doctor name	Doctor name registration is done in Tools screen.
Section▼	Select Section	Section registration is done in Tools screen.
Lipemic/ Hemolysis/ Icteric	Serum information selection. ➢ Select one out of 2-, -, +-, 2+, 3+, 4+.	
Comment	Input comment	Less than 30 characters
Sample state	Sample state displays	Clear (No order entry) Order Run Complete Error (Error has detected)
Order state	Display of order entry status	Order (First test) Re-run order Auto-rerun order

3. Test item display and selection

- During Reagent screen selection, registered reagent Items, ISE Items and calculation Items are shown in Round. By specimen selection, only the Items, suitable for the specimen, are shown.
- Order entry by Item selection.



Order screen

① Order button : Order screen is shown.

② Test item names are shown.

- Clicking Item name for order entry

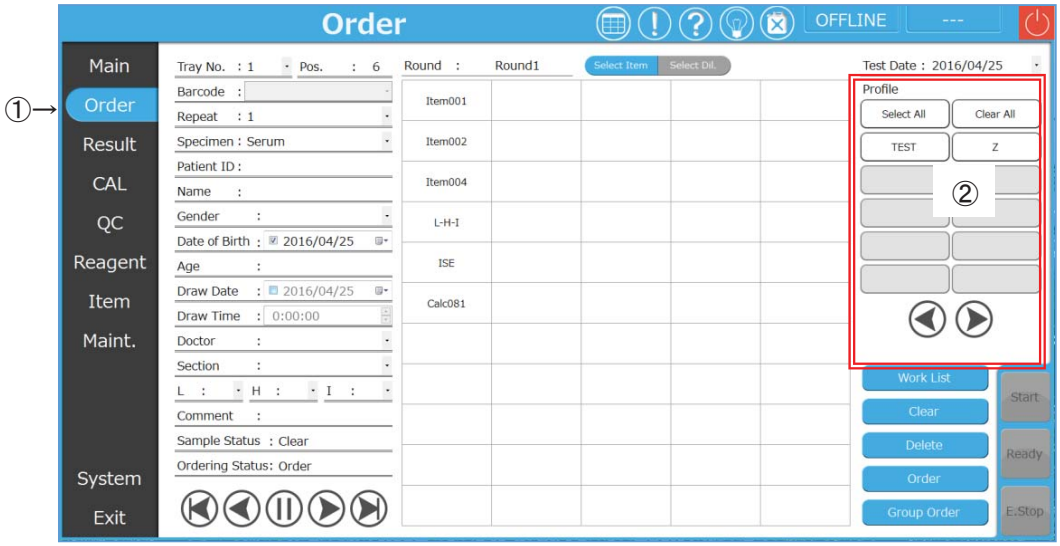
  Back color and status :

Back color	Order entry status
White	No order entry
Blue	Order is accepted
Dark blue (Item name)	Test has finished

- When selected sample dilution, display dilution ratio under the Item name.

4. Profile list display and selection

- Profile list displays.
  Group order entry can be set by profile name selection.
- Profile setting or modification is done in System screen.
  Please refer to Chapter 4, 4.9.4 Profile screen.



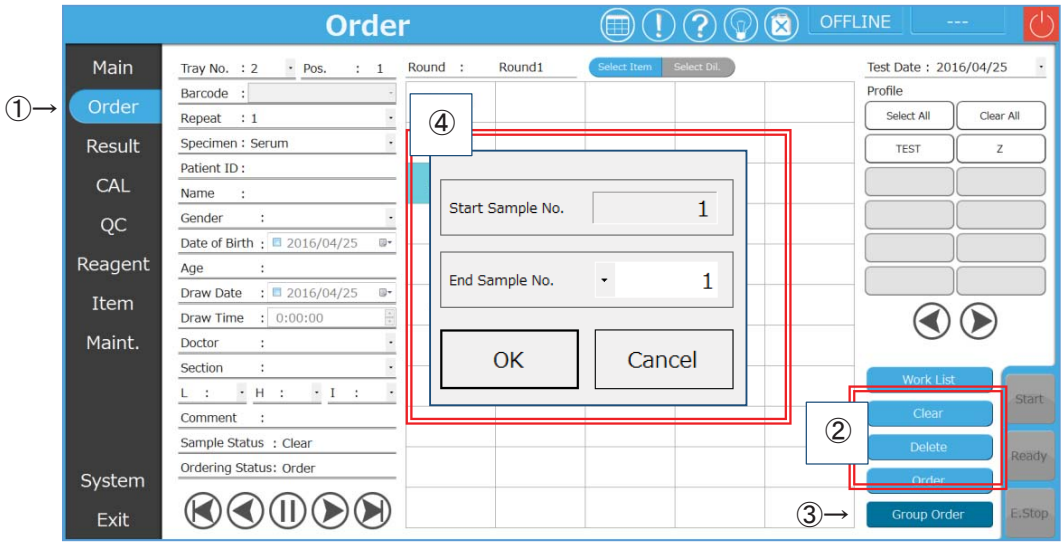
Order screen

① Order button : Order screen is shown.
② Profile : Profile name displays.
Select profile name, registered Items in profile are entry.

	Contents
Select all	All Items shown are selected and ordered.
Clear all	Clear for all Items entry.
(Profile name)	Enter the all test Items set in the profile.
◄ ►	Displays former or later profile name.

5. Order setting (Group order) button

➢ This button is used for order setting.



Order screen

① Order button : Order screen is shown.

② Buttons

	Contents
Clear	If there is a order, cancel them.
Delete	Delete the test order of displayed position number.
Order	Register the contents of displayed position number.

③ Group Order button : ④ Group order designation screen is pop-up.

➢ Group order entry registration screen is shown. Order entry of a set of test items can be applied for multiple samples in one action.

➢ Under Barcode mode, cannot be used.

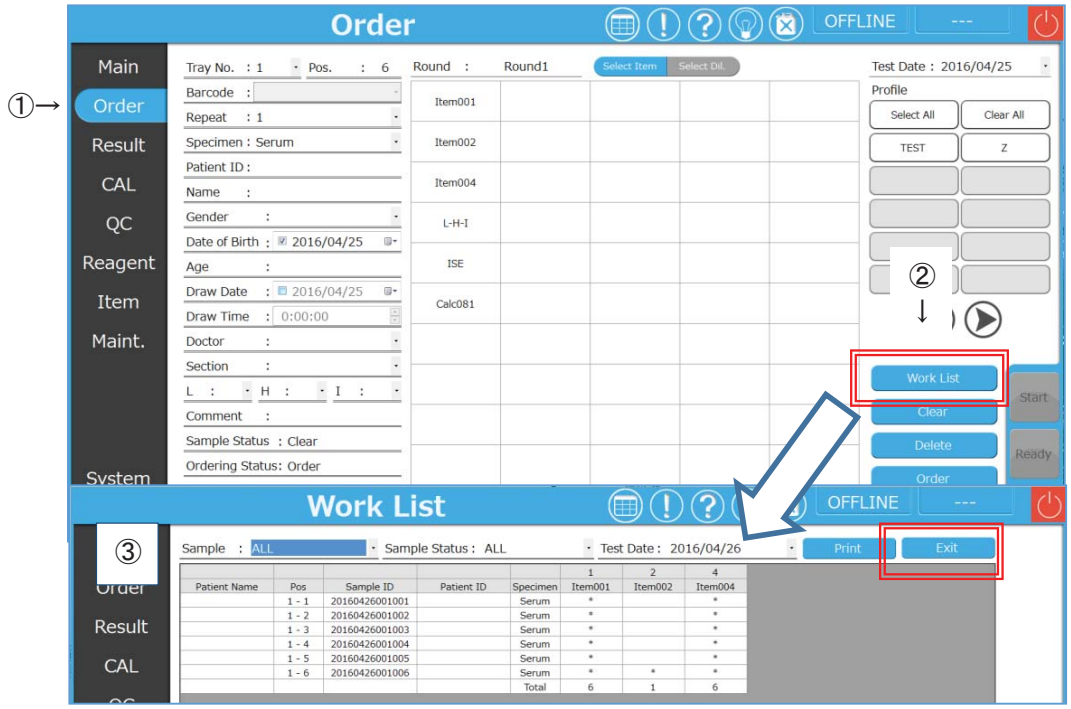
Pop-up screen

④ Group order screen

	Contents
Start sample No.	Display of starting sample number for group order entry. ➢ The sample number, which has been shown in order entry screen, when group order button is selected.
End sample No.	Select the final sample number of group order entry.
OK	Do group order entry.
Cancel	Cancel the group order entry.

6. Work list screen

- Clicking of work list button, work list screen is shown.
- This is used for order entry status confirmation.

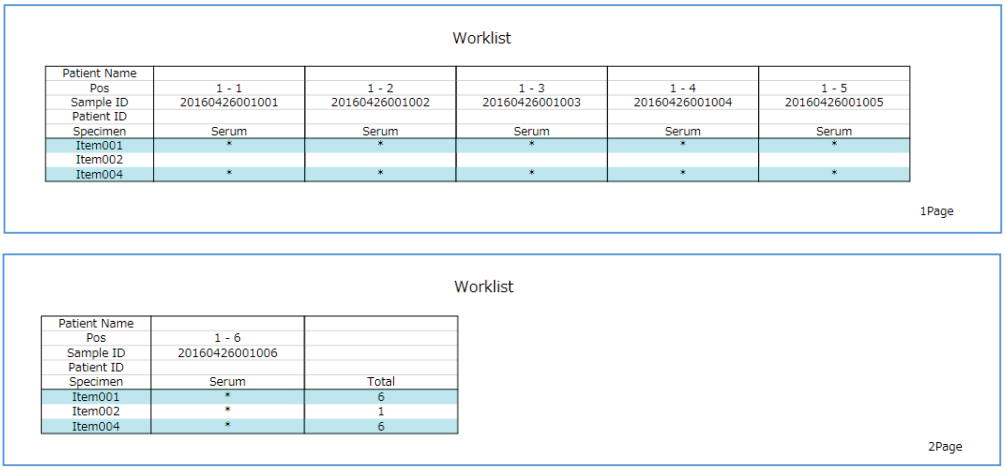


Work list screen

① Order button : Order screen is shown.
② Work list button : Order entry status list is shown.
③ Work list screen

	Contents	
Sample	Select sample kind	Select one out of All, Patients, Controls.
Sample status	Select sample status.	Select one out of All, Pending, Measured.
Test Date	Select the date to be displayed. Former date selection is possible.	
Pos.	Sample tray number (left side) and sample position number (right side) are shown.	
Sample ID	Sample ID (Automatic numbering) or barcode ID is shown.	
Patient ID	Patient ID is shown.	
Specimen	Specimen display	
Item number / Item name	If test order is registered, "*" is shown in Item name column.	
Total	Total test number for each test items are shown.	

④ Print (External printer) : Printout of displayed contents.



Worklist

Patient Name					
Pos	1 - 1	1 - 2	1 - 3	1 - 4	1 - 5
Sample ID	20160426001001	20160426001002	20160426001003	20160426001004	20160426001005
Patient ID					
Specimen	Serum	Serum	Serum	Serum	Serum
Item001	*	*	*	*	*
Item002					
Item004	*	*	*	*	*

1Page

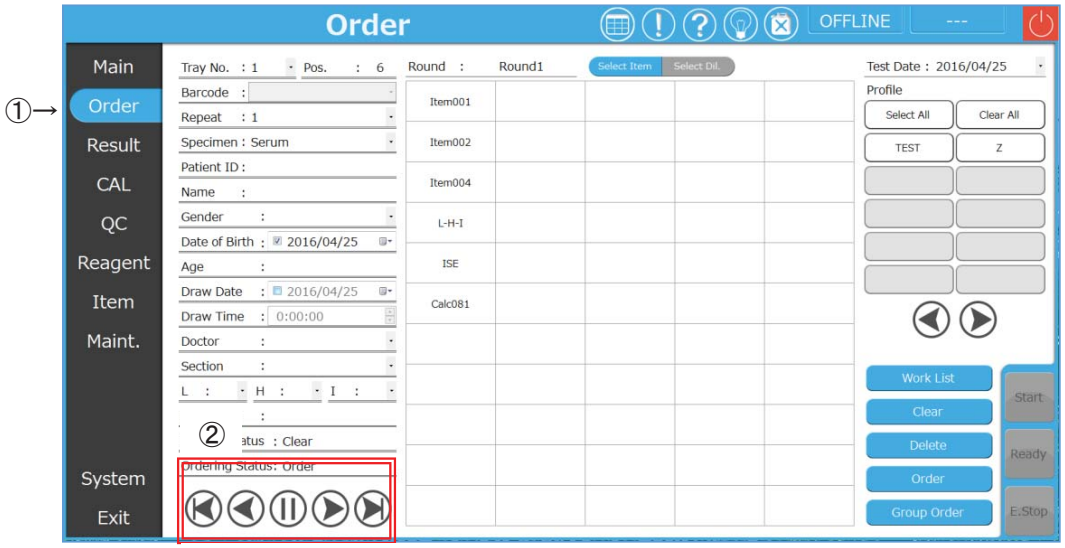
Worklist

Patient Name		
Pos	1 - 6	
Sample ID	20160426001006	
Patient ID		
Specimen	Serum	Total
Item001	*	6
Item002	*	1
Item004	*	6

2Page

7. Order screen switching button

- Order screen switching buttons are shown.
- Displays when position mode is selected. Under barcode mode, this screen is ignored. Under barcode mode, select Barcode ▼, for screen switching.



Order screen-Position setting screen

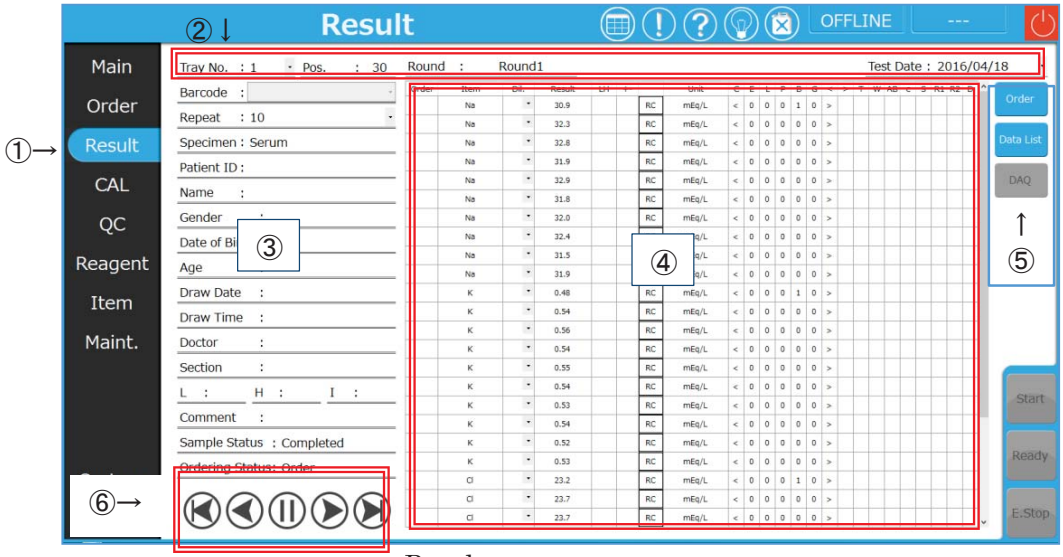
① Order button : Order screen is shown.
② Order screen switching buttons and functions

	Contents	
⏮	Former Item search button	Displays the first position of shown round.
◀		Displays the Order screen of one step smaller position number from displayed screen.
⏸	Search button	Displays an Order screen of inputted position number.
▶	Later Item search button	Displays Order screen of one step larger position number than displayed screen.
⏭		Displays the Order screen of the largest position number, among test order has already entered.

4.3 Result screen

- Test result of each sample is shown.
- Depending on the sample mode setting, (Position mode/Barcode mode) display contents are different.
  Sample mode setting can be changed in System screen. Default is Position mode.
- Rerun order is possible.
- Test result search and Patient report (Patient history) print out are possible using Data list screen.

4.3.1 Result screen display contents



Result screen

① Result button : Result screen is shown.

Result screen display contents are followings.

② Test result condition (tray, date) display and selection.

③ Sample information (Patient information) displays.

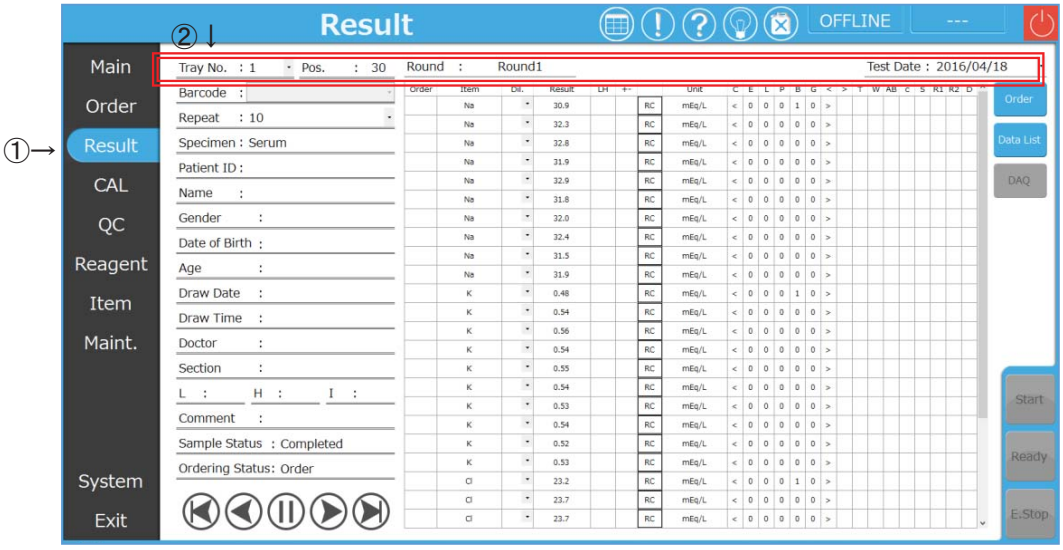
④ Test results (test Item, test result data, error content).
Rerun test Item registration.
Reaction monitor displays.

⑤ Rerun order registration.
Data list screen displays
Result request.

① Test results screen display exchange button
- This button is not shown under sample barcode mode.

1. Test results condition display

- Test result of the day is shown. Display order entry when the test incomplete.
- Former test results are also shown if date of interest is given.



Result screen

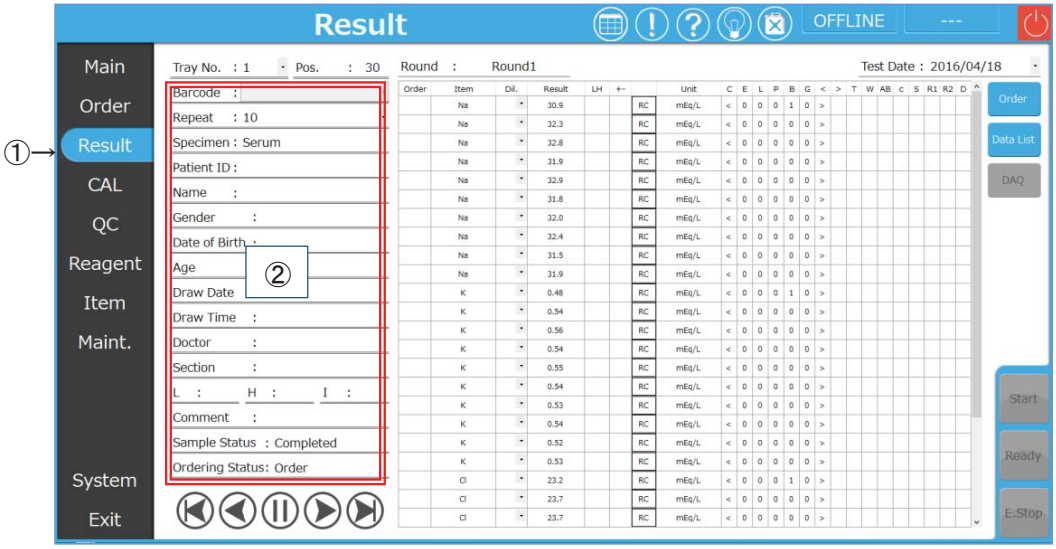
① Result button : Result screen is shown.

② Result screen and functions

	Display contents, selection contents	
Tray No.	Sample tray number selection	Select a number 1– 50
Pos.	Sample position number input	Input a position number 1～30
Round	Round name display	
Test Date	Test date display ➢ Former date selection is possible.	Default is today.

2. Result and sample information (patient information) display

➢ Display the information of order entry.



Result screen

① Result button : Result screen is shown.

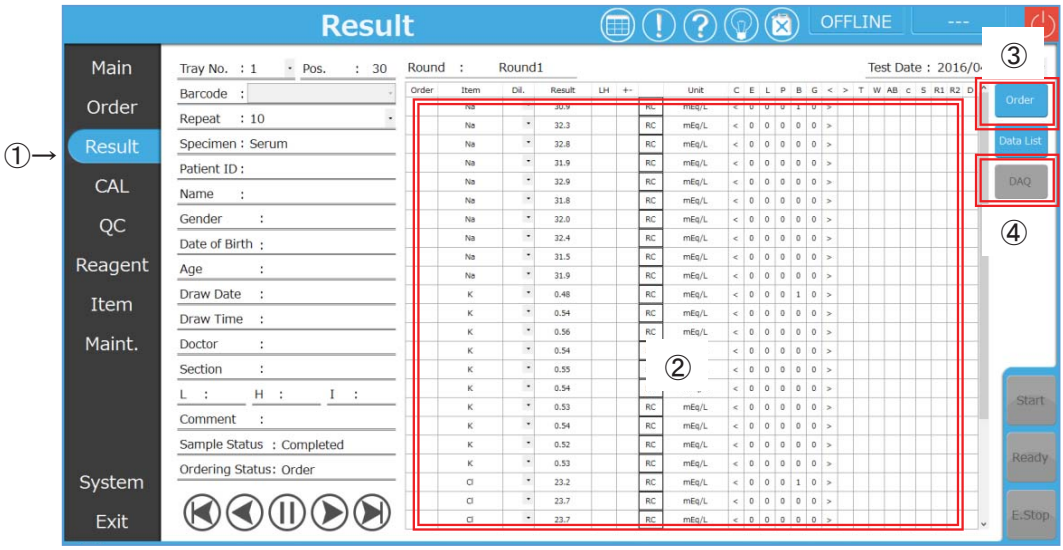
② Sample information (Patient information) displays.

	Contents・(Rerun condition input)	
Barcode	Displays barcode character string.	
Repeat ▼	Display sampling repetition number. (1-10)	
Specimen	Display sample kind	Serum Urine Plasma CSF Dialysis Other HbA1c(Wholeblood) HbA1c(Primary tube) HbA1c(Hemolyzed)
Patient ID	Display patient ID	
Name	Display patient name.	
Gender	Display gender	
Date of Birth	Display date of birth	
Age	Display age	
Drow date	Display drow date	
Drow time	Display drow time	
Doctor	Display doctor	
Section	Display section	

	Contents・(Rerun condition input)	
L : H : I	Serum information (Lipemic, Hmolysis, Icteric) display	
Comment	Display comment	
Sample status	Display sample state	Clear (No order entry) Order Run Complete Error (Error has detected)
Ordering status	Display order state	Order (First test) Re-run order Auto-rerun order

3. Test results display, Rerun order, Reaction monitor screen display button

- Test results are shown. Display order entry when the test incomplete.
- Rerun order is possible by check the rerun box.
- Clicking RC button, displays reaction monitor screen.



Result screen

① Result button : Result screen is shown.

② Result screen

	Contents
Order	Order the test. ➢ Select the box for test Item. ➢ Blue color box means order has entered. ➢ Order is able to order within day.
Item	Test Item name display
Dil. ▼	Dilution ratio display. Dilution ratio setting for rerun test is done.
Result	Test result display. Rerun test result displays lower line.
LH	If the test result is out of normal range, displays Low or High. If the test result is out of panic range, displays PL or PH.
+−	Qualitative judgment .
RC	Reaction monitor display Select RC button, reaction monitor screen displays. ➢ Please refer to Chapter 4, 4.9.3 Reaction monitor screen.
Unit	Unit display
C~D	The C-D is shown error flag. If error occurred, chenage the color to red. ➢ As for check flag, refer to chapter 6 Alarm function.

③ Order button : Rerun order for selected Item (which is shown as a blue box in Rerun box).

④ Request button : Select button when the result is not received. Receive the result and display.

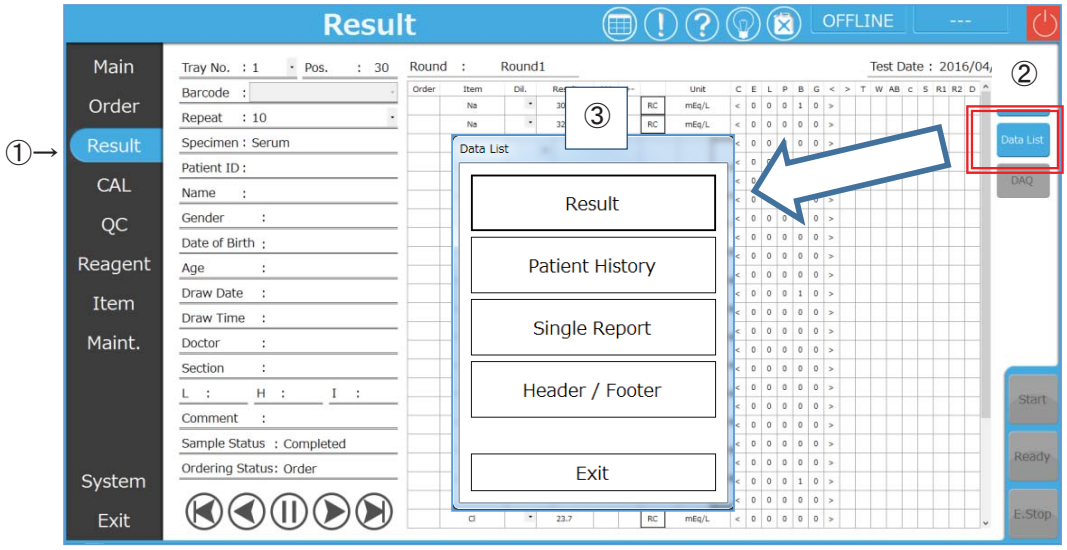
4. Data list

- Displays Data list (Patient report) screen

Data list (Patient report) screen

Display, search, print setting, and print for test result of Data list (Patient report) are done in this screen..

- To use Data list (Patient report), Patient ID input in Order screen is necessary.



Data list menu screen

① Result button : Result screen is shown.
② Data List button : Data list menu screen is popup.

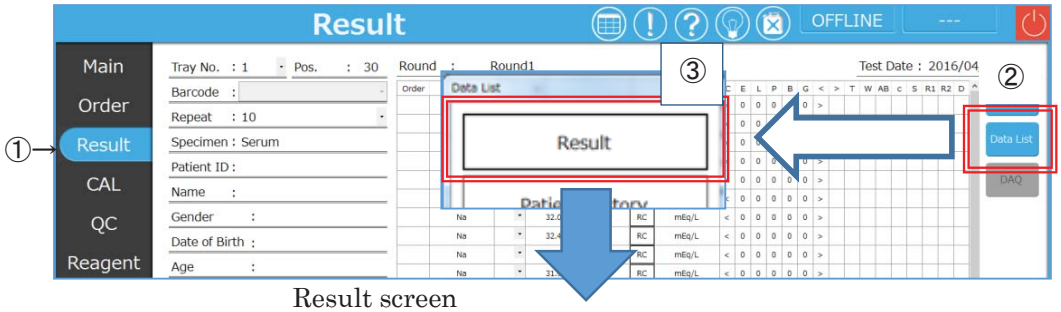
Pop-up screen

③ Buttons and functions

	Contents
Result	Test result list display, search, print
Patient History	Test result list for each patient display, search and print.
Single report	Patient report printing contents (Profile) setting, search and print.
Header／Footer	Setting of display contents for Patient report printing header and footer.
Exit	Close Data list screen

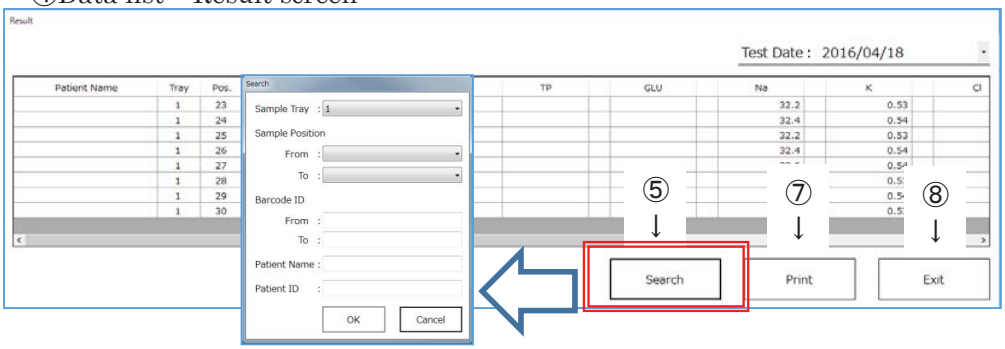
4-1. Data list – Result screen

- Test result of Data list (patient report) display, list, search and print.
- To use Data list (Patient report), Patient ID input in Order screen is necessary.



Result screen

④Data list – Result screen



⑥Search screen

① Result button : Result screen is shown.
② Data List button : Data list menus creen is popup.

Pop-up screen

③ Data list menu screen

Result button : Result screen is hown.

- Displays test result list, search and print screen.

Pop-up screen

④ Result screen : ⑥Display of search results.

	Contents
Test Date ▼	Test date display and search
Patient name	Patient name display
Tray	Tray display
Pos.	Position number display
Barcode ID	Barcode ID display
Specimen	Specimen kind display
(Item)	Display test result. ➢ If the test result is out of normal range or panic range, displays error flag..

- As for check flag, refer chapter 6 Alarm function.

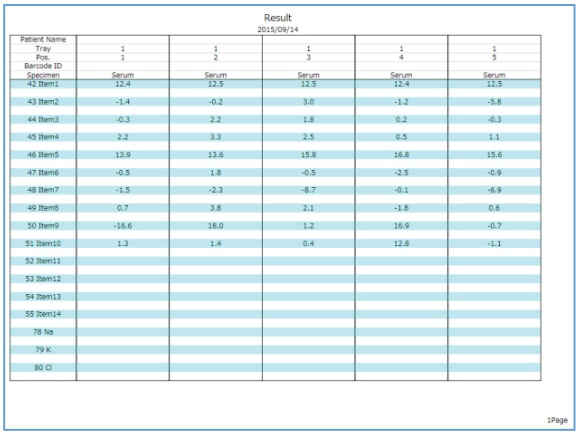
⑤ Search button : Searched screen is popup.

Pop-up screen.

⑥ Seach screen : Input search condition.

	Search condition input
Sample Tray ▼	Sample tray number selection
Sample Position From ▼ to ▼	Sample position number selection
Barcode ID From : To :	Bar code ID input
Patient Name	Patient name input
Patient ID	Patient ID input
OK	Search starts ➢ Display of searched results.
Cancel	Close search screen.

⑦ Print (External printer) : Print test results which are currently displayed.


Result
2015/09/14

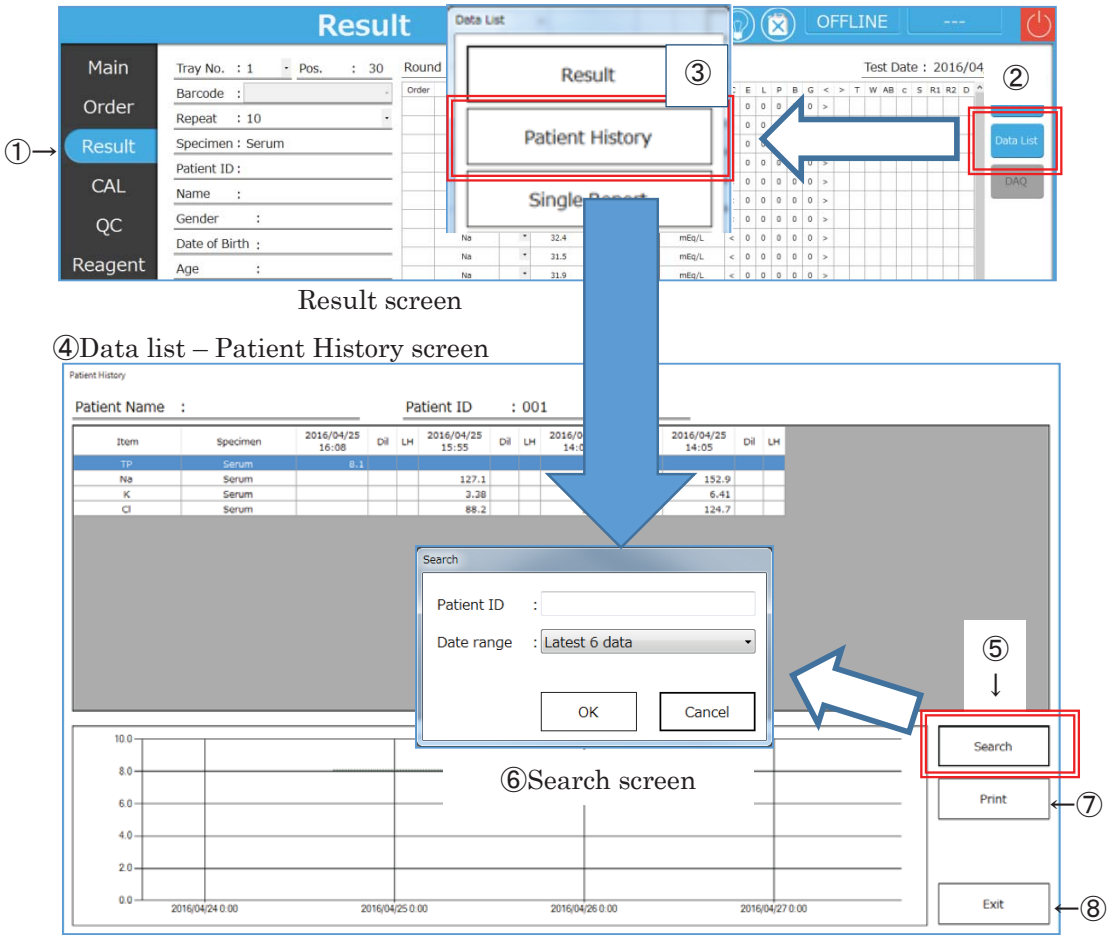
Patient Name Tray Pos. Barcode ID Specimen	1 1	1 2	1 3	1 4	1 5
	Serum	Serum	Serum	Serum	Serum
42 Item1	12.4	12.5	12.5	12.4	12.5
43 Item2	-1.4	-0.2	3.0	-1.2	-5.8
44 Item3	-0.3	2.2	1.8	0.2	-0.3
45 Item4	2.2	3.3	2.5	0.5	1.1
46 Item5	13.9	13.6	15.8	16.8	15.6
47 Item6	-0.5	1.8	-0.5	-2.5	-0.9
48 Item7	-1.5	-2.3	-8.7	-0.1	-6.9
49 Item8	0.7	3.8	2.1	-1.8	0.6
50 Item9	-16.6	18.0	1.2	16.9	-0.7
51 Item10	1.3	1.4	0.4	12.8	-1.1
52 Item11					
53 Item12					
54 Item13					
55 Item14					
78 Na					
79 K					
80 Cl					

1Page

⑧ Exit : Close result screen.

4-2. Data List - Patient History screen

- Test result history display, search, and print for individual patient
- To use Patient history, Patient ID input is necessary, in order screen.



① Result button : Result screen is shown.
② Data List button : Data list menu screen is popup.

Pop-up screen

③ Data List menu screen

Patient History button : Displays test result history for individual patient.

- Displays history rsults for searched patient.

Print out screen for individual patient

Pop-up screen

④ Patient History screen

	Contents
Patient Name	Patient name display
Patient ID	Patient ID display
Item	Test item name display
Specimen	Specimen kind display

	Contents
(File date)	Display test results.
Dil	Dilution ratio display.
LH	If the test result is out of normal range or panic range, displays error flag. ➢ As for check flag, refer chapter 6 Alarm function.

⑤ Search button : Searched screen is popup.

Pop-up screen

⑥ Search screen : Input search condition.

	Search condition input
Patient ID	Patient ID input
Date range ▼	Search period selection ➢ Select latest 6 times, 1, 3, 6 months, 1 year, all
OK	Search starts. ➢ Display of searched results.
Cancel	Close search screen.

⑦ Print (External printer) : Print test results which are currently displayed.

患者履歴

患者名：Name
患者ID：P001

項目名	検体種別	2016/02/22 17:08	Dil	LH	2016/02/02 13:51	Dil	LH	2016/01/29 20:25	Dil	LH	2016/01/29 19:49	Dil	LH
Item1	血清	14.6											
Item2	血清	14.6											
Item3	血清												
Item4	血清												
Item5	血清												
Item6	血清										3.2		
Item6	HbA1c				14.6								
Item7	血清										3.3		
Item7	HbA1c				14.6								
Item8	血清										3.2		
Item8	HbA1c				14.6								
Na	血清	-73.6											
Na	尿												
Na	HbA1c												
K	血清	-39.11											
K	尿												
K	HbA1c												
Cl	血清	-129.0											
Cl	尿												
Cl	HbA1c												
101HbA1c	HbA1c				13.0			13.0					
101HbA1c	HbA1c				13.0			13.0					
102HbA1c	HbA1c				13.0			13.0					
102HbA1c	HbA1c				13.0			13.0					
HbA1c	HbA1c				964.6			964.6					

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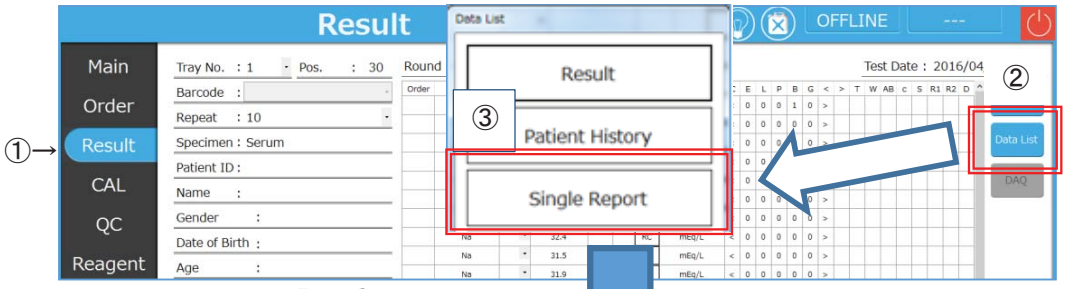
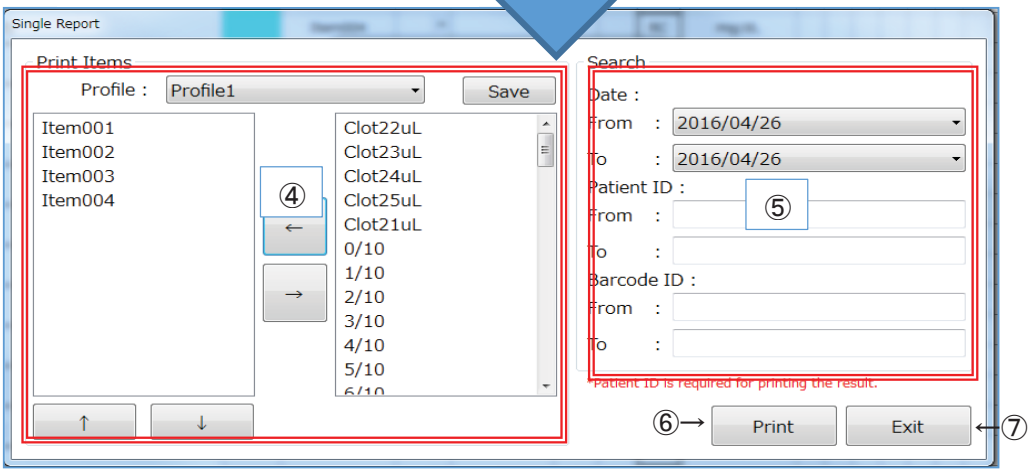
⑧ Exit : Close Patient history screen.

4-3. Data List - Single Report screen

- Patient report print contents (profile) setting, search and print
- To use Single report, Patient ID input, in Order screen, is necessary



Result screen



Data list – Single Report screen

① Result button : Result screen is shown.
② Data List button : Data list menuscreen is popup.

Pop-up screen

③ Data List menu screen Single report button.
: Patient report printing contents (Profile) setting, search and printing button screen display

Pop-up screen

④ Single report screen ; Profile setting of single report.

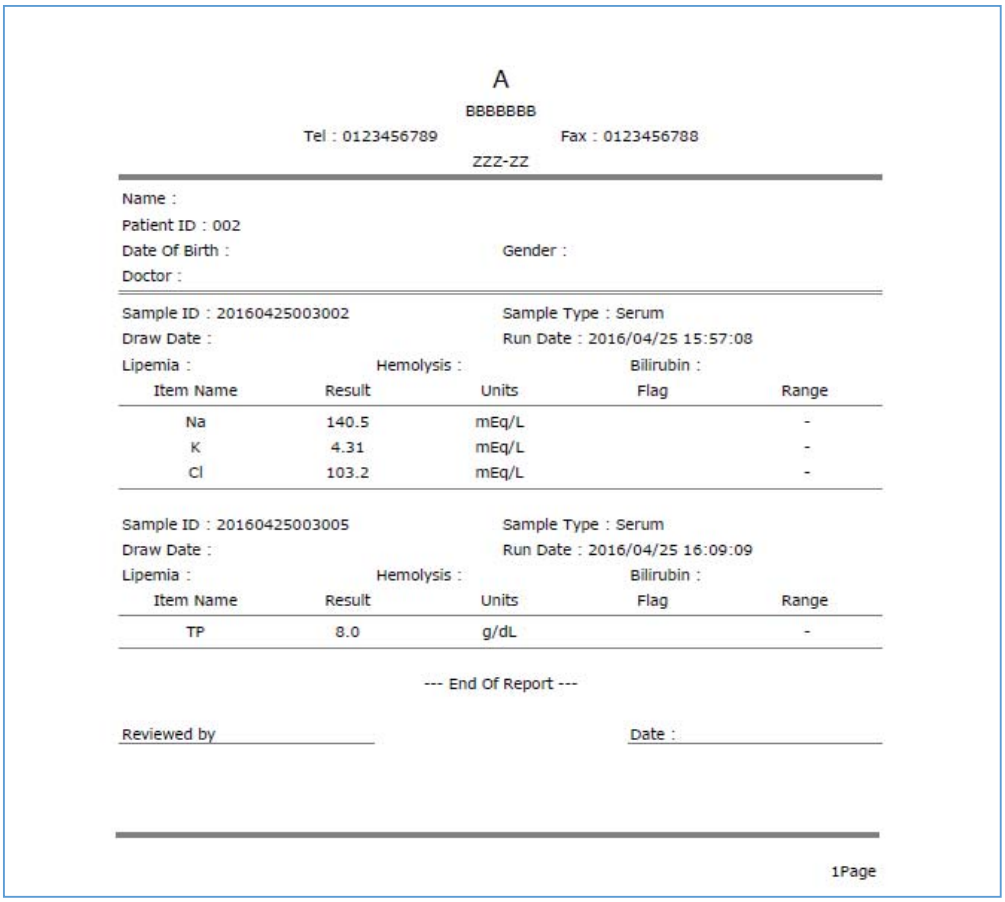
		Setting, search condition input
Print Items	Profile : ▼	Select profile name (Profile 1 – 8)
	In left side☐box	Item name which is registerd in profile display.
	In right side ☐ box	Item name display
	→←	←Register selected Item to Profile. →Delete selected Item from Profile.
	↑↓	Change the printing order of selected Item. ➢ Print from the top in order.
	Save	Store setting contents

⑤ Single report screen: Search

		Setting, search condition input
Search	Date: From ▼ to ▼	Select the date to search.
	Patient ID From to	Input is essencial. Input Patient ID to search
	Barcode ID From to	Input Barcode ID to search.

⑥ Print (External printer) : Print test results which are currently displayed.

- When the auto-print is selected for single report print in System screen, the patient report is printed out by last profile setting.



A
BBBBBBB
Tel : 0123456789 Fax : 0123456788
ZZZ-ZZ

Name :
Patient ID : 002
Date Of Birth : Gender :
Doctor :

Sample ID : 20160425003002 Sample Type : Serum
Draw Date : Run Date : 2016/04/25 15:57:08
Lipemia : Hemolysis : Bilirubin :

Item Name	Result	Units	Flag	Range
Na	140.5	mEq/L		-
K	4.31	mEq/L		-
Cl	103.2	mEq/L		-

Sample ID : 20160425003005 Sample Type : Serum
Draw Date : Run Date : 2016/04/25 16:09:09
Lipemia : Hemolysis : Bilirubin :

Item Name	Result	Units	Flag	Range
TP	8.0	g/dL		-

--- End Of Report ---

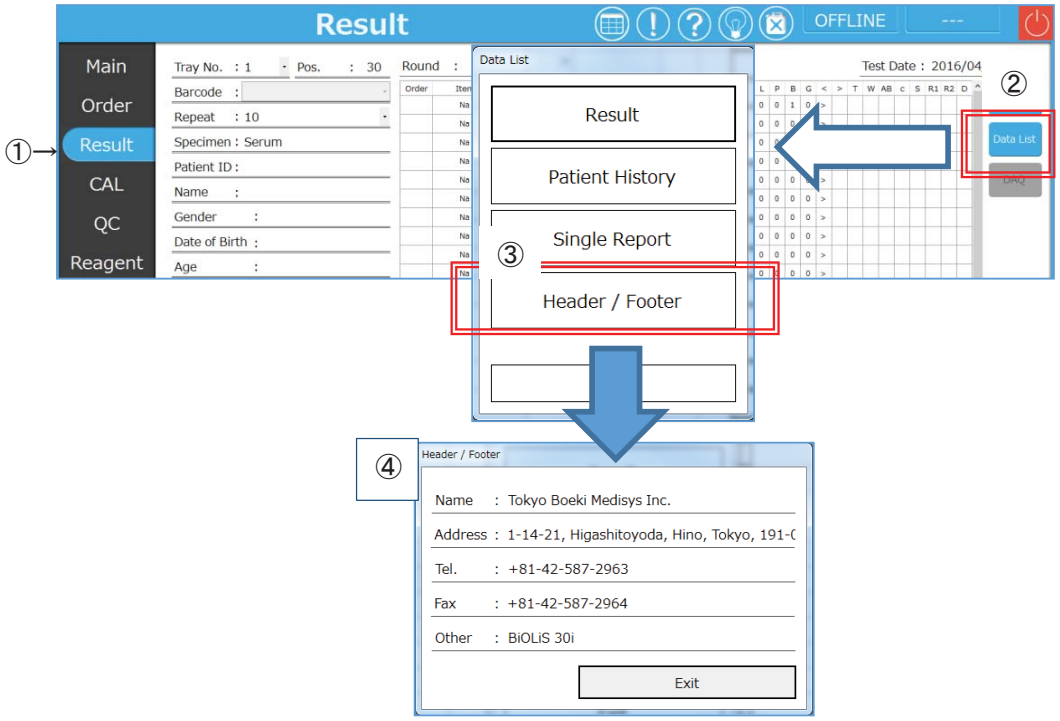
Reviewed by Date :

1Page

⑦ Exit : Close single report screen.

4-4. Data List – Header／Footer screen

➢ Header and footer setting for Data list (Patient report) screen.



Header/Footer screen

① Result button : Result screen is shown.
② Data List button : Data list menu screen is popup.

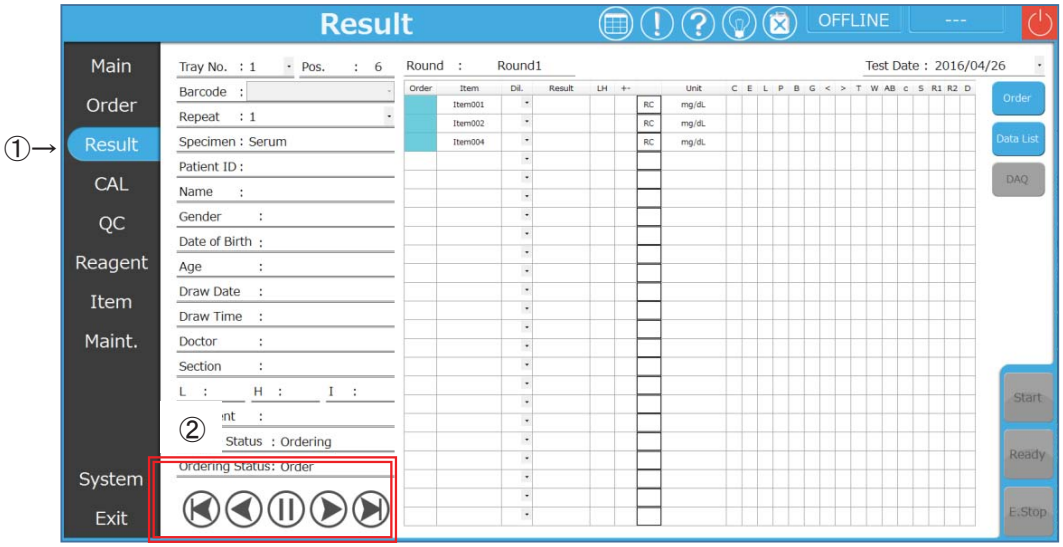
Pop-up screen
③ Data list menu screen Header/Footer button.
: Set for header /footer in patient report printing.

Pop-up screen
④ Header/Footer screen-Input and set the contents to be printed.

	Setting contents
Name	Input hospital name and so on.
Address	Input hospital address.
Tel.	Input hospital telephone number.
Fax	Input hospital ax number.
Other	Input comment.
Exit	Close Header/Footer screen.

5. Test result screen switching button

- Test result screen switching button
- Under Barcode mode, this button is not shown.
  The sample mode can be selected in System screen. Default mode is Position mode.
  If Barcode mode is used, screen switching can be done by clicking Barcode ▼.



Result screen

① Result button : Result screen is shown.

② Buttons and functions

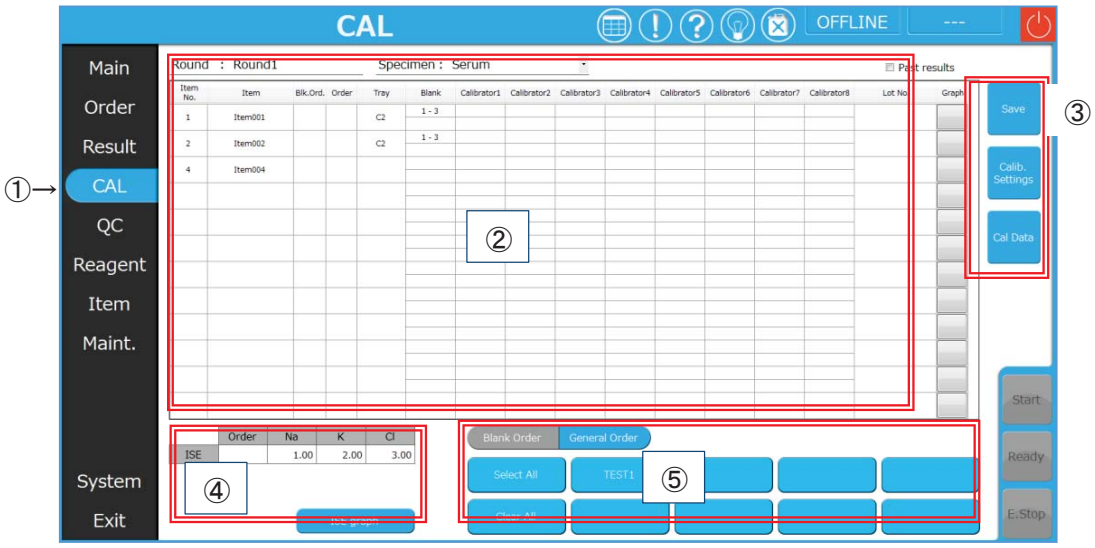
	Content	
	Former search button	Displays the first position of shown round.
		Displays test result screen, one step smaller position number than current screen.
	Search button	Displays test result screen of input position number.
	Next search button	Displays test result screen, one step larger position number than current screen.
		Displays test result screen of position number which is the largest day among file date.

4.4 Calibration screen

Clicking CAL button, calibration screen opens.

- CAL screen : Display of the Calibration results.
- Standard button : Display setting screen for calibration samples (position, repetition) including standard sample concentration.
- Cal Data button : Display of calibration result details.

4.4.1 The contens of CAL screen

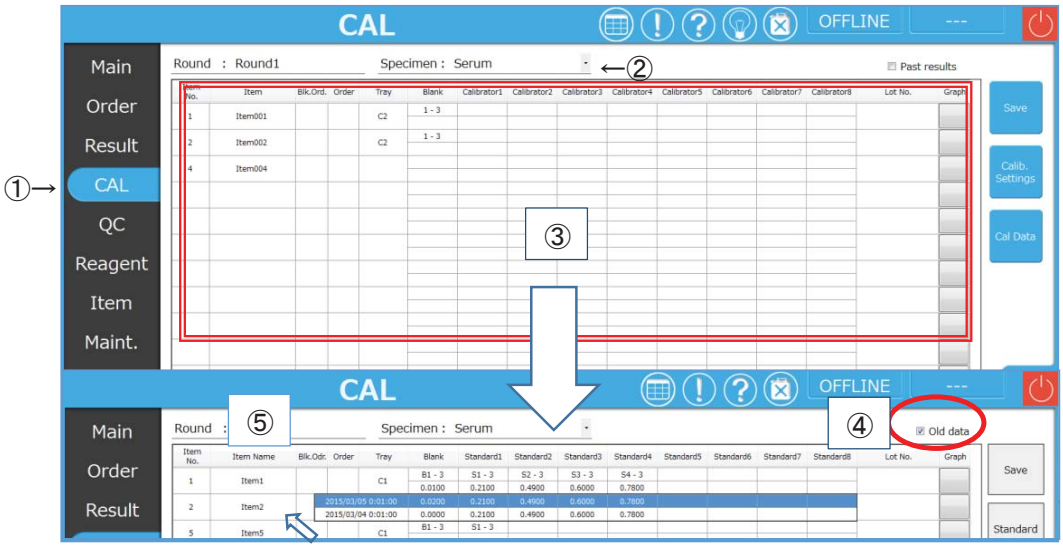


CAL screen

① CAL button : Display calibration screen.
② Display of the calibration Item, order and calibration result.
③ Display of the calibration order button.
Calibration setting, standard sample concentration input button.
Calibration result list button.
④ ISE calibration order and result display.
⑤ Display of the QC Item profile, order all and clear buttons.

6. CAL screen -Item order, results

➢ Clicking of CAL button, display of the calibration setting, order and results.



CALscreen – Old calibration result screen (Except ISE)

① CAL button : Display calibration screen.

② Specimen ▼ : Select Specimen

③ Display calibration Item order, results.

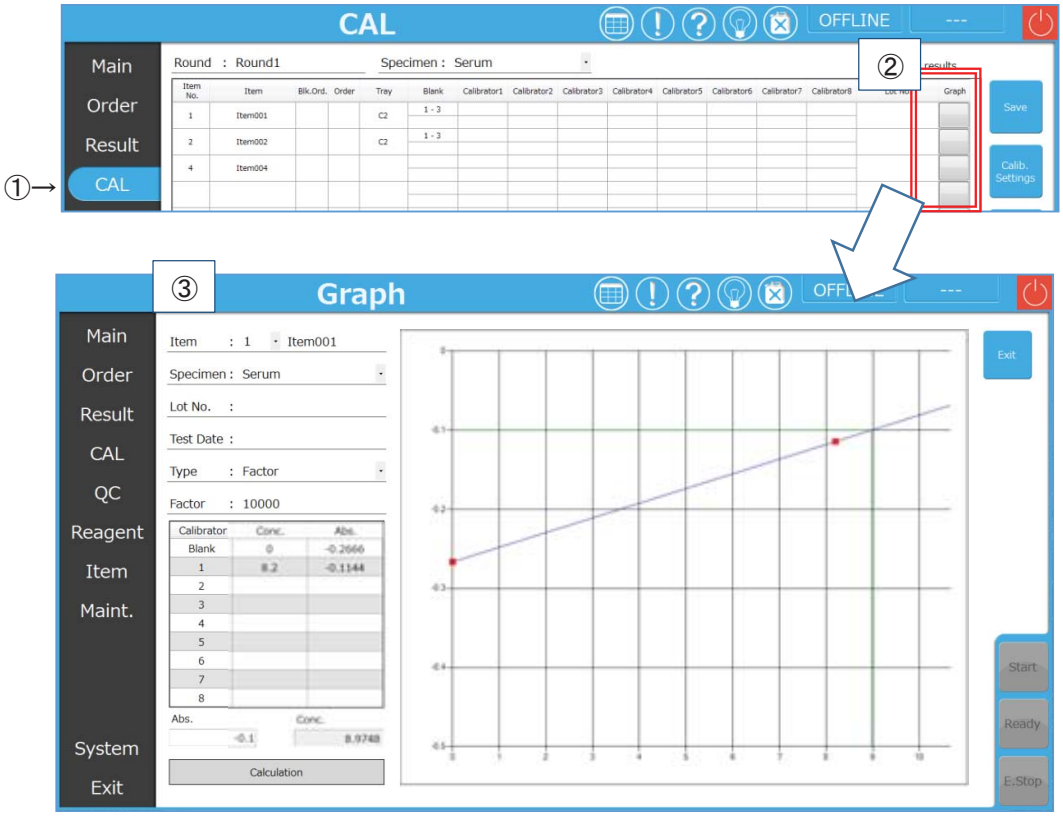
	Contents	
Round	Display reagent round name	
Specimen	Select “Specimen”.	
☐Past result	Display old calibration results. ➢ ④After レ, ⑤ select Item ➢ Clilck ISE graph button for ISE Items	
Item No.	Display by reagent round and specimen selection automatically.	Display Item number
Item		Display Item name
Blk.Odr.	Order calibration blank sample	The order status is shown by blue color.
Order	Order calibration measurement	The order status is shown by dark blue color.

➢ Tray, calibration sample positionand repetition is set in Calb.setting screen.

Tray		Display calibration tray number.
Blank	Upper	Display of the balnk sample position (left side) and repetition number (right side)
	Lower	Display of the blank sample result (Absorbance).
Calibrator 1 ～8	Upper	Display of the standard sample position (left side) and repetition number (right side)
	Lower	Display of the standard sample result (Absorbance).
Lot No.		Display of the standard sample Lot number when using reagent barcode.
Graph		Display of the calibration graph screen.

7. CAL screen – Graph screen

➢ Clicking Grap button,display of the calibration graph



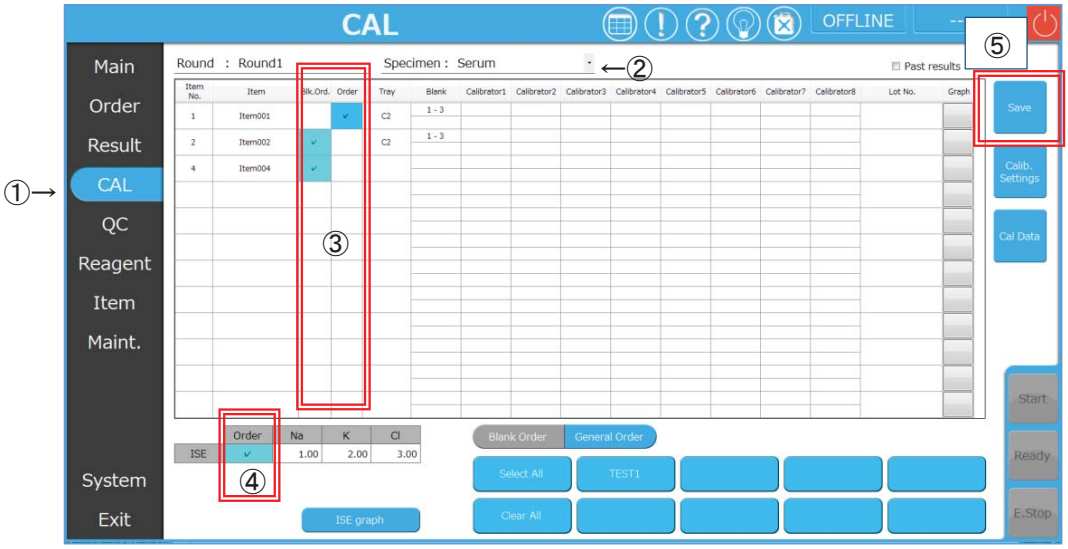
CALscreen – Graph screen

① CAL button : Display calibration screen.
② Graph button □ : Display of the selected Item graph screen.
③ Graphscreen

		Contents
Item ▼		Select Item number. (Display Item name)
Specimen ▼		Select "Specimen".
Lot No.		Display of Lot number which used in measurement.
Test Date		Display of the calibration date.
Type		Display of the calibration kind. ➢ Type is able to change for simulation.
Calibrator blank,1 ～8	Conc.	Display of the balnk and standard sample concentration.
	Abs.	Display of the calibration result (Absorbance).
Abs.□		Input the absorbance value for calculation.
Conc.		Display of concentration value by inputted value in Abs.box □.
Caluculation button		Do calculation by inputted Abs. box □.

8. Calibration order

➢ Order entry of calibration in this screen.



CAL screen

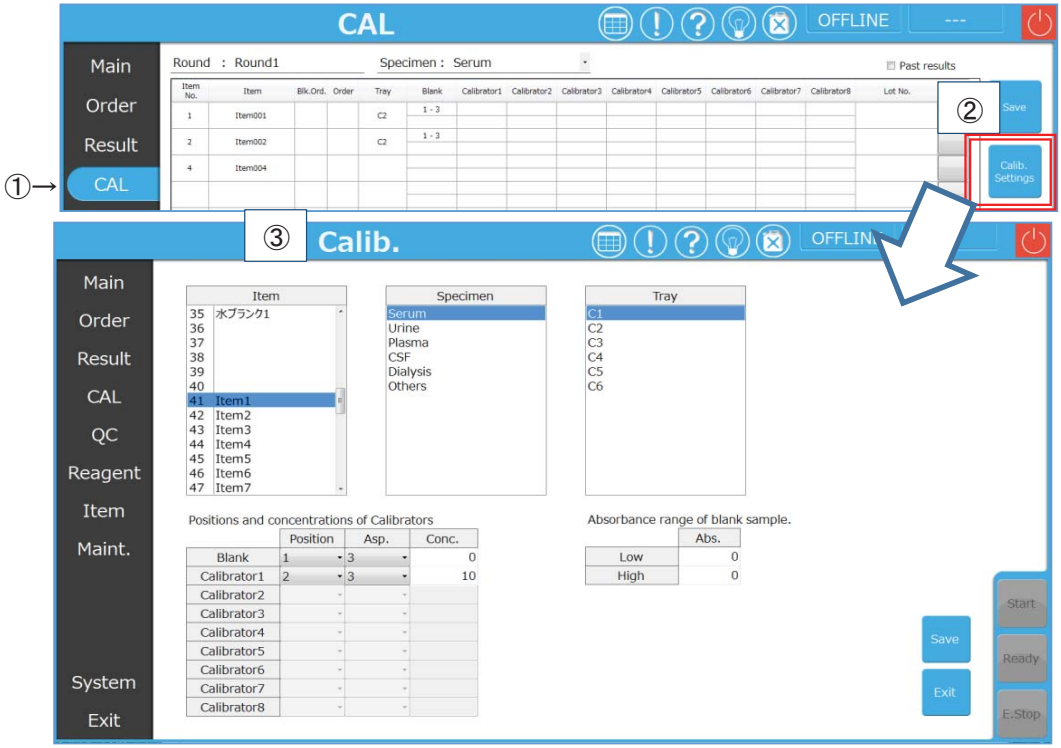
① CAL button : Display calibration screen.
② Specimen: ▼ : Select Specimen.

③ ,④ box : Chek the Item box ☑ for calibration order.
➢ The order status is shown by color in Blk.Odr. blue and Order dark blue.

⑤ Save button ; Save the orderd Item in ③, ④ box.

9. Calib. settings screen

- Setting of calibration (sample position and repetition), and input standard sample concentration.



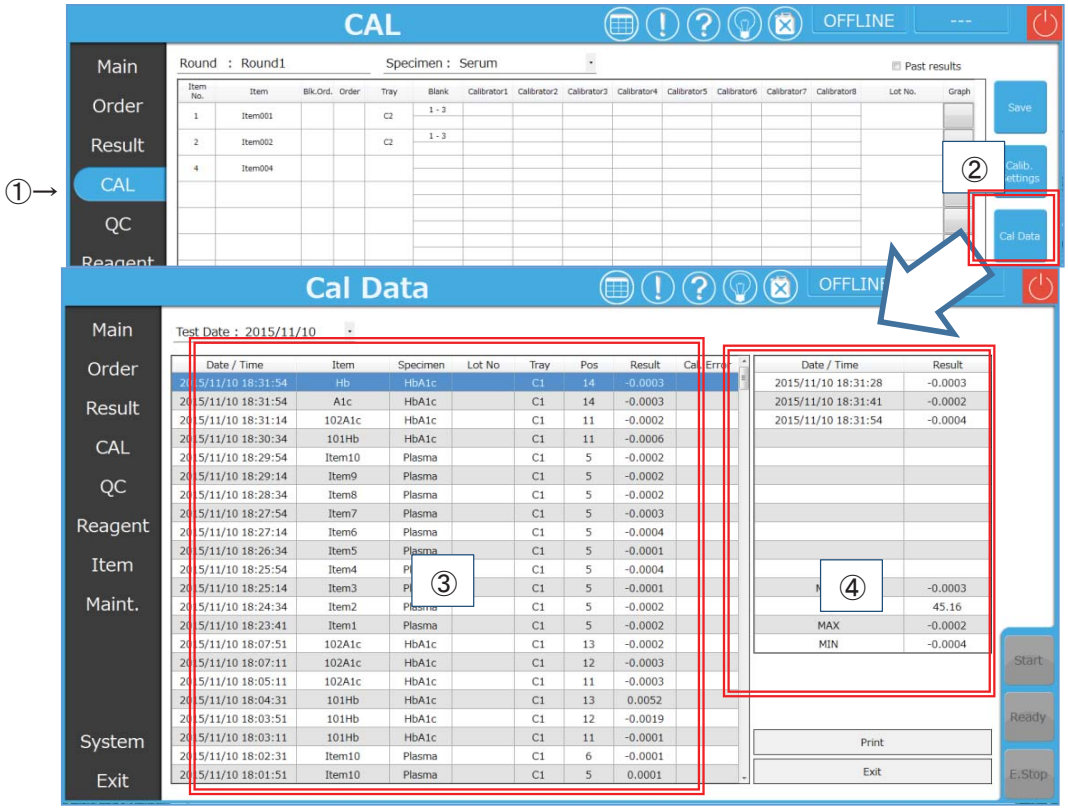
CALscreen – Standardscreen

① CAL button : Display calibration screen.
② Standard button : Display standard screen.
③ Screen and functions

		Contents
Item		Select Item name from the Item list.
Specimen		Select "Specimen" from the list.
Tray		Select calibration tray (C1-C6) from the tray list.
Position and concentration of the standard samples.		
Blank, Calibrator 1 ～8	Position	Select the position for calibration sample (1-45).
	Asp.	Select the repetition (1-10).
	Conc.	Input the concentration of blank or standard sample.
Absorbance range of blank sample.		
Low High	Abs.	Setting of absorbance limit (Low, High) for balnk sample. ➢ Display the error flag if the absorbance of balnk sample is out of range. No check is done if the value is zero or low and high values are the same.
Save		Save the selected or inputted data.
Exit		Close the calibration setting screen.

10. Cal Data screen

- Display of the calibration result list.
- The calibration results list is shown by date.



CALscreen – Cal Datascreen

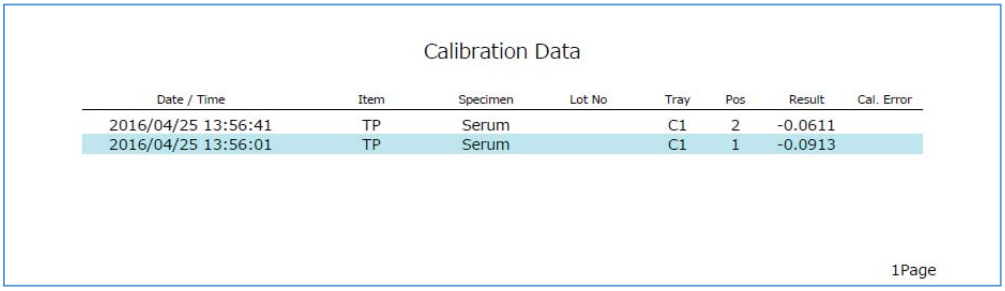
① CAL button : Display calibration screen.
② Cal Data button : Display of Cal Data screen
③ Cal Data Screen

	Contents
Test date ▼	Select the calibration date.
Date/Time	Display of calibration date and time.
Item	Display of Item name.
Specimen	Display of “Specimen”.
Lot No.	Dissply of the Lot number for calibration measurement when using the reagent barcode.
Tray	Display of the tray for calibration measurement.
Pos.	Display of the sample position for calibration measurement.
Result	Display of the calibration result (Absorbance)
Cal.Error	Display the error flag if the error occured when calibration measurement. ➢ Please refer to Chapter 6 Alarm information.

④ Cal Data screen details : Select the Item in the ③ list. Display of the details of calibration result and calculation result.

	Contents
Date/Time	Display of calibration date and time.
Result	Display of the calibration result (Absorbance)
Calculation results	
Mean	Display the value of Absorbance (Abs.) average.
CV	Display of CV(%).
MAX	Display of the maximum Absorbance (Abs.).
MIN	Display of the minimum Absorbance (Abs.).

⑤ Print (External printer) button ; Print the Cal Data list to external printer.


Calibration Data

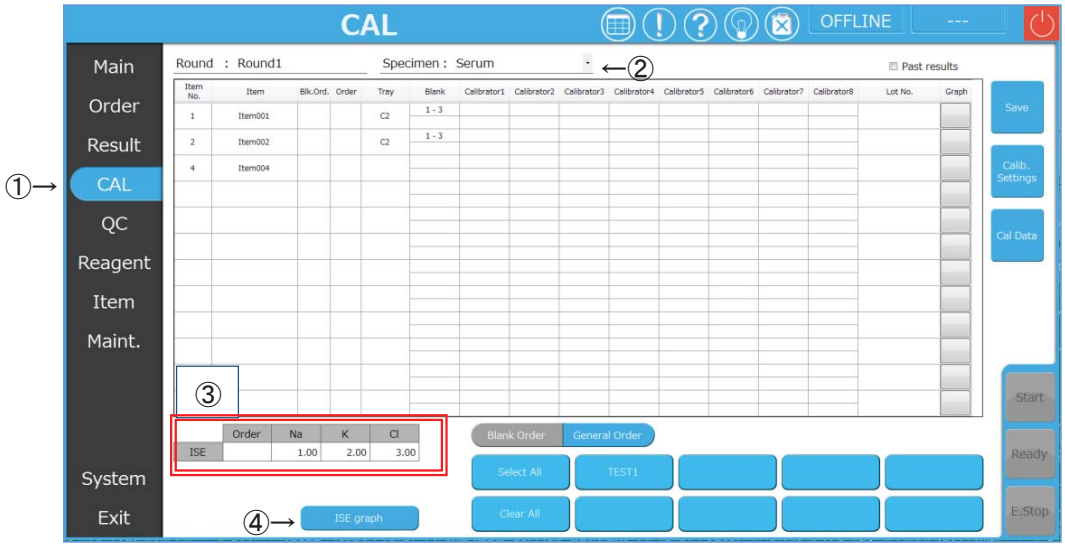
Date / Time	Item	Specimen	Lot No	Tray	Pos	Result	Cal. Error
2016/04/25 13:56:41	TP	Serum		C1	2	-0.0611	
2016/04/25 13:56:01	TP	Serum		C1	1	-0.0913	

1Page

⑥ Exit button : Close the Cal Data screen.

11. ISE CAL screen - Order and result display

➢ Calibration order and result for the ISE Items.



CAL screen

① CAL button : Display calibration screen.
② Specimen ▼ : Select Specimen.

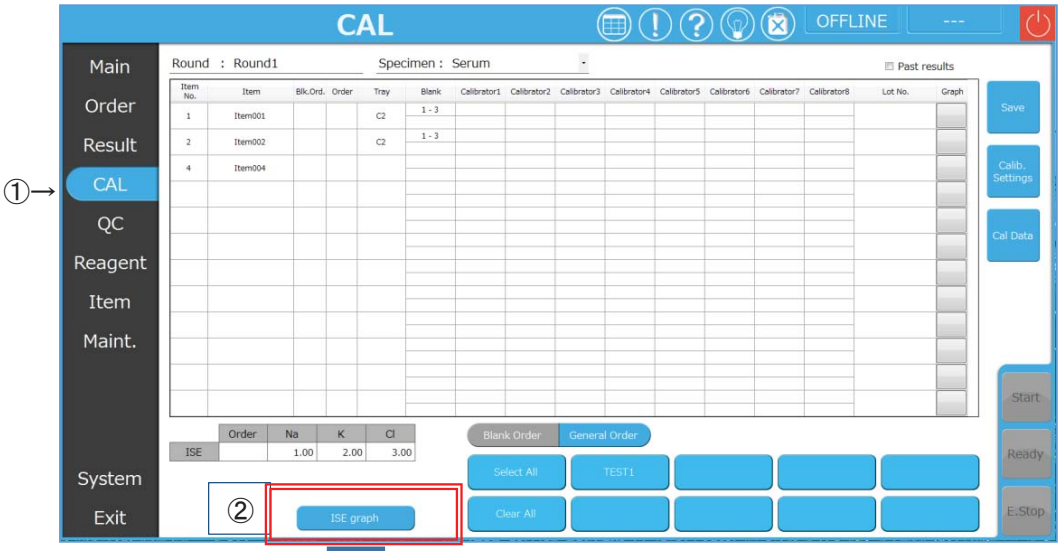
③ ISE Cal screen : Display of the ISE calibration results.

	Contents
Order	Chek the ISE Item box ☑ for calibration order. ➢ Order status is shown by blue color.
Na／K／Cl	Display of the calibration results.

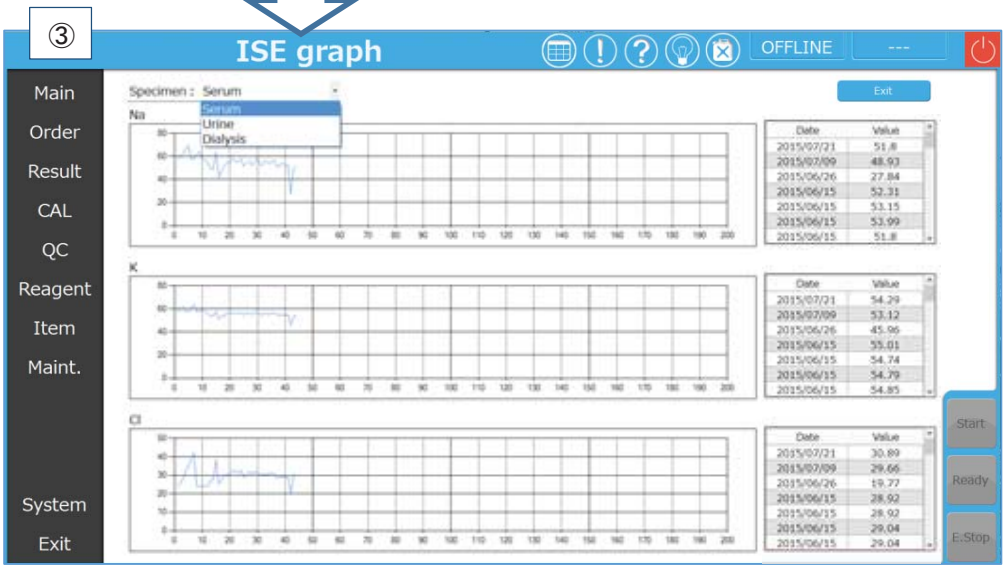
④ ISE graph button : Display of the ISE calibration graph screen.

12. ISE graph screen

➢ Clicking of ISE graph button, ISE calibration graph is shown.



CAL screen



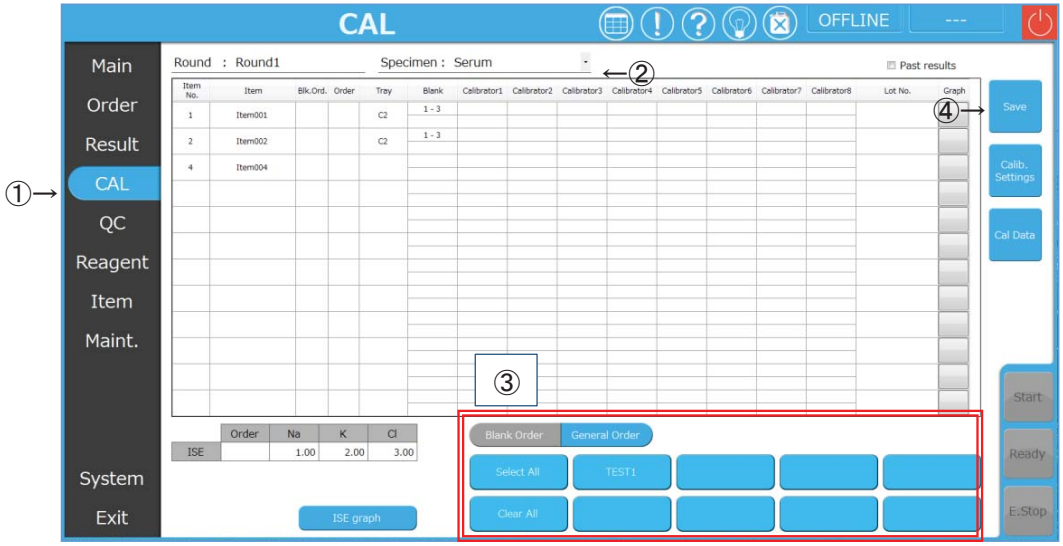
CAL screen – ISE graph screen

① CAL button : Display calibration screen.
② ISE graph button : Display of ISE calibration graph.
③ ISE graph screen

		Contents
Specimen		Select "Specimen". (Serum、Urine、Dialysis) .
Exit		Close the ISE calibration graph screen.
Na、K、Cl	(Graph)	Vertical axis ; Calibration value =Slope value (mV/dec.) Horizontal axis ; Calibration times
	Date	Display calibration date.
	Value	Display calibration value (Slope value).

13. Calibration profile, Order all and cancel button

- Perform the calibration order entry by profile, order all or cancel in one time.
- Please refer to Chapter 4. 4.9 Profile setting.
- The ISE Items can not order or cancel in one time.



CAL screen

① CAL button : Display calibration screen.
② Specimen ▼ : Select specimen.

③ Buttons and functions : Order or cancel by selection.

	Contents
Blank Order	Select for measurement order of calibration blank.
General Order	Select for measurement order of Item.
Select all	Enter for all test Items on this screen.
Clear all	All the ordered Items are canceled.
(Profile name)	Calibration order entry for profile registration Items previouly. ➢ Profile can be set maximum 8 set. ➢ Please refer to System screen-profile for profile setting.

- The ordered Item turns to blue or dark blue.

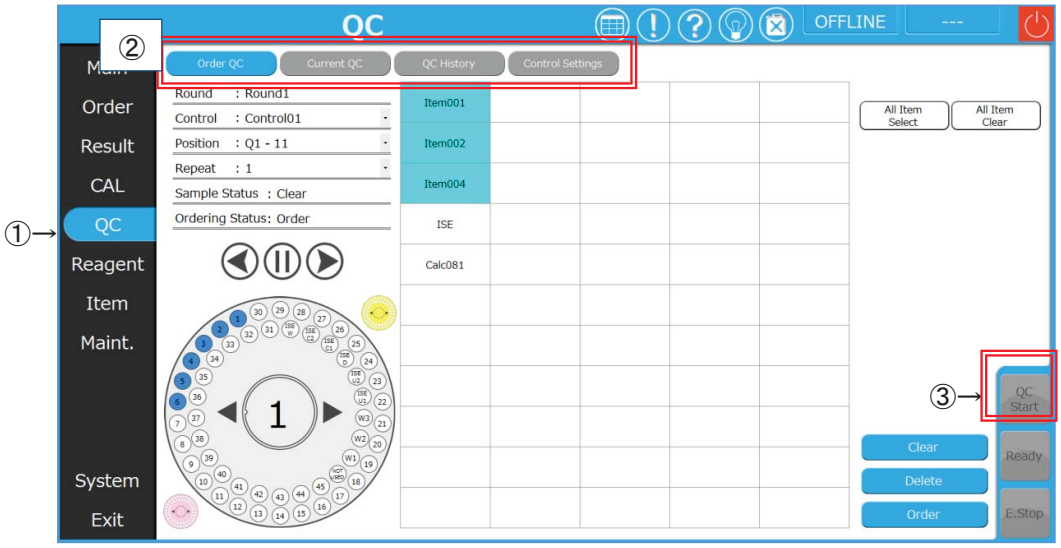
④ Save button : Save the calibration order entry.

4.5 QC screen

- QC sample measurement setting screen (parameter setting, order entry, measurement and results) displays.
- QC is controlled by WESTGARD MULTI-RULECHART method.

4.5.1 QC screen contents

- Display Controls (Order QC, Current QC, QC History, and Control setting). Display each screen by clicking buttons..



QC screen—Order QC. Screen

① QC button : Display QC screen

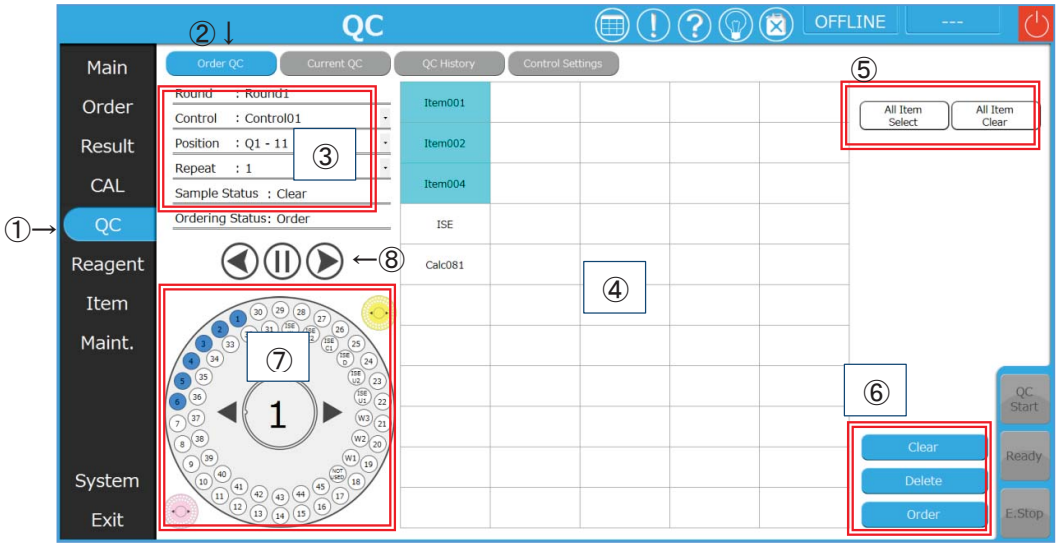
② Screen and functions

	Contents
Order QC	Entry the order of QC sample.
Current QC	Display latest QC result list.
QC History	Display day to day QC results.
Control settings	Setting for the QC measurement. ➢ Input for control sample name and setting of using QC sample. ➢ Measurement position of QC sample. ➢ Input of mean, SD, Max and Mini for QC sample. ➢ Profile setting for QC sample.

③ QC Start button : Starts the QC sample measurement.

4.5.2 Order QC screen

➢ Display of order entry screen for QC sample.



QC. screen—Order QC. Screen

① QC button : Display QC screen
② Order QC button : Order entry for QC sample.
③ Display of profile information for QC sample.
➢ Profile of QC sample is set in Control settings screen.

	Contents	
Round	Display of reagent round.	
Control ▼	Select control name of QC sample. ➢ Display control name which registerd in control settings screen.	
Position ▼	Select sample tray round and sample position. ➢ Display of selected profile position.	
#of Asp ▼	Select aspiration time.	Maximum 10
Sample state	Sample state display	Clear (No order entry) Order Run Complate Erro (Error has detected)
Order state	Display of order entry status	Order (First test) Re-run order

④ Display of test Item : The back color of ordered Item changes to blue.
➢ When select control name, order the test Items which set in control settings screen automatically.

⑤ Select all : Order entry for all test Items of QC sample on this screen.
Clear all : Cancel for all test Items of QC sample on this screen.

⑥ Order QC button : Order entry by clicking Order QC button after Item selection.

	Contents
Clear	Invalidate the input.
Delete	Delete the order entry of QC sample.
Order	Order entry of QC sample.

⑦ Tray Icon : Confirmation of QC sample position.
The color of ordered Item changes to blue.

- QC tray can be selected "ON" in System parameter.
  - Select the tray kind.
    - Patient tray : Gray
    - QC tray : Pink
    - Calinration tray : Yellow
  - Select the tray number.
    - Patient tray : 1-50
    - QC tray : Q1-Q3
    - Calinration tray : C1-C6

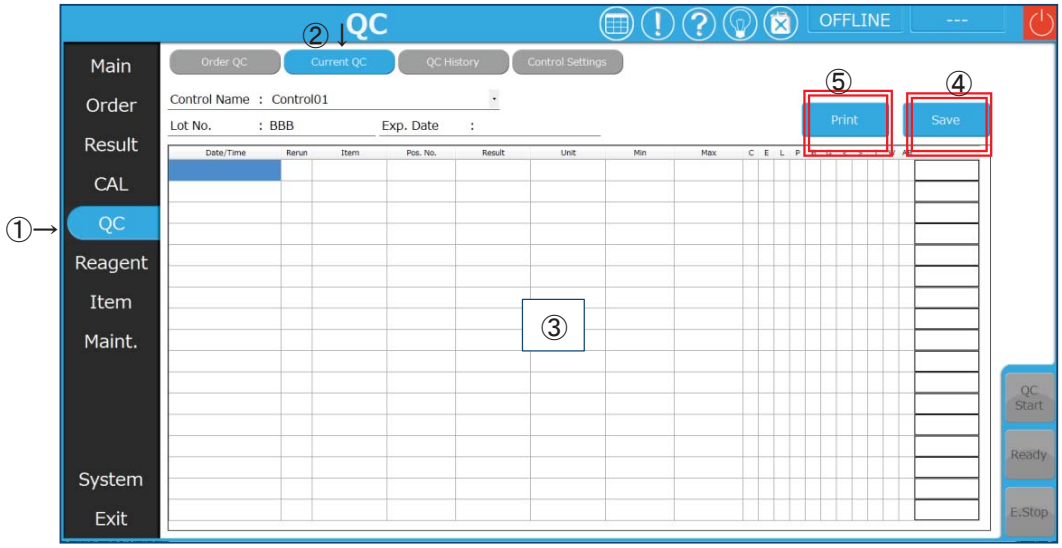
⑧ Order entry switching button

- Display QC order screen which set in QC settings screen.

	Contents	
	Former search button	Display order entry screen of former position from current screen.
	Search button	Display order screen of inputted position.
	Next search button	Display order screen of next position from current screen.

4.5.3 Current QC screen

- Display of QC results.
- The latest test results of selected QC samples are shown.



QC. screen —Current QC. screen

① QC button : Display of QC screen

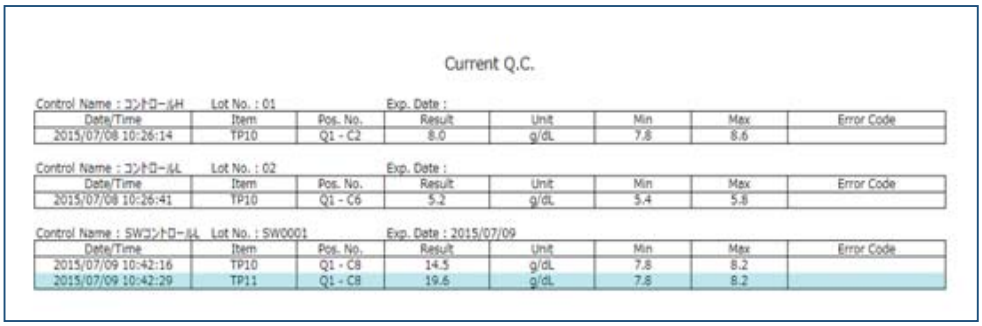
② Current QC button : The latest test results of selected QC samples are shown.

③ Screen and functions

	Contents
Control Name ▼	Select QC profile name.
Lot No.	Display of QC lot number..
Exp. date	Display of QC sample effective date.
Date / Time	Display of tested date and time.
Rerun	Select and order the rerun Item. ➢ Blue color in the box shows rerun status. ➢ Rerun order is possible within a day.
Item	Display Item name.
Pos.No.	Display of sample tray and position number. ➢ Tray (left) - Position number (right)
Result	Display of QC sample result.
Unit	Display unit.
Min	Displays the minimum value of control range
Max	Displays the maximum value of control range
C ～ AB	If error occurred, chenage the color to red.
Approval	The results are refrected to QC history screen.

④ Save button : Order entry of rerun.

⑤ Print External printer）: Print latest results of QC sample.



Current Q.C.

Control Name : ｺﾝﾄﾛｰﾙH Lot No. : 01 Exp. Date :

Date/Time	Item	Pos. No.	Result	Unit	Min	Max	Error Code
2015/07/08 10:26:14	TP10	Q1 - C2	8.0	g/dL	7.8	8.6	

Control Name : ｺﾝﾄﾛｰﾙL Lot No. : 02 Exp. Date :

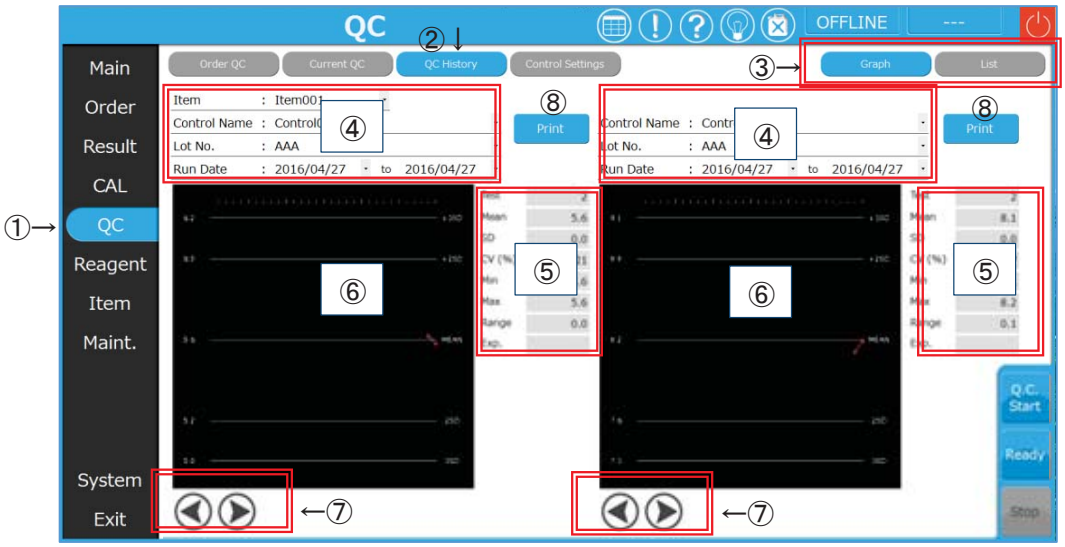
Date/Time	Item	Pos. No.	Result	Unit	Min	Max	Error Code
2015/07/08 10:26:41	TP10	Q1 - C6	5.2	g/dL	5.4	5.8	

Control Name : SWｺﾝﾄﾛｰﾙL Lot No. : SW0001 Exp. Date : 2015/07/09

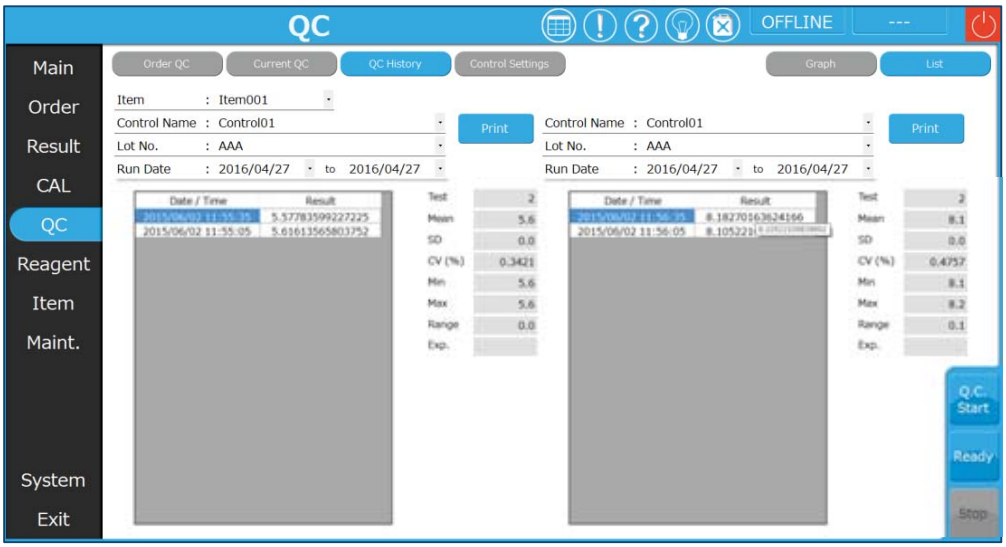
Date/Time	Item	Pos. No.	Result	Unit	Min	Max	Error Code
2015/07/09 10:42:16	TP10	Q1 - C8	14.5	g/dL	7.8	8.2	
2015/07/09 10:42:29	TP11	Q1 - C8	19.6	g/dL	7.8	8.2	

4.5.4 QC History screen

- Display of day to day QC results by graph and list.
- Display of the results which is approved in currect QC screen.
  Two QC sample results are shown in one screen.



QC History (Graph) screen



QC History (List) screen

① QC button : Display QC screen
② QC History button : Display Cumelative QC screen
③ Graph List button : Display of graph or list screen for two QC samples.
④ Screen and functions

	Contents
Item ▼	Select Item name
Control Name ▼	Select QC profile name

	Contents
Lot No. ▼	Display of QC sample lot number.
Run date: From ▼ to ▼	Select the starting date and ending date.

⑤ ④Display of Statistical calculation result

		Contents
Statistical calculation result	Test	Test number display in the set range.
	Mean	Mean display in the set range.
	SD	Standard deviation display in the set rang.
	CV(%)	Variation coefficient display in the set rang.
	Min	Minimum value display in the set range.
	Max	Maximum value display in the set range.
	Range	(Maximum value – minimum value) display in the set range.
Exp.		Effective date of set QC sample display

⑥ Display of QC results by graph and list.

Graph

- Westgard mark displays on the top.

Westgard mark	Contents
A	If QC sample data exceeds +/-2SD, random error is in expectation.
B	If QC sample data exceeds +/-3SD, accidental error is in expectation. ➢ Random error is in expectation.
C	If two kinds QC sample data exceeds 2SD in the same direction, or tow continuous data of the same QC sample exceeds 2SD in the same direction, systematic error is in expectation. ➢ Systematic error is in expectation.。
D	If the SD range of two kinds QC sample data exceeds 4SD, or SD range of the same QC sample data exceeds 4SD. ➢ Systematic error is in expectation.
E	Four continuous data of the same QC sample exceeds 1SD in the same direction. ➢ Random error is in expectation.
F	Ten continuous data of the same QC sample appears in the same direction. ➢ Systematic error is in expectation.

Random error = Unstable QC result which happens by contamination, delicate environmental difference and undefined reason. It is difficult to remove the reason which suspects the cause.

Systematic error =The QC result shows partiality from the true value.
It happens by improper standard sample and reagent, influence of interference substance and incomplete tuning of the analyzer.

List

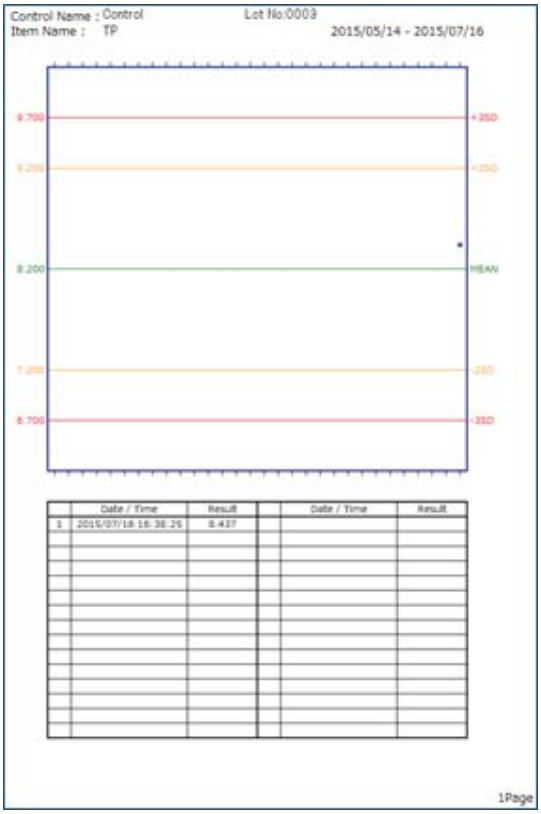
	Contents
Date / Time	Display of tested date and time.
Result	Display of QC sample result.
Delete	Delete the QC result in QC history screen

⑦ Graph screen switching button (Display in graph screen)

	Contents	
	Former search button	Display test result of former date from current screen.
	After search button	Display test result of after date from current screen.

⑧ Print (External printer) : QC screen is printed out for graph and list.

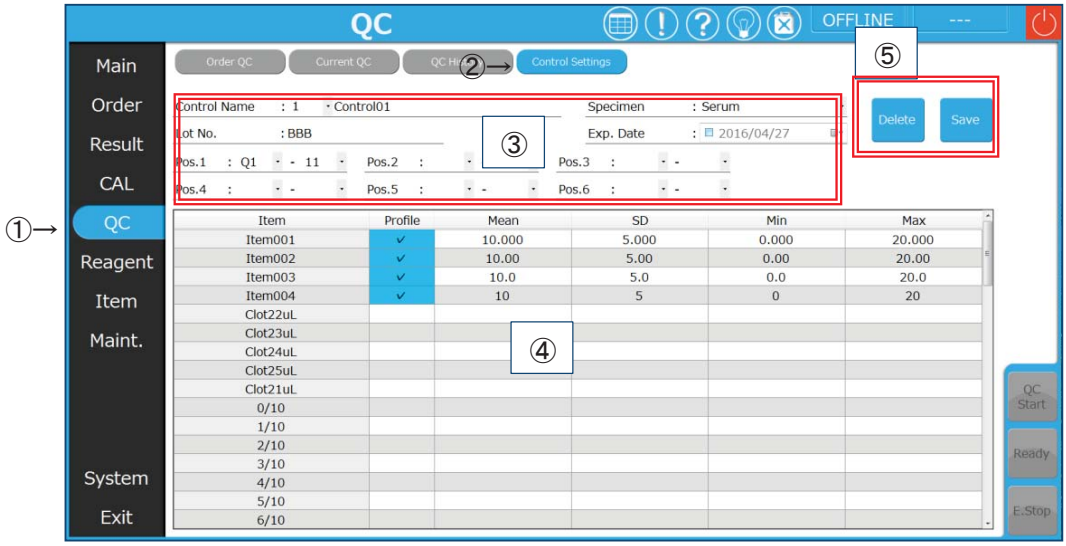
- Print both of graph and list. (Upper part is graph and down part is list)
- Print 30 times results in one page.



4.5.5 Control settings screen (QC sample setting screen)

➢ QC sample setting screen display.

1) Control name and setting of control.
2) Setting of measurement position.
3) QC parameter setting. (Mean、SD、Min、Max)
4) Setting of QC profile.



Q.C.screen—Control settings screen

① QC button : Display QC screen
② Control settings button : Control input screen is shown.
③ Setting for the following QC Items.

	Contents	
Control name ▼	Select QC profile number.	From 1～30
	Input profile name.	Max16 character
Specimen▼	Select "Specimen" (Serum, Urine, Plasma, CSF, Dialysis, Other, HbA1c)	
Lot No.	Input lot number of QC sample.	Max 8 character
Exp.Date	Check the box レ when input the expire date. Select effective date of QC sample from calendar.	
Pos.1 : ▼- ▼～ Pos.6 : ▼- ▼	Select tray and QC sample position.	

Tray	Tray No.	Position No.
Patient	1 – 50	31-45
Calibration	C1-C6	31-45
QC	Q1-Q3	1-45

➢ When using the QC tray, turn on the QC tray in System screen. Please refer to Chapter 4, 4.9.6 System setting screen.

④ Setting of Item and parameters: Input Item and control value.

	Contents
Item	Display of Item name
Profile	Select the Item by clicking check box ☑ for QC profile entry.
Mean	Input mean value for result check.
SD	Input standard deviation.
Min	Minimum value is inputted automatically. (Mean−2SD)
Max	Maximum value is inputted automatically. (Mean+2SD)

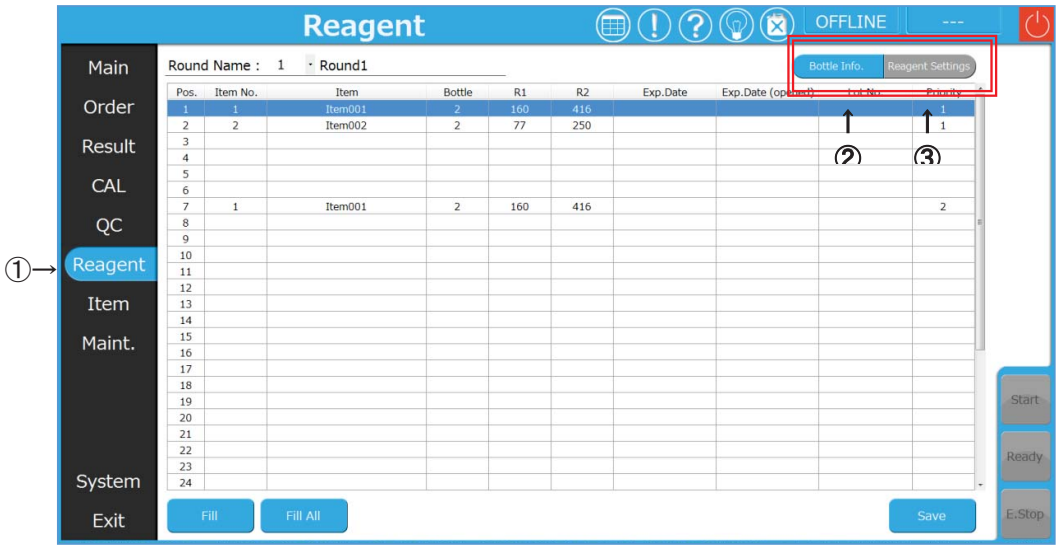
⑤ Delete button and Save button

	Contents
Delete	All the profile setting is deleted.
Save	All the profile setting is stored.

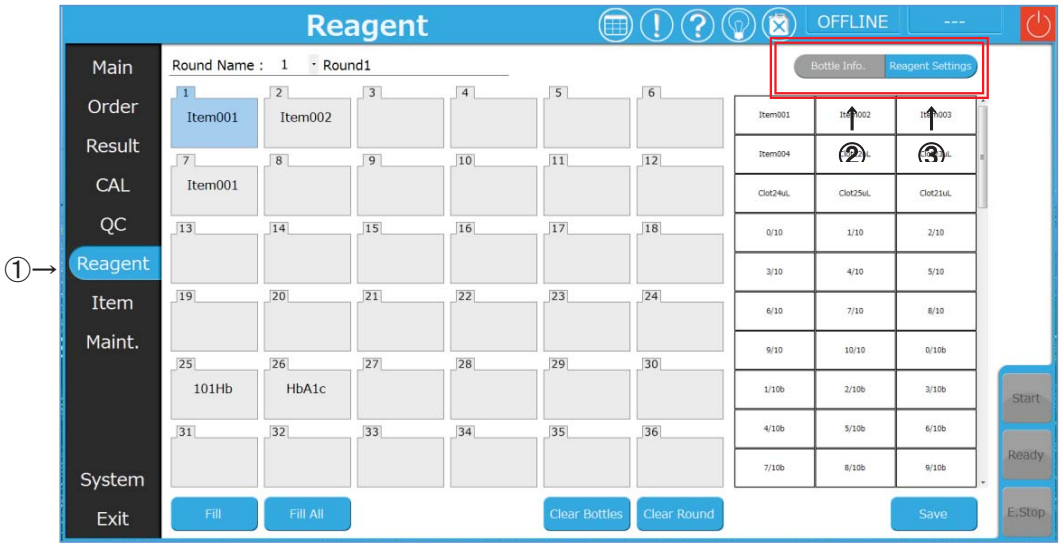
4.6 Reagent screen

- Display of setting for reagent bolltle and confirmation of bottle information.
  1) Bottle info. Screen : Input reagent round, bottle information (tray), renewal bottle and expire date.
  2) Reagent settings screen : Setting for reagent bottle (Reagent tray round,bottle position.

4.6.1 Reagent screen



Reagent screen—Bottle Info screen

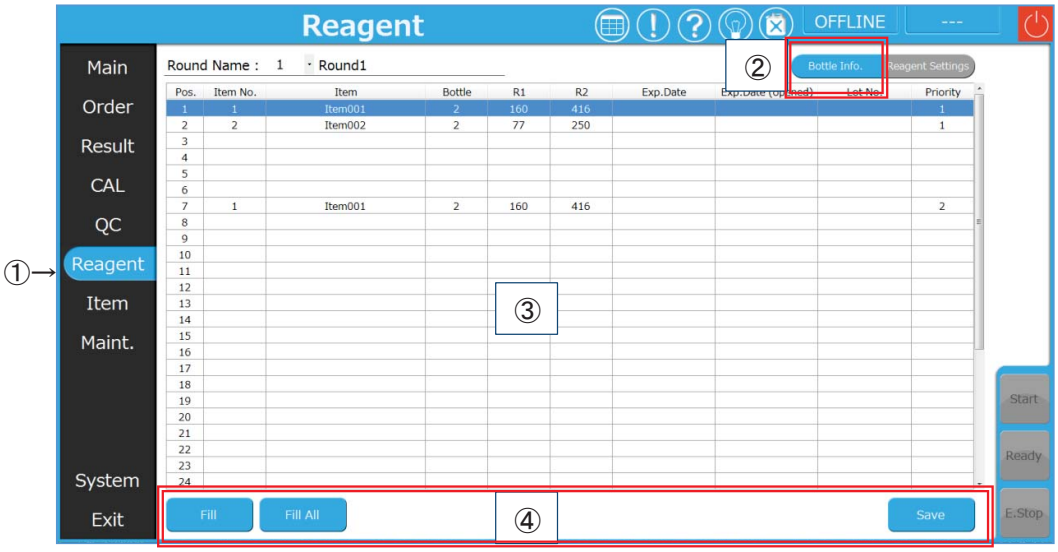


Reagent screen Reagent setings screen

① Reagent button : Display reagent screen.
② Bottle Info. button : Display of reagent bottle information screen.
③ Reagent Settings button :Display of reagent setting screen.

4.6.2 Bottle Info. screen (Reagent bottle information screen)

➢ Setting for reagent round, bolltle information (tray), renewal and expire date.



Reagent screen—Bottle Info screen

① Reagent button : Display reagent screen.
② Bottle Info. button : "Bottle Info." screen is shown.
③ Screen and functions : Display of bottle information, reagent remain and expire date.

	Contents	
Round name ▼	Select reagent round.	From 1 to 10
	Display of reagent round name. ➢ Input round name is possible. (Max10 character)	
Pos.	Bottle position number is shown. ➢ Position number for each reagent tray. 24 Item tray;1 - 24 36 Item tray; 1- 36	
Item No.	Display of Item number.	
Item name	Display of Item name.	
Bottle	Display 1 for mono reagent and 2 for double reagents.	
R1	Display of reagent remaining of R1.	
R2	Display of reagent remaining of R2.	

➢ Back color changes depending on reagent residual volume level.
➢ The alarm level and sampling stop are set in System screen. Please refer to Chapter 4, 4.9.6 System setting.

White	Enough reagent volume
Red	Below test stop level
Yellow	Below alarm level

	Contents
Exp.Date	Reagent expire date is shown.
Exp. date(open)	Reagent expire date after open is shown.

➢ Back color of over expired date changes to red.

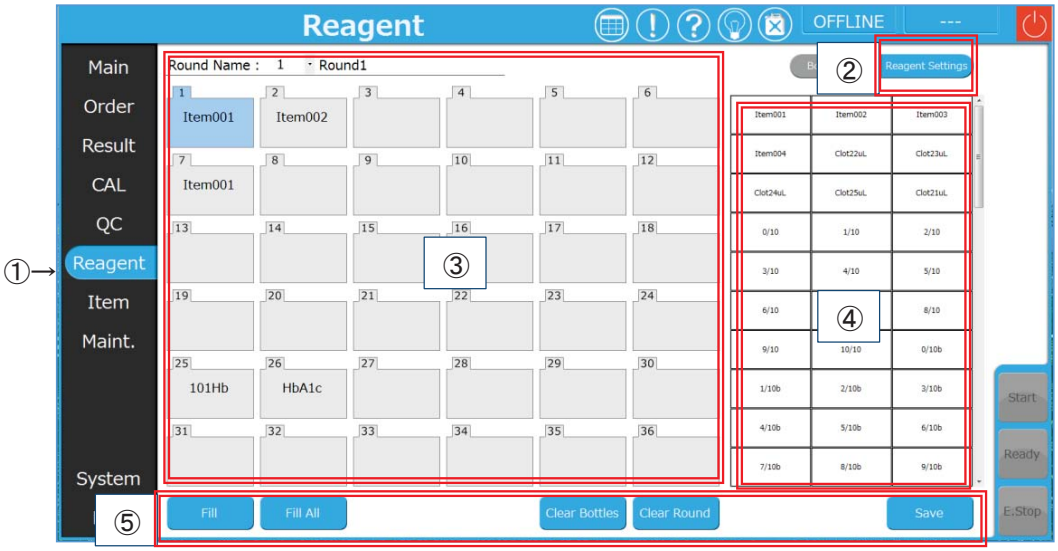
➢ Reagent barcode information is shown after reading of reagent barcode.	
Lot No.	Reagent lot number is shown.
Priority	When above two reagent bottles of the same Item, sampling priority number are shown. ➢ Set the priority by setting order, and use from priority 1. ➢ If the reagent remaining is below sampleing stop, move to next bottle.

④ Reagent remaining renewal and save button.

	Contents
Fill	Residual test volume of the selected Item is input automatically. ➢ Renewal of R1 and R2.
Fill All	Residual test volumes of all Items are input automatically. ➢ Renewal of R1 and R2.
Save	Displayed reagent informations are registered.

4.6.3 Reagent settings screen (Reagent bottle setting screen)

➢ Reagent settings screen displays.



Reagent screen —Reagent setings screen

① Reagent button : Display reagent screen.
② Reagent Settings button : Display of reagent bottle setting screen.
③ Reagent tray position screen : Display of reagent tray position and Item name

➢ Select tray position and register the Item from Item list.

	Contens	
Round name ▼	Select reagent round number.	From 1 to 10
	Display of ragent round name. ➢ Input round name is possible.	Max 10 character
1～36(24) [Item name]	Display of reagent tray position number. 24 Item tray, 1～24 36 Item tray, 1～36 ➢ Display of registered reagent Item. ➢ Back color of selected Item changes to blue.	

④ Display of registered Item list.
⑤ Renewal of reagent volume and redister button.

	Contents
Fill	Residual test volume of the selected Item is input automatically. ➢ Renewal of R1 and R2.
Fill All	Residual test volumes of all Items are input automatically. ➢ Renewal of R1 and R2.
Bottle Read	Display when using the reagent barcode. ➢ Reading of reagent bottle barcode.

➢ Reagnt barcode setting is set in system screen.
Please refer to Chapter 4, 4.9.6 System setting.

	Contents
Clear bottles	Reagent bottle information is deleted.
Clear round	Reagent round information is deleted.
Save	Displayed reagent informations are registered.

4.7 Item screen

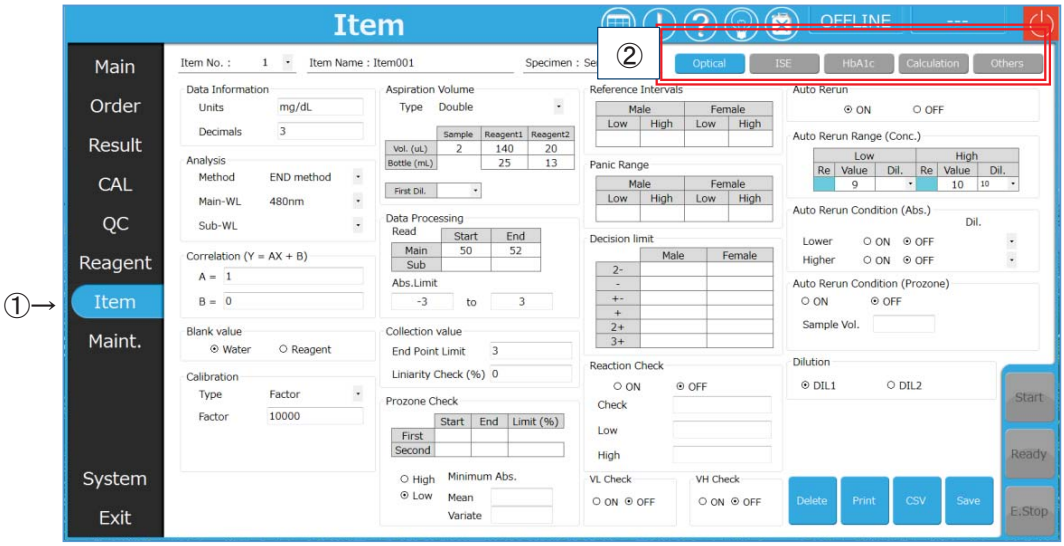
- Item parameter information screen is shown.
- This screen is used for setting of analysis condition depending on each Item.

Note: Item parameter is necessary for setting of each specimen by different Item No.

4.7.1 Item screen contents

- The following selection buttons are shown. Each screen appears by ckicking each button.

1) Optical : Optical test Items
2) ISE : ISE (Na, K, Cl) Items
3) HbA1c : HbA1c Items
4) Calculation : Calculation Items
5) Others : Serun information, detergent, diluent and lysing



Item screen—Optical screen

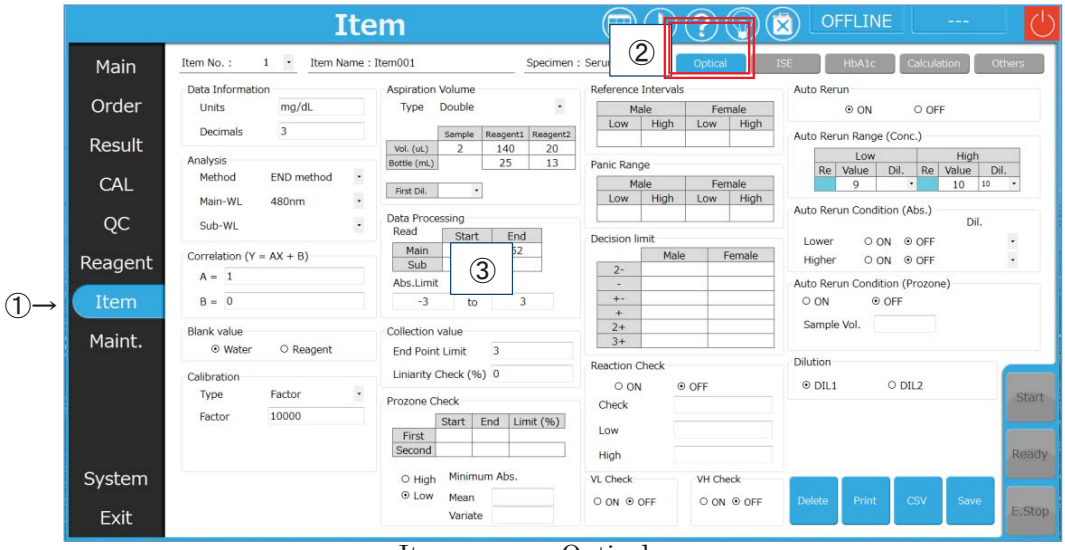
① Item button :Item screen is shown.
② Screen and functions

	Contents	Item number
Optical	Optical test Items parameter input screen.	1～77
ISE	ISE (Na, K, Cl) Items parameter input screen.	78=Na 79=K 80=Cl
HbA1c	HbA1c Items parameter input screen	101,102=Latex 106=Enzyme
Calculation	Calculation Items parameter input screen.	81～95
Others	Serum information(L-H-I), detergent, diluent and lysing parameter input screen	—

4.7.2 Optical screen

- Item parameter input screen.
- Item parameter needs to set for each specimen.

  Note: Item parameter is necessary for setting of each specimen by different Item No.



Item screen—Optical screen

① Item button : Item screen is shown.
② Optical button : Display of optical Item screen.
③ Input test conditions

	Contents	
Item No. ▼	Select Item number	1～77
Item name	Input Item name	Max 8 characters
Specimen ▼	Select "Specimen". (Serum, Urine, Plasma, CSF, Diarlysis, Other)	
Data information		
Units	Input unit	Max 8 characters
Decimals	Input decimal point	0～3
Analysis		
Type ▼	Select analysis type	END method or RATE method
Main wave ▼	Select Main wavelength	Select from following wavelengths
Sub wave ▼	Select Sub wavelength	both Main and Sub wavelength. (340,380,405,450,480,505,546,570, 600,660,700,750,800nm)
Correlation (Y=AX+B)	Input correlation value.	
A=	Input slope	Default value= 1
B=	Input intercept	Default value=0

<table>
<tr><th></th><th colspan="2">Contents</th></tr>
<tr><td><u>Blank value</u>
◎Water○Reagent</td><td>Select “Water” normally</td><td>Default=Water</td></tr>
<tr><td><u>Calibration</u>
Type</td><td colspan="2">Calibration setting
Select calibration kind.
➢ Factor,Liner1,Liner2,Exponential,Spline,Polynomial, Logit1,Logit2</td></tr>
<tr><td>In case of Factor
Factor</td><td colspan="2">Input for Factor calibration.
Input “Factor value”
➢ Input calculculated value of light pass length 10 mm.
➢ Add – (minus) for decrease reaction.</td></tr>
<tr><td>In case of Linear1

Factor Min
Factor Max

CV(Max)</td><td colspan="2">Display for Liner1 calibration. Input acceptable range.
➢ Calibration error appears when the calibration result is out of range.
Input minimum value of calibration factor.
Input maximum value of calibration factor.
Factor=Standard sampleconc./(Standard–Blank sample)Abs.
Input acceptable CV(%).
➢ Absolute value is compared for error flag.</td></tr>
<tr><td><u>Aspiration</u>

Type ▼</td><td colspan="2">Input aspiration volumes.
➢ Reaction volume range;140µL～400µL
Select “Single” or “Double”.</td></tr>
<tr><td>Vol.(µL)
Sample
Reagent1
Reagent2</td><td>
Input sample volume
Input reagent 1 volume
Input reagent 2 volume</td><td>
2.0～25µL（0.1µL step）
140～300µL(1µL step)
20～260µL(1µL step)</td></tr>
<tr><td>Bottle(mL)

Reagent1
Reagent2</td><td colspan="2">Input reagent 1 and regant 2 bottle volumes.
➢ Reagent remain is calculated by inputtrd volume.
36Item tray
<table>
<tr><th>Type</th><th>Reagent1</th><th>Reagent2</th></tr>
<tr><td>Single</td><td>40</td><td>–</td></tr>
<tr><td>Double</td><td>25</td><td>13</td></tr>
</table>
24Item tray (Option)
<table>
<tr><th>Type</th><th>Reagent1</th><th>Reagent2</th></tr>
<tr><td>Single</td><td>60</td><td>–</td></tr>
<tr><td>Double</td><td>40</td><td>20</td></tr>
</table></td></tr>
<tr><td>First dil.
Sample ▼</td><td>Select dilution ratio for first run.</td><td>Dilution ratio
0.5,6,10,20,30,40,50,60,70,80,90, 100</td></tr>
</table>

<table>
<tr><th></th><th>Contents</th></tr>
<tr><td><u>Data Process</u>
Read

Main start
Main end
Sub start
Sub end</td><td>Input data process condition.
Input reading range.

Input starting test point for main reading.
Input ending test point for main reading.
Input starting test point for sub reading.
Input ending test point for sub reading.
➢ <u>Reading point range</u>
<table>
<tr><th>Analysis types</th><th>Main-measurement interval</th><th>Sub-measurement interval</th></tr>
<tr><td>One point end assay</td><td>11 ≦ START ≦ END ≦ 54</td><td>–</td></tr>
<tr><td>Two points end assay 1</td><td>34 ≦ START ≦ END ≦ 54</td><td>11 ≦ START ≦ END ≦ 30</td></tr>
<tr><td>Two points end assay 2</td><td>SUB≦START≦END≦ 54</td><td>34≦START≦END≦START</td></tr>
<tr><td>One point rate assay</td><td>11≦START< END≦54</td><td>–</td></tr>
<tr><td>Two points rate assay 1</td><td>34 ≦ START ≦ END ≦ 54</td><td>11 ≦ START ≦ END ≦ 30</td></tr>
<tr><td>Two points rate assay 2</td><td>SUB≦ START ≦ END ≦ 54</td><td>34 ≦ START ≦ END ≦ MAIN</td></tr>
</table></td></tr>
<tr><td>Abs.Limit □to□</td><td>Input lower and upper limit values.
➢ Range -3.0～3.0 Abs.
➢ Input lower limit≦upper limit</td></tr>
<tr><td><u>Check value</u>
End point limit</td><td>
Input limit value to check optical absorbance upper limit.
➢ Input range -3.0～3.0 abs.</td></tr>
<tr><td>Linear check(%)</td><td>Input linearity standard value.
➢ Input above 0.</td></tr>
<tr><td><u>Prozone check</u>

First start/end

Second start/end

Limit(%)</td><td>Prozone phenomenon check parameter input area, for immuno-reaction.
Input starting and ending test points of basic test interval. (Input range 34～54 points)
Input starting and ending test points of reference test interval. (Input range 34～54 points)
Input comparison limit value(%).
➢ Limit value(%)=Second range slope/First range slope x 100.
➢ The slope is calculated by the least square method.</td></tr>
<tr><td>○High ◎Low</td><td>Select the check level for high or low limit.</td></tr>
<tr><td>Minimum Abs.
Mean
Variate</td><td><u>Input no prozone check conditions.</u>
Input the minimum Abs. average value of main wavelength.
Input the minimum slope value of main wave length.
The valiation is calculated by the least square method.
➢ No prozone check is done if the value below the input value.
➢ No prozone check is done if the slope value of the first interval is below zero.</td></tr>
</table>

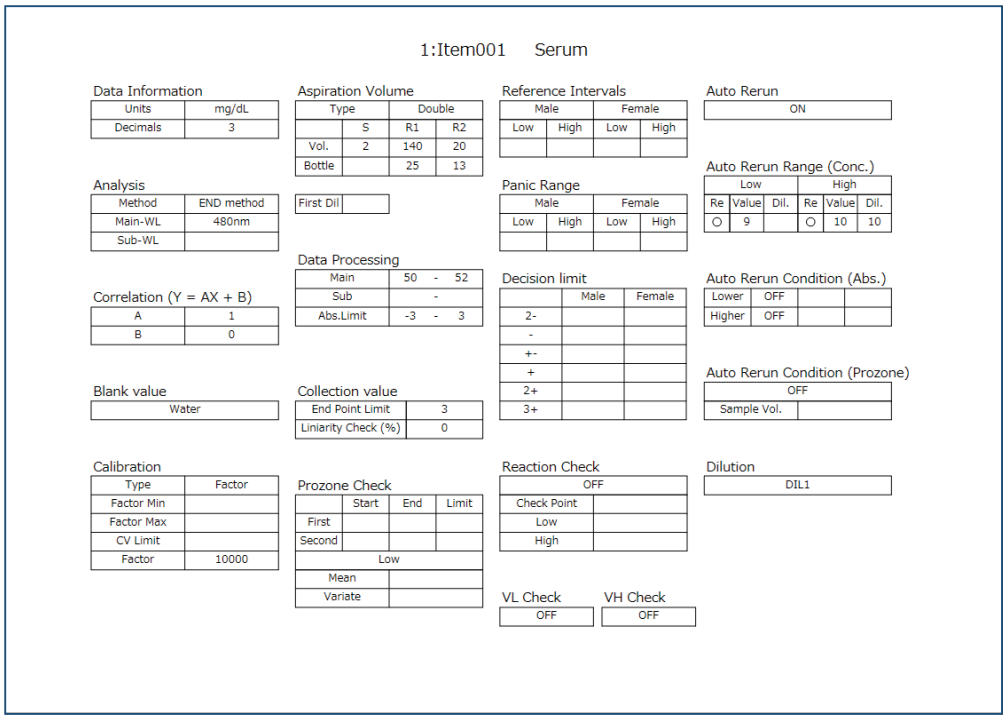
	Contents
Reference Interval Male low／ high Female low／ high	Input for reference interval. Input of lower and upper limit of male. Input of lower and upper limit of female.
Panic Range Male low／ high Female low／ high	Input panic range. Input of lower and upper limit of male. Input of lower and upper limit of female.
Qualitative Value Male／ Female 2- ～3+	Condition setting of concentration result transforms to qualitative result. ➢ Lower and upper limit of male or female can be set. ➢ Input conc. result to transformation.
Reaction check ○ON ◎OFF Check Low High	Setting of the abnormal reaction check. Select “ON” when check the abnormal Abs.. Input checking point. ➢ Input range 10～54 points Input lower limit of the check range. ➢ Input range -3.0～3.0Abs. Input upper limit of the check range. ➢ Input range -3.0～3.0Abs.
Judgement of VL/VH VL ○ON/◎OFF VH ○ON/◎OFF	In case of selected ON for multi calibration. The result lower than blank or standard lowest sample conc. appears VL flag. The result upper than highest standard sample apperas VH flag.
Auto rerun ○ON ◎OFF	Select “ON” for setting of the auto-rerun. Following settings are essential for auto-rerun. ➢ Auto Rerun switch set to ON in System screen. ➢ Set diluent bottle for dilution rerun in reagent screen.
Auto rerun condition Low/High,Re, Value, Dil	Input concentration for auto rerun. If the result lower than low limit or upper than high limt proceeds auto-rerun automatically.
Re	➢ Select when perform rerun. Back color changes to blue after order entry.
Value	Input conc. values for auto-rerun.
Dil.	Select dilution ratio for auto-rerun. ➢ 0.5, 6,10,20,30,40,50,60,70,80,90,100 ➢ The blank coloum proceeds auto-rerun without dilution. ➢ Select lower dilution ratio than first dilution for low value auto-rerun. ➢ Select higher dilution ratio than first dilution for high value auto-rerun.

	Contents
Auto rerun condition (Abs.) Lower/Higher ○ON ◎OFF	Set auto-rerun condition by Abs.. If select on, the result Abs. lower or higher than Abs. limit proceed the auto-rerun automatically.
Lower /Higher Dil.	Select dilution ratio. ➢ 0.5, 6,10,20,30,40,50,60,70,80,90,100, ➢ The blank coloum proceeds auto-rerun without dilution.
Auto rerun condition (Prozone) ○ON ◎OFF	Set auto-rerun condition by Prozone. If select on, the result out of prozone limit proceed the auto-rerun automatically.
Sample Vol.	Input sample volume for using auto-rerun. ➢ Input range 2.0～25μL
Diluent ◎DIL 1 ○DIL2	Select dilution bottle for auto-rerun orsample dilution.

④ Save and print buttons.

Delete button :Delete the displayed information.

Print (External printer) : Print out the Item screen to the external printer.

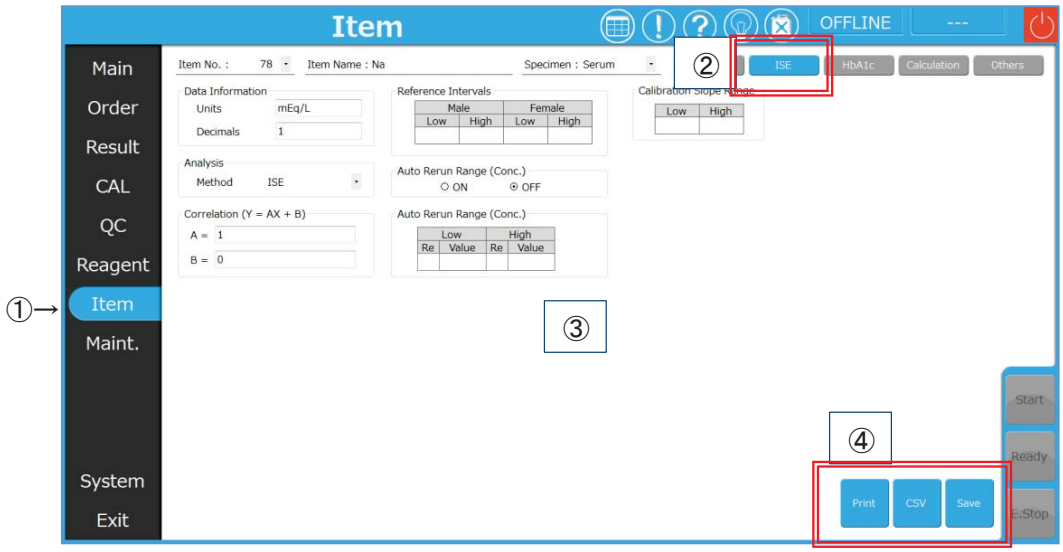


CSV button : Save the displayed information to CSV file.

Save button : Register the displayed information.

4.7.3 ISE screen

- ISE parameter screen displays.
- Item parameter needs to set for each specimen.



Item screen—ISE screen

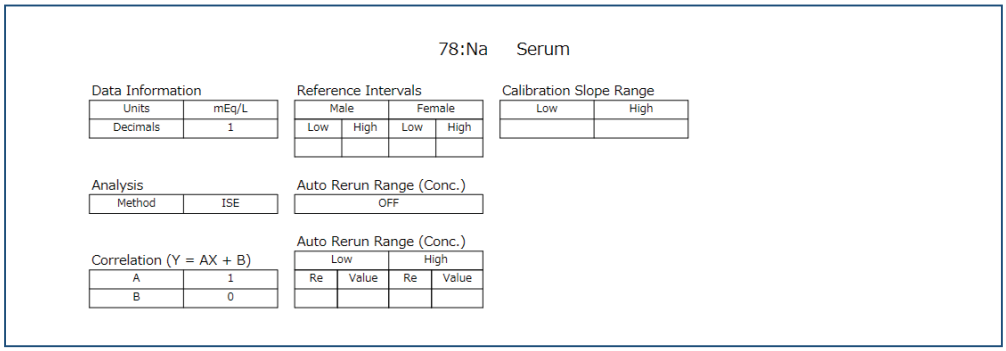
① Item button : Item screen is shown.
② ISE button : ISE screen is shown.
③ Screen and functions : Input conditions.

	Contents	
Item No.	Select Item number	No.78＝Na、No.79＝K、No.80＝Cl The numbers are fixed.
Item name	Input Item name	Less than 8 characters
Specimen	Select “Specimen”. (Serum, Plasma, Urine, Dialysis)	
Data information Units	Input unit	Less than 8 characters
Decimals	Input decimal point	Input range 0～3
Analysys Type	ISE(Fixed)	
Correlation (Y=AX+B) A= B=	Input correlation value. Input slope Input intercept	 Default value= 1 Default value=0
Reference interval Male low／ high Female low／ high	Input for reference interval. Input of lower and upper limit of male. Input of lower and upper limit of female.	

	Display and input contents
Auto rerun range (conc.) ○ON ◎OFF	Select "ON" for setting of the auto-rerun. Following settings are essential for auto-rerun. ➢ Auto rerun switch set to ON in System screen. ➢ Set diluent bottle for dilution rerun in reagent screen.
Auto rerun range (conc.) low/high Re	Auto-rerun by using concentration. If select ON, the result lower than low limit or upper than high limt proceeds auto-rerun automatically. ➢ Back color changes to blue after the order entry.
Value	Input conc. values for auto-rerun.
Calibration slope range low/high	Input of lower and higher slope limit for the ISE calibration range.

④ Print button, Save button

Print (External printer) : Print out the Item screen to the external printer.



CSV button : Save the displayed information to CSV file.

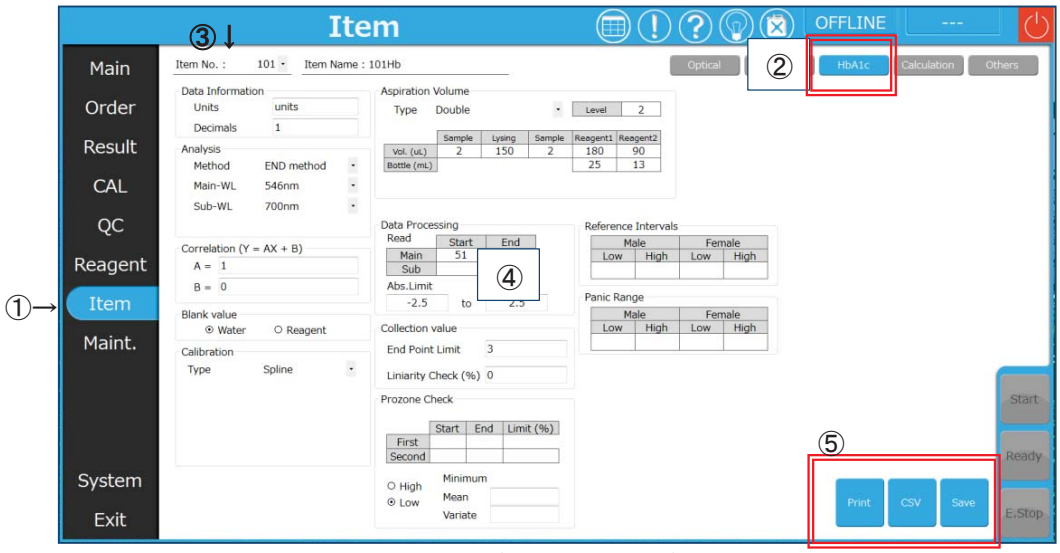
Save button : Register the displayed information.

4.7.4 HbA1c screen

- HbA1c Item parameter screen displays.
- Select Item parameter based on the reagent specification.
  - Item No.101 or No.102 is used for Latex method.
  - Item No.106 is used for enzymatic method.

1. HbA1c screen (For Latex reagent Item No.101,102)

- Ratex method Item parameter screen displays.



Item screen—HbA1c(Latex reagent) screen

① Item button : Item screen is shown.
② HbA1c button : HbA1c parameter input screen is shown.
③ HbA1c screen : Select Item No.101 or 102.
④ Display input screen

	Contents	
Item No.	Select Item number. ➢ No.101 or No.102	
Item name	Input Item name ➢ Max 8 characters ➢ Same name is not acceptable.	
Data information Units	Input unit	Max 8 characters
Decimals	Input decimal point	Input range 0～3

	Contents	
Analysis Type Main wave Sub wave	Select analysis type Select main wavelength Select sub wavelength	END method or RATE method Select from following wavelength both main and sub wavelength. (340,380,405,450,480,505,546, 570,600,660,700,750,800nm)
Correlation (Y=AX+B) A= B=	 Input correlation value. Input slope Input intercept	 Default value: 1 Default value:0
Blank value ◎Water○Reagent	 Select "Water" normally	 Default:Water
Calibration Type	Calibration setting Select calibration kind. ➢ Factor,Liner1,Liner2,Exponential,Spline,Polynomial, Logit1,Logit2	
In case of Factor Factor	Input for Factor calibration. Input "Factor value" ➢ Input calculculated value of light pass length 10 mm. ➢ Add – (minus) for decrease reaction.	
In case of Linear1 Factor Min Factor Max CV Max	Input for Liner1 calibration. Error appears when the calibration result is out of range. Input minimum value of calibration factor. Input maximum value of calibration factor. Factor=Standard sample conc./(Standard–Blank sample)Abs. Input acceptable CV(%). Absolute value is compared for error flag.	
Aspiration Type ▼	Input aspiration volumes. ➢ Total reaction volume 140µL～400µL Select "Single" or "Double".	
Level	Input aspiration levelof red blood cell from the bottm of primary tube. ➢ Default: 2mm	
Vol.(µL) Sample Lysing Sample Reagent1 Reagent2	 Input sample volume of red blood cell. Input lysing solution volume. Input hemolysed sample volume. Input R1 volume. Input R2 volume.	 2.0～25µL（0.1µL step） 140～300µL（1µL step） 2.0～25µL（0.1µL step） 140～300µL(1µL step) 20～160µL(1µL step)

<table>
<tr><th></th><th>Contents</th></tr>
<tr><td>Bottle(mL)

Reagent1
Reagent2</td><td>Input reagent 1 and regant 2 bottle volumes.
➢ Reagent remain is calculated reffering inputtrd volume.
36 Item tray
<table>
<tr><th>Type</th><th>Reagent1</th><th>Reagent2</th></tr>
<tr><td>Single</td><td>40</td><td>–</td></tr>
<tr><td>Double</td><td>25</td><td>13</td></tr>
</table>
24 Item tray
<table>
<tr><th>Type</th><th>Reagent1</th><th>Reagent2</th></tr>
<tr><td>Single</td><td>60</td><td>–</td></tr>
<tr><td>Double</td><td>40</td><td>20</td></tr>
</table>
</td></tr>
<tr><td><u>Data Process</u>
Read
Main start
Main end
Sub start
Sub end</td><td>Input data process condition.
Input reading range.
Input starting test point for main reading.
Input ending test point for main reading.
Input starting test point for sub reading.
Input ending test point for sub reading..

➢ <u>Reading point range</u>
<table>
<tr><th>Analysis types</th><th>Main-measurement interval</th><th>Sub-measurement interval</th></tr>
<tr><td>One point end assay</td><td>11 ≦ START ≦ END ≦ 54</td><td>–</td></tr>
<tr><td>Two points end assay 1</td><td>34 ≦ START ≦ END ≦ 54</td><td>11 ≦ START ≦ END ≦ 30</td></tr>
<tr><td>Two points end assay 2</td><td>SUB≦START≦END≦ 54</td><td>34≦START≦END≦START</td></tr>
<tr><td>One point rate assay</td><td>11≦START< END≦54</td><td>–</td></tr>
<tr><td>Two points rate assay 1</td><td>34 ≦ START ≦ END ≦ 54</td><td>11 ≦ START ≦ END ≦ 30</td></tr>
<tr><td>Two points rate assay 2</td><td>SUB≦ START ≦ END ≦ 54</td><td>34 ≦ START ≦ END ≦ MAIN</td></tr>
</table>
</td></tr>
<tr><td>Abs.Limit □to□</td><td>Input lower and upper limit values.
➢ Range -3.0～3.0 Abs.
➢ Input lower limit≦upper limit</td></tr>
<tr><td><u>Check value</u>
End point limit</td><td>Input the value to check optical absorbance upper limit.
➢ Input range -3.0～3.0 abs.</td></tr>
<tr><td>Linear check (%)</td><td>Input linearity standard value.
➢ Input above than 0.</td></tr>
<tr><td><u>Prozone check</u>

First start/end

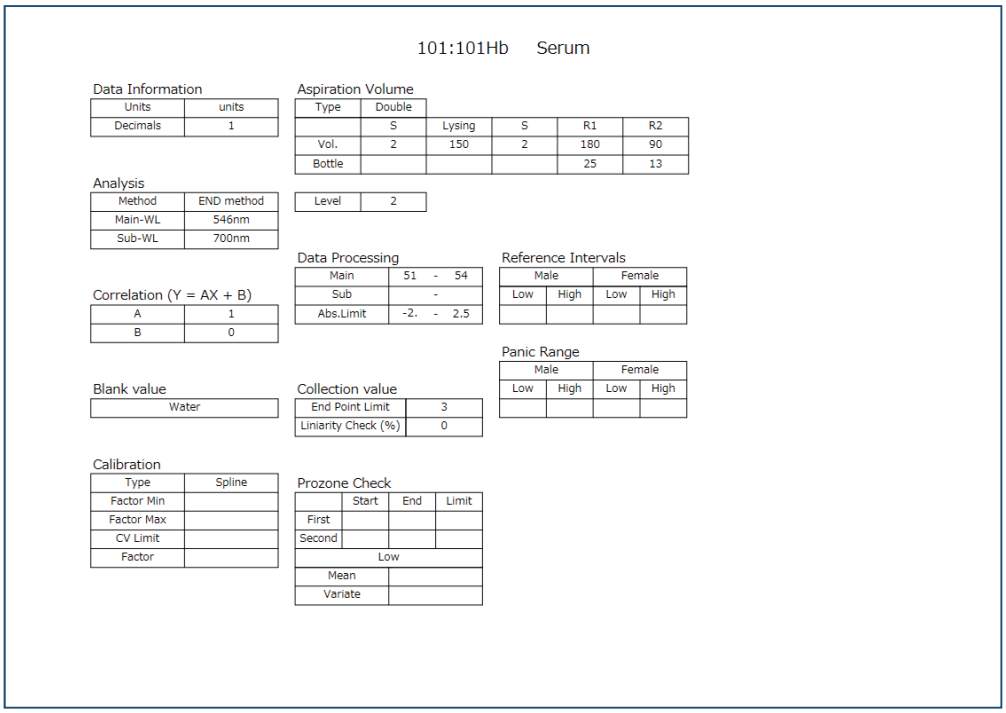
Second start/end

Limit(%)</td><td>Prozone phenomenon check parameter input area, for immuno-reaction.
Input starting and ending test points of basic test interval. (Input range 34～54 points)
Input starting and ending test points of reference test interval. (Input range 34～54 points)
Input comparison limit value(%).
➢ Limit value(%)=Second range slope/First range slope x 100.
➢ The slope is calculated by the least square method.</td></tr>
<tr><td>○High ◎Low</td><td>Select high or low limit.</td></tr>
</table>

	Contents
Minimum Abs. Mean Variate	Input no prozone check conditions. Input the minimum Abs. average value of main wavelength. Input the minimum slope value of main wave length. The valiation is calculated by the least square method. ➢ No prozone check is done if the value below the input value. ➢ No Prozone check is done if the slope value of the first interval is below zero.
Reference interval Male low／ high Female low／ high	Input for reference interval. Input of lower and upper limit of male. Input of lower and upper limit of female.
Panic range Male low／ high Female low／ high	Input panic range. Input of lower and upper limit of male. Input of lower and upper limit of female.

⑤ Print button, Save button

Print (External printer) : Print out the Item screen to the external printer.

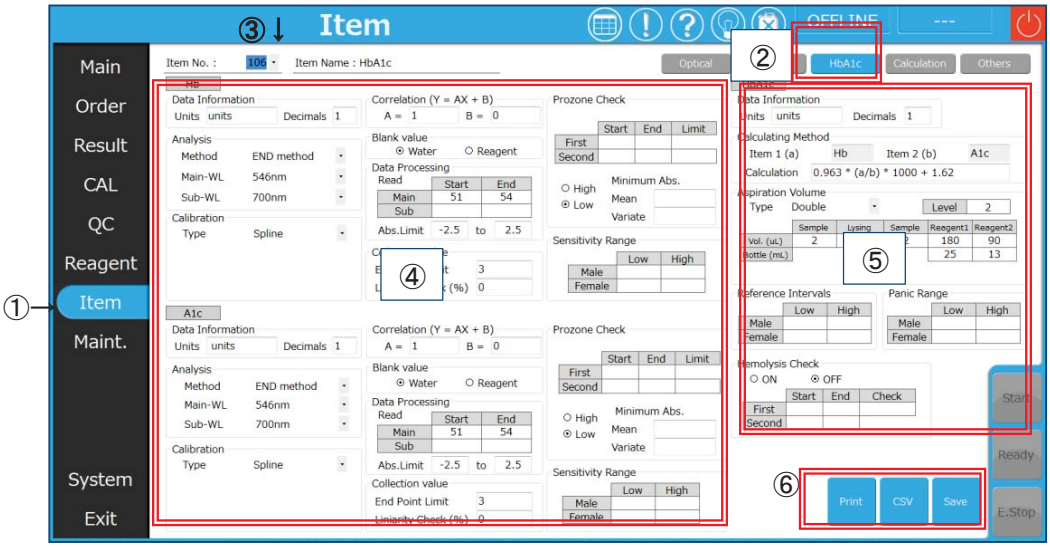


CSV button : Save the displayed information to CSV file.

Save button : Register the displayed information.

2. HbA1c screen (For enzymatic reagent Item No.106)

➢ Enzymatic method Item parameter screen displays.



Item screen—HbA1c (Enzymatic method) screen

① Item button : Item screen is shown.
② HbA1c button : HbA1c input screen is shown.
③ HbA1c screen : Select Item No.106.
➢ Display of parameter input screen for HbA1c enzymatic method.
➢ Hb, A1c, HbA1c Items are shown.

Screen and functions

	Contents
Item No.	Select Item number ➢ No. 106
Item name	Input Item name ➢ Less than 8 hcaracters ➢ Same name is not acceptable.

④ Hb、A1c input Items ; Hb,A1c are the same.

	Display and input contents	
Data Information		
Units	Input unit	Max 8 characters
Decimals	Input decimal point	Input range 0～3
Analysis		
Type	Select analysis type	END method or RATE method
Main wave	Select main wavelength	Select from following wavelength both main and sub wavelength. (340,380,405,450,480,505,546,570, 600,660,700,750,800nm)
Sub wave	Select sub wavelength	

<table>
<tr><th></th><th colspan="2">Contents</th></tr>
<tr><td><u>Calibration</u>
Type</td><td colspan="2">Calibration setting
Select calibration kind.
➢ Factor,Liner1,Liner2,Exponential,Spline,Polynomial, Logit1,Logit2</td></tr>
<tr><td>➢In case of Factor
Factor</td><td colspan="2">Input for Factor calibration.
Input "Factor value"
➢ Input calculculated value of light pass length 10 mm.
➢ Add – (minus) for decrease reaction.</td></tr>
<tr><td>➢In case of Linear1

Factor Min
Factor Max
CV Max</td><td colspan="2">Input for Liner1 calibration.
Calibration error appears when the calibration result is out og range.
Input minimum value of calibration factor.
Input maximum value of calibration factor.
Input acceptable CV(%).</td></tr>
<tr><td><u>Correlation</u>
<u>(Y=AX+B)</u>
A=
B=</td><td>Input correlation value.

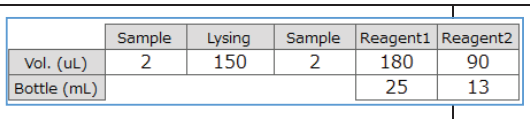
Input slope
Input intercept</td><td>

Default value= 1
Default value=0</td></tr>
<tr><td><u>Blank value</u>
◎Water○Reagent</td><td>
Select "Water" normally</td><td>
Default:Water</td></tr>
<tr><td><u>Data Process</u>

Main start
Main end
Sub start
Sub end</td><td colspan="2">Input data process condition.
Input reading range.
Input starting test point for main reading.
Input ending test point for main reading.
Input starting test point for sub reading.
Input ending test point for sub reading..
➢ <u>Reading point range</u>
<table>
<tr><th>Analysis types</th><th>Main-measurement interval</th><th>Sub-measurement interval</th></tr>
<tr><td>One point end assay</td><td>11 ≦ START ≦ END ≦ 54</td><td>–</td></tr>
<tr><td>Two points end assay 1</td><td>34 ≦ START ≦ END ≦ 54</td><td>11 ≦ START ≦ END ≦ 30</td></tr>
<tr><td>Two points end assay 2</td><td>SUB≦START≦END≦ 54</td><td>34≦START≦END≦START</td></tr>
<tr><td>One point rate assay</td><td>11≦START< END≦54</td><td>–</td></tr>
<tr><td>Two points rate assay 1</td><td>34 ≦ START ≦ END ≦ 54</td><td>11 ≦ START ≦ END ≦ 30</td></tr>
<tr><td>Two points rate assay 2</td><td>SUB≦ START ≦ END ≦ 54</td><td>34 ≦ START ≦ END ≦ MAIN</td></tr>
</table></td></tr>
<tr><td>Abs.Limit □to□</td><td colspan="2">Input lower and upper limit values.
➢ Range -3.0～3.0 Abs.
➢ Input lower limit≦upper limit</td></tr>
<tr><td><u>Check value</u>
End point limit</td><td colspan="2">
Input limit value to check optical absorbance upper limit.
➢ Input range -3.0～3.0 abs.</td></tr>
<tr><td>Linear check(%)</td><td colspan="2">Input linearity standard value.
➢ Input range above 0.</td></tr>
</table>

	Contents
Prozone check	Prozone phenomenon check parameter input area, for immuno-reaction.
First start/end	Input starting and ending test points of basic test interval. (Input range 34～54 points)
Second Start/End	Input starting and ending test points of reference test interval. (Input range 34～54 points)
Limit(%)	Input comparison limit value(%). ➢ Limit value(%)=Second range slope/First range slope x 100. ➢ The slope is calculated by the least square method.
○High ◎Low	Select high or low limit.
Minimum Abs. Mean Variate	Input no prozone check conditions. Input the minimum Abs. average value of main wavelength. Input the minimum slope value of main wave length. The valiation is calculated by the least square method. ➢ No prozone check is done if the value below the input value. ➢ No Prozone check is done if the slope value of the first interval is below zero.
Sensitive range Male/Female Lower/Upper	Input sensitive conc. of Hb and A1c. The result lower than input limit, B flag appears. The result higher than input limit, G flag appears.

⑤ HbA1c input parameter

	Contents	
Data Information Units	Input unit	Less than 8 characters
Decimals	Input deciamal point	Input range 0~3
Calculation Item1 (a) Item2 (b) Calculation	Input calculation formula of HbA1c Item1 for calculation. Fixed to Hb. Item2 for calculation. Fixed to A1c. Input calculation formula for HbA1c.	
Aspiration Type	Input aspiration volume. ➢ Total reaction volume 140μL～400μL Select single or double reagent.	
Level	Input aspiration levelof red blood cell from the bottm of the primary tube. ➢ Default 2mm	
Vol.(μL)		
①Sample	Input sample volume of red blood cell.	2.0～25μL (0.1μL step)
Lysing	Input lysing solution volume.	140～300μL (1μL step)
②Sample	Input hemolysed sample volume.	2.0～25μL (0.1μL step)

<table>
<tr><th></th><th colspan="2">Contents</th></tr>
<tr><td>Reagent1
Reagent2</td><td>Input R1 volume
Input R2 volume</td><td>140～300µL(1µL step)
20～260µL(1µL step)</td></tr>
<tr><td>Bottle(mL)

Reagent1
Reagent2</td><td colspan="2">Input reagent 1 and regant 2 bottle volumes.
➢ Reagent remain is calculated reffering inputtrd volume.
36 Item tray
<table>
<tr><th>Type</th><th>Reagent1</th><th>Reagent2</th></tr>
<tr><td>Single</td><td>40</td><td>–</td></tr>
<tr><td>Double</td><td>25</td><td>13</td></tr>
</table>
24Item tray
<table>
<tr><th>Type</th><th>Reagent1</th><th>Reagent2</th></tr>
<tr><td>Single</td><td>60</td><td>–</td></tr>
<tr><td>Double</td><td>40</td><td>20</td></tr>
</table></td></tr>
<tr><td><u>Reference range</u>
Male low／ high
Female low／ high</td><td colspan="2">Input for reference range.
Input lower and upper limit of male.
Input lower and upper limit of female.</td></tr>
<tr><td><u>Panic range</u>
Male low／ high
Female low／ high</td><td colspan="2">Input panic range.
Input lower and upper limit of male.
Input lower and upper limit of female.</td></tr>
<tr><td><u>Lysing check</u>

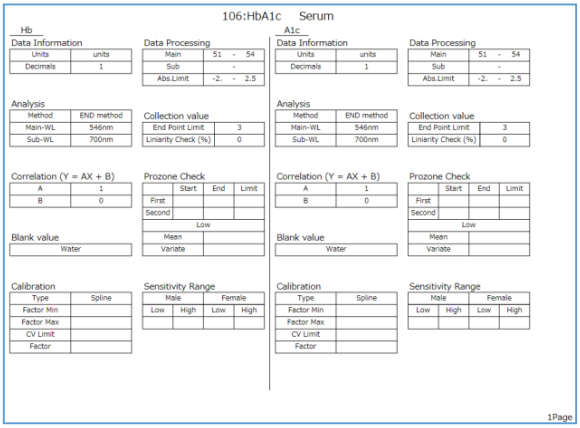
○ON ◎OFF
First start/end

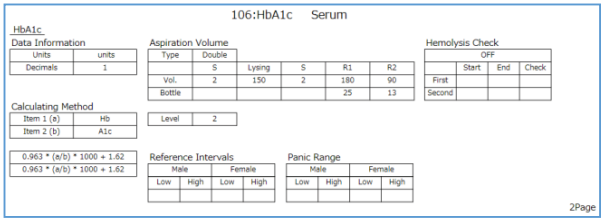
Second start/end

Check</td><td colspan="2">Check the hemolysed sample condition.
When the result upper than check value, AB flag appears.
Select ON for check the condition.
Input starting and ending test points of basic hemoly sed interval.
➢ Input range 10～54 points
Input starting and ending test points of reference interval.
➢ Input range 10～54 points
Input the check value for hemolysing.
➢ Calculation formula
Second(Mean)-First(Mean)×K factor/A1c result×100</td></tr>
</table>

⑥ Print button, Save button

Print (External printer) : Print out the Item screen to the external printer.



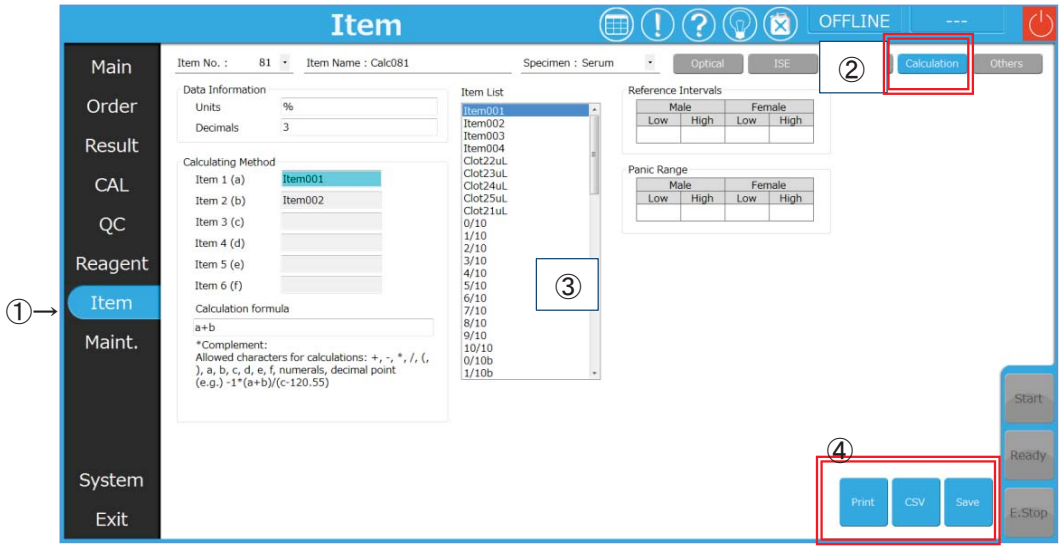


CSV button : Save the displayed information to CSV file.

Save button : Register the displayed information.

4.7.5 Calculation Screen

- Calculation Item parameter screen displays.



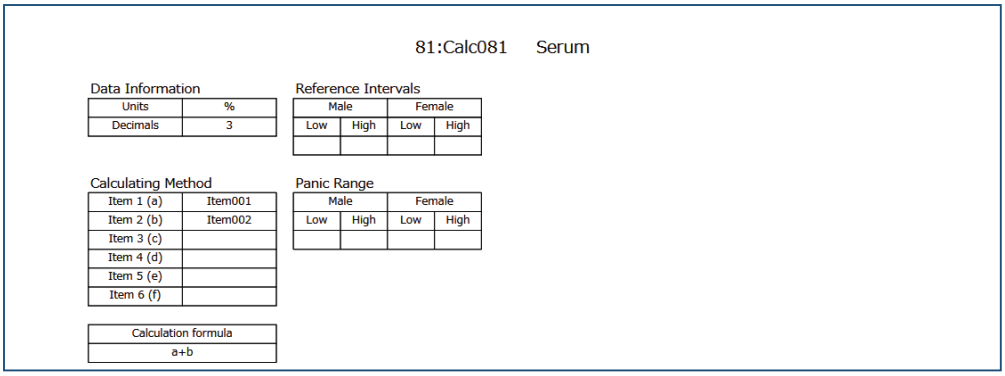
Item screen—Caluculation screen

① Item button : Item screen is shown.
② Caluculation button : Calculation input screen is shown.
③ Screen and functions : Setting for Item and calculation formula.

	Contents	
Item No.	Select Item number	Selection No.81～95
Item name	Input Item name	Less than 8 characters
Specimen	Select specimen	Serum, Urine, Plasma CSF, Diarlysis, OtherHbA1c
Data information Units	Input unit	Less than 8 characters
Decimals	Inp@ut decimal point	Input range 0～3
Calculate Item 1(a)～6(f)	Dispaly Item name. ➢ Select from the Item List. ➢ 6 Items can be use.	
Calculation formula	Input calculation formula. ➢ Follow the information on the screen.	
Item List	Display of optical Item list.	
Reference interval Male low／ high Female low／ high	Input for reference interval. Input of lower and upper limit of male. Input of lower and upper limit of female.	
Panic range Male low／ high Female low／ high	Input panic range. Input of lower and upper limit of male. Input of lower and upper limit of female.	

④ Print button, Save button

Print (External printer) : Print out the Item screen to the external printer.



81:Calc081 Serum

Data Information

Units	%
Decimals	3

Reference Intervals

Male		Female	
Low	High	Low	High

Calculating Method

Item 1 (a)	Item001
Item 2 (b)	Item002
Item 3 (c)	
Item 4 (d)	
Item 5 (e)	
Item 6 (f)	

Panic Range

Male		Female	
Low	High	Low	High

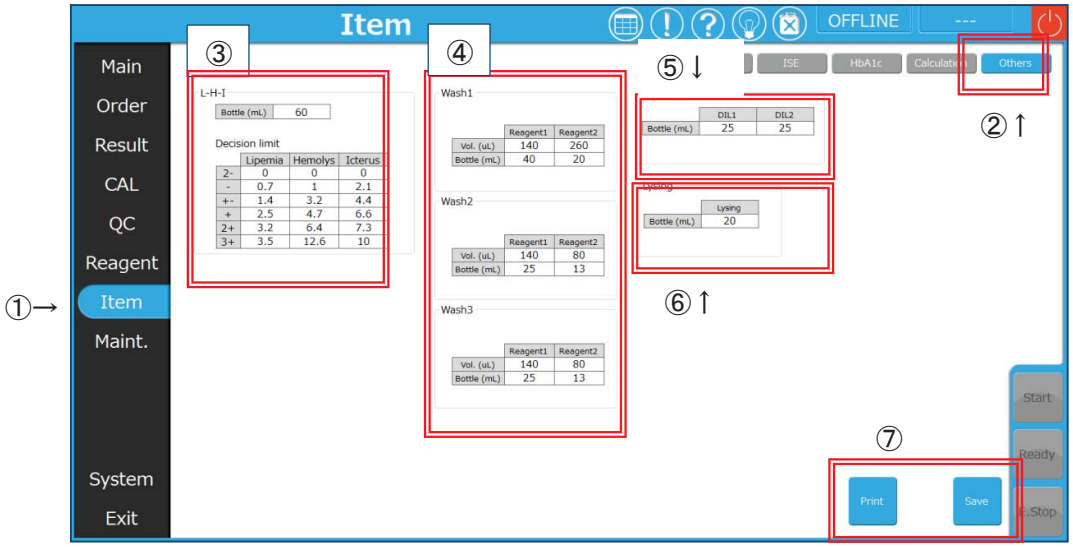
Calculation formula
a+b

CSV button : Save the displayed information to CSV file.

Save button : Register the displayed information.

4.7.6 Other (Serun information, detergent, diluent, lysing solution screen)

- Serun information, detergent, diluent, lysing solution screen display.
- Parameters are set default.



Item screen—Other screen

① Item button : Item screen is shown.
② Other button : Display of Serum information(L-H-I), Deterent(wash 1-3), Diluent, Lyzing screen.

- Item parameters and Intem number.

Item screen - Other		Itemname	Intem No.
Serum information parameta	Serum Information	L-H-I	96
Detergent parameta	Wash 1	Wash 1	113
	Wash 2	Wash 2	114
	Wash 3	Wash 3	115
Dilution parameta	Dilution	DIL 1	111
		DIL 2	112
Lysing parameta	Lysing	Lysing	99

③ Serum information parameta screen
Display of lipemic, hemolise and Icteric parameters for affects the result of serum sample.
- The parameters are fixed in the program.
- Please change the setting if the result is shown difference between analyzer and visual results.

<table>
<tr><th></th><th>Contents</th></tr>
<tr><td><u>Bottle(mL)</u></td><td>Input bottle volums for serum information Item.
➢ Residual reagent is calculated by inputted volume.
36 Item tray
<table>
<tr><th>Type</th><th>Reagent1</th></tr>
<tr><td>Single</td><td>40</td></tr>
<tr><td>Double</td><td>25</td></tr>
</table>
24 Item tray (option)
<table>
<tr><th>Type</th><th>Reagent1</th></tr>
<tr><td>Single</td><td>60</td></tr>
<tr><td>Double</td><td>40</td></tr>
</table></td></tr>
<tr><td><u>Qualitative value</u>

Lipemia / 2- ～3+
Hemolysis / 2- ～3+
Bilirubin / 2- ～3+</td><td>➢ Please change the setting if the result is shown difference between analyzer andvisual results.
Lipemia; Display of transferred qualitative value.
Hemolysis; Display of transferred qualitative value.
Bilirubin;) Display of transferred qualitative value.</td></tr>
</table>

④ Detergent（Wash1～3）screen.
Input wash parameter to contamination avoidance.
- ➢ Wash 1 to 3 are common.
- ➢ Sample volume is fixed to 25 uL.

<table>
<tr><th></th><th colspan="2">Contents</th></tr>
<tr><td>Reagent1／Reagent2
Vol.(μL)</td><td>Input detergent volums to avoiding reagent contamination.</td><td>Reagent1
140～300μL（1μL step）
Reagent2
20～260μL（1μL step）</td></tr>
<tr><td>Bottle(mL)</td><td colspan="2">Input detergent bottle volumes.
➢ Residual reagent is calculated by inputted volume
➢ Fixed to double reagents.
36 Item tray
<table>
<tr><th>Type</th><th>Reagent1</th><th>Reagent2</th></tr>
<tr><td>Single</td><td>40</td><td>–</td></tr>
<tr><td>Double</td><td>25</td><td>13</td></tr>
</table>
24 Item tray (option)
<table>
<tr><th>Type</th><th>Reagent1</th><th>Reagent2</th></tr>
<tr><td>Single</td><td>60</td><td>–</td></tr>
<tr><td>Double</td><td>40</td><td>20</td></tr>
</table></td></tr>
</table>

⑤ Diluent（Dilution solution）screen
Input bottle volume to using sample dilution.

<table>
<tr><th></th><th>Contents</th></tr>
<tr><td>Dil1／Dil2
Bottle(mL)</td><td>Input diluent bottle volum.
➢ Residual reagent is calculated by inputted volume.
36 Item tray
<table>
<tr><th>Type</th><th>Reagent1</th></tr>
<tr><td>Single</td><td>40</td></tr>
<tr><td>Double</td><td>25</td></tr>
</table>
24 Item tray (option)
<table>
<tr><th>Type</th><th>Reagent1</th></tr>
<tr><td>Single</td><td>60</td></tr>
<tr><td>Double</td><td>40</td></tr>
</table></td></tr>
</table>

⑥ Lysing（Lysing solution）screen

Input Lyzing bottle volume to using HbA1c measurement.

<table>
<tr><th></th><th>Contents</th></tr>
<tr><td>Bottle(mL)
Lysing</td><td>➢ Residual reagent is calculated by inputted volume.
36 Item tray
<table>
<tr><th>Type</th><th>Reagent1</th></tr>
<tr><td>Single</td><td>40</td></tr>
<tr><td>Double</td><td>25</td></tr>
</table>
24 Item tray
(option)
<table>
<tr><th>Type</th><th>Reagent1</th></tr>
<tr><td>Single</td><td>60</td></tr>
<tr><td>Double</td><td>40</td></tr>
</table>
</td></tr>
</table>

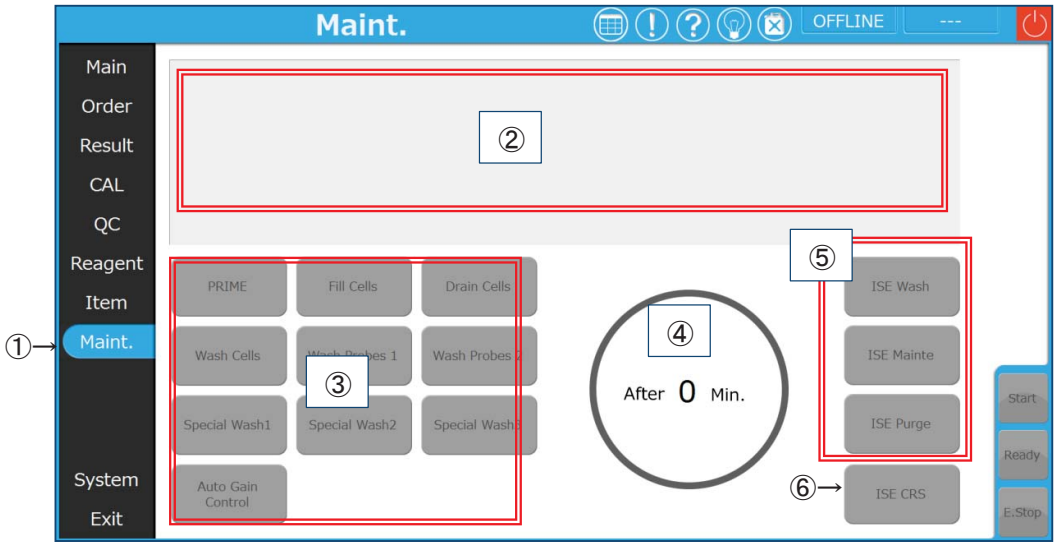
⑦ Print button, Save button

Print（External printer）　　: Print out the Item screen to the external printer.

4.8 Maintenance

➢ Maintenance information displays.

4.8.1 Maint.screen



Mainte screen

① Maint. button : Maintenance screen is shown.

② When the causor is pointed the button, maintenance information displays.

➢ When Auto-gain measurement displays gain values for details.

③ Maintenance Item

Buttons	Contents
PRIME	All the filling lines are filled with water. ➢ This function is used at the system set up or the piping tubes exchange. ➢ Wash time is about 3 minutes.
Fill Cells	Purified water or cleaning liquid will be distributed to all of the reaction cell from the R1 probe. ➢ Dispensed time is about 5 minutes.
Drain Cells	All the reaction cuvettes are drained. ➢ The required time is about 5 minutes.
Wash Cells	All of 60 reaction cuvettes are washed. ➢ Wash by all cell washing system. ➢ Wash time is about 10 minutes.
Probe Wash 1	Each probe washing is performed.(Sample,Reagent 1 and 2 probe) ➢ Set 500 uL of detergent at wash 1 position on the sample tray. ➢ Set the Wash1 bottle to the reagent tray. ➢ Wash time is about 9 minutes.

	Contents
Probe Wash 2 (For HbA1c Item probe washing)	Each probe washing is performed. (Sample,Reagent 1 and 2 probes) ➢ Set detergent tube at tray position 30 on the sample tray. (Pour the detergent till 40 mm hight.) ➢ Set the Wash1 bottle to the reagent tray. ➢ Wash time is about 9 minutes.
Special Wash 1	All the reaction cells and probes are washed in the same procedure as measurement by aspiration and dispensation of wash1 detergent instead of reagent and sample. ➢ Set the Wash1 bottle to the reagent tray. (R1 bottle 20mL, R2 bottle 11mL) ➢ Set 2mL of detergent cup at Wash1 position on the sample tray. ➢ Wash time is about 30 minutes.
Special Wash 2	All the reaction cells and probes are washed in the same procedure as measurement by aspiration and dispensation of wash2 detergent instead of reagent and sample. ➢ Set the Wash2 bottle to the reagent tray. (R1 bottle 20mL, R2 bottle 11mL) ➢ Set 2ml of detergent cup at Wash2 position on the sample tray. ➢ Wash time is about 30 minutes.
Special Wash 3	All the reaction cells and probes are washed in the same procedure as measurement by aspiration and dispensation of wash3 detergent instead of reagent and sample. ➢ Set the Wash3 bottle to the reagent tray. (R1 bottle 20mL, R2 bottle 11mL) ➢ Set 2mL of detergent cup at Wash3 position on the sample tray. ➢ Wash time is about 30 minutes.
Auto Gain	Auto Gain is performed. ➢ Please refer to Chapter 4, 4.8.3 Auto-Gain

④ The progress is indicated by the time.
- ISE Mainte and ISE purge are not displayed the progress.

⑤ ISE maintenance and functions.

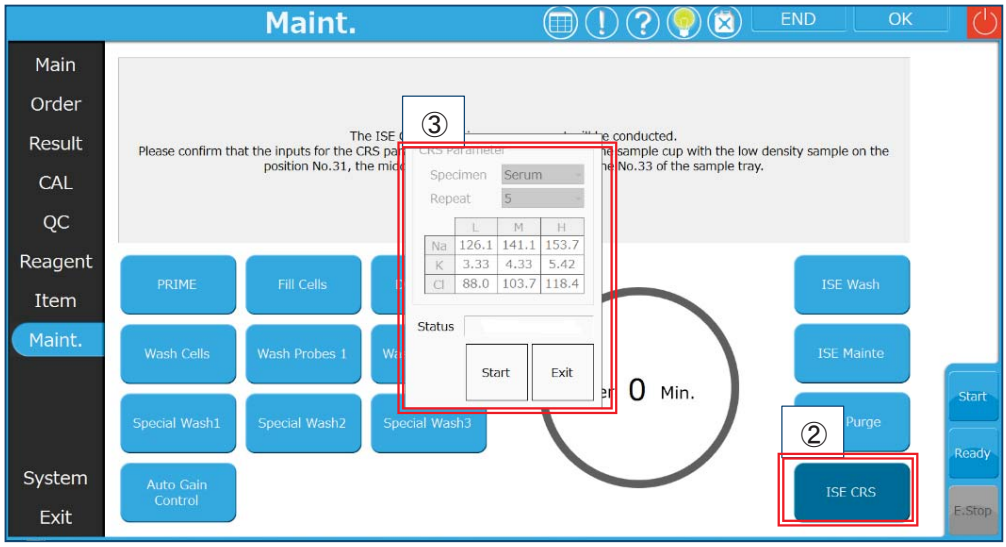
	Contents
ISE Wash	Perform the ISEwash. ➢ Set the ISE detergent at ISE wash position on the sample tray before start. ➢ Wash time is about 6 minutes.
ISE Mainte	The liquid of ISE line is drained. ➢ Perform before ISE maintenance when change the electrode.

	Contents
ISE Purge	Fill the ISE line by calibrator1. ➢ Perform after ISE maintenance when change the electrode.

⑥ ISE CRS button : The CRS measurement is used for the ISE correlation. Please refer to Chapter 4, 4.8.2. ISE CRS screen. (ISE correlation measurement)

4.8.2 ISE CRS screen (ISE correlation measurenment)

- The correlation measurement is recommended for ISE sample by usig CRS sample.
- CRS is a standard sample for ISE method.



Maintenance screen —CRS parameter screen

① Maint. button : Maintenance screen is shown.
② ISE CRS button : CRS parameter screen is shown.
③ Buttons and functions.

	Contents	
Specimen ▼	Select specimen	Serum, Urine, Plasma
Repeat ▼	Select aspiration time.	3～10 times
Na L/M/H	Input the Na conc. of low, medium and high.	
K L/M/H	Input the K conc. of low, medium and high.	
Cl L/M/H	Input the Cl conc. of low, medium and high.	
Status	Display following message. ◆ Run - CRS running ◆ After measurement - CRS success or CRS failure	
Start→E.Stop	Start the CRS measurement. ※After the start of operation, and displays the E. Stop button.	
Close	Close the CRS parameter screen.	

ISE CRS correlation procedrue

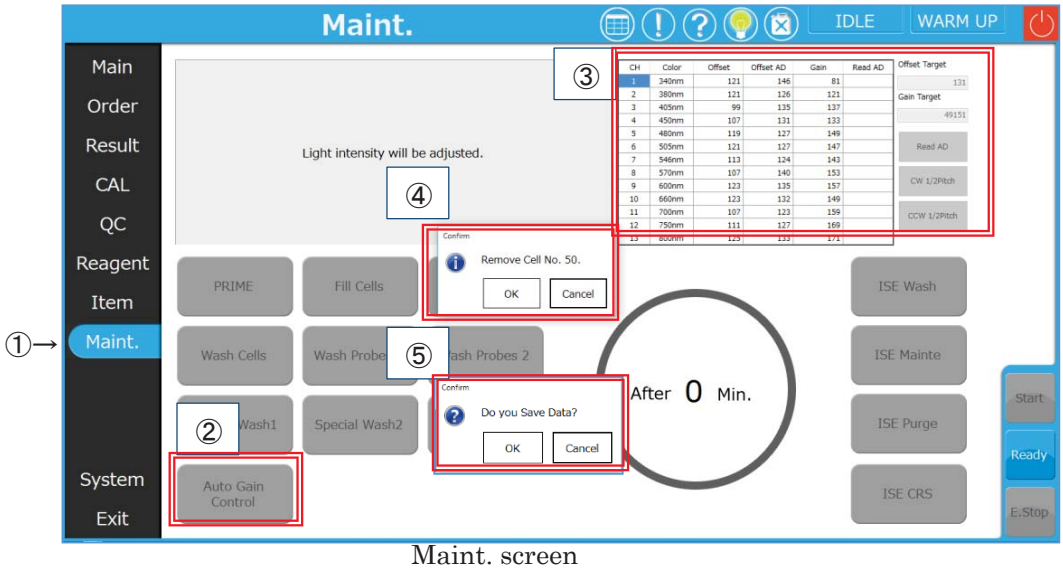
1) Click ISE CRS button.
2) Display of CRS parameter screen.
3) Input CRS parameters (Specimen, Count, Conc. value)
4) Set the sample cups for each concentration sample on the sample tray. (For setting N=5, 500uL)

- CRS Sanple positions are fixed in program.
  - 31 = Low conc. sample
  - 32 = Middle conc. sample
  - 33 = High conc. sample.

5) Click Start button, and start the CRS measurement.
   "CRS running" is shown in state culoum.
6) "CRS success" or "CRS failure" is shown after measurement.
   - If "CRS failure" is displayed, check and remove the reason of failure and rerun.
7) Click Close, and close the CRS parameter screen.
8) Set the correlation values by using calculated results automatically.

4.8.3 Auto gain screen information

➢ Autogain information screen displays. Please refer to Chapter 5 Auto gain.



Maint. screen

① Maint. button : Maintenance screen is shown.
② Auto Gain control button : Ayto gain screen is shown.
③ Auto gain screen and functions. (Setting is unnecessary)

	Contents
[CH]	Display of channel number.
[Color]	Display of wavelength.
[Offset]	Display of offset value.
[Offset AD]	Display of offset AD value.
[Gain]	Display of gain value.
[Read AD]	Display of read AD value.
Offset Target	Display of the offset target value.
Gain Target	Display of the gain target value.

➢ Following buttons can be operates under login of service engineer level.

	Contents
Read AD	Read the AD valu.
CW 1/2Pich	To move clockwise by 1/2 pitch.
CCW 1/2Pich	To move counter-clockwise by 1/2 pitch.

④ Confirmation screen : Clicking Auto gain button, pop-up screen is shown. Clicking OK button, start the auto gain measurement.

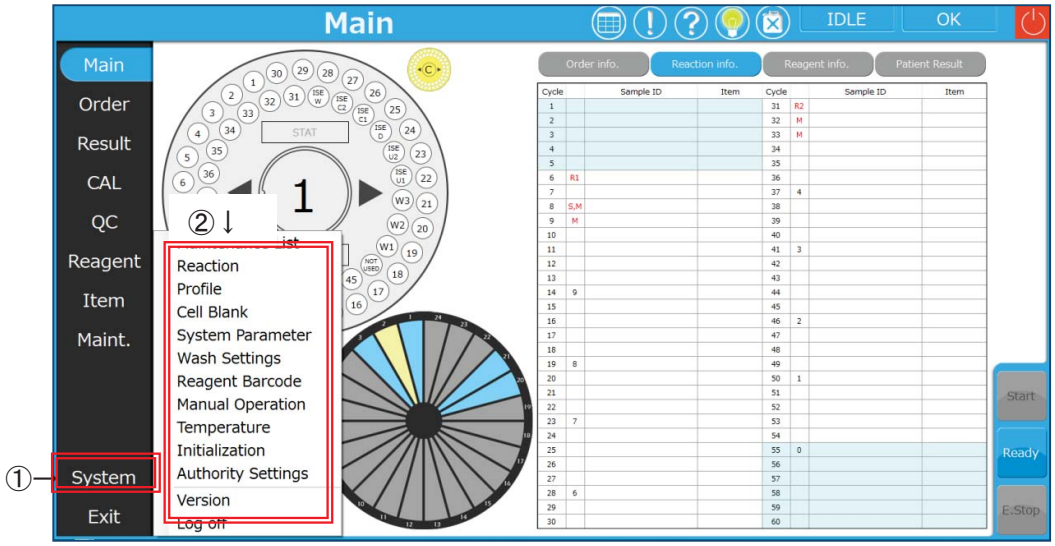
⑤ Data saving confirmation screen : After Auto gain completed, pop-up screen is shown. Clicking OK button, auto gain results are registered.

4.9 System screen

➢ System setting screen displays for system parameter setting

4.9.1 System buttons

System parameter is indicated as follows.



System screen— Menu button

① System button : Display of menu screen in System screen.

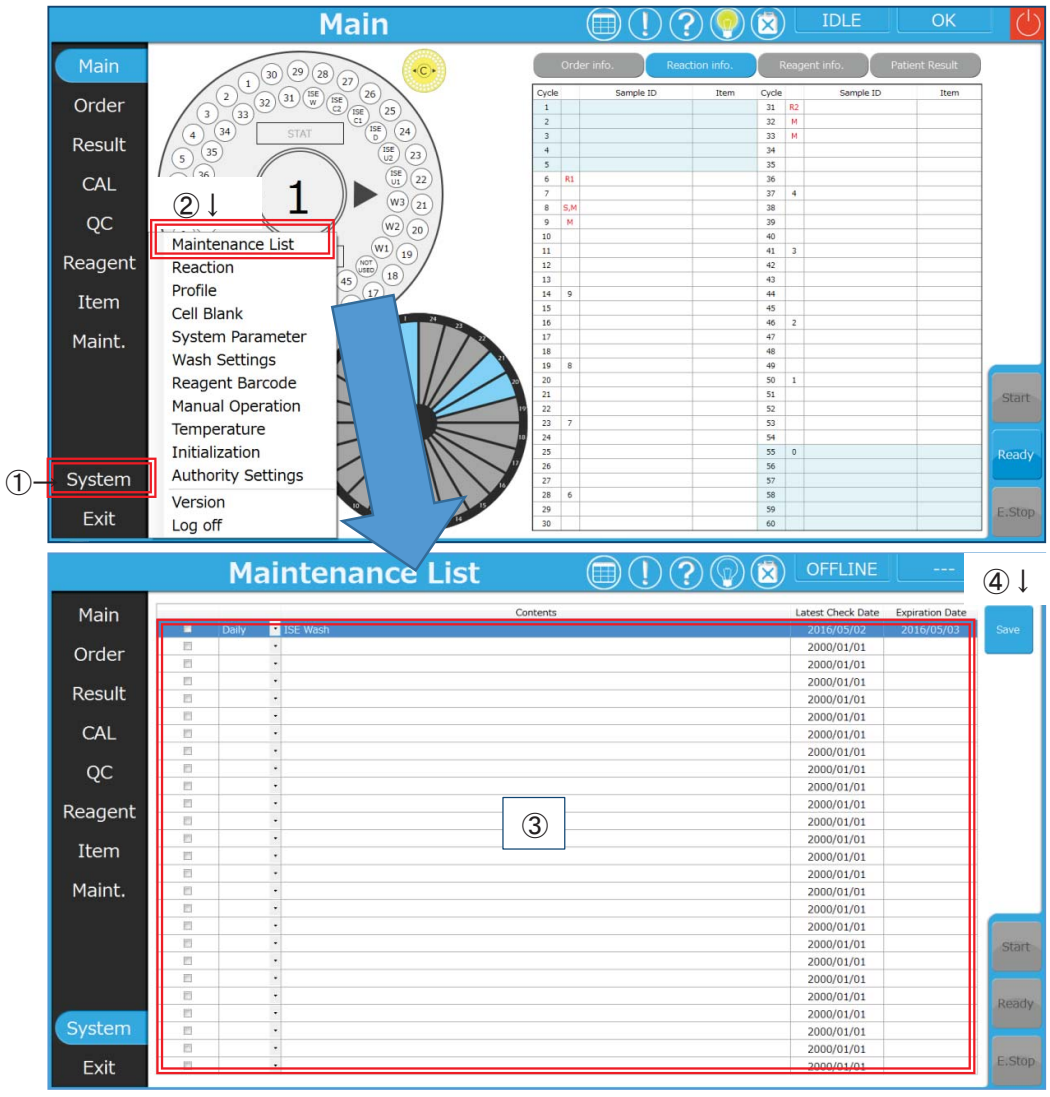
② System menu screen and functions.

Buttons	Contents
Maintenance List	Display of daily maintenance list.
Reaction	Display of reaction monitor screen.
Profile	Display of profile registration screen for calibration order and patient sample order.
Cell Blank	Display of cell blank value. Confirm the cell condition.
System Parameter	Display of sytem parameter setting screen. ➢ Setting for run sequence, reagent tray and reagent remain.
Wash Settings	Display of the setting for carry over avoidance screen (Reagent and Sample probes, reaction cell)
Reagent Barcode	Display of reagent barcode setting screen. ➢ Display when the login by service engineer level.
Manual Operation	Display of each unit movement and condition of analyzer status.
Temperature	Display of temperature monitor and pre-heater for washing water and temperature setting screen.
Initialization	Unit offset parameter values. ➢ Display when the login by service engineer level.

Buttons	Contents
Authority Settings	Display of operator level setting. ➢ Display when the login by service engineer level.
Version	Display of the version information on the system program.
Log off	Display of Log off screen. Use for change the operator level.

4.9.2 Maintenance List screen

➢ Maintenance list screen displays. Confirm the maintenance performaince.



Maintenance List screen

① System button : Display of menu screen in System screen.
② Maintenance List button : Display of Maintenance List screen.
③ Screen and functions

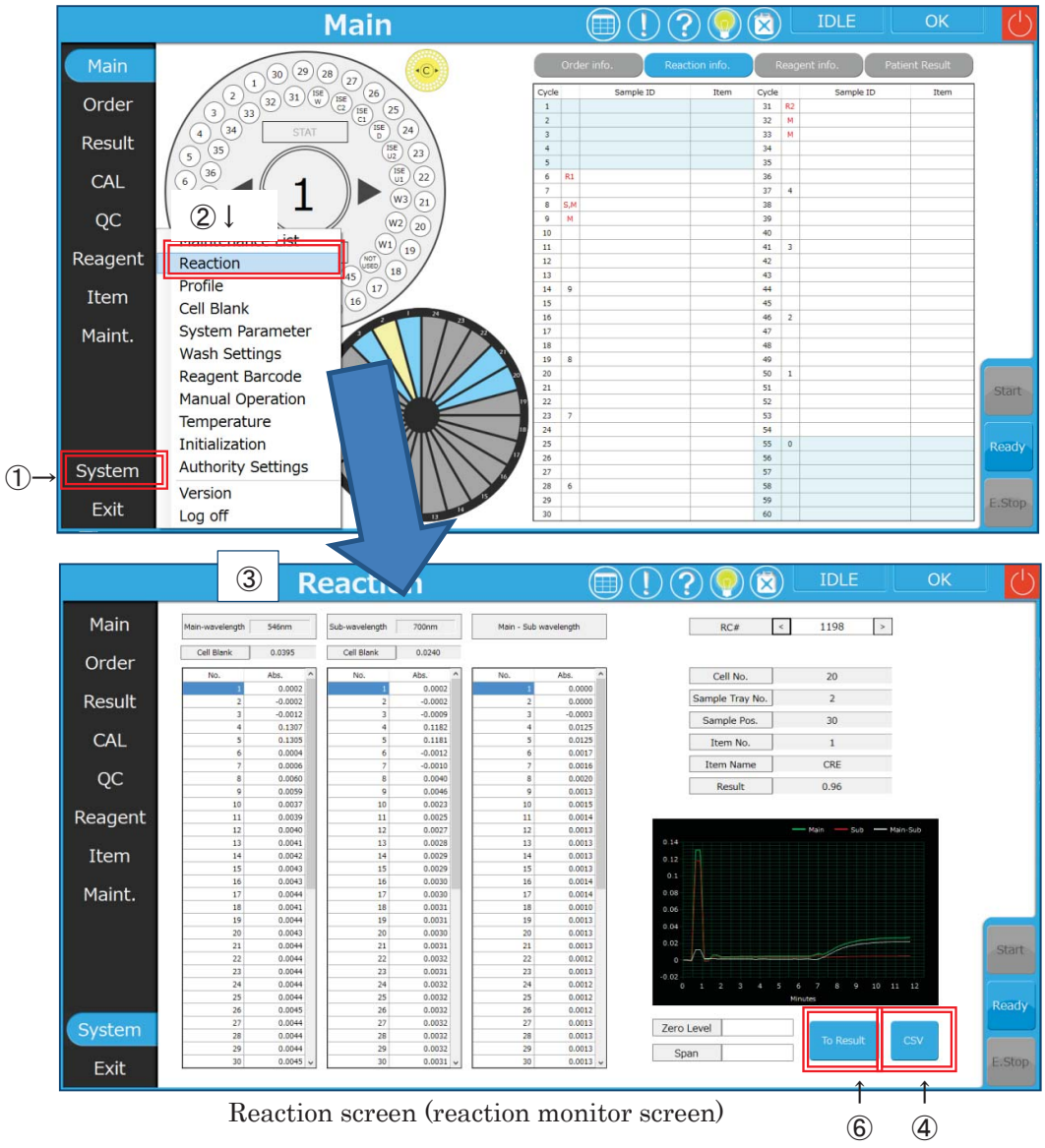
	Contents
☐	Update the performed date. ➢ Check the box after performance. Clicking Save button, update the performed date.
▼	Select the operation period. ➢ Select from Daily, Weekly, Monthly, Half year, One year and Two years.
(Details)	Input operation details.

	Contents
(Last date)	Display of the last performed date.
(Limit)	Display of the next date. ➢ Chek the box, and update the date by clicking Save button. ➢ If the date is not updated within period, the back color of related button is change to red.

④ Save button : Update the performed date and next operation date.

4.9.3 Reaction monitoy screen

- All the Reaction Abs. of each reading point and reaction graph are displayed. The Abs. of Main, sub wavelength, main – sub wavelength and measurement result.
- The reaction screen can be open form the result screen.



Reaction screen (reaction monitor screen)

Reaction monitor save screen

① System button : Display of menu buttons in System screen.
② Reaction button : Display of Reaction monitor screen.
③ Reaction monitor information

	Contents
Main Wave length / Sub wave length	Used mainand sub wavelengths display
Cell Blank/ Cell Blank	Cell blank for main and sub wavelengths display
Main - Sub wave length	(Display Abs. of Main - Sub wavelengs)
No.	Display of measuring points. (1～54)
Abs.	Display the optical absorbance resultof each measuring points for Main and Sub wavelengths.
RC# < >	Display reaction monitor number. ➢ Change the monitor screen before after by selection of < or > button. ➢ Display of reaction monitor by using RC No. in Result Log screen.
Cell No.	Display of used reaction cell number.
Sample tray No.	Display of used sample tray number.
Sample pos.	Display of used sample positionnumber.
Item No.	Display of Item number.
Item name	Display of Item name.
Result	Display of the result value. ➢ Display zero value for calibration result.
(Graph)	Display of reaction monitor graph. ➢ X axis is measuring points. Y axis is absorbance value.
Zero Level	Abs. value setting for graph display. ➢ (Y axis) basic level(-9.999～9.999 Abs.)
Span	Abs. value setting ofr graph display. ➢ (Y axis) sesitivity(-9.999～9.999 Abs.)

④ CSV button : Display of reaction monitor saving popup screen.
➢ Reaction moniotor can be save to CSV file.

Display of pop-up screen

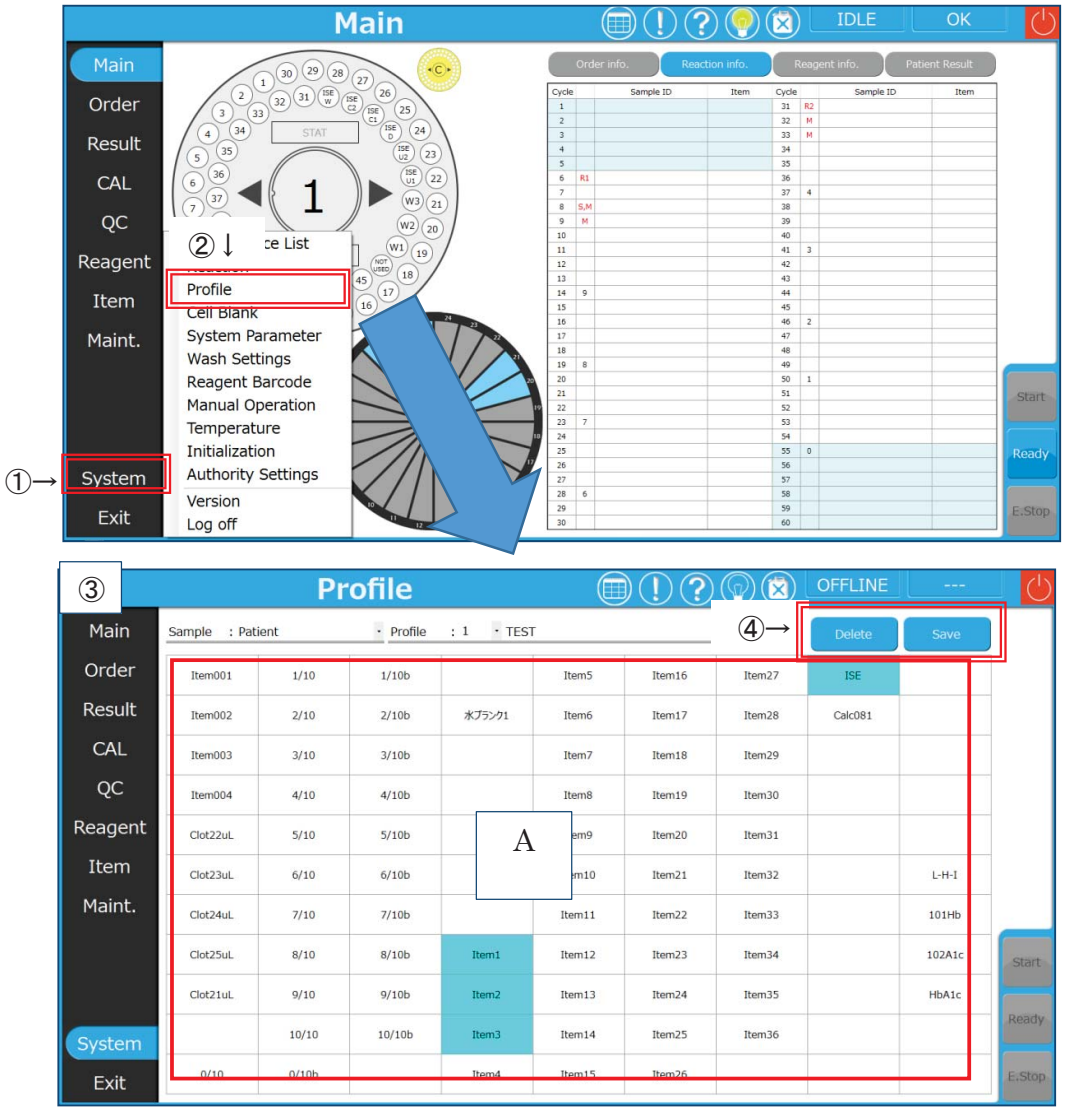
⑤ Reaction monitor saving screen

	Contents
○RC# — .	Input saving RC No.
○Date — .	Input saving date.
OK	Select port and save.
Cancel	Cancel the saving.

⑥ To Results button : Move to displayed monitor result screen.

4.9.4 Profile screen

➢ Profile entry screen for patient and calibration sample displays.



Profile screen

① System button : System menu screen is shown.
② Profile button : Profile screen is shown.
③ Buttons and functions

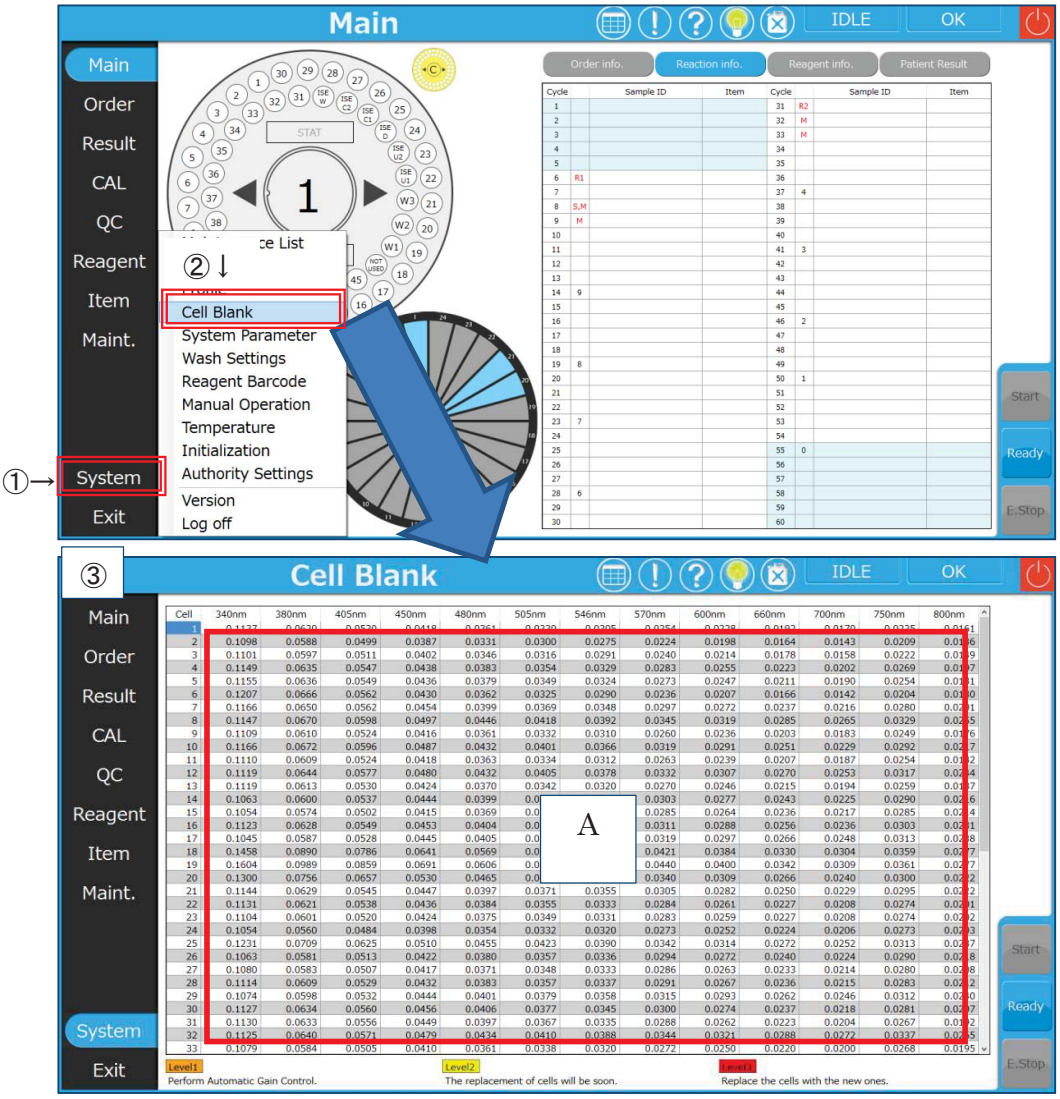
	Contents
Sample : ▼	Select for patient or calibration.
Profile : ▼_____	Select profile number and input profile name. (Max. 8 characters) ➢ For the patient ; No. 1～20 ➢ For the calibration : No.1～8

	Contents
A	Display of Item names which registerd in Item screen. ➢ Select registration Item. ➢ The back color chages to light after registration.

④ Delete button : Delete the profile registration.
Save button : Save the profile registration.

4.9.5 Cell Blank screen

- All reaction cell Abs. of warer blank are displayed for each wavelength.
- The Abs. value is updated by each measurement.
- Confirm the cell condition.



Cell Blank screen

① System button : Display of menu button in Systemscreen.
② Cell Blank button : Display of Cell Checkscreen.
③ Screen and functions

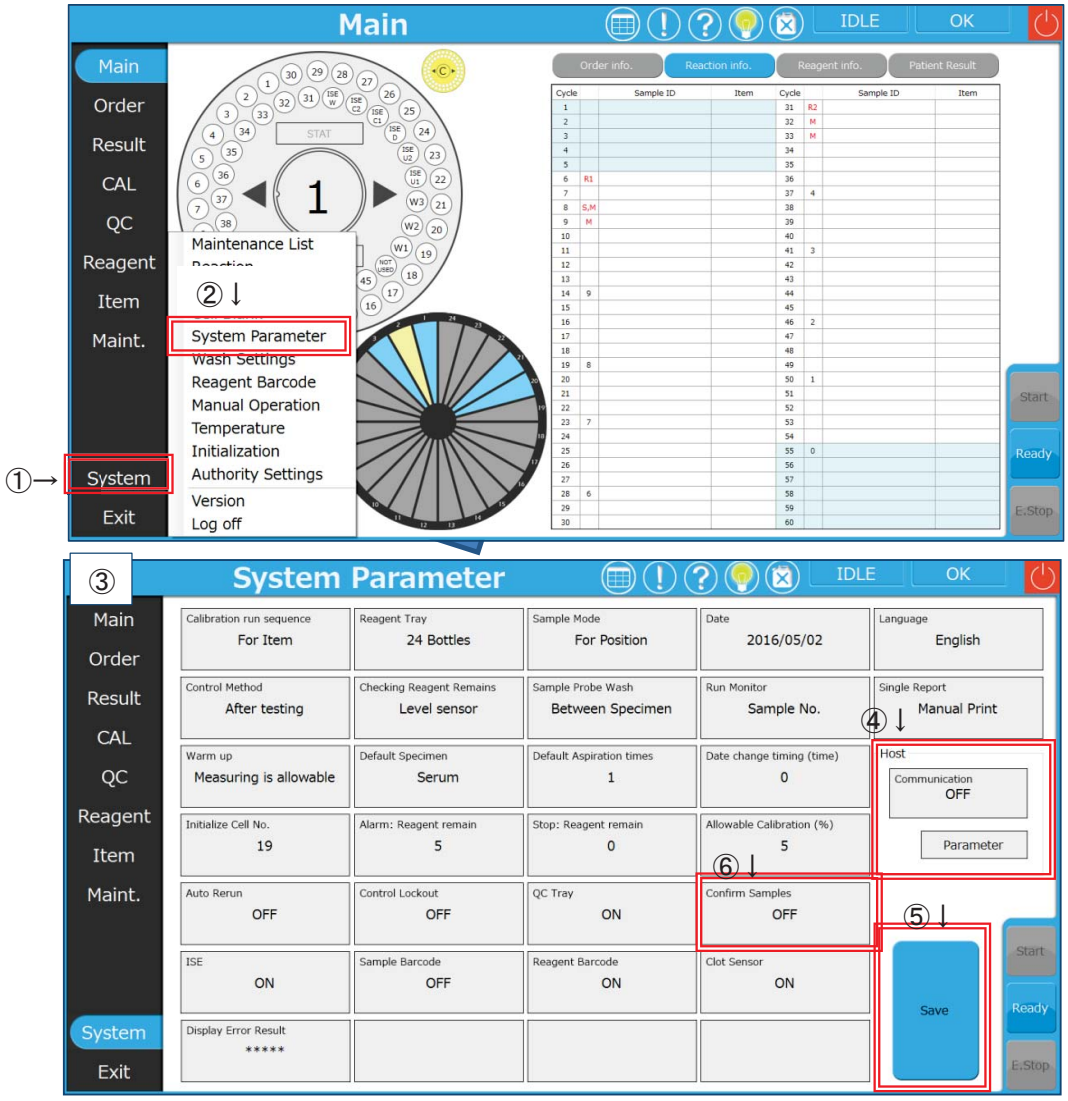
	Contents
Cell	Display the reaction cell position number.
340nm ～ 800nm	Display of each wavelength.
A	Display of cell balnk value for each reaction cell and wavelength.

- There are three level for check level (Level 1. Level 2 and Level 3). If the value is out of check level, back color change. Change the reaction cuvette if necessary.

	Contents
Level 1	Cell blank is abnormal.(Abs. is too light) ➢ If the value below than level 1, back color is chaged to orange. ➢ Please perform the auto-gain.
Level 2	The time for exchange is coming soon. ➢ If the value above than level 2, back color is changed to yellow. ➢ Please prepare the reaction cell exchange.
Level 3	Cell blank is abnormal. (Dirty) ➢ If cell blank value above than level 3, back color is changed to red. ➢ Please change the reaction cells to new one.

4.9.6 System Parameter screen

- Setting of measurement sequence, reagent tray and reagent remain.
- Parameters are set by the user requirement.



Parameter screen

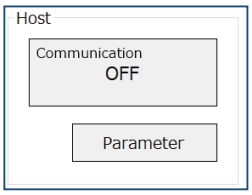
① System button : Display of menu screen in System screen.
② Parameter button : Display of Parameter screen.
③ Screen and functions

	Contents	Default
Calibration run sequence	Select the sequence of calibration measurement. ➢ Select by Sample or by Item	Item
Reagent Tray	Select the reagent tray. ➢ Select 24 Bottles or 36 Bottles.	36 bottles

	Contents	Default
Sample Mode	Selection for using sample position or sample barcode. Display of order screen and result screen change by selected mode. ➢ Select Position or by Barcode.	Position
Date	System date setting. ➢ Selection from calendar	
Language	Language selection. ➢ Select English or Japanese	Japanese
Control method	Selection for measurement timing of control sample after calibration. (None) Discontinue (Last) Continue after calibration. ➢ Select None or Last	Last
Checking Reagent Remain	Reagent remain selection (In case of "Count") The residual test count is shown which calculated by Item parameter value automatically. Count down one by one aspiration. (In case of "Level sensor") The residual test count is shown which calculated by probe movement automatically. ➢ Select count or level sensor.	Level sensor
Sample Probe Wash	Sample probe wash pattern setting ➢ Select Between Items, between specimen and Between samples.	Specimen
Run Monitor	Selection for display of reaction info. in main screen. ➢ Select by Sample No., Barcode and Patient ID.	Sample No.
Single Report	Selection of print method for single report. ➢ Select by auto-print or manual print.	Manual
Warm up	Selection for start the measurement during the analyzer [WARM-UP] condition. Measurment enable Measurment disable	Disable
Default Specimen	Selection for display of default specimen in order screen. ➢ Select by Serum, Urine, Plasma, CSF, Dialysis, Other, HbA1c(Whole blood, Primary tube, Hemolyzed)	Serum
Default Aspiration times	Setting for default display of aspiration time in order screen. ➢ Select from 1～10	1
Date change timing (time)	Select date changing time.	0

	Contents	Default
Initialize cell No. (Start cell No.)	Display of reaction cell position number for next measurement start. ➢ Input reaction cell position number. ➢ Start reaction cell position can be set after ready.	
Alarm: Reagent remain	Setting of warning level for reagent remaining. ➢ Input alarm level of test count. ➢ Alarm will show when exceeds the level.	Default 5
Stop: Reagent remain	Setting of stop level for reagent remaining. ➢ Input stop level of test count or %. (In case of the setting is "Count" ➢ Stop the sampling automatically and display alarm (In case of the setting is "Level) ➢ Display alarm, and continue the sampleing unitl "S" flag occurrence.	Default 0
Allowable Calibration (%)	Setting of acceptable calibration variation between the former results. (Standard Abs.-Blank Abs.) ➢ Display error when exceeds the setting.	Default 5
Auto Rerun	Select whether to execute automatic rerun ➢ Select ON or OFF	OFF
Control Lockout	Selection for no order entry of the test item is acceptable when a test result of control sample is a error B – F of Westgard check. ➢ Select ON or OFF	OFF
QC Tray	Select ON when using the QC tray. ➢ Display QC sample tray (Pink).	OFF
Confirm sample	Select ON when perform the sample detection. Set in following condition. ➢ The screen changes depending on the LIS setting and sample probe wash setting. ➢ Please refer to Chapter 4, 4.9.7 Sample confirmation screen.	ON
ISE	Setting of ISE Item measurement.	OFF
Sample Barcode	Setting of sample barcode.	OFF
Reagent Barcode	Setting of reagent barcode.	OFF
Clot Sensor	Setting of clot seneor.	ON
Display Error Result	Selection for display of data error. ➢ Select value or asterisk (*).	******

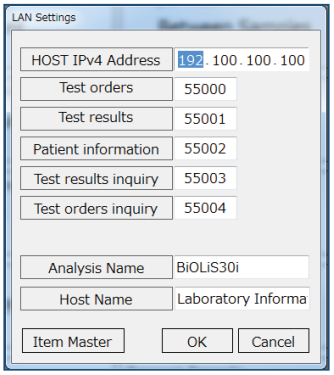
④ Display of LIS communicartion
Refer to bi-directional communication specification.



Host

Select the LIS communication.

- Select ON or OFF.(Default OFF)



LAN Settings screen

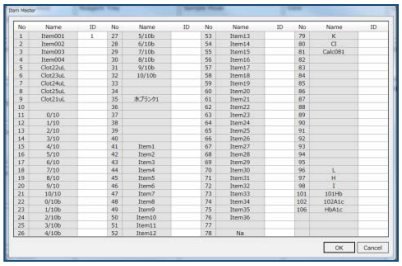
LAN settings

- Setting for LANcommunication condition.

HOST IPv4 Address : Setting of Host IP address (IPv4).

Test orders
Test results
Patien information
Test reults inquiry
Test orders inquiry

Analysis name :
Host name : Laboratory Information System
Item master : Dysplay Item master screen.



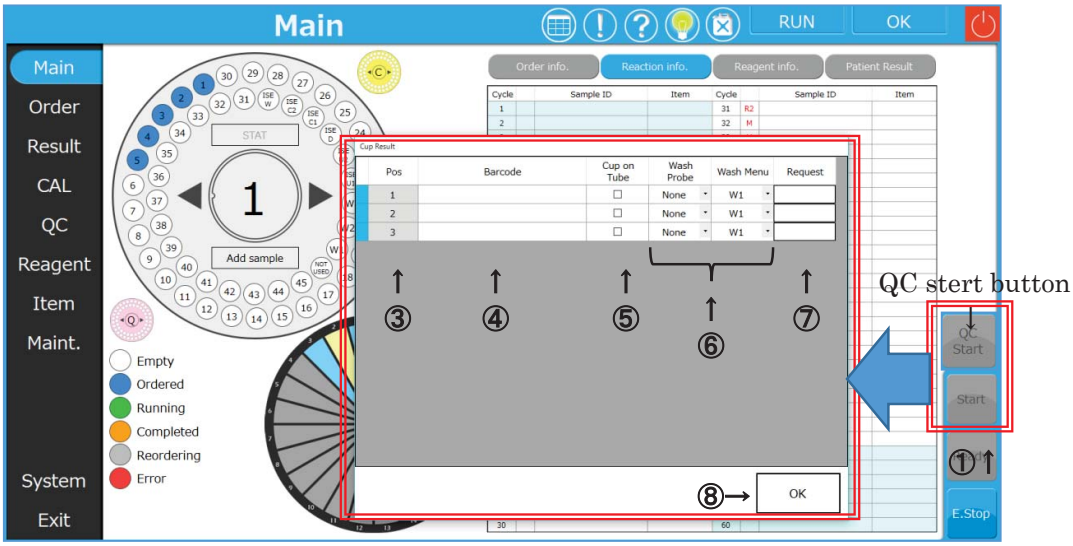
Item Master screen

OK : Save the LANsetting
Cancel : Cancel the setting and close the LAN setting

⑤ Save button : Register the displayed screen.

4.9.7 Samlpe confirmation screen

- Popup screen displays after clicking Start button. Start the mensurement after sample existing.
- Display when sample confirmation is On in system screen.the
- The screen changes depending on the LIS setting and sample probe wash setting.



Cup Result screen

① Start button
QC start button : Sample confirmation popup screen is shown.

② Sample confirmation screen : Confirm setting and start the measurement.

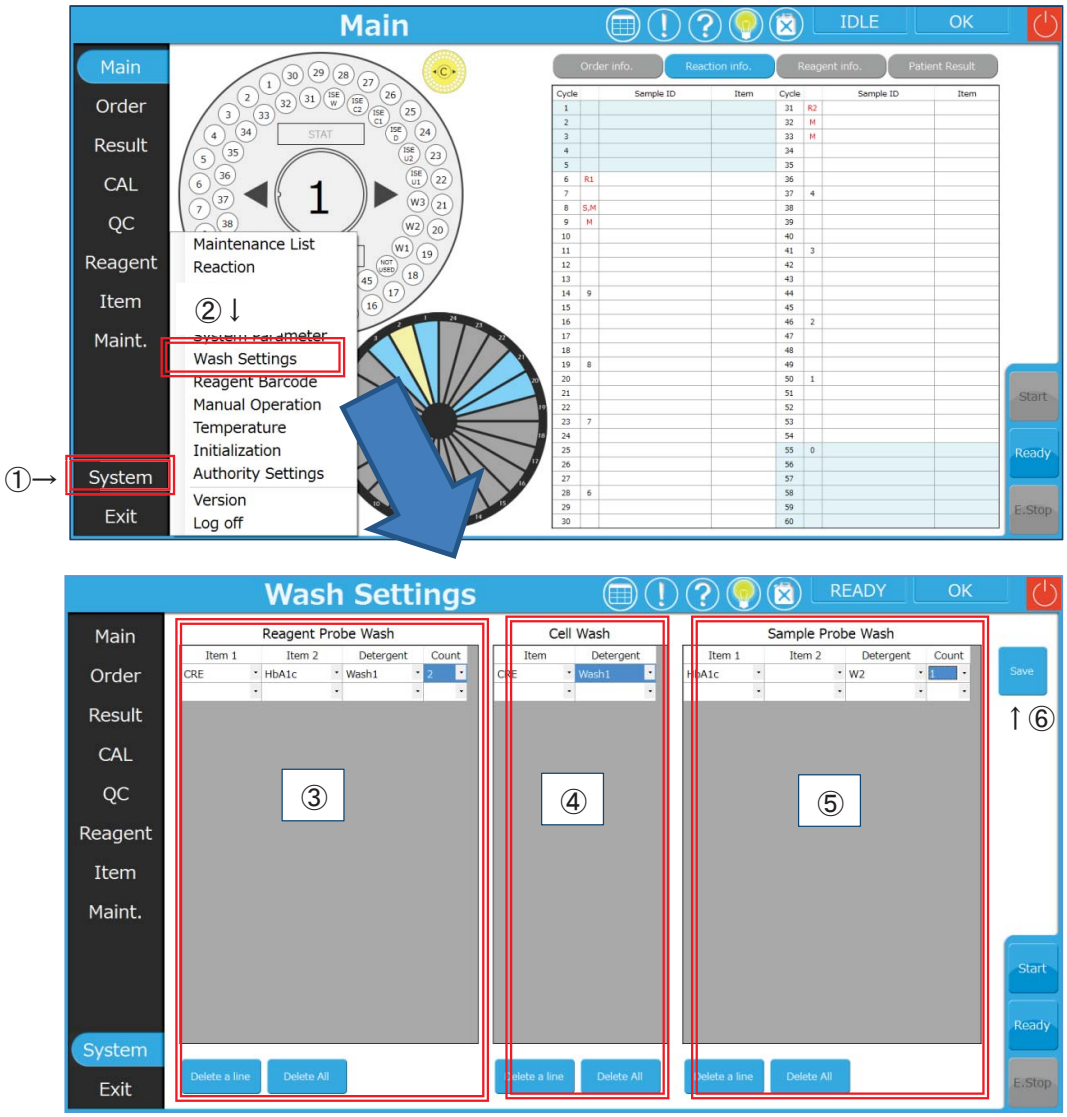
		Contents
②	Pos	➢ In case of sample is set, sample position number on the sample tray displays. ➢ If the sample is ordered, left column turns to blue.
④	Barcode	In case of sample barcode setting, display of readed chalacter. ➢ Manual input is possible when barcode reading is failed or error occured.
⑤	Cup on Tube ☐	Select when the sample cup is used on the primary tube.
In case of the sample probe washing is selected "Between Samples".		
⑥	Wash Probe	When perform the sample probe wash, select the wash timing before, after, before and after.
	Wash Menu	Select the detergent from W1-3.

		Contents
In case of the LIS communication setting is ON.		
⑦	Request	Request the sample barcode information. ➢ If the barcode reading is failed or error occurred, correct manually first. Then click Request button for corrected information.

⑧ OK button : Start the measurement.

4.9.8 Wash Settings screen (Carry over avoidance)

- Setting screen of wash configuration screen dispalys.
- Setting for Sampl probe (between Item and specimen), reagent probe and reaction cell.



Wash Settings screen

① System button : Display of System menu screen.
② Wash Configuration button : Display of Wash Configuration screen.
③ Reagent Probe Wash screen

	Contents
Item1	Select of carryover effecting test Item. ➢ Blank in Item selction means all the Items.
Item2	Select of carryover sensitive test Item. ➢ Blank in Item selction means all the Items.

	Contents
Detergent	Select of cleaning solution (Wash1-3) or water to avoid carryover.
Count	Select washing time (1-10).
Delete a line	Setting of the selected line is deleted.
Delete All	All the settings are deleted.

➢ When select the [Water], detergent bottle setting is unnecessary.

④ Cell Wash screen

	Contents
Item1	Select of carryover effecting test Item. ➢ Blank in Item selction means all the Items.
Detergent	Select of cleaning solution (Wash1-3) or water to avoid carryover.
Delete a line	Setting of the selected line is deleted.
Delete All	All the settings are deleted.

⑤ Sample Probe Wash screen

➢ The screen is changed depending on the sample probe wash setting.

➢ When the sample probe washing is set by sample, this setting is unnecessary. Set in Sample confirmation screen.

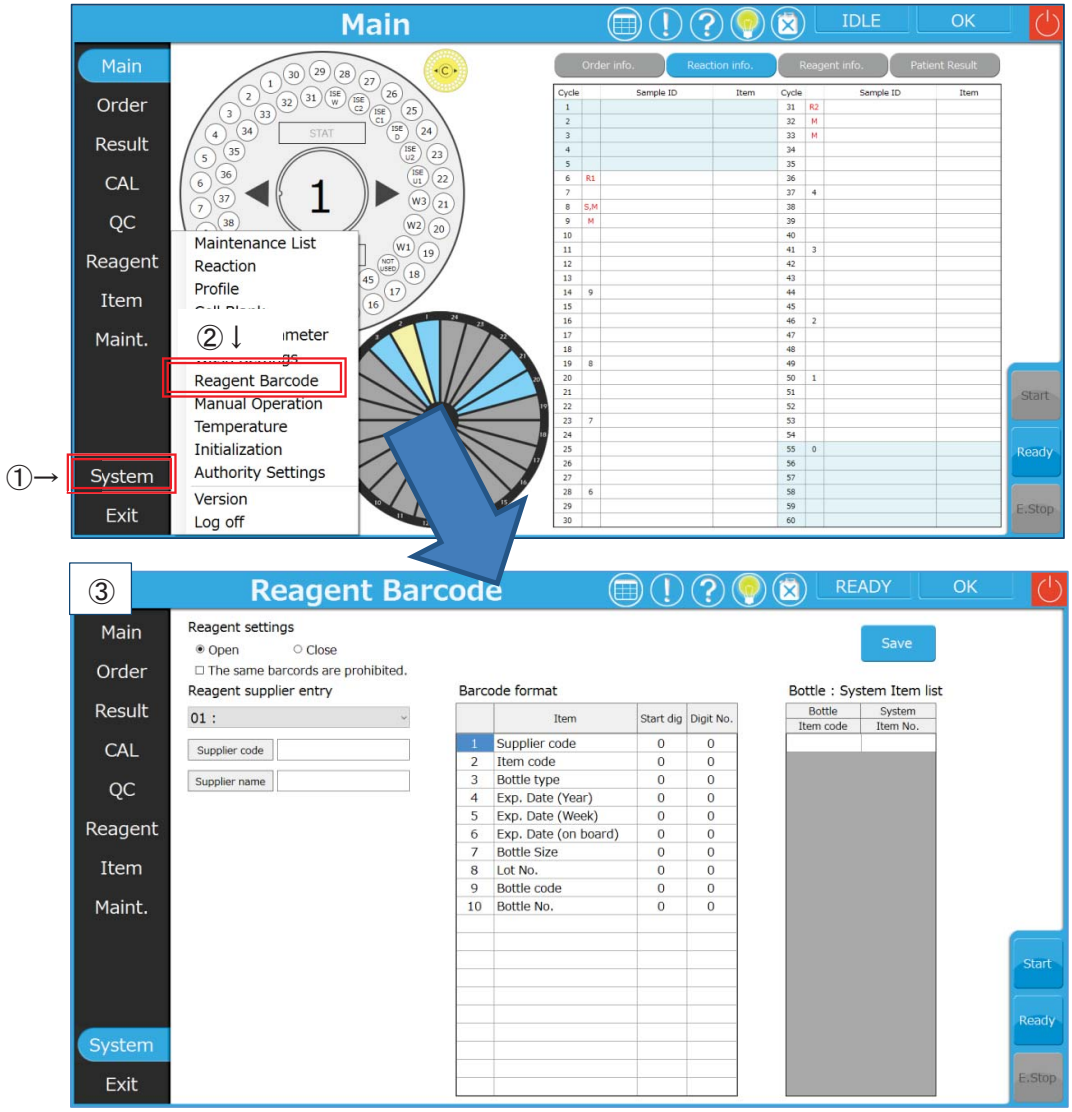
	Contents
Item1	Select of carryover effecting test Item or specimen. ➢ Blank in Item selction means all the Items.
Item2	Select of carryover sensitive test Item.or specimen. ➢ Blank in Item selction means all the Items.
Detergent	Select of cleaning solution (Wash 1-3) or water to avoid carryover.
Count	Select washing time (1-10).
Delete a line	Setting of the selected line is deleted.
Delete All	All the settings are deleted.

⑥ Save button ; Register the displayed screen.

4.9.9 Reagent Barcode screen

Reagent barcode is set in this screen.

- ReagentBarcode is displayed by the user level.
- Input the reagent barcode format and maker code.
- Please refer to reagent barcode specification.

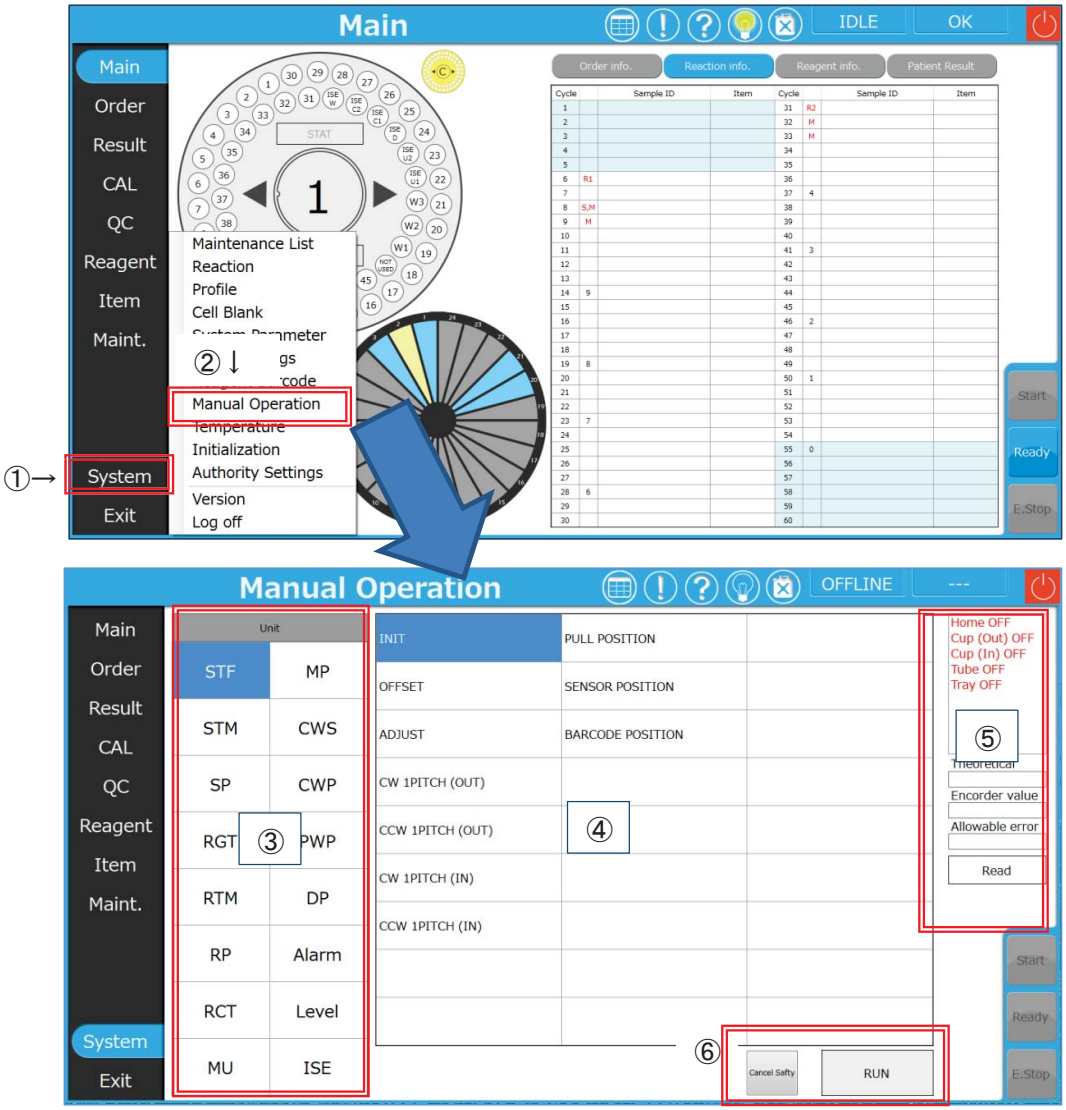


Reagent Barcode screen

① System button : Display of System menu screen.
② Reagent Barcode button : Display of Reagent Barcode screen.
③ Display of reagent barcode setting screen.

4.9.10 Manual Operation screen

Unit movement operates manually. Confirm the analyzer condition.



Manual Operation screen

① System button : Display of System menu screen.
② Manual Function button : Display of Manual Function screen.
③ Unit : Display of unit name for manual function.

Unit (abbreviations)	Unit name	Movements
STF	Sampler	Rotation of sampler
STM	Sample probe	Rotation of sample probe Up/Down movement of sample probe
SP	Sample pump	Aspiration/Dispensation movement of samplepump

Unit (abbreviations)	Unit name	Movements
RGT	Reagent tray	Rotation of reagent tray
RTM	Reagent probe	Rotation of reagent probe Up/Down movement of reagent probe
RP	Reagent pump	Aspiration/Dispensation movement of reagent pump
RCT	Reaction tray	Rotation of reaction tray
MU	Mixing unit	Up/Down movement of mixing unit
MP	Mixing pump	Movement of mixing pump
CWS	Cuvette washing station	Up/Down movement of reaction cell washing station
CWP	Cuvette washing pump	Aspiration/Dispensation movement of reaction cell washing pump
PWP	Probe washing pump	Aspiration/Dispensation movement of probe washing pump
DP	Drainage pump	Movement of drainage pump

	Contents
Alarm	Display of error state.
Level	Display of liquid level statre for sample and reagent probes.
ISE	ISE unitmovement and display of ISE unitstate.

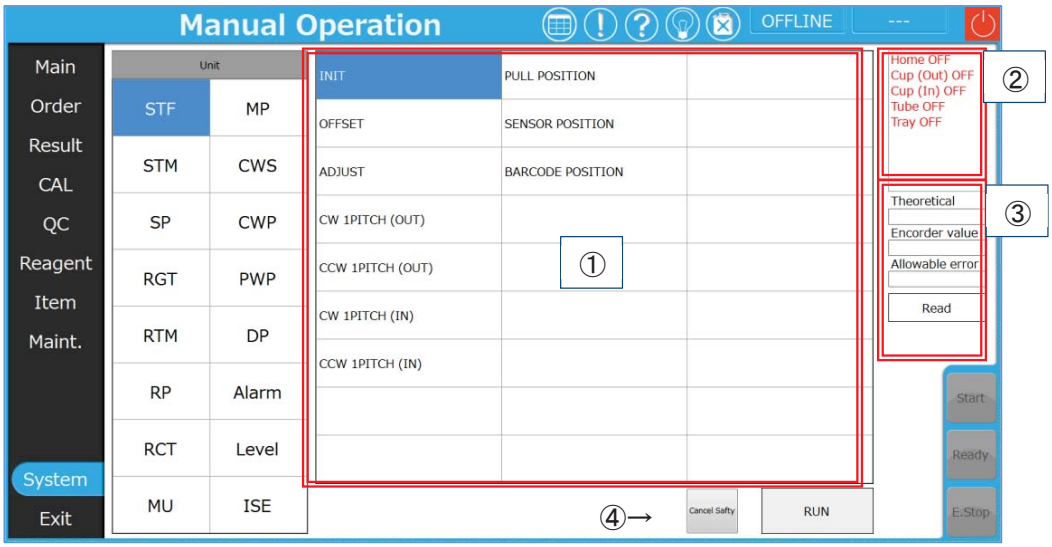
④ Displays of manual function.
- Display the function by each unit movement.
  Move the unit by clicking RUN or double click.
  Move the unit by clicking CW, CCW, Up and Down button or double clicking..
- Back color turns to blue after selecting the function.

⑤ Each sensor state shows ON or OFF.

⑥ Common button for each unit screen.

Button	Contents
Cancel Safety	Select when operating with "NO Safety". ➢ No work for ISE function.
RUN	Perform selected function.

1. STF



STF screen

① Functions

		Movements
1	INIT	To move to the home position.
2	OFFSET	
3	ADJUST 0 x0.09deg = 0 CW ↔ CCW	To input the angle to move by value, and to select the direction of CW/CCW rotation.
4	CW 1PITCH (OUT)	To move the outside cups clockwise by one pitch.
5	CCW 1PITCH (OUT)	To move the outside cups counter-clockwise by one pitch.
6	CW 1PITCH (IN)	To move the inside cups clockwise by one pitch.
7	CCW 1PITCH (IN)	To move the inside cups counter-clockwise by one pitch.
8	PULL POSITION 0 No.	To move the aspiration position of selected cup. ➢ Input the cup position number.
9	SENSOR POSITION (IN) 0 No.	To move the cup sensor position of selected cup. ➢ Input the cup position number.
10	BARCODE POSITION 0 No.	To move the barcode position of selected cup position. ➢ Input the cup position number.

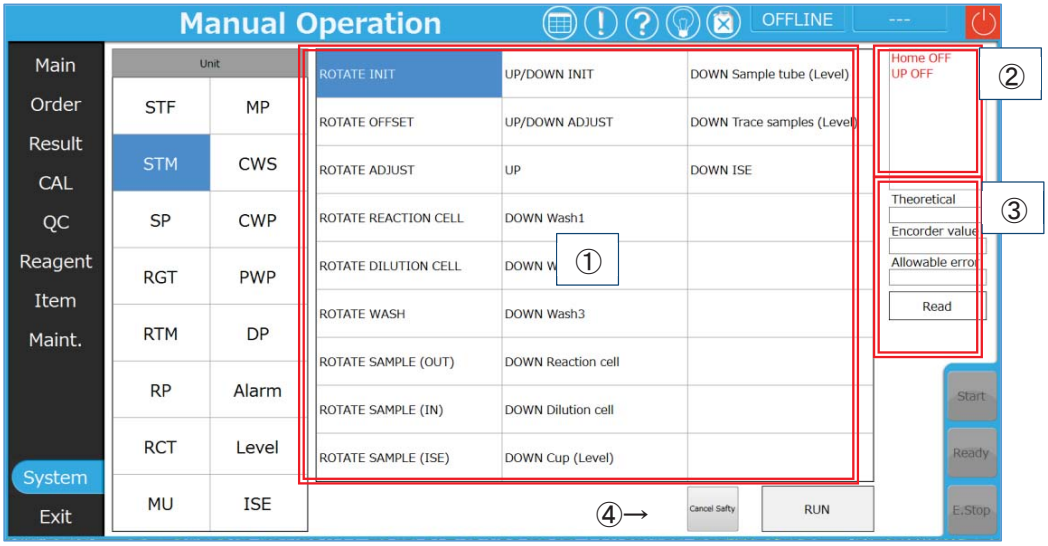
② Each sensor condition shows ON or OFF.

③ Clicking Read button, encoder value is shown.
(Theoretical,Actual value,Allowable error)

④ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with “NO Safety”.
RUN	Perform selected function.

2. STM



STM screen

① Functions

		Movements
1	ROTATE INIT	To move to the home position.
2	OFFSET	
3	ROTATE ADJUST 	To input the angle to move by value, and to select the direction of CW/CCW rotation.
4	ROTATE REACTION CELL	To move the reaction cell position.
5	ROTATE DILUTION CELL	To move the dilution cell position.
6	ROTATE WASH	To move the washing trough.
7	ROTATE SAMPLE (OUT)	To move the aspiration position of outside sample cup.
8	ROTATE SAMPLE (IN)	To move the aspiration position of inside sample cup.
9	ROTATE SAMPLE (ISE)	To move the ISE sample pot.
10	UP/DOWN INIT	To move the home position.
11	UP/DOWN ADJUST 	To input the distance by value ans select the direction of UP/DOWN.
12	UP	To move the up position.
13	DOWN Wash1	To move the down position to the trouph.
14	DOWN Wash2	To move the down position to the washing position for primary tube.
15	DOWN Wash3	To move the down position to the dispensation position of washing water.
16	DOWN Reaction cell	To move the down position to the sample dispensation position at reaction cell.

		Movements
17	DOWN Dilution cell	To move the down position to the dilution sample aspiration position at reaction cell.
18	DOWN CUP (Level)	To move the down position of cup by level sensor.
19	DOWN Primary tube (Level)	To move the down position of primary tube by level sensor.
20	DOWN Trace samples (Level)	To move the down position of micro cup by level sensor.
21	DOWN ISE	To move the down position of ISE sample pot.

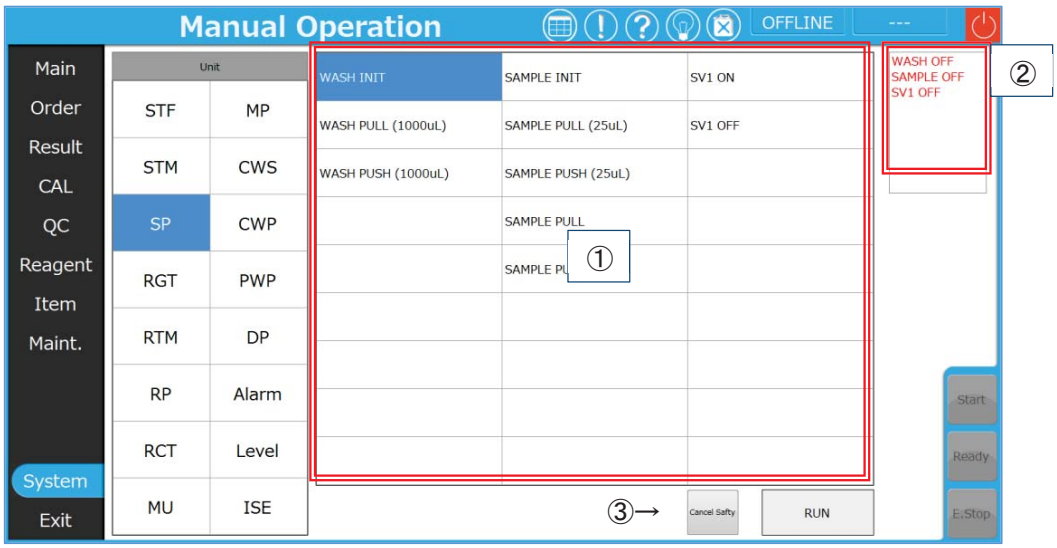
② Each sensor condition shows ON or OFF.

③ Clicking read button, encoder value is shown.
(Theoretical,Actual value,Allowable error)

④ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with "NO Safety".
RUN	Perform selected function.

3. SP



SP screen

① Functions

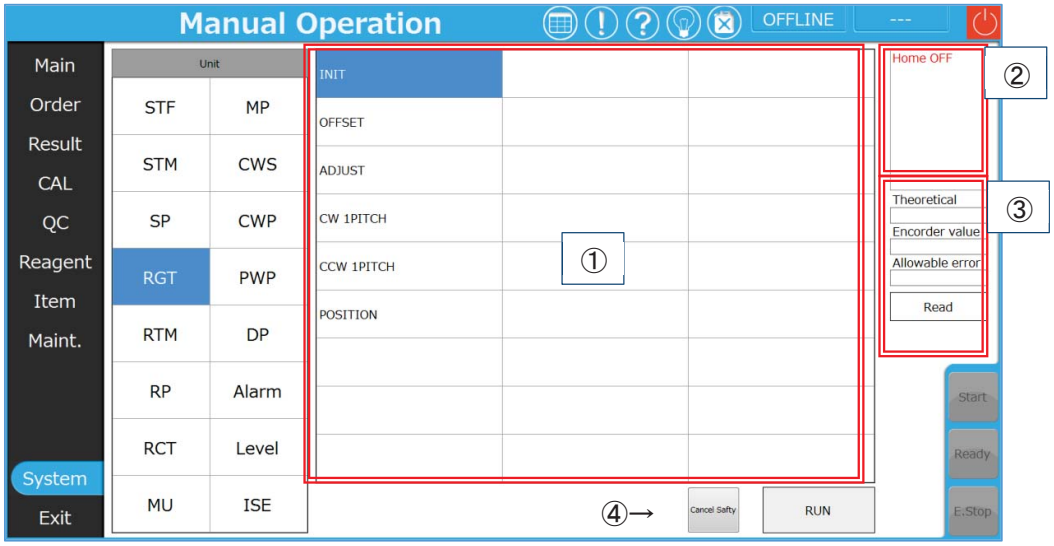
		Movements
1	WASH INIT	The washing side of pump; To move to the home position
2	WASH PULL (1000uL)	The washing side of pump; Aspiration movement (1000uL).
3	WASH PUSH (1000uL)	The washing side of pump; Dispensation movement (1000uL).
4	SAMPLE INIT	The sample side of pump; To move to the home position
5	SAMPLE PULL (25uL)	The sample side of pump; Aspiration movement (25uL)
6	SAMPLE PUSH (25uL)	The sample side of pump; Dispensation movement (25uL)
7	SAMPLE PULL 0 x0.1ul = 0	The sample side of pump; Aspiration movement ➢ Input aspiration volume.
8	SAMPLE PUSH 0 x0.1ul = 0	The sample side of pump; Dispensation movement ➢ Input dispensation volume.
9	SV1 ON	Electromagnetic valve EV-1 ON
10	SV1 OFF	Electromagnetic valve EV-1 OFF

② Each sensor condition shows ON or OFF.

③ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with "NO Safety".
RUN	Perform selected function.

4. RGT



RGT screen

① Functions

		Movements
1	INIT	To move to the home position.
2	OFFSET	
3	ADJUST 	To input the angle to move by value, and to select the direction of CW/CCW rotation.
4	CW 1PITCH	To move the clockwise by one bottle.
5	CCW 1PITCH	To move the counter clockwise by one bottle
6	POSITION 	Selected bottle to move the aspiration position. ➢ Input bottle position number. ➢ In case of 36 Item tray, move to No.1～36 for R1 and No.37～72 for R2.

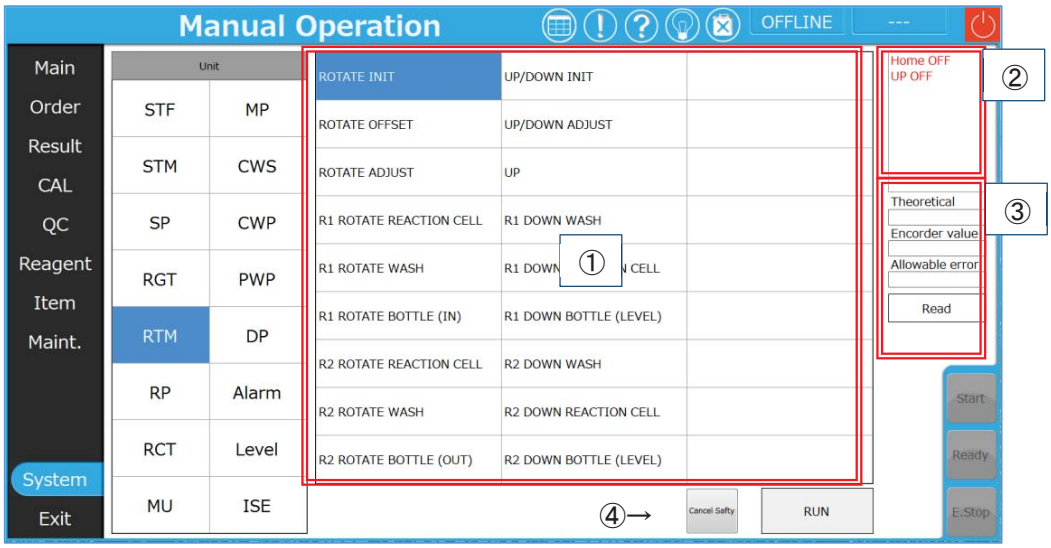
② Each sensor condition shows ON or OFF.

③ Clicking Read button, encoder value is shown.
(Theoretical,Actual value,Allowable error,Position)

④ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with “NO Safety”.
RUN	Perform selected function.

5. RTM



RTM screen

① Functions

		Movements
1	ROTATE INIT	To move to the home position.(on the reaction cell)
2	ROTATE OFFSET	
3	ROTATE ADJUST 	To input the angle to move by value, and to select the direction of CW/CCW rotation.
4	R1 ROTATE REACTION CELL	To move R1 probe to the reaction cell.
5	R1 ROTATE WASHING WASH	To move R1 probe to the washing trough.
6	R1 ROTATE BOTTOLE (IN)	To move R1 probe to the aspiration position.
7	R2 ROTATE REACTION CELL	To move R2 probe to the reaction cell.
8	R2 ROTATE WASHING WASH	To movee R2 probe to the washing trough.
9	R2 ROTATE BOTTOLE (OUT)	To move R2probe to the aspiration position.
10	UP/DOWN INIT	To move to the home position.
11	UP/DOWN ADJUST 	To input the angle to move by value, and to select the Up/DOWN direction..
12	UP	To move to the home position.
13	R1 DOWN WASH	To move the down position R1 probe to washing trough.
14	R1 DOWN REACTION CELL	To move the down position R1 probe to the reaction cell position.

		Movements
15	R1 DOWN BOTTLE(LEVEL)	To move the down position of R1 probe by level sensor.
16	R2 DOWN WASH	To move the down position R2 probe to the washing trough.
17	R2 DOWN REACTION CELL	To move the down position R2 probe to the reaction cell position.
18	R2 DOWN BOTTLE(LEVEL)	To move the down position of R2 probe by level sensor.

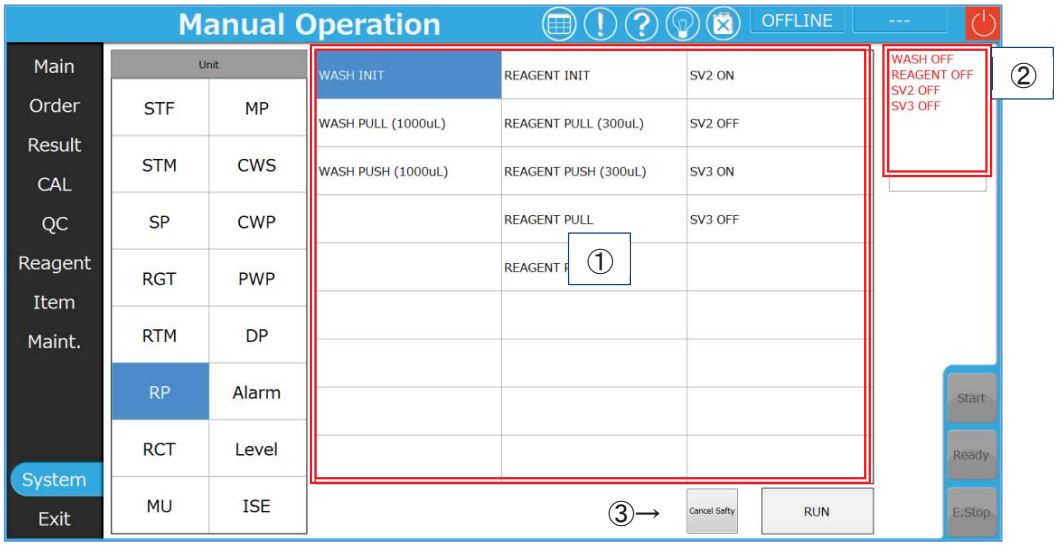
② Each sensor condition shows ON or OFF.

③ Clicking Read button, encoder value is shown.
(Theoretical,Actual value,Allowable error)

④ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with "NO Safety".
RUN	Perform selected function.

6. RP



RP screen

① Functions

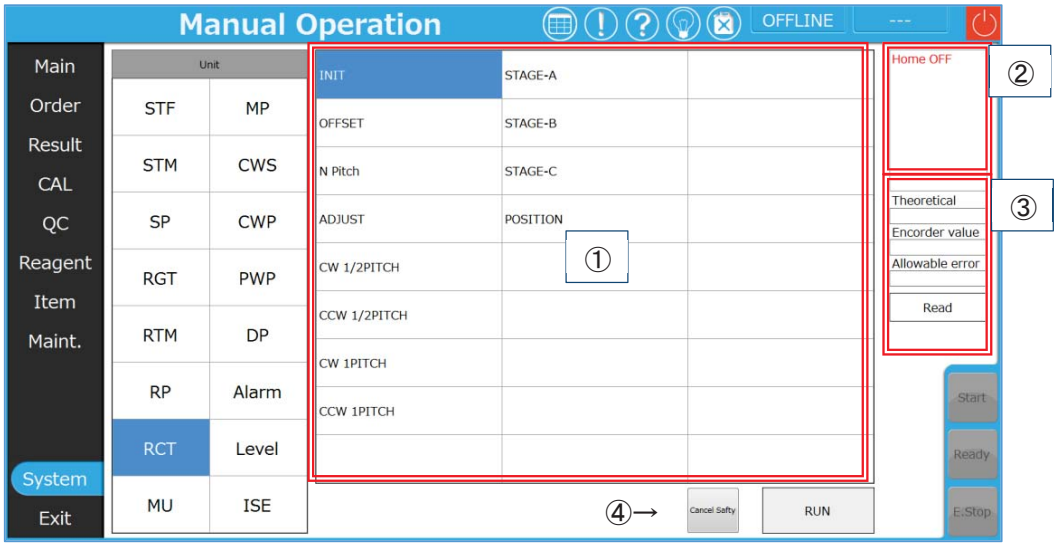
		Movements
1	WASH INIT	The washing side of pump; To move to the home position
2	WASH PULL (1000uL)	The washing side of pump; Aspiration movement (1000uL).
3	WASH PUSH (1000uL)	The washing side of pump; Dispensation movement (1000uL).
4	REAGENT INIT	The reagent side of pump; To move to the home position
5	REAGENT PULL (300uL)	The reagent side of pump; Aspiration movement (300uL).
6	REAGENT PUSH (300uL)	The reagent side of pump; Dispensation movement (300uL).
7	REAGENT PULL 0 ul	The reagent side of pump; Aspiration movement ➢ Input aspiration volume.
8	REAGENT PUSH 0 ul	The reagent side of pump; Dispensation movement ➢ Input dispensation volume.
9	SV2 ON	Electromagnetic valve EV-2 ON
10	SV2 OFF	Electromagnetic valve EV-2 OFF
11	SV3 ON	Electromagnetic valve EV-3 ON
12	SV3 OFF	Electromagnetic valve EV-3 OFF

② Each sensor condition shows ON or OFF.

③ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with "NO Safety".
RUN	Perform selected function.

7. RCT



RCT screen

① Functions

		Movements
1	INIT	To move to the home position.
2	OFFSET	
3	N Pitch 0 Pitch	To move by inputted pitch.
4	ADJUST 0 x0.06deg = 0 CW	To input the angle to move by value, and to select the direction of CW/CCW rotation.
5	CW 1/2 PITCH	To move clockwise by 1/2 pitch.
6	CCW 1/2 PITCH	To move counter-clockwise by 1/2 pitch.
7	CW 1 PITCH	To move clockwise by one pitch.
8	CCW 1 PITCH	To move counter-clockwise by one pitch.
9	STAGE-A	To move counter-clockwise by 13 pitches.
10	STAGE-B	To move counter-clockwise by 21 pitches
11	STAGE-C	To move counter-clockwise by 27 pitches.
12	POSITION 1 No.	Input position number. Move to position unmber.

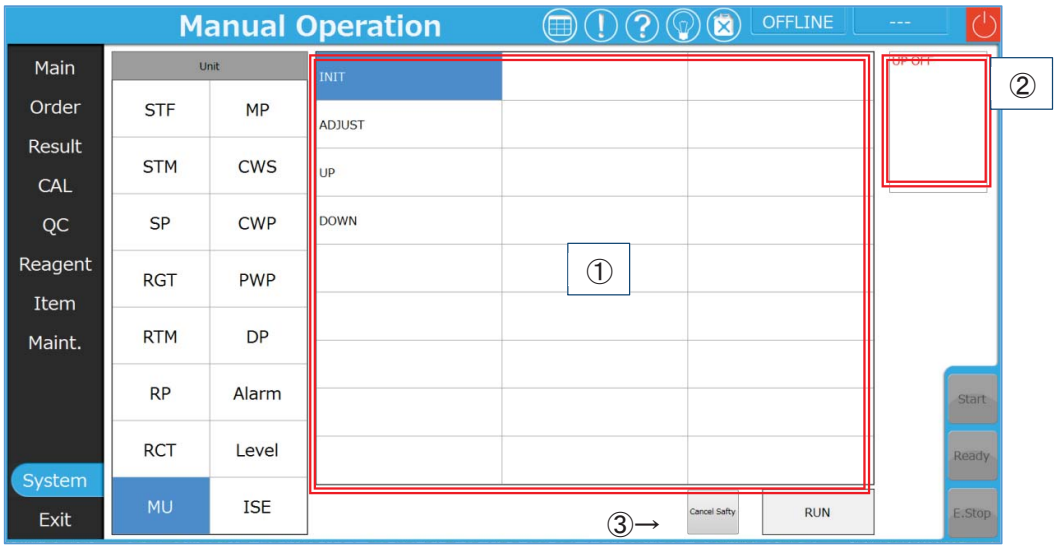
② Each sensor condition shows ON or OFF.

③ Clicking Read button, encoder value is shown.
(Theoretical,Actual value,Allowable error)

④ Perform the function by clicking button.

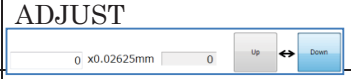
	Movements
Cancel Safety	Select when operating with “NO Safety”.
RUN	Perform selected function.

8. MU



MU screen

① Functions

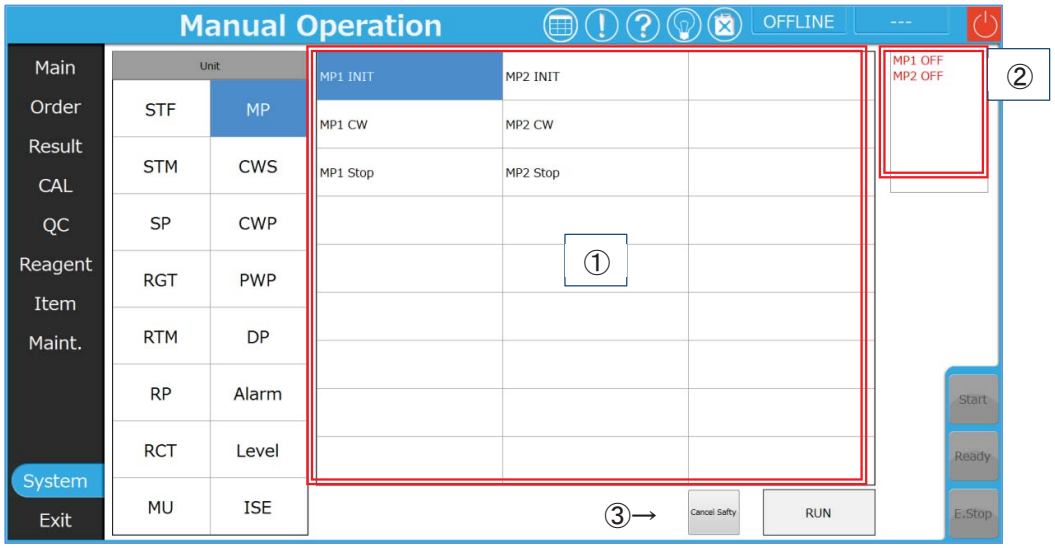
		Movements
1	INIT	To move to the home position.
2	ADJUST 	To input the distance to move by value,and select the direction of Up or Down.
3	UP	Up by setting pulse from the reaction cell.
4	DOWN	Down by setting pulse from the reaction cell.

② Each sensor condition shows ON or OFF.

③ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with "NO Safety".
RUN	Perform selected function.

9. MP



MP screen

① Functions

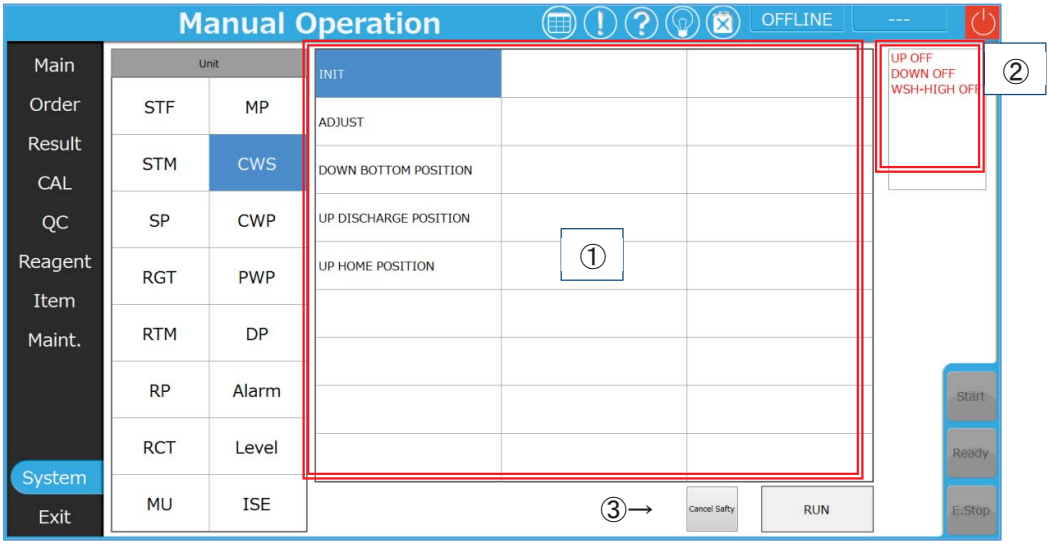
		Movements
1	MP1INIT	MP1 : To move to the home position
2	MP1 CW	To move to one cycle turn (Stops after one cycle turn).
3	MP1 Stop	Stop the turn.
4	MP2 INIT	MP2 : To move to the home position
5	MP2 CW	To move to one cycle turn (Stops after one cycle turn).
6	MP2 Stop	Stop the turn.

② Each sensor condition shows ON or OFF.

③ Perform the function by clicking button.

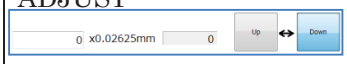
	Movements
Cancel Safety	Select when operating with “NO Safety”.
RUN	Perform selected function.

10. CWS



CWS screen

① Functions

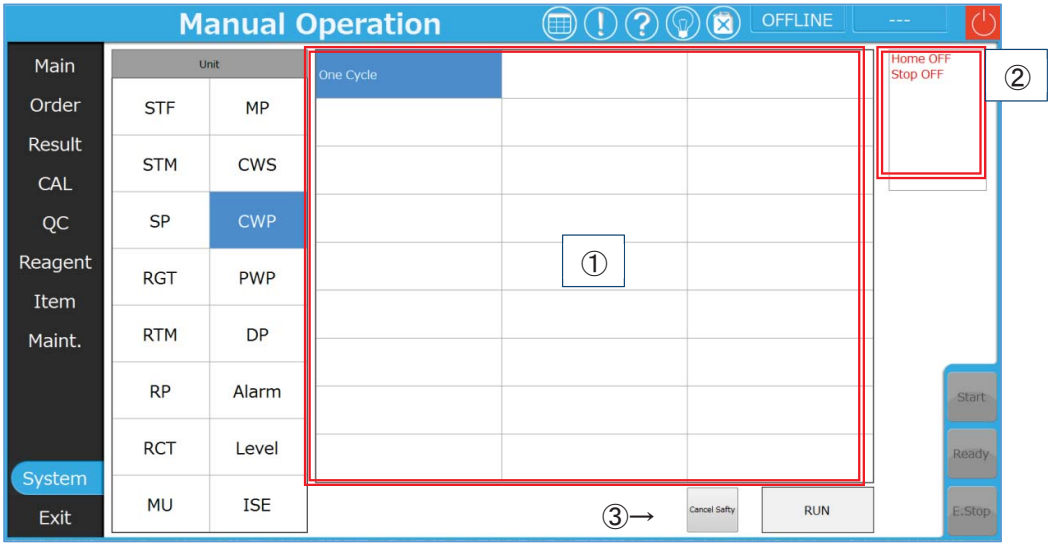
		Movements
1	INIT	To move to the home position.
2	ADJUST 	To input the distance to move by value and select the direction of Up or Down..
3	DOWN BOTTOM POSITION	To move the CWS to bottom position.
4	UP DISCHARGE POSITION	To move the CWS to dispensation position.
5	UP HOME POSITION	To move to the home position.(up)

② Each sensor condition shows ON or OFF.

③ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with "NO Safety".
RUN	Perform selected function.

11. CWP



CWP screen

① Function

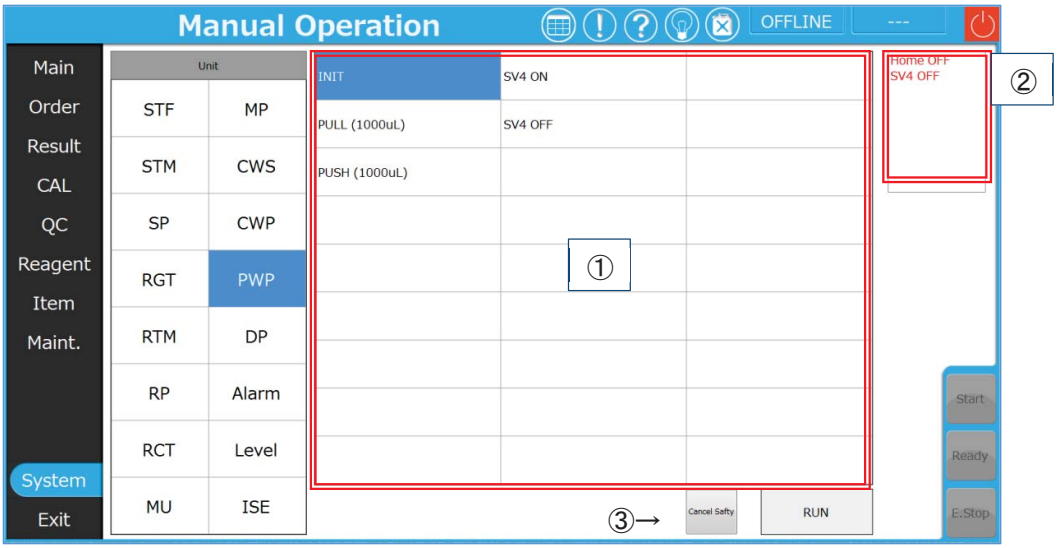
		Movement
1	One Cycle	Aspiration and dispensation

② Each sensor condition shows ON or OFF.

③ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with “NO Safety”.
RUN	Perform selected function.

12. PWP



PWP screen

① Functions

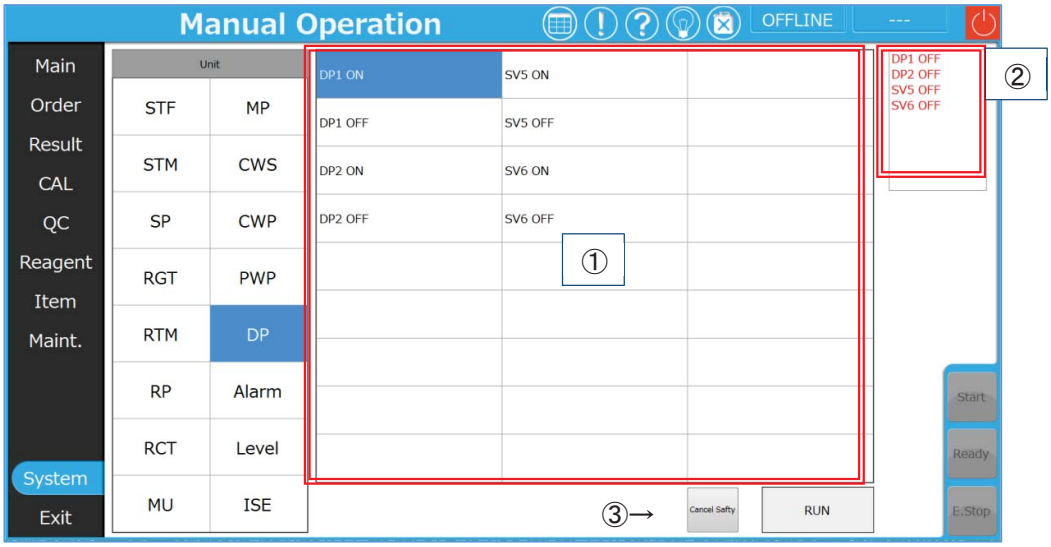
		Movements
1	INIT	To move to the home position.
2	PULL (1000 uL)	Aspiration movement (1000 uL)
3	PUSH (1000 uL)	Dispensation movement(1000 uL)
4	SV4 ON	Electromagnetic valve EV-4 ON
5	SV4 OFF	Electromagnetic valve EV-4 OFF

② Each sensor condition shows ON or OFF.

③ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with "NO Safety".
RUN	Perform selected function.

13. DP



DP screen

① Functions

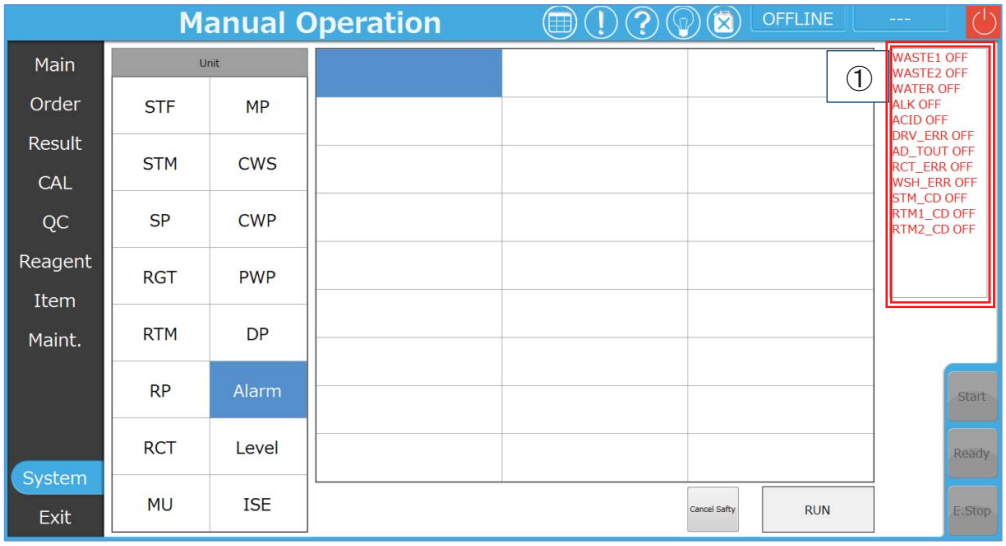
		Movements
1	DP1 ON	DP1 movement ON
2	DP1 OFF	DP1 movement OFF
3	DP2 ON	DP2 movement ON
4	DP2 OFF	DP2 movement OFF
5	SV5 ON	Electromagnetic valve EV-5 ON
6	SV5 OFF	Electromagnetic valve EV-5 OFF
7	SV6 ON	Electromagnetic valve EV-6 ON
8	SV6 OFF	Electromagnetic valve EV-6 OFF

② Each sensor condition shows ON or OFF.

③ Perform the function by clicking button.

	Movements
Cancel Safety	Select when operating with “NO Safety”.
RUN	Perform selected function.

14. Alarm

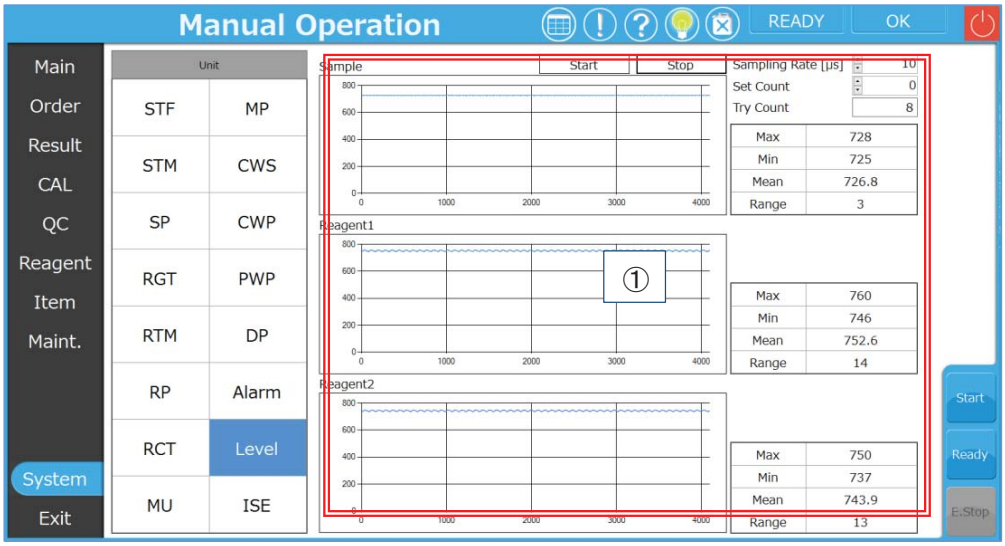


Alarm screen

① Display of the error condition. (exp. Tank error)

- ON means error occurred.

15. Level

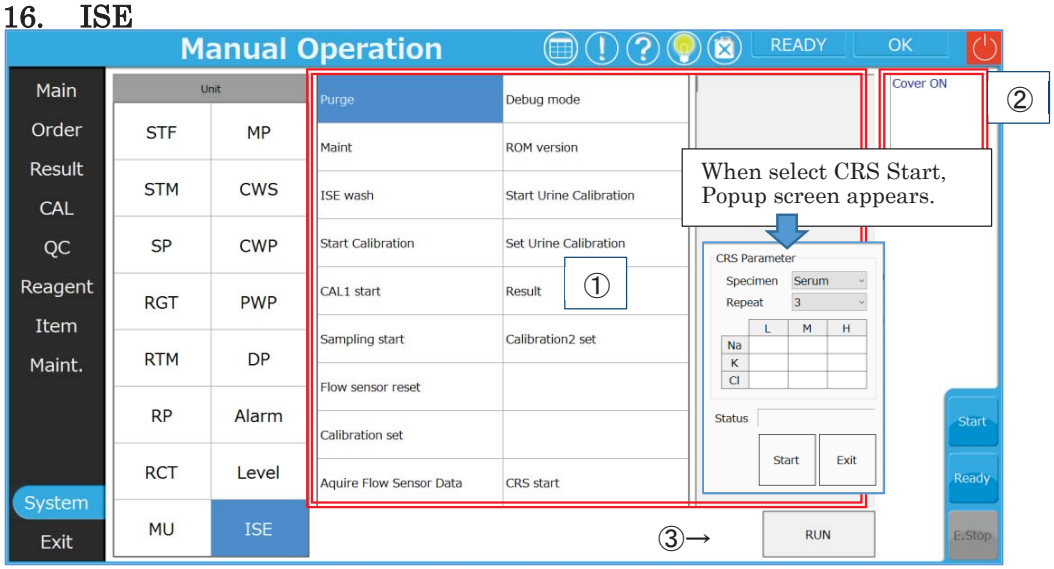


Level screen

① Display of the liqud level conditions for sample probe, reagent1 and reagent 2 probes.

		Contents
Sample		
1	Start	Start data reading.
2	Stop	Stop data reading.
3	Sampling Rate(μs)	Select interval of liquid level information.
4	Set count	Select repitation count (∞ in case 0).
5	Try count	Display of action count.
Sample, Reagent 1 and Reagent 2.		
1	(Left side)	Display of graph.
2	Max	Display of maximum value.
3	Min	Display of minimum value.
4	Mean	Display of average.
5	Range	Display of range.

16. ISE



ISE screen

① Functions

		Movement and display contents
1	Purge	Cal-1 is sent to the sample pot and electrodeline.
2	Maint	The liquid is discharged from the electrode line.
3	ISE Wash	Wash to clean up the ISE unit. ➢ Set a sample cup with ISE wash solution brfore start.
4	Start Calibration	Start the serum calibration measurement.
5	CAL1 start	Start the CAL1 measurement by filled liquid in sample pot.
6	Sampling start	Start the patient sample measurement.
7	Flow sensor reset	Setting of air level sensor.
8	Calibration set	Send the calibration result to the analyzer.
9	Aquire Flow sensor Data	Reading of air flow sensor.
10	Debug mode	Debug mode start and cancel.
11	ROM version	Display of the ROM version.
12	Start Urine Calibration	Start the urine calibration measurement.
13	Set Urine Calibration	Send the urine calibrationresult to the analyzer.
14	Result	Reading of latest result.
15	Calibration2 set	
16	CRS start	Start CRS measurement for ISEcorrelation）. ➢ Input the boxes in pop-upscreen.

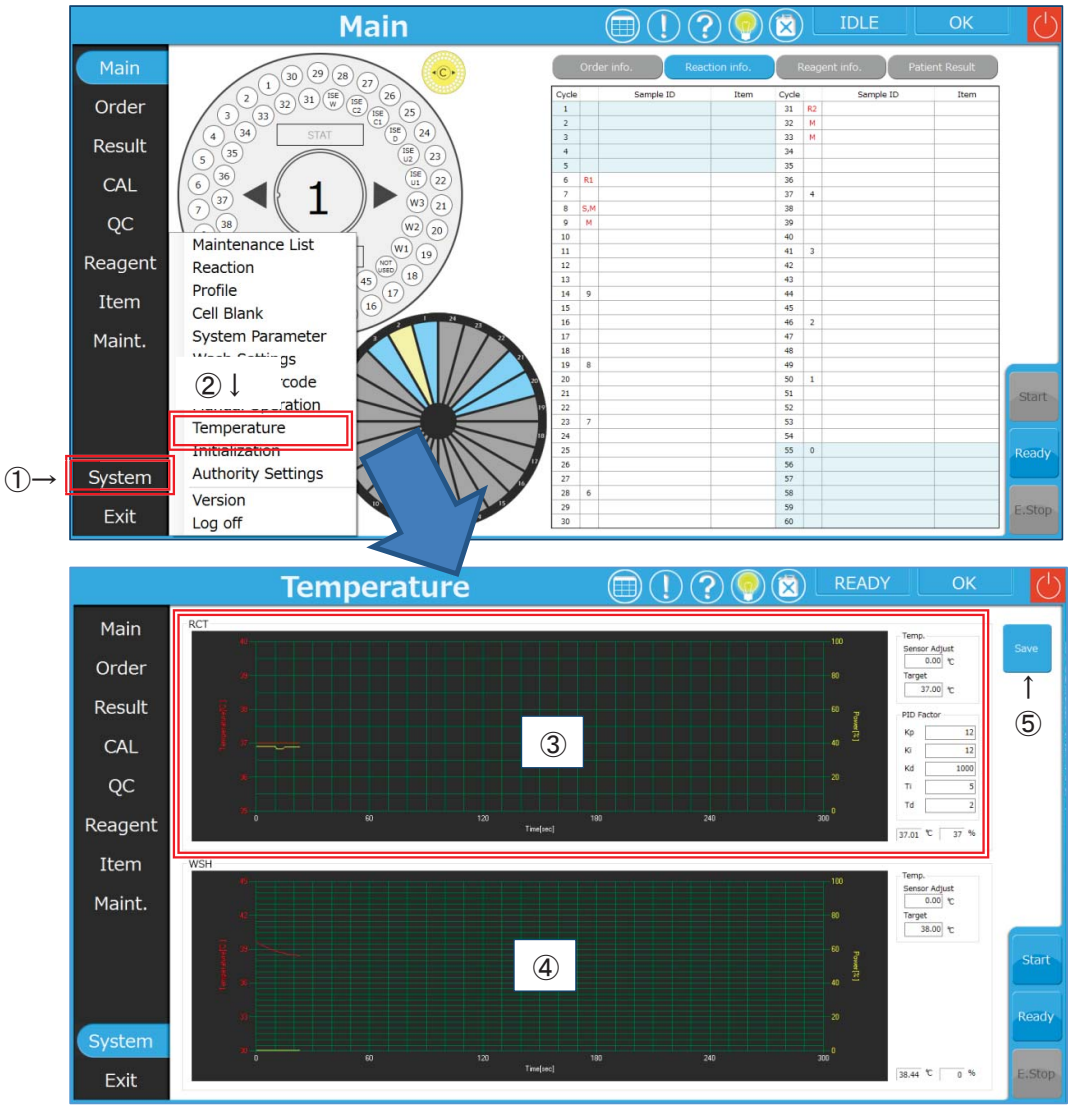
② Each sensor condition shows ON or OFF.
③ Perform the function by Clicking buttons.

	Movement
RUN	Perform selected function

4.9.11 Temperature screen

RCT and WSH temperature screen are shown.

- When intallation set up or changes the PC, input the temperature values to sensor agjust by attached parameter sheet.



Temperature screen

① System button : Display of System menuscreen
② Temperature button : Display of Temperature screen.
③ Display of RCT (Reaction tray) temperature graph,

- Temperature screen is shown by user level.

	Contents
Temp. Sensor Adjust ☐ ℃ Target 37.00℃	 Input the value in attached parameter sheet. Display of target value.

➢ PID Factor is shown by user level.

	Contents
PID Factor Kp 12,Ki 12、Kd 1000,Ti 5,Td 2	Display of the controls.
℃ %	Display of the RCT temperature and humidity.

④ Display of WSH (Washing water of pre-heater) temperature graph.

➢ Temperature screen is shown by user level.

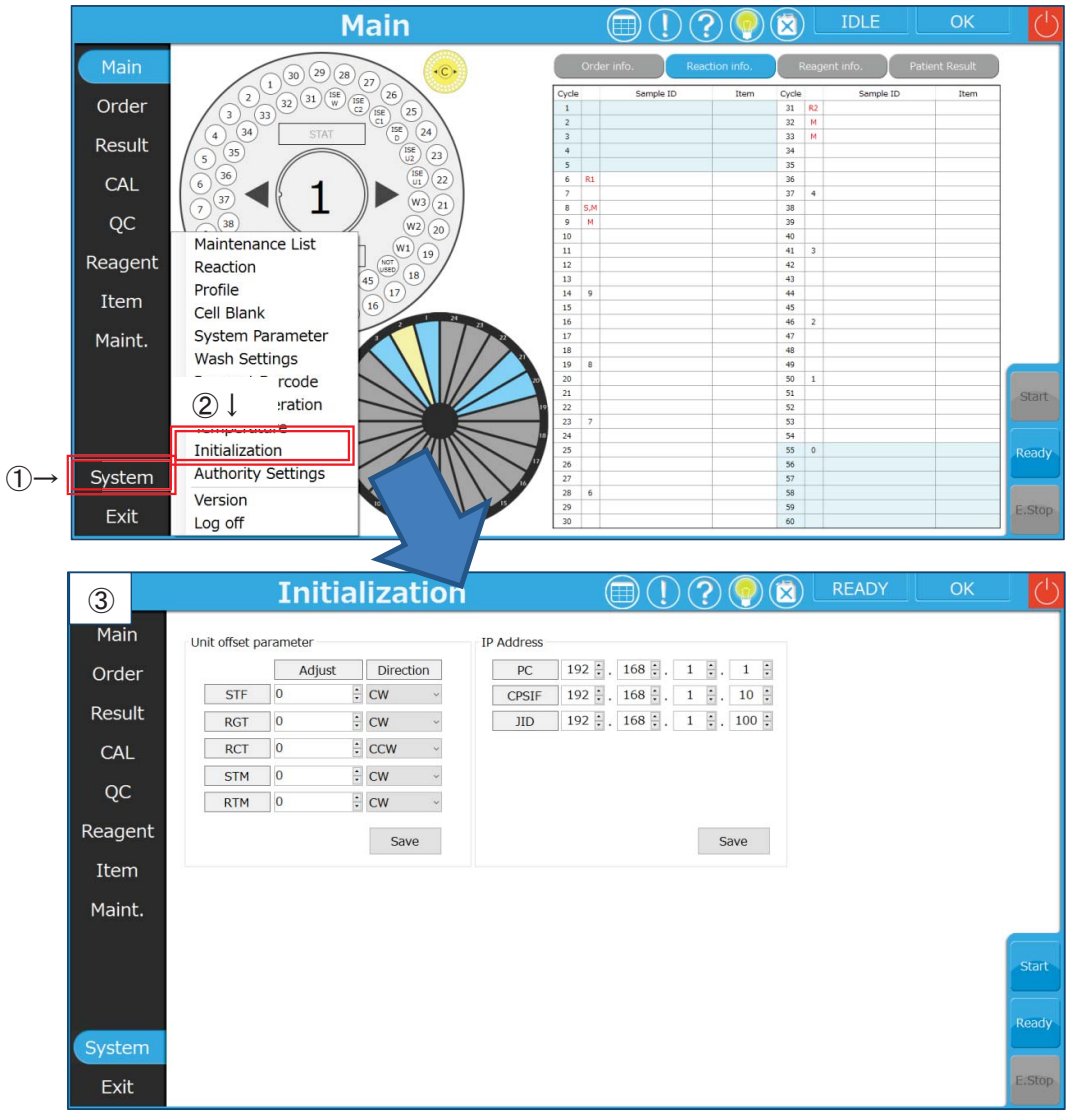
	Contents
Temp. Sensor Adjust ℃ Target 38.00℃	 Input the value in attached parameter sheet. Display of target value.
℃ %	Display of the WSH temperature and humidity

⑤ Save button : Register the screen information.

4.9.12 Initialization screen

Input of offset parameter screen is shown.

- Initialyze screen is shown by the user level.



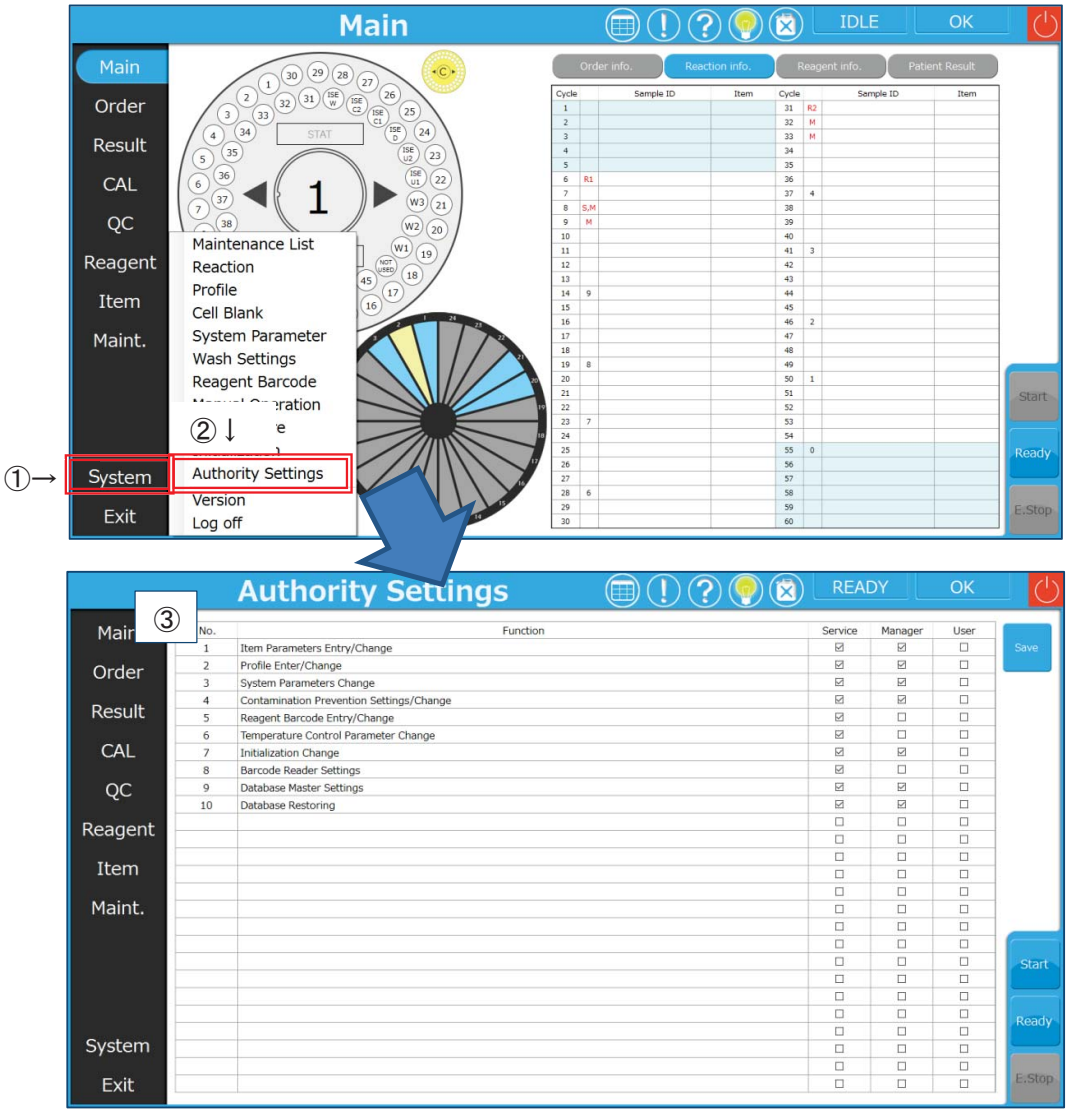
Initializetion screen

① System button : Display of System menu screen.
② Initializetion button : Display of Initializetion screen.
③ Display of offset values for each unit.

4.9.13 Authority Settings screen

Setting of operation level for each user.

➢ The screen is shown after Login by sevice engineer level.

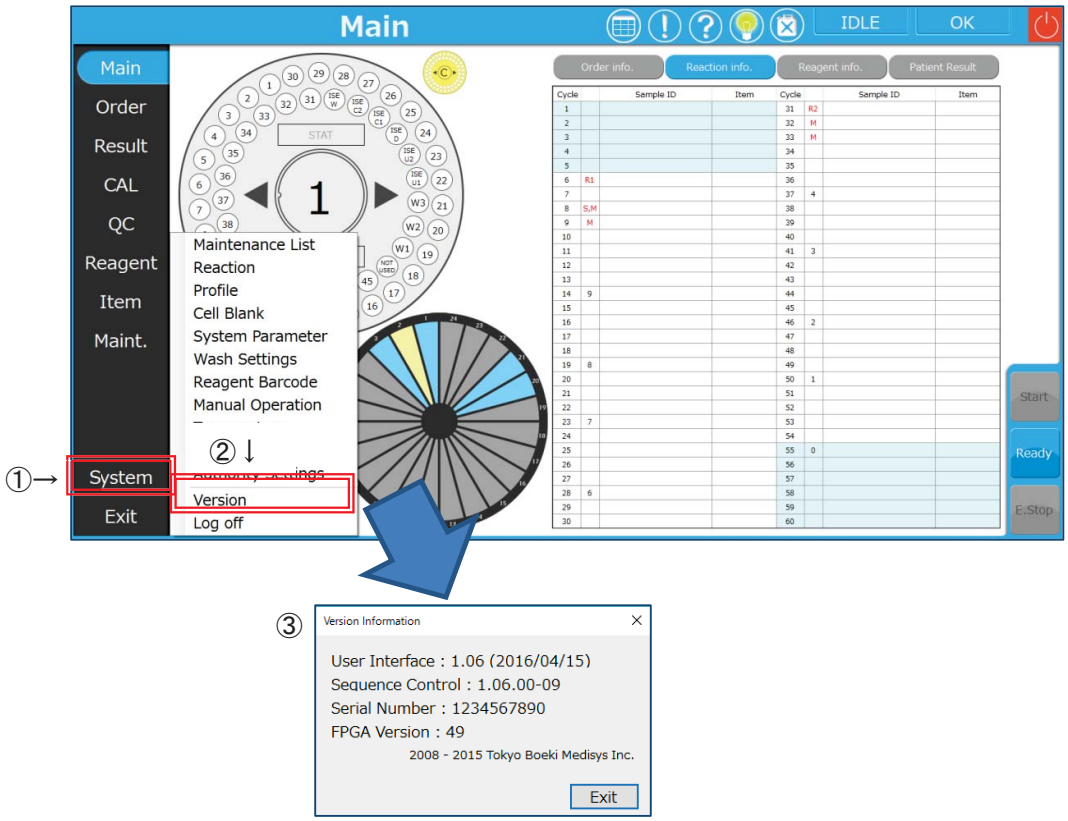


Authority Settings screen

① System button : Display of System menu screen.
② Authority Settings button : Display of Authority settings screen
③ Set the operation level for each user.

4.9.14 Version screen

➢ Version information of system program is shown.



Version Information screen

① System butto : Display of System menu screen.
② Version button : Display of Version Information screen.

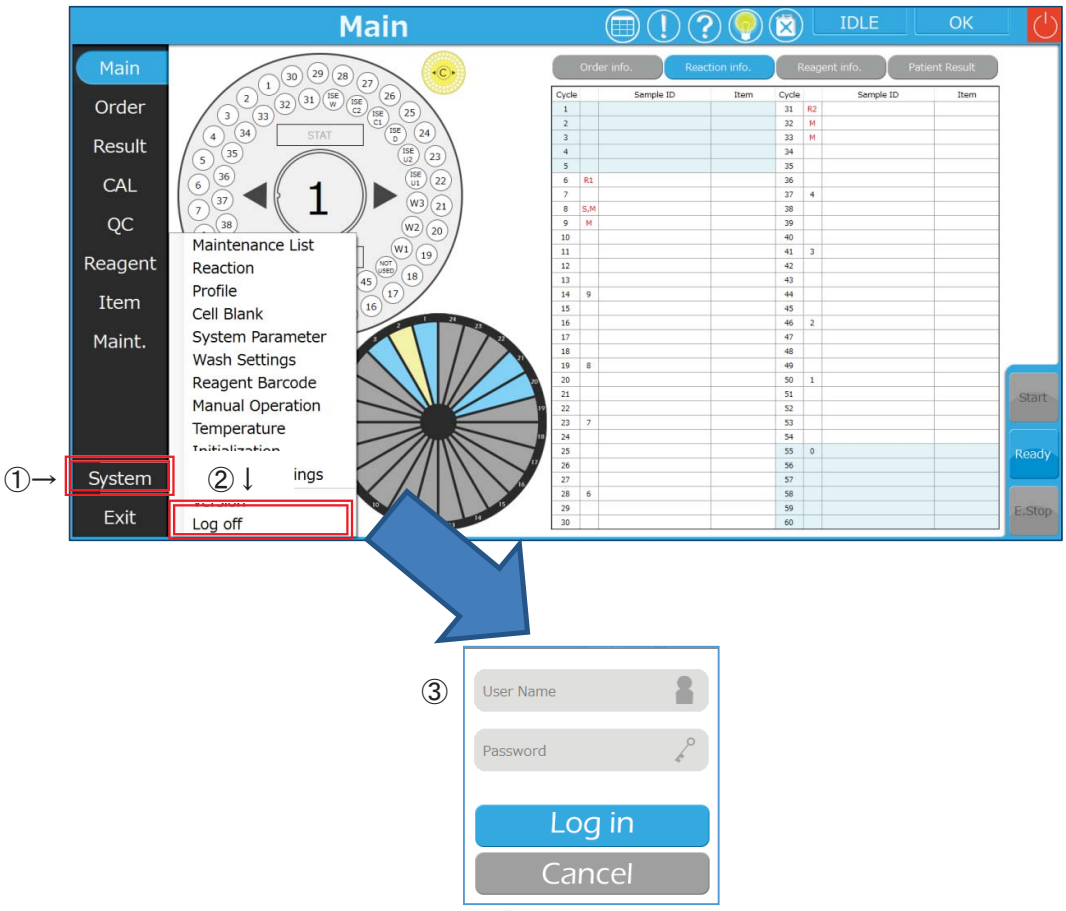
Display of pop-up screen

③ Version Information

	Contents
User Interface	Display of system program version number on the PC.
Sequence Control	Display of control program version number on the analyzer.
Serial Number	Display of analyzer serial number.
FPGA Version	Display of FPGA version number.
Exit	Close the Version screen.

4.9.15 Log in screen

➢ The use level changing screen is shown.



Log in screen

① System button : Display of System menu screen.
② Log off button : Log in screen is popup.

Popup screen

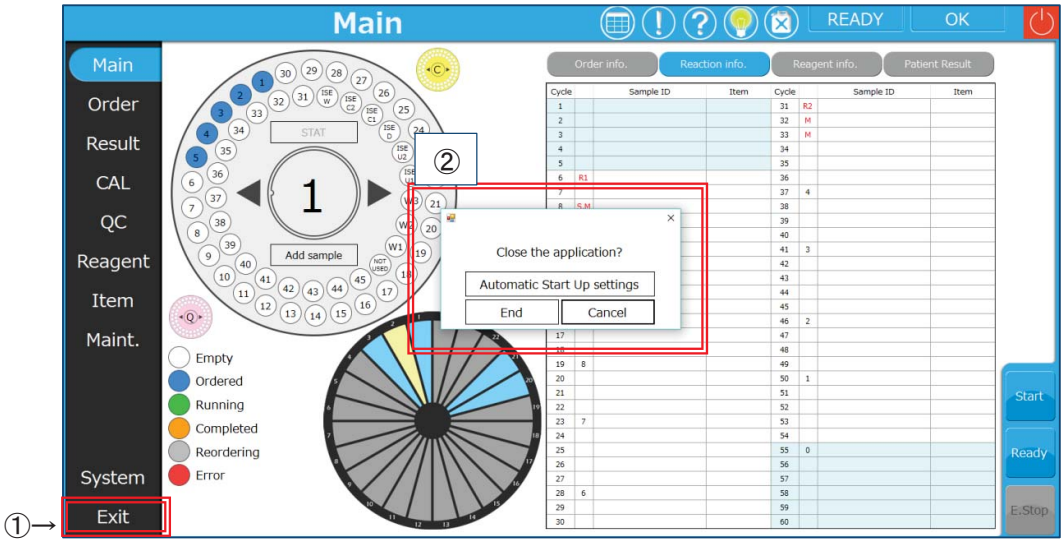
③ Log off screen.

	Input and display contents
User Name	Inputthe user level name.
Password	Input the password.
Log in	Log in by inputted level.
Cancel	Close the Log off screen. ➢ System power turns OFF ➢ Click system Icon when open the operation screen again.

4.10 Exit screen

Shut down of system program and automatic maintenance setting screen is shown.

4.10.1 Exit button



Main screen — Exit screen

① Exit button : Display of Exit screen.

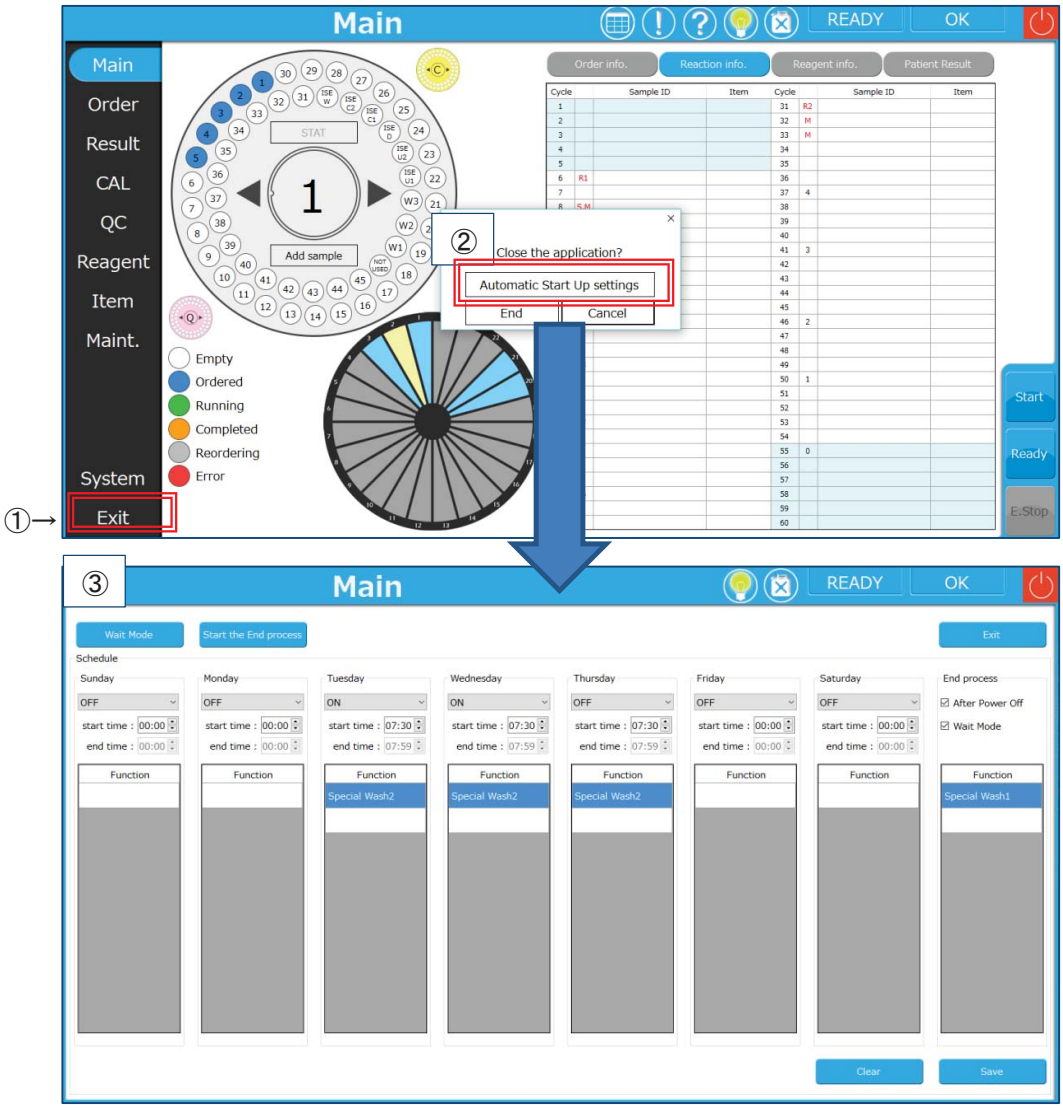
Display of pop-up screen

② Buttons and functions

	Contents
Setup schedule start	Display of the setting screen for automatic start up and maintenance procedurte.
End	Turn OFF the system switch and exit the system program.
Cancel	Close the exit screen.

4.10.2 Setup schedule start screen

➢ Auto-start, shut down time and automatic mentenance setting screen displays.



Setup schedule start screen

① Exit button : Display of Exit screen (End of Application).

Display of pop-up screen

② Exit screen : Select the Setup schedule start.

③ Setup schedule buttons and functions.

	Contents
Wait Mode	Move to auto-start waiting mode.
Start the End process	Start the maintenance at end of the day.

	Contents
Schedule	Set the auto-start and maintenance procedure after start up.
Sunday～Saturday	➢ Set the maintenance for each week day.
ON/OFF	Select on, if the analyzer is st auto-start and maintenance.
Start time	Select the maintenance start time.
End time	Display of the maintenance end time automatically.
Function▼	Select the function of automatic maintenance. ➢ Select the function from the list. ➢ Automatic power on is done if the functionis not selected.
End process	➢ Set the maintenance of end of the day and setting after shutdown.
□After Power OFF	In case of power off after maintenance, check the box ☑.
□Wait Mode	In case of move to auto-start mode, chek the box ☑.
Function▼	Display of maintenance list. Select the automatic maintenance function.
Clear	Delete the displayed information.
Seve	Register the displayed information.
Exit	Close the setup schedule screen.

Chapter 5 Maintenance

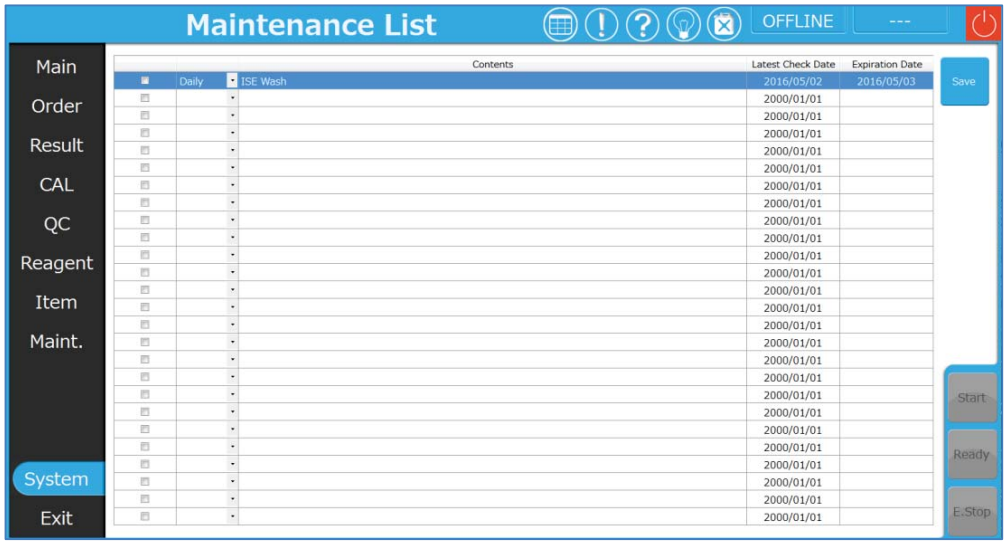
5.1 Safety caution

- Please follow the warning and safety caution which informed in “Chapter Preface” of operation manual.

When do maintenance operation, wear protective globes, mask and glasses to avoid infection.

5.2 Preparation of maintenance list and update the date.

- Please prepare “Maintenance list” for analyzer maintenance and parts exchange. Manage the list by updating the date.



Maintenance list screen

Order	Buttons & screen		Operation & Display
Prepare maintenance list.			
1	①	System	Open System screen.
2	②	Maint. list	Open Maintenance list screen.
3	③	▼	Select maintenance period. (Daily, Weekly, Monthly, 3 months, half year, one year, two years)
4	④	Content	Input operation.
5	⑤	Save	Register the operation.
Update the operation date.			
6	⑥	Check box	Check the box □ after operation.
7	⑤	Save	Update the operation date and next operation date.
8	⑦ ⑧	Latest date Expiration date	Display updated date. Display expiration date.

5.3 Maintenance list

5.3.1 Periodic check and Periodic exchange

➢ Periodic check list (for customer)

	Contents	dairy	week	1 mth	3 mth	6 mth	1 yr	if need	Remarks
1	Cleaning of sample probe	○							
2	Cleaning of reagent probe	○							
3	Check of the SP water leak	○							
4	Check of the RP water leak	○							
5	Check of the PWP water leak	○							
6	Check of the water supply tank volume	○							
7	Check of the volume and purity of pure water machine	○							
8	Check of the volume Alkaline detergent tank	○							
9	Check of the volume Acid detergent tank	○							
10	Check of the drainage tank volume	○							
11	Cleaning and check of the strain of the cell cover	○							
12	Cleaning of cooling filter.							○	
13	Special washing							○	
ISE unit									
14	Cleaning of sample pot.	○							
15	Cleaning of ISE sample line	○							

➢ Periodic exchange list (for customer)

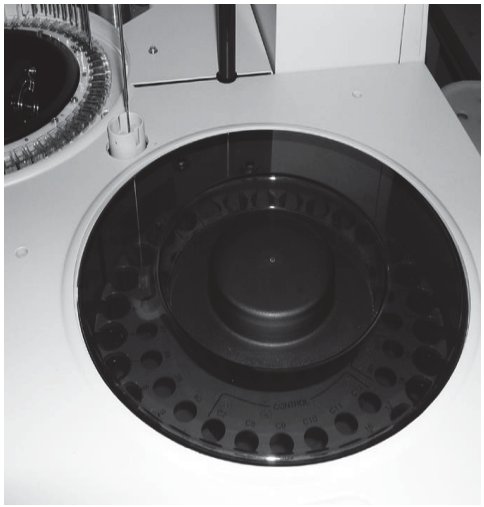
	Contents	dairy	week	1 mth	3 mth	6 mth	1 yr	if need	Remarks
1	Exchange of reaction cells							○	
2	Exchange of lamp							○	
3	Exchange of sample probe							○	
4	Exchange of reagent probe							○	
5	Exchange of water filter					○			
ISE unit									
6	Exchange of Cal 1 pack							○	
7	Exchange of Na electrode							○	
8	Exchange of K electrode							○	
9	Exchange of Cl electrode							○	
10	Exchange of Ref. electrode							○	
11	Exchange of roller pump tube.				○				
12	Exchange of pinch valve tube.						○		

5.4 Maintenance procedure

5.4.1 Sample probe check and cleaning

- Confirmation of sample probe bending.
- Remove the dirt (protein) of probe tip.

Inspection period	Everyday
Necessary parts	Gloves, KIMWIPE, DI water, Nylon wire



1) Turn off the PC and analyzer system power switch before starting the maintenance operation.
2) Remove the sample tray cover.
3) Remove a sample tray if it is inserted.
4) Confirm the probe straight.
5) Pull up STM arm by hand and move and rotate to above the sampler.
6) Wipe out the dirt at the outside of probe tip by KIMWIPE or other material soaked in DI water.
   - Thread the nylon wire from probe tip and clean up the sample probe if necessary.

Note

Be careful not to bend the probe tip.

7) Return STM arm to washing position by hand.
8) Reset sampler tray cover at the proper position.

5.4.2 Reagent probe check and cleaning

- Confirmation of reagent probe bending.
- Remove the dirt (protein) of probe tip.

Inspection period	Everyday
Necessary parts	Gloves, KIMWIPE, DI water

1) Turn off PC and the analyzer system power switch before starting the maintenance operation.
2) Remove reagent tray cover.
3) Remove the reagent tray.
4) Move up RTM arm by hand and rotate R1 to the reagent bottle position.
5) Wipe out the dirt at the outside of probe tip by KIMWIPE or other material soaked in DI water.

6) Return RTM to the home position by hand. Rotate R2 probe by hand and clean up the R2.

Note

Be careful not to bend the probe tip.

7) Return RTM to the home position by hand. (R2 is front side)
8) Place back reagent tray and tray cover.

5.4.3 Leakage of pumps (SP, RP, PWP)

- Confirmation of water leakage.

Inspection period	Everyday
Necessary parts	None

5.4.4 Confirmation of the water supply tank volume

- Check the water tank volume.

Inspection period	Everyday
Necessary parts	None

5.4.5 Confirmation of the water purification system and purity of pure water machine

- Check the water supply system.

Inspection period	Everyday
Necessary parts	Follow the purify system manual.

5.4.6 Confirmation of the volume Alkaline and Acid detergent tanks

- Check the Alkaline and Acid detergent volumes.
- Refill the detergent if required.
  (Alkaline＝Dilute to 2% for use ,Acid＝Dilute to 1% for use.

Inspection period	Everyday
Necessary parts	In case of confirmation: No In case of refill the detergent : ・Gloves ・Washing Solution Alkaline (Fast Detergent 1):(Code SP2208) ・Washing Solution Acid (Fast Detergent 2):(Code SP2209)

5.4.7 Drainage reservoir

- Confirmation of drainage reservoir volume.
- Clean up the dirt of float sensor which can't detect the liquid level correctly.

Inspection period	Everyday
Necessary parts	In case of confirmation: No In case of waste: Gloves, KIMWIPE

1) Loosing cap of the reservoir and pull up the float switch unit.

2) Wipe out water around the filter and other part by KIMWIPE for better working condition.

3) Confirm if the float switch moves up and down smoothly.

4) If you find dirt around the float switch, wash out dart by tap water with brush.

5) Return the float switch unit into the drainage reservoir.

6) Tighten the cap.

5.4.8 Cleaning and confirmation of the strain on the cell cover

- Clean up the cell cover if necessary.

Inspection period	Everyday
Necessary parts	Gloves, KIMWIPE, DI water

5.4.9 Cleaning of cooling filter

- Clean up the reagent tray cooling filter.

Inspection period	If necessary
Necessary parts	Gloves

5.4.10 Special wash

- The dirt of reaction cells, sample probe and reagent probes are influenced to the measurement results. Clean up by using special wash program.
- Use 6% diluted solution of detergent.

Inspection period	If necessary.
Necessary parts	Gloves Washing Solution Alkaline (Fast Detergent 1):(Code SP2208) Washing Solution Acid (Fast Detergent 2):(Code SP2209)
Wash time	About 30 minutes

- Special wash means?
  All the reaction cells and probes are washed in the same procedure as measurement by aspiration and dispensation of detergent instead of reagent and sample.

- Kinds of using detergent
  Select the detergent depending on the target.
  - Alkaline detergent: For protein base stain
  - Acid detergent: For metallic base stain

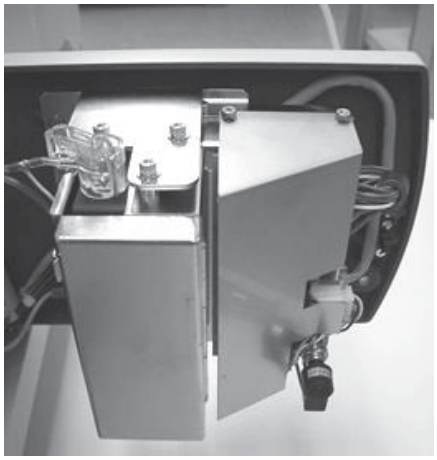
- Special wash button
  There are three kinds of special wash buttons.
  Special wash 1: Use reagent bottle wash 1 and sample tray position W1.
  Special wash 2: Use reagent bottle wash 2 and sample tray position W2.
  Special wash 3: Use reagent bottle wash 3 and sample tray position W3.

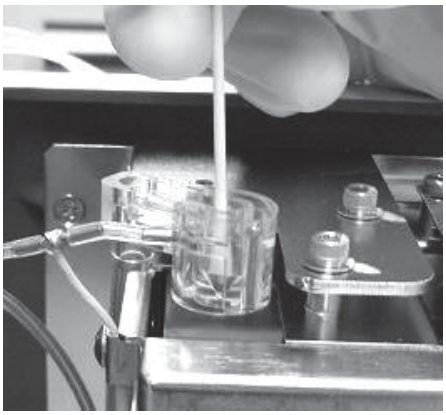
- Special wash procedure
  1) Set detergent bottle on the reagent tray.
  2) Set detergent cup at cup position(W1, W2, W3) on the sample tray.
     - Please refer to Chapter 3 Routine operation procedure.
     - Pour the detergent to R 1 bottle 20mL, R2 bottle 11mL and Sample cup 2mL.
  3) Click Maint. button in main screen, and open maintenance screen.
  4) Pointed and click the button in Special wash 1, Special wash 2 and Special wash 3.
  5) Start the washing.
  6) Stop automatically after washing.

5.4.11 Cleaning of ISE sample pot

➢ Clean up the sample pot to avoiding the clot for ISE sample line.

Inspection period	Everyday
Necessary parts	Gloves, Cotton swab (narrow type), DI water





1) Open the ISE door on the right panel of the system at right angles to the system for ISE storage facing front.

2) Clicking Maint button in the main screen.

3) Clicking ISE Mainte, and empty the ISE line.

4) Moisten the cotton swab with DI water.

5) Confirm no liquid in sample pot. Clicking ISE Maint again if liquid is found in sample pot.

6) Insert cotton swab to clean up inside of the pot.
Note:
Be careful not remain the thread which makes clot.

7) Close the ISE door.

8) Click ISE Purge button, and refill the sample line.

5.4.12 ISE Wash (Cleaning of ISE sample line)

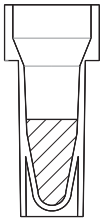
- Clean up the ISE sample line.
- After ISE wash, calibration is necessary before starting ISE test.

Inspection period	Everyday
Necessary parts	Gloves, Cleaning Solution (25ml) (Code 20-27-0479F) ※As necessary use ISE Cleaner 1% (25ml) (Code 50-27-0781)
Wash time	About 6 minutes

Note

It is recommended to do cleaning by ISE Cleaner 1% once a week when the ISE test is measured above 60 test per week.

ISE Washing solution
400uL

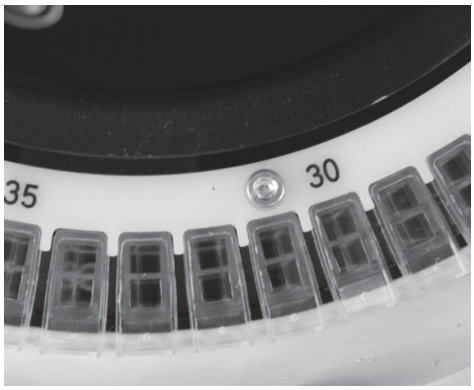


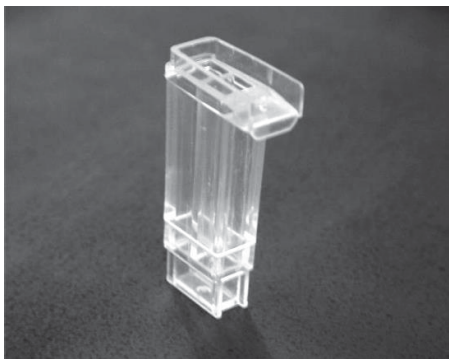
1) Pour the 400uL washing solution in sample cup.
2) Set the detergent cup at the ISE Wash position on a sample tray.
3) Clicking Maint. button.
4) Clicking ISE Wash button.
5) Upon clicking, cleaning solution is dispensed in ISE to clean up the inside of ISE sample line.
6) Remove the sample cup after cleaning

5.4.13 Reaction cell exchange

- The dirty cells are influenced to the measurement results. Please exchange the reaction cells when the cell condition of back color shows red in cell check screen.
- Change all the 60 cells at once.

Exchange interval	If necessary
Necessary parts	Gloves, Hexagonal wrench (2.5mm) Cuvette -8U (60 Pieces) (Code 23-07-0055)





1) Turn off PC and the analyzer system power switch.
2) Pull up RTM arm and turn to tough.
3) Pull up cell cover and remove it.
4) Rotate reaction tray by hand so that a reaction cell group comes to the front.
   Note
   20 reaction cells are held by the cell holder. Cell position number is on the cell holder in 5 intervals.
5) Loosen cell holder screws (3 screws) by hexagonal wrench (2.5 mm) so that you can remove cell holder.
6) Pull up cell holder and remove it.
7) Pull up the cell, to be replaced, by fingers.
8) Insert a new reaction cell, confirming the direction to insert.
   Note
   Do not touch the optical path face of a reaction cell by fingers.
9) After the reaction cell insertion, fix a cell holder by a hexagonal wrench.
10) When you have finished cell replacement, confirm each cuvette is set properly, by rotating the tray carefully by hand.
11) Power ON PC and analyzer.
12) Initialize the analyzer.
13) Set the cell cover to the proper position. Fit the cell cover cut part to the pin.

5.4.14 Exchange of lamp

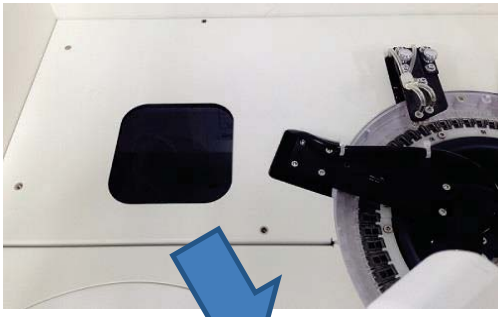
- The lamp deterioration is influenced to the measurement results. Please exchange the lamp if the life time is over (about 1200 hours).
- After finishing the lamp exchange, adjust the gain and update the remaining time. Refer to Chapter 5, 5.3.14 Auto-gain.

Exchange interval	If necessary
Necessary parts	Gloves, Halogen lamp (Code 60-00-0001)

Caution

 Caution  High temperature

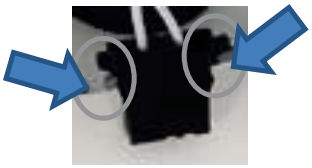
The temperature of the lamp rises during operation, and it might cause burn on your fingers. Don't touch directly.

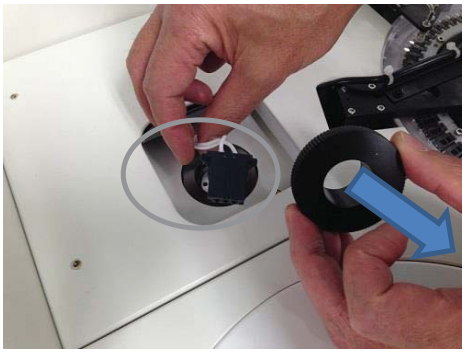


1) Turn off the PC and the system power switch and wait for ten minutes to cool the lamp and lamp house before starting the maintenance operation.

2) Open top cover.
3) Slide and open the lamp house cover.

4) Remove the lamp connector by pressing both side fixing pins.

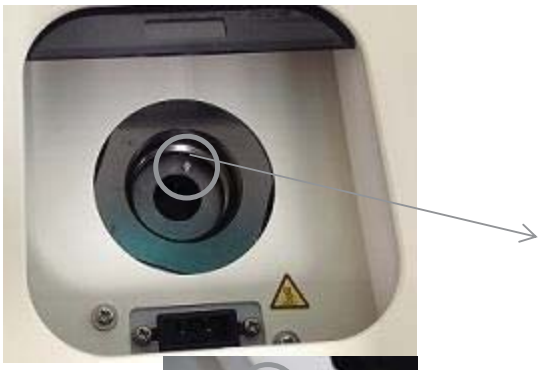




5) Turn the lamp holding plate to counter clockwise, and remove it.
6) Pull up the lamp from lamp hol ding ring by pressing both side fixing pins on the white connecto r.
7) Holding the wiring by fingers, pull up the lamp.
Note
Don't touch the lamp which rises high temperature.

8) Set a new lamp, fitting the slit of the lamp flange to the pin on the lamp holding plate.
Note
Do not touch the glass surface of the lamp.

9) Path the lamp to fixing ring by pressing the pin.
10) Turn the lamp holding plate to clockwise , and fix it.
11) Connect the connector.
12) Replace the lamp cover by sliding down.
13) Select lamp Icon in main screen.
14) Select change button, and update remain time.



New lamp

5.4.15 Auto gain (Gain adjustment)

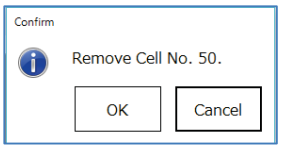
➢ When finishing the lamp exchange, perform to adjust the gain (Adjustment of the intensity of light).

Inspection period	After lamp exchange
Necessary parts	Gloves, Hexagonal wrench (2.5mm)

Note

Please perform the gain adjustment with stable lamp.

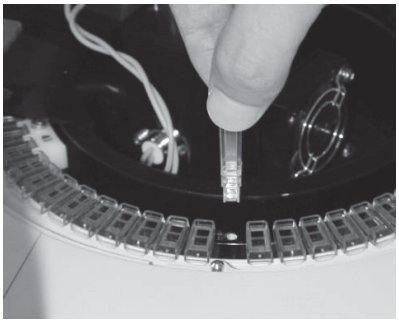
1) Turn on the PC and system power switch and wait for 20 – 30 minutes.
2) Clicking Mainte. button, maintenance screen is shown.
3) Clicking Auto Gain button.
4) Pop-up screen is shown after analyzer movement.

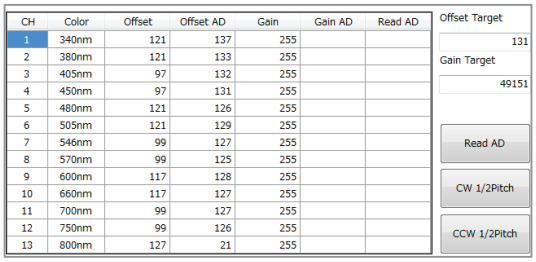


5) Remove the reaction cell of No.50 position.
Refer to Chapter 5, 5.3.13 Reaction cell exchange.

Note

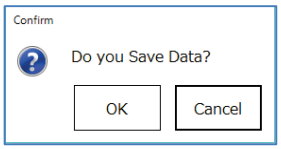
Do not touch the optical path face of a reaction cell by fingers.





CH	Color	Offset	Offset AD	Gain	Gain AD	Read AD
1	340nm	121	137	255		
2	380nm	121	133	255		
3	405nm	97	132	255		
4	450nm	97	131	255		
5	480nm	121	126	255		
6	505nm	121	129	255		
7	546nm	99	127	255		
8	570nm	99	125	255		
9	600nm	117	128	255		
10	660nm	117	127	255		
11	700nm	99	127	255		
12	750nm	99	126	255		
13	800nm	127	21	255		

6) Clicking OK button.
7) The gain for all the wavelengths is automatically executed.
8) The auto-gain information is shown on the screen.
9) When finishing the auto-gain, popup screen is shown.



10) Clicking OK button, saving the data.

5.4.16 Exchange of sample probe

- Please exchange the sample probe to keeping the accuracy and precision when required.

Exchange interval	If necessary
Necessary parts	Gloves, Sample probe (Code 60-02-0020)

5.4.17 Exchange of reagent probe

- Please exchange the reagent probe to keeping the accuracy and precision when required.

Exchange interval	If necessary
Necessary parts	Reagent probe(Code 60-03-0034)

5.4.18 Exchange of Water filter

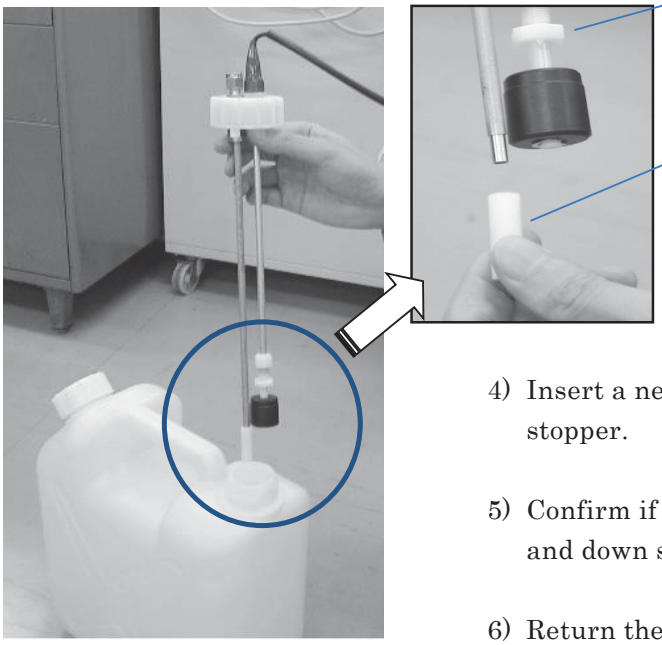
➢ Please exchange the water filter to avoiding the influence of measurement results.

Exchange interval	Every 6 months.
Necessary parts	Gloves, KIMWIPE, Water filter (Code SP2058)

1) Loosen the cap of the water reservoir and pull up the filter and the float switch unit.

2) Wipe out water around filter and other parts by KIMWIPE for better working condition.

3) The old filter is pulled down to remove.



4) Insert a new filter till the filter hits a stopper.

5) Confirm if the float switch moves up and down smoothly.

6) Return the filter and the float switch unit into the water reservoir.

7) Tighten the cap.

5.4.19 Exchange of Calibrator 1 (Cal-1)

- The ISE unit is filling the sample line and electrodes by Calibrator 1 automatically. Please change the Calibrator 1 to avoiding the dryness.

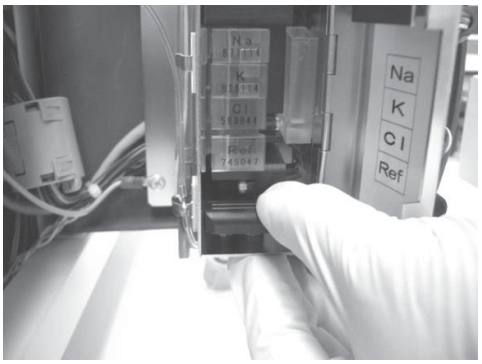
Exchange interval	One month after open or when necessary
Necessary parts	Gloves, Calibrator 1 F(420ml) (Code 20-27-0477F)

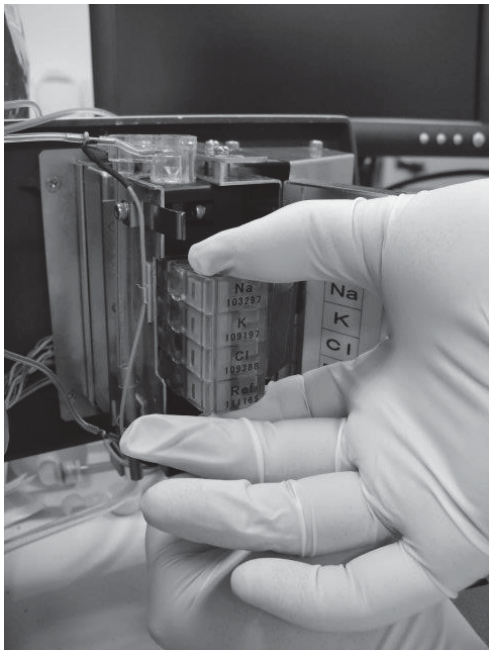
1) Clicking Maint. button.
2) Clicking ISE Maint button, and empty the ISE line.
3) Holding the used Cal-1 pack upside up, remove the cap. Take off the cap from hook to dispose.
4) Keeping the new Cal-1 pack upside up, and unscrew the cap.
5) Screw the cap into new Cal-1 pack, holding it upside up to removing the air.
6) Hang up the new Cal-1 pack.
7) Perform ISE Purge order in ISE Maint. screen.
8) Repeat ordering ISE Purge till no bubble comes out from the tube and the liquid is sucked up.
9) Confirming that no error occurs.
   Note
   Please check totally when error occurred.

5.4.20 Exchange of electrode

➢ The deterioration of electrode reduces the slope value. The slope error or drift error occurs. Please change the electrode if the error can't solved after ISE maintenance.

Exchange interval	If necessary
Necessary parts	Gloves, Na Electrode F (Code 20-27-0474F) K Electrode F (Code 20-27-0475F) Cl Electrode F (Code 20-27-0476F) Reference Electrodes F (Code 20-27-0473F)



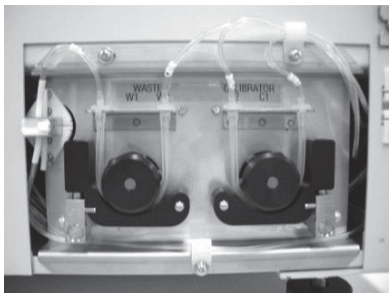


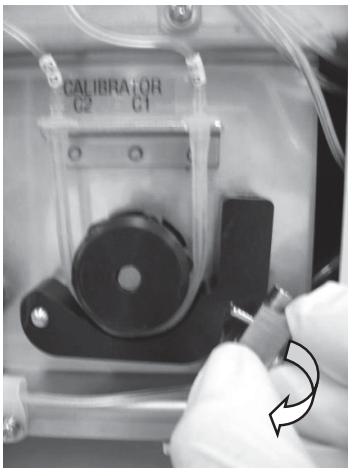
1) Open the ISE door on the right panel of the system at right angles to the system for ISE storage facing front.
2) Clicking Maint. button.
3) Clicking ISE Maint button, and empty the ISE line.
4) Open the electrode cover, and press holding plate.
5) While holding the plate down, pullout electrode.
6) Draw the fixing plate from the old electrode.
7) Insert the fixing plate to the new electrodes.
8) Keep holding the plate down, and insert the new electrode pushing back.
9) Perform ISE Purge order, and refill the line.
10) Confirm there is no leakage from the electrode.
    Note
    If leakage is found, repeat from 6 to 9 again.
11) Confirming no error occurred.
    Note
    Please check totally when error occurred.
12) Close the electrode cover, and close ISE door.

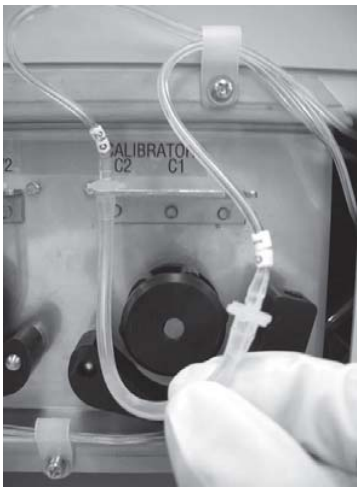
5.4.21 Exchange of roller pump tube

- The deterioration of roller pump tube influences the liquid flow. Please change it periodically.
- Please exchange the pump tubes both calibrator and waste simultaneously.

Exchange interval	Every 3 months
Necessary parts	Gloves, Screw driver Roller Pump Tube B (2 pieces of tubes) (Code 20-30-0610) Roller Pump Tube Grease (Code 20-30-0581)





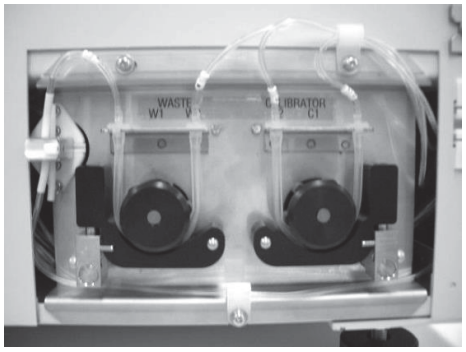


1) Remove Cal-1 pack from the hook to prevent leaking from the tube.
2) Loose the fixing screw, and remove front panel by disconnecting the connectors.
3) Clicking Maint button.
4) Clicking ISE Maint button, and empty the ISE line.
5) Turn the lever presser 90 degrees to outside, loosen the lever.
6) Remove the pump tube joint from the hook.
7) Remove the pump tube and exchange to new pump tube.
8) Paste the grease of roller pump tube to new one thinly.
9) Hang the pump tube joint on the center of the roller.
10) By pressing the lever, turn the lever presser 90 degrees to inside
11) Hang Cal-1 pack on the hook.
12) Perform ISE Purge order, and refill the line.
13) Repeat ISE Purge order till no bubble comes out from the tube and the liquid is sucked up.
14) Confirming no error occurs.
    Note
    Please check totally when error occurred.
15) Connect the connectors, and replace the front panel.

5.4.22 Exchange of pinch valve (PV) tube

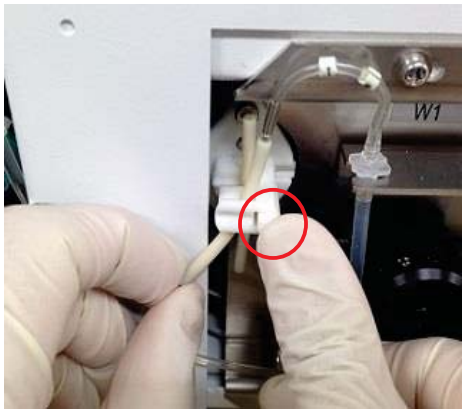
- The deterioration of pinch valve tube influences the liquid flow. Please change it periodically.
- Please exchange the PV tubes both front and rear side simultaneously.

Exchange interval	Every one year
Necessary parts	Gloves, Screw driver Pinch Valve Tube F (Code 20-27-0487F)

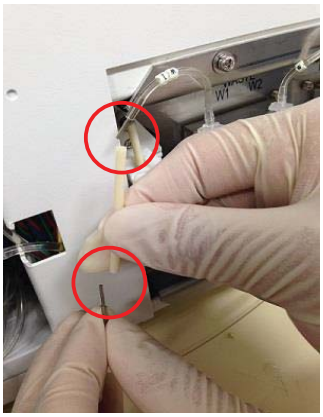


1) Remove Cal-1 pack from the hook to prevent leaking from the tube.
2) Loose the fixing screw, and remove front panel by disconnecting the connectors.
3) Clicking Maint button.
4) Clicking ISE Maint button, and empty the ISE line.
5) Remove the fitting .
   Pull under part of fitting in front.

6) By pressing the fixing projection, remove the front PV tube.
   Keep the tube connection.



7) Remove the PV tube inserted in the groove of pinch valve.
8) Exchange to new PV tube.
9) Remove the rear PV tube.
   Please use tweezers to removing easily.
10) Assemble the rear PV tube.
   The rear tube has no connection.
   Please use tweezers to set easily.



11) Assemble the front PV tube
The front tube is connecting the tube.

12) Insert the fitting.
13) Hang Cal-1 pack on the hook.
14) Perform ISE Purge order and refill the line.
15) Repeat ISE Purge order till no bubble comes out from the tube and the liquid is sucked up.

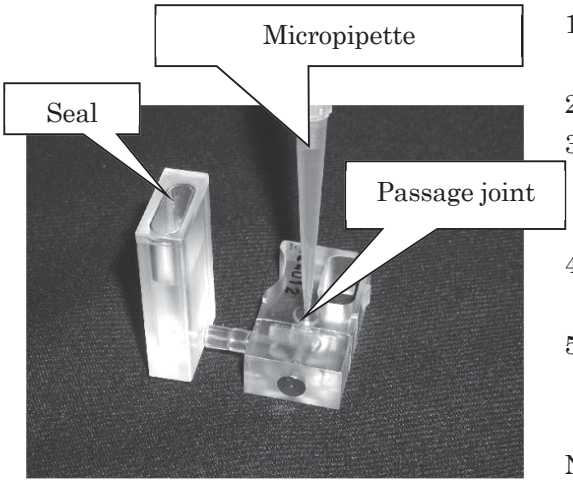
16) Confirming no error occurs.
Note
Please check totally when error occurred.

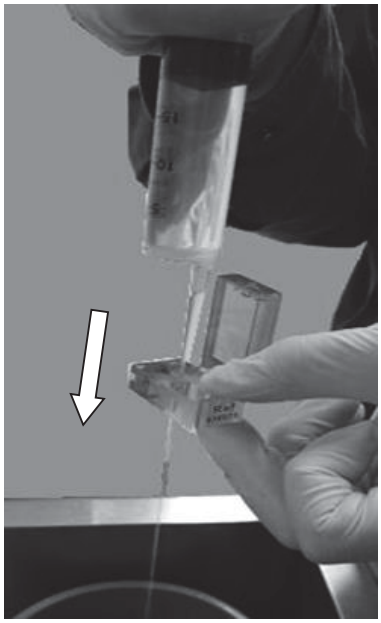
17) Connect the connectors, and replace the front panel.

5.4.23 Removal of bubbles at electrode

- The ISE unit can't detect the ions if the electrode has a bubble inside.
- When exchange the electrode, removal of bubbles is essential.
  The explanation is given for Ref electrode, but keep other electrodes likewise.

Inspection period	When exchange the electrode, if necessary
Necessary parts	Gloves, Syringe(with tip), DI water





1) Peel off the seal on the air hole of the electrode, and leave it open.
2) Fill the syringe with DI water.
3) Insert the tip of the syringe from the end of the passage joint to the ion passage.
4) Make a rush of DI water from the syringe.
5) The bubble is removed, and DI water spills over from the end of the passage joint.

Note

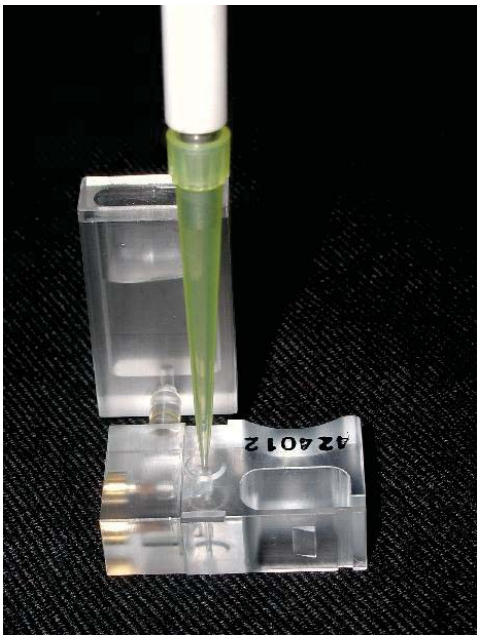
Please use 10mL syringe.
Don't rush strongly why the electrode membrane will damage.
Don't push till finish the liquid inside the syringe. It makes another bubble.

5) Pull out thesyringe.
6) Make sure that no bubble is in the ion passage of the electrode.
   If there is still any bubble, repeat the procedure from 2).
7) Wipe off the spilt liquid all over the electrode, if any.

5.4.24 Storage of electrodes

➢ In case of turning off the power of ISE unit more than four days, keep the electrodes as follows.
The explanation is given for Ref electrode, but keep other electrodes likewise.

Inspection period	When storage the electrode
Necessary parts	・Gloves, Syringe (with tip) ・Calibrator A (20mL) + Calibrator B (20mL) set (Code60-22-0263F)

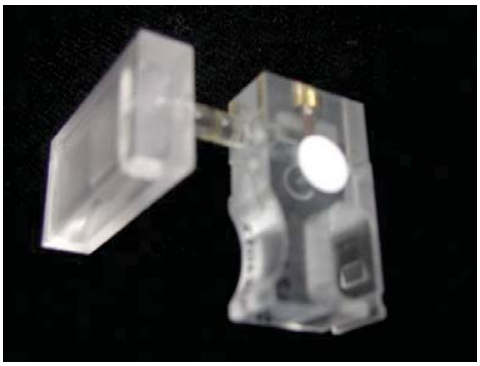


1) Remove the electrode.
Refer to Chapter5,5.4.20Exchange of Electrode
2) Fill the syringe with Calibrator A or B.
3) Fill the passage of the electrode with Calibrator A or B, using syringe.
4) Fix the attached seals to the both ends of the passage not to let the liquid leak out.

Note

Wipe off around the exits before fixing the seals. Also, wipe out the spilt liquid.

5) Put the electrodes in each case to keep at the room temperature.



Consumables List

	Code No.	Parts Name	Qty.	Memo
1	20-22-0391	Sample Cup	1000 pieces	
2	60-00-0001	Halogen lamp	1	
3	SP2058	Water filter	5 Pieces	
4	23-07-0055	Cuvette -8U	60 Pieces	
5	23-30-0676	Drying Nozzle Tip	2 Pieces	
6	SP2208	Washing Solution Alkaline (Fast Detergent 1)	500ML X5 Pieces	
7	SP2209	Washing Solution Acid (Fast Detergent 2)	500ML X5 Pieces	
8	60-08-0083	Packing	4 Pieces	
9	60-02-0020	Sample Probe	1	
10	60-03-0034	Reagent Probe	1	
11	20-22-0396	Reagent bottle 60ml (with Cap)	20 Pieces	for 24 item tray
12	60-22-0265	Reagent Bottle - T2 40ml (with cap)	20 pieces	for 24 item tray
13	60-22-0264	Reagent Bottle - T2 20ml (with cap)	20 pieces	for 24 item tray
14	SP2225	Reagent bottle Cap	20 Pieces	
15	20-30-0584	Reagent bottle 40ml (with Cap)	20 Pieces	for 36 item tray
16	20-22-0397	Reagent bottle 25ml (with Cap)	20 Pieces	for 36 item tray
17	20-22-0398	Reagent bottle 13ml (with Cap)	20 Pieces	for 36 item tray
18	20-22-0399	Reagent bottle Cap	20 Pieces	

- ISE accessory

	Code No.	Parts Name	Qty.	Memo
1	20-27-0474F	Na Electrode F	1	
2	20-27-0475F	K Electrode F	1	
3	20-27-0476F	Cl Electrode F	1	
4	20-27-0473F	Reference Electrodes F	1	
5	20-27-0477F	Calibrator 1 F (420ml)	1	
6	60-22-0263F	Calibrator A (20mL) + Calibrator B (20mL) set	1+1	
7	20-27-0479F	Cleaning Solution (25ml)	1	
8	50-27-0781	ISE Cleaner (1%)	1	
9	20-30-0610	Roller Pump Tube B for New roller pump	2 pieces of tubes	
10	20-27-0487F	Pinch Valve Tube F	2 pieces of tubes	
11	20-27-0488F	Piping Tube Set F	7 pieces of tubes	
12	20-27-0480	Urine Calibrator 1, 2	10 ampoules	
13	20-27-0482	Urine Diluent (500ml)	1	
14	20-27-0483F	Dialysis Liquid Calibrator D F	20 Pieces	

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