Biolyzer® 200

analyticon®

User Manual

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Foreword

This clinical chemistry analyzer consists of main analyzer including software, and software on operational PC. And the analyzer is used with operational PC and printer, and can interact with the host computer.

In the case of applying barcode reader to ASP (Auto Sampler) unit as an optional unit, all of the samples and reagents for measurements including samples obtained from patients are fully controlled by bar codes and thus enables the analyzer to perform the entire process of the analysis automatically.

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WARNING AND NOTICES FOR SAFE USE

Meanings of warning symbols

Warning about	
	Biohazard
	Electric shock
	High temperature
	Injury
	Action to be taken as directed by the “OPERATORS MANUAL”

WARNING LABELS

The following warning labels are affixed on the places that are the potentially hazardous.

Warning labels	Warning about	Places
	RISK OF ELECTRIC SHOCK	Power supply inlet, power supply portion
	DO NOT TOUCH MOVING PARTS	Covers of SPT, RPT and MIX1
	HOT SURFACE	DTR
	RISK OF ELECTRIC SHOCK TURN THE POWER OFF BEFORE ANY WORK	Front frame
	THE TANK CONTAINS HAZARDOUS MATERIAL	Waste tanks (2 tanks)
	CONTAINS HAZARDOUS MATERIAL SERUM, PLASMA OR URINE	Mosaic 2, SWU panel on right side cover
	RISK OF INJURY TURN THE POWER OFF BEFORE OPENING THIS PANEL	Lid for replacing halogen lamp, lid of ISE tank, lid for replacing ISE electrode
	Action to be taken as directed by the “OPERATOR’S MANUAL”	IRU heat insulation plate, fans on rear frame (2 fans), right frame, left frame

WARNING FOR SAFE USE

	During operation, do not touch samples, reagents, nozzles and any other moving mechanical parts in the analyzer. During operation, shut cover all the time.
	Never touch patients' samples with bare hands to prevent operator from possible infection. Handle SPT nozzle, RPT nozzle, IRU cuvettes, WU nozzles and MIX paddles in the same way.
	Give special consideration to keep skin and mucous membrane from contact with reagents to prevent operator from possible infection.
	Read the statements of virtues that came with reagents prior to their use.
	The contact with the wastes such as used cuvettes and solutions may cause infection. Handle them with gloved hands without exception. Follow the national or local laws and rules when they are thrown out. There are two kinds of liquid wastes drained from this analyzer, i.e. high- and low-concentrated wastes.
	The access to the conductive parts within the analyzer may cause serious electric shock. Leave any maintenance and repair of electrical parts inside the equipment to qualified service personnel.
	Never leave reagent bottles on the working table (upper surface inside the analyzer). Careless handling of reagent bottles may cause tumble and leak.
	Do not make a modification to the analyzer.
	Exchange the halogen lamp for a new one after a lapse of 30 minutes since the power switch of the analyzer is turned off to avoid danger of burns.

NOTICES FOR USE (SAFETY AND PREVENTION AGAINST DANGER)

The user is requested to read this instruction before he uses the analyzer for the first time and becomes acquainted with how to operate the analyzer. If the equipment is used in a manner not specified by the manufacture, the protection may be impaired.

1 Only qualified personnel should use the analyzer.

2 The following precautions should be taken when the analyzer is installed:

a Keep the analyzer out of the rain and any other water splash.

b Avoid areas that are adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust and air containing salt, sulfur, etc.

c Pay attention to inclination, vibration, shock (including shock during transportation), etc.

d When the analyzer is lifted, do it in a team of four or more. Lift carefully the analyzer by grabbing grips embedded in four bottom corners of the analyzer by one each hand and supporting the other places of the bottom by another each hand.

e Do not install the analyzer at the place adjacent to the storage room of chemicals or the place where any gas is likely to be generated.
At the installation of analyzer, the space from wall to the back of analyzer is needed 100 mm more to ventilate.

f Pay attention on the used frequency, voltage and current (or power consumption). The power cable of analyzer that is accompanied with the accessory package or specified by the analyzer's manufacture should be used for the analyzer main unit. Make sure that the outlet of power source is correctly and well grounded by customer's site.

g When the analyzer is used in the U.S.A. together with accessories including PC, visual display and printer, use UL-certified accessories.

h When the analyzer is used in the Member states of EC together with accessories including PC, visual display and printer, use CE-marking accessories.

i Connect the analyzer to the operational PC using accompanying LAN cable. When the other cable is used, this may cause the analyzer to suffer from disturbing noise or exert an adverse effect on its surroundings.

3 The following cautions should be exercised before the analyzer is operated:

a Check that the contact conditions of switches and indicators are appropriate and that the analyzer is ready to be activated correctly.

b Make sure that the analyzer is correctly and well grounded. (Refer to 2.6.)

c Make sure that all the necessary electrical cables are correctly connected.

d Extreme care must be taken not to result in misdiagnosis or pose any danger to the analyzer or human body when the analyzer in conjunction with other equipments.

e Wipe the nozzle tips of SPT and RPT several times with cloth or alikeness impregnated with rubbing alcohol before the analyzer is used. At this time, do not forget to put medical rubber gloves or alikeness on. Pay also attention to prevent bare skins of hands or arms from being touched by or pricked with the nozzle tip.

f Exchange the halogen lamp for a new one after a lapse of 30 minutes since the power switch of the analyzer is turned off to avoid danger of burns. Keep hands away from glass part of new halogen lamp. Make sure that there is no crack or breakage in the glass part. Make sure also that gas does not have been leaked.

4 The following cautions should be exercised during operation.

a Pay attentions on not to exceed time and volume which is necessary for diagnosis and treatment.

b Keep monitoring the behaviour of whole system in order to detect any malfunction.

c Take immediate corrective measures including shutdown of operation when any malfunction is detected in the analyzer.

d Avoid possibilities of any direct access by patients.

5 The following cautions should be exercised after the use of the analyzer.

a Turn off the power after every operational switch and control is restored to its pre-use state as directed.

b Do not remove the line cord plugs from receptacles by cords not to give undue stress to cords.

c Wipe the nozzle tips of SPT and RPT several times with cloth or alikeness impregnated with rubbing alcohol after the analyzer was used. At this time, do not forget to put medical rubber gloves or alikeness on. Pay also attention to prevent bare skins of hands or arms from being touched by or pricked with the nozzle tip.

d Pay attentions to the storage area:

– Keep the analyzer out of the rain and any other water splash.

– Avoid areas that are adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust and air containing salt, sulfur, etc.

– Pay attention to inclination, vibration, shock (including shock during transportation), etc.

– Avoid areas adjacent to the storage room of chemicals or areas that are likely to generate gasses.

e Organize and store parts and cords associated with the analyzer after they have been cleaned.

f Keep the analyzer clean not to cause any inconvenience to the next use.

6 In the event of trouble, call authorized service engineer for any repair.

When the safety mechanism is damaged, make contact to authorized service engineer after pulling out the power cable from the main source outlet.

7 Maintenance and checks

a It is importance for the analyzer and its associated parts to be periodically checked.

b Make sure without fail that the analyzer operates normally and correctly, when it is reused after being kept unused for some time.

c Do not use any parts and materials for repairs or consumables without being specified by the analyzer's manufacture.

8 Prohibit any alteration and/or modification to the analyzer without permission by manufacture.

9 The following precautions shall be taken when the cleaning procedure will be performed.

a Appropriate decontamination have to be carried out if hazardous material is split onto or into the analyzer.

b No decontamination or cleaning agents are used which could cause a HAZARD as a result of a reaction with parts of the analyzer or with material contained in it.

c Our agent is consulted if there is any doubt about the compatibility of decontamination or cleaning agents with parts of the analyzer or with material contained in it.

10 When you discard the analyzer from the field, you should consult our agents in advance.

Technical Specifications

1. Kind of Device — Clinical Chemistry Analyzer
2. Usage — General chemistry as photometric assay
   Immunology as photometric assay (Latex reagent available)
3. Assay type — 1 point end, 2 point end, 1 point rate, 2 point rate
4. Type of calibration — Factor, linear, Point to Point, Log Logit, Exponential, Spline
5. Through put — 180 tests per hour
6. Incubation time — One reagent assay: 10 minutes
   Two reagent assay: 5 minutes for R1 + 5 minutes for R2
7. Sample type — Serum, Plasma and Urine
8. Number of simultaneous measurement
   40 items (Max.) + Electrolyte: 3 items
9. Components
   (1) Main Analyzer
   CHS (Chassis Unit)
   IRU (Incubation Reaction Unit)
   ASP (Auto Sampler Unit)
   RCU (Reagent Container Unit)
   RPT (Reagent Pipette Unit)
   SPT (Sample Pipette Unit)
   RPP (Reagent Pump Unit)
   SPP (Sample Pump Unit)
   WPP (Wash Pump Unit)
   DTR (Detector Unit)
   MIX (Mixing Stirrer Unit)
   SWU (Supply Water Unit)
   WU (Wash Unit)
   POW (Power Unit)
   CNT (Control Unit)
   (2) Optional Accessories
   Personal Computer: 1
   CRT Display: 1
   Keyboard: 1
   Mouse: 1
   Printer: 1
   (3) External Tank
   System water tank: 1
   Wash solution tank: 3
   Waste fluid tank: 2
   (4) Optional Unit
   Electrolyte measurement unit (ISE)
   Bar-code reader for sample tube
   Liquid Level Sensor Unit for External Tanks
   (External-Tank Rack with Overflow detecting sensors for waste fluid tanks and Empty detecting sensors for wash solutions / system water tanks)

9-1 IRU (Incubation Reaction Unit)

Heating method:	Direct heat with silicon-rubber heater
Heating range:	37±0.3°C

9-2 Cuvette

Material:	PYREX
Size:	8 mm (W) x 6.23 mm (D) x 30 mm (H)
Light length:	6 mm
Quantity:	45
Minimum volume:	180 µl
Maximum volume:	500 µl

9-3 ASP (Auto Sampler Unit)

Valid tube:	Diameter 13~16 mm
Length:	53~100 mm
Turn-table:	Removable type
Number of tubes:	Maximum 40

9-4 SPT(Sample Pipette Unit)/SPP(Sample Pump Unit)

Number of pipette:	1
Pump type:	Syringe pump
Liquid detection:	Conjugation of electric-capacitance detection
Sampling volume:	2~35 µl (0.1 µl/1 step)

9-5 RCU(Reagent Container Unit)

Turn-table:	Removable type
Number of bottles:	Maximum 40 (20 bottles each for 100 ml and 20 ml type)
Cooling method:	Cooling with Peltier element
Cooling range:	8°C~15°C
Reagent inventory:	Count the dispensing volume of reagent

9-6 RPT (Reagent Pipette Unit)/RPP(Reagent Pump Unit)

Number of pipette:	1
Pump type:	Syringe pump
Liquid detection:	Conjugation of electric-capacitance detection
Sampling volume:	20~400 µl (1 µl/1 step)

9-7 DTR (Detector Unit)

Measurement:	Absorption of light (1 or 2 wavelength measurement)
Selectable wavelength:	8 wavelengths (340, 415, 450, 510, 570, 600, 700, 800 nm)
Wavelength selection:	Change of Interference filter
Light source:	Halogen lamp
Cooling for light source:	Air-cooled by fan

9-8 MIX (Mixing Stirrer Unit)

Stirring mechanism:	Stirring-bar rotating by stepping motor

9-9 SWU (Supply Water Unit)

Liquid waste through nozzle of WU:	8 pieces of diaphragm pump
Liquid waste at trough:	1 piece of diaphragm pump
Supply water at trough:	5 pieces of diaphragm pump
Supply detergent at trough:	1 piece of diaphragm pump

9-10 WPP (Wash Pump Unit)

Supply detergent and water for cuvette cleaning: 4 pieces of syringe pump

9-11 WU (Wash Unit)
Cleaning mechanism: 8 steps cleaning
1st step: Waste of liquid and discharge of detergent
2nd step: Waste of liquid and discharge of purified water
3rd step: Waste of liquid and discharge of detergent
4th step: Waste of liquid and discharge of purified water
5th step: Waste of liquid and discharge of purified water
6th step: Waste of liquid and discharge of purified water
7th step: Waste of liquid
8th step: Waste of liquid with wipe tip

9-12 Power Unit
Source: AC 100~120 V (allowance: ± 10%), 5.5 A (Max.) Or
AC 200~240 V (allowance: ± 10%), 2.8 A (Max.)
50/60 Hz, Less than 700 VA

10. Other functions
Auto start/shutoff, Emergency sample insertion, Automatic sample dilution, Water blank measurement, Reagent blank measurement, Test selection by profile, Host communication via RS232C

11. Environment (without condensation and freezing)
Temperature: Operation: +15°C~+30°C, Storage/Transport: -10~+50°C
Humidity: Operation: 45~85%, Storage/Transport: 45~85%
Pressure: Operation: 800~1060 (hPa), Storage/Transport: 500~1060(hPa)
Altitude: Less than 2,000m (indoor use only)

12. Measurements
Figure (Main unit): 770 mm (W) x 620 mm (D) x 505 mm (H)
Weight (Main unit): 135 Kg

13. Connectors on Main Analyzer
1) Electrical Connectors
Appliance inlet (for connection to power line)
RJ-45 modular jack (for connection between Main Analyzer and Operational PC)
D-sub receptacle (for connection between Analyzer and optional External-Tank Rack)
2) Piping Connectors (for connection between Analyzer and External-Tanks)
System water
High conc. waste
Low conc. waste
Wash solution 1
Wash solution 2
Wash solution 3

14. Maximum sound level
60 dB (When the hatch is closed and the operator is distant 1meter or more from the Main Analyzer.)

15. Definition of INSTALLATION CATEGORY in IEC60664
Primary circuit: CAT II
Secondary circuit: CAT I

16. Pollution degree in IEC61010-1, UL61010A-1
Pollution degree: 1 and 2

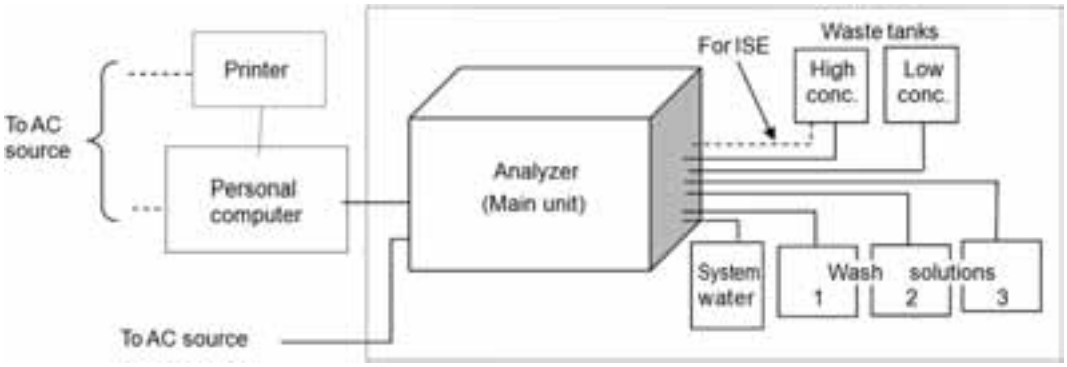
17. The rating and the characteristics of fuses

Type	Size	Rating	Characteristics	Location and Part No.
Glass tube fuse	5×20mm	1.6A/250V	Time lag- Acting, Slo-Blo	PCB:25P3222(ASP/RCU_DRV) F1
Glass tube fuse	5×20mm	3.15A/250V	Time lag- Acting, Slo-Blo	PCB:25P3221(SWU_DRV) F1
Glass tube fuse	5×20mm	5A/250V	Time lag- Acting, Slo-Blo	PCB:25P3220(PP_DRV) F1 PCB:25P3222(ASP/RCU_DRV) F2 & F3
Glass tube fuse	5×20mm	10A/125V	Medium-Acting, MITI	PCB:25P3216/25P3231(IRU_DRV) F1

Glass tube fuse	5×20mm	6A/125V	Medium-Acting, MITI	Appliance inlet F1 & F2 - For use at source voltage 100V-120V
	5×20mm	6.3A/250V	Time lag- Acting, Slo-Blo	Appliance inlet F1 & F2 - For use at source voltage 200V-240V
	Check that the source voltage and fuse rating are appropriate.			

SYSTEM CONFIGURATION and EQUIPMENT LIST

A) SYSTEM CONFIGURATION



Note: Objects are described by solid line are shown standard supplies. When ISE (Option) is added to the analyzer, its waste liquid tube is connected to the high conc. tank.

B) EQUIPMENT LIST

No.	Equipment	Model/Type/Spec.	Q'ty	Remarks
1	Main Analyzer		1	Optional: Sample bar code reader and ISE unit.
2	Operational PC (Option)	Personal computer PC/AT compatible, MS windows XP Pro. Installed and can be operated normally. Serial port: 1 or more (RS232C) Parallel port: 1 or more LAN port: 1 or more (10baseT/100baseTX)	1	With keyboard and mouse. In the U.S.A, UL-certified PC has to be used. In the Member states of EC, a CE-marking PC has to be used.
3	CRT display (Option)	15-inch or larger, XGA	1	In the U.S.A, UL-certified CRT display has to be used. In the Member states of EC, a CE-marking CRT display has to be used.
4	Printer (Option)	Accommodates paper size of A4	1	In the U.S.A, UL-certified printer has to be used. In the Member states of EC, a CE-marking printer has to be used.
5	External tanks	System water (20 L) High conc. waste (10 L) Low conc. waste (20 L) Wash solution (5 L or 2 L)	1 set	With plastic tube for each tanks. 2 L tanks are for using liquid level sensor unit only. (Option)
		Liquid level sensor unit	1set	Option

No.	Equipment	Model/Type/Spec.	Q'ty	Remarks
6	Accessories	Cable for LAN : 1	1 set	10base-T/100base-TX
		Power cable for main unit : 1		See the packing list.
		Sample tray :1		For ASP unit
		ASP lid : 1		For ASP unit
		Reagent bottle tray : 1		For RCU unit
		RCU lid : 1		For RCU unit
		Wash solution No.10-2 : 1		
		Packing list : 1		
		Operation manual : 1		
		ISE electrode (Na, K, Cl, Ref): 1 ISE Calibrant A: 1 (255ml) ISE Calibrant B: 1 (125ml) ISE Urine Diluent: 1 (125ml) Cleaning Solution: 1 (125ml) Waste liquid tube: 1500 mm	1 set	For optional ISE unit only
7	Spare parts and Tools	Glass tube fuse 1.6A/250V : 1	1 set	PCB:25P3222(ASP/RCU_DRV) F1
		Glass tube fuse 3.15A/250V : 1		PCB:25P3221(SWU_DRV) F1
		Glass tube fuse 5A/250V : 3		PCB:25P3220(PP_DRV) F1, PCB:25P3222(ASP/RCU_DRV) F2 & F3
		Glass tube fuse 6A/125V : 2 (- FOR USE IN USA) or Glass tube fuse 6.3A/250V : 2 (- FOR USE IN OTHER COUNTRIES)		Appliance inlet F1 & F2 (- FOR USE IN USA) Appliance inlet F1 & F2 (- FOR USE IN OTHER COUNTRIES)
		Glass tube fuse 10A/125V : 1		PCB:25P3216/25P3231(IRU_DRV) F1
		Halogen lamp : 1		
		Syringe tip (PTEF tip) TEF010 : 1 TEF050 : 1 TEF250 : 3 TEF500 : 3	1 set	
		Plunger tip insertion die	1	
		Tool set (+) Screw driver (No.123-C100) : 1 Hexagonal wrench (1.5 mm) : 1 Hexagonal wrench (0.9 mm) : 1	1 set	

C) Packaging

Items 1 and, if provided 2 through 4 in the equipment list, are packed individually in each designated package. Items 5 (not included Sample tray, ASP lid, Reagent bottle tray and RCU lid) through 7 are packed in one package. Sample tray, ASP lid, Reagent bottle tray, RCU lid are packed in another package. All packages are sent at the same time.

Chapter 1

Equipment overview

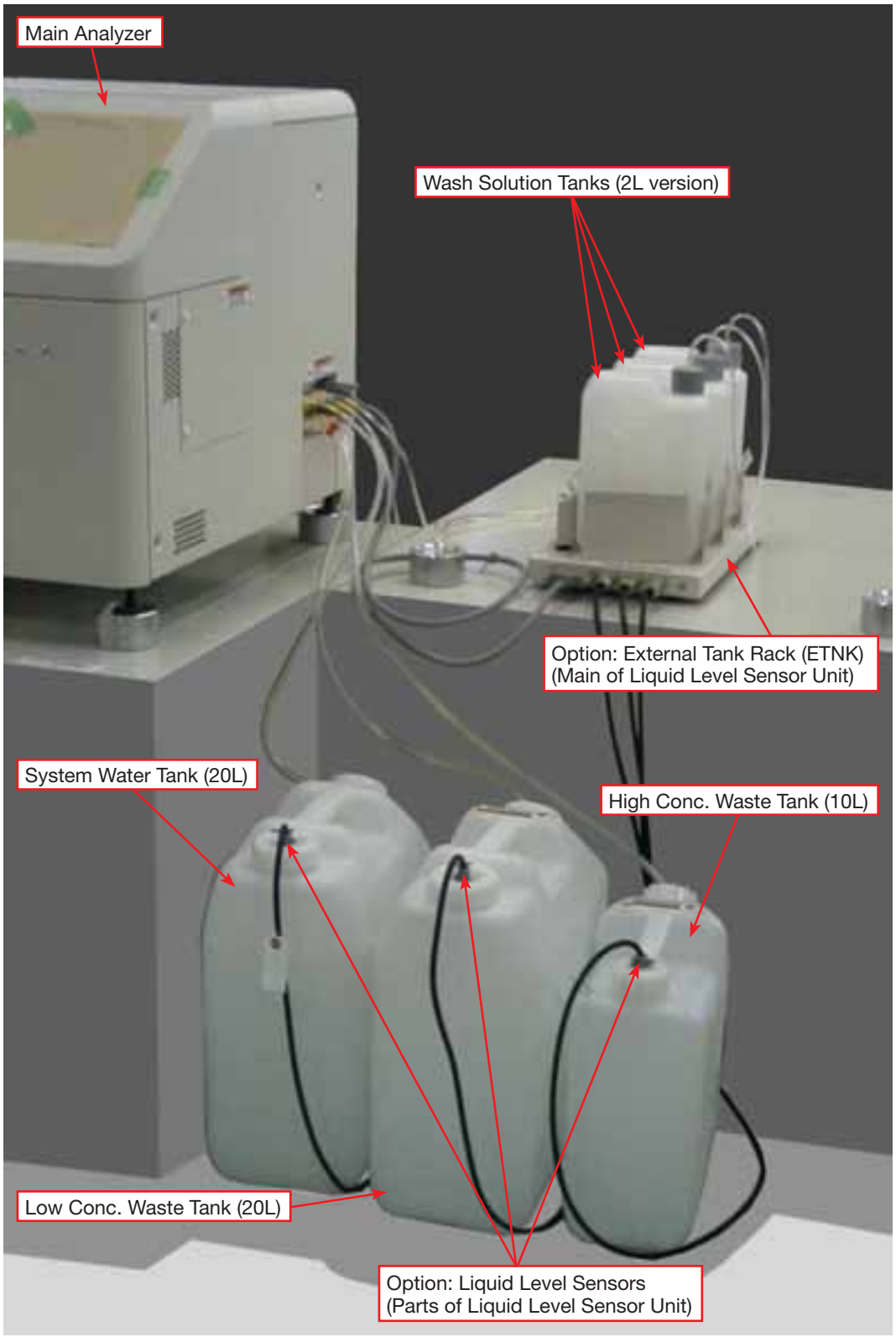
This chapter provides the user with necessary background on the analyzer for its use. The user is requested to read before starting operation.

This chapter consists of:

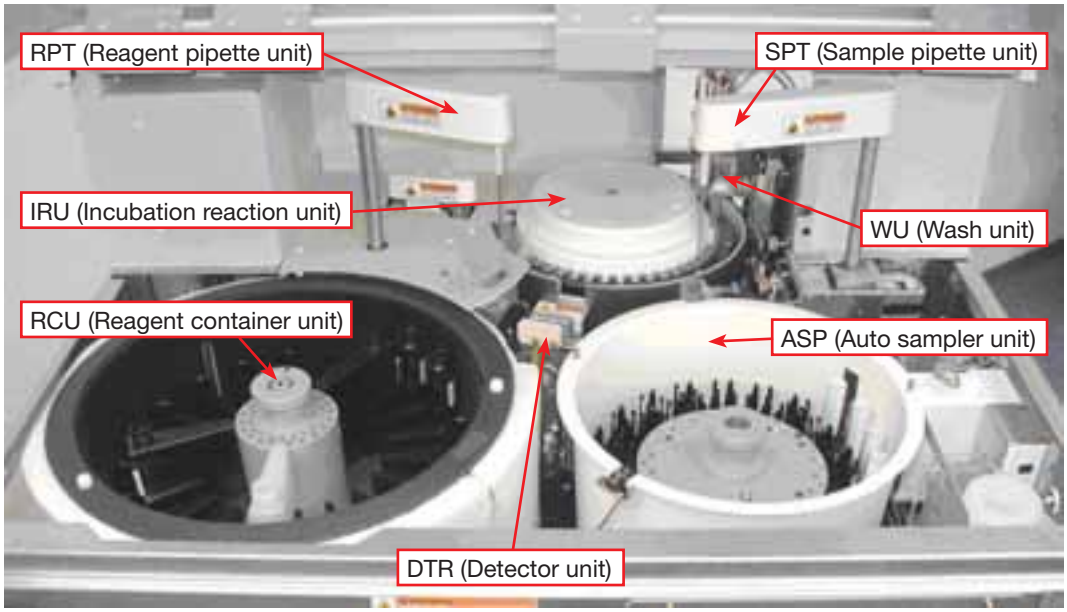
1.1 Designation of each unit

View at an angle to the left

View at an angle to the right


Main Analyzer
Wash Solution Tanks (2L version)
Option: External Tank Rack (ETNK)
(Main of Liquid Level Sensor Unit)
System Water Tank (20L)
High Conc. Waste Tank (10L)
Low Conc. Waste Tank (20L)
Option: Liquid Level Sensors
(Parts of Liquid Level Sensor Unit)

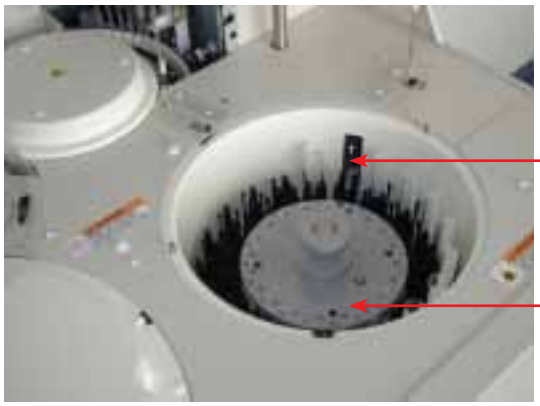

IRU (Incubation reaction unit)
RCU (Reagent container unit)
SPT (Sample pipette unit)
RPT (Reagent pipette unit)
ASP (Auto sampler unit)


RPT (Reagent pipette unit)
SPT (Sample pipette unit)
IRU (Incubation reaction unit)
WU (Wash unit)
RCU (Reagent container unit)
ASP (Auto sampler unit)
DTR (Detector unit)

1.2 Functionality of each unit

This section contains the description of each unit constituting the system.

1.2.1 Auto sampler unit (ASP)

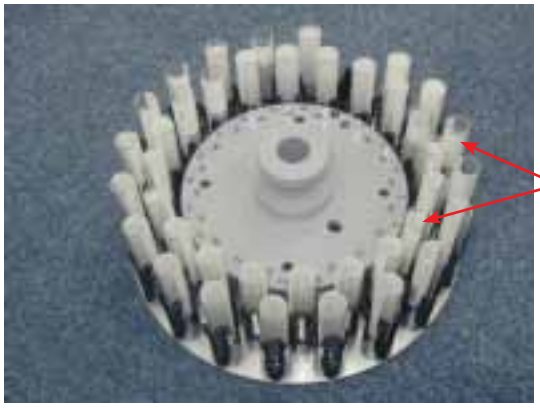


The auto sampler unit (ASP) consists of a removable turntable with sample tube holder and rotating mechanism and a bar code reader for identifying samples. But barcode reader is option.

The ASP accommodates 40 sample tubes. Each sample is aspirated by the sample pipette unit (SPT) and dispensed into cuvettes of the incubation reaction unit (IRU).

Emergency sample is set at position of which number is instructed in the popped up picture.

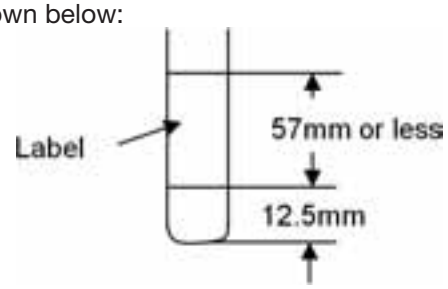
A) Turntable (ASP tray)



The sample tubes with barcode label affixed are inserted into the tube holder. 40 sample tubes in total can be accommodated (20 tubes each on inner and outer circumferences).

The types of usable sample tubes are shown below:

Diameter:	13 mm – 16 mm
Length:	53 mm – 100 mm
Extent of label fitting:	See right drawing.



B) Barcode reader (Option)

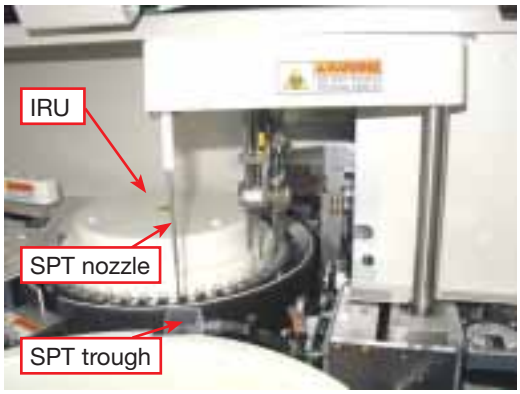
The barcode reader reads barcode of the label affixed on the outer surface of the sample tube.

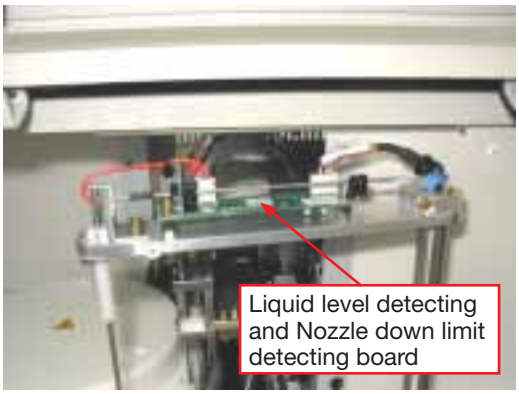
When the barcode is not read by the reader even if the barcode label exists, the appropriate error message is indicated.

The readable barcodes are as follows:

Symbol	Valid character and symbol
NW-7	Numerals (0 – 9), symbols (-, $, /, ., +)
Code39	Numerals (0 – 9), alphabetical characters, symbols (-, $, /, ., +)
ITF	numerals only (0 – 9)
UPC	numerals only (0 – 9)
Code128: Set A, Set B	numerals (0 – 9), alphabetical characters (uppercase/lowercase), symbols (!, “, #, $, (,), *, +, . ,/, :, ;, <, >, =, ?, @, [,]) ***Note: In the case of Set B, it is not effective to use the alphabetical characters of lowercase type.***

1.2.2 Sample pipette unit (SPT)





The sample pipette unit (SPT) consists of an up-and-down movement mechanism, rotating mechanism, liquid level sensor and nozzle down limit sensor. The sample pipette is connected to the syringe for sample aspiration via resin tube. The sample on the ASP unit is aspirated by the pipette and then dispensed into cuvettes (reaction cells) in the IRU unit.

When an optional ISE unit is fitted and the ISE measurement is performed, the SPT aspirates sample for ISE measurement and dispenses it into the sample port of the ISE unit.

A) Liquid level sensor

When the tip of the nozzle reaches and touches the sample surface, the electrostatic capacitance of the metallic nozzle varies. The variation of the capacitance is detected and consequently the level of sample is detected.

B) Nozzle down limit sensor

When the tip of nozzle hits the bottom of sample tube (or sample cup) due to the insufficient volume of sample in it, the lower limit sensor detects that the tip of nozzle hits the bottom and stops its downward movement.

C) SPT trough

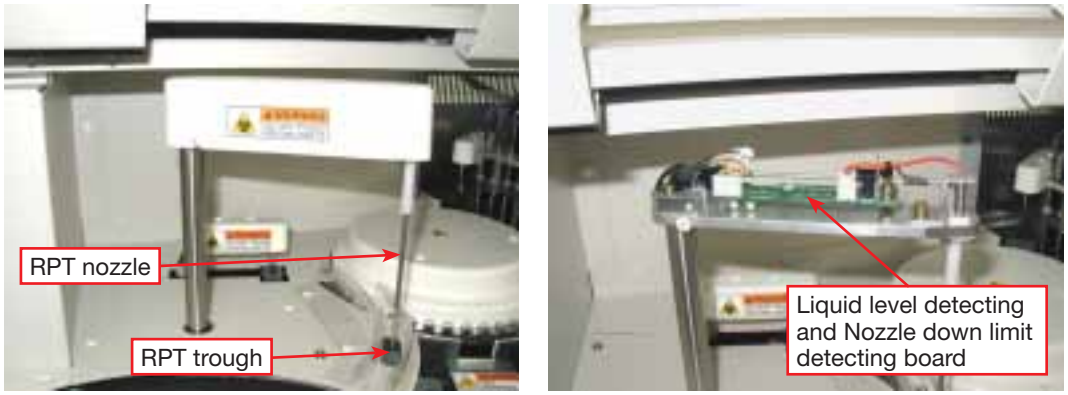
After dispensation is completed, the tip of the SPT nozzle is washed with system water in the SPT trough.

D) Dummy volume of sample

Necessary dummy volume of sample is 5µL.

When 10µL of sample is needed for measurement, 15µL of sample is aspirated inclusive dummy volume.

1.2.3 Reagent pipette unit (RPT)



The reagent pipette unit (RPT) consists of an up-and-down movement mechanism, rotating mechanism, level sensor and lower limit sensor. The reagent pipette aspirates primary or secondary reagent contained in the reagent container unit (RCU) and dispenses it into cuvettes (reaction cells) in the IRU unit.

A) Liquid level sensor

When the tip of the nozzle reaches and touches the reagent surface, the electrostatic capacitance of the metallic nozzle varies. The variation of the capacitance is detected and consequently the level of reagent is detected.

B) Nozzle down limit sensor

When the tip of nozzle hits the bottom of reagent bottle due to the insufficient volume of reagent in it, the lower limit sensor detects that the tip of nozzle hits the bottom and stops its downward movement.

C) RPT trough

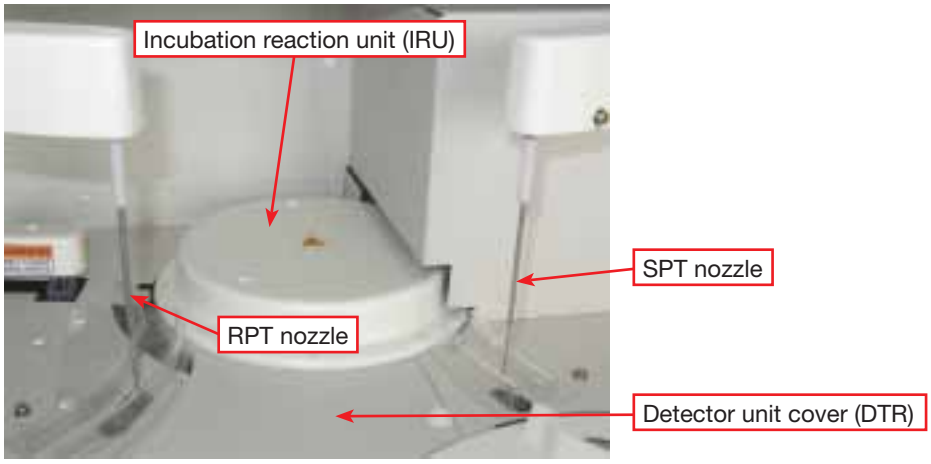
After dispensation is completed, the tip of the RPT nozzle is washed with pure water or wash solution in the RPT trough.

D) Dummy volume of reagent

Necessary dummy volume of reagent is 15 µL.

When 100 µL of reagent for measurement is needed, the necessary amount of reagent is 115 µL inclusive dummy volume.

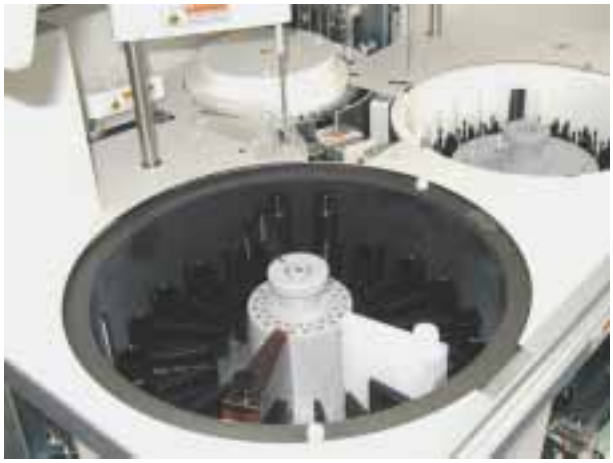
1.2.4 Incubation reaction unit (IRU)



The incubation reaction unit (IRU) consists of the cuvette holder and rotating mechanism.

IRU is provided with 45 hard glass cuvettes on its outer circumference and the temperature inside is kept at 37ºC constantly. The cuvettes are moved at 20-second step and a series of process including dispensation, stirring, photometric measurement and washing are performed.

1.2.5 Reagent container unit (RCU)



The reagent container unit (RCU) consists of a reagent tray (reagent bottle tray), bar code reader, cooler, sensor and rotating mechanism.

The reagent tray of the RCU accommodates at maximum 40 reagent bottles.

The reagent tray rotates and the required reagent bottle is moved to the position where the reagent is aspirated. At this position, the reagent is aspirated by the RPT and then dispensed into cuvettes in the IRU unit.

A) Reagent tray

The reagent tray of the RCU accommodates at maximum 40 reagent bottles.

The type of usable reagent bottles is shown below;

(1) Inner circumference: 100 ml

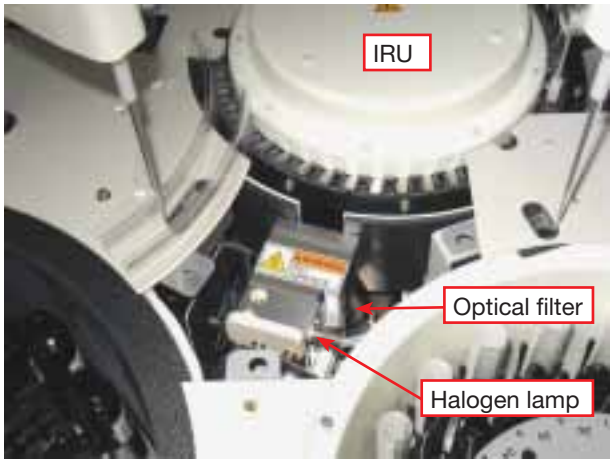
(2) Outer circumference: 20 ml

Note: 20 ml and 50 ml with optional adapter can be set at inner circumference of the reagent tray.

B) Cooler

Even if the analyzer is in the sleep mode, the temperature inside the RCU unit is kept within the specified limits by the Peltier element which is controlled by CPU.

1.2.6 Detector unit (DTR)



The detector unit (DTR) consists of the optical measurement system and filter rotating mechanism.

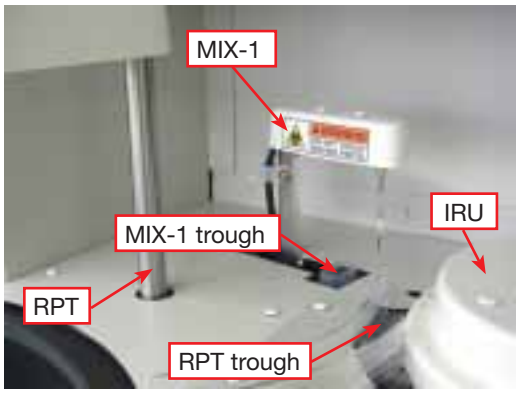
The absorbance inside the cuvette of the IRU unit is measured by using a photometer. Measurement is performed with any combinations of 2 wavelengths selected from 8 wavelengths.

A) Photometer

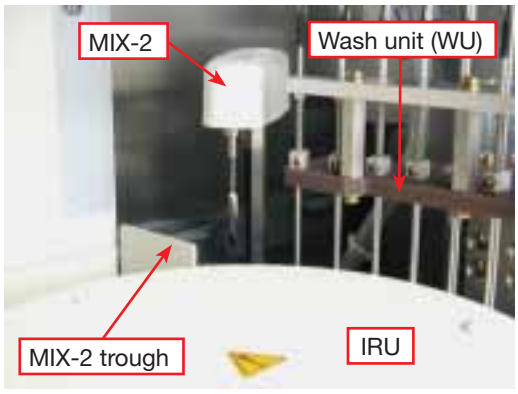
The photometer consists of an illuminator (halogen lamp), lenses, optical filter and photoreceptor (photodiode). The lenses are comprised of a condenser and focusing lenses. The condenser lens converts the light from the halogen lamp into collimated light beam which is then focused through the focusing lens in the cuvette. The optical filter allows only the light with wavelength to be used for measurement to pass through. The photoreceptor converts the strength of light passing through the solution in cuvette into electrical signal.

1.2.7 Mixing stirrer unit (MIX-1/MIX-2)

The mixing stirrer unit (MIX) consists of the up-and-down mechanism and the paddle rotating mechanism.



MIX-1 (primary reagent side)



MIX-2 (secondary reagent side)

A) MIX-1

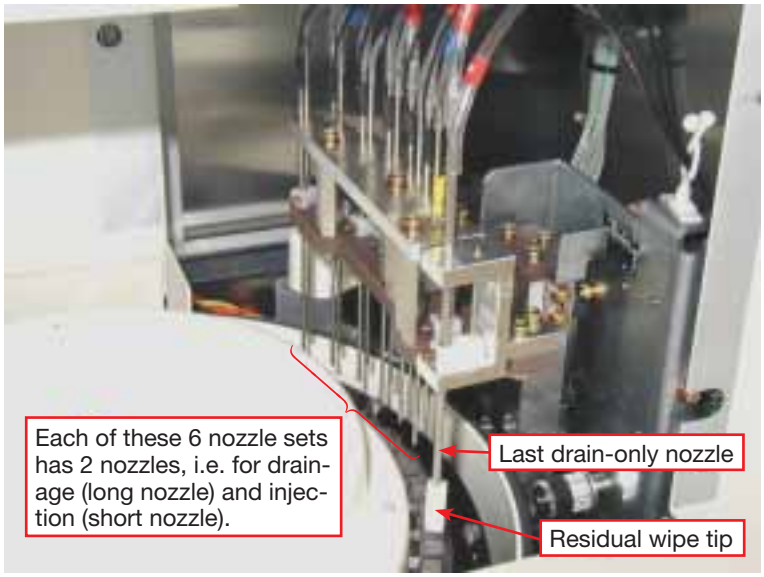
The sample and the primary reagent dispensed into cuvettes are stirred by rotating the paddle. The paddle is washed in the MIX-1 trough with system water.

B) MIX-2

The secondary reagent dispensed into cuvettes is stirred by rotating the paddle.

The paddle is washed in the MIX-2 trough with pure water.

1.2.8 Wash unit (WU)

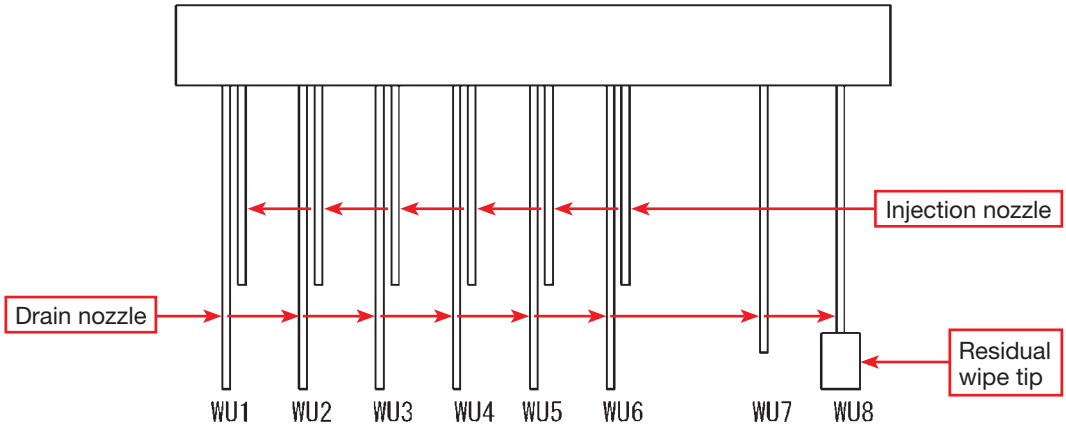


The wash unit (WU) is to wash the insides of cuvettes in which the measurement of specimen have been completed and allow them to be reused. The WU consists of 7 stages of drainage and injection nozzles (one of them is for drainage only), one stage of residual wipe tip, nozzle up-and-down mechanism and overflow sensor. The processed solution in the cuvette is drained at the end of the completion of measurement and then their insides are washed with system water or wash solution.

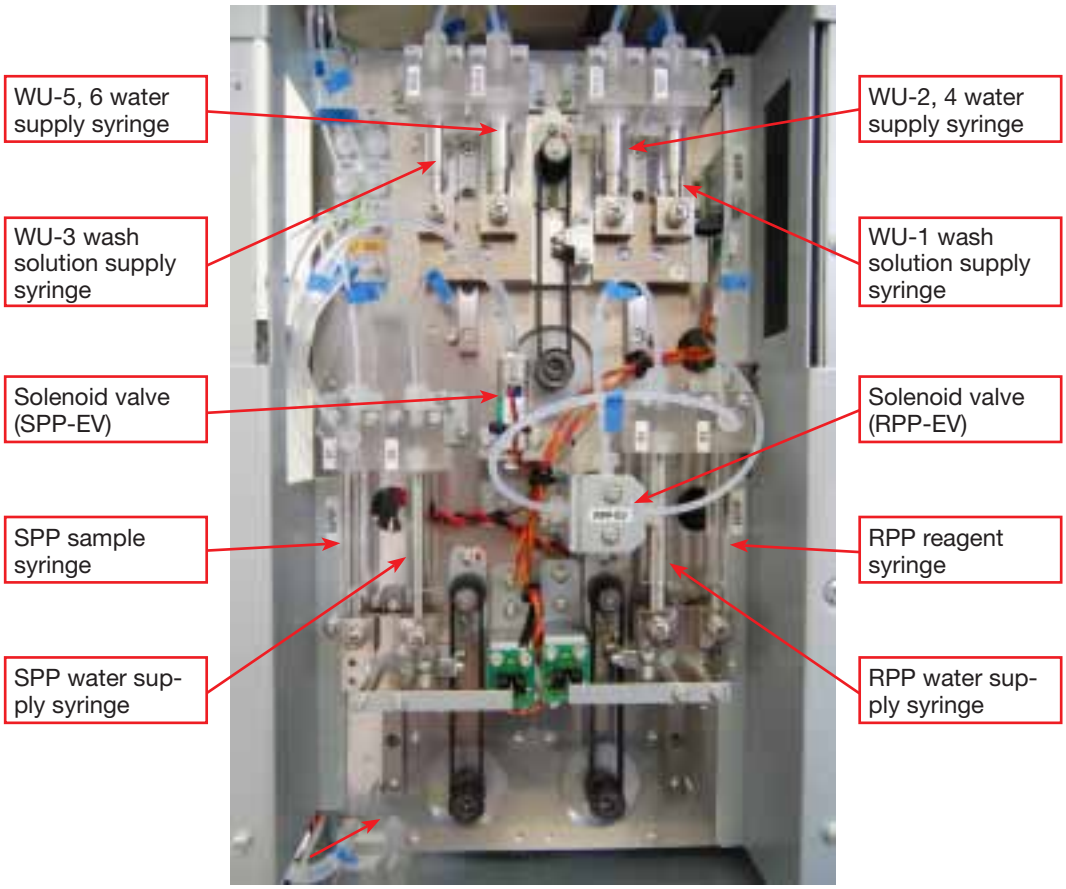
The drain nozzle is connected to the drain pump of the SWU unit via resin tube.

The injection nozzle is connected to the syringe of the WPP unit via resin tube.

The overflow sensor observes whether the liquid in the cuvette is fully drained or not.



1.2.9 Pump unit (PP)



Side view (left)

A) Syringe

The PP unit is provided with 8 syringes each for the WU and for the SPP and RPP, and solenoid valves.

(1) WU-1 wash solution supply syringe	Aspirates wash solution from the wash solution tank and supply it into cuvette via WU-1 nozzle to wash cuvette (4 syringes moves together).
(2) WU-2, 4 water supply syringes	Aspirate pure water from the system water tank and supply it into cuvette via WU-2 and -4 nozzles to wash cuvette (4 syringes moves together).
(3) WU-3 wash solution supply syringe	Aspirates wash solution from the wash solution tank and supply it into cuvette via WU-3 nozzle to wash cuvette (4 syringes moves together).
(4) WU-5, 6 water supply syringes	Aspirate pure water from the system water tank and supply it into cuvette via WU-5 and -6 nozzles to wash cuvette (4 syringes moves together).
(5) SPP sample syringe	Aspirates sample via SPT nozzle and dispenses it into the cuvettes in the IRU (linked with SPP water supply syringe).

(6) SPP water supply syringe	Aspirates pure water from the system water tank to fill it in SPP line and at the time of dispensation of sample, the sample at the tip of the SPP nozzle is pushed out by the water (linked with SPP sample syringe).
(7) RPP reagent syringe	Aspirates reagent via RPT nozzle and dispenses it into the cuvettes in the IRU (linked with RPP water supply syringe).
(8) RPP water supply syringe	Aspirates pure water from the system water tank to fill it in RPT line and at the time of dispensation of reagent, the reagent at the tip of the RPT nozzle is pushed out by the water (linked with RPP reagent syringe).

B) Solenoid valve

Each solenoid valve switches pump from aspiration to dispensation line and vice versa.

(1) SPP-EV	For switching between aspiration of pure water into and dispensation from the SPP line.
(2) RPP-EV	For switching between aspiration of pure water into and dispensation from the RPP line.
(3) WPP-EV1 – WPP-EV6	For switching between aspiration of pure water into syringe and dispensation into cuvette for washing.

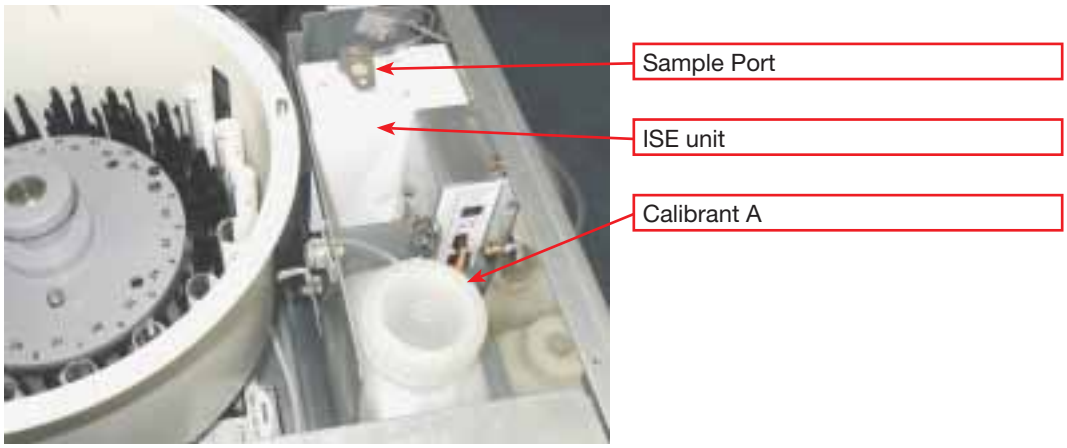
1.2.10 Supply water unit (SWU)

Side view (right)

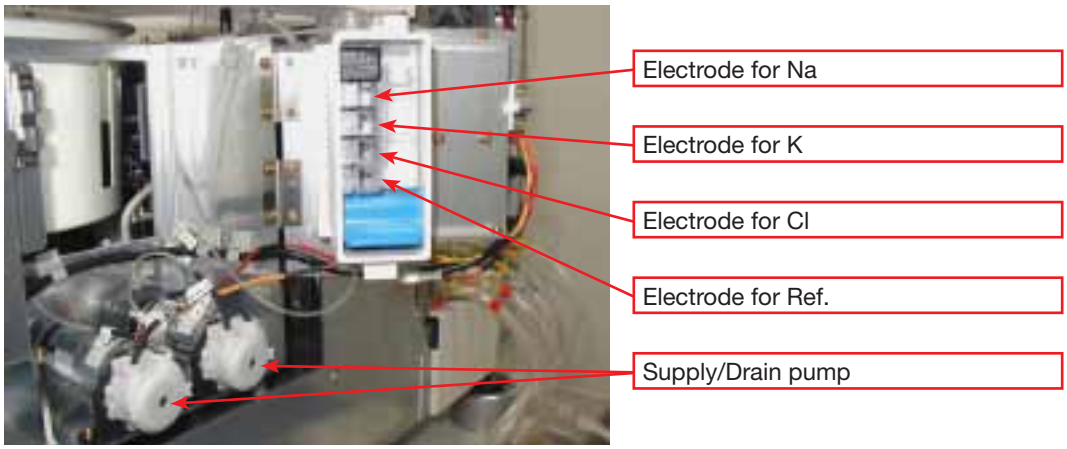
The SWU unit is located on the right-hand side of the analyzer and consists of diaphragm pumps for drain of the wash unit (WU) and water supply and drain of various troughs.

(1) Diaphragm pumps for WU-1 – WU-7	: 7 pcs (PML3912-NF10, DC24V)
(2) Diaphragm pump for WU-8	: 1 pc (PML3914-NF30, DC24V)
(3) Diaphragm pump for pure water supply to RPT trough	: 2 pcs (at the side of trough and the bottom, PML3911-NF10, DC24V)
(4) Diaphragm pump for wash solution supply to RPT trough	: 1 pc (PML3911-NF10, DC24V)
(5) Diaphragm pump for pure water supply to SPT trough	: 1 pc (PML3911-NF10, DC24V)
(6) Diaphragm pump for pure water supply to MIX-1 trough	: 1 pc (PML3912-NF10, DC24V)
(7) Diaphragm pump for pure water supply to MIX-2 trough	: 1 pc (PML3912-NF10, DC24V)
(8) Diaphragm pump for drainage from RPT/SPT/ MIX-1/MIX-2 troughs	: 1 pc (PML3914-NF30, DC24V)

1.2.11 Ion selective electrode unit (ISE) (option)



Top view (Right)



Side view (Right)

The concentration of electrolyte (sodium: Na, potassium: K, chloride: Cl) contained in serum, plasma or urine is measured by the ion electrode of the ISE unit which is placed on the right-hand side of the analyzer. This unit is optionally supplied.

The ISE unit consists of ISE module, ion electrode, supply and drain pump.

(1) ISE module — This module unit is fitted electrodes (Na, K, Cl and Reference) and controls pumps, measurement of concentration by electrodes and rinsing movement. Communication to the analyzer is carried out through RS232C.

(2) Ion electrode — This unit consists of Na, K, Cl and Reference electrodes. The bottles of Calibrant B and dedicated wash solution are placed in the ASP unit and both solutions are supplied by the SPT in the same way as for the sample.

(3) Supply pump — This pump performs the infusing of Calibrant A into ISE module.

(4) Drain pump — This pump performs the transferring of liquid in ISE module.

The following solutions are requested for the ISE unit:

(1) Calibrant A — Calibrant A is used at the time of one-point calibration.
The one-point calibration is carried out at the same time when the Calibrant A is dispensed to wash electrodes every time the sample measurement is performed. 120µl of Calibrant A is automatically dispensed into the ISE unit every 30 minutes to prevent the electrode from drying during standby cycle.
Its dedicated bottle is placed beside the ISE unit.

(2) Calibrant B — Calibrant B is used at the time of two-point calibration.
As necessary, 500µl of Calibrant-B is dispensed into a sample cup which is placed at No. 18 position of the ASP tray. The two-point calibration should be carried out at the beginning of the day and at least once every 8 hours.
The dispensation is carried out using [Sequence (F9)] of the job menu [Maintenance].

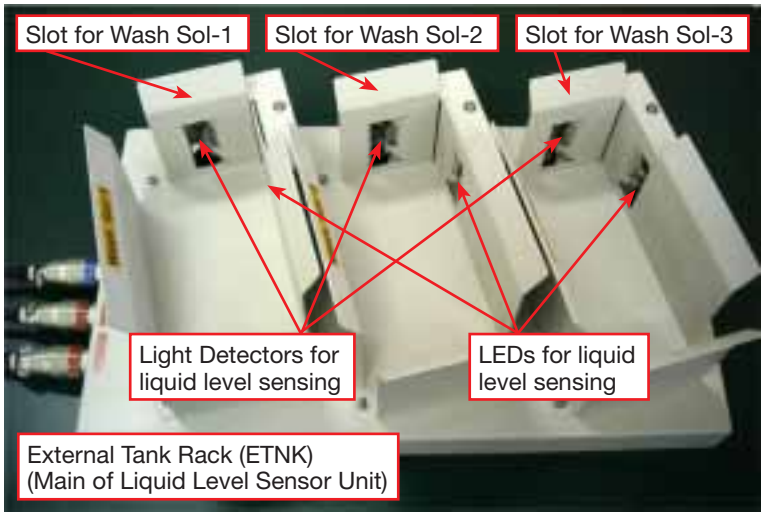
(3) Wash solution — The wash solution needs to be dispensed into the unit to avoid deposition of protein on the electrodes.
As necessary, 600µl of the wash solution is dispensed into a sample cup and it is placed at No. 18 position of the ASP tray.
The dispensation is carried out using [Sequence (F9)] of the job menu [Maintenance].
This function should be carried out once a day at the end of work. When more than 50 samples of measurement are carried out, the washing must be carried out 8 hours interval.

(4) Diluent — The diluent is used to dilute urine to one-tenth in concentration. It is contained in a reagent bottle which is placed in the RCU unit. The necessary volume for diluting one sample is 315µl. The dilution is carried out using a cuvette in the IRU unit and therefore one cycle of chemistry analysis is allocated to this processing.
The diluent should be pre-registered as a regent code in the [System (F9)] picture of the job menu [System Parameters].

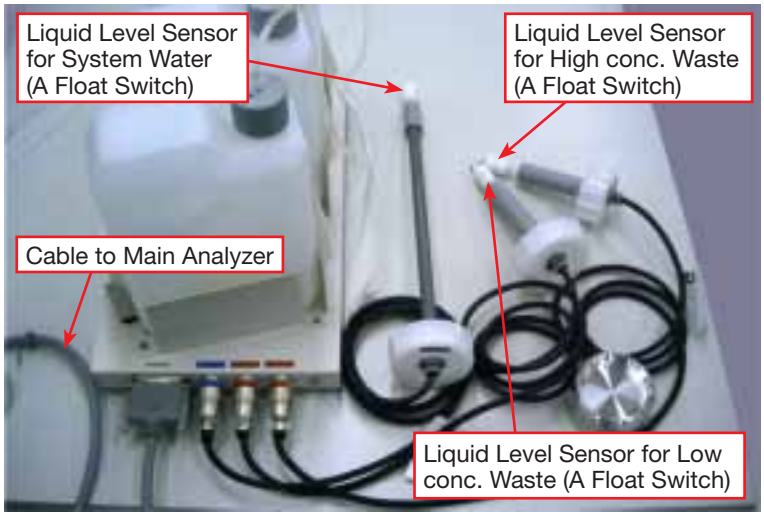
(5) Sampling volume at each measurement

Measurement	Volume
In the case of analytic measurement	Sample: 100 µl
In the case of full calibration	Calibrant-A: 200 µl, Calibrant-B: 100 µl
	Calibrant-A: 120 µl, Calibrant-B: 100 µl
In the case of 1-point calibration	Calibrant-A: 120 µl

1.2.12 Liquid level sensor unit for external tank (option)



Top view of External Tank Rack (ETNK)



Connection of Liquid Level Sensor Unit

The Liquid Level Sensor Unit is located on the outside of the Main Analyzer, and connected to the Main Analyzer (SWU Panel on the right-hand side) with a D-sub cable. The unit has a Tank Rack for the Wash Solution Tanks, and has optical or float switch sensor for liquid level sensing against each external tank.

A) External Tank Rack (ETNK)

It is the main of the Liquid Level Sensor Unit, and it has 3 slots for the Wash Solution Tanks (2 L version), a D-sub receptacle for the connection to the Main Analyzer, and receptacles for the Liquid Level Sensors (Float Switches). Each slot has an optical sensor to detect the empty of each Wash Solution Tank.

(1) Optical sensors: Each optical sensor is composed by one-pare of the “LLRD” PCB (25P3141) and the “LLED” PCB (25P3142). The “LLRD” PCB has a Light Detector (IS-486), and the “LLED” PCB has an infrared LED (GL-480).

(2) D-sub receptacle: It is for the connection to the Main Analyzer. It has 25 male contacts.

(3) One-touch receptacles: They are for the connection to the Liquid Level Sensors (Float Switches). Each has 3 female contacts.

B) Liquid Level Sensors (Float Switches)

Each Sensor assembly is composed by a Float Switch, a Screw Tap of each tank, exclusive column, a one-touch plug, and cable. Each Float Switch is mounted on the tip of each column. The Sensor for System Water detects empty of the System Water Tank, and the Sensor for Low or High Conc. Waste detects overflow of each corresponded tank.

(1) Float Switches: Each Float Switch detects empty or overflow of each corresponded Tank. It is mounted on the tip of each exclusive column.

(2) One-touch plugs: Each One-touch plug is to be connected to each corresponded One-touch receptacle on the External Tank Rack. Each has 3 male contacts.

1.3 Measurement flow

1.3.1 Normal measurement flow

Assuming that the required test selection of method has been set on the operational PC and necessary calibration of method has already existed, or the calibrator for the calibration measurement is set at the head on the ASP unit, read the following descriptions.

A) Reagent management (RCU Scan)

“RCU Scan” means that the reagent information is drawn up by reading bar code labels attached to the reagent bottles during one turn of reagent tray in the RCU unit. This process is performed prior to pressing the start key [F1].

B) Preparation

The following operations are performed for preparation of measurement by pressing the start key [F1].

(1) Initialization of hardware
Each unit returns its original position.

(2) Gain setting of absorbance meter
Gain adjustment of halogen lamp is automatically carried out.

(3) Prime
Each pump and syringe operates and sent out solution into each line to release air with nozzles being situated at their respective troughs.

(4) Readout of bar code of sample (only for with bar code control)
An inquiry is made to the PC about measuring schedule on each sample tube in time for sampling (to be in consistency with test selection)

C) Primary reagent measurement

Where there is no shortage of the primary and secondary reagents, pure water, wash solution (and diluent if applicable), the following operational sequence is performed.

(1) Dispensation of primary reagent
The RPT aspirates primary reagent kept in the RCU and dispenses it into cuvettes of the IRU. The RCU and IRU rotate to the respective positions where the reagent is aspirated and dispensed by the RPT.

(2) Dispensation of sample
The SPT aspirates sample kept in the ASP unit and dispenses it into cuvettes in which the primary reagent has already been dispensed. The ASP and IRU rotates to the respective position where the sample is aspirated and dispensed by the SPT.

(3) Stirring
The primary reagent and sample which have been dispensed into the cuvette of the IRU are sufficiently stirred by the paddle (MIX-1). The IRU rotates to the stirring position.

(4) Photometering (1 – 13)
The cuvette in which the primary reagent and sample have been stirred is photometered 13 times every 20 seconds and time course data of the primary reagent is collected. The IRU rotates to the photometering position.

D) Secondary reagent measurement

(1) Dispensation of secondary reagent
The RPT aspirates secondary reagent kept in the RCU and dispenses it into cuvettes of the IRU for which the measurement of the primary reagent has completed.
The RCU and IRU rotate to the respective positions where the reagent is aspirated and dispensed by the RPT.

(2) Stirring
The secondary reagent which has been dispensed into the cuvette of the IRU is sufficiently stirred by the paddle (MIX-2). The IRU rotates to the stirring position.

(3) Photometering (14 – 26)
The cuvette in which the secondary reagent has been stirred is photometered 13 times every 20 seconds and time course data of the secondary reagent is collected. The IRU rotates to the photometering position.

E) Wash

The cuvette for which the time course data of the secondary reagent has been collected moves to the WU unit and the liquid in it is drained and its inside is washed.

1.3.2 Dilution of sample

For the sample of high concentration which exceeds the measuring range of the analyzer, the measurement can be performed after such a sample is diluted. The sample is diluted in accordance with sample and diluent volumes at the time of dilution, and sampling volume, which were specified by the analytical conditions (method conditions). The measurement result is output as the measured concentration corrected in proportion of the volume of diluent.

1.3.3 Reagent blank measurement

The absorbance of the cuvette is measured when only the primary reagent (R1) is dispensed and when both primary and secondary (R2) regents are dispensed. The measurement result is corrected for the measured reagent blank value of each cuvette and consequently the accuracy of the measurement result can be improved.

1.3.4 Water blank measurement

The absorbance measurement of each cuvette in which only water is dispensed is called as “Water blank measurement”. The water blank measurement is carried out on individual cuvettes in which only water is dispensed. The final measurement result is corrected in terms of cuvette-specific difference for the measured water blank value.

The result of the water blank measurement is also used to serve as a guide for assessing stain on the cuvettes. The water blank measurement is performed by selecting the job menu [Maintenance] and then implementing “Cuvette Check” of the function menu [Sequence (F9)].

1.3.5 ISE measurement

The ISE measurement is carried out only when the optional ISE unit is incorporated. The ISE unit measures the concentration of electrolyte (Na, K, and Cl) contained in serum, plasma or urine by the ion electrode. When urine is measured, it is diluted to one-tenth in its concentration.

The diluent for urine must be pre-registered as a reagent code on the [System Parameters] picture.

Test selection is executed using the [Test Selection (F10)] picture of the job menu [Run Monitor (F5)].

The prime, cleaning and calibration are carried out using [Sequence (F9)] picture of the job menu [Maintenance].

1.3.6 Emergency interruption ([Ctrl] + [F2])

When the ongoing measurement is interrupted in case of necessity, the operation of the analyzer can be stopped by pressing [Ctrl] and [F2] keys simultaneously.

Aside from the above, the operation may stop when some kind of abnormal condition which is unavoidable arises in the analyzer.

If the emergency interruption occurs by any reason, the measurements carried out till then become invalid. Before the measurement resumed, the following procedures must be followed:

(1) The cause of the emergency interruption is resolved. For example, in case of the intentional interruption due to erroneous setting of measurement conditions, such an erroneous setting must be corrected.

(2) When the emergency interruption occurs in the system, open the cover of the analyzer and check that there is any item which interferes with the operation of the analyzer. When the cause of emergency interruption is unknown, please get in touch with our customer services.

1.3.7 Easy start of measurement ([Shift] + [F1])

When the operator wants to easily start the analyzer for analytic measurement without any settings of the test selection, the analyzer can be started by pressing [Ctrl] and [F1] keys simultaneously after the sample cup or tube is set in the slot of ASP at will.

This function is available for ASP with barcode reader and without barcode reader.

For ASP without barcode reader, if there are empty slot on ASP, the error (SS error) will be occurred for the empty slot.

The measurement is carried out in accordance with the all executable method items as the chemistry parameter. Of course, the required reagent(s) must be set in the RCU and registered into the system. If one reagent volume is shortage or becomes shortage, its method item is not measured.

If the test selection is defined for the particular samples, they are going to carry out the measurement depending on the present test selection, and for the undefined sample(s), the execution of measurement is carried out in according to the executable method as previous description.

This function is very useful for the employment of measurement which is limited number of measuring items, for example about 5 items or less, as one measurement occasion.

1.3.8 Printout of picture ([Ctrl] + [F5])

The current displayed picture on screen can be printed out by pressing [Ctrl] and [F5] keys simultaneously. But it is not available during measurement.

1.3.9 Stop the alarm sound ([Shift] + [ESC])

To stop the alarm sound, press the [Shift] and [ESC] keys simultaneously.

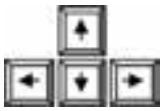
1.4 Basic operational information

This clause contains the description about functions of each key, menu structure, method of data entry, layout of operational pictures, etc.

1.4.1 Keyboards

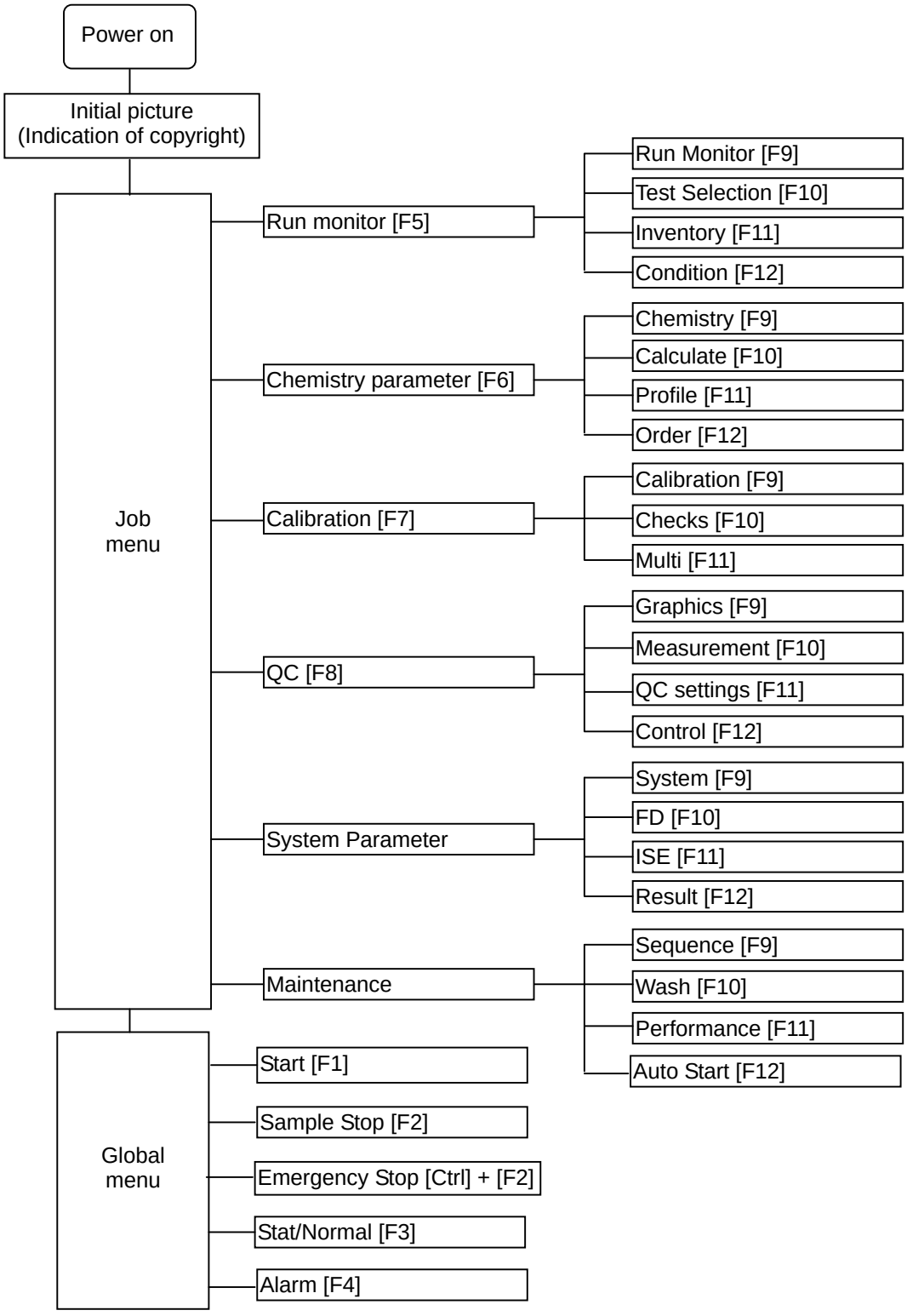
The analyzer is operated by using either keyboards of the PC or a mouse.
The functions of each key except character and numerical keys are shown below. The key ID's in the list are the symbols which are used throughout this manual.

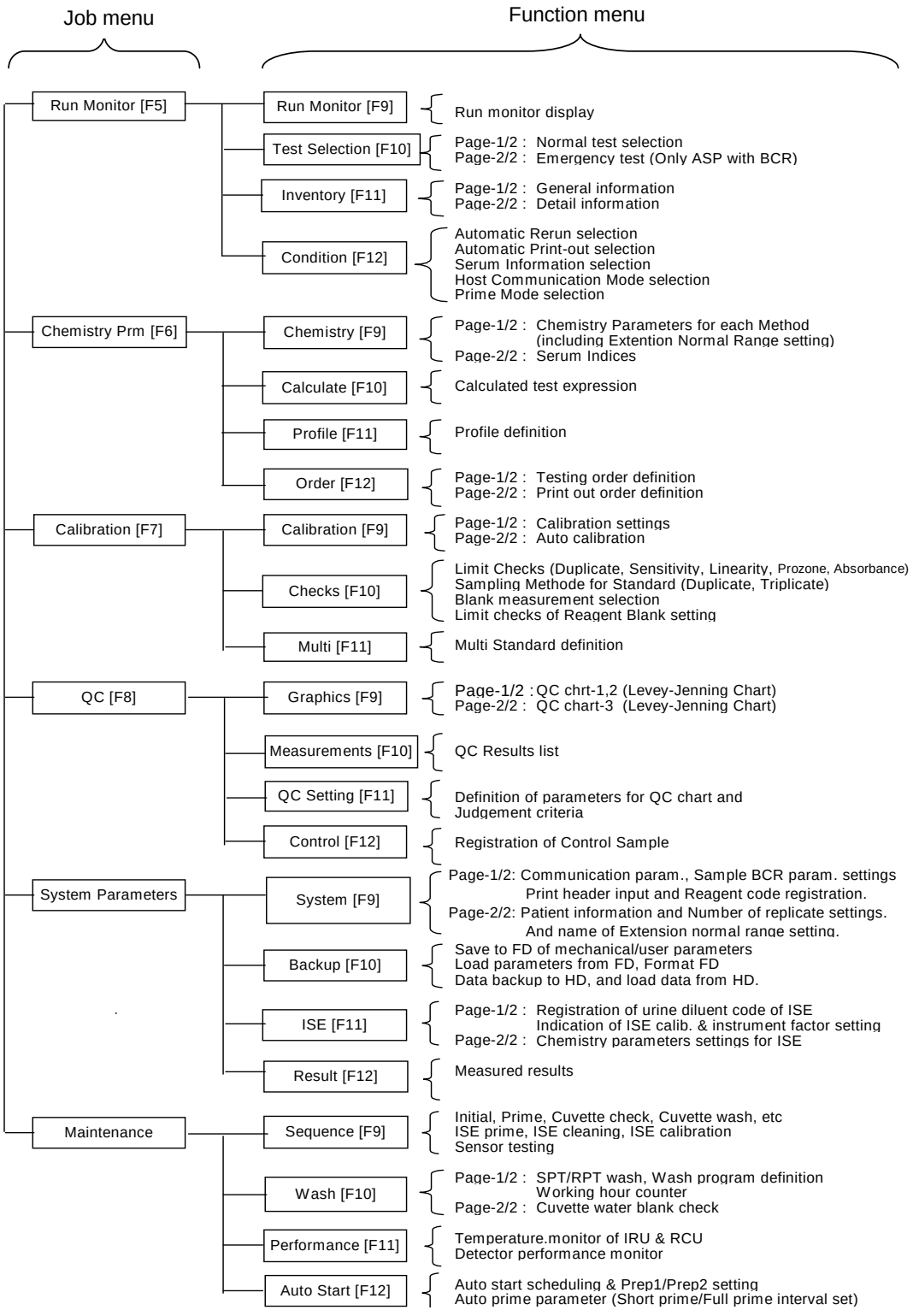
Function key	ID	Function	Description
F1	[F1]	Start	To start or resume measurement.
F2	[F2]	Stop	To stop sampling. Processing of sample whose sampling has been completed is carried on.
F3	[F3]	Stat/Normal	To display the picture on which emergency or normal sample is added.
F4	[F4]	Alarm	To display the alarm picture.
F5	[F5]	Run Monitor	To display the picture of routine operation.
F6	[F6]	Chemistry Parameter	To display the picture of analytical conditions.
F7	[F7]	Calibration	To display the calibration picture.
F8	[F8]	QC	To display the picture of quality control.
F9	[F9]	Picture selection	The assigned function (picture) is dependent on the menu.
F10	[F10]		
F11	[F11]		
F12	[F12]		
Tab	[TAB]	Tab	To move the pointer for selecting wanted item in the picture. The pointer is moved to the reverse direction by pressing [Shift] + [Tab] keys.
Enter	[Enter]	Registration	To register the entered data.
Shift	[Shift]	Shift	The pointer is moved to the reverse direction by pressing [Shift] + [Tab] keys.
			To initiate the easy start of measurement by pressing [Shift] + [F1] keys.
			To stop alarm sound intentionally by pressing [Shift] + [ESC] keys.

	[B-Space]	Deletion of character	To delete characters in the input field one by one.
	[Ctrl]	Control	To terminate measurement intentionally by pressing [Ctrl] + [F2] keys.
			To print out the picture by pressing [Ctrl] + [F5] keys.
	[Home]	Home	To move the cursor to the head of the items in the scroll or list box.
	[End]	End	To move the cursor to the tail of the items in the scroll or list box.
	[PgUp]	Page up	To turn pages forward when a menu consists of multiple pages.
	[PgDn]	Page down	To turn pages backward when a menu consists of multiple pages.
	[Space]	Space	To select item of the menu to be chosen.
	[Cursor]	Cursor	To select an item among selectable (fixed) items, e.g. qualitative or quantitative selection of analytical conditions.
	[ESC]	Escape	To interrupt processing or close window.

1.4.2 Menu structure

The various kinds of operational pictures can be selected by the menu in order to operate the analyzer as shown below.

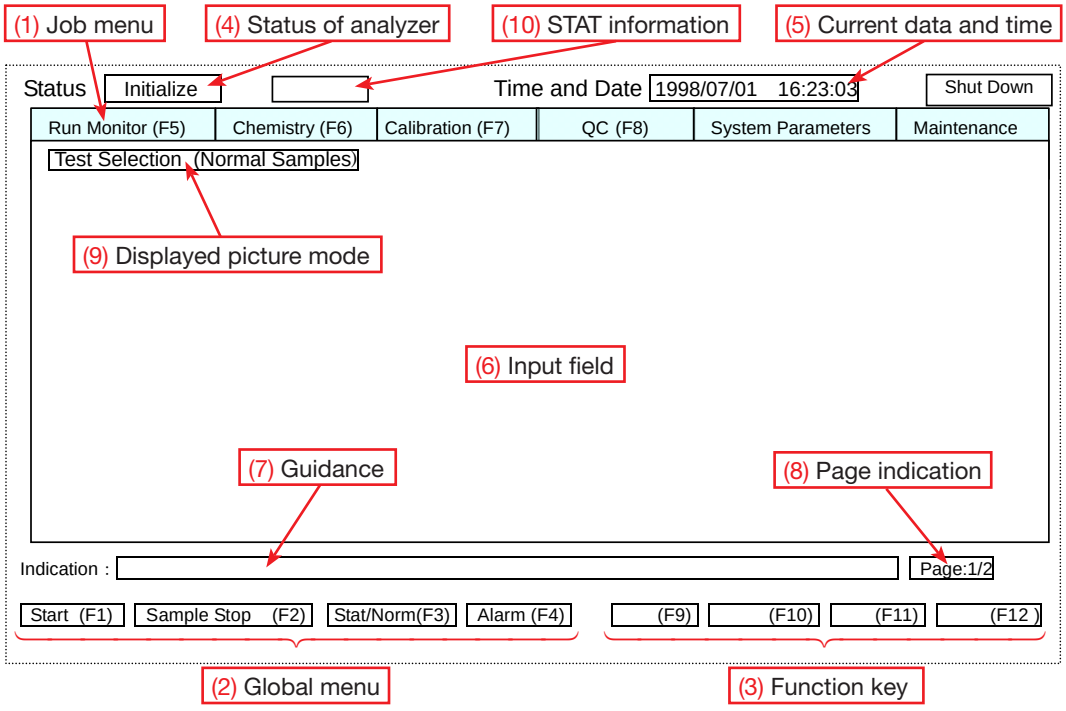



Job menu
Function menu
Run Monitor [F5]
Run Monitor [F9]
Run monitor display
Test Selection [F10]
Page-1/2 : Normal test selection
Page-2/2 : Emergency test (Only ASP with BCR)
Inventory [F11]
Page-1/2 : General information
Page-2/2 : Detail information
Condition [F12]
Automatic Rerun selection
Automatic Print-out selection
Serum Information selection
Host Communication Mode selection
Prime Mode selection
Chemistry Prm [F6]
Chemistry [F9]
Page-1/2 : Chemistry Parameters for each Method
(including Extention Normal Range setting)
Page-2/2 : Serum Indices
Calculate [F10]
Calculated test expression
Profile [F11]
Profile definition
Order [F12]
Page-1/2 : Testing order definition
Page-2/2 : Print out order definition
Calibration [F7]
Calibration [F9]
Page-1/2 : Calibration settings
Page-2/2 : Auto calibration
Checks [F10]
Limit Checks (Duplicate, Sensitivity, Linearity, Prozone, Absorbance)
Sampling Methode for Standard (Duplicate, Triplicate)
Blank measurement selection
Limit checks of Reagent Blank setting
Multi [F11]
Multi Standard definition
QC [F8]
Graphics [F9]
Page-1/2 : QC chrt-1,2 (Levey-Jenning Chart)
Page-2/2 : QC chart-3 (Levey-Jenning Chart)
Measurements [F10]
QC Results list
QC Setting [F11]
Definition of parameters for QC chart and
Judgement criteria
Control [F12]
Registration of Control Sample
System Parameters
System [F9]
Page-1/2: Communication param., Sample BCR param. settings
Print header input and Reagent code registration.
Page-2/2: Patient information and Number of replicate settings.
And name of Extension normal range setting.
Backup [F10]
Save to FD of mechanical/user parameters
Load parameters from FD, Format FD
Data backup to HD, and load data from HD.
ISE [F11]
Page-1/2 : Registration of urine diluent code of ISE
Indication of ISE calib. & instrument factor setting
Page-2/2 : Chemistry parameters settings for ISE
Result [F12]
Measured results
Maintenance
Sequence [F9]
Initial, Prime, Cuvette check, Cuvette wash, etc
ISE prime, ISE cleaning, ISE calibration
Sensor testing
Wash [F10]
Page-1/2 : SPT/RPT wash, Wash program definition
Working hour counter
Page-2/2 : Cuvette water blank check
Performance [F11]
Temperature.monitor of IRU & RCU
Detector performance monitor
Auto Start [F12]
Auto start scheduling & Prep1/Prep2 setting
Auto prime parameter (Short prime/Full prime interval set)

1.4.3 Layout of operational picture on the screen

The layout of operational picture of this analyzer is displayed on the screen as shown below.

The picture is selected by pressing displayed function key on the screen (e.g. [F5] key for Run Monitor) or by positioning the pointer over the wanted item and clicking the left button of the mouse. The System Parameters and Maintenance are usually not used at frequent intervals and thus no function key is prepared for them.



(1) Job menu

The following job menu tags are displayed.

Run Monitor (F5)	See “2.7.1 Monitoring of measurement”.
Chemistry Prm (F6)	See “3.2 Analytical Conditions”.
Calibration (F7)	See “2.3 Calibration Measurements”.
QC (F8)	See “2.11 Quality Control”.
System Parameters	See “3.6 System Parameters”.
Maintenance	See “4.7 Maintenance picture”.

(2) Global menu

These menu items are always displayed at the position shown in the above picture and can be executed in any job menu picture.

Start (F1)	When this button is clicked on, the analyzer is started or re-sumed the measurement. During measurement, this button is flickered with yellow colour.
Sample Stop (F2)	When this button is clicked on during measurement, the action of sampling by SPT in order to analyze is suspended, and this button and “Start (F1)” button are flickered with yellow colour until “Start (F1)” button is clicked on again.

Stat/Normal (F3)	When operator wants to add the emergency or normal sample, this button is clicked on. During the processing of sample addition, this button is flickered with yellow colour. At that time, “Start (F1)” button is not flickered.
Alarm (F4)	When this button is clicked on, the alarm message picture is displayed. When the alarm or error is taken place, this button is flickered with red colour.

(3) Function key

The function keys are used to execute functions and to display information in relation to each job menu picture. The displayed items are different depending on each job menu picture.

(4) Status of analyzer

The following operational status of the analyzer is displayed.

Analyzer initialization in progress.
Analyzer initialization completed.
Analyzer initialization interrupted.
Prime sequence in progress.
Prime sequence completed.
Measurement in progress.
Measurement completed.
Sampling restart in progress.
Sampling restart ready.
Sampling stop in progress.
Sampling stop ready.
Emergency stop.
Emergency stop in progress.
Emergency stop completed.
Analyzer restart in progress.
Analyzer restart completed.
Analyzer restart interrupted.
Sensor reading in progress.
Sensor reading completed.

(5) Current date and time

Current date and time are displayed.

(6) Input field

Each picture and window is displayed in this field for entry of data and parameters.

(7) Guidance

Operational instruction is displayed. When moved to the other input window, range of values to be entered into the window or entry method is displayed.

(8) Page indication

The page is displayed when a certain menu has a multiple pages. The pages can be turned by [PgUp] or [PgDn] keys.

(9) Displayed picture mode

The title of the currently displayed picture mode is indicated.

(10) STAT information

During the emergency sample is executed, “STAT” message, (background is red.) is displayed. But when the normal measurement is proceeding fills its block with blank code.

Chapter 2

Procedure of routine check

This chapter provides the operational procedures for routine check.

This chapter consists of:

2.1 Checks prior to work and power-on

2.1.1 Checks prior to work

A) System water tank and waste tank

Confirm that;

1. The system water tank is filled with pure water;
2. Each waste tank is emptied;
3. If waste liquid still remains in waste tank(s), the tip(s) of each waste drain tube stays above the waste liquid level, and
4. The tip of pure water supply tube is located in the bottom of the system water tank.

During measurement, check periodically that the system water tank is not empty and the tip of the waste drain tube does not touch the waste liquid level. When the tip of the waste drain tube touches the waste liquid level, the flow of the liquid is adversely affected and this may cause a trouble.

B) Wash solution tank

Confirm that;

1. Each wash solution tank is filled with sufficient wash solution, and
2. The tips of wash solution supply tubes are located in the bottom of the tanks.

C) ISE unit (option)

Before performing measurement with the ISE unit, confirm that;

1. Electrode unit (Na, K, Cl and Reference electrodes) whose term of validity is not expired is installed;
2. The calibrant A bottle beside the ISE unit is filled with sufficient liquid;
3. Cleaning was carried out at the end of the last ISE measurement, and
4. The calibrant A is flowing from the side of sample port by executing of ISE prime.

In the following cases, ISE prime should be carried out 10 times more.

5. First measurement of ISE.
6. At the time of exchanging of the calibrant A.
7. At the time of being pulled up the tube from the calibrant A

When the main unit is on after it was kept off, 2-calibrator calibration must be carried out.

In order to perform 2-calibrator calibration, the sample cup contained the calibrant B is placed at No. 18 position on the ASP tray. Therefore, 2-calibrator calibration is carried out by using [Sequence (F9)] of the job menu [Maintenance].

Note: As much as possible, the analyzer should be kept on, because 120 µL of Calibrant A is automatically dispensed into the ISE unit every 30 minutes to prevent the electrodes from drying. Even under the sleep condition, this function is performed. Just after turning on the analyzer, 5 times of ISE prime are carried out automatically. All electrodes should be fitted to the ISE module; otherwise the liquid of Calibrant A is flooded into the inside of analyzer. It may be caused serious problem. Thus, don't forget the fitting of electrodes before ISE measurement.

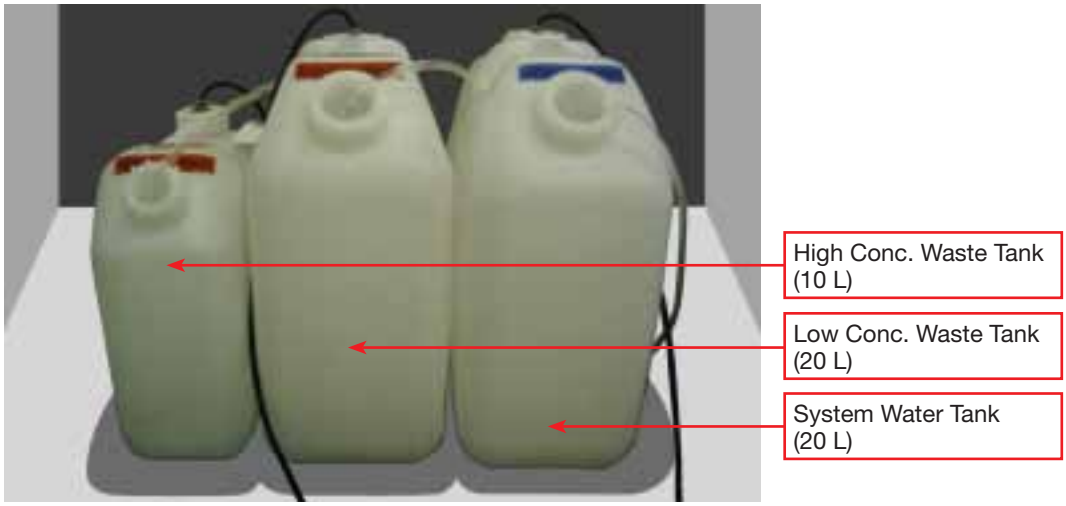
2.1.2 Preparation of external tank solutions

The external tanks of the system water, wash solution, low conc. waste and high conc. waste are to be placed near the right-hand side of the analyzer, and to be connected to the analyzer (SWU panel) with the corresponded tubes.

At just before measurement, the external tanks of the system water and wash solution are filled with the corresponded liquids, and the tanks of the low conc. waste and high conc. waste are to be empty.

And confirm that;

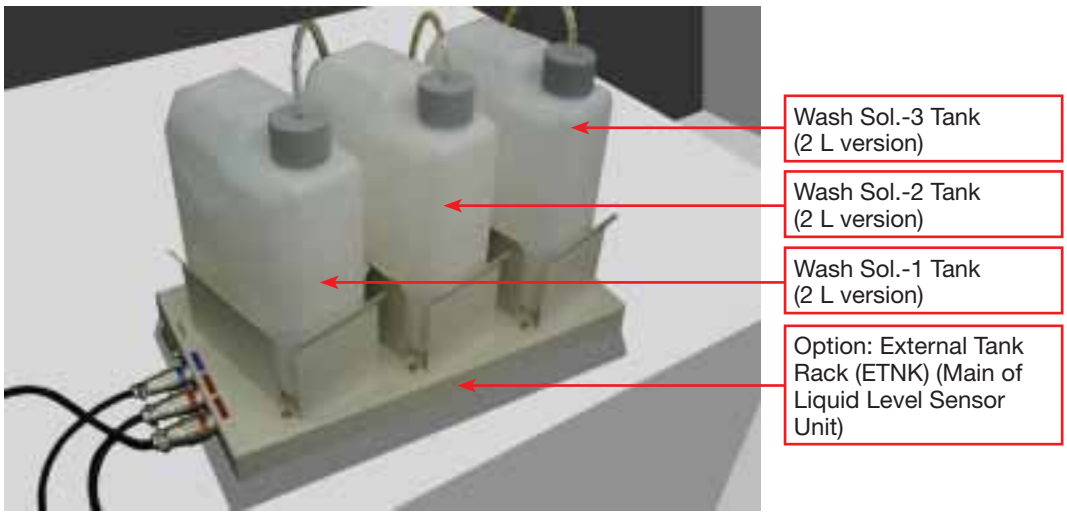
1. The tips of tubes for supplying liquid are located in the bottom of the each tank.
2. The tips of waste drain tubes are out of the liquid level.



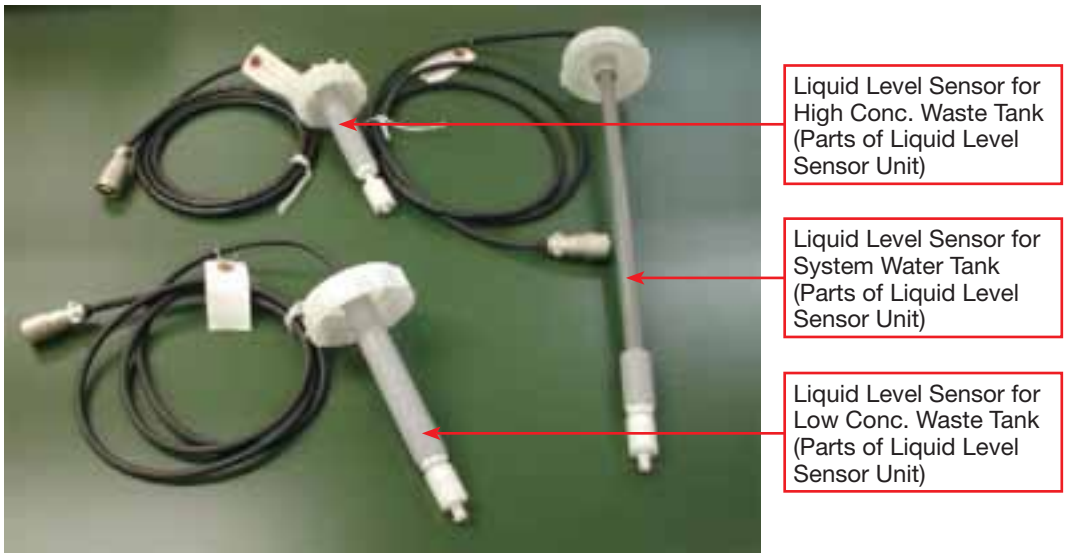
External Tanks (1)

Tube connection of SWU Panel (on the right-hand side of the analyzer)

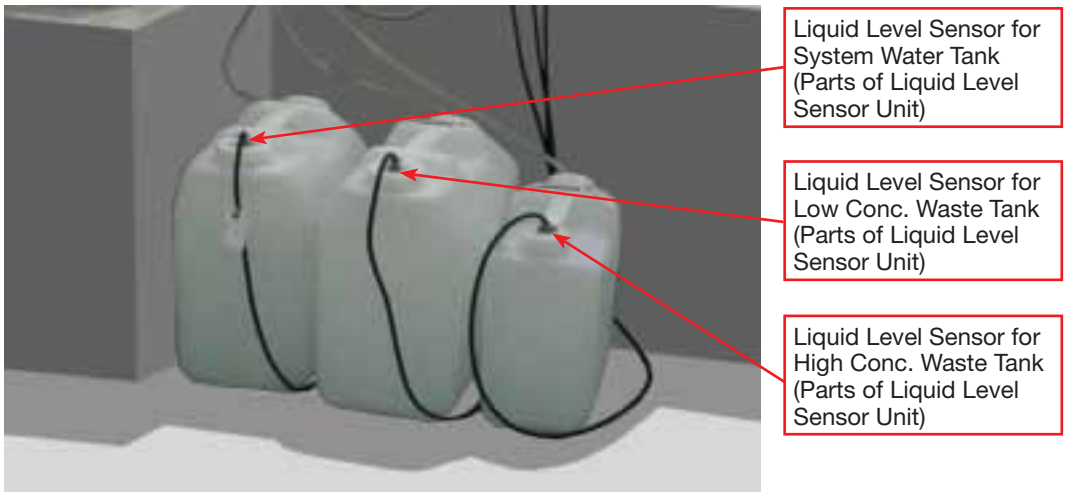
If you use the Liquid Level Sensor Unit for External Tanks (option), you have to place 3 tanks of 2 L on the External Tank Rack (ETNK: Main of Liquid Level Sensor Unit) for Wash Solutions, and set the Liquid Level Sensors (Float Switches; parts of Liquid Level Sensor Unit) on the corresponded 10 L and 20 L tanks.



Setting of External Tank Rack



Liquid Level Sensors (Float switches)



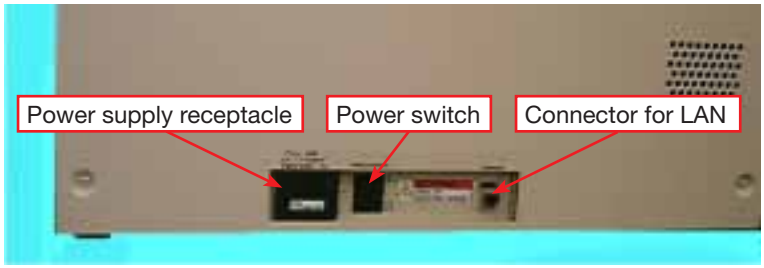
Setting of Liquid Level Sensors (Float switches)

2.1.3 Power-on

A) Power-on of main unit

If the main unit is attached the ISE unit, all electrodes and Calibrant A solution should be fitted to the ISE unit in advance with the power switch is turned on.

The power switch is located on the left side panel of the main unit.



B) Power-on of personal computer (PC)

Power the PC which is connected to the main unit.

Normally, the software for the main unit starts up automatically when the PC is powered on.

After installation of the analyzer, when the PC is powered on, the analyzer should be carried out the prime sufficiently in order to deflate the tubing line of the water and solution.

And also the prime mode setting should be performed in advance with the starting of measurement, which is performed in the function menu [Condition (F12)] picture of the job menu [Run Monitor (F5)]. (Default setting is set to “Auto Prime Mode”.)

Thereafter, when the measurement is started, the priming is performed in accordance with the prime mode, if operator changes the prime mode setting.

C) Automatic preparation mode in advance of measurement

Before measurement, operator selects one of the below modes.

1. Full prime mode: At the round start, full prime and auto-gain process are performed.

2. Auto prime mode (default setting): When the measurement is started, the priming is performed either the long prime or short prime in accordance with “Auto Prime Parameter”. “Auto Prime Parameter” is specified in the function menu [Auto Start (F12)] picture of the job menu [Maintenance].

(1) Full prime: Execution of the long priming as below

Long Prime Mode

Pump or syringe name	Operating period
SWU MX1 Pump for Mix-1 trough	ON:18 sec
SWU MX2 Pump for Mix-2 trough	ON:16 sec
SWU Water Pump for SPT trough	ON: 3 sec
SPP-S1 Syringe for SPP unit	Water discharge: 1500µl x 10 times
RPT-water1 Pump for RPT trough	ON: 3 sec
RPT-water2 Pump for RPT trough	ON: 3 sec
RPT-detergent Pump for RPT trough	ON: 3 sec
RPP Syringe for RPP unit	Water discharge: 2000µl x 10 times
WPP-1,3 Syringe for WU1 and WU3	Water prime: 600µl x 10 times
WPP-1,3 Syringe for WU1 and WU3	Solution prime: 500µl x 10 times
WPP-2, 4, 5, 6 Syringe for WU2, 4, 5 and WU6	Water prime: 600µl x 20 times

(2) Short prime: Execution of the short priming as below.

Short Prime Mode

Pump or syringe name	Operating period
SWU MX1 Pump for Mix-1 trough	ON:1 sec
SWU MX2 Pump for Mix-2 trough	ON:1 sec
SWU Water Pump for SPT trough	ON: 1 sec
SPP-S1 Syringe for SPP unit	Water discharge: 1500µl x 1 time
RPT-water1 Pump for RPT trough	ON: 1 sec
RPT-water2 Pump for RPT trough	ON: 1 sec
RPT-detergent Pump for RPT trough	ON: 1 sec
RPP Syringe for RPP unit	Water discharge: 2000µl x 1 time

Number of short prime execution is able to be specified in the function menu [Auto start (F12)] picture of the job menu [Maintenance].

3. Skip mode: If operator selects this mode, when the measurement is started, prime and auto-gain process are skipped for this round. But this skip mode becomes invalid after this round is completed.

Function menu [Condition (F12)] picture of the job menu [Run Monitor (F5)]

When the “Auto Prime Mode” is selected from above “Prime Mode”, the priming procedure is automatically executed in accordance with below parameters by system just after pressing START key to start the measurement.

Function menu [Auto Start (F12)] picture of the job menu [Maintenance].

4. When the time of start of measurement is within the time specified in “Short prime interval” from last completion of measurement, system will execute the auto-gain adjustment without any priming.

5. When the time of start of measurement is greater than the time specified in “Short prime interval” but less than the time specified in “Full prime interval”, system will execute the short priming with specified number in “Number of Short Prime” and the auto-gain adjustment.

6. When the time of start of measurement is greater than the time specified in “Full prime interval” from last completion of measurement, system will execute the long priming and the auto-gain adjustment.

D) Automatic ISE priming

Just after turning on the analyzer, 5 times of ISE prime are carried out automatically. All electrodes should be fitted to the ISE module; otherwise the liquid of Calibrant A is flooded into the inside of analyzer. It may be caused serious problem. Thus, don't forget the fitting of the electrodes to the ISE.

E) Power-on of printer

Power on the printer. At this time, make sure that the printer paper is correctly loaded.

2.1.4 Power-off

A) Shut-down of PC

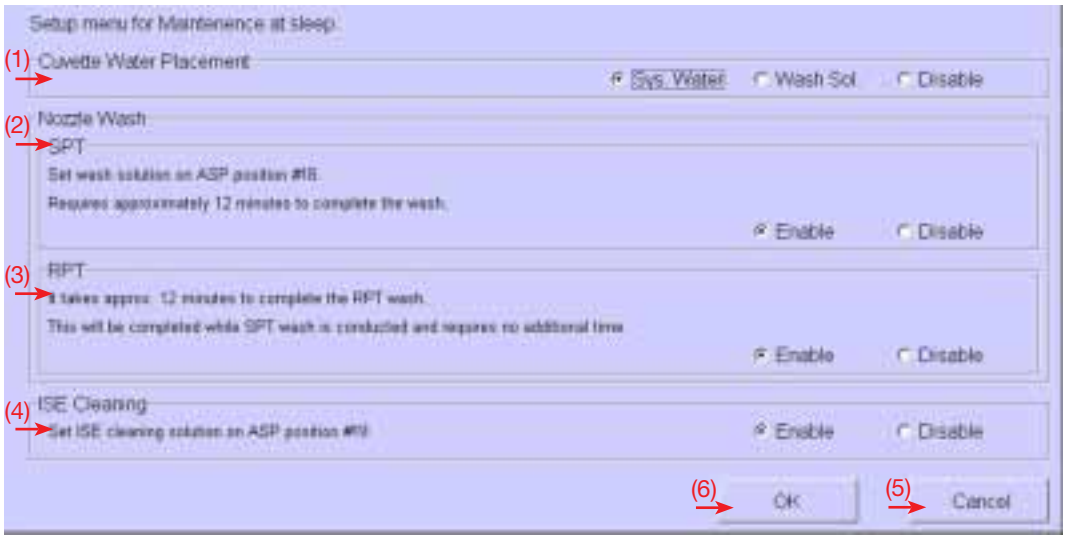
The following function is selectable when you click Shut Down on the upper right-hand corner of the screen. Either one of "Sleep" or "Power Off" is selected.

1. Sleep: Where the "Sleep" mode is selected, the system is kept under the sleep condition until it will be activated at the time of the day of the week specified on the [Auto Start [12]] picture of job menu [Maintenance].
   During sleeping, the temperature inside the RCU unit is kept at 8 to 15ºC and the calibrant A is dispensed into the ISE unit every 30 minutes for prevention of the electrodes from drying.
2. Power Off: Where the "Power Off" mode is selected, the system is switched off and the temperature inside the RCU unit is not controlled.
3. Cancel: When the "Cancel" is selected, the Shut Down mode selection becomes invalid.

B) Procedure of "Sleep" selection

1. When the Shut Down tag on the upper right-hand corner of the screen is clicked on, the shut down mode selection picture is popped up.

2. When the Sleep button is clicked on, the following popup menu is displayed so that the items to be performed before going to the sleep mode are designated.



(1) Select whether the cuvette water placement is performed before going to the sleep mode. (Refer to "4.7.2 Nozzle Wash [Wash (F10)] Page: 1/2".)

Sys. Water : All cuvettes are filled with system water (purified water).

Wash Sol. : All cuvettes are filled with wash solution where is placed in the RCU.

Disable : Cuvette water placement is invalid.

Note: Beforehand the registered bottle containing the wash solution is placed in the RCU. Diluted C1 solution (1/100) should be used as the wash solution.

(2) Select whether SPT nozzle wash is performed before going to the sleep mode.

Enable : SPT nozzle wash by wash solution is performed.

Disable : SPT nozzle wash is invalid.

When "Enable" is selected, a sample cup being filled with wash solution should be placed in the ASP position #18 before clicking on the OK button.

It takes about 12 minutes to complete this nozzle wash process.

Note: Diluted C1 solution (1/100) is used as the wash solution.

(3) Select whether RPT nozzle wash is performed before going to the sleep mode.

Enable : RPT nozzle wash by wash solution is performed.

Disable : RPT nozzle wash is invalid.

When "Enable" is selected, the registered bottle containing the wash solution should be placed in the RCU before clicking on the OK button. (Same as "Wash Sol." of (1).)

It takes about 12 minutes to complete this nozzle wash process.

Note: The sort of applied wash solution and its name should be set in advance. (See "(5) of 4.7.2 Nozzle Wash [Wash (F10)] Page: 1/2".)

(4) Select whether ISE cleaning is performed before going to the sleep mode.

Enable : ISE cleaning is performed.

Disable : ISE cleaning is not performed.

When "Enable" is selected, a sample cup being contained ISE cleaning solution should be placed in the ASP position #19 before clicking on the OK button.

Note: If ISE unit (option) is not installed in the analyzer, this selection will not appeared.

(5) When click on the Cancel button, the system returns to the condition of before cricking on the Shut Down tag on the upper right-hand corner at the screen.

(6) When click on the OK button, the system starts to execute the cuvette water displacement and the previous selected items that have been designated in the popup menu. The analyzer goes to the sleep mode thereafter.

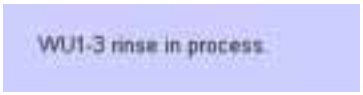
3. Executing the cuvette water displacement and the other selected items.

(1) Carrying out the system initialization.

(2) Carrying out the cuvette water displacement.

(3) Carrying out the system initialization. (Same as previous picture)

(4) Carrying out the rinsing WU1 and WU3 with purified water.



(5) Carrying out the system initialization. (Same as previous picture)

(6) Carrying out the ISE cleaning (3 times) when “Enable” has been selected.

(7) Carrying out the system initialization. (Same as previous picture)

(8) Carrying out the nozzle wash (SPT and/or RPT) when “Enable” has been selected.

(9) Carrying out the system initialization. (Same as previous picture)

(10) Carrying out the cuvette water placement when “Sys. Water” or “Wash Sol.” has been selected.

(11) Carrying out the system initialization. (Same as previous picture)

4. Preparing process for going to the sleep mode.

Carrying out the preparation process for the sleep mode.

5. Entering the sleep mode.

The [Auto Start (F12)] screen of the job menu [Maintenance] is displayed in the screen and the “Sleep” mode is established.

C) Shut-down of main unit

1. If the “Sleep” is selected, do not cut the power supply for both main unit and PC and leave them on to enable them to be reactivated automatically.

2. If the “Power Off” is selected, the temperature control inside the RCU unit is disabled.

D) Power-off of printer

Cut the power supply for the printer as necessary.

2.2 Preparation and placement of reagent

Necessary reagents, diluents and wash solutions for analyses are placed in the reagent tray. The reagent tray accommodates 40 bottles of them in total.

2.2.1 Placement and registration of reagents, diluents and wash solutions

The bottles of reagent, diluent and wash solution may be placed at any position of the reagent tray.

The registration of them is carried out in accordance with the following procedures:

1. Remove the lid of the reagent container unit (RCU) and take out the reagent tray.
2. Remove caps of bottles and place them in the tray.
3. Put back the loaded tray into the RCU.

Then turn the tray gently until its pin guide snaps on at the specified position.

4. Close the lid of the RCU.
5. When page 1/2 of [Inventory (F11)] picture of job menu [Run Monitor (F5)] is selected, the currently registered bottles are indicated.

The number of inside cell except the row of “Test” in the below picture shows the slot number of RCU where reagent bottle is loaded.

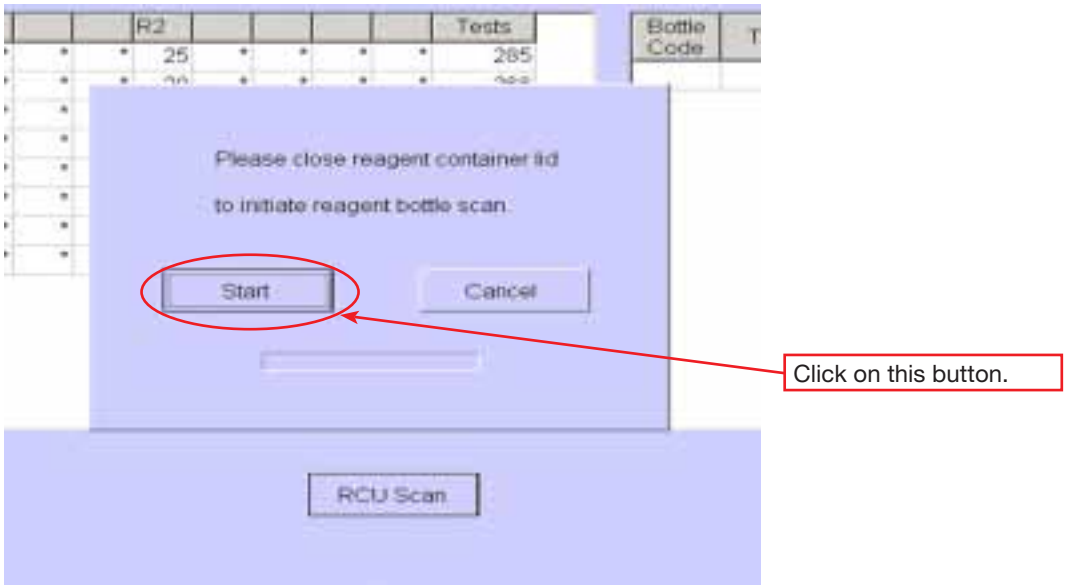
If each cell is coloured with red, pink or yellow, the meaning is;

(1) Red : Insufficient reagent inventory.

(2) Pink : Date expired.

(3) Yellow : Stability overdue.

6. When RCU Scan button in the picture is clicked on, the following pop-up window is displayed. The RCU starts rotating for registration update of the bottles of reagent, diluent and wash solution in the reagent tray by clicking on Start button.

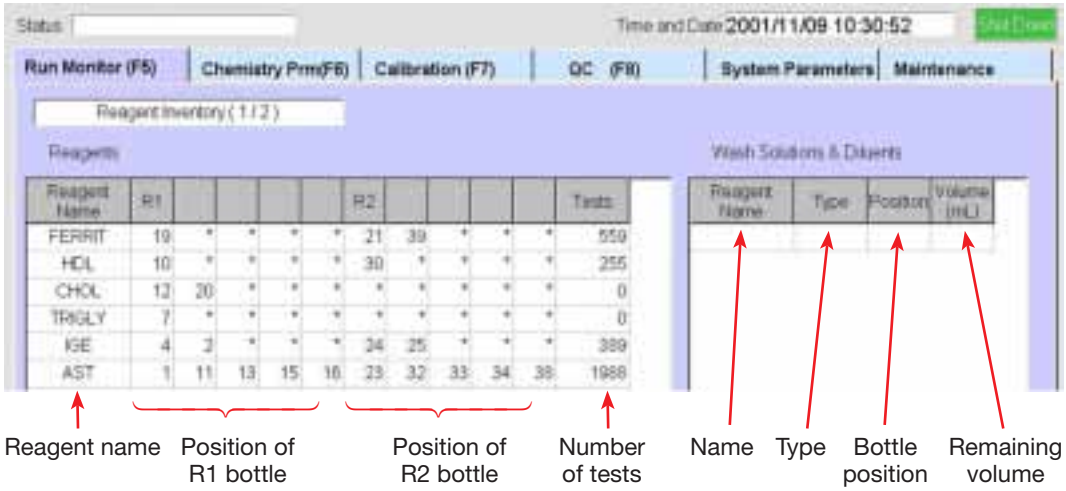


2.2.2 Check of reagent remaining volume

After RCU Scan has been executed or where the reagent bottles have already been placed, the remaining volumes of each reagent are checked according to the following procedures.

The remaining volumes of each reagent can be checked on pages 1/2 and 2/2 of [Inventory (F11)] picture of job menu [Run Monitor (F5)]

A) Page 1/2 picture



B) Page 2/2 picture

More detailed information than the page 1/2 can be seen.

If operator wants to manually input the barcode of any bottles, it is allowable on this picture.

See the following description at item-(9).

(1) RCU Position:

Bottle position (RCU slot number: 1 - 40)

(2) Reagent Name:

This name that is registered in the [System (F9)] picture of job menu [System Parameters] is applied.

(3) Reagent Type:

Discrimination of reagent type (R1, R2, Wash or Diluent).

(4) Bottle Size:

Distinction of bottle size (L: Large size, M: Middle size, S: Small size) is displayed on this cell.

(5) Volume (mL):

Remaining volume (minimum unit: 0.1mL).

(6) Tests:

Number of possible tests (R1 or R2 whichever is less number of tests with remaining volume.).

(7) Method Name:

Applied method name.

(8) Vol/Test (µL):

Necessary reagent volume per a test (minimum unit: 1µL). R1 or R2 whichever is greater volume of use.

(9) Stability Term:

Remaining days of stability terms for respective reagents is displayed. When the stability is overdue, its line is shown with yellow colour.

(10) Barcode:

Barcode label is displayed.

Barcode can be modified/entered with a keyboard by double clicking the mouse on this cell.

Note: When the remaining volume for applicable reagent becomes short for measurement, this line is displayed with red colour. When the applicable reagent is expired, this line is displayed with pink colour. When the stability term for applicable reagent that has been specified in "System Parameters" screen exceeds, this line is displayed with yellow colour.

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(11) RCU Scan:

When RCU Scan button is clicked on, following menu is popped up in centre of picture.

And the RCU rotates and the reagents are registered by clicking on Start button.

(12) Save:

Setting parameters are saved when this button is clicked on.

(13) Delete:

Specify any desired slot line by clicking on the corresponding reagent bottle number and click on Delete button to delete the reagent in that line. If such a deletion is made effective, click on Save button.

(14) Cancel:

Before clicking on Save button, if this Cancel button is clicked on, any modified parameters are returned to original.

(15) Volume Reset:

Specify the desired bottle volume cell by clicking, and click on Volume Reset Volume Reset button. Its reagent volume is re-set to full volume. If such a modification is made effective, click on Save button.

2.3 Calibration Measurement

The periodical calibration is required for each method in order to perform stable and accurate measurement. The calibration measurement for certain method is performed according to the settings of “Chemistry Parameters” pictures (Page 1/2 and 2/2).

There are two kinds of calibrations as shown below:

1. Full calibration: The calibration curve is made using all the necessary calibrators for calibration and the master calibration curve is then updated.
2. Re-calibration: The work calibration curve is corrected and updated using one or two selected calibrators.

The following two kinds of calibration curves are provided:

3. Master calibration curve: The calibration curve obtained from the full calibration (at the beginning, Master calibration curve = Work calibration curve)
4. Work calibration curve: The calibration curve corrected by the re-calibration.

The one used for the routine measurement is the work calibration curve.

In the case of using different lot number of reagent to get the calibration curve, two sets of calibration curves are respectively stored in the equipment as “New” and “Old”.

[For example]

1st : Measured calibration curve is stored in the new area.

2nd : Measured calibration curve that was used the different lot number of reagent in the 1st and 2nd measurement is stored in the new area after original curve in the new area is moved to the old area.

3rd : Measured calibration curve that was used the different lot number of reagent in the 1st, 2nd and 3rd measurement is stored in the new area, after old area’s curve is eliminated and new area’s curve is moved to the old area.

In the case of using same lot number of reagent, the newly obtained calibration curve is always stored in the new area after the original curve in the new area is moved to the old area.

When any error is taken place during calibration measurement, the measurement result does not become available for the calibration curve. But when the valid term of reagent for the calibration measurement is expired, the measurement result is used for calculation of calibration curve.

Where a measured variation of absorbance (ΔABS) is out of calibration curve, its result of concentration is found from low or high end of calibration point or expanded calibration curve. In both case, the flag of “OVR” is attached to its result. This case is available when “Spline”, “Point to Point” and “Log-Logit” are selected for equation type as calibration curve, but in the case of “Factor”, “Linear” and “Exponential” are selected, the flag of “OVR” is not attached to result even if the concentration is out of calibration curve.

How to specify the extending of min. and max. calibration, refer to “(2) Optional settings – D: Miscellaneous settings” of “3.6.1 System Parameters [System(F9) Page 1/2]”.

2.3.1 Calibration measurement order

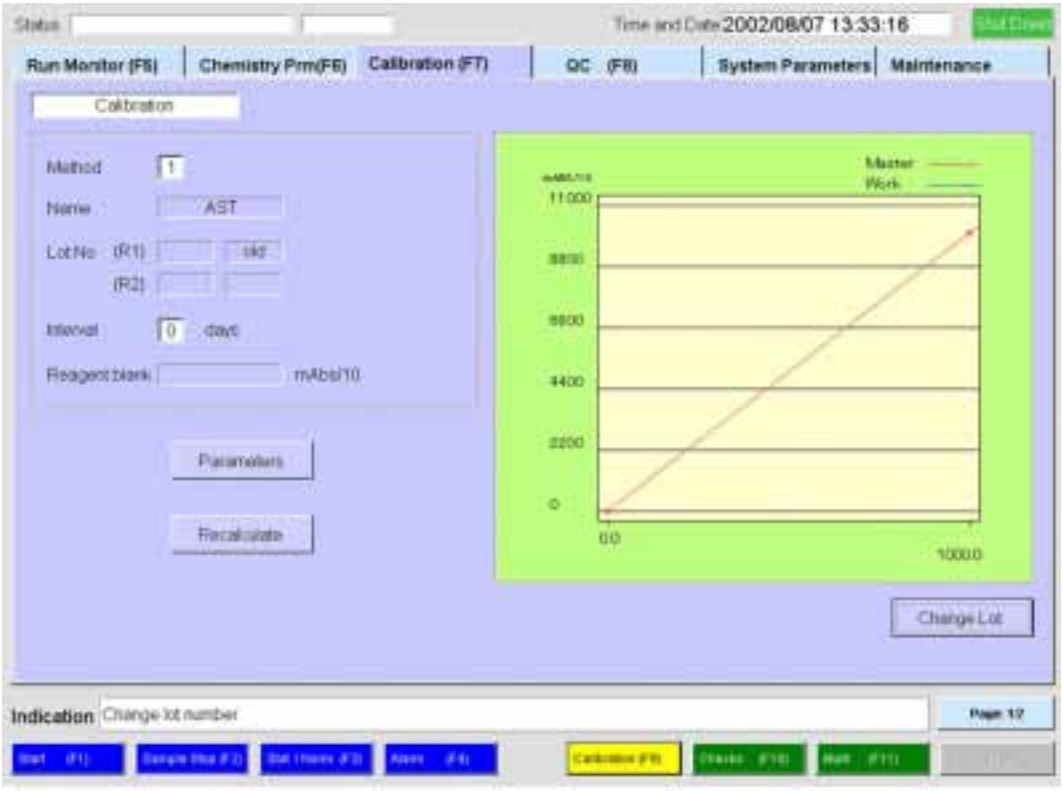
Where the ASP unit is provided with the barcode reader, there is no need to order the calibration measurement with the relevant picture on the screen. The calibration order is given by placing the required number of calibrators in the equipment. The judgement of full

calibration or re-calibration (one-calibrator or two-calibrator calibration) to be performed is made depending on the number of calibrators placed in the equipment. The calibrator is normally placed at the front of normal sample in the ASP unit. Where the ASP unit is not provided with the barcode reader, refer to the input method of sample order in “2.4.10 Test Selection for Off-line mode (ASP without BCR)”.

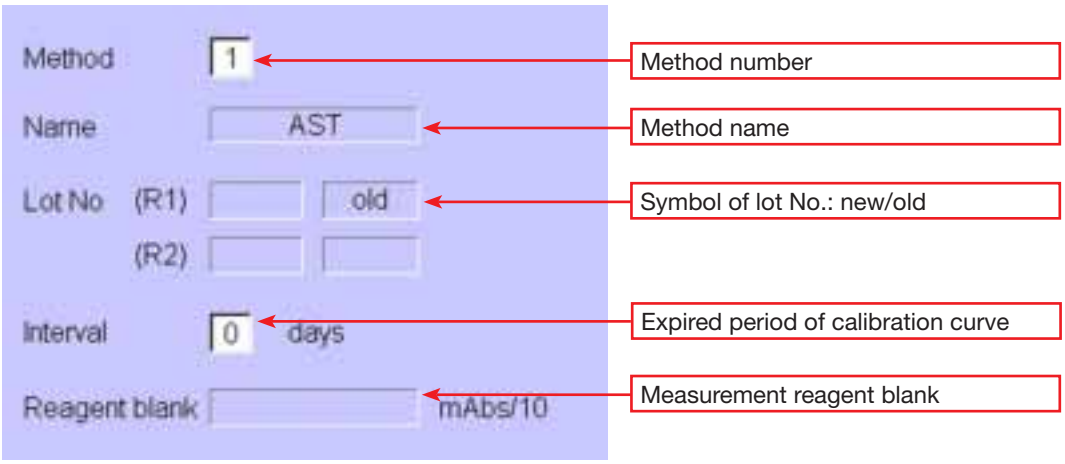
2.3.2 Settings of calibrator concentrations

When calibration measurement is performed, concentration values of each calibrator are entered beforehand.

1. Select job menu [Calibration (F7)] picture.
2. Select function menu [Calibration (F9)] picture.



3. The method may be selected by either one of the following two ways:



(1) Move the cursor on “Method” and enter the required method number in the box using the numeric keys, or

(2) Press [SPACE] key to display the pop-up window showing registered methods and click on the desired method number in it.

01. AST	02. UREA	03. CHOLE	04. TRIGLY	05. FERRIT
06. IGE	07. ALK	08. HDL	09. ast2	10. urea2
11. chole2	12. trigl2	13. ferri2	14. ige2	15. alk2
16. hdl2	17. ast3	18. urea3	19. chole3	20. trigl3
21. ferri3	22. ige3	23. alk3	24. hdl3	25.
26.	27.	28.	29.	30.
31.	32.	33.	34.	35.
36.	37.	38.	39.	40.
41.	42.	43.	44.	45.
46.	47.	48.	49.	50.
51.	52.	53.	54.	55.
56.	57.	58.	59.	60.

When the method code is specified, the method name in “Name” column is automatically displayed.

4. Lot numbers of the reagent bottles which are placed in RCU and are registered to the analyzer to be used in the calibration measurement are automatically displayed in the lot number columns as R1 and R2.

5. Next of the lot number boxes for R1 and R2 are for displaying of lot symbol (old or new).

This symbol is selected by clicking on Change Lot button that is displayed at the bottom of right-hand side on the screen. Please refer to the picture at previous page.

6. Expired of the calibration curve can be specified in the “Interval” box.

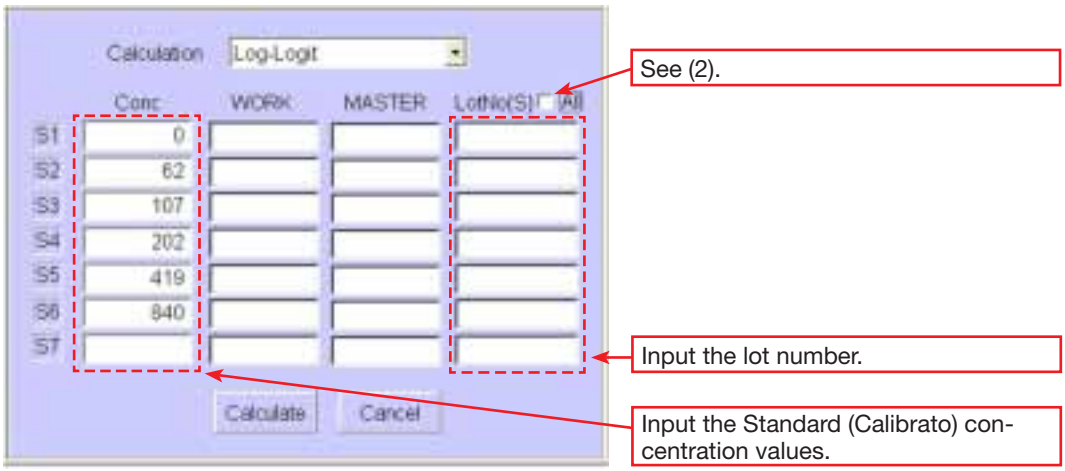
0 day : Expired period is not checked.

1 to 9 days : This number of days mean elapse days from last measured calibration curve is checked. When the term expires, warning is occurred in the “Test Selection”.

7. When the reagent blank has measured, its value is displayed in the “Reagent blank” box.

8. When the calibration curve already exists, its curve is displayed on the right-hand side of the screen. Otherwise, this region is blank.

9. The standard concentration values of calibrators are then entered. Click on Parameters button to display the following pop-up window.



(1) Enter standard concentration values of required number of bottle into the “Conc.” boxes as shown in the statement of virtues accompanied with reagent kits.

Absorbance values (mAbs/10) are automatically entered in the “Work” and “Master” boxes upon the completion of the calibration measurements for each calibrator placed in the analyzer. When “Factor” calibration type is selected, the concentration input is not needed.

(2) Lot number of the standard (calibrator) can be specified by inputting its number.

When “Factor” calibration type is selected, the lot number input is not needed.

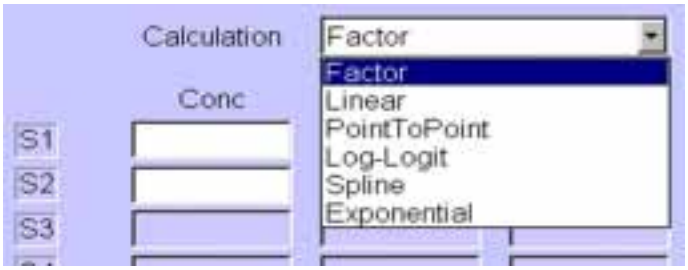
Check in the box of “All”;

☑ All: Only the lot number for S1 is allowed entering but the others (S2 to S’) can not be entered. After the lot number of S1 is entered, other lot numbers for calibrators are automatically set.

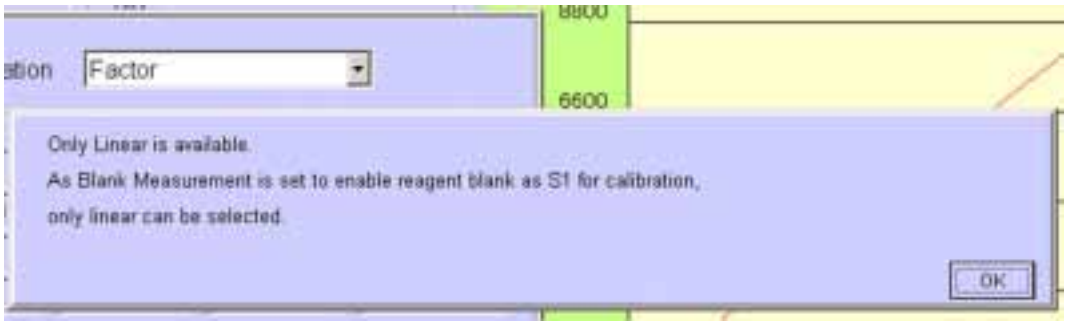
No check in the box of “All”:

☐ All: Lot number of calibrators can be entered individually (S1 to S7).

(3) Select the required equation for calibration curve calculation from the pull-down menu of “Calculation” box.



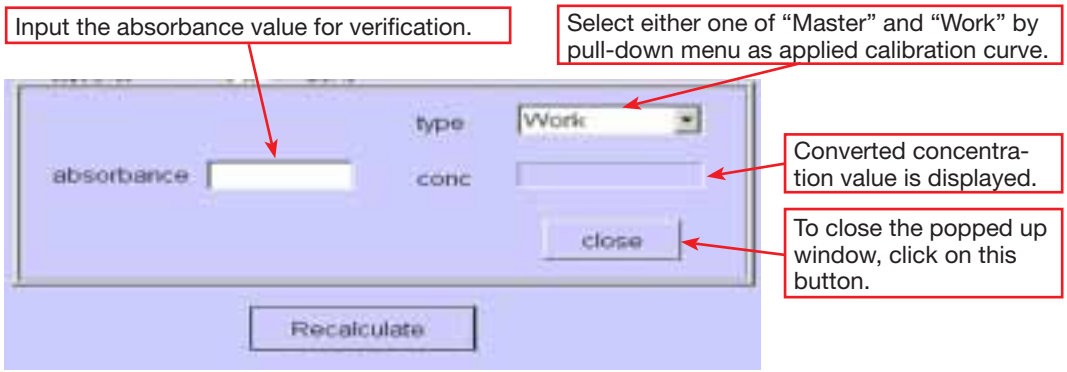
When the “Enable reagent blank” is set to “Enable” in the function menu [Checks (F10)] of job menu [Calibration (F7)], the type of calibration curve except “Linear” cannot be selected. If such selection is done, the following error message will be appeared in the screen. (See “2.3.5 Confirmation of judgement criteria and measuring conditions [Checks (F10)]”.)



(4) Click on Calculate button to store data of the standard concentration values necessary for the calibration.

10. To verify the conversion of absorbance to concentration by using current calibration curve, click on Recalculate button.

The following window is popped up and either one of “Master” and “Work” can be selected for applied calibration curve. Input the absorbance value for verification, then converted concentration value is outputted into the conc. box.



2.3.3 K Factor

The method to convert a measured absorbance into concentration is usually such that an equation is obtained based on a calibrator and then a concentration of sample is obtained using the equation. In this case, the calibration measurement on the calibrator must be performed before measuring sample.

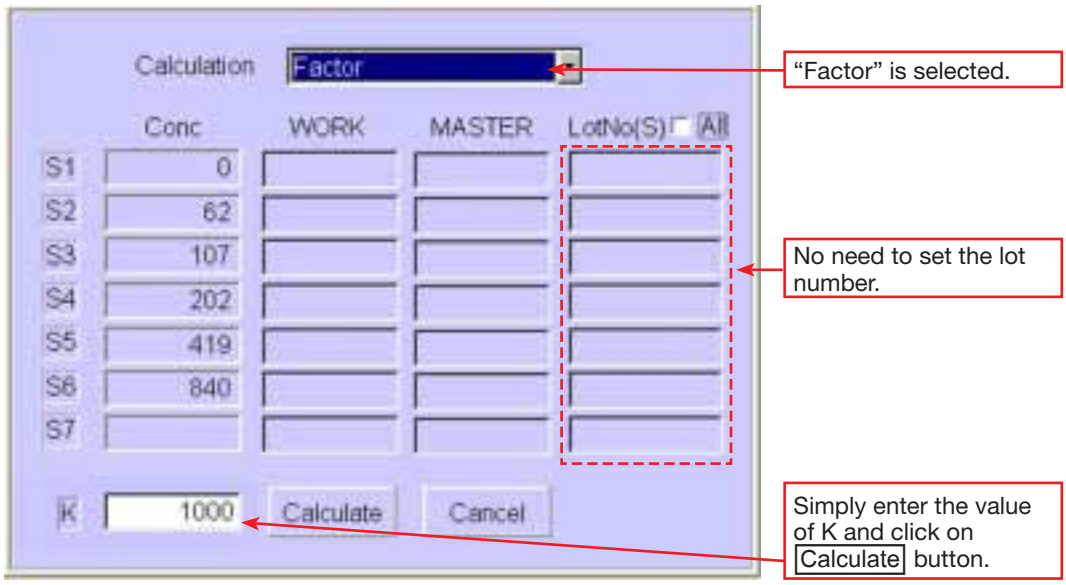
When it is known that the concentration of sample varies linearly, the measured absorbance may be converted into the concentration using the following equation:

$Con = K \cdot A + B$ where Con: concentration, A: measured absorbance, K: factor (conversion gradient), B: initial concentration.

This conversion method by defining the parameter K is called as “K-Factor” method.

When “Factor” is selected as the type of calibration, the calculation equation is defined only by specifying K factor. At the time of defining the equation, the initial concentration B is zero, which will however be corrected by S1 blank. (Refer to “2.3.5 Confirmation of judgement criteria and measuring condition”.)

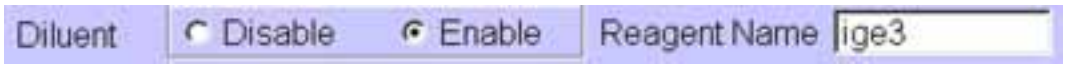
Note: Don’t set any concentration value in the “Conc.” column. In the case of using K-Factor, “Lot No.” should be selected “NEW”.



2.3.4 Full calibration using a single calibrator

The full calibration can be performed using not multiple calibrators but a single calibrator of highest concentration, by means of automatic dilution measurement.

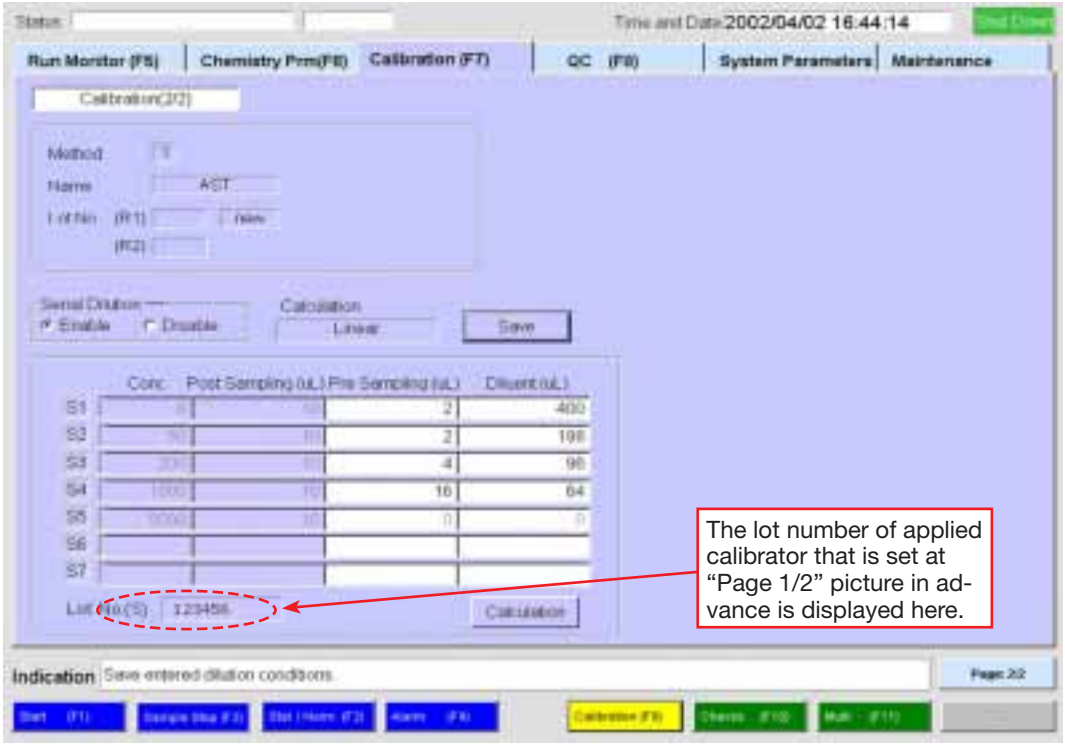
This type of calibration can be performed provided that the setting of the diluents in the [Chemistry (F9)] picture of the job menu [Chemistry Prm (F6)] are specified as shown below:



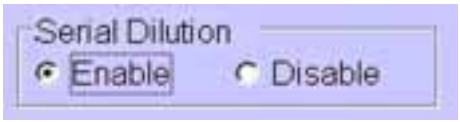
The diluent registered as the above must be placed in the RCU and its volume needs to be confirmed in the [Inventory (F11)] picture of job menu [Run monitor (F5)].

1. The method, type of calibration curve and necessary concentration for the calibration need to be specified in page 1/2 of the [Calibration (F9)] of job menu [Calibration (F7)].

2. Select page 2/2 of the [Calibration (F9)] of job menu [Calibration (F7)].

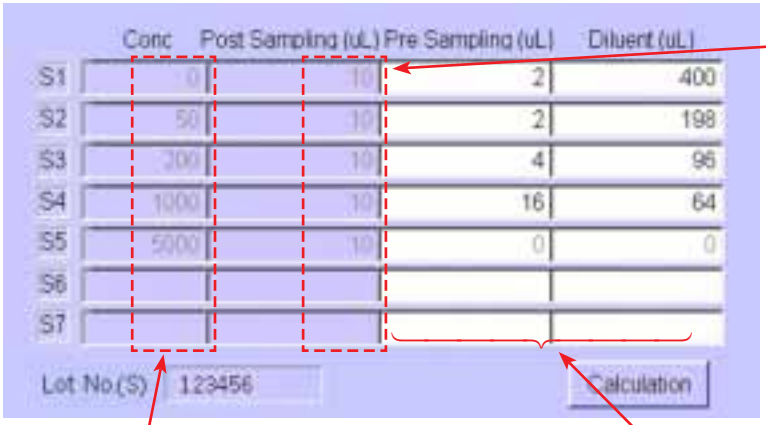


3. Set the "Serial Dilution" at "Enable" box.



Note: When a normal standard or multi standard has been specified as the sample type of test selection for the calibration measurement of this method in the [Test Selection (F10)] menu of [Run Monitor (F5)], don't set to "Enable" at "Serial Dilution" box. If set to "Enable", a calibration measurement for this method will not be performed.

4. Click on the Calculation button, and confirm the ratio of diluent to automatically calculated calibrator.



(1) Pre-sampling volume: 2 - 35 µL

(2) Diluent volume: Maximum 400 µL

After automatic calculation of the dilution ratio is done, when the calculated volume of pre-sampling and diluent are coloured with red, it means that calculated ratio is not harmonize with target dilution ratio.

Also the automatically calculated pre-sampling and diluent volumes can be changed to the practical ones if necessary.

Click on the Save button after the values have been changed.

When the automatic dilution calculation needs to be performed again, click on Calculation button.

5. After all of the above settings have been completed, place a calibrator of high concentration in the ASP unit and initiate the measurement. The calibrator is automatically diluted and the full calibration is performed.

2.3.5 Confirmation of judgement criteria and measuring conditions: [Checks (F10)]

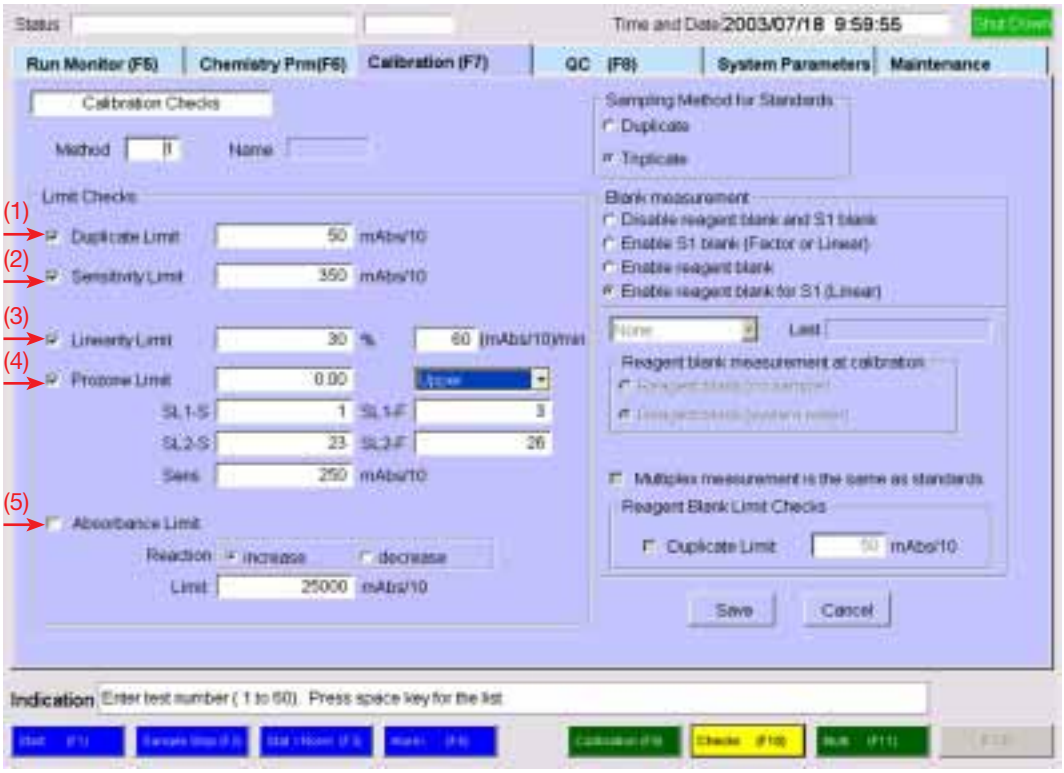
The various judgement criteria at the time of measurement are defined in order to ensure the correct calibration curve.

The criteria and measuring conditions are predefined for each method and thus usually there is no need to be changed by the user.

The predefined judgement criteria and measuring conditions can be checked and modified by the following procedures:

1. Select job menu [Calibration (F7)].

2. Select the function menu [Checks (F10)] screen.



3. The method may be selected by either one of the following two ways:

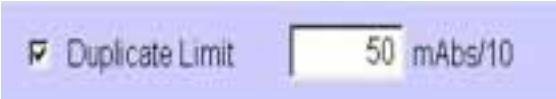
1 Move the cursor on “Method” and enter the required method number in the box using the numeric keys, or

2 Press SPACE key to display the pop-up window showing registered methods and click on the desired method number in it.

4. Applicability of various judgement criteria and their limit values are specified in the “Limit Checks” rectangle. Enter tick mark into respective small box for each criterion to be made effective ☑.

(1) Duplicate Limit (allowable variation limit)

The value is entered to check the difference between absorbance values obtained from the duplicate or triplicate measurements. In the case of triplicate measurements, the difference between maximum and minimum values is checked.



(2) Sensitivity (allowable sensitivity limit)

This is the value to check the difference in absorbance between the first and last calibrator.

(3) Linearity Limit (linearity check of reaction)

The ratio (%) and minimum check limit (mAbs/10) of the measurement range-2 (Measuring Points-2) slope are entered. This check is applicable only to Rate method.

(4) Prozone Limit (check of prozone phenomenon: check of immuno-nephelometric measurement)

The prozone check is applied to the End or Rate-assay. In the calibration measurement, this limit check is not applied.

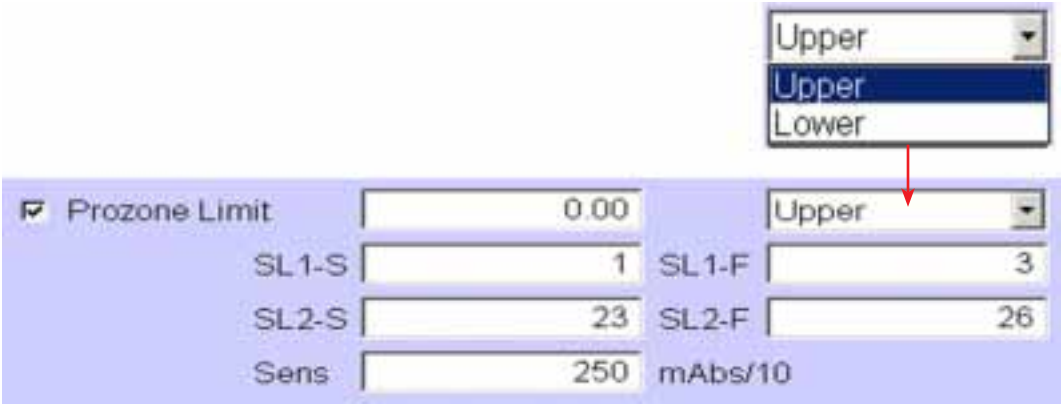
Prozone Limit value (P) is defined as below formula.

$$P = \frac{(ABS_{SL2-F} - ABS_{SL2-S}) / (t_{SL2-F} - t_{SL2-S})}{(ABS_{SL1-F} - ABS_{SL1-S}) / (t_{SL1-F} - t_{SL1-S})} \times 100$$

Two type of check method are available;

- Upper: It is assessed whether the prozone value is over than specified value or not.
- Lower: It is assessed whether the prozone value is lower than specified value or not.

And also the check method is selected by means of pull-down menu at the next of “Prozone Limit” input field.



Prozone Limit: Maximum allowable prozone limit is entered.
SL1-S: The 1st measuring point number of slope range 1 is entered.
SL1-F: The last measuring point number of slope range 1 is entered.
SL2-S: The 2nd measuring point number of slope range 2 is entered.
SL2-F: The last measuring point number of slope range 2 is entered.
Sens.: Sensitivity limit value is entered.

Prozone check is not performed if the calculated sensitivity value (S) is lower than specified value (Sens.), i.e. Sens. value > S.
Sensitivity (S) is calculated by below formula.

(5) Absorbance Limit
This is to define the limit of absorbance for the Rate method.

The conditions of “Chemistry Parameter” are therefore as shown below:

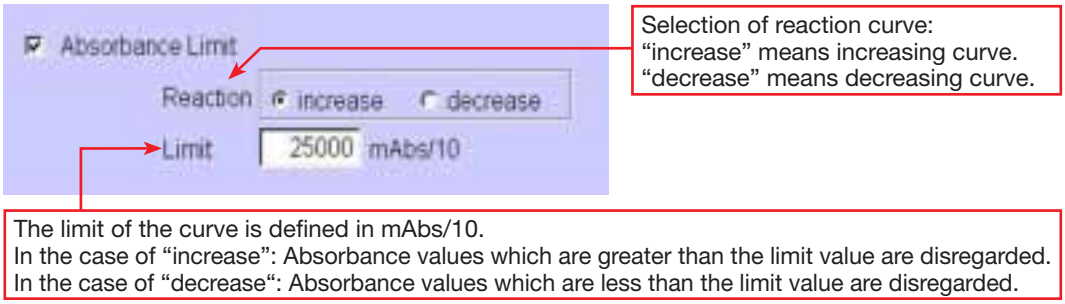
Assay Type: Rate

Measuring Point 1: ☑ Disable

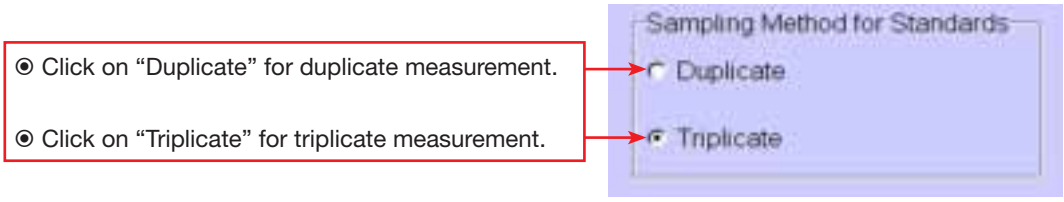
2: Start [m1]

End [m2] where 1 ≤ m1 ≤ m2 ≤ 26.

This absorbance limit is valid for the method the conditions of “Chemistry Parameter” of which are defined as the above.



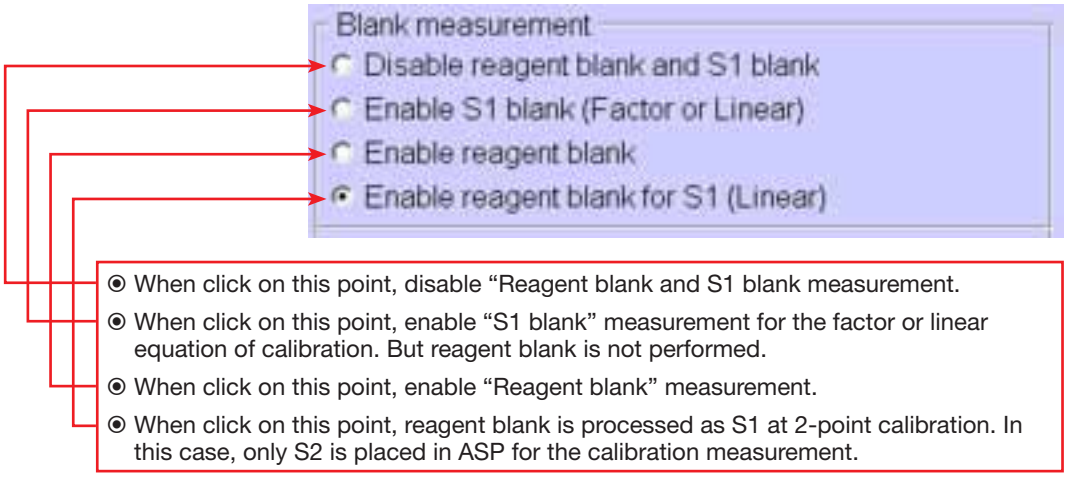
5. Sampling Method for Standard, number of measurement, is specified.



6. Select the “Blank measurement”.

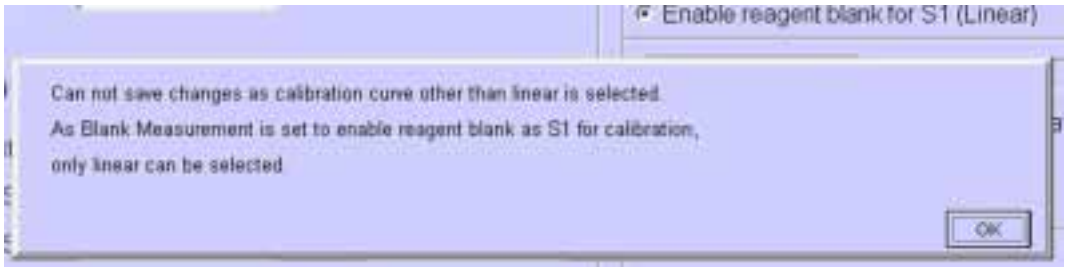
Take care not to mismatch in the reagent blank selection between calibrator and general sample measurement. When a calibration curve was obtained without reagent blank measurement, a general sample should be measured in condition of without reagent blank.

When click on this point, disable “Reagent blank and S1 blank” measurement.

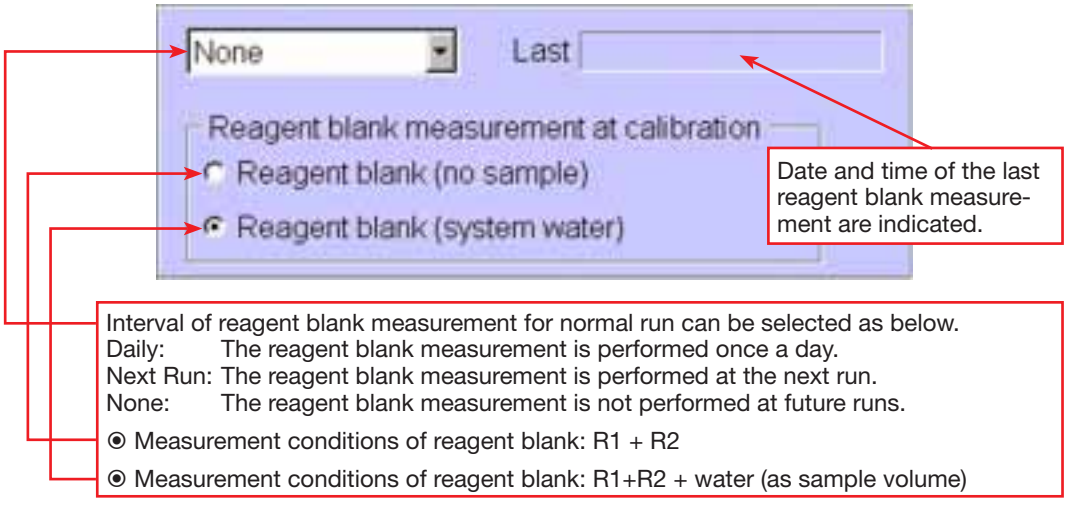


When the “Enable reagent blank for S1 (Linear)” is set to “Enable”, the type of calibration curve should be designated “Liner” in the function menu [Calibration (F9), Page 1/2] of job menu [Calibration (F7)]. Otherwise the following error message will be appeared in the screen.

(See “2.3.2 Settings of calibrator concentrations”)

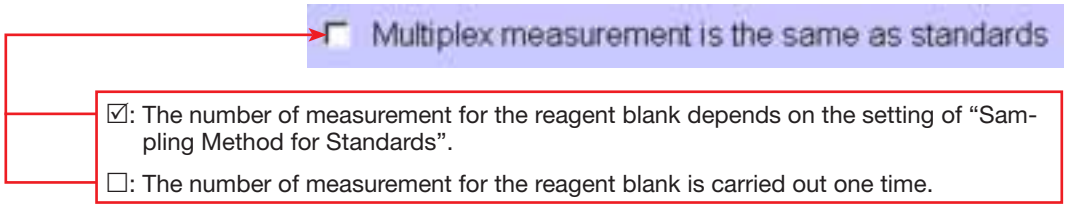


7. When “Enable reagent blank” is set up to enable, the interval of reagent blank for normal run and the conditions of reagent blank during calibration measurement are specified.



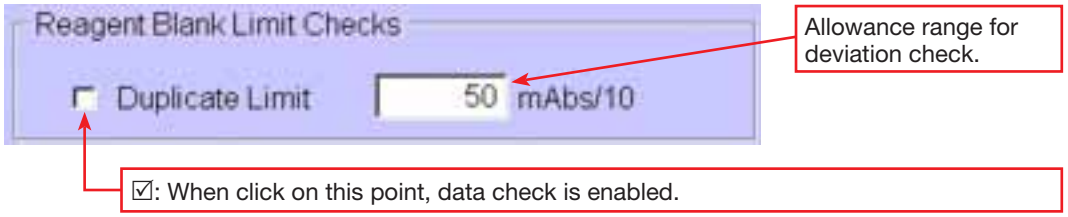
8. Specifying the number of measurement for the reagent blank.

In terms of the number of measurement for the reagent blank, if this term is not specified, its number is defined either “Duplicate” or “Triplicate”.



9. Reagent blank limit check

When “Enable reagent blank” is made effective and “Duplicate” or “Triplicate” is selected for the reagent blank measurement, the deviation of measured results on each same concentration is checked.



10. Saving of judgement criteria and measuring conditions

Save button: Click on this button to save entered parameters.

Cancel button: Click on this button when the entered parameters are not saved.

2.3.6 Registration of Multi-standard: [Multi (F11)]

For multiple methods, a common calibrator (standard) can be defined.

Ten (10) sets can be specified as the multi-standard and seven (7) kinds of calibrators per a set can be registered.

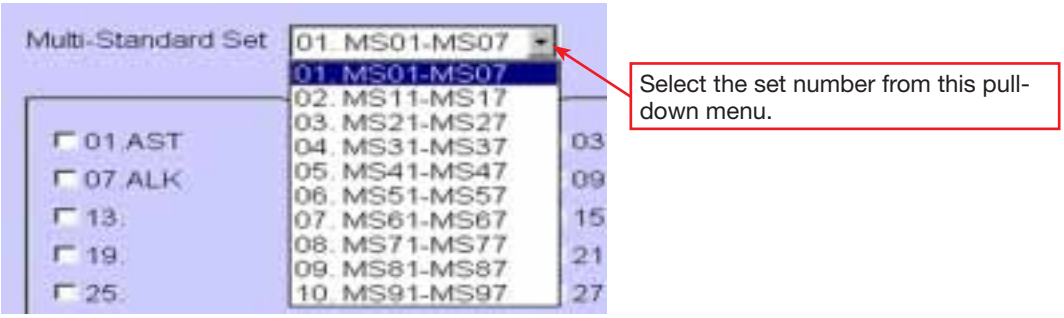
Set No.	Multi-standard set	Barcode
1	MS01 – MS07	95000001 – 95000007
2	MS11 – MS17	95000011 – 95000017
3	MS21 – MS27	95000021 – 95000027
4	MS31 – MS37	95000031 – 95000037
5	MS41 – MS47	95000041 – 95000047
6	MS51 – MS57	95000051 – 95000057
7	MS61 – MS67	95000061 – 95000067
8	MS71 – MS77	95000071 – 95000077
9	MS81 – MS87	95000081 – 95000087
10	MS91 – MS97	95000091 – 95000097

The multi-standard is registered according to the following procedures:

1. Select job menu [Calibration (F7)].

2. Select the function menu [Multi (F11)].

3. Open the pop-up window of “Multi Standard Set” and specify the set number.



4. Enter tick marks ☑ into the boxes of the common methods in the following list of methods (01 – 60).

In the list of methods, the ones registered in the [Chemistry Parameters] picture are indicated.

The above picture shows that the set of MS01 – MS07 is allocated to AST, FERRIT and ALK.

For example, assuming that the calibrator for full calibration of methods ticked in the above is common with a set of five (5) calibrators Std-1 to Std-5:
Attach MS01 bar code label (95000001) to Std-1;
Attach MS02 bar code label (95000002) to Std-2;
Attach MS03 bar code label (95000003) to Std-3;
Attach MS04 bar code label (95000004) to Std-4; and
Attach MS05 bar code label (95000005) to Std-5.
This defines one set of multi-standard.

5. The registered numbers are saved by clicking Save button.

2.4 Test Selection

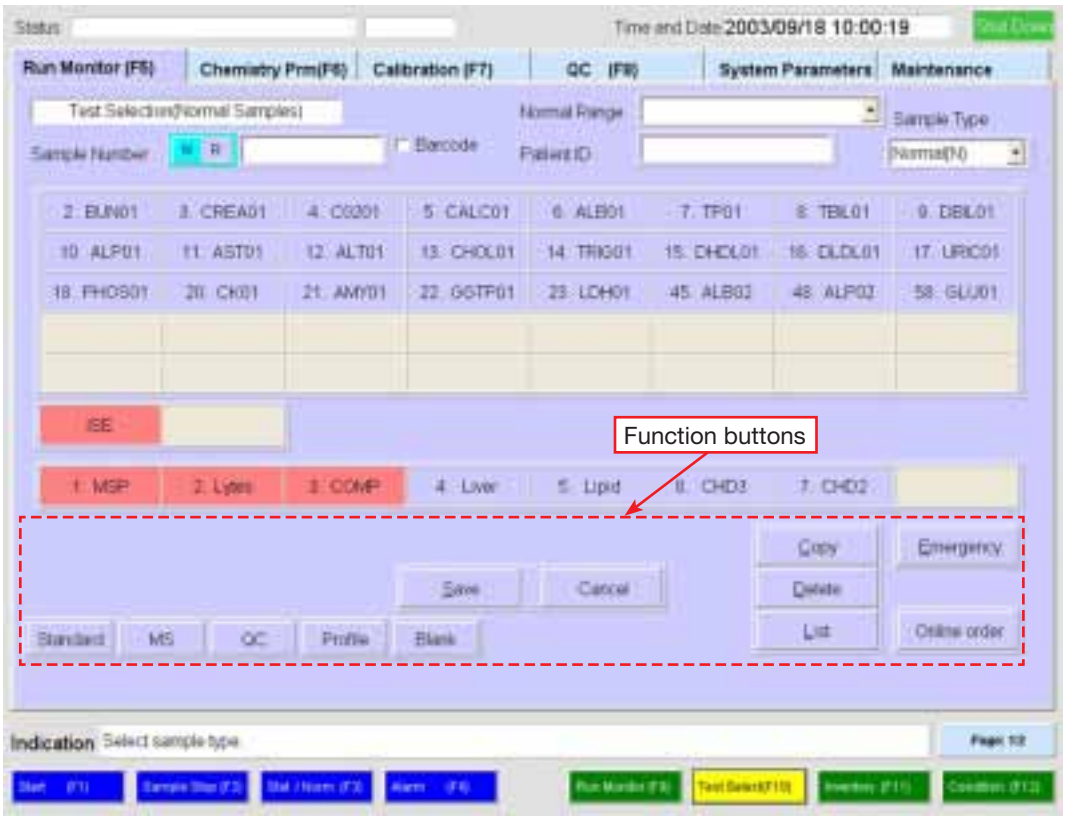
The procedures of test selection are different between the ASP with the barcode reader (BCR) and without BCR.

The test selection of normal and emergency sample for which measurement has been normally completed is deleted automatically, but being not normal completion of sample's order and profile's order are not deleted. In addition, all mask conditions are canceled after completion of measurement.

2.4.1 Masking procedure for ASP with BCR

A) In case of ASP with BCR (Option)

The sample number and method for sample (Test Selection) can be specified selecting the page 1/2 and 2/2 of the function menu [Test Select (F10)] of job menu [Run Monitor (F5)].



[Function buttons]

Standard	: to mask the method for standard item.	For Mask selecting
MS	: to mask the method for multi-standard item.	
QC	: to mask QC method.	
Profile	: to mask the profile items.	
Blank	: to mask the method for blank measurement.	
Save	: to save settings data.	For T/S settings making effectiveness or not
Cancel	: to cancel settings data.	

Copy	: to copy test selection.	For T/S editing
Delete	: to delete test selection from list.	
List	: to list saved test selection	
Emergency	: to changeover the screen between normal and emergency selection.	
Online order	: to request the test selection data to host, in the case of selecting “On Line Batch1” or “On Line Batch2” mode in the function menu [Condition (F12)] of [Run Monitor (F5)].	

When the identical reagent to QC sample and standard sample is registered to apply the measurement for more than 2 methods and also one standard sample for multiple methods is defined as the multi-standard, the mask function is available to selection of wishing method(s) in order to apply the actual test selection.

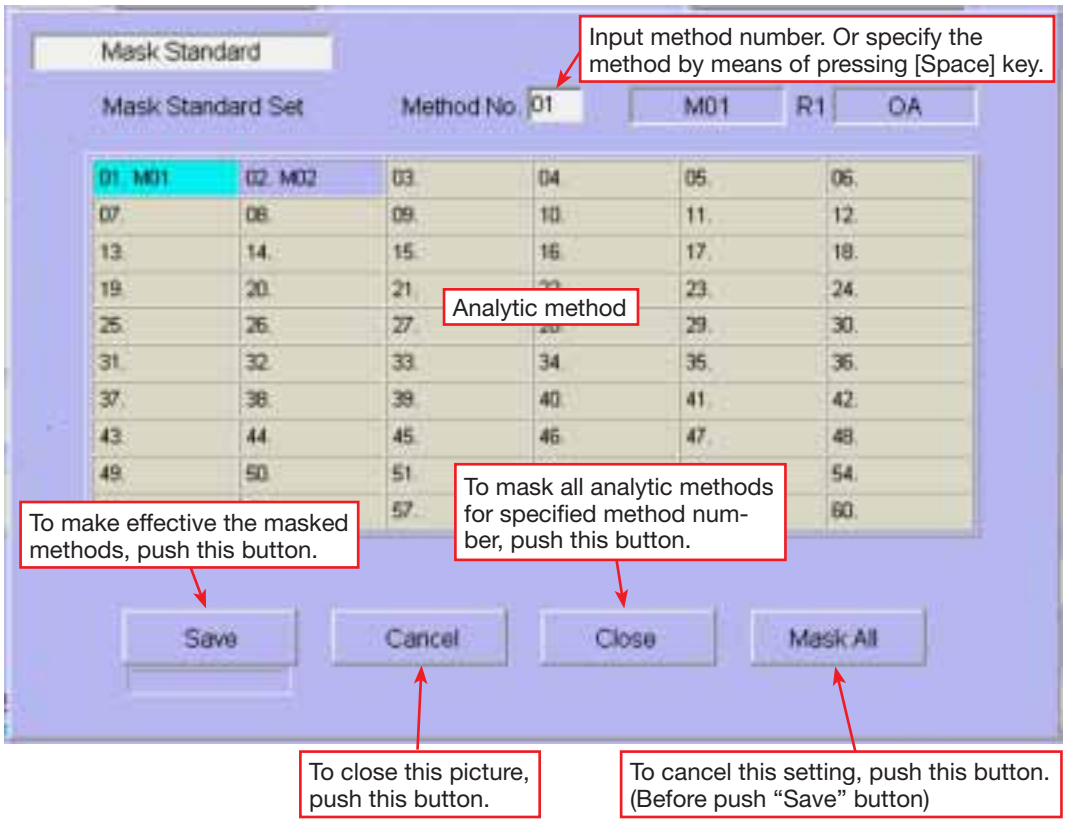
The following is procedure of mask function.

1. Clicking on the mask selection button. (Standard or MS or QC or Profile or Blank)

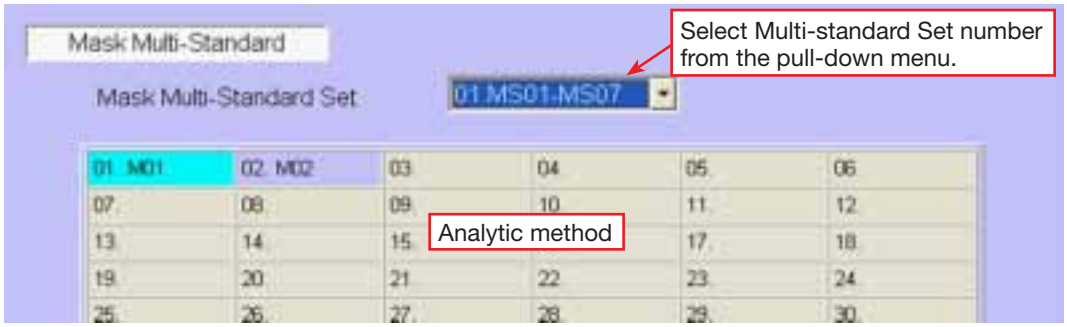
2. Popped up the mask setting picture in the center of screen as below picture.

The method with blue color is allowed to measure and the method with background color (pale blue) is inhibited. The method that is clicked on turns to background or blue color and its test selection is masked or unmasked. When the same method is clicked again, the method turns over from masked or unmasked to unmask or mask.

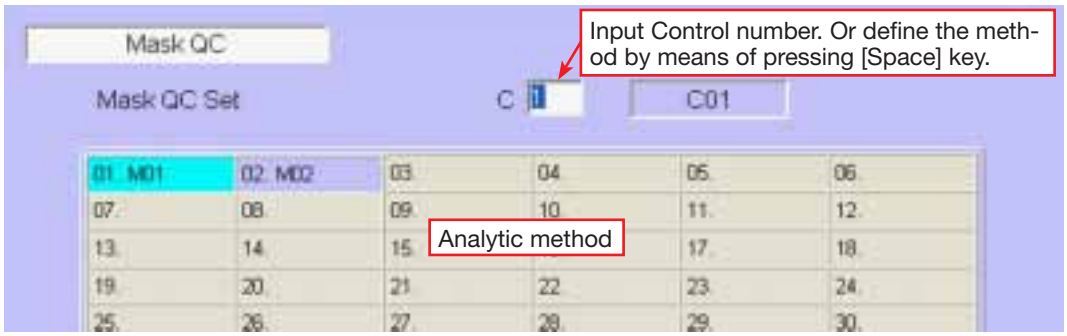
(1) In case of Standard. (Normal sample)



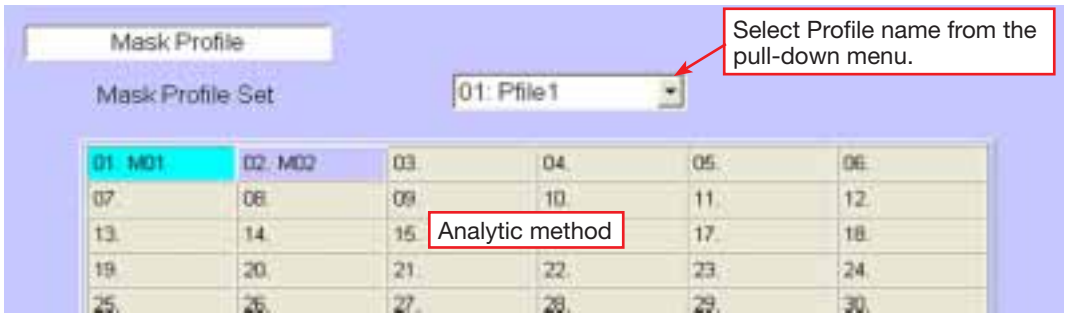
(2) In case of MS. (Multi-standard)



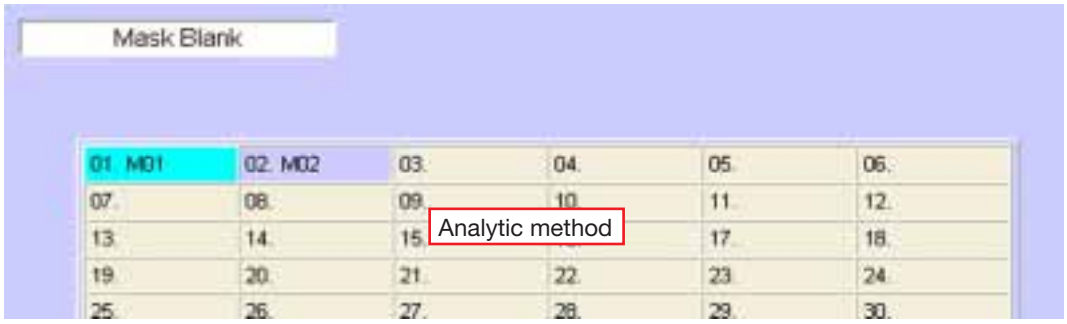
(3) In case of QC. (QC control)



(4) In case of Profile.



(5) In case of Blank. (Blank measurement)



3. After selecting valid item(s), one of following buttons is clicked on.

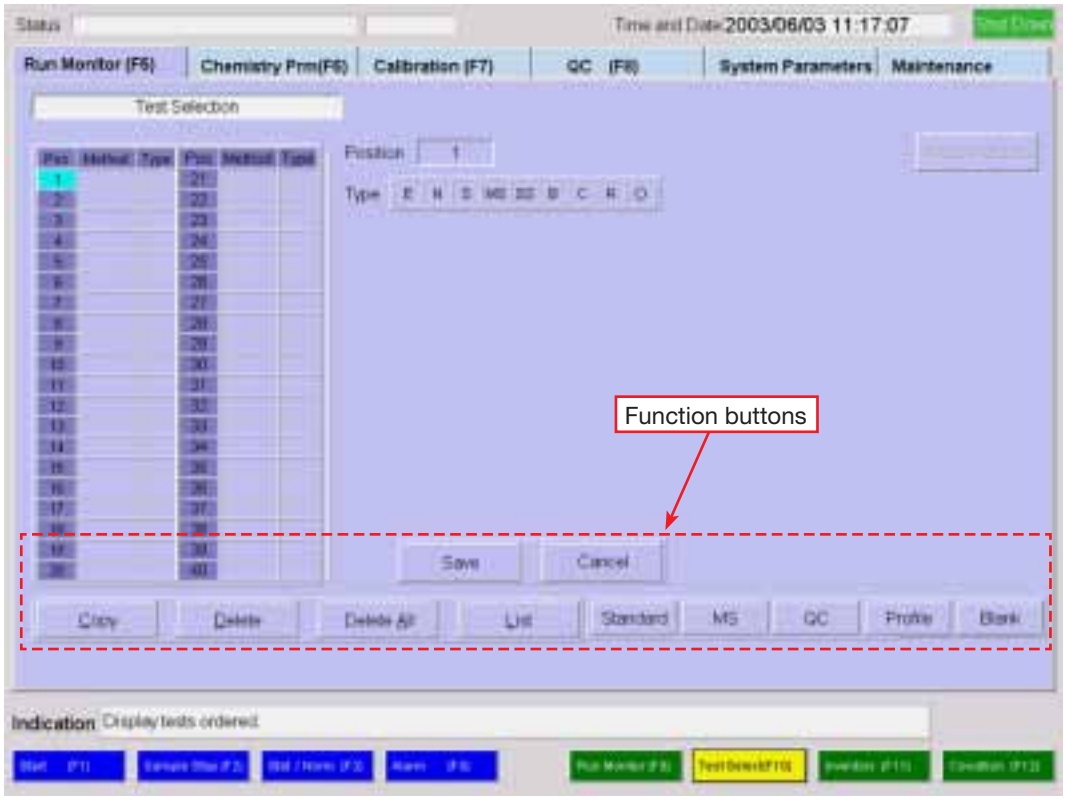
Save : to make masking item(s) effectively.

Cancel : to cancel this setting.

Close : to close this popped up picture.

Note: All mask conditions are canceled after completion of a measurement.

B) In case of ASP without BCR

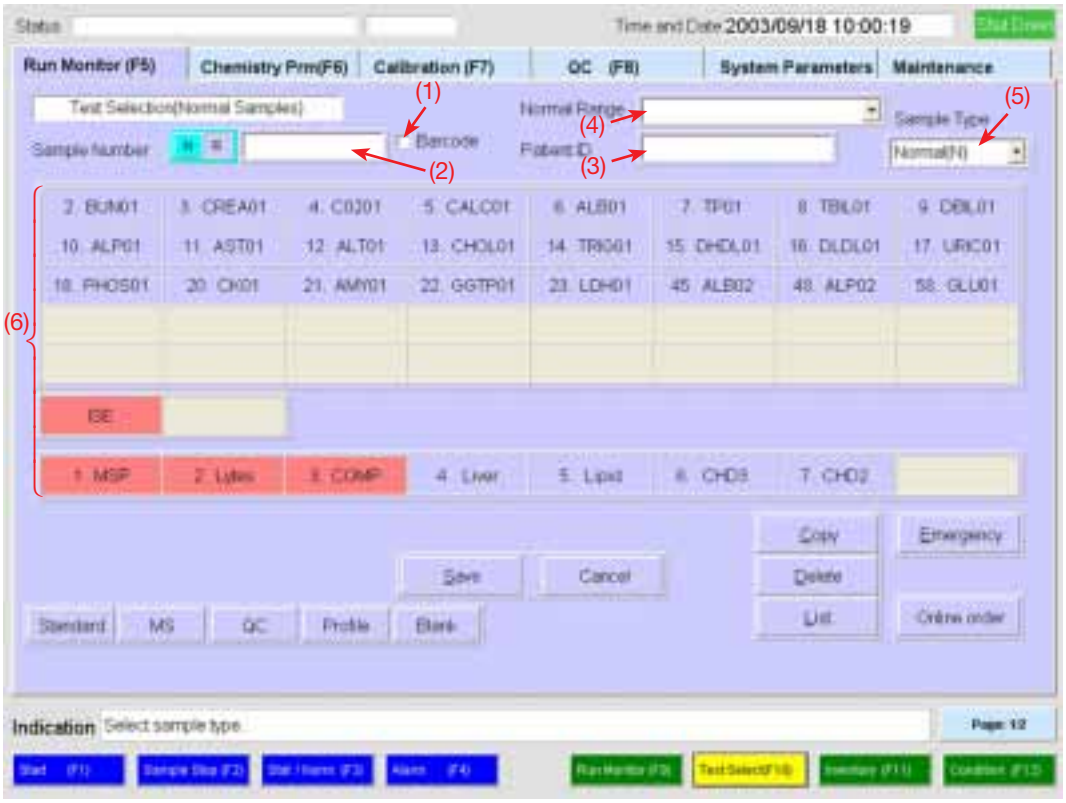


[Function buttons]

Standard	: to mask the method for standard item.	For Mask selecting
MS	: to mask the method for multi-standard item.	
QC	: to mask QC method.	
Profile	: to mask the profile items.	
Blank	: to mask the method for blank measurement.	
Clear All Mask	: to clear all mask settings.	
Save	: to save settings data.	For T/S settings making effectiveness or not
Cancel	: to cancel settings data.	
Copy	: to copy test selection.	For T/S editing
Delete	: to delete test selection from list.	
List	: to list saved test selection	

The Masking procedure is in the same way of ASP with BCR. Refer to previous description “A) In case of ASP with BCR”.

2.4.2 Test selection of Normal and Emergency sample (ASP with BCR: Option)



The picture of page 1/2 of function menu [Test Select (F10)] is used for Normal and Replicate Sample.

And also the picture of page 2/2 of function menu [test Select (F10)] is used for Emergency sample.

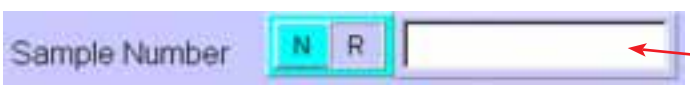
(1) Specify number of input digit for Sample Number:

☑: The input number of digit is applied same as barcode label of the normal and emergency sample. In this case, the sample number can be entered by handy barcode reader instead of the keyboard in the following item (3).

☐: For the normal sample, number of input digit is applied 3 to 12 characters. For the emergency sample, number of input digit is applied 3 characters. In this case, the following item (3) is available.

(2) Entry of Sample Number:

In case the [Page: 1/2] (for Normal Sample);



Sample number entry field.
N: 3 to 12 characters
R: 2 characters

Allowed characters for the sample number and patient ID:

Numeral characters	: 0 to 9
Alphabetical characters	: A to Z and a to z
Symbols	: !, #, $, (,), +, -, ., /, ;, <, =, >, ?, @, [,], {, }, ~

Select either “N” (normal sample) or “R” (replicate sample) by clicking on the corresponding symbol.

The replicate sample is the sample with a certain number for which the measurement is repeated. The number of replicate runs need to be specified in the page 2/2 of job menu [System Parameters].

N: Don’t use “9” at the top of character string in case of 8 characters expression.
It would be better to avoid entering “xxx” as the sample number because it would be occurred a sort of confusion with emergency sample in the “Run Monitor” screen.
Where the pediatric cup is assigned, four characters can be entered as the sample number that is the lower four digits of sample barcode that is attached to the pediatric tube. (Barcode: 8999XXXX, underlined 4 characters are available.)

R: Two characters can be entered.
Where the pediatric cup is assigned, two characters can be entered for replicate sample number that is the part of barcode number attached to the pediatric tube.
(Barcode: 94006001 to 940099XX or 94006001 to 94009Z01 or 94006001 to 94009z01, under lined 2 digits are available.)

In the case of “Emergency Sample” ([Page: 2/2]);

For the emergency sample, 3 characters in a string are available.

When the previous “Barcode” box is clicked on, 8 characters should be entered as the sample number of emergency sample. (Refer to “2.6.3 Types of barcode labels”)

(3) Entry of patient ID:

Patient ID number is entered.

After the setting of the patient ID number is completed, the following picture is popped-up to select whether the patient information is made valid or invalid.

When click on the Cancel button, the processing proceeds to “Selection of method” immediately.

When click on the OK button, the picture of patient information settings is popped up on the screen. The patient information can be newly made or be modified. (See “2.4.3 Entry of patient information”.)

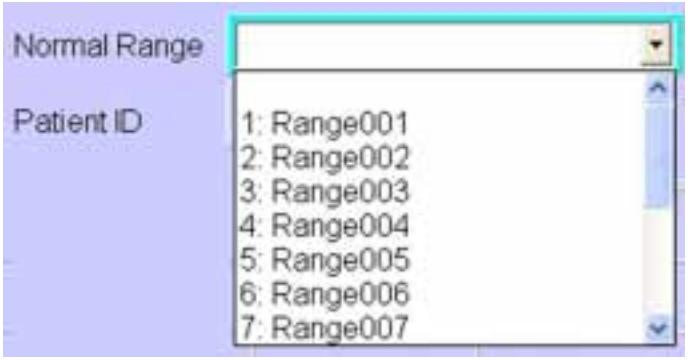
(4) Specify the normal range type.

Normal range to be applied the measurement is possible to select one of the following types.

1. Ordinary normal range (Male, Female, Child).

If you want to apply the ordinary normal range, select the blank selection.

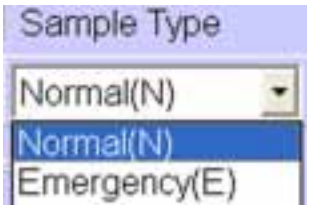
2. Extension normal range.
If you want to apply the extension normal range, select one of the extension normal ranges by means of the pull-down menu as below picture.



In advance, the necessary values for normal ranges are set in the chemistry parameters screen ([Chemistry Prm (F6)] – [Chemistry (F9)]).

(5) Sample type selection for its barcode:

Select whether a normal sample is dealt with STAT (emergency) sample in spite of having normal sample barcode on it.



Normal (N): Normal sample that is attached normal sample barcode is dealt with normal sample.

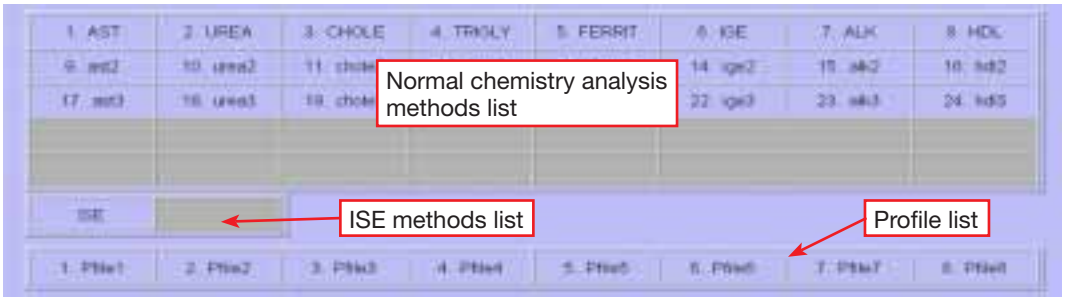
Emergency (E): Normal sample that is attached normal sample barcode is dealt with emergency sample.

Pediatric (P): Normal sample that is attacked normal sample barcode is dealt with pediatric sample.

E and P: Normal sample that is attached normal sample barcode is dealt with emergency sample and pediatric sample.

(6) Selection of method:

The list of measurable reagents is shown as below. In the list, only reagents which exist in the RCU and have been registered are indicated. The RCU can accommodate 40 bottles of reagents in total and thus 40 methods for normal sample can be displayed here.



The test selection is executed by selecting required methods from the list by a mouse. Multiple methods can be selected for one sample.

Red color method of general sample:	**Calibration curve of its method is expired.**
Red color method of ISE:	**ISE calibration is not yet performed.**
Yellow color method:	**Control measurement is expired.**

When the optional ISE unit is installed, the “ISE methods list” is indicated below the “Normal sample methods list”. When the ISE method is colored with red, its calibration data is not effective. Therefore, ISE calibration should be performed in advance with ISE measurement.

Maximum 8 selectable method buttons as the profile list are shown under the “ISE methods list”.

After completion of setting the test selection, Save button should be clicked on to make effective.

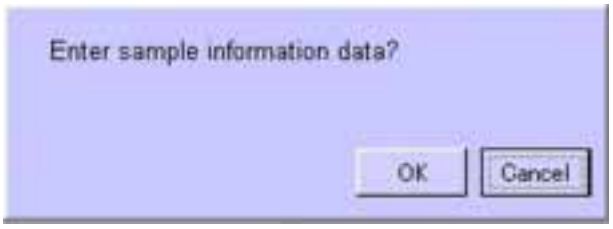
2.4.3 Entry of patient information

When test selection is made, the sample numbers and patient ID’s are defined. In general, such patient ID’s need to be defined in advance for each patient in the function menu [System (F9), page 2/2] picture of job menu [System Parameters]. (See “3.6.2 System parameters (2/2)”.)

But even if there is not defined specified patient ID’s information in advance, it is possible to newly create or modify the patient information to the patient ID specified in the test selection.

After the Patient ID has been entered in the “Test Selection” screen, the patient information is created or modified in accordance with the following procedures either for the case of ASP with BCR” or ASP without BCR”.

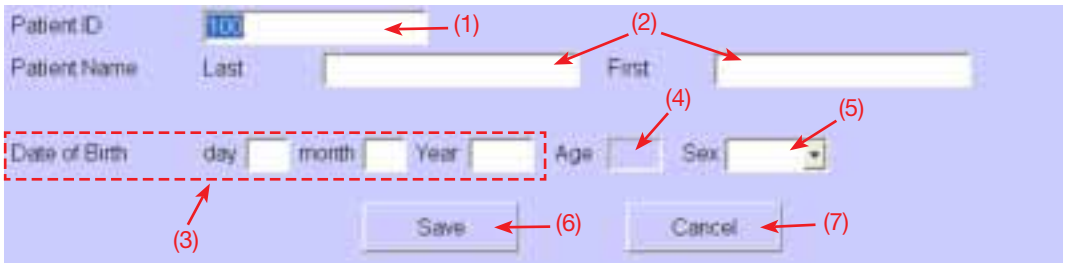
1. Define whether the Patient ID is made valid or invalid.



(1) Click on the Cancel button when the Patient ID is made invalid.

(2) Click on the OK button when the Patient ID is made valid.

2. In case that the Patient ID has been made valid, the following pop-up picture is displayed. It is possible to newly create or modify the patient information.



(1) Patient ID;

(2) Patient Name (Last name and First name);

(3) Date of Birth (day, month and year);

(4) Age;

(5) Sex (None, Male and Female);

Above mentioned items are outputted automatically, when the patient information has already been entered in the function menu [System (F9), page 2/2] of job menu [System Parameters].

Otherwise, these parts are able to be newly added in this test selection. But while execution of measurement, it is not possible to be modified/edited except that the patient information is created newly.

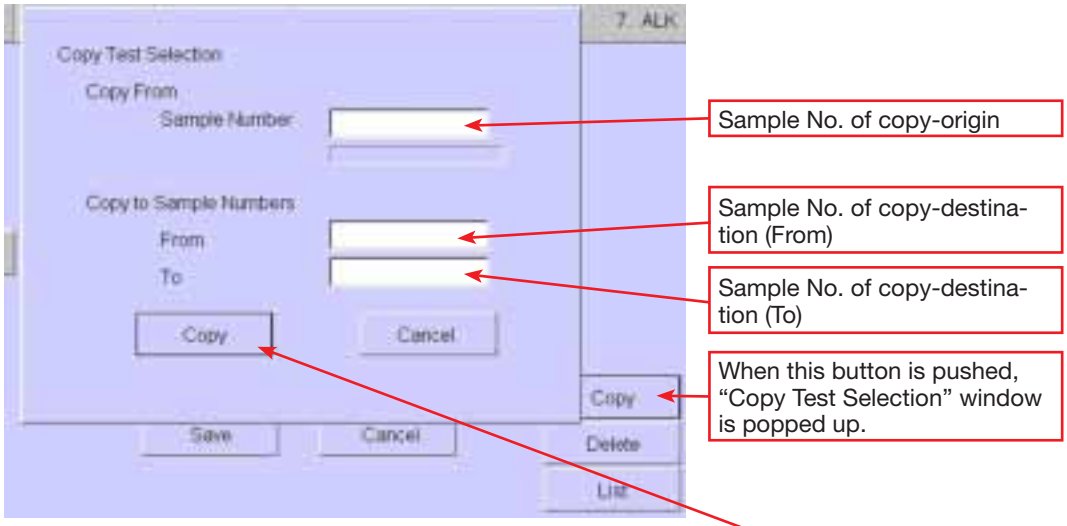
(6) Click on the Save button to save the entered patient information.

(7) Click on the Cancel button to cancel and not to save the entered patient information.

2.4.4 Copy of Test Selection (ASP with BCR)

The same method can be assigned to multiple samples by means of this function.

The pop-up window “Copy Test Selection” is displayed by clicking on Copy button in the [Test Select (F10)] picture (see picture below).



Enter the sample number of copy-origin whose test selection has already been made into the “Sample Number” box of “Copy From”. Thereafter, enter the sample numbers into both “From” and “To” boxes of “Copy to Sample Number” and then click on the Copy

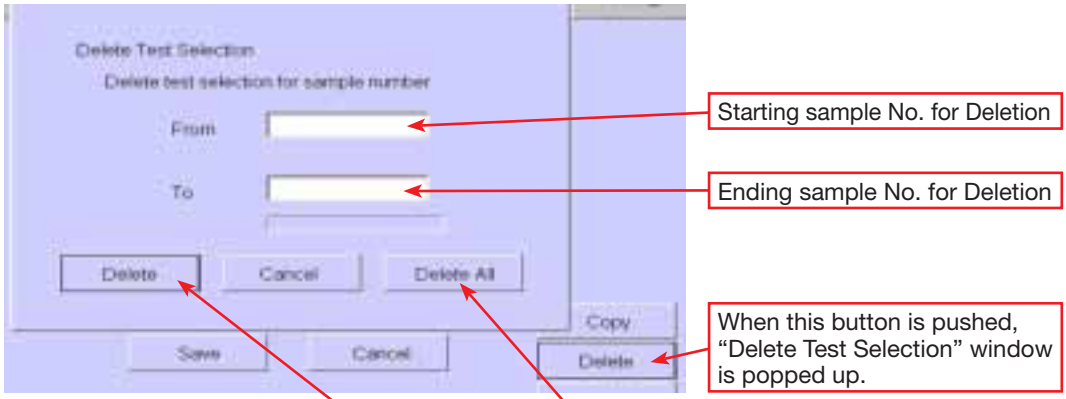
button in the pop-up window to assign the method defined for the sample of “Copy From” to samples of “Copy to Sample Number”. Order of sample number applied to “From” and “To” is in accordance with the selection of “Sample number increment”. (See “3.6.2 System parameters [System (F9)] Page 1/2”.)

2.4.5 Deletion of Test Selection

The test selection of normal and emergency sample for which measurement has been normally completed is deleted automatically, but being not normal completion of sample’s order and profile’s order are not deleted. Above is applied to both ASP with BCR and without BCR.

If necessary, delete such a test selection before the next round of measurement is initiated. When the date is shifted to a new date and further analyzer is re-started, test selection is deleted the pop-up window of “Delete Test Selection” is displayed by clicking on the Delete button in the [Test Select (F10)] picture.

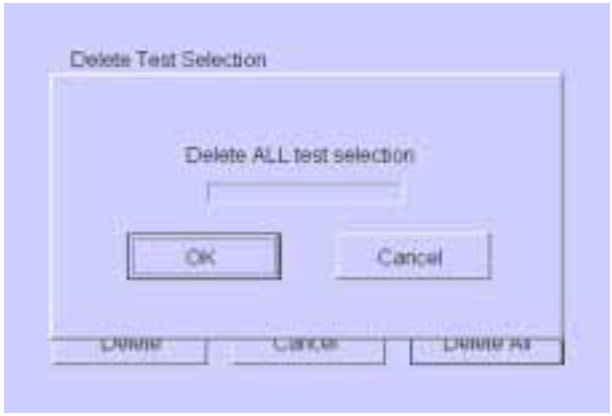
Order of sample number applied to “From” and “To” is in accordance with the selection of “Sample number increment”. (See “3.6.2 System parameters [System (F9)] Page 1/2”.)



Enter both starting and ending sample numbers for deletion into “From” and “To” boxes respectively and then click on the Delete button in the “Delete Test Selection” window to delete the test selection for the specified sample numbers (From – To).

When the entire test selections are deleted, click on the Delete All button in the “Delete Test Selection” window. And the following message is displayed to ascertain operator’s action.

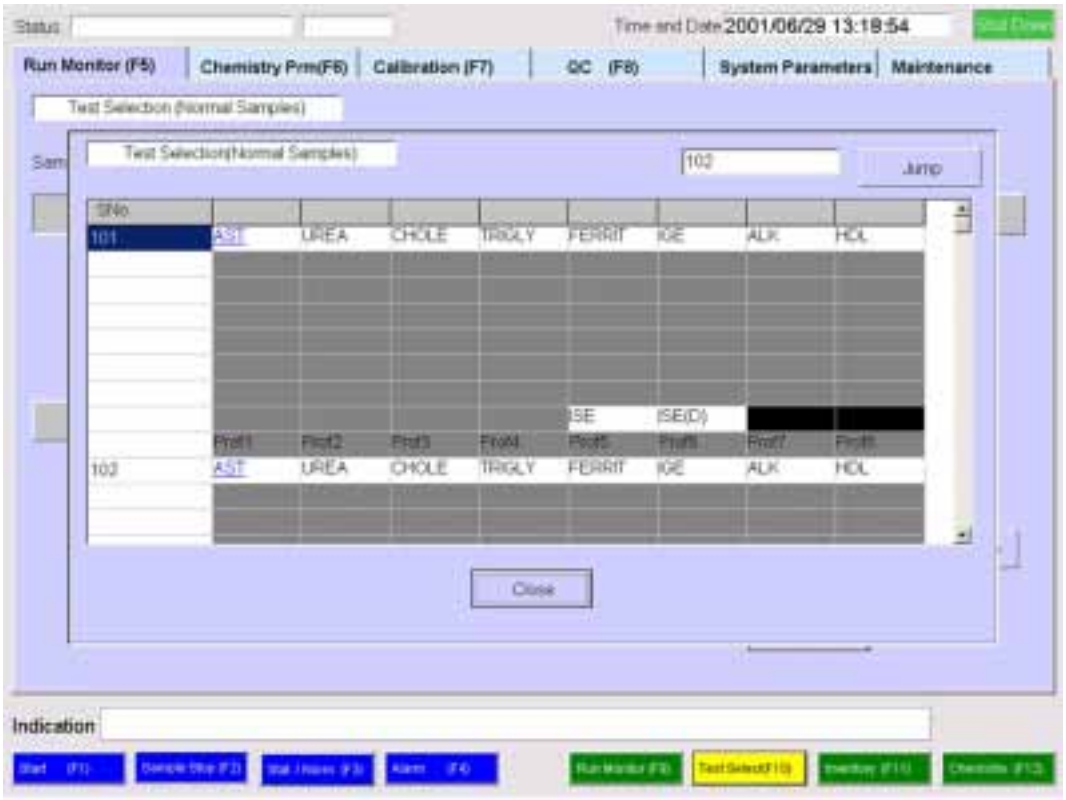
To perform the deletion of all test selection, click on the OK button.



2.4.6 Confirmation of Test Selection (ASP with BCR)

The registered test selection can be displayed, confirmed and corrected.

The pop-up window “Test Selection (Normal Samples)” is displayed by clicking on List button in the function menu [Test Select (F10)] picture.



1. Methods underlined and in blue color (e.g. AST): being selected

2. Methods on white background and in black color (e.g. UREA, etc.): being not selected (Candidates for selection)

3. Gray background: not candidates for selection.

The status of selection can be inverted by specifying the method name indicated in the list and then pressing the [SPACE] key (or clicking the mouse button). That is that the method being selected turns to the selection-release status and vice versa.

Click on the Close button in the picture to close the list.

2.4.7 Test Selection for QC sample

The test selection for the QC sample does not need to be made. The equipment recognizes the registered method for the QC sample by reading the bar code label attached on it when it is placed in the equipment and corresponding measurement is automatically performed.

2.4.8 Test Selection of Method-to-Method computation

There is no need to make the test selection of method-to-method computation. The computation is automatically performed when the measurement result is output for the item included in the registered method-to-method computation equation.

2.4.9 Expired alarm of Calibration and Control measurement

When the day of expired is set in the following items;

1. Calibration interval: Function menu Calibration (F9) of job menu Calibration (F7)
2. QC setting interval: Function menu QC Setting (F11) of job menu QC (F8)

If its expired date becomes invalid, method corresponded with expired is colored with red (Calibration) and yellow (Control) in the test selection screen as alarm.

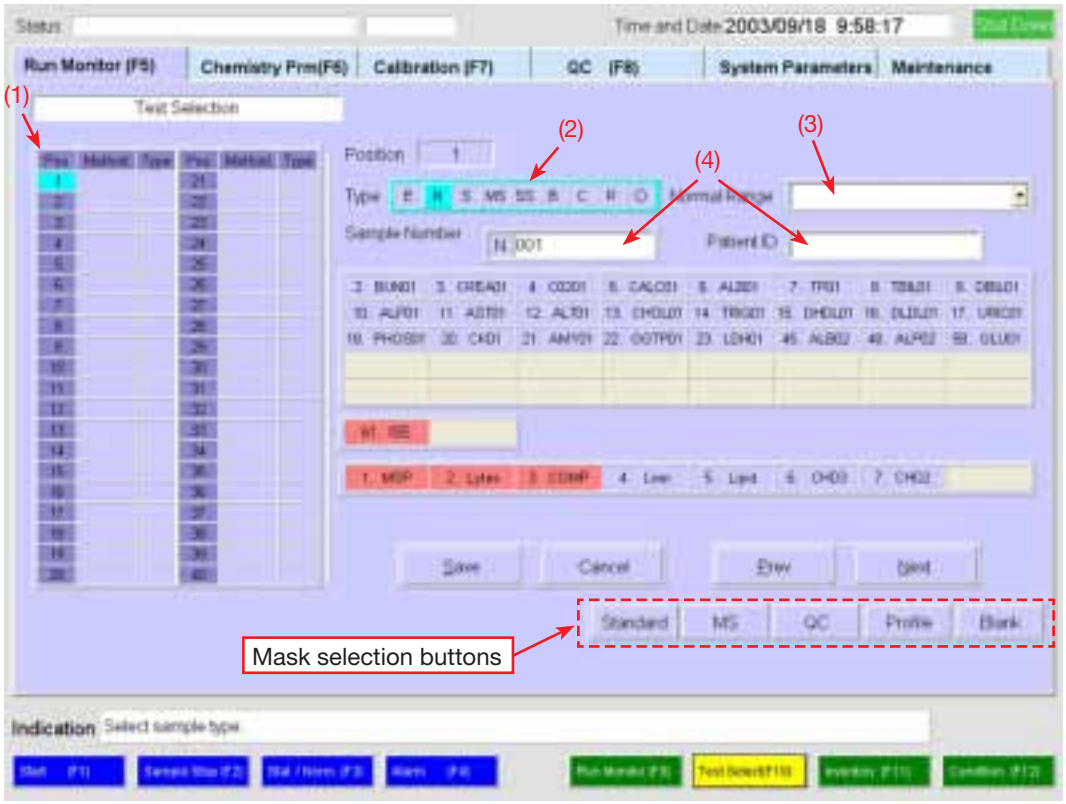
When ISE calibration measurement is not yet carried out, the method of ISE in the test selection screen is colored with red.

Even if these alarms are issued, the measurement is carried out normally. And error flag is attached in its result.

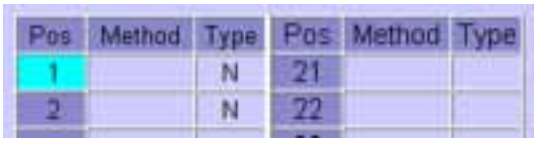
2.4.10 Test Selection for Off-line mode (ASP without BCR)

The picture of Test Selection is displayed by selecting the function menu [Test Select (F10)] of job menu [Run Monitor (F5)]. When the new test selection is made, check the currently set test selection by moving an arrow key (← or →) in the column of "Pos" number which corresponds to the slot number of the ASP unit. Press the Tab key at the desired position in the column of "Pos" number to display the test selection picture at right.

Expired check of the calibration curve and control measurement are performed same as ASP with BCR.

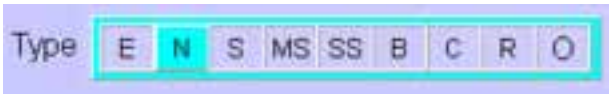


(1) Specify the slot number by a mouse or arrow key.



The numbers in the column of "Pos" correspond to the slot numbers of the ASP unit. The necessary picture for the test selection is displayed at right by pressing the Tab key after the slot number in which the sample is to be placed is specified by the arrow key (← or →).

(2) Specify the type of sample.



E: Emergency sample
N: Normal sample

S: Normal standard sample
MS: Multi standard sample
SS: Serial dilution standard sample
B: Blank sample (for one point compensation of “Factor” and “Linear”)
C: Control sample
R: Replicate sample
[O: On-line sample (This is appeared in the case of on-line mode.)]

Click on either one of above mentioned to specify the type of sample.

(3) Specify the normal range type.

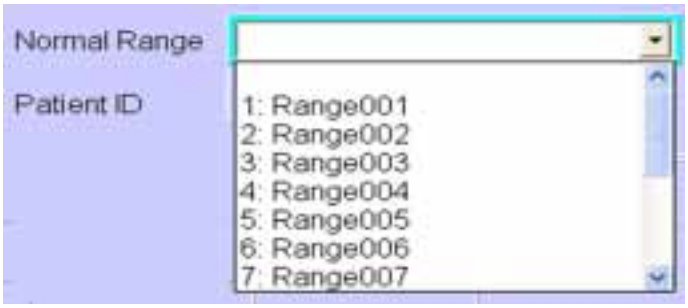
Normal range to be applied the measurement selected one of the following types.

1. Ordinary normal range (Male, Female, Child).

If you want to apply the ordinary normal range, select the blank selection.

2. Extension normal range.

If you want to apply the extension normal range, select one of the extension normal ranges by means of the pull-down menu as below picture.



In advance, the necessary values for normal ranges are set in the chemistry parameters screen ([Chemistry Prm (F6)] – [Chemistry (F9)]).

(4) Entry of sample number and patient ID for emergency sample (E) and normal sample (N).

Sample Number: Enter 3 to 12 characters.

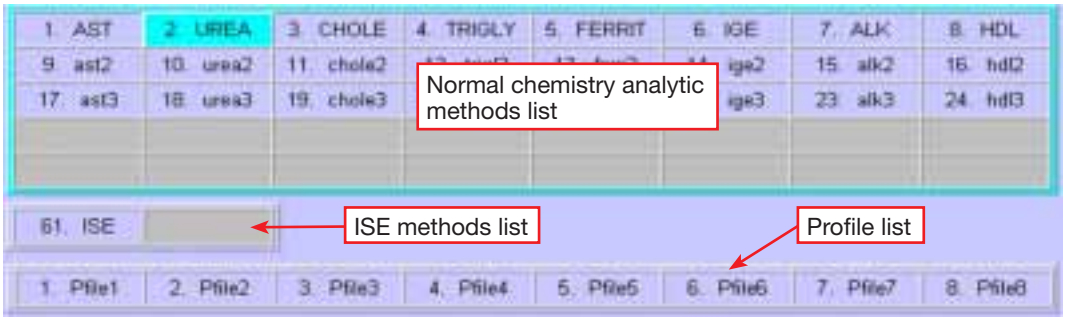
Patient ID: Up to 13 characters can be entered.

Allowed characters for the sample number and patient ID:
Numeral characters : 0 to 9
Alphabetical characters : A to Z and a to z
Symbols : !, #, $, (,), +, -, ., /, :, <, =, >, ?, @, [,], {, }, ~

After completion of “Patient ID” setting, the operator can select whether the Patient ID is made valid or invalid. If the proper information of patient information is selected, the patient information is possible to make newly or modify the already existing it. Its procedure is same as the “2.4.1 Test Selection of Normal and Emergency Sample (ASP with BCR)”. (See “2.4.3 Entry of patient information”.)

When the type of sample is Emergency (E) or Normal (N), follow the below procedure to specify the method.

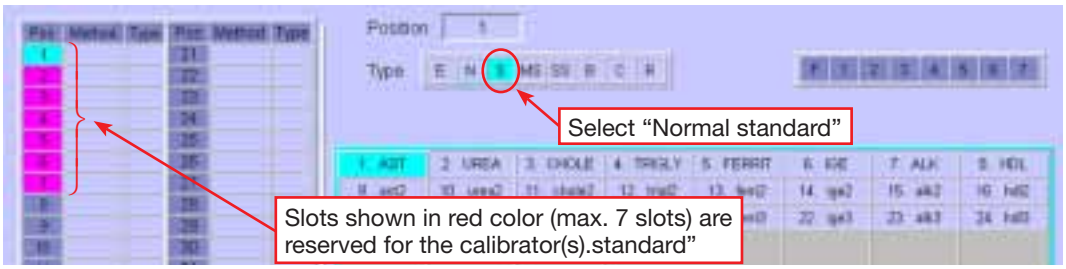
The method that is clicked on turns to blue color and its test selection is established. When the same method is clicked on again, the method is released from the test selection.



A) Type of sample: Normal Standard (S)

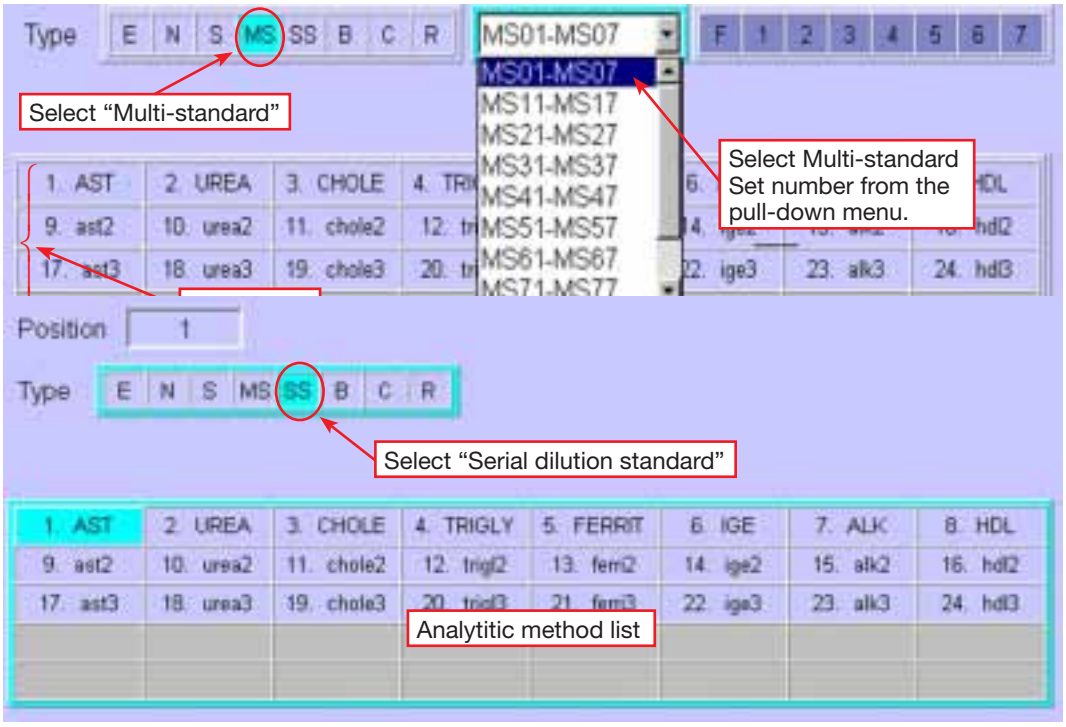
When the type of sample is Normal standard (S), maximum 7 slots are secured as shown in the following picture (shown in red color in the “Pos” column).

The required number of slots is selected by clicking the corresponding numbering box.



B) Type of sample: Multi-standard (MS)

When the type of sample is Multi-standard (M), the set number is selected as below picture. In this case, such numbers must have been set in the Multi (F11) screen of job menu Calibration (F7) in advance.



The method that is clicked on turns to blue color and its test selection is established. When the same method is clicked on again, the method is released from the test selection.

In the case of the blank sample, the analytic method is not specified in the analytic method list.

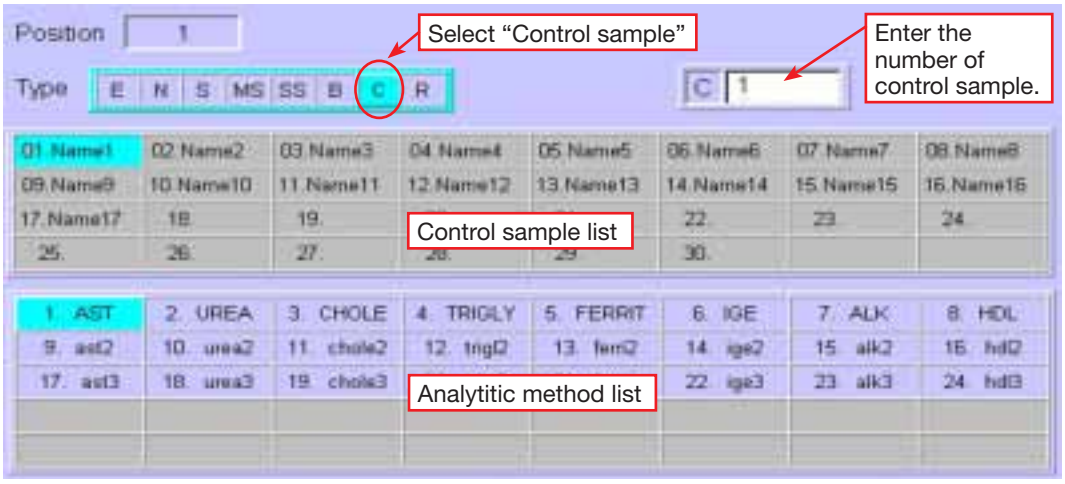
D) Type of sample: Control Sample (B)

In the case of selecting the blank sample (B) as type of sample, the analytic method is automatically selected in accordance with the setting of “Blank measurement” in the function menu [Checks (F10)] picture of job menu [Calibration (F7)].

E) Type of sample: Control Sample (C)

When the type of sample is the control sample (C), follow the procedure below to specify the method.

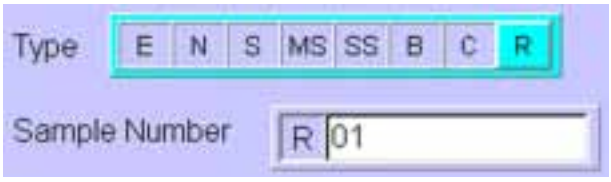
After selecting of sample type, the number of control sample must be entered in the control number box at the next of sample type box.



The analytic method is automatically selected in accordance with the control sample, which has already been registered (see the [Control (F12)] and [QC Setting (F11)] of job menu [QC (F8)]), and there is no need to select the analytic method. But the actual analyzing method of control sample can be changeable by means of the mask function.

F) Type of sample: Replicate Sample (R)

In the case of Replicate (R), enter 2-digit sample number.



G) Saving

Test selection is saved and established by clicking the Save button.

When requested to move to the newer position number, click the Next button.
When requested to move to the older position number, click the Prev button.

Note: After completion of the measurement, the color of slot number (ASP) in the list at left hand side in the screen is changed according to the status of measurement the same as information of sample proceeding picture in the [Run Monitor] screen. (See "2.7 Initiation of measurement and monitoring".)

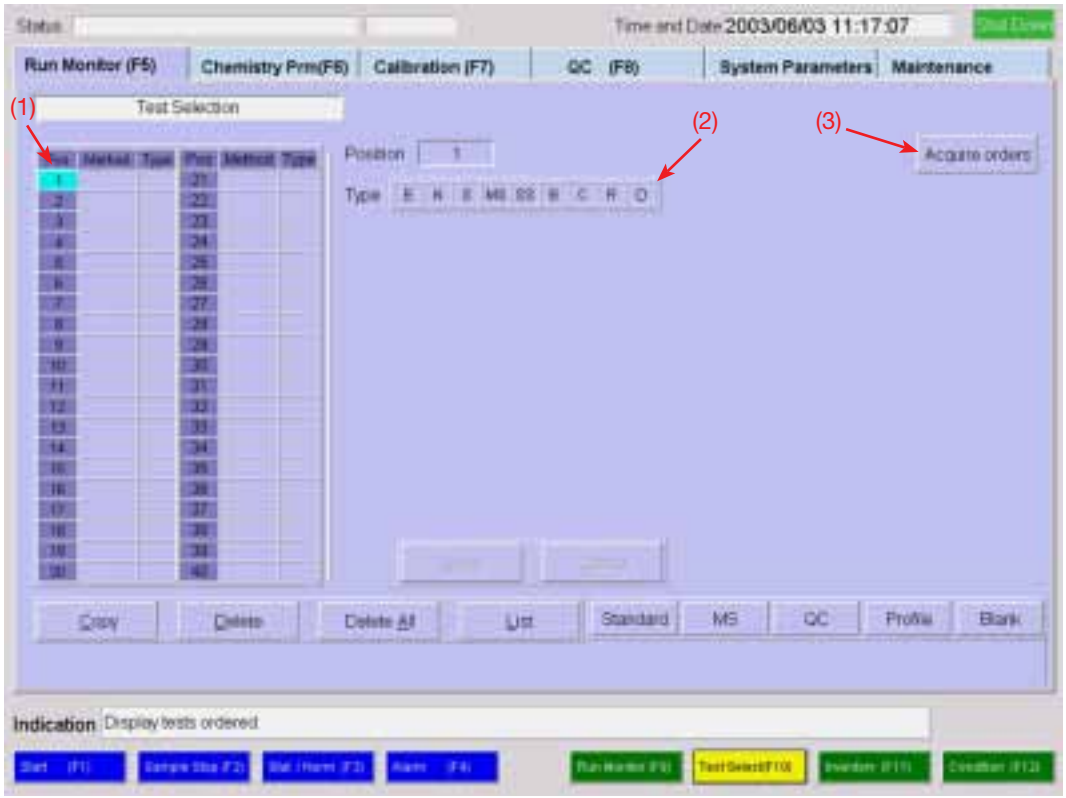
This indication is also applied to the "2.4.11 Test Selection for On-line mode (ASP without BCR)".

Green: Sampling started.
Blue: Range over
Purple: Rerun required
Red: Error
Sky blue: Process completed
White: Not processed
Yellow: Not test ordered

In case of ASP without BCR, this indication is useful for the addition of sample.

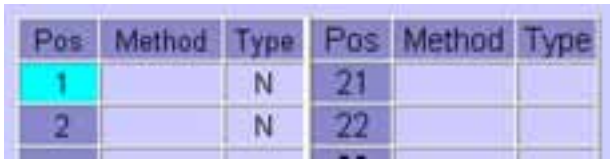
2.4.11 Test Selection for On-line mode (ASP without BCR)

In the case of Online Mode (ASP without BCR), following picture is displayed by selecting the function menu [Test Select (F10)] of job menu [Run Monitor (F5)].



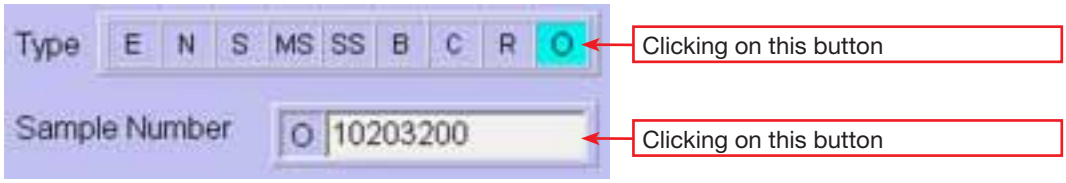
(1) Specify the slot number by the mouse or arrow key.

The numbers in the column of “Pos” correspond to the slot numbers of the ASP unit.



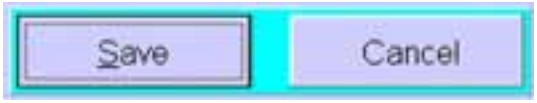
(2) Specify the type of sample and sample number for the on-line mode.

Click on “O” button, after that a sample number entry box is appeared just below the sample type definition button. So, enter the sample number into “Sample Number” box.



It is allowable to enter the numeric code with number of digit from 3 to 12 (except 90000000 to 99999999) in the Sample Number box.

And [Save] button should be clicked on to define the sample position in the ASP.

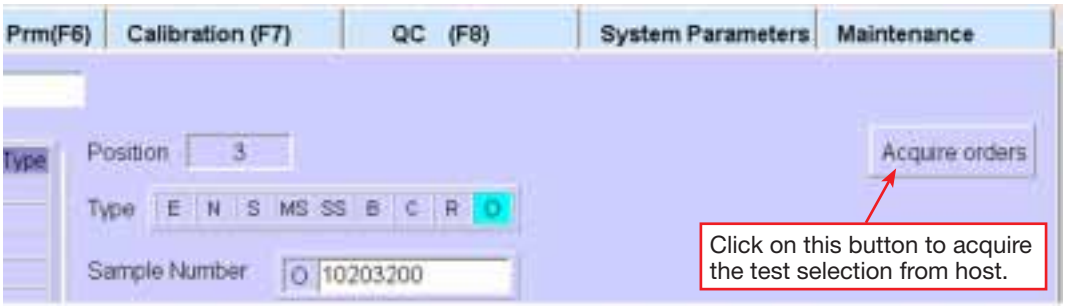


Repeat the procedure of (1) to (2) for all samples to be measured.

And to define the test order for the samples, the following procedure is needed.

(3) Acquire the test selection from the host computer.

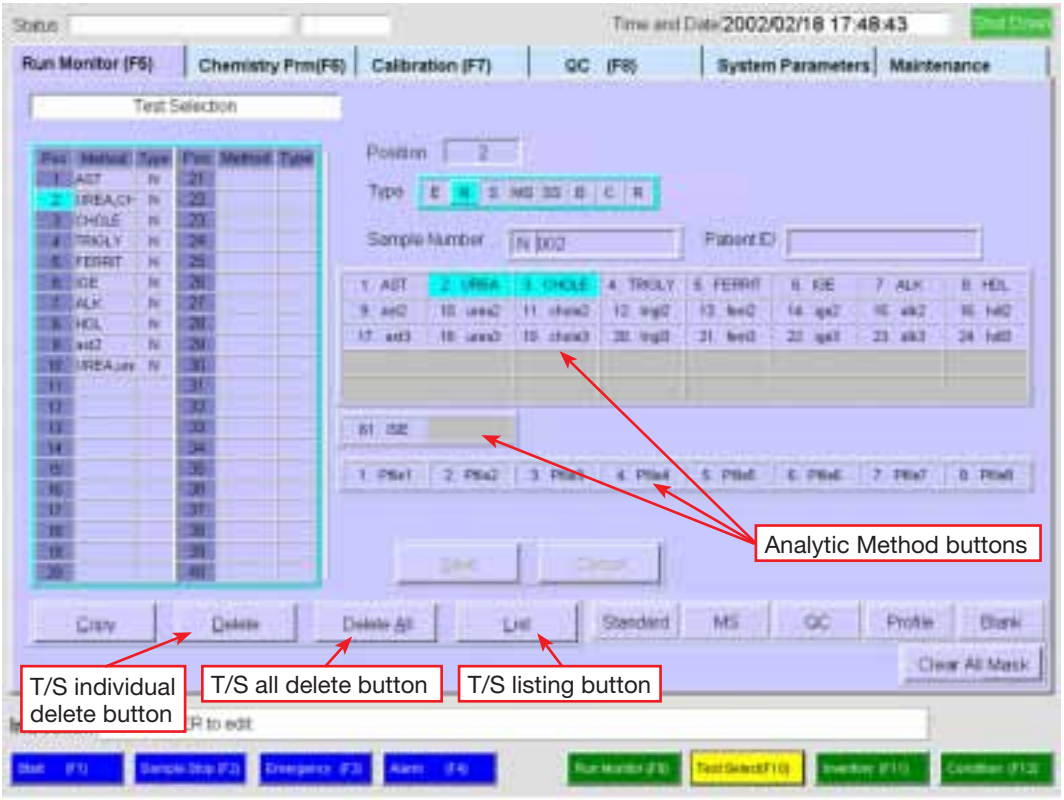
After completion of sample setting and specifying the slot number for the ASP, the test selection should be acquired from the host computer. In order to get the test selection, click on the Acquire Order button at upper-right corner on the screen.



During the communicating between the host, the following message is popped up.

2.4.12 Confirmation of Test Selection (ASP without BCR)

The following description is for confirming test selection made for the sample placed in the ASP unit. Even in the case of on-line batch mode (ASP without BCR), you can confirm the test selection by using same procedure which is described in this paragraph.



Follow the procedures below for confirming the test selection:

1. Select sample position number by moving the arrow key (→ or ←) in the column of "Pos" number for which the method buttons are shown in blue colour in the right picture (including for ISE methods or profile method buttons) and the test selection has been made.

2. If the test selection of the specified "Pos" number is deleted, click on the Delete button.

3. If the test selection of the entire "Pos" numbers is deleted, click on the Delete All button.

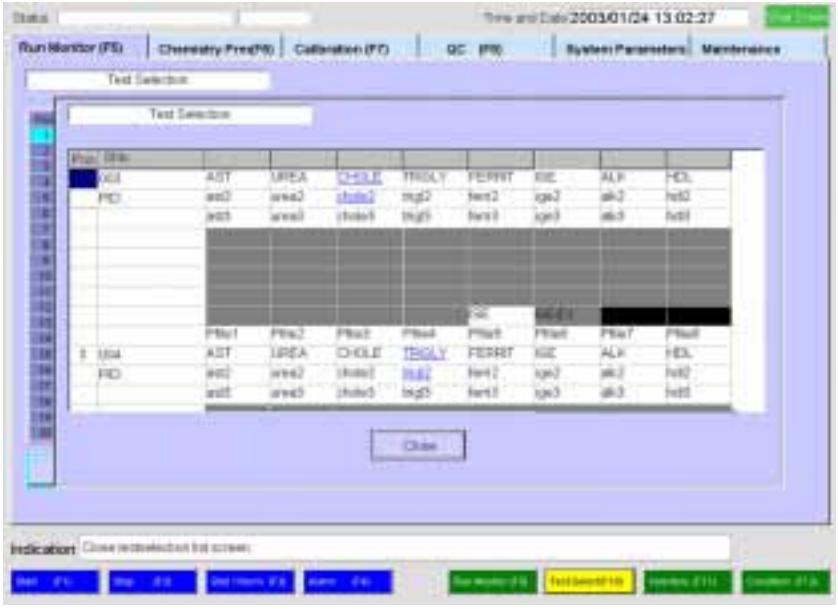
4. When List button is clicked on, the registered test selection can be displayed, confirmed.

(1) Methods underlined and in blue colour (e.g. AST): being selected.

(2) Methods on white background and in black colour (e.g. UREA, etc.): being not selected. (Candidates for selection)

(3) Gray background: not candidates for selection.

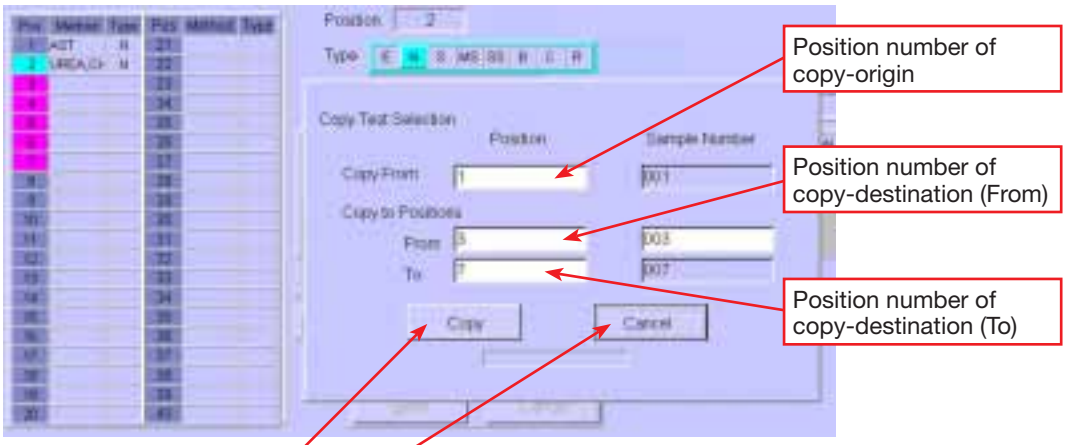
Note: In the case of ASP without BCR (barcode reader), it is not possible to change the status of test selection in the displayed list, not same as ASP with barcode reader.



5. When the test selection is copied, click on the Copy button to show the pop-up window “Copy Test Selection” and follow the procedure below:

(1) Enter into “Copy From” (copy origin) box the position number whose test selection is to be copied.

(2) Enter position numbers into both “From” and “To” boxes of “Copy to Positions” (copy destination). Sample number needs to be entered to “From” of “Copy to Positions” as well. The position numbers in the “Pos” column specified by „From” and “To” boxes turn to red colour and are defined as the copy-destination.



(3) Click on the Copy button to execute copying.

(4) Click on the Cancel button to execute copying once again.

2.4.13 Operation with Host computer connected

When the host computer is connected to this analyzer, the data entry for the test selection can be done at the host computer. The data entry is carried out in on-line batch or on-line real time mode. The mode change is made in the [Condition (F12)] picture of job menu [Run Monitor (F5)].

A) Test selection in the on-line batch mode

In the case of on-line batch mode, the information of test selection is loaded at a time prior to the initiation of chemistry analysis. Operation for this mode is as follows:

1. When “Online orders” button (ASP with BCR) or “Acquire orders” button (ASP without BCR) is clicked on at [Test Selection (F10)] screen of job menu [Run Monitor (F5)] , the test selection data are transmitted from the host computer to the analyzer.

2. After the methods based on the information of test selection are registered and the necessary reagents and samples are loaded, the measurement is initiated.

3. The test selection for emergency sample can be made on the screen of the analyzer.

4. When the “On Line Batch 1” is selected as “Host Communication Mode”, the measurement results are transferred to the host computer at the time of result obtained for one method.

5. When the “On Line Batch 2” is selected as “Host Communication Mode”, the measurement results are stored in the analyzer. If necessary, the measurement results are transferred to the host by using batch function, which is performed by selecting function menu [Result (F12)] of the job menu [System Parameters].

B) Confirmation of test selection

The information of test selection sent from the host computer can be checked in the picture or on the printed hard copy prior to the commencement of measurement. The check procedures are the same as the one without the host computer.

C) Test selection in the on-line real time mode

In the on-line real time mode, a query addressed to the host computer is raised for methods. The sequence of the operation for this mode is as follows:

1. After the methods are registered and the necessary reagents and samples are loaded, the measurement is initiated.

2. In the case of the ASP with BCR, the barcode reader in the analyzer reads the sample barcode and raises a query for the methods to the host computer, and then initiates measurement. This sequence is repeated for each sample.

But in the case of the ASP without BCR, it is not needed to read the barcode of sample since the sample position in the ASP and its sample code is defined in advance.

3. The measurement results are stored in the analyzer itself and can be transferred to the host computer in real time.

4. The test selection can be made on the screen of the analyzer only for the emergency sample.

2.5 Settings of Measurement Conditions

The following conditions can be defined in the function menu [Condition (F12)] picture of the job menu [Run Monitor (F5)].

For respective selections of the condition, they become effective while the analyzer stays stand-by condition. It means that the selection of condition does not become effective while the analyzer is running.

2.5.1 Automatic Rerun

The following re-run conditions are specified:

1. No Rerun: Rerun will not be performed.
2. Enable Rerun: Rerun is performed when the re-run situation arises.

Both sample and diluent volumes at the time of re-run need to have been defined in the Chemistry (F9) picture of job menu Chemistry Params (F6).

2.5.2 Automatic Print out

The following printout conditions are specified:

1. Enable: Measurement results (including QC result) are printed out.
2. Disable: Measurement results are not printed out.

2.5.3 Serum Information

Whether or not the measurement of serum information (haemolysis, turbidity, icterus) is performed, is specified.

1. Enable: Serum measurement is performed.
2. Disable: Serum measurement is not performed.

2.5.4 Host Communication Mode

The conditions of communications with the host computer are defined.

1. Off Line:
Measurement is performed in accordance with the test selection specified by the PC and nothing to do with the host computer.

2. On Line Batch:

3. On Line Batch 2:
Measurement is performed in accordance with the test selection transferred from the host computer without raising a query to it.
In the case of selecting “On Line Batch 1”, the measurement results of normal, emergency and control sample are automatically sent to the host computer at each time of obtaining the measurement result.
In the case of selecting “On Line Batch2”, the measurement results are not sent to the host, only saved to internal area.

4. On Line Real time:
Every time the barcode of sample is read, a query is raised to the host computer. Or in the case of ASP without BCR, instead of reading the barcode of sample, the sample code and its position in ASP are defined in the “Test Selection” picture in advance in order to be used by analyzer in query. The measurement results of normal and emergency sample are automatically sent to the host computer.

2.5.5 Host Communication

The communication protocols with host computer are defined.

1. Normal:
“ASTM E1381” protocol is applied to communicate with the host computer, when this item is selected.

2. No Handshake:
There is no protocol to communicate with the host computer, when this item is selected.

2.5.6 Prime Mode

When the measurement is started by pressing START key, normally the priming of each pumps and syringes and auto-gain adjustment are performed in accordance with following selection.

In the case this mode is changed, after analyzer is re-started by turning power off and back to on, the changed its mode becomes effective. But the skip mode becomes available without re-starting the system.

1. Skip: In case of this mode being selected, priming and auto-gain adjustment are skipped. After this round is completed, this mode selection is automatically cancelled.

2. Full Prime Mode: At any time when the measurement is started, the priming of each pumps and syringes are performed on the long prime mode.
And also auto-gain adjustment is performed.

3. Auto Prime Mode: In the case of this mode being selected, just after the measurement is started, the priming is performed on short or long prime mode.
The prime mode is automatically selected in accordance with "Auto Prime Parameter". And the auto-gain adjustment is also performed.
"Auto Prime Parameter" is specified in the function menu [Auto Start (F12)] picture of the job menu [Maintenance].

Long Prime Mode

Pump or syringe name	Operating period
SWU MX1 Pump for Mix-1 trough	ON:18 sec
SWU MX2 Pump for Mix-2 trough	ON:16 sec
SWU Water Pump for SPT trough	ON: 3 sec
SPP-S1 Syringe for SPP unit	Water discharge: 1500 µl x 10 times
RPT-water1 Pump for RPT trough	ON: 3 sec
RPT-water2 Pump for RPT trough	ON: 3 sec
RPT-detergent Pump for RPT trough	ON: 3 sec
RPP Syringe for RPP unit	Water discharge: 2000 µl x 10 times
WPP-1,3 Syringe for WU1 and WU3	Water prime: 600 µl x 10 times
WPP-1,3 Syringe for WU1 and WU3	Solution prime: 500 µl x 10 times
WPP-2, 4, 5, 6 Syringe for WU2, 4, 5 and WU6	Water prime: 600 µl x 20 times

Short Prim Mode

Pump or syringe name	Operating period
SWU MX1 Pump for Mix-1 trough	ON:1 sec
SWU MX2 Pump for Mix-2 trough	ON:1 sec
SWU Water Pump for SPT trough	ON: 1 sec
SPP-S1 Syringe for SPP unit	Water discharge: 1500 µl x 1 time
RPT-water1 Pump for RPT trough	ON: 1 sec
RPT-water2 Pump for RPT trough	ON: 1 sec
RPT-detergent Pump for RPT trough	ON: 1 sec
RPP Syringe for RPP unit	Water discharge: 2000 µl x 1 time

2.6 Preparation and placement of sample

The analyzer accommodates 40 samples in total (Normal, Emergency, Quality control and Calibrator) in sample tubes or cups. When the ASP is provided with the bar code reader, the sample tubes with caps removed and bar code labels attached can be placed directly in the sample rack. In case that the sample cups are used, they need to be put on tubes bearing the bar code labels and then placed in the sample rack. In either case, bar code labels must be affixed on tubes to identify patient and sample.

2.6.1 Sample container

A) Types of sample cup

The following types of sample cup can be used:

(1) Child cup (to be put on the dedicated adaptor bearing bar code label)

(2) Dedicated bottle (to be loaded in the disposable adaptor)

B) Types of sample tube

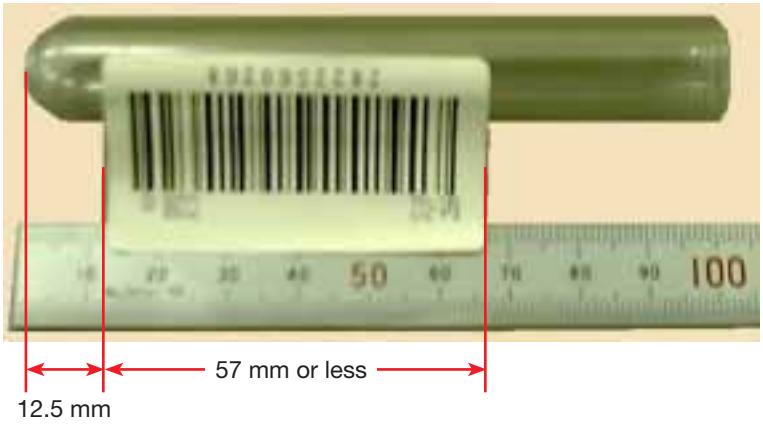
Sample tubes of 13 and 16 mm in diameter and 53 and 100 mm in length can be used (adaptor is used as necessary).

2.6.2 Specifications of bar codes

Item	Description
Symbols	NW-7, Code39, ITF, UPC, Code128 (Set A, B, C)
Maximum number of digits	The bar codes must be in conformity with one of the following bar modules and with bar code printing range. The maximum allowable number of digits varies depending on symbols.
	NW-7: 3 to 12 digits Code39: 3 to 8 digits ITF: 3 to 12 digits UPC: 3 to 12 digits Code128 (Set A): 3 to 12 digits Code128 (Set B): 3 to 12 digits Code128 (Set C): 3 to 12 digits
Bar module	• Fine bar: 0.25 to 1.0 mm • Bar length ≥ 15 mm
Barcode printing range	• Bar code printing area ≤ 57 mm • Blank portions of 4 mm are provided at both side of bar code.
Printing	• Black on white background (B633) • Numeric coding information is printed beside bar code. • Printing on thermal paper is not allowed in order to prevent bar code from time varying degradation. • Quality standard ANSI MH10.8M applies.
Positioning of barcode label	• The position is such that there is no obstacle between the bar code printing area and the bar code reader. • Angle alignment deviation: within ±1°

A) Barcode attachment to the tube or bottle

Barcode label is attached to the tube or bottle as below drawing.



2.6.3 Types of barcode labels

The following four types of barcode labels are used depending on the types of samples.

Allowable characters to the barcode label for normal sample (include online sample), emergency sample and replicate sample are;

Numeral characters	: 0 to 9
Alphabetical characters	: A to Z and a to z
Symbols	: !, “, #, $, (,), +, -, ., /, ;, <, =, >, ?, @, [,], {, }, ~

A) Normal sample

The barcode labels which can be used are the ones bearing sample numbers in 3 to 12 characters. In the case of 8 characters, don’t use “9” at the top of character string.

B) Emergency sample

The emergency sample barcode label is used for the emergency sample.

The numeric codes in 8 digits can be used for barcode labels of emergency sample.

The bar code is defined as 99000nnn, where “nnn” is allowed using numerical or alphabetical or symbolical characters as previous mentioned.

C) Replicate sample

The bar code label is used for the case that the same sample is measured repeatedly.

The bar code is defined as 9400nn01, where “nn” is allowed using numerical or alphabetical or symbolical characters as previous mentioned.

D) Quality control sample

The numeric codes in 8 digits can be used for barcode labels of quality control sample.

The bar code is defined as 970000nn, where “nn” is from 01 to 30.

E) Normal standard sample (Calibrator)

The numeric codes in 8 digits of 980xxxxy can be used for barcode labels of calibrator. The “xxxx” is from 0001 to 9999, which is applied for reagent code. And the “y” is from 1 to 7.

The calibrator is provided in dedicated bottle and together with disposable adaptor with barcode affixed. The barcode contains the information about sample type code, method code, liquid number (concentration, etc.), etc.

Disposable adaptors loaded with these calibrators are placed in the analyzer.

F) Multi standard sample (Calibrator)

The numeric codes in 8 digits of 950000xy can be used for barcode labels of multi standard calibrator. The “x” is from 0 to 9 and “y” is from 1 to 7. (Refer to “2.3.6 Registration of Multi-standard”.)

G) Single standard sample (Calibrator to be diluted)

This standard sample is used for normal standard, which is diluted by means of automatic dilution calculation. (Refer to “2.3.4 Full calibration using a single calibrator”.)

The numeric codes in 8 digits of 930nnnn0 can be used for bar code labels of single standard calibrator. The “nnnn” is from 0001 to 9999.

H) One point calibration sample

This barcode is defined for one point calibration sample as 95100001. And this code can be used for S1 compensation on the Factor and Linear calibration method.

2.6.4 Placement of samples

When the samples are placed in the auto sampler (ASP) unit, their positions are not specifically designated for the types of samples. The ASP unit rotates in the counter clockwise direction and the samples are aspirated in the order in which samples reach the SPT aspirating position.

Place sample following the rules below:

(1) Place calibrators at the front of normal samples. Otherwise, the samples placed at the front of the calibrators are subject to the calibration curve obtained by the past round.

(2) There is no need for calibrators to be placed in order of their sample number (concentration values). However, where the calibrators have the same methods, place them consecutively.

(3) Quality control sample may be placed at any position but preferably be immediately after calibrator.

2.7 Initiation of measurement and monitoring

2.7.1 Initiation of measurement

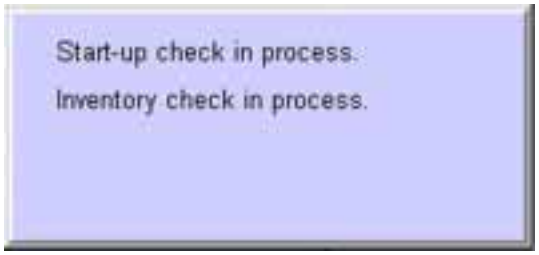
The analyzer performs automatically sample measurement, computation and printout of measurement results and transfer of the measurement results to the host computer by pressing [F1] key or clicking on [Start (F1)].

The photo-metering part in the analyzer is stabilized at least 30 minutes after switched on. Pay particular attention to this fact when the [Start] key is pressed.

2.7.2 Monitoring of measurement

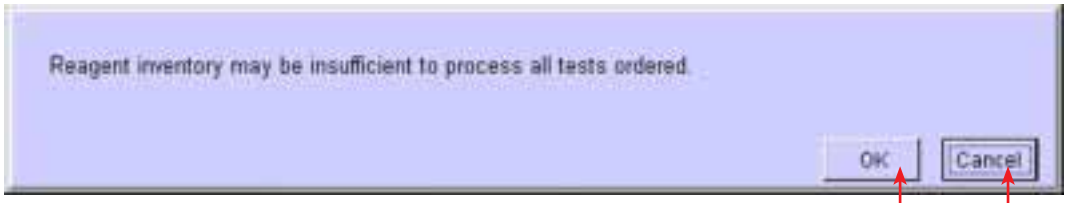
The progress of measurement can be monitored on the [Run Monitor (F9)] picture of job menu [Run Monitor (F5)].

Just after pressing [F1] key or clicking on [Start (F1)] key, analyzer begins to check for starting-up and reagent inventory. To announce this checking process for operator, the following message is popped up at the centre of run-monitor screen.



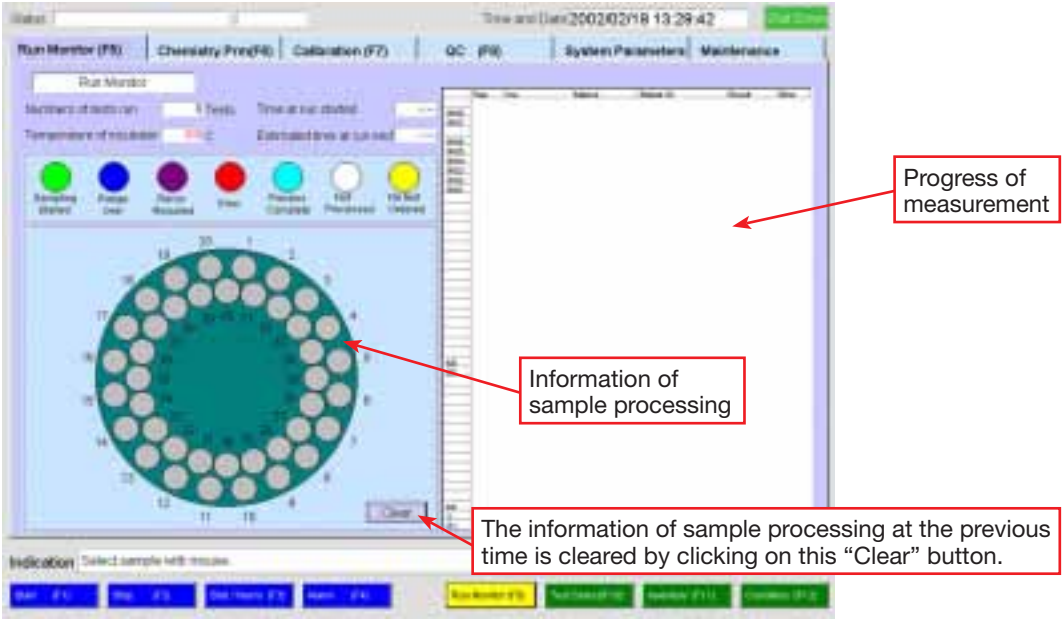
When reagent short is found the warning message is popped up at the centre of screen as shown below.

And the alarm code-6101 is simultaneously issued.



OK: When this button is clicked on, measurement process is continued.

Cancel: When this button is clicked on, measurement process is terminated.



A) Number of tests run

The number of tests to be measured for which the test selection was made is indicated. Quality control samples and calibrators are not counted.

B) Indication of temperature in Incubation Reaction Unit (IRU)

The current temperature in the IRU is indicated. The measurement can not be initiated unless the temperature falls within the specified range (37 ± 0.5°C).

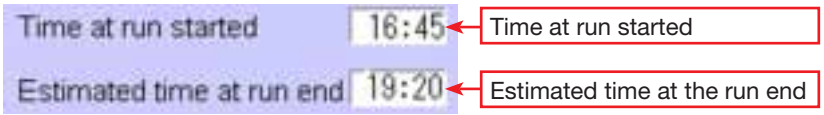
C) Indication of times of both start and end of measurement

The time at the run started and the estimated time at the run end are indicated.

The time of “Estimated time at run end” is changed as progressing of the measurements.

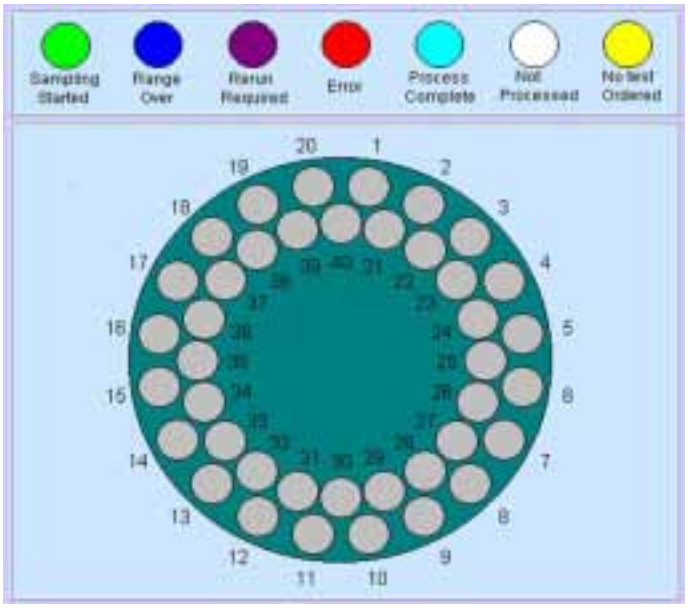
At the time when the replication sample(s) or calibrator(s) is/are definite for test selection, its time of processing needed are added to the estimated time at run end.

As a matter of course, ISE is taken account of the processing time in the estimated time at run end.



D) Information of sample processing

The information of sample processing is displayed in the left half portion of the [Run Monitor (F9)] picture of job menu [Run Monitor (F5)] and identified in colour codes.

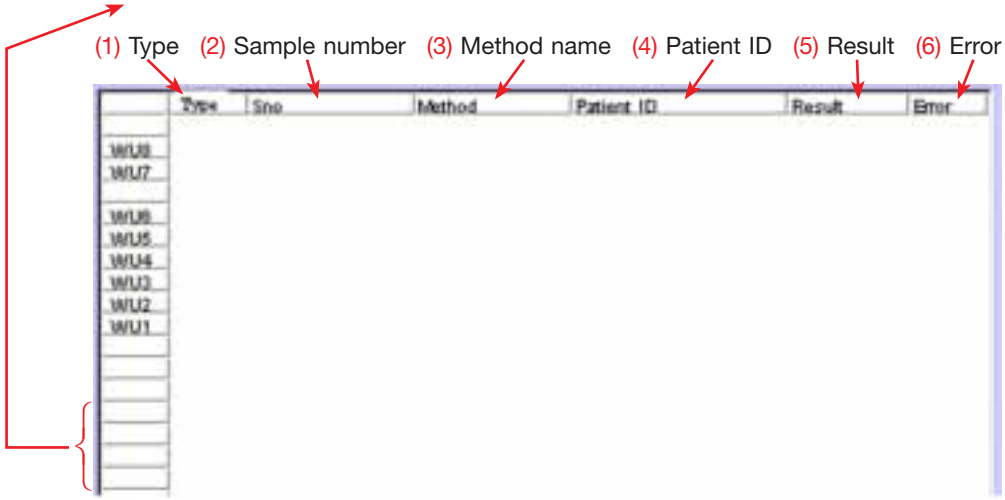


Green:	Sampling Started
Blue:	Range Over
Purple:	Re-run Required
Red:	Error
Sky-blue:	Process Completed
White:	Not Processed
Yellow:	Not Test Ordered

E) Progress of measurement

The progress of measurement is displayed in the right half portion of the [Run monitor (F9)] picture and the status of each sample from its sampling to the end of reaction is shown.

The results of measurements (concentration value) are also displayed at nearby below 4 or 5 lines from “WU1”.



(1) “Type” column

The meanings of information shown in the “Type” column of the above picture are as follows:

1) Normal and emergency samples

None	Normal measurement (1st time)
A>	Re-run (Greater than higher limit.)
A<	Re-run (Less than lower limit.)
D1	Diluted re-run
DF	Dilution Factor

2) Quality control (QC) sample

C1	Control sample

3) Calibrator

#1	1st measurement
#2	2nd measurement
#3	3rd measurement

(2) "Sno." column

The meanings of information shown in the "Sno." column of the above picture are as follows:

Normal sample Emergency sample Replicate sample	3 to 12 characters (See "2.6.3 Types of barcode labels".) Ennn to Ennn (nnn: Numerical/Alphabetical/Symbolical) Rnn to Rnn (nn: Numerical/Alphabetical/Symbolical)
QC sample	C01 to C30
Calibrator Multi calibrator Single calibrator Blank sample	S000011 to S999997 MS01 to MS97 SS000011 to SS999997 B

(3) "Method" column

Method numbers are indicated.

(4) "Patient ID" column

The patient identification code entered in the [Test Selection (F10)] picture of job menu [Run Monitor (F5)] is shown in the "Patient ID" column.

(5) "Error" column

The meanings of information shown in the "Error" column of the above picture are as follows:

SS	Insufficient volume of sample
SI1	Aspiration of sample disabled at ASP position
SI2	Aspiration of diluent disabled at IRU position
R1S	Insufficient volume of primary reagent (R1)
R2S	Insufficient volume of secondary reagent (R2)
DS	Aspiration of diluent disabled at RCU position
WS	Aspiration of wash solution disabled at RCU position
TE1	Lower temperature of IRU than 35 centigrade
TE2	Higher temperature of IRU than 39 centigrade
TE3	Higher temperature of RCU than 15 centigrade
R1B	R1 reagent bottle not registered
R2B	R2 reagent bottle not registered
DB	Diluent bottle not registered
WB	Wash solution bottle not registered
IE1	No response from ISE
IE2	No measurement result obtained from ISE
EST	Error arises during measurement and sampling interrupted
LOT	Reserved
CLT	Reserved

R1W	Wash of RPT between methods failed (timing of R1 reagent)
R2W	Wash of RPT between methods failed (timing of R2 reagent)
EXP	Period of validity of reagent expiry
STB	Period of stability of reagent expired
CTO	These flags are not outputted on the run monitor screen. (Refer to “4.6.2 Measurement result error flags”.)
OVR	
CA?	
CAL	
LIN	
PRO	
AB1	
AB2	
DUP	
SEN	

2.7.3 Interruption and Resumption of measurement

The analyzer comes to rest when all measurement has been completed. During measurement, it can be interrupted and resumed manually.

A) Interruption of sampling ([Stop (F2)])

Sampling is interrupted by pressing [F2] key or by positioning the pointer in [Stop (F2)] and clicking the left button of the mouse. However, for the samples whose sampling operation has been completed, their measurements are carried on.

B) Emergency stop ([Ctrl] + [F2])

Entire processing operations come to stop by pressing [Ctrl] and [F2] keys simultaneously.

C) Resumption of measurement ([Start (F1)])

The measurement can be resumed by pressing [F1] key or clicking on the [Start (F1)] button while the (photometric) measurement of samples whose sampling operation has been completed is ongoing.

2.7.4 The function of Liquid level sensor unit for external tanks (ETNK) (an optional function)

The analyzer watches the following condition by each Liquid Level Sensor corresponding to the use for each tank.

1. System Water Tank: It is sensed that the System Water is empty.
2. Wash Sol.-1,2, or 3 Tank: It is sensed that each Wash Solution is empty.
3. Low or High Conc. Waste Tank: It is sensed that each Waste is overflow.

When one of the above conditions is detected, the alarm indication, the operation of the analyzer, and the restoration method are as the following.

A) During the prime operation

Name of Tank	Alarm Indication	Operation of Analyzer	Restoration Method
System Water	E2606	Emergency Stop	Fill the tank with System Water, and register the order, and operate the start method.
Wash Sol.-1	E2607	Emergency Stop	Fill the tank with Wash Solution, and register the order, and operate the start method.
Wash Sol.-2	E2608	Emergency Stop	Fill the tank with Wash Solution, and register the order, and operate the start method.
Wash Sol.-3	E2605	Emergency Stop	Fill the tank with Wash Solution, and register the order, and operate the start method.
Low Conc. Waste	E2609	Emergency Stop	Make the tank empty, and register the order, and operate the start method.
High Conc. Waste	E2610	Emergency Stop	Make the tank empty, and register the order, and operate the start method.

B) During the running operation

Name of Tank	Alarm Indication	Operation of Analyzer	Restoration Method
System Water	E2676	Sampling Stop	Fill the tank with System Water, and operate the start method. If the factor of the alarm is cancelled, sampling is resumed.
Wash Sol.-1	E2677	Sampling Stop	Fill the tank with Wash Solution, and operate the start method. If the factor of the alarm is cancelled, sampling is resumed.
Wash Sol.-2	E2678	Sampling Stop	Fill the tank with Wash Solution, and operate the start method. If the factor of the alarm is cancelled, sampling is resumed.
Wash Sol.-3	E2675	Sampling Stop	Fill the tank with Wash Solution, and operate the start method. If the factor of the alarm is cancelled, sampling is resumed.
Low Conc. Waste	E2679	Sampling Stop	Make the tank empty, and operate the start method. If the factor of the alarm is cancelled, sampling is resumed.
High Conc. Waste	E2680	Sampling Stop	Make the tank empty, and operate the start method. If the factor of the alarm is cancelled, sampling is resumed.

2.8 Addition of Sample

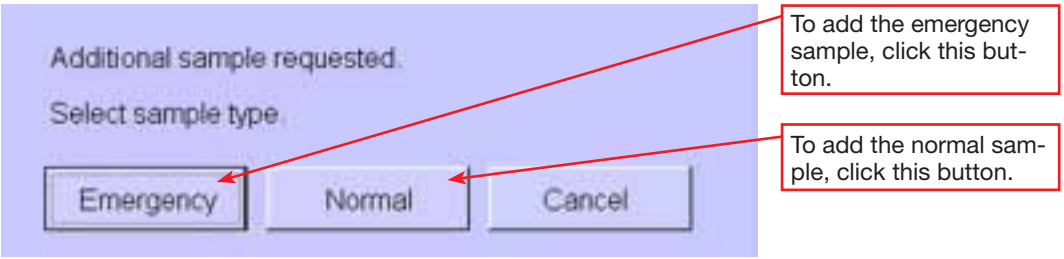
2.8.1 Addition of Emergency Sample (ASP with BCR)

When an emergency sample is added during measurement, make the test selection in accordance with the following procedures and place it in the analyzer. The placed emergency sample is then processed.

The function of addition of emergency sample is effective, when the replicate sample is not loaded.

1. When an emergency sample is to be added, the test selection should be made in advance. Select the function menu [Test Selection (F10)] or press the [F10] key. And by pressing key of [Page Up], the Test Selection screen of page-2/2 is selected. The testing order of the emergency sample is able to be set on this screen in the same way as for the normal sample.
Refer to "2.4.2 Test Selection of Normal and Emergency sample (ASP with BCR: Option).

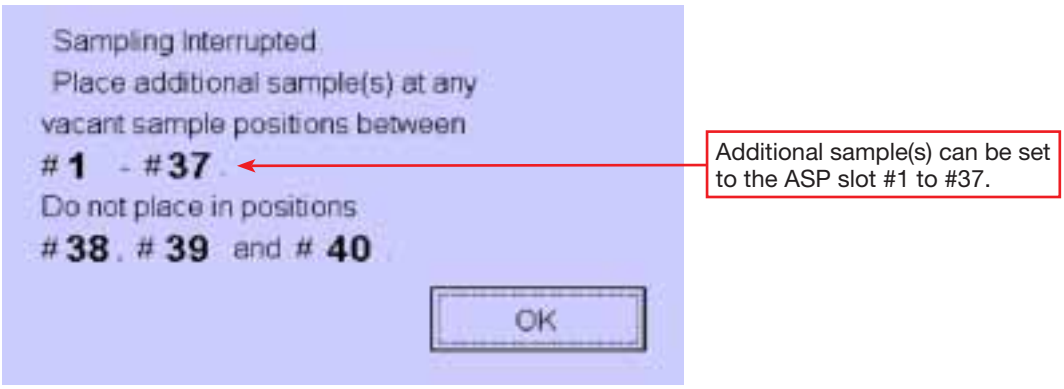
2. Click on the job menu [Stat/Norm (F3)].
The following pop-up window appears in the centre of the screen.



3. The following message appears on the screen until the sampling interruption process is completed.

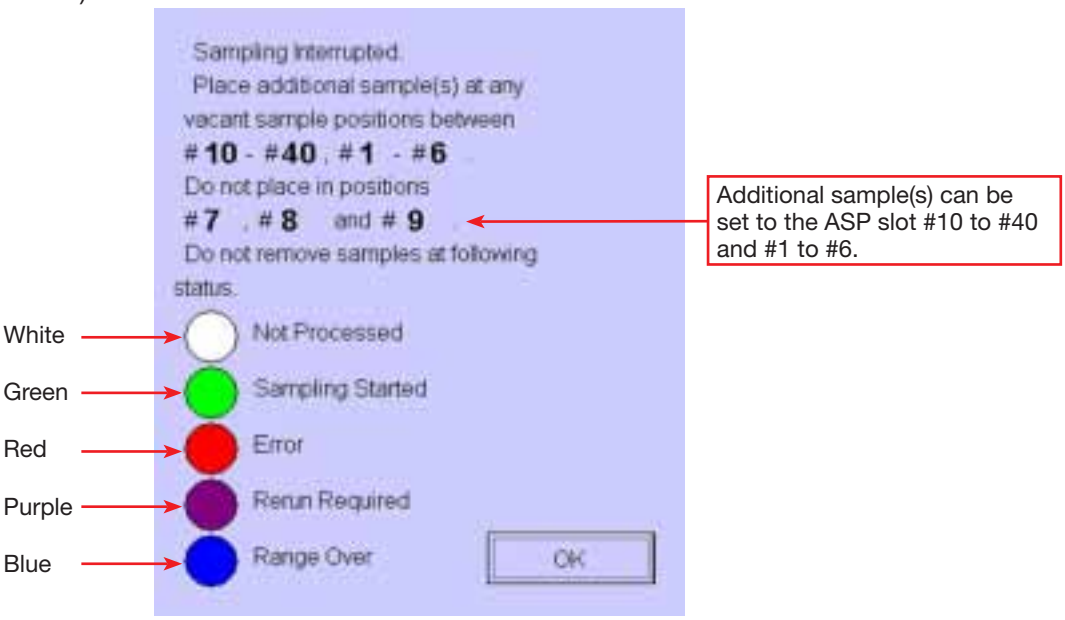
4. The following message is displayed when the ASP is ready to accept the emergency sample after the sampling interruption process has been completed. And also the available position number in ASP to set the emergency sample and not removable samples are instructed.

(1) Rerun condition is set "No reruns". (See "2.5 Settings of Measurement Conditions".)



As an example, above picture shows the emergency sample(s) is/are able to put at ASP slot position #1 to #37.

(2)Rerun condition is set “Enable rerun”. (See “2.5 Settings of Measurement Conditions”.)



5. Click on the OK button in the popped up message, after the emergency sample is placed in the ASP unit. Emergency sample is moved to the sampling position, and is going to be measured in preference to the other normal sample.

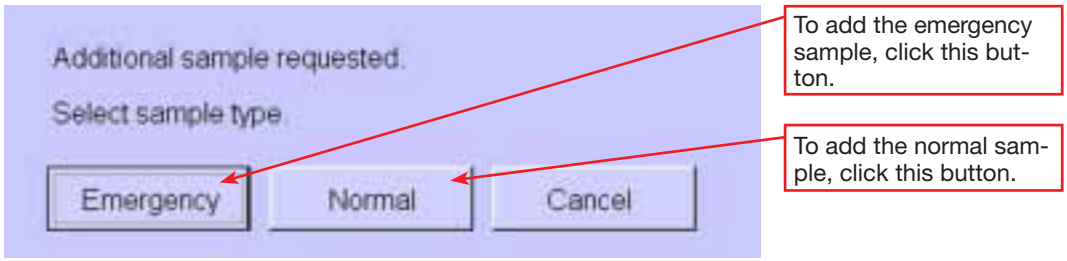
Note: The emergency code should be printed on the barcode label of emergency sample or the sample type should be selected “Emergency (E)” in the [Test Selection (F10), Page: 1/2] of [Run Monitor (F5)] in advance when the normal sample code is employed as the emergency sample. Otherwise, the added sample will not be processed correctly.

2.8.2 Addition of Emergency Sample (ASP without BCR)

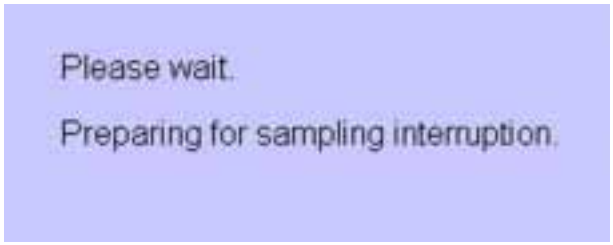
The function of addition of emergency sample is effective, when the replicate sample is not loaded.

1. Click on the job menu [Stat/Norm (F3)].

The following pop-up window appears in the centre of the “Run Monitor” picture.

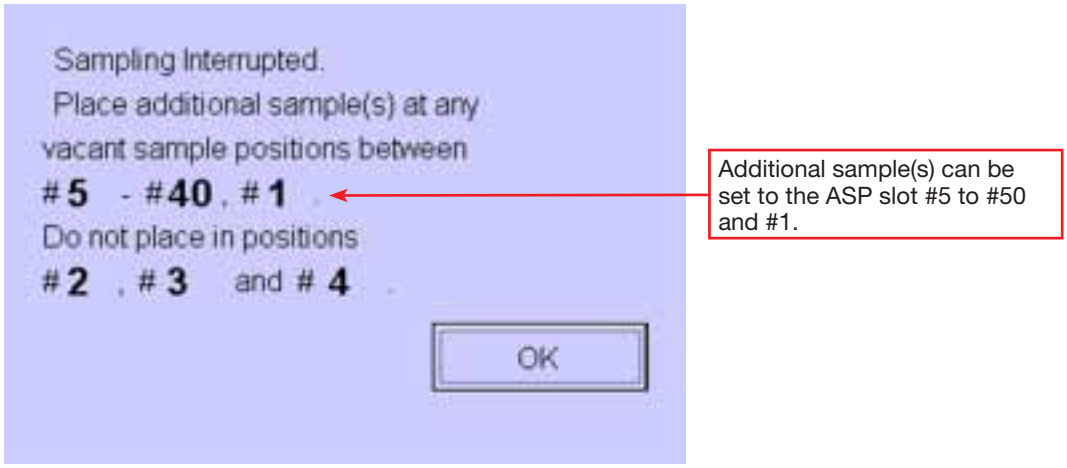


2. The following message appears on the screen until the sampling interruption process is completed.

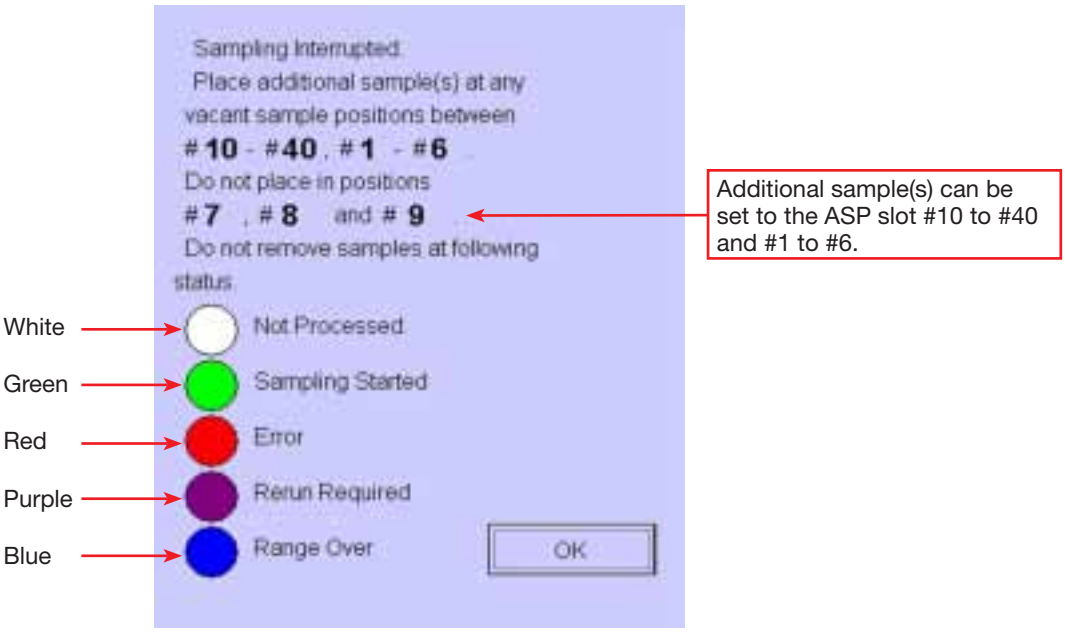


3. The following message is displayed when the ASP is ready to accept the emergency sample after the sampling interruption process has been completed.

(1) Rerun condition is set “No reruns”. (See “2.5 Settings of Measurement Conditions”.)



(2) Rerun condition is set “Enable rerun”. (See “2.5 Settings of Measurement Conditions”.)



4. Put the emergency sample at the specified place of the sample tray in the ASP unit. And click on the OK button.

5. The [Test Selection] picture is selected automatically and thus, in the picture, specifies the type of sample “E”. (See “2.4.10 Test Selection for off-line mode (ASP without BCR)”.)

6. Clicking on the job menu [Stat/Norm (F3)] or [Start (F1)], the emergency sample is moved to the sampling position, and is going to be measured in preference to the other normal sample.

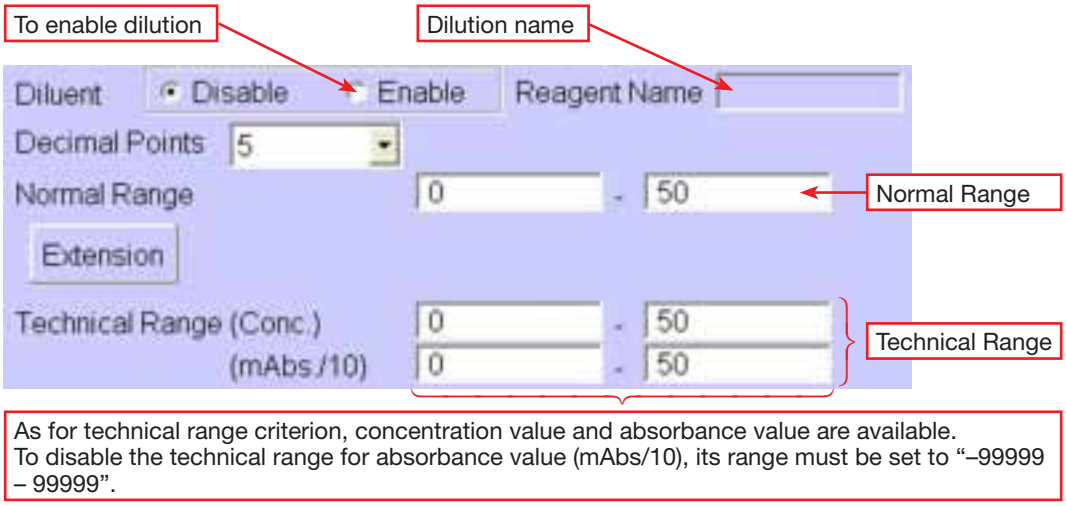
2.8.3 Addition of Normal Sample

When a normal sample is to be added, click on the job menu [Stat/Norm (F3)] and press Normal button in the pop-up message. Since then the procedure is to be referred “2.8.1 Addition of emergency sample (ASP with BCR)” and “2.8.2 Addition of Emergency Sample (ASP without BCR)”. But added normal sample is proceeded in due order placed in the tray of ASP.

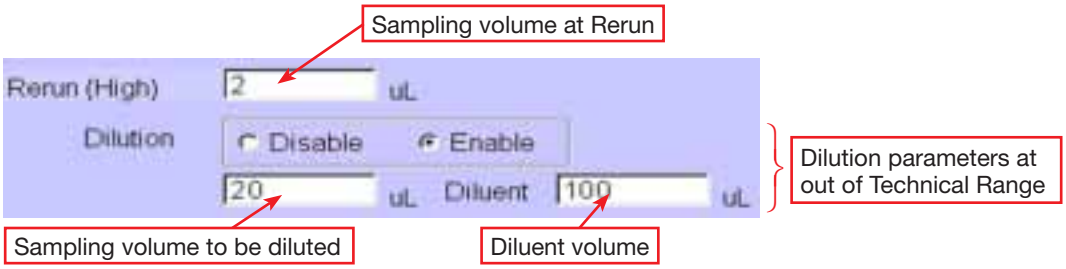
2.9 Measurement of Sample for Rerun

Where the “Rerun” volume of a sample was specified in the [Chemistry (F9)] picture of the job menu [Chemistry Prm (F6)], the sample is identified after the measurement result of the round has been output and its rerun is automatically initiated in accordance with the settings in the [Chemistry (F9)] picture of the job menu [Chemistry Prm (F6)].When the measurement result is out of Technical Range, it is subjected to the rerun.

When the measurement failed due to the insufficient volume of sample or reagent, perform such a measurement in the next round. The conditions of rerun set in the [Chemistry (F9)] picture of the job menu [Chemistry Prm (F6)] are shown below:



The following picture is the case of “High”. There are two types of settings (“High” and “Low”) as the dilution parameter settings for the rerun.



2.9.1 Measurement of sample for rerun.

1. Out of Technical Range “High”.
2. Out of Technical Range “Low”.
3. AB1 error occurs.

The measurement is performed in accordance with the settings of “Dilution” in the [Chemistry Prm (F6)]. See “3.2 Analytical Conditions [Chemistry Prm (F6)]” in detail.

2.9.2 Resultant value of rerun

1. In the case of diluted rerun, the resultant value is the value corrected for the dilution ratio.

2. The measurement result that is before rerun executing and the resultant value of rerun are stored in the analyzer. And also, the flag “r” is attached to the resultant value of rerun to distinguish from original result.

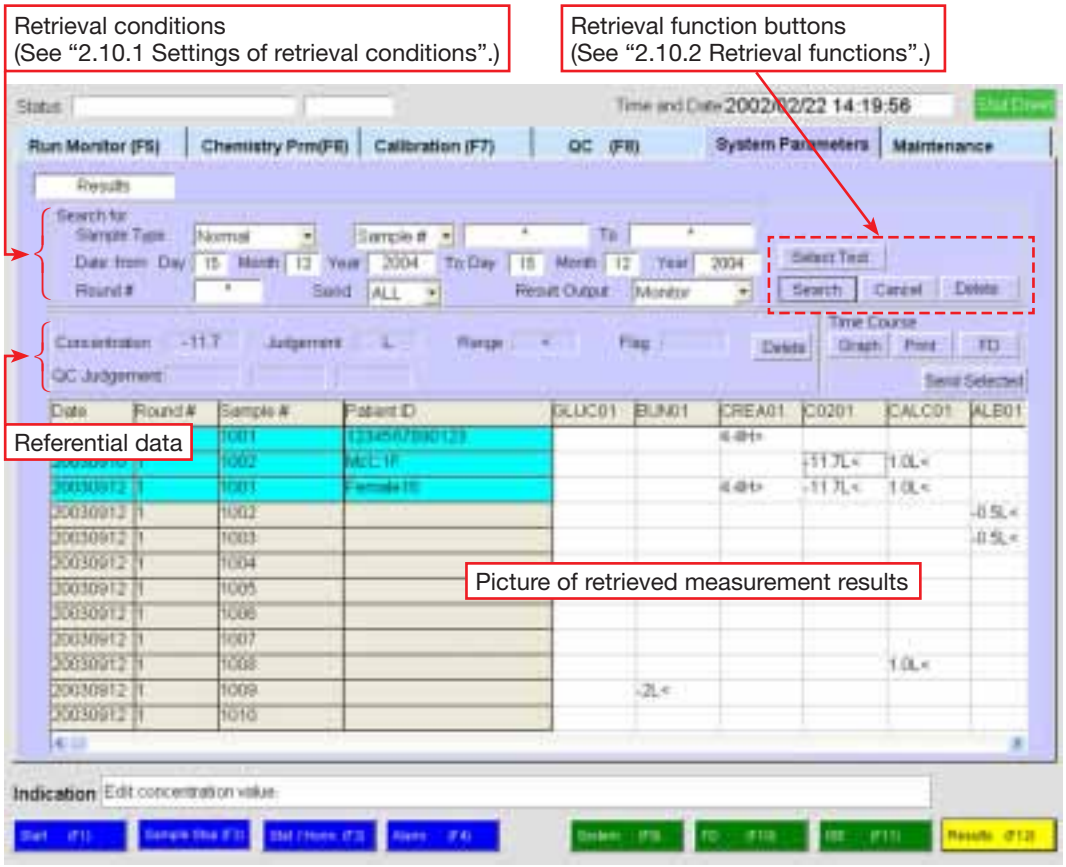
3. The resultant value of rerun that is out of technical range is dealt like below:

Case	Reaction mode	Resultant value (Concentration) (Common to output for display, print, FD and ASTM)
Measured concentration value before rerun execution is greater than upper limit of technical range for concentration.		Upper limit value of technical range for concentration is outputted.
Measured concentration value before rerun execution is less than lower limit of technical range for concentration.		Lower limit value of technical range for concentration is outputted.
Measured absorbance value before re-run execution is greater than upper limit of technical range for absorbance.	Increase	Upper limit value of technical range for concentration is outputted.
	Decrease	Lower limit value of technical range for concentration is outputted.
Measured absorbance value before rerun execution is less than lower limit of technical range for absorbance.	Increase	Lower limit value of technical range for concentration is outputted.
	Decrease	Upper limit value of technical range for concentration is outputted.

See “2.3.5 Confirmation of judgement criteria and measuring conditions”.

2.10 Reproduction of Measurement Results

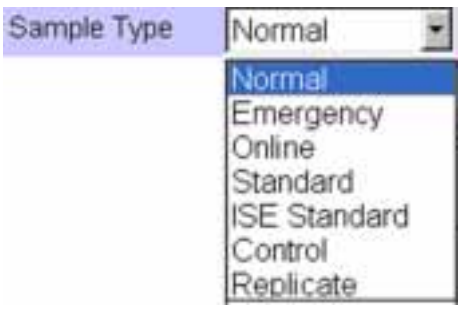
The measurement results can be reproduced on the display in the function menu [Result (F12)] picture of the job menu [System Parameters]. Specify the data of measurement to reproduce the corresponding measurement results on the display or in the form of hard copy. The reproduced data on the display can not be edited, but the “Delete” function is only allowed. The time course of the specified measurement results can also be displayed.



2.10.1 Settings of retrieval conditions

In order to extract the measurement result from the internal data base, it is needed to set the retrieval conditions as below items.

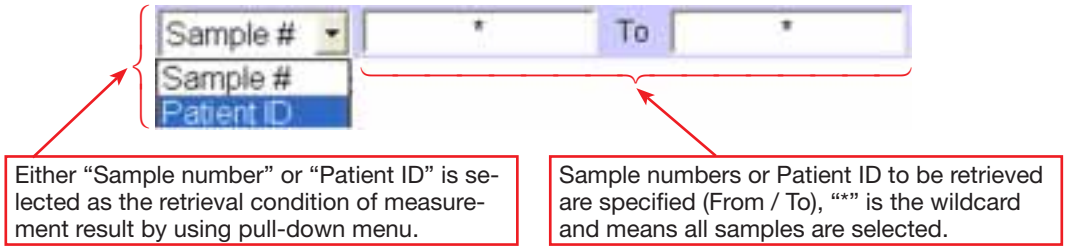
“Sample Type” setting box



The sample type to be retrieved is selected from Normal, Emergency, Online, Standard, ISE Standard, Control and Replicate by using pull-down menu.

"Sample # (From – To)" setting box

These settings are effective against the sample type of "Normal", "Emergency", "Online" and "Replicate".



"Dates from and Date to" setting box

Dates of the measurements to be retrieved are specified. "*" is the wildcard and means that all samples are selected.

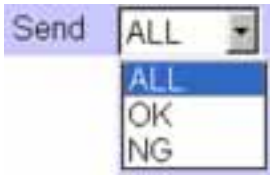
"Round #" setting box

The round number of the measurement results to be retrieved is specified.

"*" is the wildcard and means that all samples are selected.

"Send" selecting box (This is available for online data.)

This selection is applied to only the measurement results which have been got by means of the online measurement.

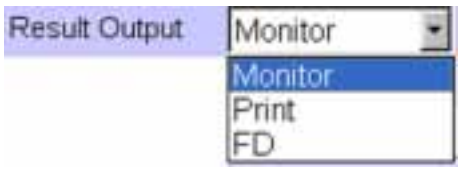


All: Reference data are all measurement results by measured online mode.
OK: Reference data are the measurement results which were correctly transferred to the Host.
NG: Reference data are the measurement results which were not correctly transferred to the Host.

"Result Output" selecting box

Output destination of the measurement results to be retrieved is chosen one among the destination list from pull-down menu. Destination depends on the sample type.

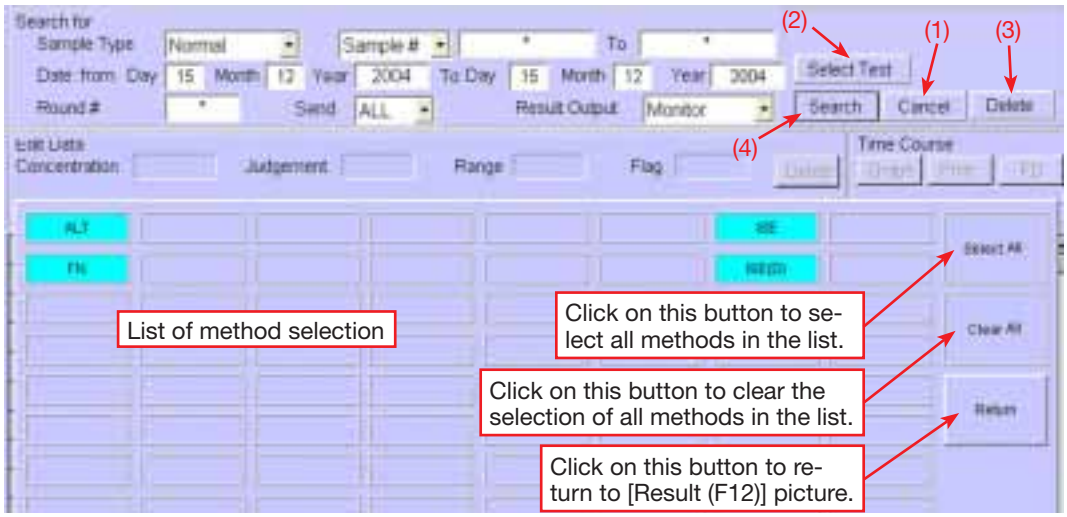
As for the output of Control result, refer to the "Optional settings" in the function menu [System (F9)] of job menu [System Parameters].



Sample type	Destination
Normal, Emergency, Online, Control	1)Monitor, 2)Print, 3)FD, 4)Host(*1)
Standard, ISE standard, Replicate	1)Monitor, 2)Print, 3)FD

*1: To make effective this destination (Host), “Send QC Result”, one of optional setting flags (Details button), should be set effective in the function menu [System (F9)] of job menu [System Parameters] and choose whichever “On Line Barch1” or “On Line Batch2” or “On Line Real time” among the “Host Communication Mode” selection picture in the function menu [Condition (F12)] of job menu [Run Monitor (F5)].

2.10.2 Retrieval functions



(1) “Cancel” button

When this button is clicked the settings of “Date from” and “to” are reseted to the wild card (“*”).

(2) “Select Test” button

The above method selection picture (List of method selection) is displayed by clicking on this button. Click on the methods to be selected, and then the colour changes to blue.

(3) “Delete” button

If operator wants to delete the extracted data, click on this Delete button.

After clicking on the Delete button, the pop-up message picture is appeared on the screen due to confirmation of the deletion as below picture.

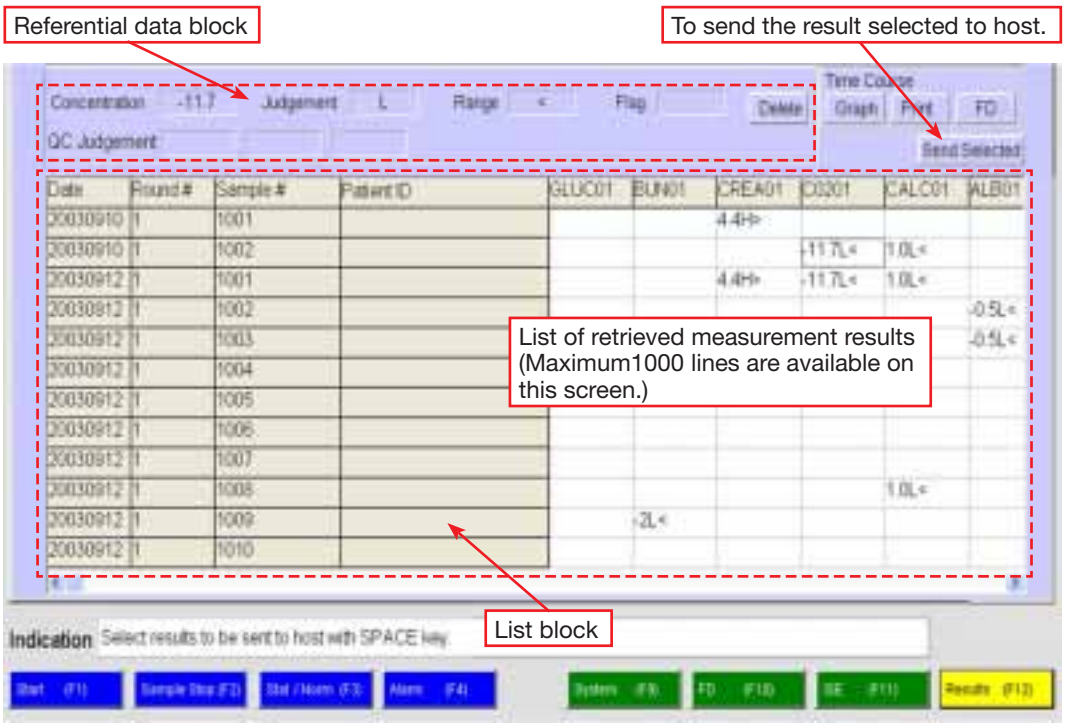
When the Yes button is clicked on, all of retrieved measurement results are deleted from the internal database. **Thus, the practicing of this function should be fully taken care.**

(4) "Search" button

When this button is clicked on, the extracting of measurement result begins in accordance with the retrieval conditions and selected method. And the retrieved results are outputted.

A) Sample Type: Normal/Emergency/Online/Replicate ("Monitor" is selected as "Result Output".)

When the sample type is selected "Normal", "Emergency", "Online" or "Replicate", the list block is similar. The difference is the sample number expression.



A measurement result in the list area is assigned at random by clicking on it by using mouse to make work the function buttons of "Time Course". And also, different information about the assigned result is outputted to the referential data block.

<Function buttons for "Time Course">

See "2.10.3 Output of time course data".

Graph: When click on this button, the time course data of assigned measurement result is plotted graphically on the screen.

Print: When click on this button, the time course data of assigned measurement result is printed on the hard copy.

FD: When click on this button, the time course data of assigned measurement result is outputted to the floppy disk.

<Function button for "Send Selected"> Send Selected

When the host communication mode is selected to online mode (Online Bach1 or Online Bach2 or Online Real time), a result or results in the retrieved measurement results can be outputted to the host by pushing Send Selected button.

The procedures are shown below.

1. Put the cursor on a result and click on it by mouse.

2. Push the space key. The colour of record (one line) is changed to blue; it means its record is ready to be outputted to the host.

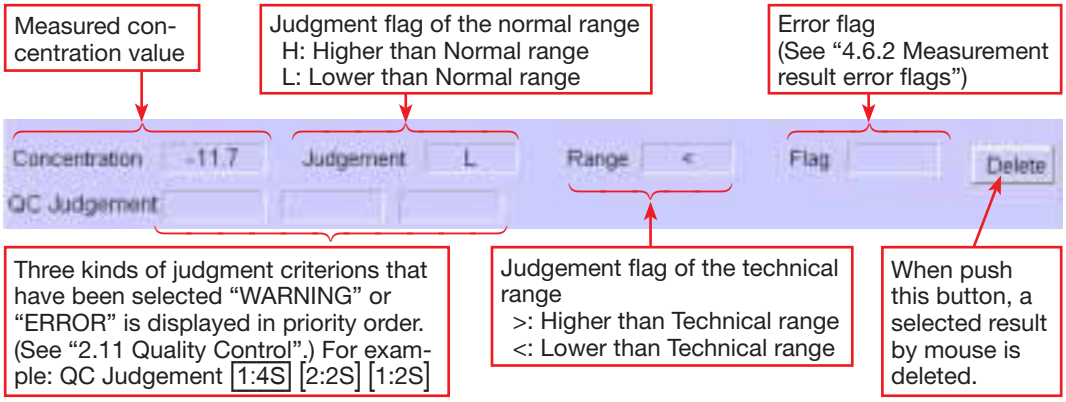
3. If there is a yet more result to be sent to the host, repeat above steps (1 to 2).

4. after fulfilment of the record assignment in accordance with above steps,

push the [Send Selected] button. Then the assigned records are sent to the host.

<Referential data block>

Every referential data such as concentration value, normal range judgement flag, technical range judgement flag, measurement result flag and QC judgement result (for only QC result) are displayed to the referential block as to a result selected by mouse among the list of retrieved measurement results as above picture.



<Deletion of one by one>

A result which is selected by mouse among the retrieved measurement results can be deleted one by one. The procedures are shown below.

1. Put the cursor on the unnecessary result and click on it by mouse.

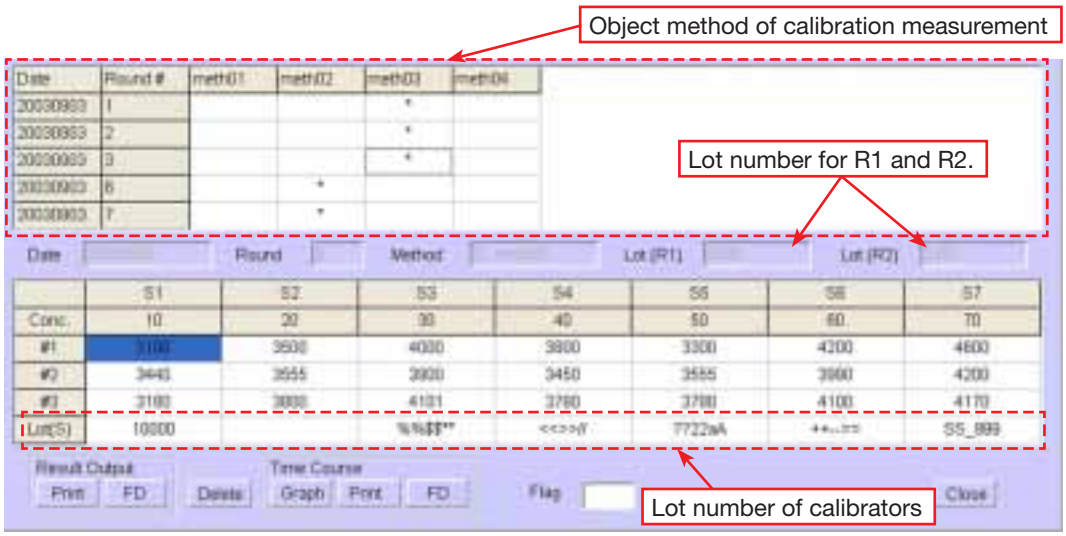
2. Push the [Delete] button. Then the selected result is deleted from the internal database.

When repeat above steps (1 through 2), you can delete consecutively unnecessary result one by one.

B) Sample Type: Standard ("Monitor" is selected as "Result Output".)

As for "Standard", the listed block for retrieved measurement results is shown below.

When a single calibrator of highest concentration was used as the standard sample, the lot number is shown only one for the highest concentration.



As for the above picture, upper area is for the object method of calibration measurement and lower area is for measurement result of calibration.

When click on a "*" (asterisk) part in the upper area, its calibration results (absorbance value) are appeared in the lower area.

<Function buttons for "Result Output" & "Delete">

Print: When click on this button, the calibration result of assigned method in the upper area is outputted to the printer. (See the example-3 in "2.10.4 Example of print-out".)

FD: When click on this button, the calibration result of assigned method in the upper area is outputted to the floppy disk.

Delete: When click on this button, the calibration result of assigned method in the upper area is deleted.

<Function buttons for "Time Course">

See "2.10.3 Output of time course data".

Graph: When click on this button, the time-course data of calibration result for assigned method in the upper area is plotted graphically on the screen.

Print: When click on this button, the calibration result for assigned method in the upper area is printed in time sequence on the hard copy.

FD: When click on this button, the time-course data of calibration result for assigned method in the upper area is outputted to the floppy disk.

<Function button for leaving "Standard" picture>

Close: When click on this button, you can close this picture.

C) Sample Type: Control ("Monitor" is selected as "Result Output".)

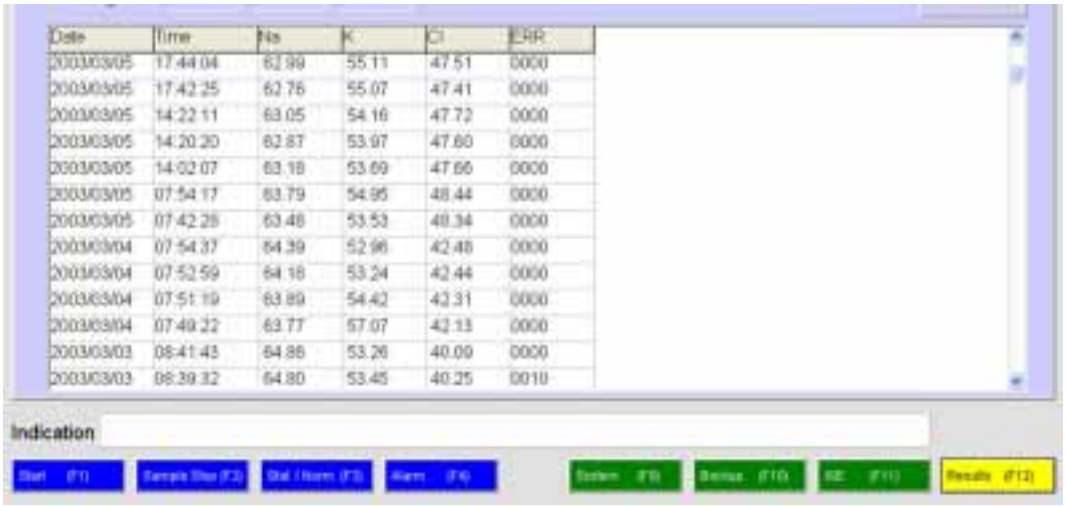
As for "Control", the listed retrieved measurement results are shown in the below picture.

For each retrieved measurement result in the list, it can be dealt with same as normal sample.

D) Sample Type: ISE Standard (“Monitor” is selected as “Result Output”.)

As for “ISE Standard”, the listed retrieved measurement results are shown below picture.

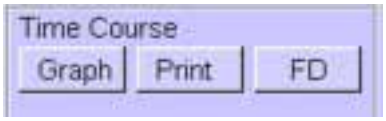
These retrieved measurement results are only displayed on the screen.



2.10.3 Output of time course data

The time course of the measurement results appeared in the “Picture of retrieved measurement results” can be plotted graphically on the screen or output in the form of hard copy or to the floppy disc.

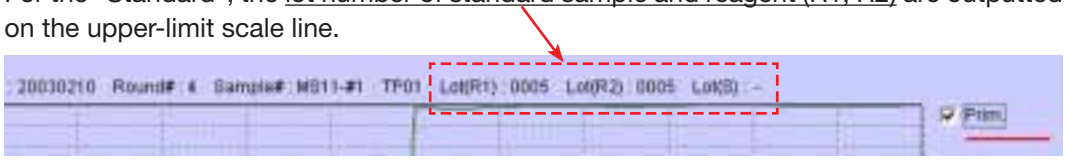
1. Specify the measurement data by clicking on it.



2. The time course is plotted graphically on the screen by clicking on the Graph button. The measurement data is printed in time sequence on the hard copy, when Print button

is clicked on. Also the measurement data are outputted to the floppy disc by clicking on the FS button.

For the “Standard”, the lot number of standard sample and reagent (R1, R2) are outputted on the upper-limit scale line.



Plotting line for each wave length

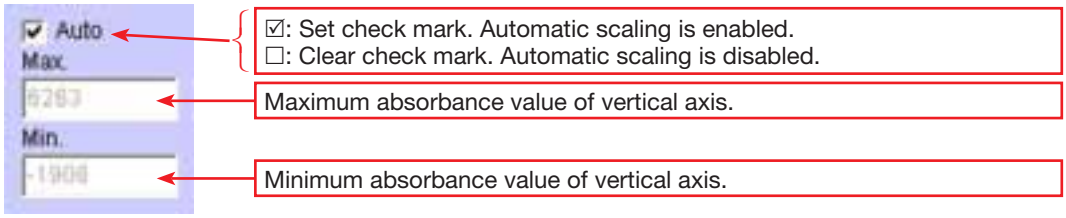
Red line : Primary wave length
Green line : Secondary wave length
Yellow line : Differential value (Primary – Secondary)

Each wave length has a plotting definition box.

☑: Set check mark. Plotting is enabled.
☐: Clear check mark. Plotting is disabled.

Automatic scaling for vertical axis

As for plotting area, the scale for horizontal axis is fixed but the scale for vertical axis is variable and it can be automatically calculated.



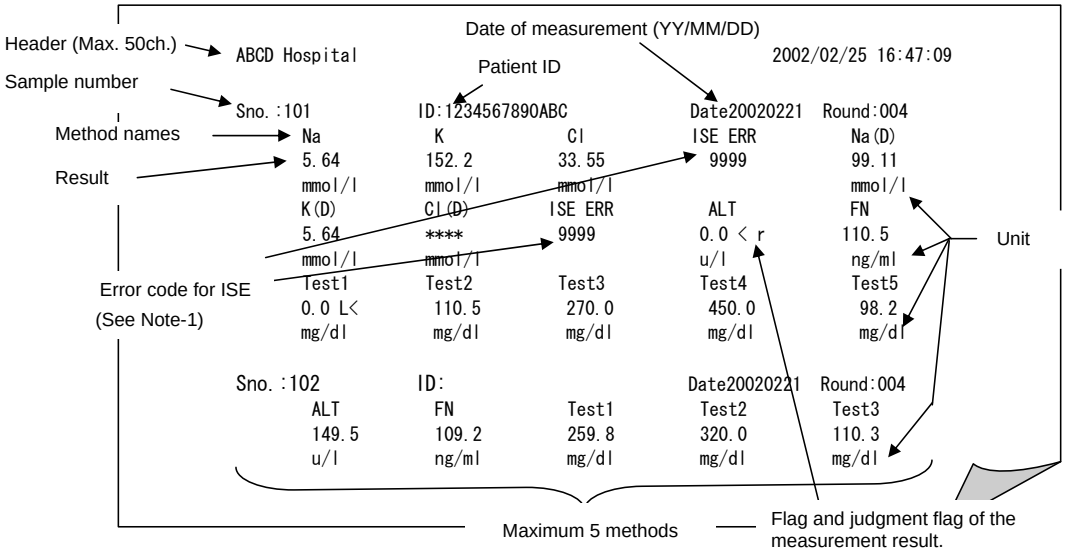
When the automatic scaling is not selected, plotting range (maximum and minimum value) should be set by manual.

2.10.4 Examples of printout

A) Example-1 (Normal sample and ISE)

This sample is for the date of February 21, 2002 and round number of 4.

As for the header, refer to “Print Header “ input field in section 3.6.1 “System Parameters Page 1/2”.

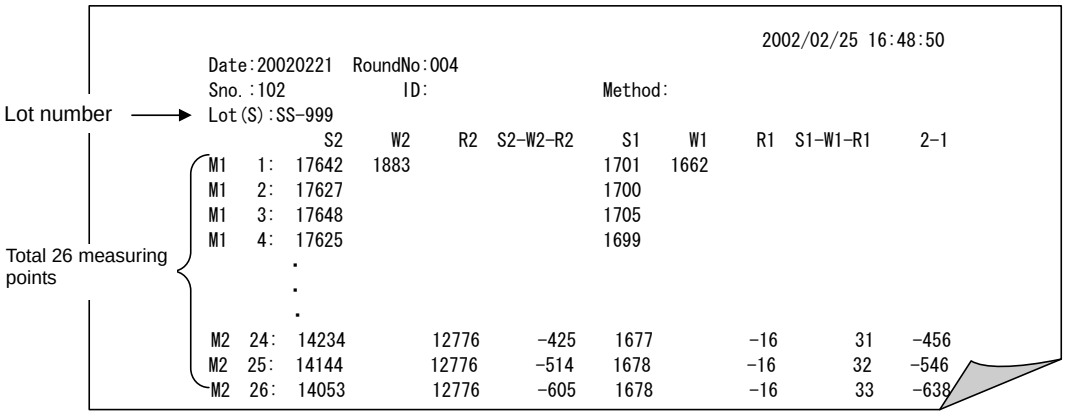


Note-1: When ISE error code is zero(0000), ISE ERR block is not printed.

When an ISE error is occurred, its result is printed with “*****”.

B) Example-2 (Time course of normal sample)

This sample is for the printed time course data.

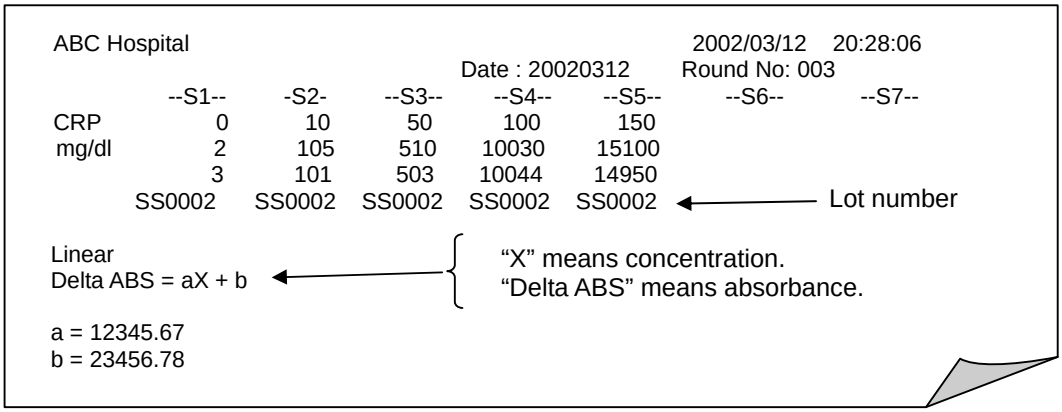


C) Example-3 (Calibration result)

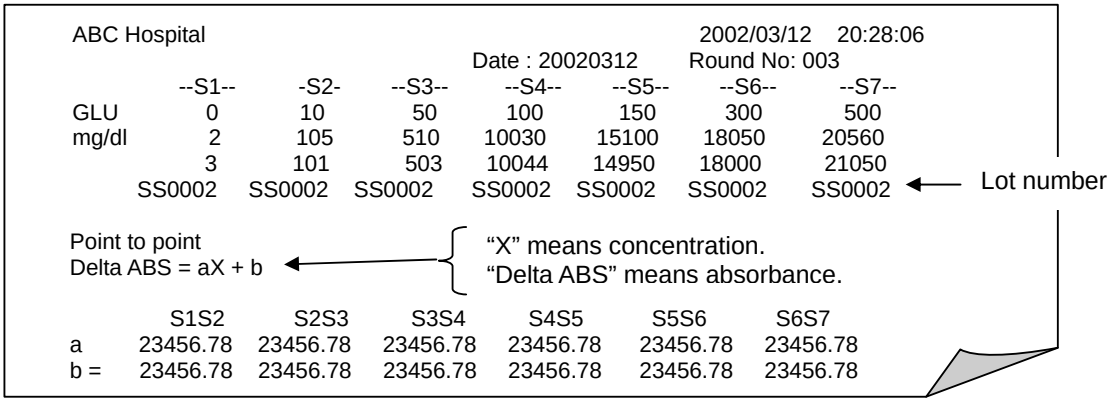
This sample is for the printed coefficient of calibration result.

This sample is printed when the calibration measurement is performed normally.

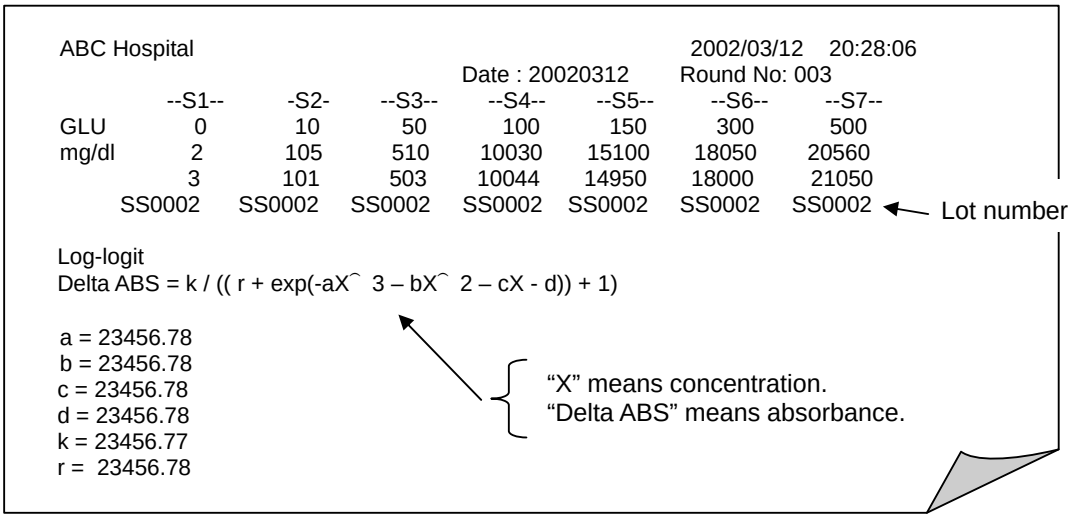
1. Linear



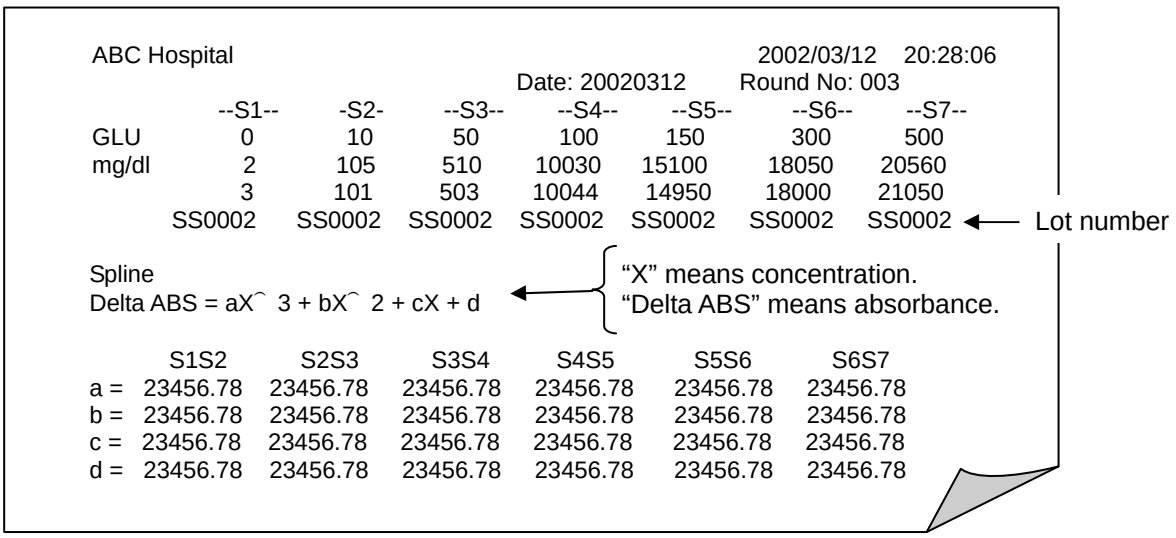
2. Point to point



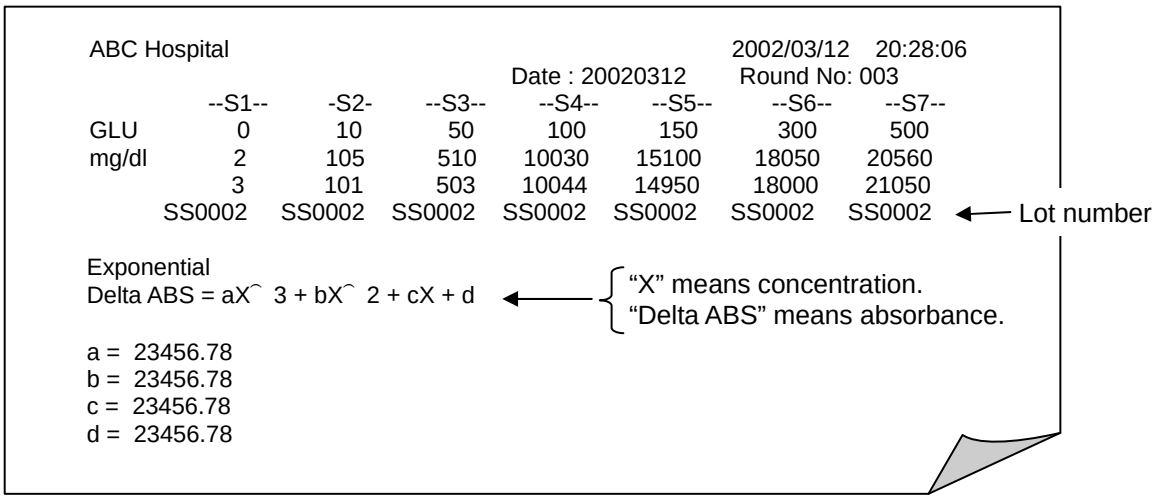
3. Log-logit



4. Spline



5. Exponential



2.11 Quality Control: [F8]

The measurement results of quality control (QC) sample for a period of approximately 6 months are stored in the database.

After the pointer is positioned in the [QC (F8)] and the left button of the mouse is clicked, either one of the following function menus can be selected.

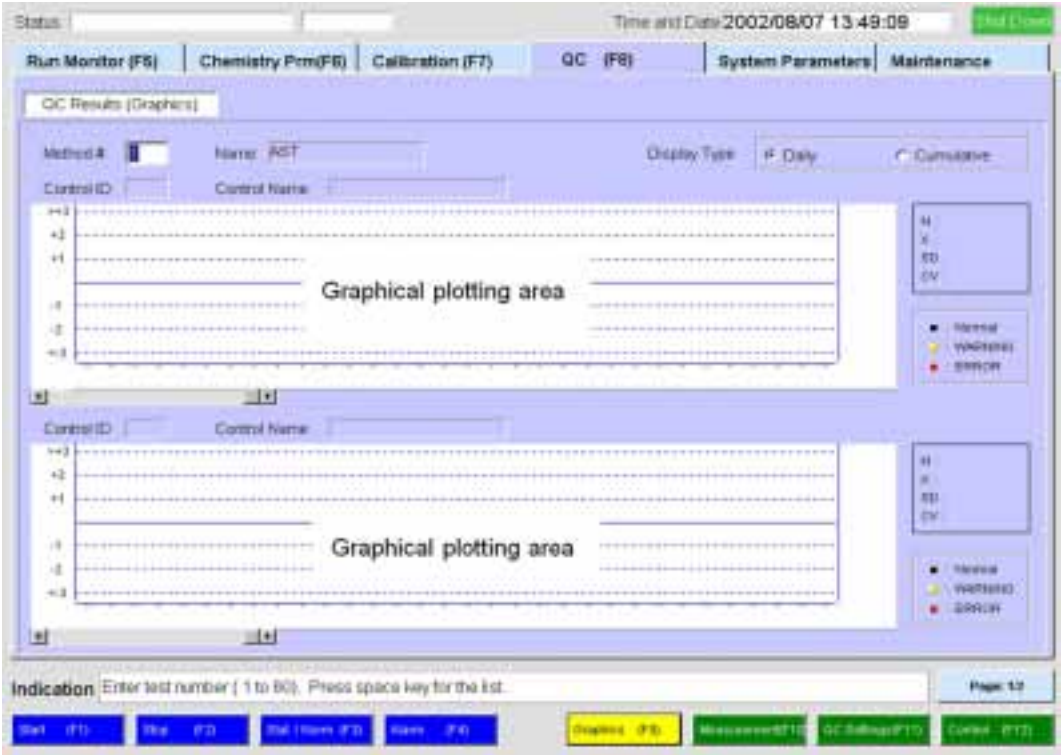
1. Graphic: [F9] (Graphic display of measurement results of QC sample)
2. Measurement: [F10] (Display of measurement results of QC sample)
3. QC Settings: [F11] (Settings for graphic display)
4. Control: [F12] (Registration of QC samples)

2.11.1 Graphic display [Graph (F9)]

The Levey-Jennings control chart is applied to representation of the measurement results of quality control sample.

At the maximum, the measurement data for 3 types of QC samples can be graphically displayed on a method basis.

3 types of graphic displays, i.e. daily and cumulatively basis, can be shown on the screen. The third type of display selected is shown in the page 2/2.



(1) Setting of method number

Move the cursor to “Method #” box and enter the required method number in the box using the numeric key, or

Press [SPACE] key to display the pop-up window showing registered methods and click on the desired method number in it.

When ISE is selected as the method number (61 or 62), ISE testing item box is displayed at next of “Display Type”. Select one of them (Na/K/Cl).

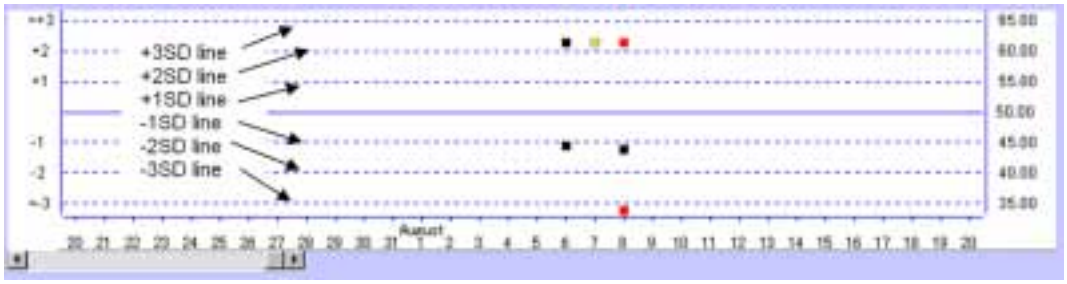
(2) Type selection of graphic display

(a) Daily: All measurement results of QC sample on each day are displayed separately.

All results in a day are plotted on the separate vertical axis.

(b) Cumulative: All measurement results of QC sample on each day are displayed cumulatively.

All results in a day are plotted on the one vertical axis.

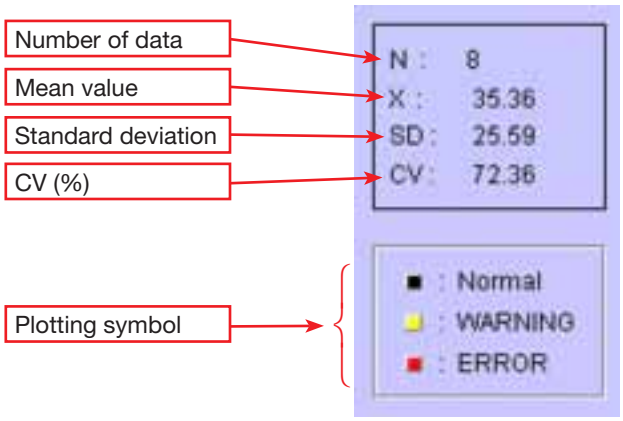


(3) Indication of QC sample ID and its name

The name registered in the QC name registration picture [QC Setting (F11)] is automatically indicated.

(4) Number of data (N)/Mean value(X)/Standard deviation (SD)/CV (%)

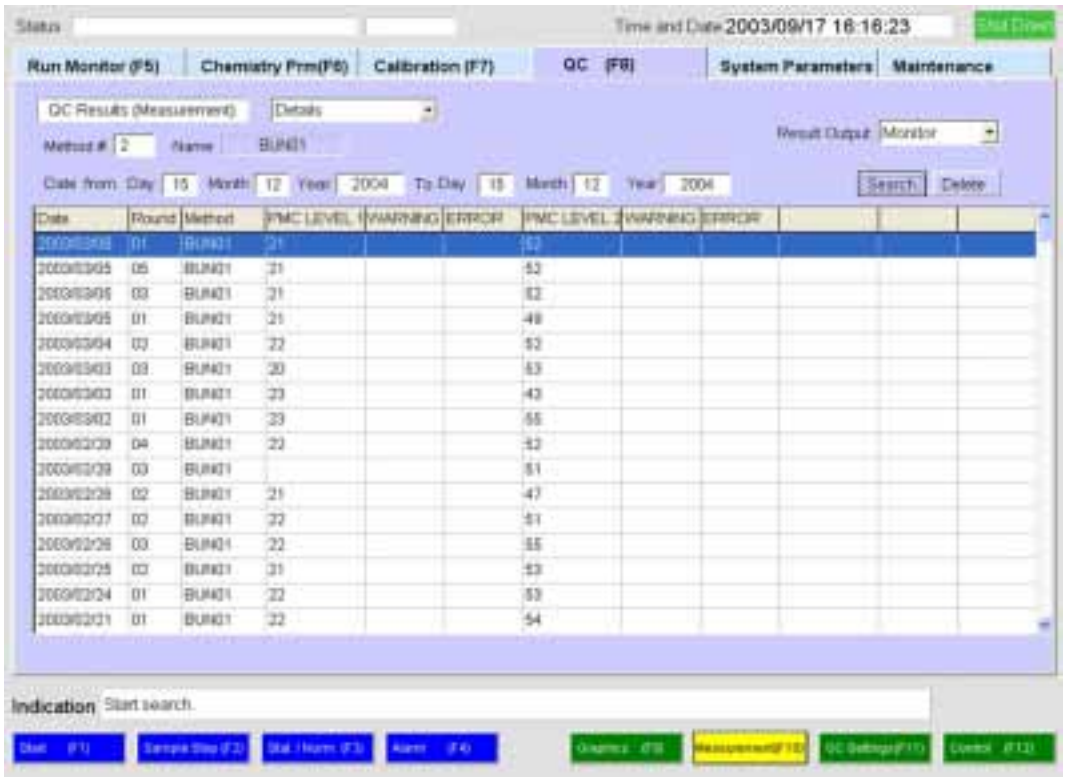
The number of data, mean value, standard deviation and CV are automatically calculated from all measurement results of QC sample, but the measurement results which belong the “ERROR” of which rule is defined in the “2.11.3 Settings for graphic display” are not included to these calculation.



2.11.2 Measurement results of QC [Measurement (F10)]

The measurement results of specified QC sample stored in the database are reproduced and displayed in order of date on the screen by entering the method number.

This function is performed by selecting the function menu [Measurement (F10)] of job menu [QC (F8)].



A) Selection of the reproduction type

The following three types are selectable as the reproduction type.

(1) Details

The measurement results of specified QC sample are retrieved in accordance with specified period (date from and date to).

(2) Daily

The measurement results of specified QC sample are retrieved in accordance with specified day.

(3) Cumulative

It deals with the measurement results of specified QC sample in specified period as the cumulative result.

Either one of “Details”, “Daily” and “Cumulative” can be selected from the pull-down menu by clicking on the triangular marks.

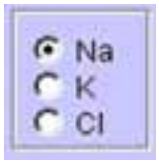
B) Setting of the method number

Move the cursor to “Method #” box and enter the required method number in the box using the numeric key, or

Press [SPACE] key to display the pop-up window showing registered methods and click on the desired method number in it.

Depending on the reproduction type, the wildcard (“*”: asterisk) can be used for the method number. (In the case of “Details”, the wildcard cannot be used for the method number setting.)

When ISE is selected as the method number 61 or 62, ISE item box is displayed at next of “Result Output” box. Select either one of “Na”, “K” and “Cl”. (Na/K/Cl).



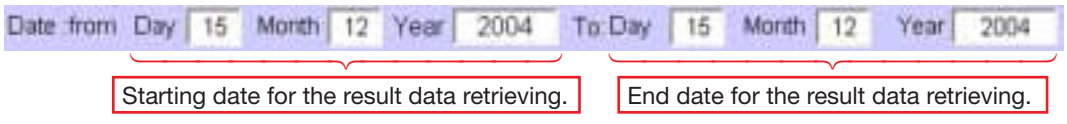
C) Selection of the output device

The output device of retrieved QC result is specified.

Either one of “Monitor”, “Print” and “FD” can be selected from the pull-down menu by clicking on the triangular marks.

D) Setting of the Date from and Date to

Dates of the measurements to be retrieved are specified by using keyboard. “*” is the wildcard and means unlimited number.



E) Retrieving the QC result

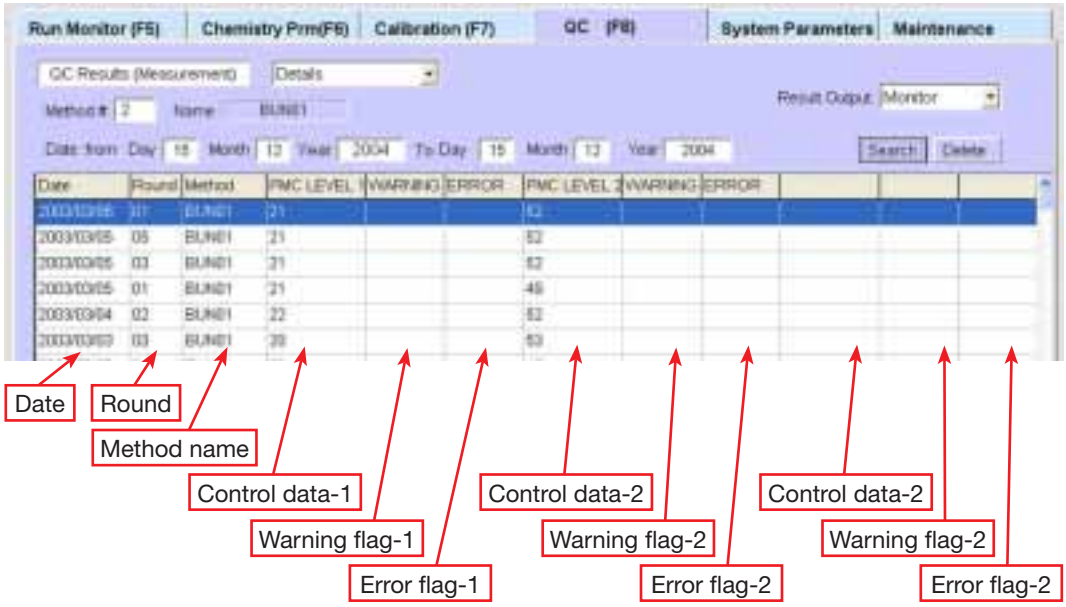
Search button: When this button is clicked on, the retrieving of the QC result starts under the condition of specified method number, reproduction type and period (Date from and Date to).

Delete button: When this button clicked on, all retrieved data are deleted from the data base.
Whatever output device is selected, this deletion procedure is executed.

(1) Reproduction type is selected "Details":

When the "Details" is selected for the reproduction type, the retrieved results are displayed on the screen by clicking on the Search button. (See below picture.)

Note: In case "Details" is selected for the reproduction type, the wildcard ("*") cannot apply to the setting of the method number.



(2) Reproduction type is selected "Daily":

In case "Daily" is selected for the reproduction type, the retrieving keys are Method number, Control ID number, Date and Round number.

<Method number setting>

The way of setting is to be referred to the said description "B) Setting of the method number".

<Date setting>

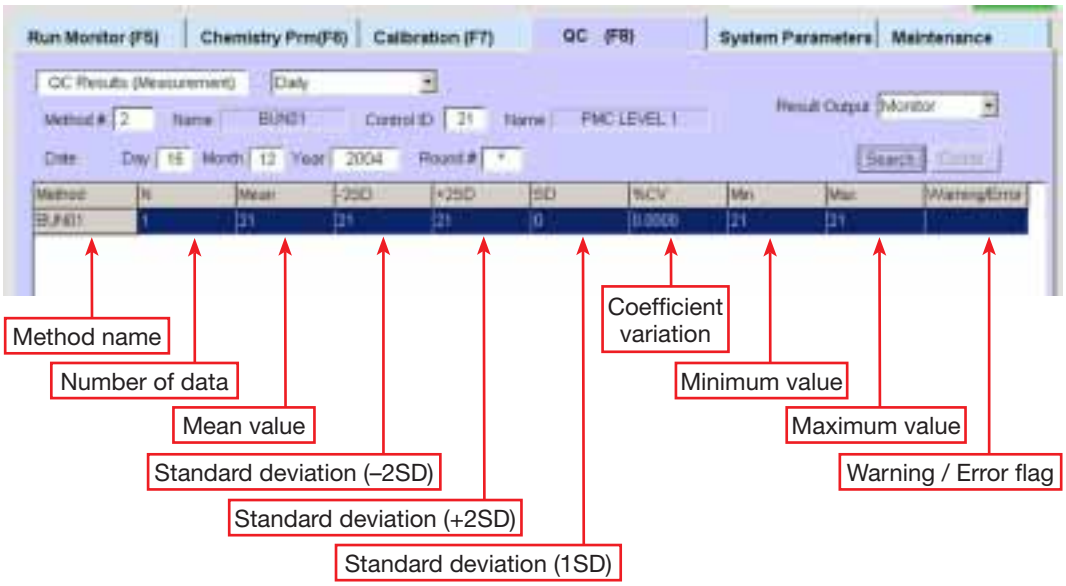
A specific day is set for retrieving QC result. The way of setting is similar to the said description "D) Setting of the Date from and Date to".

<Round number setting>

A specific round number is set for retrieving QC result. When the wildcard is used for the round number, all rounds in which QC measurement had been performed becomes retrieval range.

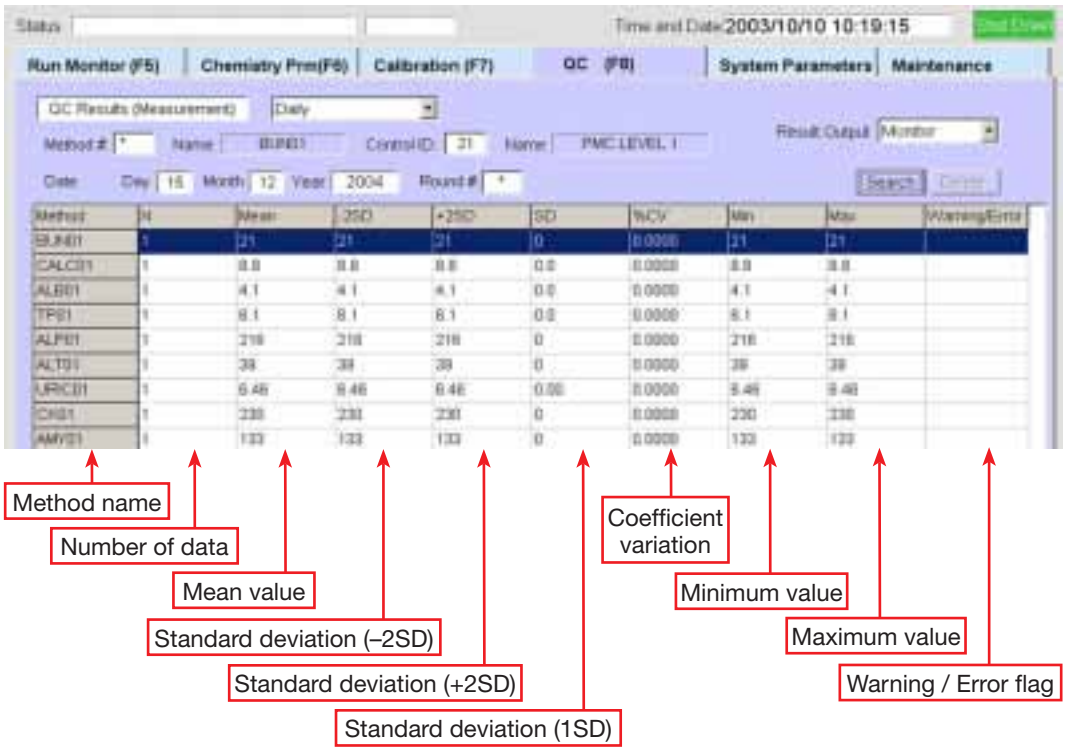
The retrieved QC measurement results are displayed on the screen by clicking on the Search button as below picture.

Example: "Method #" is set "2" for the "Daily".



Example: "Method #" is set the wildcard ("*") for the "Daily".

In case the wildcard ("*") is used for the method number, "Control ID" should be set in advance.



(3) Reproduction type is selected "Cumulative":

In case the "Cumulative" is selected for the reproduction type, the retrieving keys are Method number, Control ID number, Date and Round number.

<Method number setting>

The way of setting is to be referred to the said description "B) Setting of the method number".

<Date setting>

A specific day is set for retrieving QC result. The way of setting is to be referred to the said description "D) Setting of the Date from and Date to".

<Round number setting>

A specific round number is set for retrieving QC result. When the wildcard is used for the round number, all rounds in which QC measurement had been performed becomes retrieval range.

The retrieved results are displayed on the screen by clicking on the Search button.
(See below picture.)

Example: "Method #" is set "2" for the "Cumulative".

Example: "Method #" is set the wildcard ("*") for the "Cumulative".

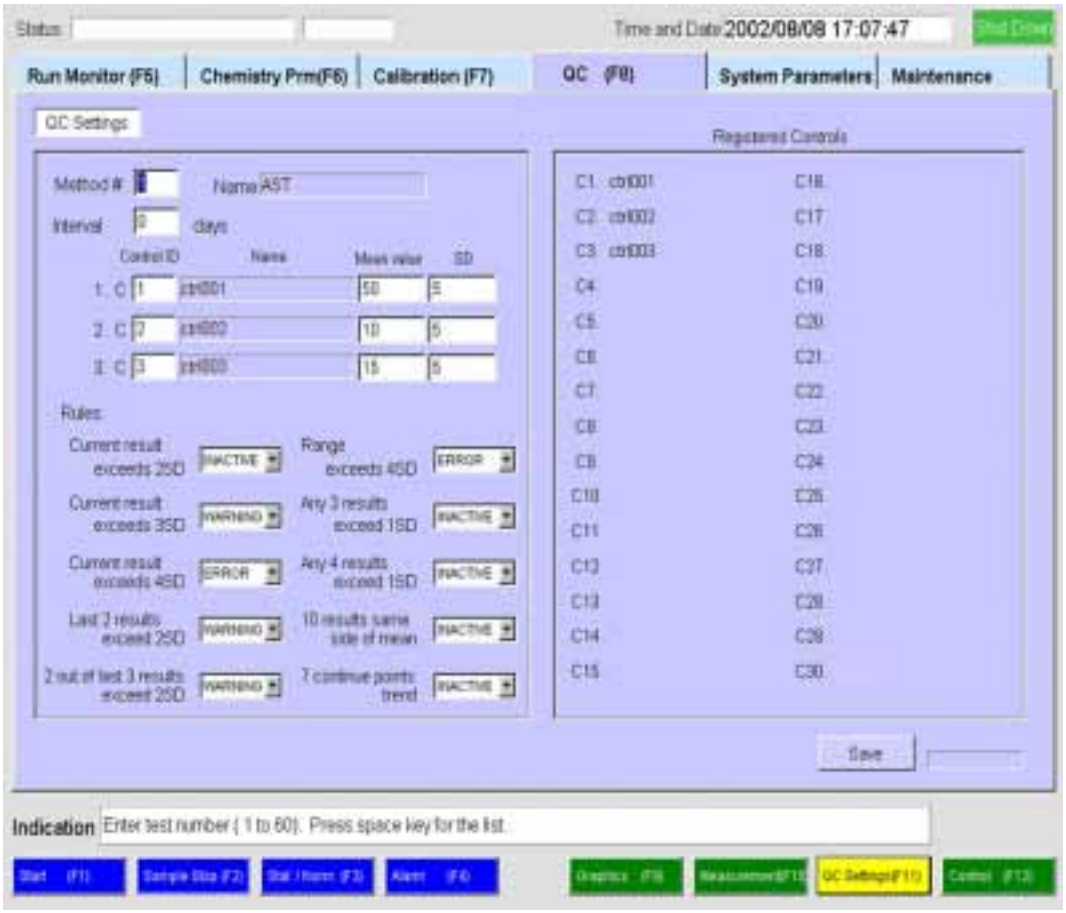
In case the wildcard ("*") is used for the method number, "Control ID" should be set in advance.

Judgment priority

Priority	Judgment condition	Status expression
1	Current result exceeds 4SD	1:4S
2	Current result exceeds 3SD	1:3S
3	Last 2 results exceed 2SD	2:2S
4	Current result exceeds 2SD	1:2S
5	2 out of last 3 results exceed 2SD	2/3:2S
6	Range exceeds 4SD	R:4S
7	7 continue points trend	7:T[+] · · · Increasing 7:T[–] · · · Decreasing
8	Any 4 results exceed 1SD	4:1S
9	Any 3 results exceed 1SD	3:1S
10	10 results same side of mean	10:T[+] · · · Greater than mean 10:T[–] · · · Less than mean

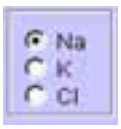
2.11.3 Settings for graphic display [QC Setting (F11)]

The necessary data for the graphic display on each QC sample is to be entered.



(1) Method#: Enter the method number.

When the method number of 61 or 62 (ISE) is selected, ISE testing item box is displayed at next of “Name” box as below picture.



(2) Name: Method name (No need to enter the name since it is automatically defined by the method number).

(3) Interval: The term of validity for QC measurement.

If the measured date of the latest QC result(s) is passed the specified valid day, warning will be occurred in the function menu [Test Selection (F10)] of the job menu [Run Monitor (F5)].

(4) Control ID: Enter the required QC sample number referring to the list indicated at right (Registered Controls).

(5) Name: QC sample name (No need to enter the name since it is automatically defined by the control ID).

(6) Mean Value: Enter the mean concentration value of the specified QC sample.

(Data which includes an “ERROR” condition are not included for the calculation.)

(7) SD: Enter the standard deviation value of the specified QC sample. The limits of standard deviation (SD) are plotted in dotted lines on the graphic display.

(Data which includes “ERROR” condition are not included for the calculation.)

(8) Rules: Select the judgment condition of the QC results.

1) Current result exceeds 2SD

2) Current result exceeds 3SD

3) Current result exceeds 4SD

4) Last 2 results exceed 2SD

5) Out of last 3 result exceeds 2SD

6) Range exceeds 4SD

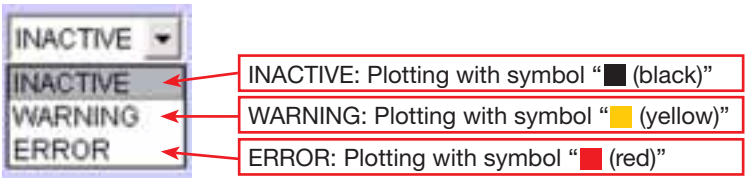
7) Any 3 results exceed 1SD

8) Any 4 results exceed 1SD

9) 10 results same side of mean

10) 7 continue point’s trend

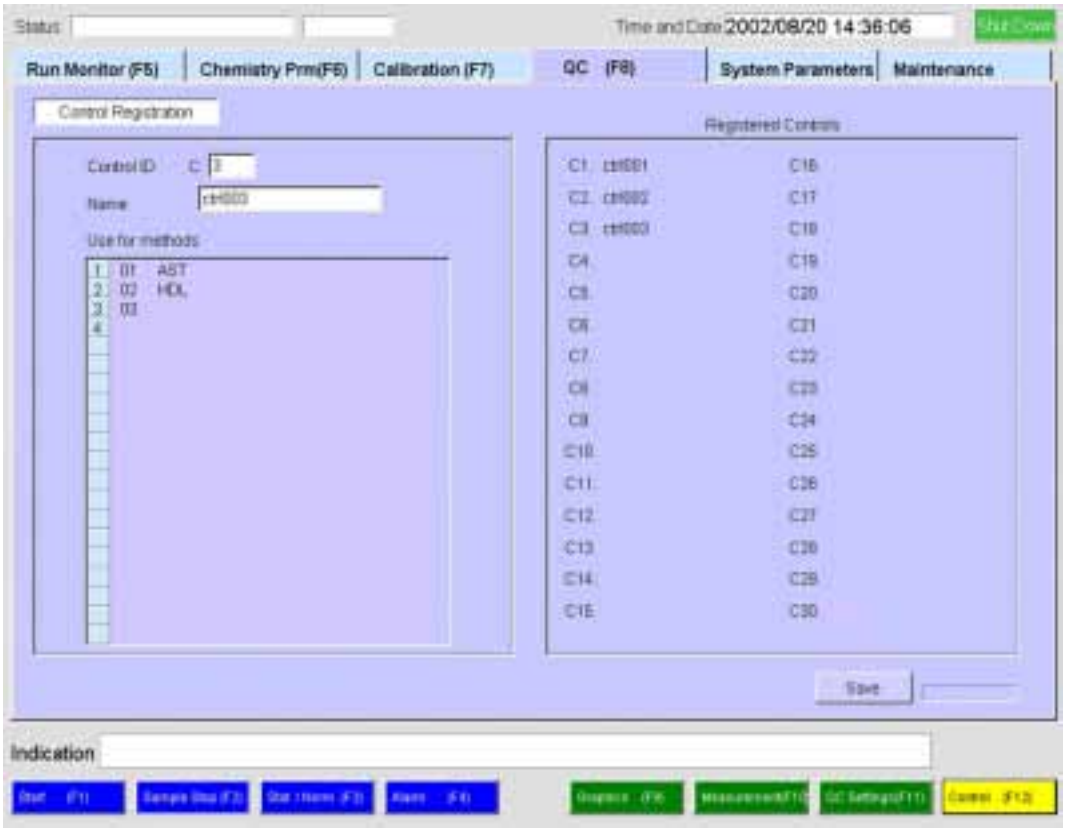
For each judgment condition, select one of the applied classifications from the pull-down menu as below picture.



(9) Save: Click on this button to save the data set in the above items.

2.11.4 Registration of QC samples [Control (F12)]

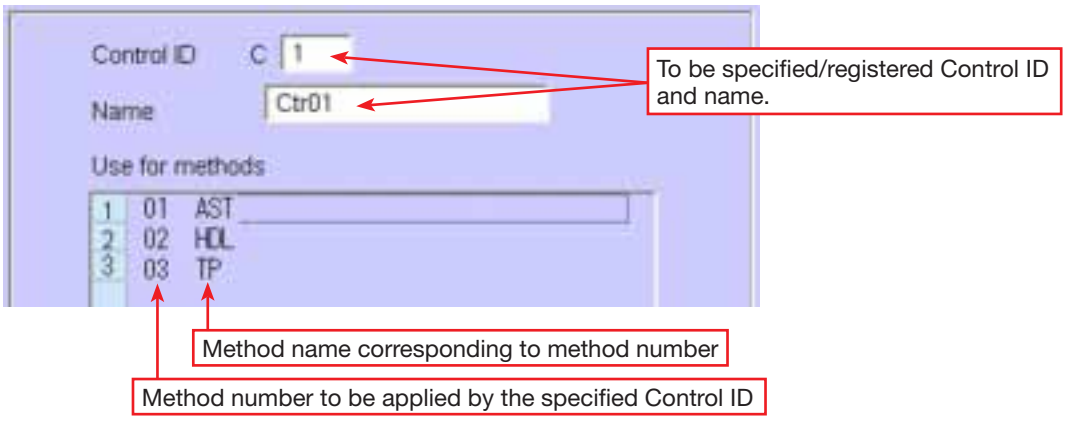
The names of QC samples to be used in the analyzer are to be registered.
It means that which control sample is used for which method/methods.
Total 30 QC samples (C1 – C30) can be registered.



(1) Control ID: Enter the control ID number.
(2) Name: Enter the control name.
(3) Save Click on this button to save the data set in the above steps.

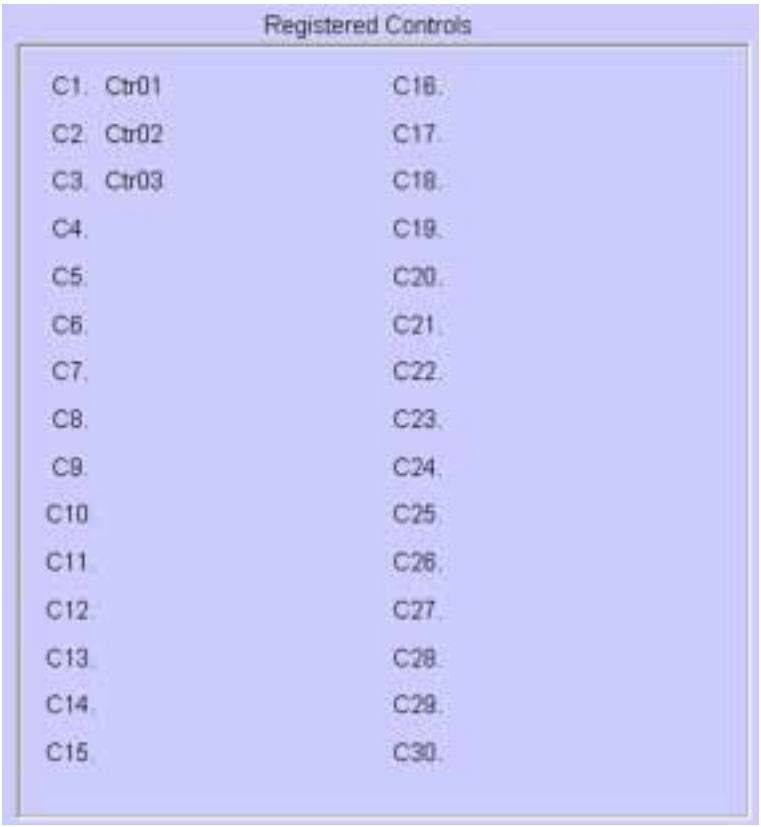
List of “Use for methods”

Method number and name in terms of a specified Control ID is listed in this area. Individual method is determined in the menu [QC Setting (F11)] under the job menu [QC (F8)].



List of “Registered Controls”

All control names which have been registered in this function menu are listed, maximum 30 QC samples, and this list is utilized for the [QC Settings (F11)] under the job menu [QC (F8)].



Chapter 3

Settings and their alterations of operational conditions

This chapter provides the procedures of settings and their alterations of operational conditions including analytical conditions, method-to-method computation, profile registration, system parameters, new registration of samples, order of printout, etc.

This chapter consists of:

3.1 Functional items

This chapter addresses how to enter and change the operational conditions and parameters of each functional item. Such functional items are shown below:

Functional item	Description	Reference page
Analytical conditions (Chemistry Parameters)	Analytical conditions have been predefined but part of them can be altered as necessary.	139
Serum Information (Serum Information)	Entry of various parameters for the measurements of turbidity (L), haemolysis (H) and icterus (I) in the serum.	147
Method-to-method computation (Calculate)	The equation is defined to derive the computed result using results obtained from multiple methods.	150
Profile (Profile)	The profile (check in a set) is specified to enable the multiple methods to be selected at a time.	152
Order of measurements and printout	The measuring order of methods and the printing order of measurement results are specified.	154
System parameters	Specification of serial communications with host computer, date, time and specification of bar code are specified. Optional settings and preparation of print header can be done.	156
Registration of reagents	Each bottle code and bottle size (large, medium or small) of reagents, wash solutions and diluents placed in the RCU are entered.	162
Replicate Sample	Setting of the number of replication.	164
Patient information definition	Making up the patient information.	165
Backup operation	This is the function to save the analyzer-specific parameters and user parameters to and load them from floppy disc.	167
ISE parameters (1)	The bottle code of diluent for urine measurement is entered.	170
	Results of ISE calibration are outputted. Settings of volume adjustment and instrument factor of ISE.	170
ISE parameters (2)	Setting of Normal range for ISE.	172

3.2 Analytical Conditions [Chemistry Prm (F6)]

In the function menu [Chemistry (F9)] of the job menu [Chemistry Prm (F6)],

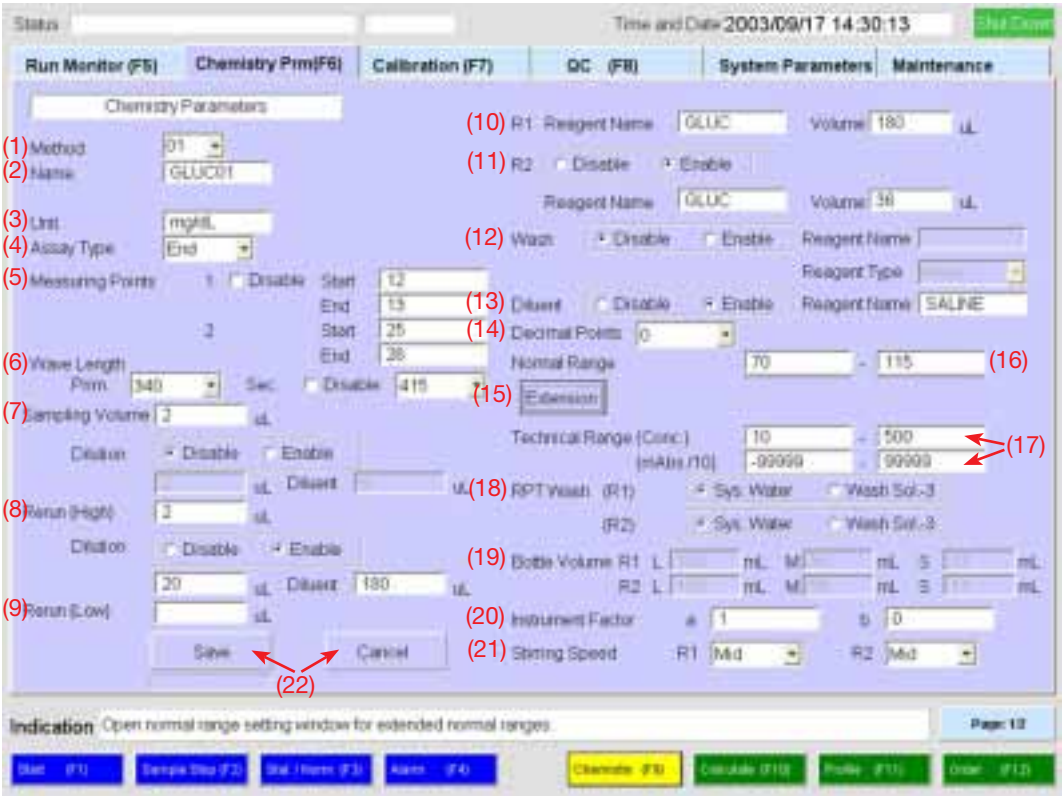
At page 1/2: sampling volumes of reagents and sample for each method and various measuring conditions can be set, and

At page 2/2: various parameters about serum information can be set.

Normally, the pre-defined conditions are used as they were. The great attention should be given to the meanings of such pre-defined values before they will be modified. If the pre-defined values have been modified and they cannot be reset to their original values, this may result in problems for the measurements afterward.

3.2.1 Method Conditions: [Chemistry (F9)] Page 1/2

This is to define the various parameters including measurement conditions, sampling volume, dilution conditions, type of reagent, etc. The following conditions need to be defined for all methods registered in the analyzer.



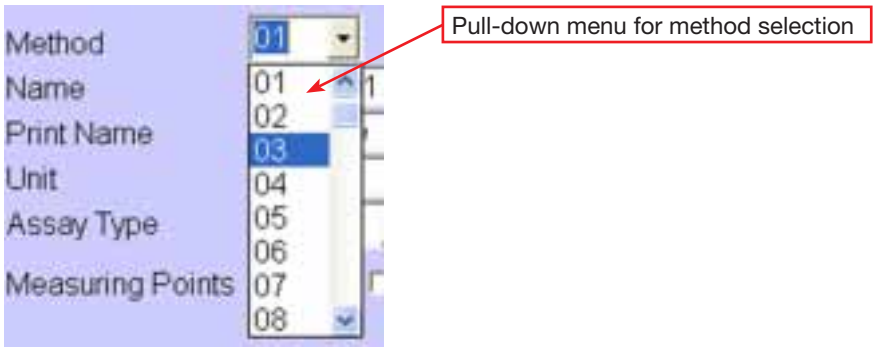
Each item for which the conditions need to be defined can be selected by moving a cursor in the above picture with [Tab] key (or [Tab] + [Shift] keys).

(1) Method

There are two ways for selection of method number.

1. Select from the combo box (pull-down menu).

When click on the triangular mark at “Method” box, you can select the necessary method number from the pull-down menu.



2. Select from the method list by pressing [SPACE] key.

The following pop-up window is showing the list of methods by pressing the [SPACE] key. The wanted methods are selected by moving the cursor to and clicking on them.

01. AST	02. UREA	03. CHOLE	04. TRIGLY	05. FERRIT
06. IGE	07. ALK	08. HDL	09. ast2	10. urea2
11. chole2	12. trigl2	13. ferri2	14. ige2	15. alk2
16. hdl2	17. ast3	18. urea3	19. chole3	20. trigl3
21. ferri3	22. ige3	23. alk3	24. hdl3	25.
26.	27.	28.	29.	30.
31.	32.	33.	34.	35.
36.	37.	38.	39.	40.
41.	42.	43.	44.	45.
46.	47.	48.	49.	50.
51.	52.	53.	54.	55.
56.	57.	58.	59.	60.

(2) Name

Enter the method name in alphabets, numeric, symbols or their combination.

The method name is automatically indicated upon entering the method number in the above step.

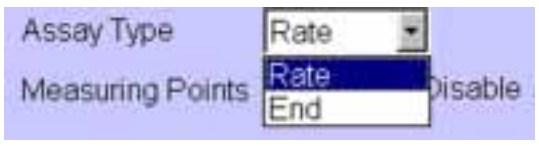
Note: It is prohibited to give the name in duplicate, even if the different method number is applied.

(3) Unit

Enter the unit of concentration value obtained as a result of the measurement.

(4) Assay Type

This is to select either one of two assay types, i.e. Rate-method and End-method. Select the required assay type from the pull-down menu.



(5) Measuring Points

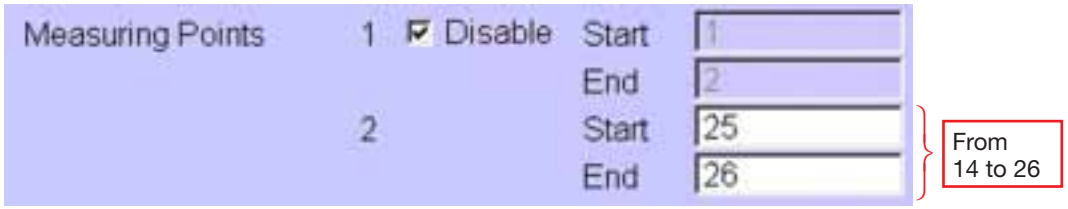
This is to specify the measuring points on the time course.

First of all, whether or not the Measuring Point-1 is enabled is selected.

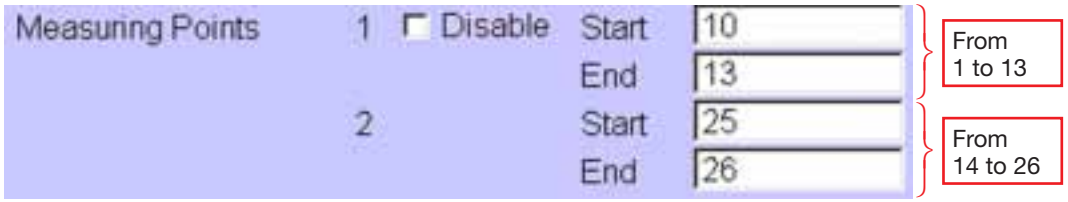
Where the small box beside “Disable” is clicked on ☑, only the Measuring Point-2 becomes effective and thus the measuring points are entered into “Start” and “End” boxes of the Measuring Point-2.

When the Measuring Points-1 is disabled, the measuring points of Measuring Point-2 are entered into its “Start” and “End” boxes.

[Measuring Point-2: 14 to 26 and Start < End]



When the Measuring Point-1 is enabled, the measuring points are entered into “Start” and “End” boxes of both Measuring Point-1 and Measuring Point-2.



[Measuring Point-1: 1 to 13 and Start < End]

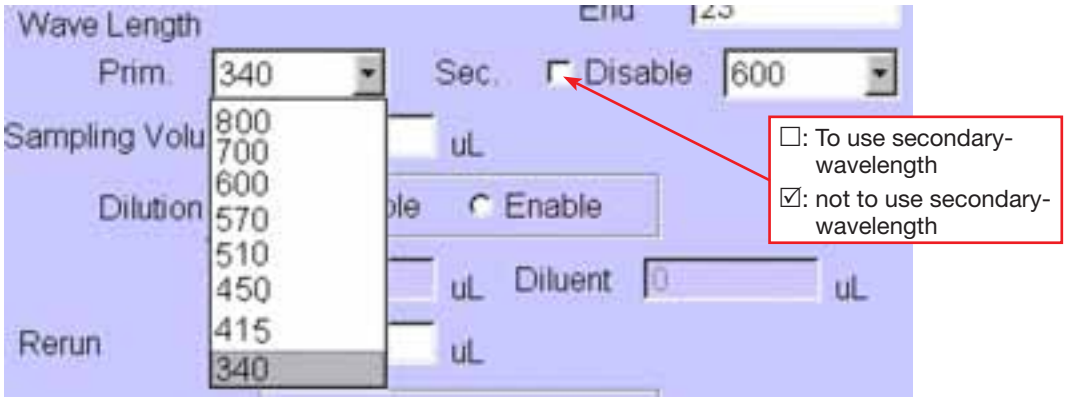
[Measuring Point-2: 14 to 26 and Start < End]

(6) Wave Length

The wavelengths of the optical filter are selected for measuring concentration (absorbance).

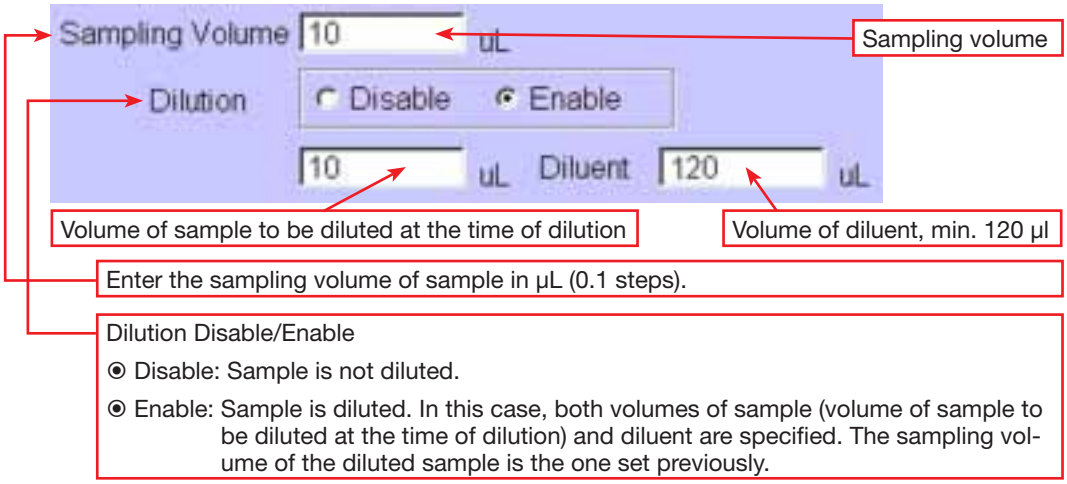
The measurement can be performed using two wavelengths, i.e. primary and secondary-wavelength. The primary-wavelength is selected from the pull-down menu.

The secondary-wavelength can be selected in the same way as for the primary-wavelength. When the secondary-wavelength is not used, click on the small box beside the “Disable”.



(7) Sampling Volume

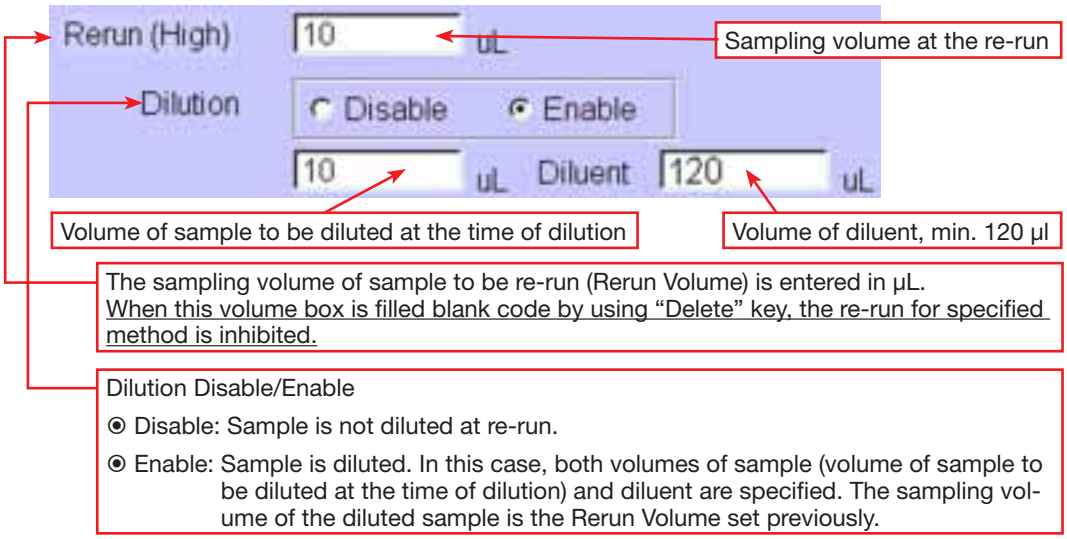
Enter the sampling volume whose limit is 2 to 35.



(8) Rerun (High): Depending on the "Technical Range"

When the measurement result is out of the Technical Range (greater then high limit), it is effective to apply the re-run function in order to perform the second measurement.

As for the re-run condition, following items are defined in advance with the re-run execution.



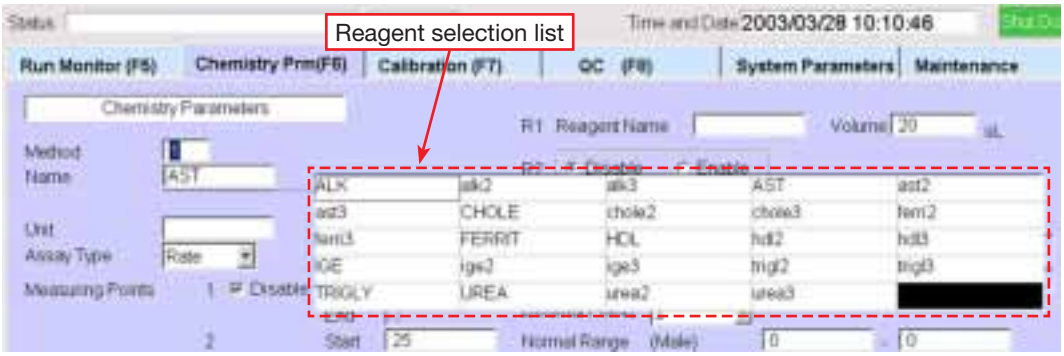
(9) Rerun (Low): Depending on the "Technical Range"

When the measurement result is out of the Technical Range (lower then low limit), it is effective to apply the re-run function in order to perform the second measurement.

When this volume box is filled blank code by using "Delete" key, the re-run for specified method is inhibited.

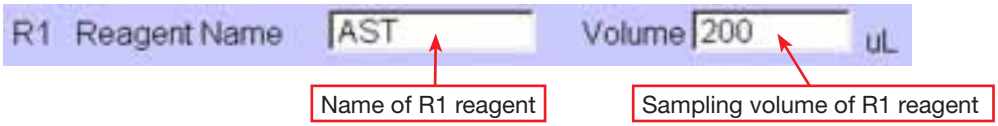
(10) R1 Reagent Name & Volume

The following pop-up window of the reagent selection list is displayed by moving the cursor onto the entry box “R1 Reagent Name” and pressing the [SPACE] key. Click on the reagent name to be used in the list.



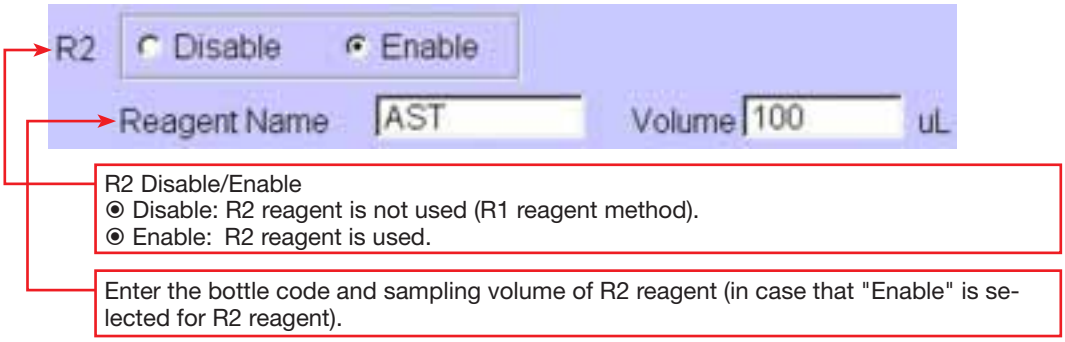
After the R1 reagent name is specified, it’s sampling volume need to be entered.

Note: Aggregated sampling volume of R1 reagent and sample must be 180 µL or more.



(11) R2 Reagent Name & Volume

Where the R2 reagent is to be used, select “Enable”. The pop-up window of the reagent selection list is displayed by moving the cursor onto the entry box “Reagent Name” and pressing the [SPACE] key. Click on the reagent name to be used in the list.

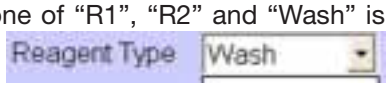


(12) Wash

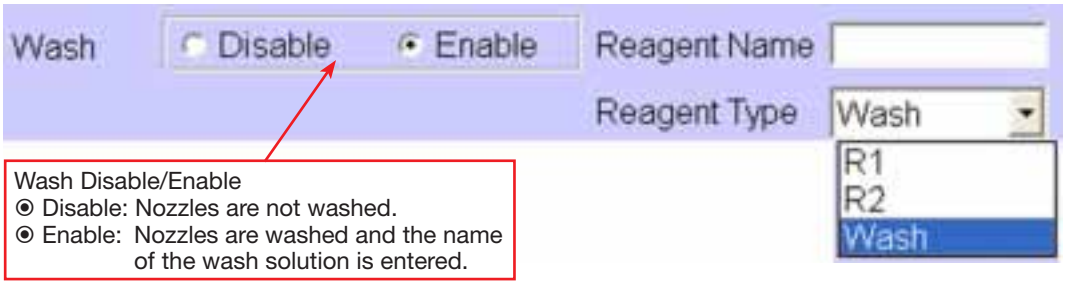
As for the nozzle wash function, either one of enable and disable can be selected.

When “Enable” of wash function is selected, the wash solution for washing nozzles (RPT/SPT) is specified as below;

1. Select “Reagent Type” as the wash solution. Either one of “R1”, “R2” and “Wash” is selected by pull-down menu at “Reagent Type” box.



2. Move the cursor onto the entry box “Reagent Name” and press the [SPACE] key. Click on the reagent name to be used in the list.



When “Enable” is selected, RPT and SPT nozzles are washed before the measurement is performed in accordance with the method defined in the [chemistry (F9)] screen. To be more specific, the wash solution that have been specified at the entry box “Reagent Type” and “Reagent Name” in advance is initially aspirated by the RPT from the bottle contained in the RCU. The solution is then dispensed into cuvette of the IRU. Secondarily, the IRU rotates to the sampling position of the SPT and then the SPT nozzle descends into the cuvette. The SPT nozzle aspirates the wash solution at the cuvette and moves to SPT trough position. SPT nozzle dispenses the wash solution to the dispensing position at SPT trough, and after that SPT nozzle is washed by purified water at there.

(13) Diluent

The diluent is specified.

When “Enable” is selected, the name of diluent bottle is entered. The pop-up window of the diluent selection list is displayed by moving the cursor onto the entry box “Reagent Name” and pressing the [SPACE] key. Click on the applicable bottle name to be used in the list.

(14) Decimal point

The significance number of decimal places is defined for the measurement result.

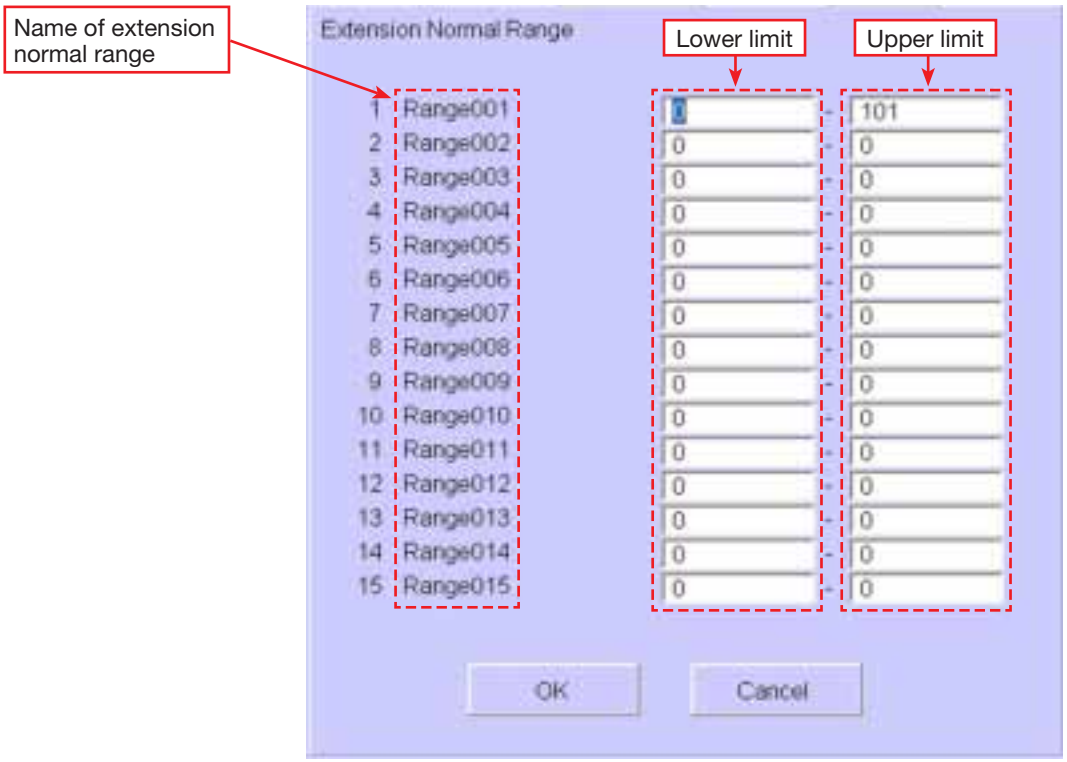
Either one of 0, 1, 2, 3, 4 or 5 can be selected from the pull-down menu.

(15) Extension button

This button is for defining the additional normal range for the extensional usage.

When Extension button is clicked on, the following pop-up window is displayed on the screen.

The lower and upper limit of the extensional normal range is defined to each criterion box whose name had been defined in the “Extension Normal Range Name” of the function menu [System (F9)] of job menu [System Parameters].



After setting of the extensional normal range vale, the setting data are saved when click on the OK button.

When this extended normal range is made effective in the test selection ([Test Select (F10)] – [Run Monitor (F5)]), they are applied to judgement criterion of normal range to the measurement result. (Refer to next item “Normal Range”.)

(16) Normal Range

The upper and lower limit of normal range is defined.

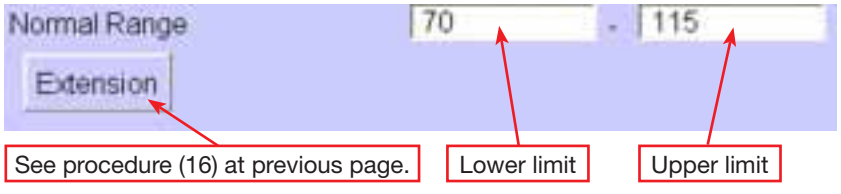
There are two types of normal range such as ordinary and extension normal range.

Individually, they are applied to suit the test sample.

When the measured concentration value is lower than the specified lower limit, the flag “L” goes with the output of the measurement result.

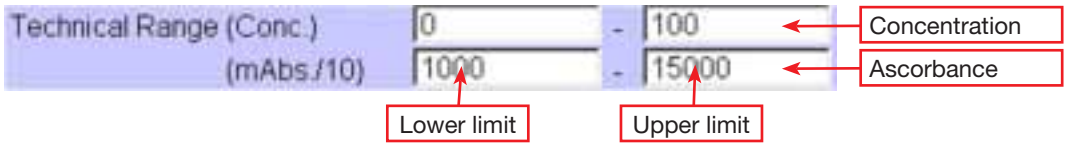
When the measured concentration value is higher than the specified upper limit, the flag “H” goes with the output of the measurement result.

When the extension normal range is selected, it is given priority to selected extension normal range as the judgement criterion of normal range.



(17) Technical Range

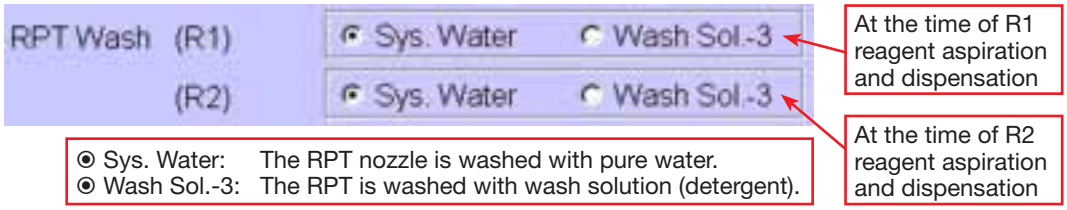
The upper and lower limit of the technically valid range is defined. This range is used to check the reliability of the measurement results. The range is set in the terms of concentration and absorbance.



Note: When the technical range (mAbs/10) is defined the range from –99999 to 99999, the judgement of absorbance becomes inactivation.

(18) RPT Wash

The wash solution for the RPT is specified.



(19) Bottle Volume

The Bottle maximum volumes of R1 and R2 reagents are displayed.

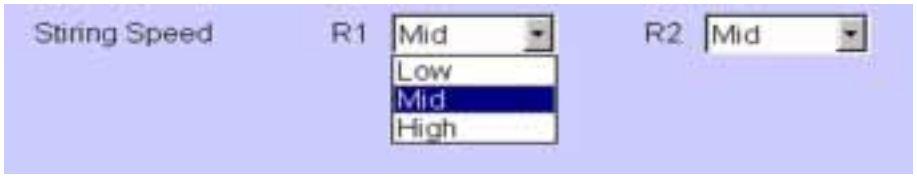
(20) Instrument Factor (Correlation correction factor)

The linear correction is applied to all the measurement results. An inclination (a) and intercept (b) are entered. If 0 (zero) is entered for the inclination (a), no correction is executed.

(21) Stirring Speed

The stirring speed of Mix-1 and Mix-2 is specified.

Either one of Low, Mid or High can be selected from the pull-down menu.



(22) Save/Cancel

Click on the Save button to save the parameters for the method set in the above.

Otherwise, click on the Cancel button.

3.2.2 Serum Information [Chemistry (F9)] Page 2/2

Where “Enable” of “Serum Information” is selected in the [Condition (F12)] of the job menu [Run Monitor (F5)], the serum information of a sample can be measured.

Depending on the assay method, chemical or its metabolite may affect the measurement results in the case of high turbidity, haemolysis, Bilirubin, etc. in the serum. Through the use of this phenomena, the levels of turbidity (L), haemolysis (H) and icterus (I) are numerically expressed and can be determined qualitatively.

<Method of measurement>

• Photometering points: 2 points measurement

$$\text{Turbidity (L)} = \frac{1}{C/10}(\alpha-\beta)$$

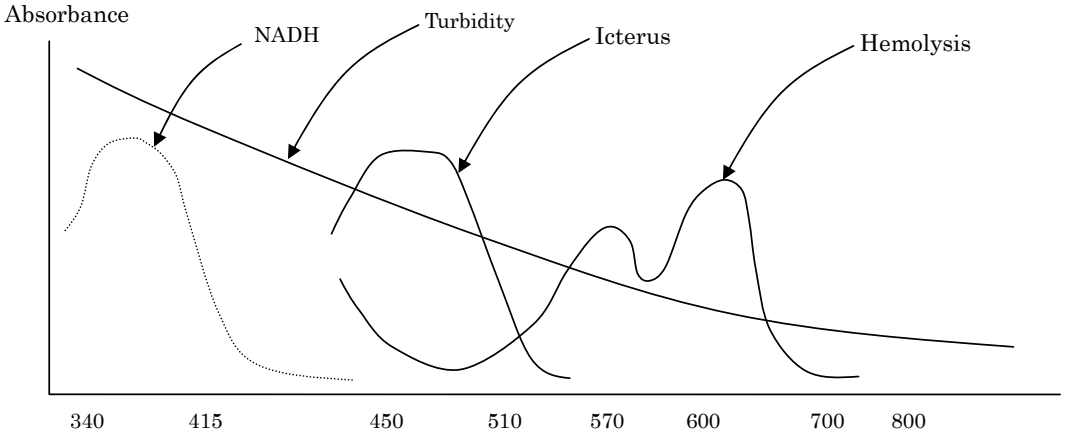
$$\text{Hemolyis (H)} = \frac{1}{A/10}((\gamma-\alpha) - (B/10^5)(\alpha-\beta))$$

$$\text{Icterus (I)} = \frac{1}{D/10}((\delta-\varepsilon) - (E/10^5)(\alpha-\beta) - (F/10^5)(\alpha-\beta))$$

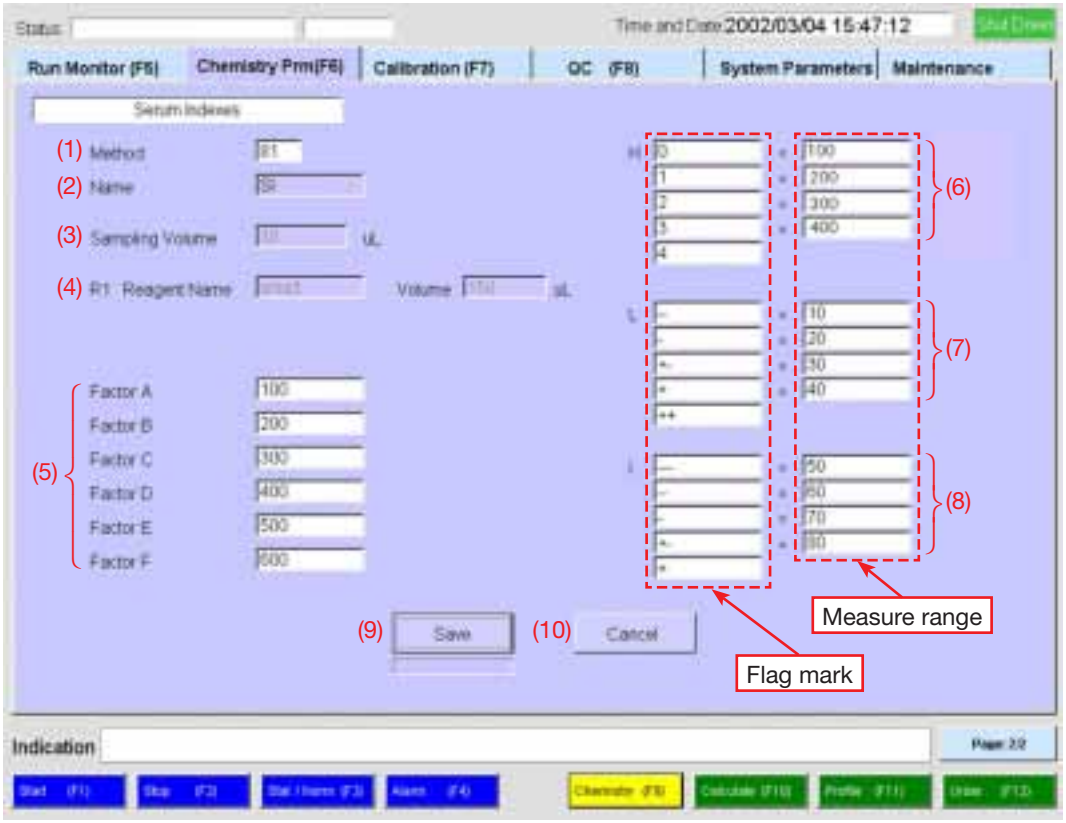
Where A, B, C, D, E and F are constants and client entry items.

λxxx represents the absorbance values of each wavelength λrxxx which are obtained from measurements of sample and phosphoric acid buffer and corrected by water blank λwxxx. For example, in the case of wavelength of 600 nm,

λ 600 = λ r600 – λ w600.



<Picture for entry of serum information>



(1) Method: 81 (fixed number)

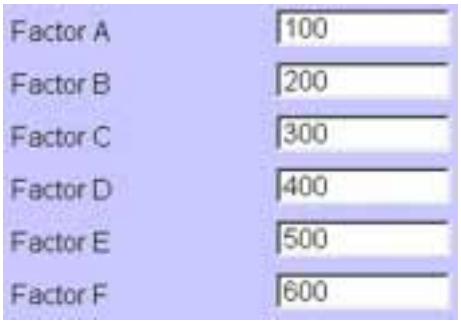
(2) Name: SI (fixed)

(3) Sampling Volume: Sampling volume of sample (µL)

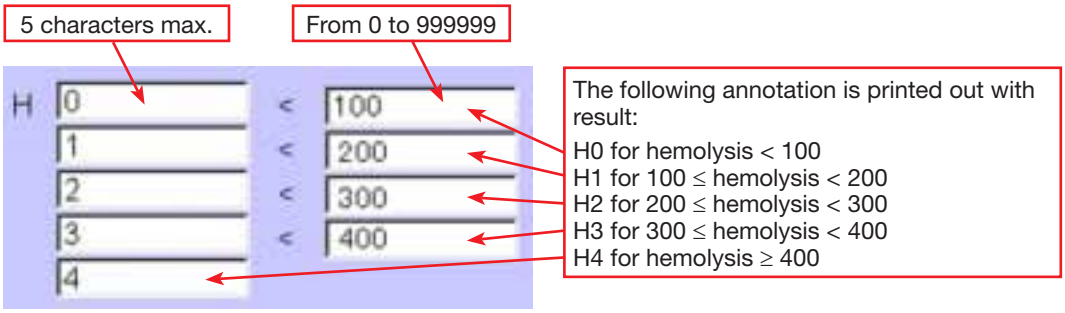
(4) R1 Reagent Name: Specify the reagent which has already been registered. For example, the bottle of phosphoric acid buffer solution is specified.

Volume: Sampling volume of R1 reagent (µL)

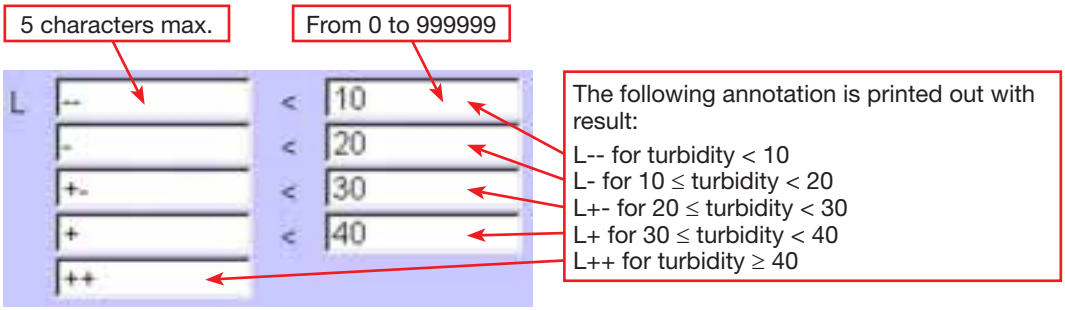
(5) Factor A to F: 0 – 999999



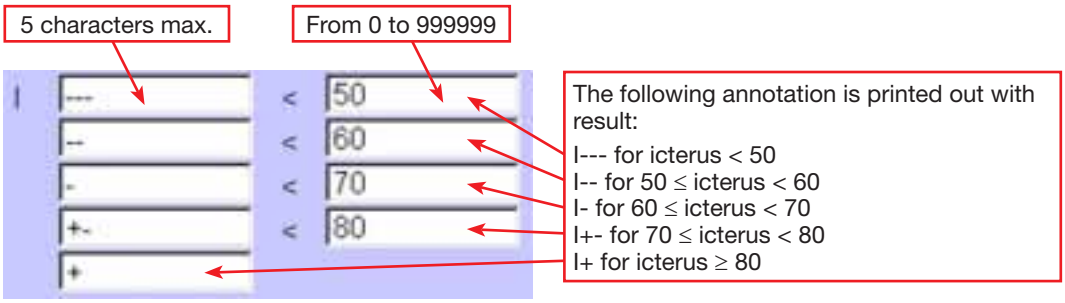
(6) Haemolysis range (Example)



(7) Turbidity range (Example)



(8) Icterus range (Example)



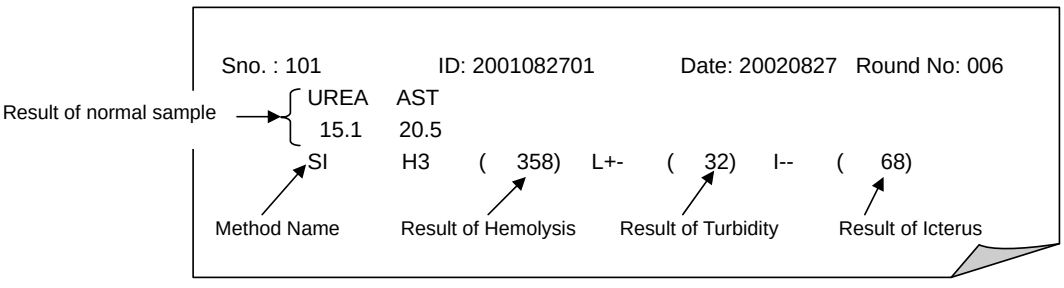
(9) Save button

Click on this button to save the information entered in the above steps.

(10) Cancel button

When click on this button, setting data are not saved.

When the measurement result of serum information is outputted to the printer, its information is printed together with the result of normal sample and ISE. An example is shown below.



3.3 Method-to-Method Computation

This is a calculation method that is obtained by specifying the calculation equation and using the results of two or more methods.

The method numbers assigned to this computation method are the numbers from 71 to 80.

The calculation equation can be set freely but the usable operators are the symbols of four fundamental operations (+, –, x, ÷) and round brackets "(" and ")". The square brackets "{" and "}" are used to enclose the method number.

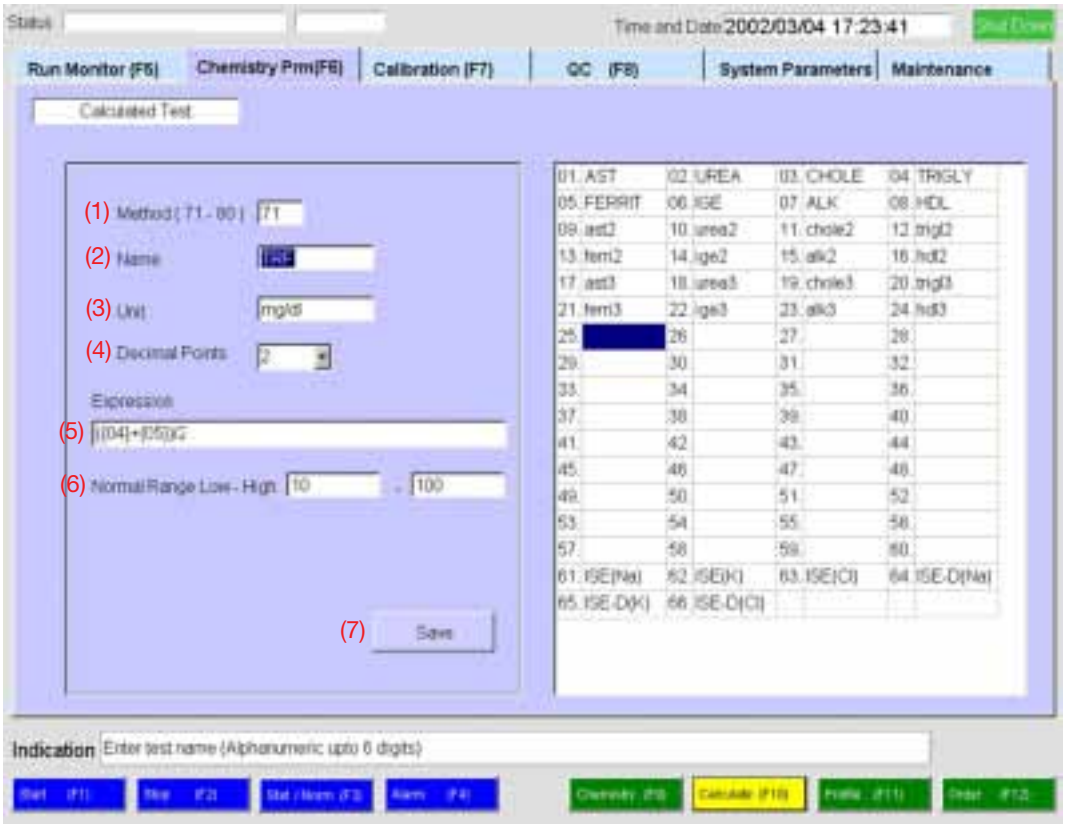
The signs of "*" and "/" are used for multiplication and division respectively.

The method-to-method computation is executed in the function menu [Calculate (F10)] picture of the job menu [Chemistry Prm (F6)].

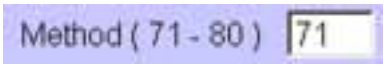
3.3.1 Method-to-Method Computation [Calculate (F10)]

The following explanation is based on the example shown below:

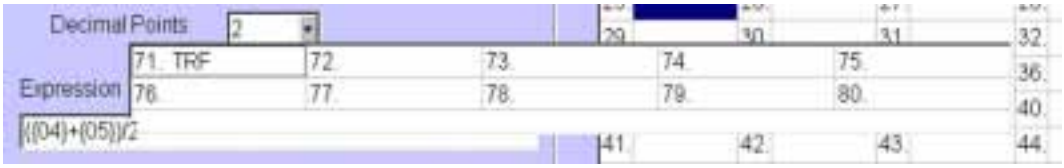
Method No.: 71
Name: TRF
Computation: TRF = (TRIGLY+FERRIT)/2



(1) Method (71 – 80): Method number can be specified from 71 to 80.



When move the cursor onto the entry field of "Method" and press the SPACE key to display the pop-up window in the centre of the screen in order to check the list of method-to-method calculation currently registered. Press the ESC key to close this pop-up window.



(2) Name: Method name can be entered in the form of maximum 6 characters.

(3) Unit: Up to 6 characters can be entered as the unit of concentration for the computed result.

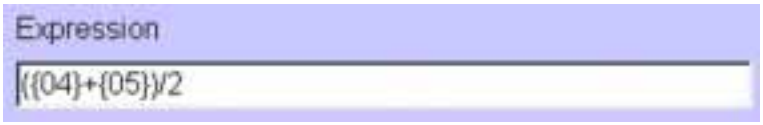
(4) Decimal Point: The significance number of decimal places is defined for the measurement result.

(5) Expression:

The calculation equation is entered. The usable operators are the symbols of four fundamental operations (+, –, *, /), round brackets "(" and ")" and square brackets "{" and "}".

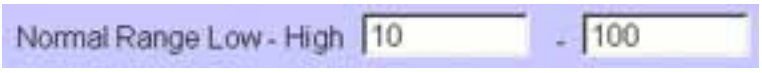
Refer to the list at right screen for necessary method numbers for the computation.

Move the cursor onto the expression input field, and click on the mouse to fix the input field. Then, move the arrow cursor to the wanted method that is on the list at right (Method list) and click on the mouse. So, its method number with square brackets, e.g. “{04}”, is entered automatically in the expression field.



(6) Normal Range Low – High:

Upper and lower limits of the normal range for the computed result are entered.



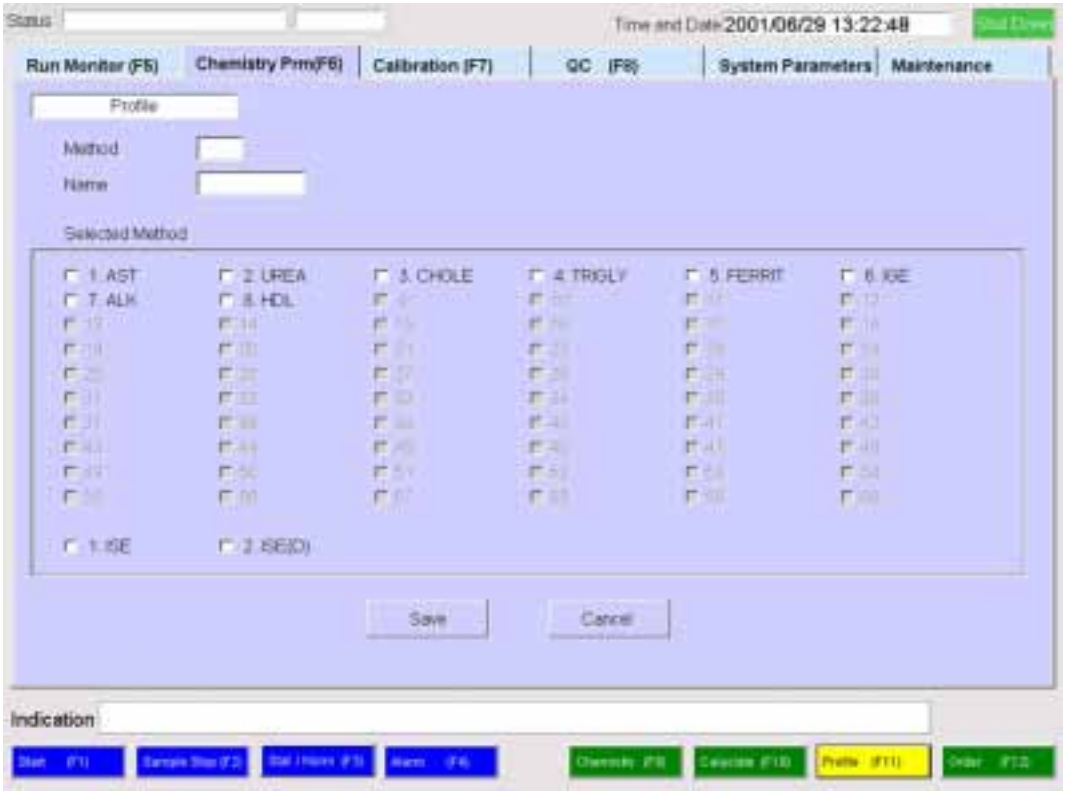
(7) Save **button:** Click on this button to save the above settings.

3.4 Profile

The multiple methods are registered together in order to enables the registered methods to be selected at a time. This function is called as "Profile".

Select the [Profile (F11)] picture of the job menu [Chemistry Prm (F6)] to set the necessary parameters to use this function.

3.4.1 Profile [Profile (F11)]



A) Profile compilation procedures

Up to 8 files can be registered as the profile.

The profile is compiled in accordance with the following procedures:

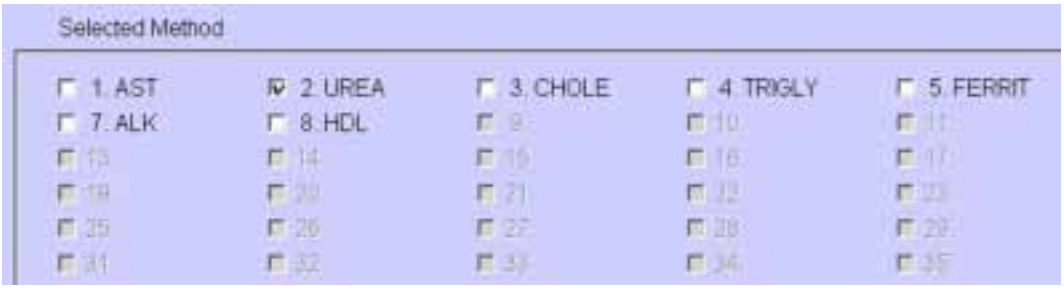
(1) Enter the method number to be compiled.

When move the cursor onto the entry field of “Method” and press the [SPACE] key to display the pop-up window in the centre of the screen in order to check the list of profile number currently registered. Press the [ESC] key to close this pop-up window.

(2) Enter the method name.

(3) Select from the list "Selected Method" methods which are to be registered together as a profile. Move the cursor onto the small box beside the method number and click the left

button of the mouse. A tick mark ☑ appears in the box and the method is selected. Click on the box again to cancel the selection.



(4) Click on the Save button to register the above selection as a profile. Otherwise, click on the Cancel button.

3.5 Order of Measurements and Printout

The measuring order of methods and the printing order of measurement results are specified.

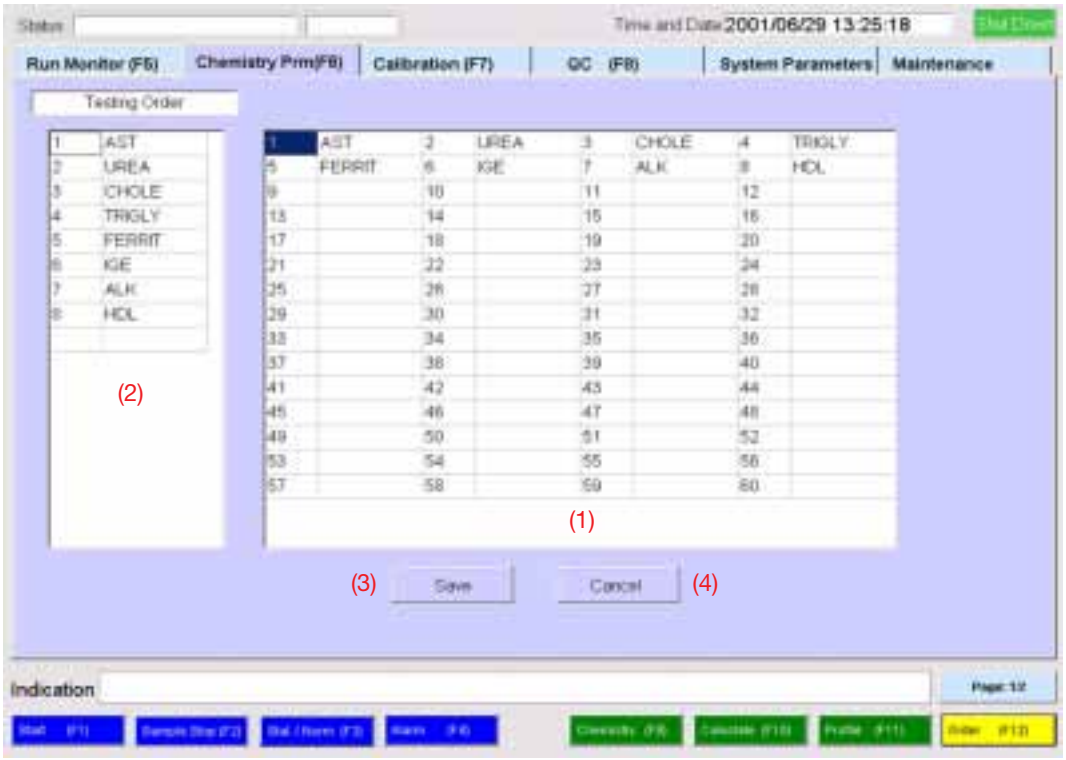
Select the function menu [Order (F12)] picture of the job menu [Chemistry Prm (F6)] and follow the procedures shown below.

3.5.1 Measuring order of methods [Order (F12)] Page 1/2

The measuring order of the methods is specified based on the reagents and wash solutions which have been registered in the analyzer. Please note that in the case of ISE measurement, its measuring order cannot be changed.

<How to define the measuring order>

Click on the method number and drag it to the "Measuring order list" at left to define the measuring order of methods.



(1) Method list: Normal biochemical measurement methods (maximum 60 methods) and wash solution numbers are indicated. (ISE method is not included.)

(2) Measuring order list: The measuring order of methods is indicated.

(3) Save button: Click on this button to save the defined measuring order.

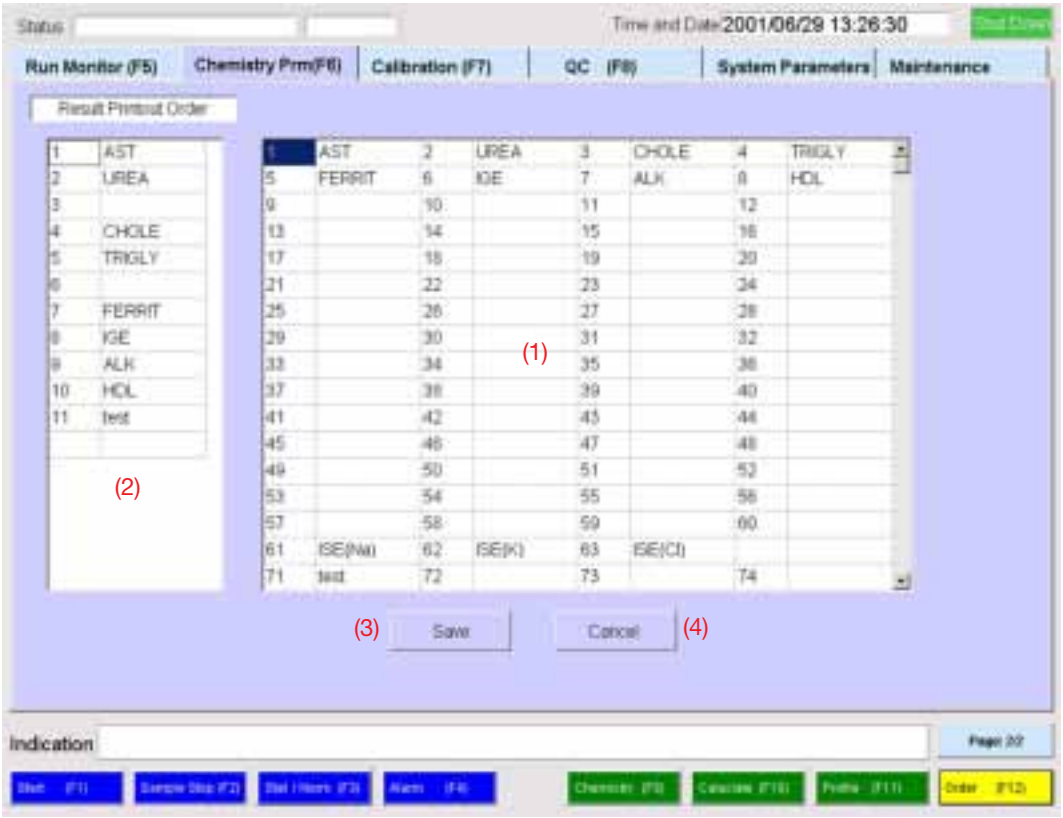
(4) Cancel button: Click on this button to cancel the defined measuring order.

3.5.2 Printing order of measurement results [Order (F12)] Page 2/2

The order of the measurement results to be printed by the printer is specified.

<How to define the printing order>

Click on the method number and drag it to the "Printing order list" at left to define the printing order of measurement results.



(1) Method list: Methods are indicated (calculate and ISE methods are included).

(2) Printing order list: The printing order of measurement results is indicated.

(3) Save button: Click on this button to save the defined measuring order.

(4) Cancel button: Click on this button to cancel the defined measuring order.

3.6 System Parameters

The conditions of the overall system including registration of reagents, operation of floppy disk, reproduction of measurement results, etc. can be set.

Either one of the following function menus can be selected after the job menu [System Parameters] has been selected.

1. System [F9]: Entry of system parameters and registration of reagents and number of replicate setting.
2. FD [F10]: Operation of floppy disk.
3. ISE [F11]: Registration of ISE diluent code, output of ISE calibration result and instrument factor setting of ISE.
4. Result [F12]: Compilation of measurement results.

3.6.1 System Parameters [System (F9)] Page 1/2

The following system parameters need to be checked and entered using the [System Parameters] screen soon after the analyzer has been newly installed on the site.

(1) Settings of communication conditions in the case that the host computer is connected.

(2) Optional settings.

(3) Initial settings of date and time.

(4) Defining whether or not the ASP unit is provided with barcode reader (BCR).

(5) Specifying the type of barcode to be used if the BCR in the ASP is provided.

(6) Volume setting of audible alarm.

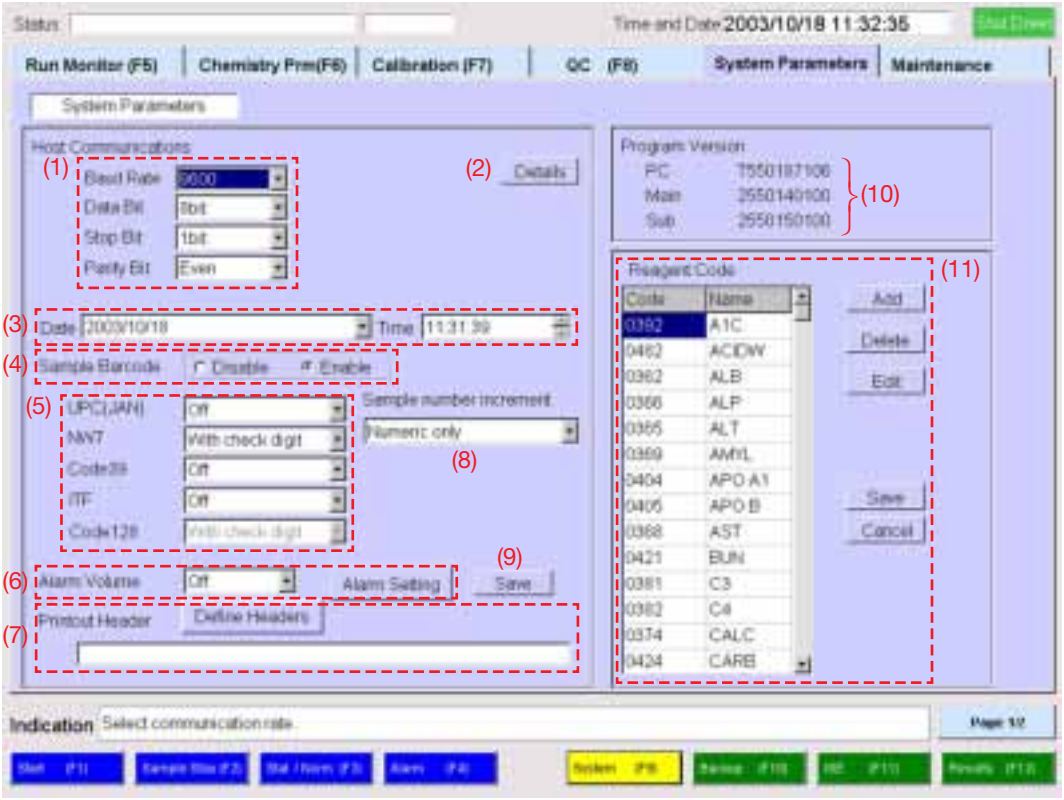
(7) Entry of the header printed on hard copies.

(8) Selection of the sample number increment.

(9) Saving function for above settings.

(10) Reference of program version number.

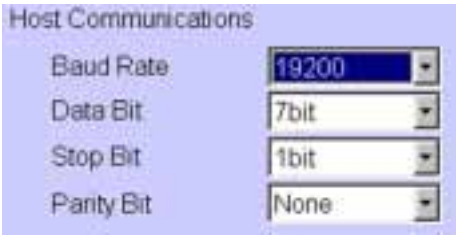
(11) Registration of reagent names and codes.



(1) Host Communications: Conditions of communications with host computer

Conditions of communications with the host computer are to be set up.

Item	Description	Remarks
Baud Rate	19200/9600/4800 bps	Default: 9600 bps
Data Bit	7/8 bits	Default: 8 bits
Stop Bit	1/2 bits	Default: 2 bits
Parity Bit	None/Even/Odd	Default: None



(2) Optional settings

These settings are to restrict the output of data.

A. In case the host communication line is established. (Host Communications)

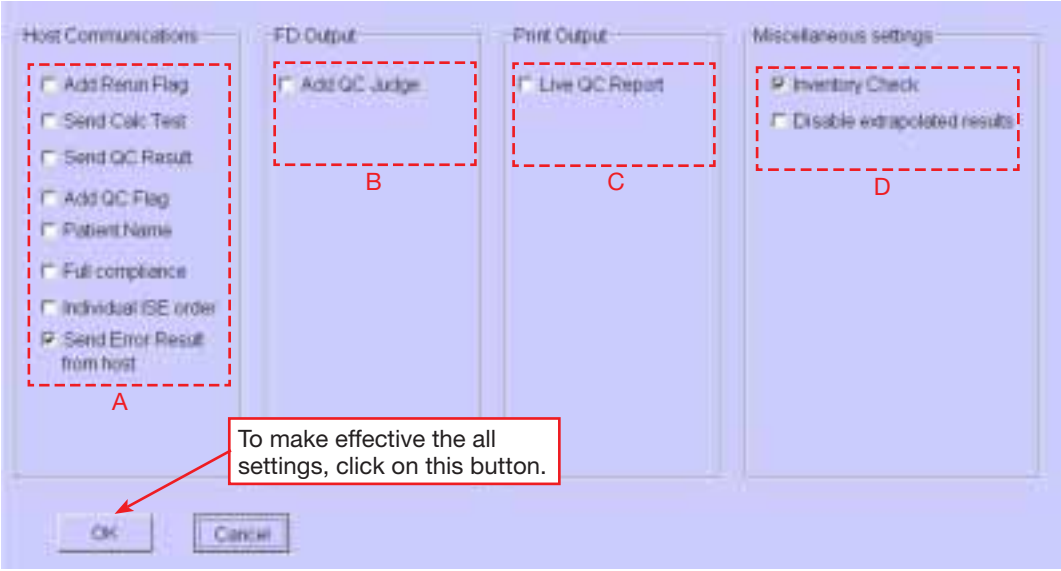
B. In case the QC results are outputted to the floppy disk in the [Result (F12)] of [System Parameters]. (FD Output)

C. In case the QC report is outputted to the printer in the real time. (Print Output)

D. Miscellaneous settings

Because the host computer or customer's floppy disk may be not accepted some kind of measurement result such as the normal result with re-run flag, result of "Calculation Test" and QC result (with judgment flag or not). Depending on the situation of host computer, it can be selected the condition for the data whether they are transmitted to the host computer or not.

When the Detail button is clicked on, the following popup window is displayed in the screen.



A: Host Communications

Add Rerun Flag

☑: When the result is outputted to the host, the re-run flag is attached, if re-run is performed.

☐: When the result is outputted to the host, the re-run flag is not attached, even if re-run is performed.

Send Calc Test

☑: Outputting the result of "Calculation Test" to the host is enabled.

☐: Outputting the result of "Calculation Test" to the host is disabled.

Send Calc Test

☑: Outputting the result of "Calculation Test" to the host is enabled.

☐: Outputting the result of "Calculation Test" to the host is disabled.

Send QC Result

☑: Outputting of QC result to the host is enabled.

☐: Outputting of QC result to the host is disabled.

Add QC Flag

☑: When QC result is outputted to the host, the judgment flag is attached.

☐: When QC result is outputted to the host, the judgment flag is not attached.

Patient Name

☑: Patient name is described in order of last name, first name and middle name.

☐: Patient name is described in order of last name, middle name, and first name.

Full compliance with ASTM rules

☑: Online communication is full compatible with ASTM rules.

☐: Online communication is not full compatible with ASTM rules.

Individual ISE order from host
☑: Testing order of ISE that is transmitted from host is individual method such as Method No-61:Na, 62:K, 63:Cl, 64:Na(diluted), 65:K(diluted) and 66:Cl(diluted).
☐: Testing order of ISE that is transmitted from host is block form such as Method No-61: Na, K, Cl and 62: Na (diluted), K (diluted), Cl (diluted).

Send Error Result
☑: Measurement result is sent to host even if it has error flag.
☐: Measurement result that has error flag is not sent to host.

B: FD Output

Add QC judge
☑: When the QC results are outputted to the floppy disk in the [Results (F12)] screen of [System Parameters], the judgment condition flag (1:4S, 1:3S, etc) is attached to the QC result.
☐: The judgment condition flag (1:4S, 1:3S, etc) is not attached to QC result at outputting to the floppy disk in the [Results (F12)] screen of [System Parameters].

C: Print Output

Live QC Report
☑: QC report is printed at real-time (during measurement).
☐: QC report cannot be printed at real-time. After measurement, printout is possible.

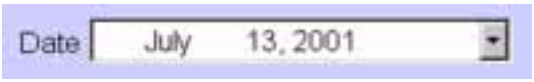
D: Miscellaneous settings

Inventory Check
☑: Inventory check is performed at the time when the measurement is started up.
☐: Inventory check is not performed at the time when the measurement is started up.

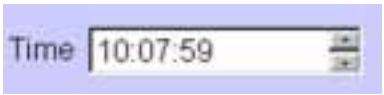
Disable extrapolated result
☑: Minimum or maximum point of the calibration curve is applied to measurement result as concentration value.
☐: Measurement result is calculated from extended calibration curve as concentration value.

(3) Date and Time settings

Enter the date (month, day, and year) by clicking on the triangular mark.



Enter the time (hour, minute, second) by clicking on the triangular marks.

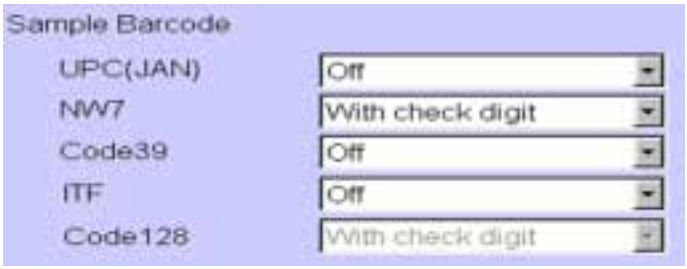


(4) Making enable or disable sample barcode reader

Make sure that a check mark is put on "Enable" for the ASP with BCR or "Disable" for the ASP without BCR.

(5) Definition of sample barcode

The type of bar code label to be used is defined.



Type		Description	Remarks
UPC(JAN)	OFF:	invalid	Default: OFF
	With check digit:	valid in case with check digit	
	Without check digit:	valid in case without check digit	
NW7	OFF:	invalid	Default: with check digit
	With check digit:	valid in case with check digit	
	Without check digit:	valid in case without check digit	
Code39	OFF:	invalid	Default: OFF
	With check digit:	valid in case with check digit	
	Without check digit:	valid in case without check digit	
ITF	OFF:	invalid	Default: OFF
	With check digit:	valid in case with check digit	
	Without check digit:	valid in case without check digit	
Code128	With check digit:	valid in case with check digit	Selection is not available.

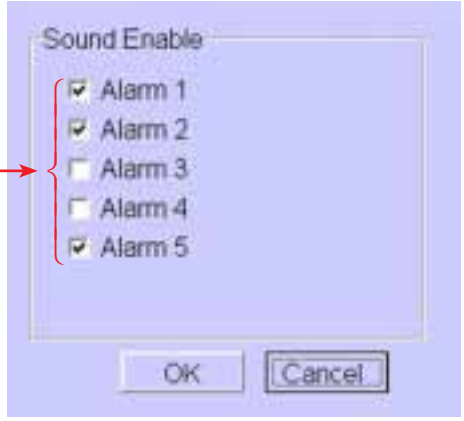
(6) Alarm Volume and Alarm Setting

Alarm volume:
Select the volume of audible alarm from the pull-down menu (OFF – 9) for the enabled alarm in the popup window of “Sound Enable”.

Alarm Setting:
Alarm type (Alarm 1 to Alarm 5) can be selected to sound alarm. When Alarm Setting button is clicked on, the following popup window is displayed. Then you can select the type of alarm to sound alarm among list in the popup window.

Alarm 1: Emergency stop condition is occurred.
Alarm 2: Sampling stop condition is occurred.
Alarm 3: Warning condition is occurred.
Alarm 4: Error condition is occurred in the PC.
Alarm 5: Error condition is occurred at the time when the rotation of ASP is completed.

☑: Alarm sound is enabled.
☐: Alarm sound is disabled.



(7) Printout Header: Define printout header

■ Header of the result printout

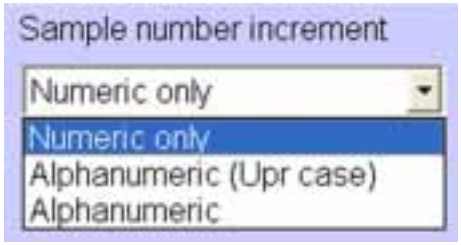
This header is used for the real time printout. (See the Example-1 of "2.10.2 "Examples of printout".)

Enter the header to be printed on hard copies. (Maximum 50 characters)

■ Header of the patient report (This function is not available.)

(8) Sample number increment

This combo box is used for definition of ascending order for the sample number.



This definition is applied to the following cases:

■ Setting of sample number in the test selection screen.

■ Copying of sample number in the test selection screen.

There are three kinds of definition type:

■ Numeric only

Allowable characters are only numerical codes.

Ascending order

Example (2-digits): 01 to 99

■ Alphanumeric (Upper case)

Allowable characters are numeric and alphabetic but the alphabetic characters of upper-case are only available.

Ascending order

Example (2-digit): 01 to 09 and 0A to 0Z and 10 to 99 and 9A to ZZ

■ Alphanumeric

Allowable characters are numeric and alphabetic and also both of upper-case and lower-case of alphabetic characters are available.

Ascending order

Example (2-digit): 01 to 09 and 0A to 0Z and 0a to 0z and 10 to 99 and 9A to ZZ and Za to zz.

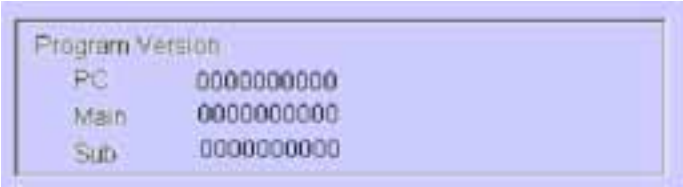
(9) Saving faction

The settings entered in the above steps are saved by clicking on the Save button.

(10) Program Version: Program version numbers in use

The program version numbers in use are indicated.

If any of the following three version numbers does not appear in the window, the analyzer does not work correctly. Make sure that three version numbers are indicated.



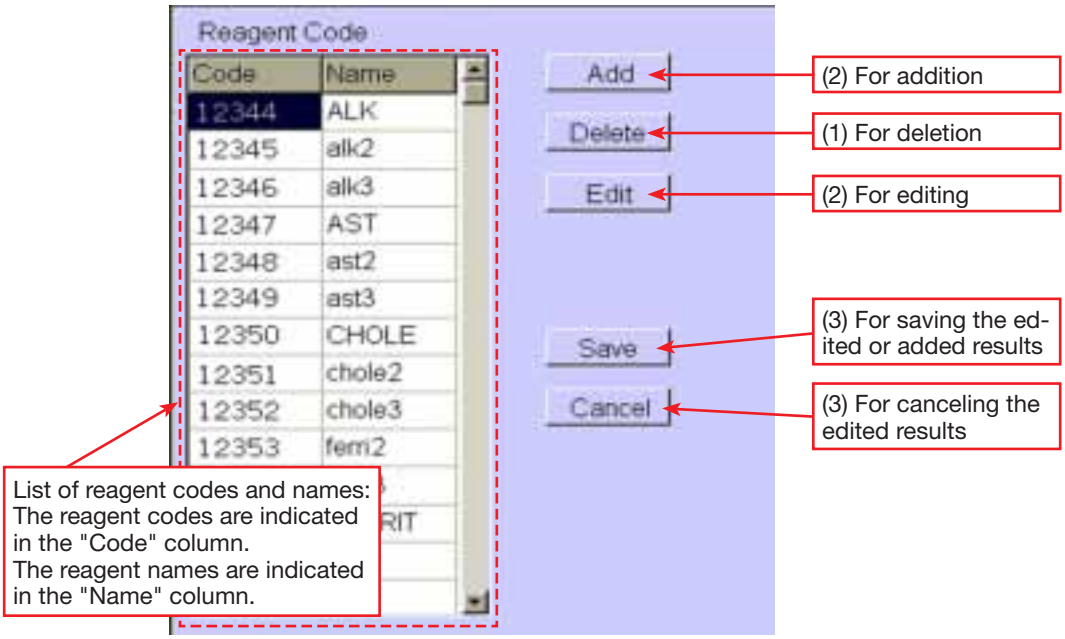
(11) Registration of reagent names and codes

The contents in the reagent list can be edited (registered, changed, and deleted).

The reagents to be used by the analyzer need to be registered soon after that it is newly installed.

The reagent codes of R1 reagent, R2 reagent, Wash solution and diluent can be registered or edited by clicking on the Add or Edit button in the following picture.

Usually, this editing function is allowed to the limited reagents that are having open reagent code number.



1. Deletion

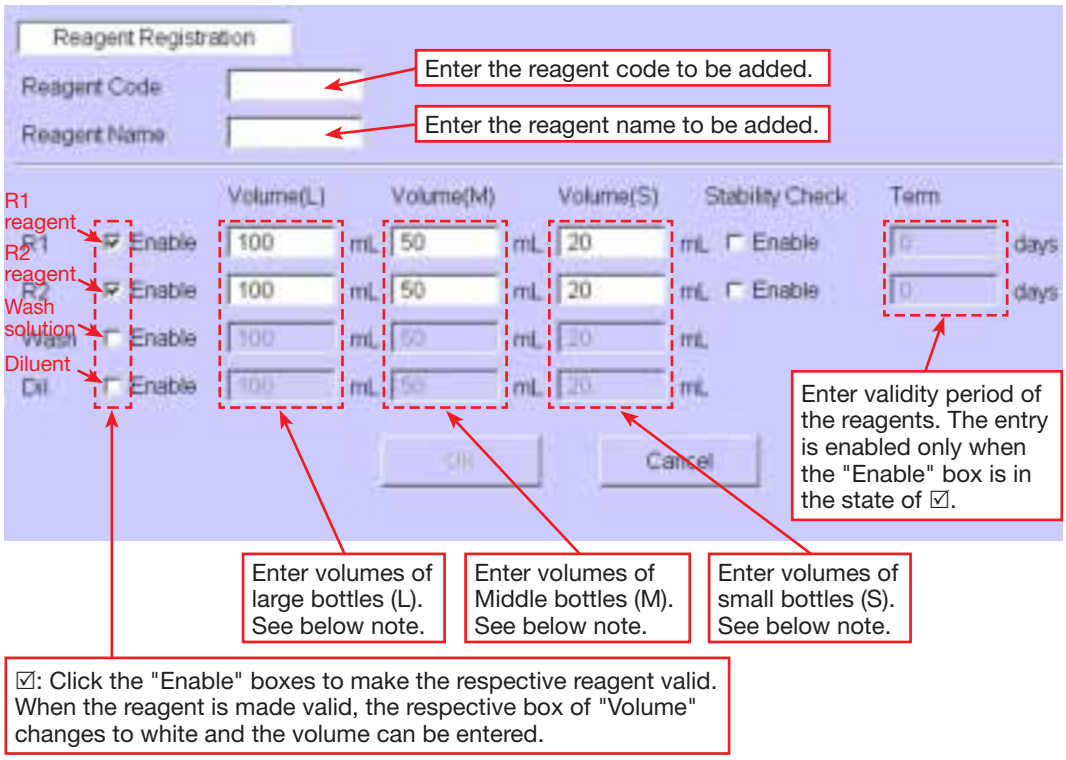
Select reagent code by clicking on its code or name in the list, and click on the Delete button to delete the reagent from the list.

2. Addition and editing

Click on the Add button to add a reagent and the Edit button to edit the reagent.

The following pop-up window is displayed by clicking on the Add button or the Edit button.

Then each volume of the reagent and validity term is specified in respective field as below picture. As click on the OK button, the pop-up window is closed.



Note;
Dead volume of S-type bottle (20mL): Approx. 0.6mL
Dead volume of M-type bottle (50mL): Approx. 2.6mL
Dead volume of L-type bottle (100mL): Approx. 5mL

3. Saving or cancelling the edited or added result

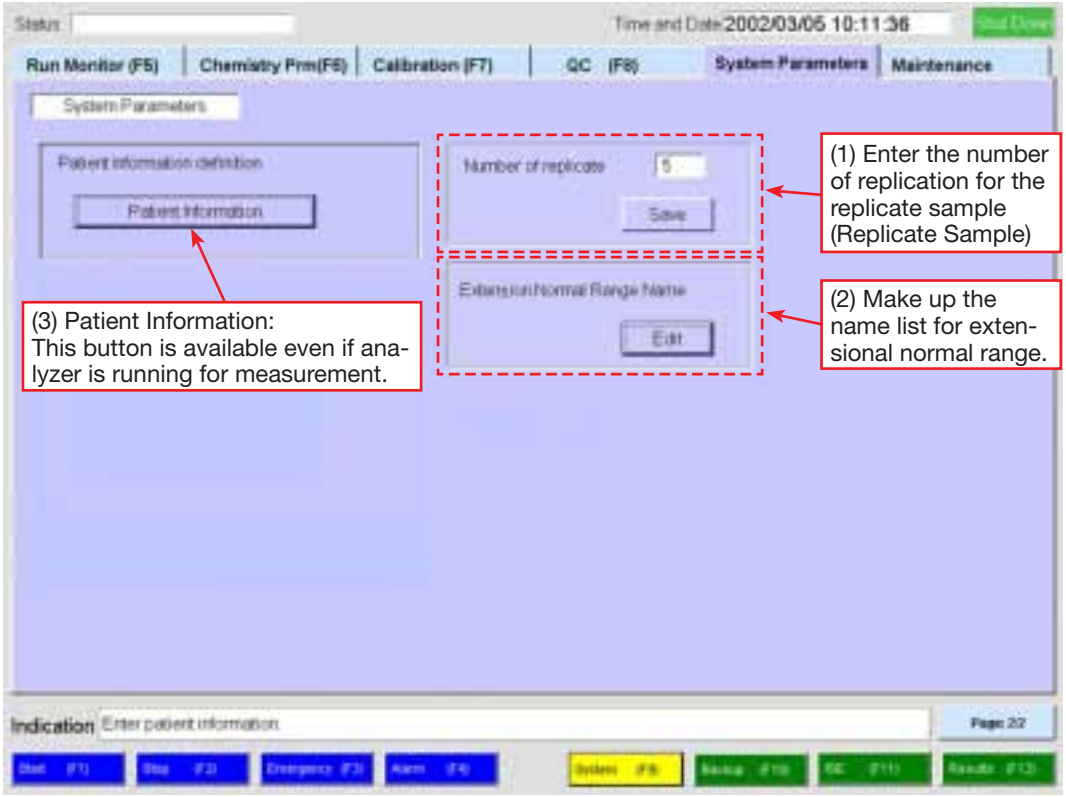
After closing the pop-up window, the edited or added result can be saved by clicking on the Save button.

If you want to cancel the edited or added result, click on the Cancel button.

3.6.2 System parameters [System (F9)] Page 2/2

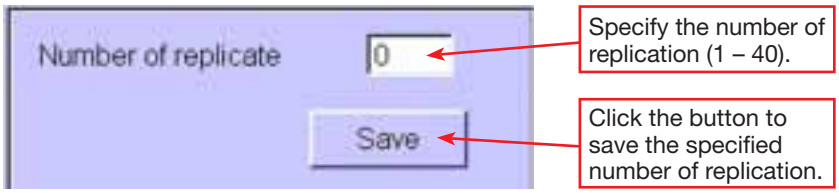
Select the function menu [System (F9)] picture of the job menu [System Parameter] and then press [PgUp] or [PgDn] key to open its page 2/2.

Enter the number of replication for the Replicate Sample and the patient information in the page 2/2 picture.



(1) Setting of the number of replication for Replicate Sample

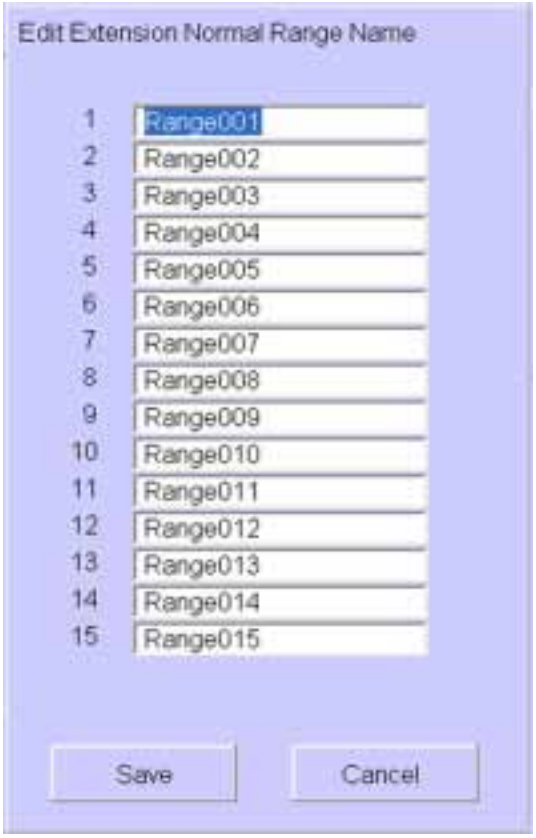
The Replicate Sample is the sample to which the specific sample number is assigned and on which the same method is repeatedly performed (see 2.4 "Test selection").



(2) Extension Normal Range Name

The name list of extensional normal range should be prepared before definition of the extensional normal range in the chemistry parameter screen.

When the Edit button is clicked on, the following popup window is displayed on the screen and every extensional normal range is named or edited here.



After completion of naming, by clicking on the Save button, all name information are saved.

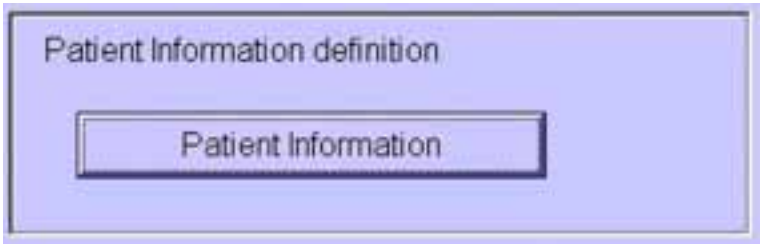
(3) Patient information definition

The different information related to the patient are defined and edited in this picture.

The data for the necessary number of patients can be prepared in advance.

The patient means the person from which the measuring sample is collected.

1. Maximum number of patient information: 9999
   9999 of patient information can be saved in the database, and a specified patient data can be edited.
   When the patient information is filled in the database, an operator should delete unnecessary patient information to add new patient information.
2. Make up the patient information
   Click on the Patient information button to enter the respective data about the following information:

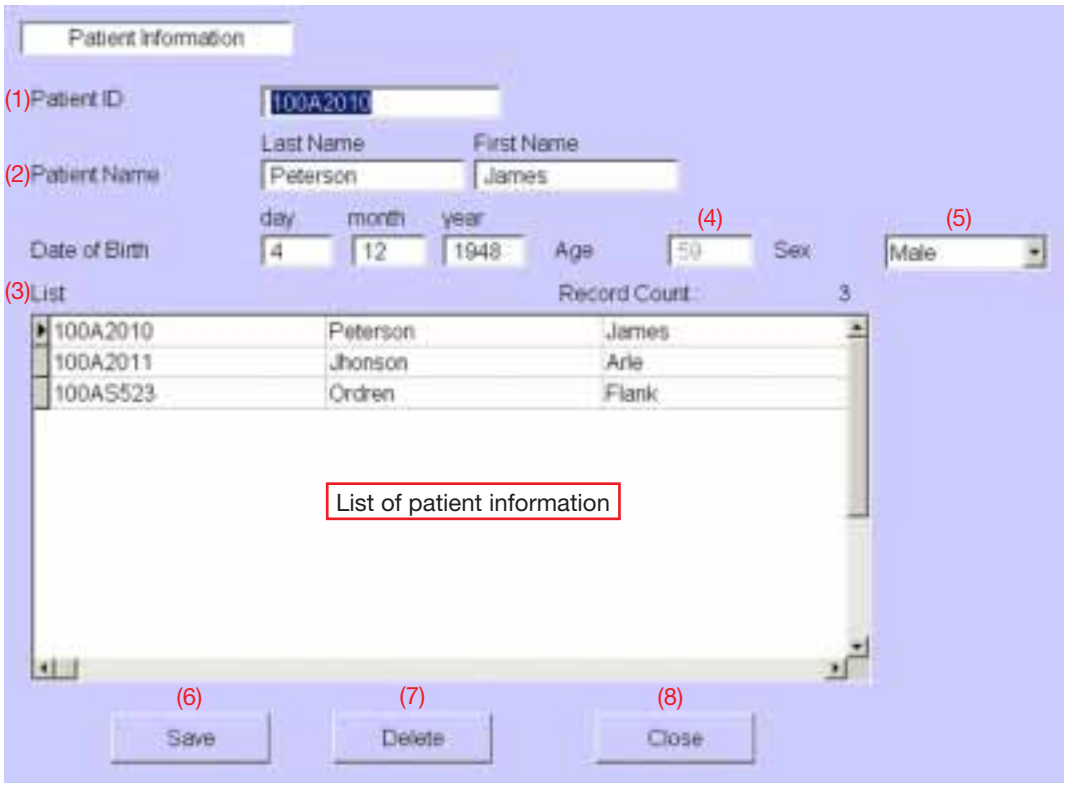


Even though analyzer is performing the measurement, the Patient information button is available.

The information entered will be used to facilitate the compilation of the patient information at the time of test selection.

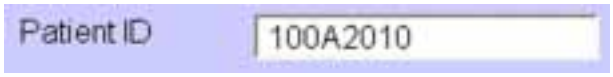
In order to edit the patient information, specify to be edited Patient ID by mouse clicking from the list that is displayed on the screen as the list of patient information.

1. The following screen is pop-upped by clicking on the Patient information button.



(1) Patient ID: Enter the patient identification number. (A Maximum of 13 characters.)

This data (Patient ID) is not compilation. If this is changed, separate information will be added as new patient information.



(2) Patient Name: Enter/edit the patient name. (Maximum 12 characters for each field.)

(3) Date of Birth: Enter/edit the date of patient's birth.

(4) Age: Age is calculated automatically after setting of date of birth.

(5) Sex: Select either “Male” or “Female” by pull-down menu.

(6) Save**:** Click on this button to save the created/edited information.

When the information which is edited or created is newly, it is available as “Save” function. But the case of already being information of patient, the saving function is not activated.

(7) Delete**:** When this button is clicked on, being selected patient information is deleted.

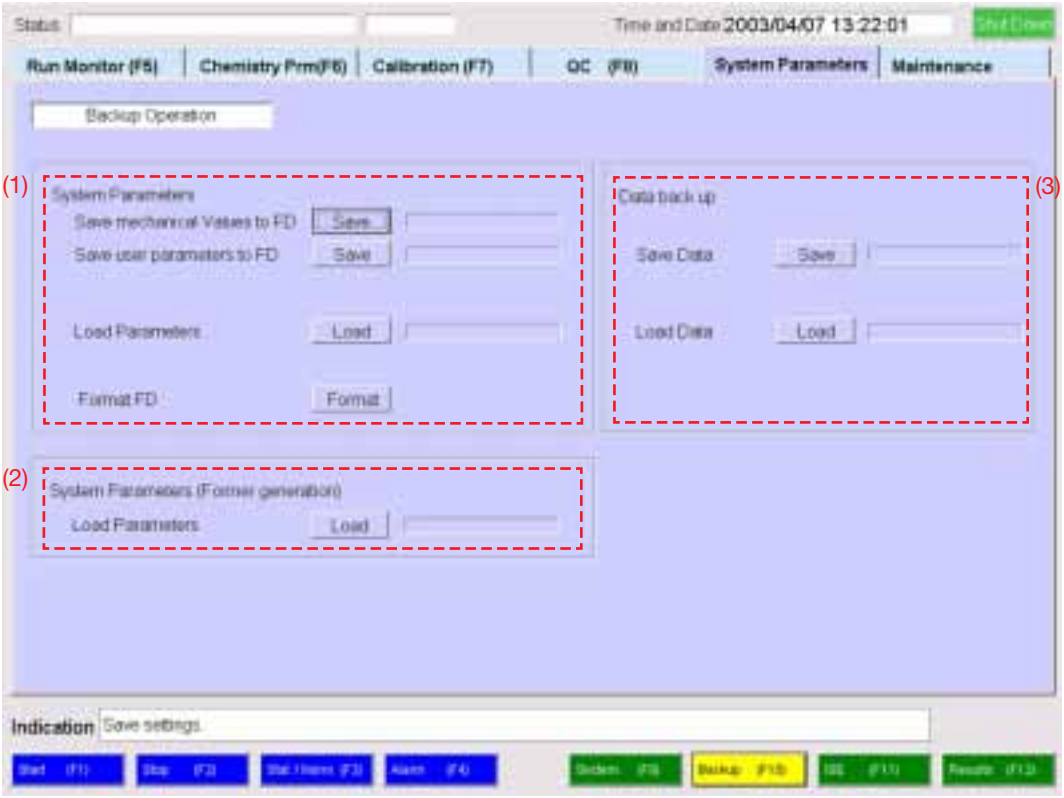
During measurement, the patient information is not deleted even if Delete button is clicked on.

To delete patient information, target is selected from the “List of patient information” by mouse clicking in advance.

(8) Close**:** To go out this screen, click on this button.

3.6.3 Backup Operation [Backup (F10)]

Data can be saved to or downloaded from floppy disk or hard disk in the following function menu [Backup (F10)] picture.



(1) Save/download “System Parameters” to/from FD

1. Save mechanical values to the floppy disk

Insert a floppy disk into the FD drive of the NT PC and click on the Save button to save the mechanical values to the floppy disk.

2. Save user parameters to FD

Insert a floppy disk into the FD drive of the NT PC and click on the Save button to save the user parameters to the disk.

The types of files to which the user parameters are saved and from which they are loaded.

File name	Description
FD1Version.txt	Version number of database
FD2Version.txt	Version number of database
analysis.DB	Methods
AnalysisISE.db	ISE Methods
AnalysisISE2.db	ISE Methods 2
AnalysisSI.db	SI Method
AnalysisSI2.db	SI Method 2
AndCalc.db	Method-to-method computation
assaycon.db	Chemistry parameters
AttendingList.db	Attendant list for patient information
AutoStart.db	Time of activation of analyzer
AutoStartPrep.db	Setting status of Auto Start Prep
CalcItem.db	Method-to-method computation methods
CalibCheck.db	Calibration check
CalibRBSet.db	Reagent blank settings for calibration
CalibSet.db	Settings of calibration
CalibSng.db	-----
CtrlList.db	QC settings
CtrlName.db	QC names
ExNormalRange.db	Extensional normal range data
ExRangeName.db	Name of extensional normal range
LocationList.db	Location list of patient information
Mainte.db	Maintenance settings
MultiStd.db	Settings of Muti-standard
OrderingList.db	Ordering list of patient information
PhlebotomistList.db	-----
PrintJunjo.db	Printing order
Profile.db	Profile conditions
Race.db	Race for patient information
RcuRegntRx.db	Reagent bottle information of RCU
ReagentBlank.db	Reagent blank
ReferralList.db	-----
SampleJunjo.db	Sampling conditions
SiyakuBottle.db	Reagent bottle related information
SiyakuName.db	Reagent names
SiyakuType.db	Reagent type related information
System.db	System parameters
WashProgram.db	Settings of Wash program

3. Load Parameters

Insert the floppy disk to which parameters are saved into the FD drive of the NT PC and click on the Load button to download them from the floppy disk.

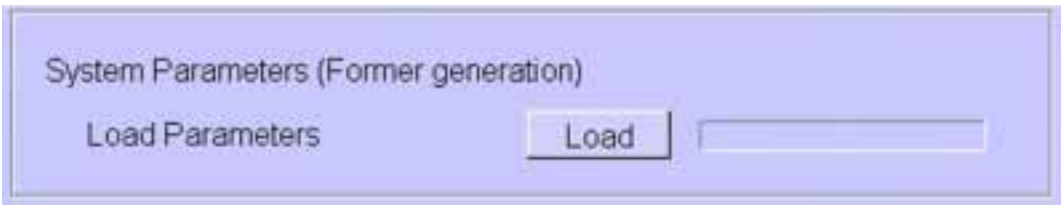
4. Format FD

Insert the floppy disk into the FD drive of the NT PC and click on the Format button to initialize the floppy disk.

(2) Load "System Parameters" (Former generation)

The floppy disk that was saved the user parameters at the time of just before software version of NT PC is able to be converted to use for this new version's software.

Insert the floppy disk to which parameters are saved into the FD drive of the NT PC and click on the Load button to download them from the disk.

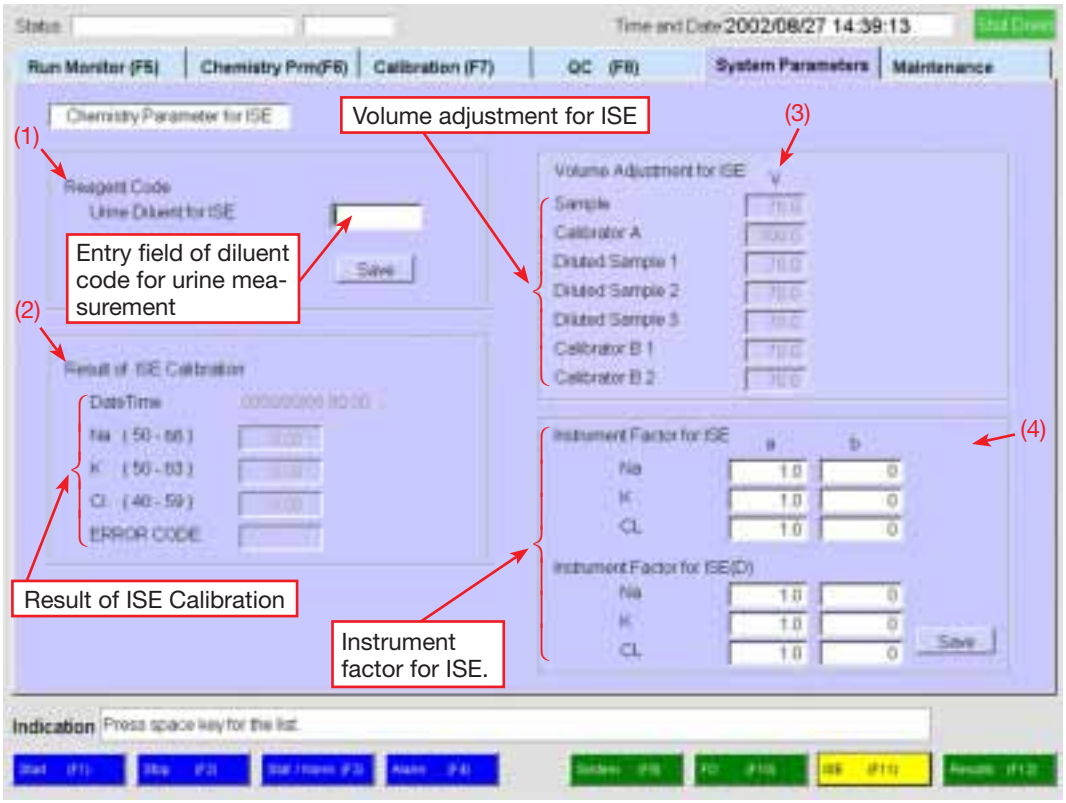


(3) Data Backup

All data, including the mechanical data, chemistry parameters, QC data and measured result data, are saved to the HD (hard disk) of PC. And also these saved data can be loaded from the HD by means of the load function. But the valid data which can be loaded from H.D are saved at the time of just before software version of PC or this new version's software.

3.6.4 Entry of ISE parameters-1: Chemistry Parameter for ISE [ISE (F11) Page: 1/2]

The bottle code of diluent for ISE measurement can be specified in the function menu [ISE (F11)] page-1/2 picture of the job menu [System Parameters].

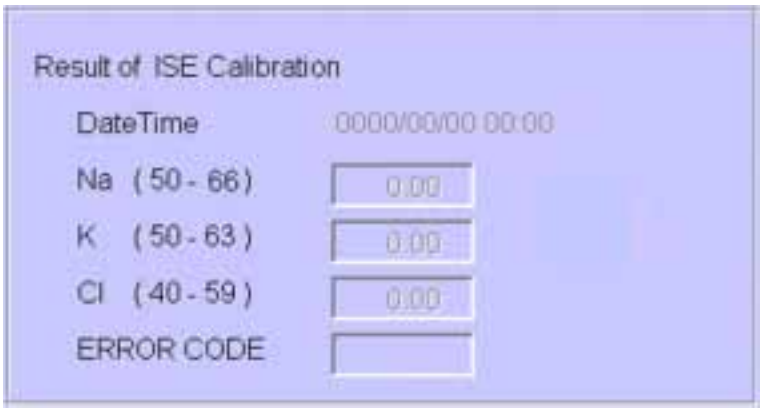


(1) Reagent Code for Urine Diluent

Enter the urine diluent bottle code specified in the function menu [System (F9)] page 1/2 picture of the job menu [System Parameters].

(2) Result of ISE Calibration

When the calibration of ISE finished, each result is outputted this area and printed to the printer.

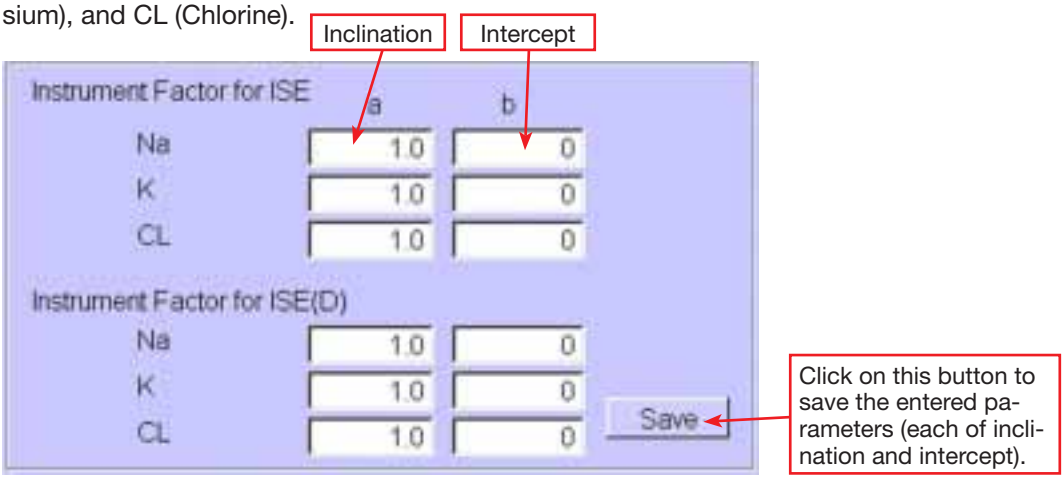


(3) Volume Adjustment for ISE

These are the parameters for adjusting the accuracy of aspiration and dispensation volumes of various ISE solutions and not accessible to the user.

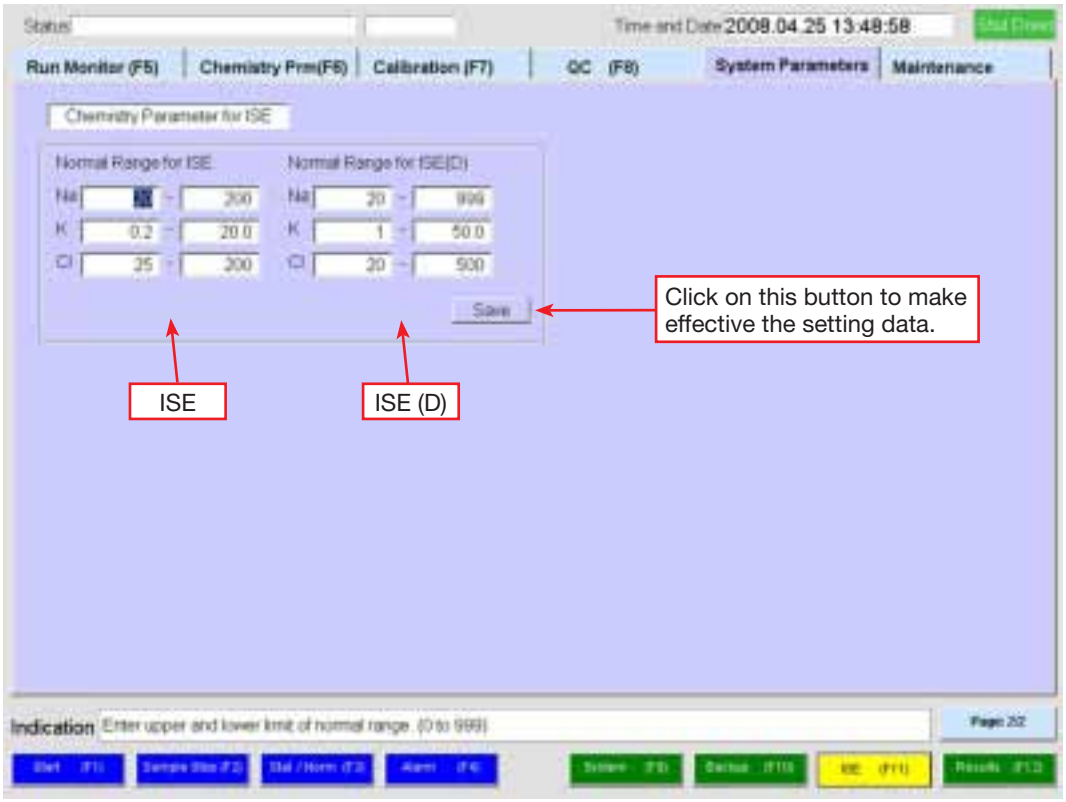
(4) Instrument factor for ISE

The liner correction is applied to the ISE measurement result of Na (Sodium), K (Potassium), and CL (Chlorine).



3.6.5 Entry of ISE parameters-2 (Normal range): Chemistry Parameter for ISE [ISE (F11) Page: 2/2]

The normal range of ISE can be specified in the function menu [ISE (F11) Page: 2/2] picture of the job menu [System Parameters].



For ISE measurement, following two kinds of measurement can be accepted to this analyzer.

(a) ISE: No diluted measurement

(b) ISE (D): Diluted measurement

The measurement result for patient is separated into male, female and child.

In advance with measurement, the normal range of each patient can be defined in order to judge the result.

After completion of the setting of normal range for each patient, click on the Save button to make effective the setting data.

Chapter 4

Maintenance

This chapter provides the procedures of the necessary and minimal amount of maintenance in order to ensure that the analyzer operates correctly and provides the accurate measurement results.

This chapter consists of:

4.1 Maintenance Program

4.1.1 Maintenance Intervals

Perform each maintenance work at the following intervals.

Interval	Check point and action
Before initiation of assay	1. Fill system water tank with purified water (system water). 2. Check if the tip of supply tube is stayed at bottom of the system water tank. 3. Check the remaining volume of all solution tanks (Sol-1, Sol-2, and Sol-3). 4. Check if the tip of supply tube is stayed at bottom of the each solution tank. 5. Empty waste tanks (High and low concentration tank). 6. Check if the tip of drain tube is stayed at bottom of the each waste tank respectively. 7. Check the stain of cuvette. (See 4.1.3) 8. Check the remaining volume of Calibrant A for ISE. 9. Check the term of validity of Calibrant B before practicing of ISE calibration. 10. Before ISE cleaning, check the term of validity of ISE cleaning solution. 11. Check the remaining amount of the printing paper.
Daily	1. Wipe out stains on the work table using cloth impregnated with neutral detergent. 2. Clean the nozzle for SPT and RPT. (See 4.8.2) 3. Practice ISE cleaning per 50 tests. (See 4.7.1)
Weekly	1. Clean the ASP unit. (See 4.8.5) 2. Clean the RCU unit. (See 4.8.6) 3. Clean the nozzles for WU unit. (See 4.8.3) 4. Clean nozzle covers and stirrers using cotton swabs impregnated with alcohol. 5. Check the fluency of solution at RPT trough. (See 4.1.2)
Two weeks	1. Clean the supply and drainage system. (See 4.1.5)
Monthly	1. Clean the external tanks. (See 4.8.1) 2. Clean the all cuvettes in the IRU unit. (See 4.1.4) Following items should be performed by authorized service engineer. 3. Check the in-line filter at WU unit and waste chamber line.
As necessary	1. Exchange the halogen lamp (every 1,000 hours of use). (See 4.9.3) 2. Exchange the plunger tips of syringes (every 150 hours of use). (See 4.9.1) 3. Exchange the pipetting nozzles (every one year of use). (See 4.9.2) 4. Exchange the ISE electrode (See 4.9.4). Following items should be performed by authorized service engineer. 5. Exchange the pump unit for ISE. 6. Exchange the diaphragm pumps (every 1,000 hours of use). 7. Exchange cuvettes (depending on measurement results of water blank). 8. Exchange the stirrer (every one year of use).

4.1.2 Check the fluency of solution at RPT trough

<Procedure>

(1) Perform the RPT nozzle washing “R.P.T (C)”:

Call up the function menu [Wash (F10) Page 1/2] picture of the job menu [Maintenance] and click on the Start button of “R.P.T (C)” to carry out RPT nozzle washing by solution.

(2) While execution of the RPT nozzle washing, confirm the spouting out of solution from RPT trough. If the solution is not fully spouted out from RPT trough, repeat procedure (1) several times. Still, you can not see the fully spouting out the solution, please contact the authorized service engineer.

4.1.3 Check the cuvette condition

This check item is performed to get the proper analytic result in advance of the measurement.

<Procedure>

(1) Select the function menu [Wash (F10) Page 2/2] of the job menu [Maintenance] to check the cuvette condition. The value of water blank for each cuvette is displayed on the picture.

When the value is out of the judgment value, its value is displayed with red or yellow colour. (See “4.7.6 Results of Cuvette Check [Wash (F10)] Page 2/2)”.

(2) If the value which is out of the judgment value exists, practice the following items;

(a) Select the function menu [Sequence (F9)] picture of the job menu [Maintenance].

(b) Click on Start button of the “Cuvette Wash” to initiate the cuvette washing.

(See “4.7.1 Combined Operation [Sequence (F9)]”.)

(3) Perform again procedure (1) to assess the cuvette condition after cuvette washing.

If the value which is out of the judgment value still exists, take out its dirty cuvette from IRU. And wipe the inside and outside of cuvette by using soft cloth or paper to clean the dirty. If necessary, exchange of dirty cuvette for new one.

Caution: In the case of (3), please contact the authorized service engineer.

4.1.4 Washing the cuvette

This washing item would be performed at a monthly interval in order to get the proper analytic result.

<Procedure>

(1) Dispense 600 µl of the wash solution (No.10-2) that is diluted 200 times by purified water to the all cuvettes in the IRU by using hand-pipette. During this action, it should be to turn the power of the analyzer off for safety.

(2) After dispensing the wash solution to the cuvettes, re-start the analyzer by means of turning on the power switch of the analyzer. And leave the analyzer for overnight, over than

10 hours by selecting “Sleep mode”. At this time, there is no need to perform the “Cuvette water placement”.

(3) After starting up the analyzer, perform twice the following procedure for the cuvette washing.

(a) Select the function menu [Sequence (F9)] picture of the job menu [Maintenance].

(b) Click on Start button of the “Cuvette Wash” to initiate the cuvette washing.
(See “4.7.1 Combined Operation [Sequence (F9)]”.)

It would be better to prepare the cuvette wash program in the “Prep-1 or Prep-2” of the automatic start-up menu in advance. (See “4.7.8 Automatic Start-up [Auto Start (F12)]”.)

4.1.5 Cleaning of water supply lines

Wash the water supply lines in accordance with the following procedure to protect them against breeding of bacteria. (It would be better to be carried out once per two or three weeks.)

Refer to the tubing wash function in the “4.7.2 Nozzle Wash [Wash (F10)], Page: 1/2”.)

<Procedure>

(1) Remove the tubes of wash solution (Sol-1, 2, 3) from each external tanks and put them into another tank contained purified water, which would be better to be prepared separately from the system water tank.

(2) Call up the function menu [Wash (F10)] of the job menu [Maintenance] and click on the Start button of “Tubing wash” function to carry out the rinsing tubes in purified water tank.

(See the item 1. of “(8) Tubing wash” at page 4-32.)

(3) Prepare the diluted cleaning solution by using the wash solution(C-1). Dilution ratio as follows;

One (1) part the wash solution (C-1) solution and ninety-nine (99) parts purified water.

And pour the above diluted solution of 1,000ml more into another external tank which is prepared additionally. And put the all supply tubes except drain tubes into this tank.

(See the item 3. of “(8) Tubing wash” at page 4-32.)

(4) And continue the “Tubing wash” sequence.

(See the item 3. and 4. of “(8) Tubing wash” at page 4-32.)

(5) Remove the all supply tubes from diluted cleaning solution tank and put them into the tank contained purified water which is prepared separately from the system water tank.

And continue the “Tubing wash” sequence to rinse the tubes in purified water.

(See the item 5. and 6. at of “(8) Tubing wash” page 4-33.)

(6) Take out the all supply tubes, and put them respectively into the regular tanks (system water tank and each solution tank).

And continue the “Tubing wash” sequence to restore the original condition.

(See item 7. and 8. of “(8) Tubing wash” at page 4-33.)

(7) Perform the “Cuvette Wash” in the [Sequence (F9)] picture.

(See “4.7.1 “Combined Operation [Sequence (F9)]”.)

4.2 Actions to be taken in the event of trouble

When any abnormal conditions are found in the analyzer, the operator is requested to check the following items:

1. Preparation and preservation methods of reagents;
2. Preparation and preservation methods of sample;
3. Operational procedures of the analyzer, and
4. Maintenance work.

When such an abnormal conditions is considered to be caused by an electrical or mechanical failure, do not try to carry out the inspection of the analyzer's innards by your own and call for service at our customer service department.

In the event of a trouble, the corresponding alarm message is indicated. Deal with the trouble referring to in Chapter 5 "List of alarm codes". It is presumed that the trouble will be solved and the proper operation will be resumed in many cases.

4.2.1 Information requested by our customer service department

When any technical service will be called for at our customer service department, the following information is requested to be prepared:

A) Trouble in assay

1. Serial number of analyzer in use;
2. Method code in question;
3. Explanation of encountered trouble;
4. Serial number and lot number of reagent, calibrator and QC sample in use;
5. A few calibration results that were carried out recently;
6. A few measurement results of QC sample that were carried out recently and other measurement results.

B) Trouble in analyzer

1. Serial number of analyzer in use;
2. Software version numbers in use (PC, Mechanical and Sub-CPU);
3. Explanation of relevant alarm and problem, and any other information about the analyzer in use and maintenance;

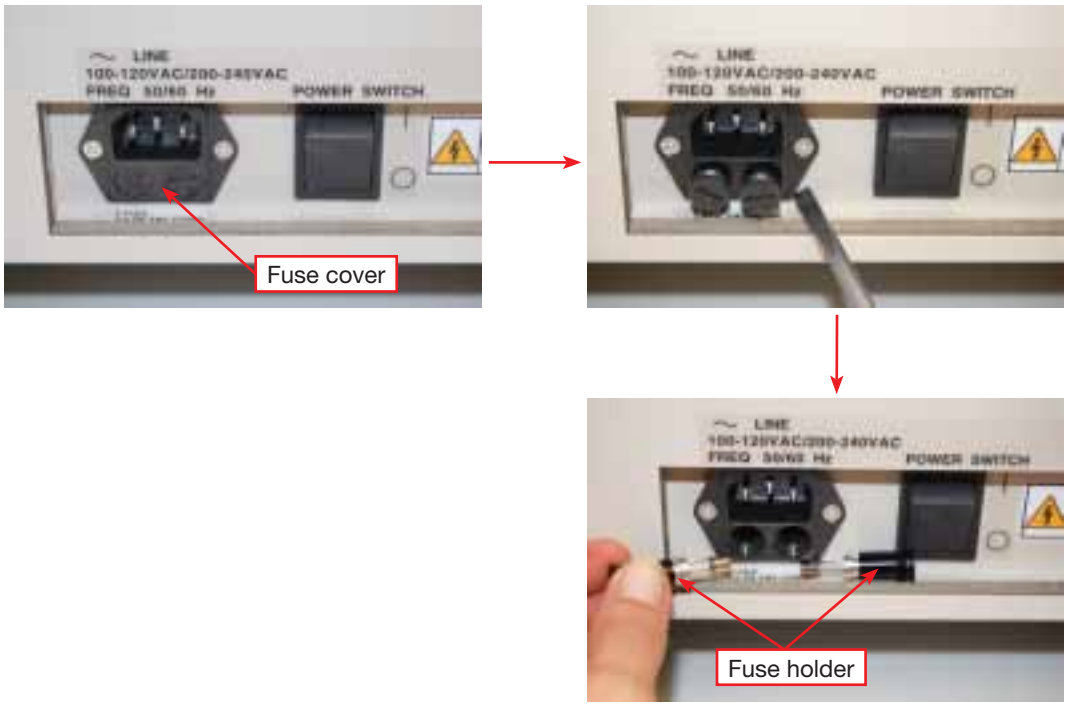
4.3 Malfunction at the time of power-on

If the analyzer cannot be activated, follow the procedures shown below:

1. Check that the main switch located on the left side panel of the analyzer is at "ON" position.

2. Check that the main fuses are not burnt.
When the main fuses are checked, turn the main switch off without fail and then pull out the plug of power supply cable from its receptacle on the analyzer. Open up the fuse cover and pull the fuses out.

3. Check that the breaker of the power supply system to which the analyzer is connected is not off.



4.4 Anomalous measurement results

There may be two cases that the analytical errors are noticed, i.e., by error flag or unexpected results. In the following cases, troubleshooting is requested.

1. Error flag is set to the calibration results.
2. Error flag is set to the measurement results of QC sample or normal sample.
3. The measurement results of QC sample are out of range of judgement criteria.

Investigate which situation shown below is applicable to the error in the measurement results of calibration, QC sample or normal sample. Based on the investigation, further check may be requested.

4. The resultant values obtained from measurements of a specific method are high for all samples.
5. The resultant values obtained from measurements of a specific method are low for all samples.
6. Erroneous results are randomly derived from measurement.
7. Two or more anomalous measurement results are observed:
   – from all methods, or
   – randomly

4.4.1 Check of preparation of reagent, calibrator or QC sample

Perform the following checks in order to track down the cause for high, low or random resultant measurement results.

When a reagent, calibrator or QC sample is prepared, read the respective statement of virtues carefully and follow its instruction.

A) Preparation of reagent

1. Was there any change of the reagent?
2. Is the term of validity of the prepared reagent still valid?
3. Was the reagent prepared according to the correct procedures?
4. Was the reagent prepared using fresh, non-bacteria contaminated and deionised water or appropriate diluent?

B) Preparation of QC sample

1. Was the volume used for preparation correct?
2. Does the sample have been preserved as recommended?
3. Is the term of validity of the sample still valid?
4. Was the sample prepared using a pipette calibrated in terms of volume?
5. Is the term of validity of the sample lot still valid?
6. Was the sample prepared using appropriate diluent?

C) Preparation of calibrator

1. Was there any change of the lot number?
2. Was the calibrator prepared using volume correctly?

3. Does the calibrator have been preserved as recommended?
4. Is the term of validity of the calibrator still valid?
5. Was the calibrator prepared using a pipette calibrated in terms of volume?
6. Was the calibrator prepared using appropriate diluent?

The further checks are requested to track down the cause referring to the following lists after the above checks have been completed.

4.4.2 High result values from a specific method for all samples

Cause	Action
1. Incorrect calibration results	Check the preparation of the calibrator. Check that the calibration settings are correct. The calibration is performed again if necessary.
2. Too high inside temperature of IRU unit	Check the temperature shown in the [Run Monitor (page 1/2)] picture. Call for service at our customer service department when the indicated temperature deviates from the specified value of 37 ± 0.3ºC.
3. Improper preparation of reagent	Check the preparation of the reagent.
4. Improper preparation of calibrator	Check the preparation of the calibrator.

4.4.3 Low result values from a specific method for all samples

Cause	Action
1. Expiration of the term of validity of reagent	See the statement of virtues which comes together with the reagent kit for its stability.
2. Improper preparation of reagent	Check the preparation of the reagent.
3. Improper preservation of reagent	See the statement of virtues which comes together with the reagent kit for its proper preservation method.
4. Too low inside temperature of IRU unit	Check the temperature shown in the [Run Monitor (page 1/2)] picture. Call for service at our customer service department when the indicated temperature deviates from the specified value of 37 ± 0.3ºC.
5. Improper preparation of calibrator	Check the preparation of the calibrator.
6. Excessive volume of reagent dispensed	Check if there is any leakage or drip at junction of reagent sampling system.

4.4.4 Randomly derived erroneous measurement results

Cause	Action
1. Stains on SPT or RPT	Perform nozzle washing in the [Wash [F10]] picture of the job menu [Maintenance] and check that the enough wash water is dispensed into the trough. Call for service at our customer service department in vase of trouble.
2. Fibrin clots formed on specific sample tube or sample cup	Clean the SPT nozzle.
3. Insufficient water or solution supply from respective external tank	Check if the tip of water or solution tube is positioned below the water or solution level. Call for service at our customer service department in vase of trouble.
4. Insufficient stirring	Check if the stirrer rotates in the centre of cuvette and at the correct speed.

4.4.5 Anomalous result values from all methods for a sample

Cause	Action
1. Improper preparation of reagent	Prepare newly the reagent referring to the statement of virtues which comes together with the reagent kit.
2. Expiration of term of validity, contamination or paleness of reagent	Prepare newly the reagent referring to the statement of virtues which comes together with the reagent kit.

4.4.6 Two or more anomalous and random measurement results

Cause	Action
1. Leakage in the SPT or RPT sampling system	Check junctions of probe and syringe.
2. Anomalous inside temperature of IRU unit	Check the temperature shown in the [Run Monitor (page 1/2)] picture. Call for service at our customer service department when the indicated temperature deviates from the specified value of 37 ± 0.3°C.
3. Insufficient stirring	Check if the stirrer rotates in the centre of cuvette and at the correct speed. (Mix-1 and Mix-2)
4. Stain of Pipettes (SPT and RPT) and stirrers	Check if the pipettes and stirrers are washed well at respective trough. (SPT, RPT, Mix-1 and Mix-2)

4.5 Equipment malfunction

The performance of troubleshooting should be limited to an extent described in this manual. It may be difficult for the user to deal with the problem, the troubleshooting of which is beyond this limited extent. In such a case, call our customer service department for service.

4.5.1 Detection of mechanical problem

All the mechanical movements are controlled and monitored by the computer. When a problem arises, the computer becomes aware of it and generates the visual error message to call the operator's attention.

In the event of the problem that may affect the performance of the analyzer, the sampling stop or emergency stop will be executed. In the case of sampling stop mode, the analyzer carries on and completes the processing of the sample that is not affected by the problem. In the case of problem that may affect the entire measurements of sample, the emergency stop will be executed.

The analyzer generates two types of error messages, i.e., result-related flag and equipment alarm.

Problem may arise, which is not monitored by the computer. Any alarm message may not be indicated on the display for such a problem. Such a problem includes abrasion of parts, leakage in the sampling system, etc. When this type of problem occures, decide whether the processing of sample is carried on or the measurement is terminated, considering that such problem may result in a damage to the analyzer or erroneous outcome of measurements.

4.5.2 Error messages for each unit

See Chapter 5 "List of alarm codes".

4.6 Error flags associated with measurement results

When the measurement result is higher or lower than the defined value, the appropriate error flag is printed out together with the result.

4.6.1 Measurement result assessment flag

The measurement result assessment flags printed out together with the measurement result are shown in the following list.

No.	Flag	Cause	Action
1	H (Higher than upper limit of judgement value)	The measurement result shows higher value than the specified normal range.	For information only to the user. Chemistry Parameters should be checked.
2	L (Lower than lower limit of judgement value)	The measurement result shows lower value than the specified normal range.	For information only to the user. Chemistry Parameters should be checked.
3	>	The measurement result shows higher value than the technical range.	For information only to the user. Chemistry Parameters should be checked.
4	<	The measurement result shows lower value than the technical range.	For information only to the user. Chemistry Parameters should be checked.
5	r	The measurement result shows result of rerun execution.	For information only to the user. Chemistry Parameters should be checked.

4.6.2 Measurement result error flags

The measurement result error flags printed out together with the measurement result are shown in the following list.

No.	Flag	Cause	Action
1	SS	Tip of the SPT hits the bottom at the time of aspiration of sample at the ASP unit. (Sample could not be aspirated.)	Check the sample volume in the sample tube or sample cup.
2	SI1	Tip of the SPT hits the bottom at the time of dispensation of sample at the IRU. (Sample could not be dispensed.)	Check the level sensor and its associated parts.
3	SI2	Tip of the SPT hits the bottom at the time of aspiration of diluent at the IRU. (Diluent could not be aspirated.)	Check the level sensor and its associated parts.

4	R1S	Tip of the RPT hits the bottom at the time of aspiration of R1 at the RCU. (Shortage of R1 reagent)	Check the volume of R1 reagent in its bottle.
5	R2S	Tip of the RPT hits the bottom at the time of aspiration of R2 at the RCU. (Shortage of R2 reagent)	Check the volume of R2 reagent in its bottle.
6	DS	Tip of the RPT hits the bottom at the time of aspiration of diluent at the RCU. (Shortage of diluent)	Check the volume of diluent in its bottle.
7	WS	Tip of the RPT hits the bottom at the time of aspiration of wash solution at the RCU. (Shortage of wash solution)	Check the volume of wash solution in its bottle.
8	TE1	Inside temperature of the IRU is lower than 35ºC.	Check the IRU unit.
9	TE2	Inside temperature of the IRU is higher than 39ºC.	Check the IRU unit.
10	TE3	Inside temperature of the RCU is higher than 15ºC.	Check the RCU unit.
11	R1B	R1 reagent bottle has not been registered.	Check that the bar code on the label is the registered one.
12	R2B	R2 reagent bottle has not been registered.	Check that the bar code on the label is the registered one.
13	DB	Diluent bottle has not been registered.	Check that the bar code on the label is the registered one.
14	WB	Wash solution bottle has not been registered.	Check that the bar code on the label is the registered one.
15	IE1	No response from ISE unit to sampling start command.	Check the ISE unit.
16	IE2	No measurement result is sent from ISE unit.	Check the ISE unit.
17	EST	Error arises during run and sampling is interrupted.	Check the error number.
18	LOT	Mismatch between R1 and R2 lot numbers.	Use R1 and R2 bears same lot number.
19	R1W	RPT wash between methods fails. (Timing of R1)	Check the relevant alarm.
20	R2W	RPT wash between methods fails. (Timing of R2)	Check the relevant alarm.
21	EXP	Term of validity of reagent has expired.	Exchange the reagent to the valid one.
22	STB	Term of validity of reagent stability has expired.	Exchange the reagent to the valid one.
23	SPW	SPT wash has been failed.	Check the relevant alarm.

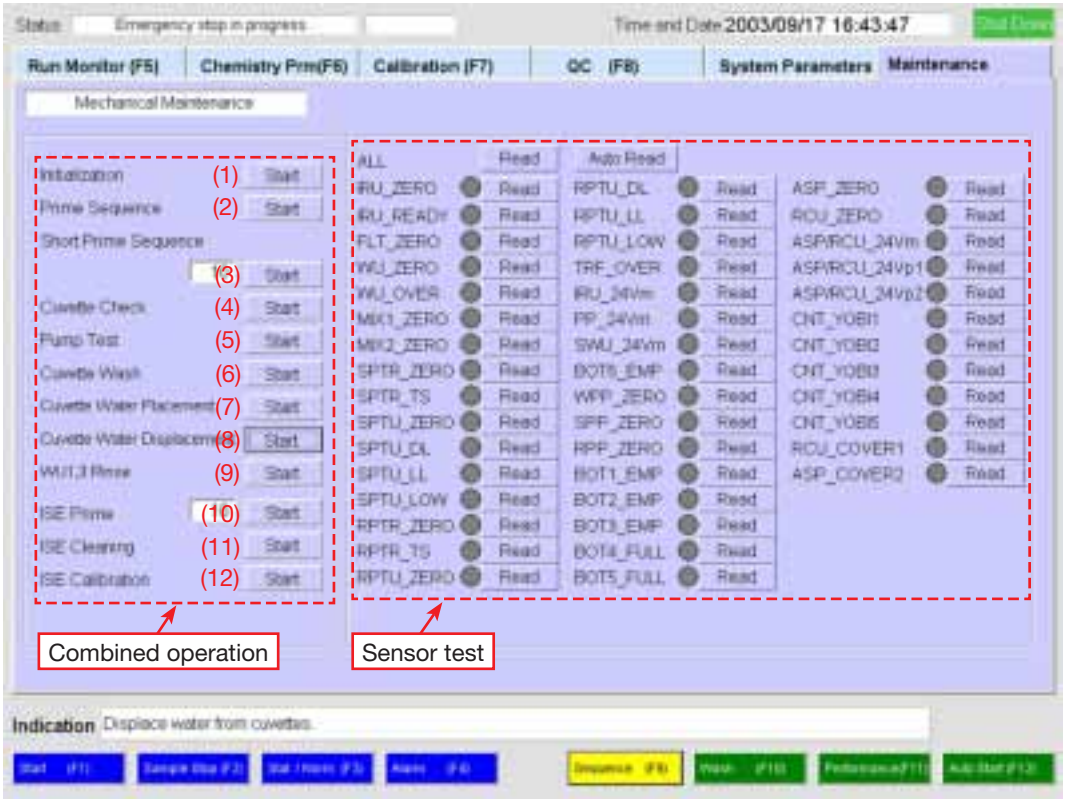
24	CTO	Term of validity of calibration has exceeded for obtained result.	Perform the calibration measurement for the relevant method, and try again the same measurement, if necessary.
25	DUP	Variation in calibration results is out of allowable range. (Variation in duplicate and triplicate measurement results)	Check the adequacy of value for the duplicate limit, and perform again same calibration measurement.
26	SEN	Difference in absorbance between Std (min) and STD (max) is out of allowable range for the calibration measurement.	Check the adequacy of value for the sensitivity limit, and perform again same calibration measurement.
27	CAL	Calibration measurement failed.	Check the applied calibration parameters.
28	CA?	Conversion to concentration is disabled.	Check the applied calibration parameters.
29	CLT	Used reagent lot # in the sample or control measurement is different from the reagent in the calibration measurement.	For information to the user. Try another measurement after re-calibration is performed, if necessary.
30	LIN	Linearity is out of allowable range.	Check the adequacy of value for the linearity limit, and perform again same calibration measurement, if necessary.
31	PRO	Prozone is out of allowable range.	Check the adequacy of value for the prozone limit, and perform again same measurement, if necessary.
32	AB1	All measured values are out of the absorbance limit or first one measured value is in the absorbance limit but the others are out of the absorbance limit.	Check the adequacy of value for the absorbance limit, and perform again same measurement, if necessary
33	AB2	There are not more than 3 consecutive measured values in the absorbance limit.	Check the adequacy of value for the absorbance limit, and perform again same measurement, if necessary.
34	OVR	Concentration is out of calibration curve. (Applied calibration curves are Spline, Point-to-point and Log-logit.)	Check the applied calibration parameters, and perform again measurement of calibration, if necessary.

4.7 Maintenance Picture

The following maintenance picture is indicated by clicking on the job menu [Maintenance]. This picture is provided with test function of individual operations of each unit and monitoring function of each sensor state.

4.7.1 Combined Operation [Sequence (F9)]

Several combined operation can be executed or various sensor states can be monitored.



A) Combined Operation

(1) Initialization

This is to initialize the mechanical parts of each unit.

After click on the Start button, the popup message is appeared to prompt operator to select either OK or Start button.

OK: Initialization is performed.

Cancel: The popup message is disappeared without any performance.

(2) Prime Sequence (Long prime)

This is to perform the long prime sequence for all pumps and syringes in order to deflate the tubing line of water and solution.

After click on the [Start] button, the popup message is appeared to prompt operator to select either [OK] or [Cancel] button.

[OK]: Prim sequence is performed.

[Cancel]: The popup message is disappeared without any performance.

(3) Short Prime Sequence

This is to perform the short prime sequence.

Number of execution count should be entered into the input field.

After click on the [Start] button, the popup message is appeared to prompt operator to select either [OK] or [Cancel] button.

[OK]: Short prime sequence is performed.

[Cancel]: The popup message is disappeared without any performance.

(4) Cuvette Check

This is to perform water blank measurement to assess the degree of stains on cuvettes.

The absorbance data of water blank is stored to the internal data base which is reflected in the function menu [Wash (F10) Page 2/2] picture of the job menu [Maintenance].

After click on the [Start] button, the popup message is appeared to prompt operator to select either [OK] or [Cancel] button.

[OK]: Cuvette check is performed.

[Cancel]: The popup message is disappeared without any performance.

(5) Pump Test

All pumps can be selectively activated for specified period to check their function.

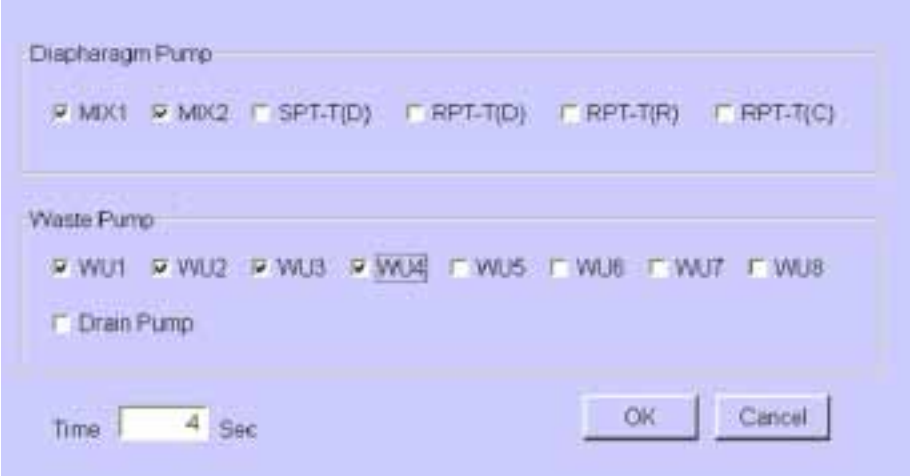
When clicked on [Start] button, the following popup window is displayed on the screen.

1. Select testing pump by means of clicking at the check mark in the both group “Diaphragm Pump” and “Waste Pump”.

2. Enter the operating time into the “Time” box.

3. Click on the [OK] button to start this pump test.

4. To terminate this test, click on [Cancel] button. Then return to original screen.



(6) Cuvette Wash

45 cuvettes placed in the IRU unit are washed.

After click on the Start button, the popup message is appeared to prompt operator to select either OK or Cancel button.

OK: Cuvette wash is performed.

Cancel: The popup message is disappeared without any performance.

(7) Cuvette Water Placement

This is to fill 45 cuvettes in the IRU unit with water.

The purpose of this treatment is to prevent cuvettes from being stained during the period that the analyzer is left unused for a long time.

The cuvettes are filled with water by the RPT nozzle.

After clicking on Start button, the following window is popped up to select the supply water.

System water: When this button is clicked on, the system water (purified water) is supplied by RPT into each cuvette.

Wash solution: When this button is clicked on, the wash solution is supplied by RPT into each cuvette. RPT aspirates the wash solution at C-port of RPT trough and dispenses them into cuvette. Therefore, the line of wash solution-3 must be connected to the wash solution tank.

Cancel: When this button is clicked on, the liquid dispensing process for the cuvette is not performed.

(8) Cuvette Water Displacement

This is to pump out the water which was filled in cuvettes to prevent them from being stained. The water is pumped out by the wash unit (WU).

After click on the Start button, the popup message is appeared to prompt operator to select either OK or Cancel button.

OK: Cuvette water displacement is performed.

Cancel: Cancel : The popup message is disappeared without any performance.

(9) WU1,3 Rinse

This is to perform the movement of syringe for WU-1 and 3 for washing the lines by water. The aim of this treatment is to prevent the accumulating of impurities contained solution in the WU1 and WU3 line by means of washing by purified water.

After click on the Start button, the popup message is appeared to prompt operator to select either OK or Cancel button.

OK: WU1,3 Rinse is performed.

Cancel: The popup message is disappeared without any performance.

(10) ISE Prime

This is to deflate the lines of the ISE unit by means of pouring the Calibrant-A into the sample port of ISE. Number of execution count should be entered into the input field.

After click on the Start button, the popup message is appeared to prompt operator to select either OK or Cancel button.

OK: ISE prime is performed.

Cancel: The popup message is disappeared without any performance.

(11) ISE Cleaning

This is to perform the cleaning line of the ISE unit.

In advance of performing this sequence, a cup or tube contained cleaning liquid (600 µl) should be placed on #19 slot of ASP.

After click on the Start button, the following popup message is appeared to prompt operator to select either OK or Cancel button.

OK: ISE cleaning is performed. After completing this sequence, 5 times of ISE prime are carried out.

Cancel: The popup message is disappeared without any performance.

(12) ISE Calibration

2 point calibration is performed. The cup or tube contained the Calibrant-B (500µl) should be placed on #18 slot of ASP.

Calibration result is outputted to the function menu [ISE (F11)] picture of job menu [System Parameters].

After click on the Start button, the following popup message is appeared to prompt operator to select either OK or Cancel button.

OK: ISE cleaning is performed. After completing this sequence, 5 times of ISE prime are carried out.

Cancel: The popup message is disappeared without any performance.

As the description above, individual operation is initiated by clicking on the Start button beside each operation designation. Upon clicking on the Start button, the following pop-up window is displayed in the centre of the screen.

If there is no problem, click on the OK button. Upon clicking, the following pop-up window is displayed to show that the operation is in progress.

Click on the Stop button to stop the operation in progress.

The following pop-up window is displayed during the emergency stop processing.

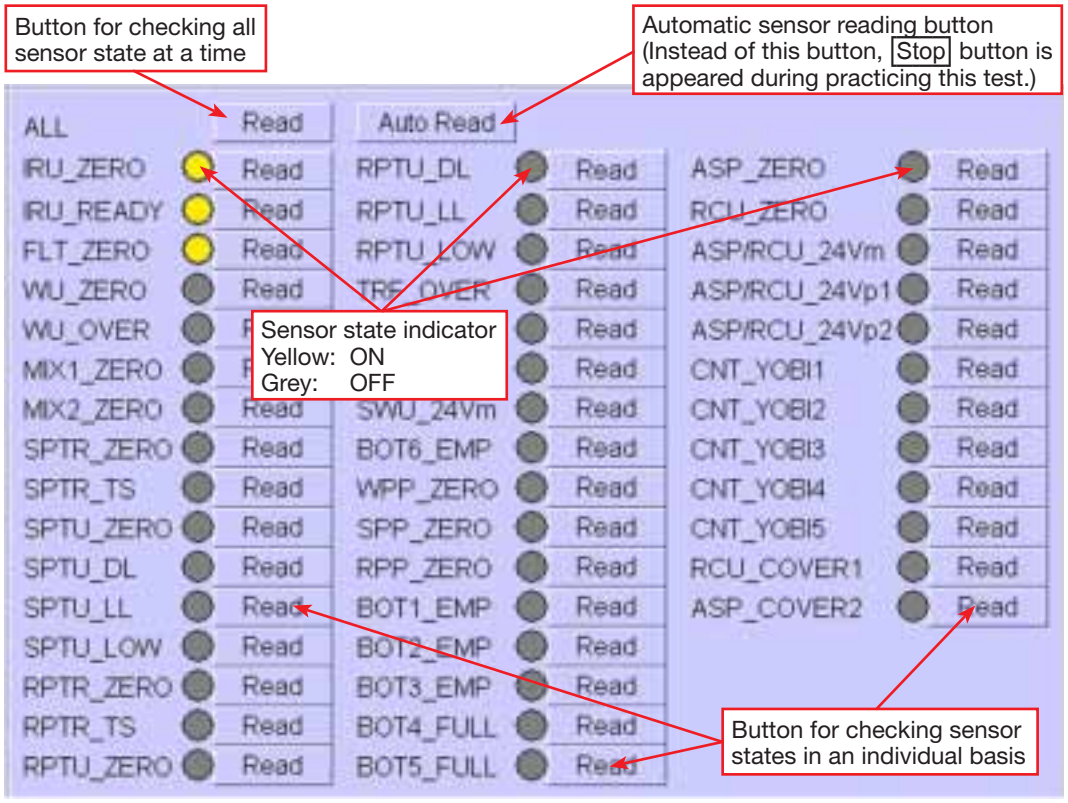
B) Sensor tests

This is to test whether each sensor in the analyzer is in operating state or not.

When the sensor is ON state, the circle area beside the Read button is illuminated in yellow.

Read: The current sensor state is checked by clicking on this button.
The sensor test can be carried out in an individual sensor basis or for all sensors at a time.

Auto Read: This function is to check all sensor state at every 3 seconds.
Just after Auto Read button is clicked on, reading sensor status stars and Stop button is appeared instead of Auto Read button. To terminate this test, click on Stop button.



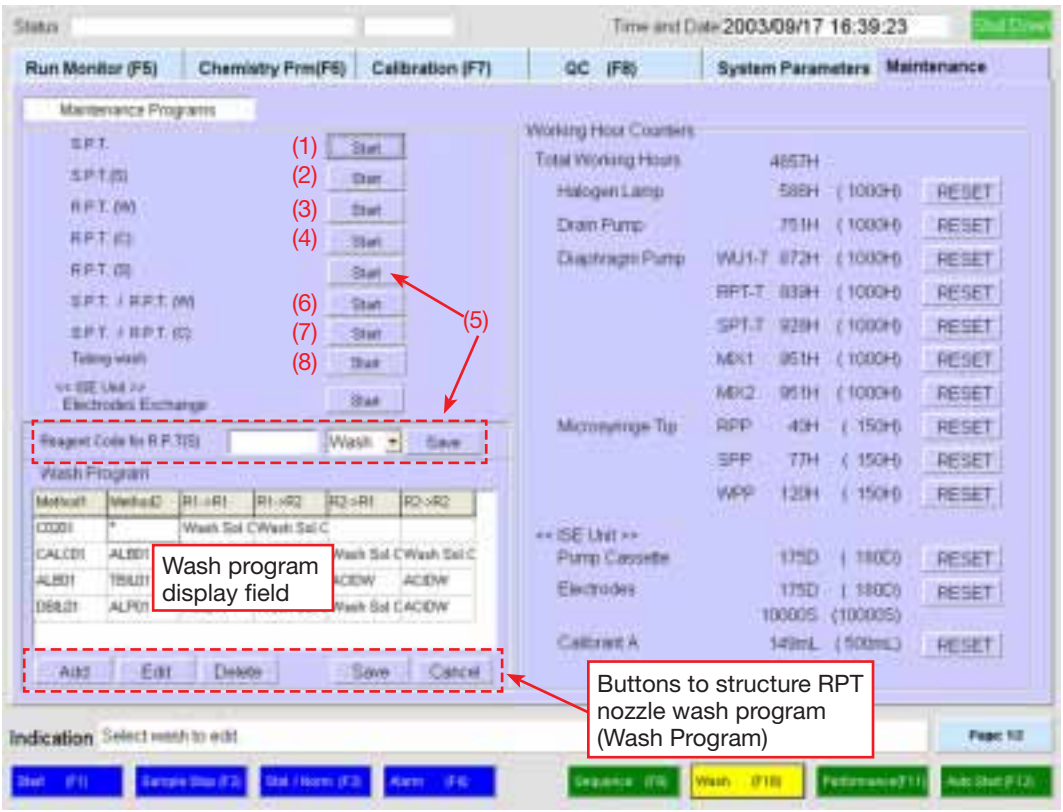
Sensor name	Unit designation	Description
IRU_ZERO	IRU	Zero position of cuvette turntable Yellow (ON): Zero position, Disconnection: Yellow (ON)
IRU_READY	IRU	Ready position of cuvette turntable by cuvette Yellow (ON): Normal position, Disconnection: Grey (OFF)
FLT_ZERO	DTR	Zero position of optical filter disk Yellow (ON): Zero position, Disconnection: Grey (OFF)
WU_ZERO	WU	Zero position (upper limit) of WU nozzle Yellow (ON): Zero position, Disconnection: Yellow (ON)
WU_OVER	WU	Overflow of cuvette This sensor can not test in the “Maintenance” mode.
MIX1_ZERO	MIX-1	Zero position of stirrer (MIX-1) Yellow (ON): Zero position, Disconnection: Yellow (ON)

MIX2_ZERO	MIX-2	Zero position of stirrer (MIX-2) Yellow (ON): Zero position, Disconnection: Yellow (ON)
SPTR_ZERO	SPT (Rotate)	Zero position of SPT rotary movement Yellow (ON): Zero position, Disconnection: Grey (OFF)
SPTR_TS	SPT (Rotate)	Dispensation position of SPT rotary movement at trough Yellow (ON): Dispensation position, Disconnection: Grey (OFF)
SPTU_ZERO	SPT (Up & Down)	Zero position (upper limit) of SPT up-and-down movement Yellow (ON): Zero position, Disconnection: Yellow (ON)
SPTU_DL	SPT (Up & Down)	Zero position (lower limit) of SPT up-and-down movement Yellow (ON): Lower limit, Disconnection: Yellow (ON)
SPTU_LL	SPT (Up & Down)	Level detection of SPT up-and-down movement This sensor can not test in the “Maintenance” mode.
SPTU_LOW	SPT (Up & Down)	Not used
RPTR_ZERO	RPT (Rotate)	Zero position of RPT rotary movement Yellow (ON): Zero position, Disconnection: Grey (OFF)
RPTR_TS	RPT (Rotate)	Dispensation position of RPT rotary movement at trough Yellow (ON): Dispensation position, Disconnection: Grey (OFF)
RPTU_ZERO	RPT (Up & Down)	Zero position (upper limit) of RPT up-and-down movement Yellow (ON): Zero position, Disconnection: Yellow (ON)
RPTU_DL	RPT (Up & Down)	Zero position (lower limit) of RPT up-and-down movement Yellow (ON): Lower limit, Disconnection: Yellow (ON)
RPTU_LL	RPT (Up & Down)	Level detection of RPT up-and-down movement This sensor can not test in the “Maintenance” mode.
RPTU_LOW	RPT (Up & Down)	Not used
TRF_OVER	Trough	Overflow at waste chamber (SPT, RPT, MIX-1, MIX-2) Yellow (ON): Overflow, Disconnection: Grey (OFF)
IRU_24Vm	IRU	Monitor of 24 VDC (IRU motor) Yellow (ON): 24V
PP_24Vm	PP	Monitor of 24 VDC (SPP, RPP and WPP motors and solenoid valve) Yellow (ON): 24V
SWU_24Vm	SWU	Monitor of 24 VDC (SWU pump) Yellow (ON): 24V
BOT6_EMP	External tank	Empty detection of wash solution tank 3 Yellow(ON): Liquid exists (not empty)
WPP_ZERO	WPP	Zero position (upper limit) of WPP syringe Yellow (ON): Zero position, Disconnection: Yellow (ON)
SPP_ZERO	SPP	Zero position (upper limit) of SPP syringe Yellow (ON): Zero position, Disconnection: Yellow (ON)
RPP_ZERO	RPP	Zero position (upper limit) of RPP syringe Yellow (ON): Zero position, Disconnection: Yellow (ON)
BOT1_EMP	External tank	Empty detection of pure water tank Yellow (ON): water exists (not empty)
BOT2_EMP	External tank	Empty detection of wash solution tank 1 Yellow (ON): Liquid exists (not empty)
BOT3_EMP	External tank	Empty detection of wash solution tank 2 Yellow (ON): Liquid exists (not empty)
BOT4_FULL	External tank	Fill-up detection of low concentration waste tank Yellow (ON): Empty
BOT5_FULL	External tank	Fill-up detection of high concentration waste tank Yellow (ON): Empty

ASP_ZERO	ASP	Zero position of ASP turntable Yellow (ON): Zero position, Disconnection: Yellow (ON)
RCU_ZERO	RCU	Zero position of RCU turntable Yellow (ON): Zero position, Disconnection: Yellow (ON)
ASP/ RCU_24Vm	ASP/RCU	Monitor of 24 VDC (ASP, RCU motor) Yellow (ON): 24V
ASP/ RCU24Vp1	ASP/RCU	Monitor (1) of 24 VDC (Power supply of Peltier for RCU cooler) Yellow (ON): 24V
ASP/ RCU_24Vp2	ASP/RCU	Monitor (2) of 24 VDC (Power supply of Peltier for RCU cooler) Yellow (ON): 24V
CONT_YOBI1		Not used
CONT_YOBI2		Not used
CONT_YOBI3		Not used
CONT_YOBI4		Not used
CONT_YOBI5		Not used
RCU_COVER1	RCU	Lid detection of RCU Yellow (ON): With lid, Disconnection: Grey (OFF)
ASP_COVER2	ASP	Lid detection of ASP Yellow (ON): With lid, Disconnection: Grey (OFF)

4.7.2 Nozzle Wash [Wash (F10)] Page: 1/2

Select the function menu [Wash (F10)] page 1/2 picture of the job menu [Maintenance].



<Pipette nozzle wash>

The pipette nozzles are washed with pure water in the respective trough (SPT and RPT trough).

(a) SPT trough that has D-position.

D-position (Drainage position) where is to discharge the holding liquid in SPT, for example aspirated system water from its inner line, and has the purified water supply hole at the side in order to clean the outside of nozzle.

(b) RPT trough that has D-position, R-position and C-position.

D-position (Drainage position) where is to discharge the holding liquid in RPT, for example aspirated system water from its inner line.

R-position (Rinsing position to aspirate the purified water spouted out vertically to rinse the inside of nozzle.

C-position (Cleaning position) to aspirate the wash solution spouted out vertically to rinse the inside of nozzle.

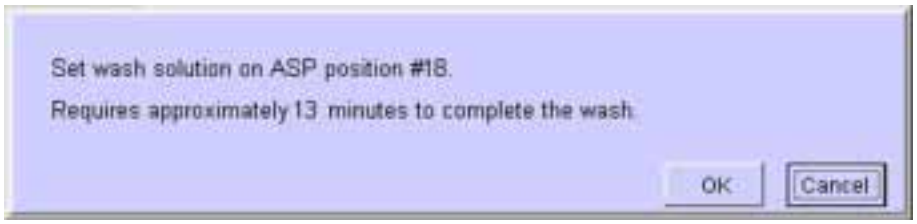
(1) S.P.T.: SPT nozzle wash with purified water

By clicking on the Start button, SPT discharges the system water at D-position of SPT trough to rinse the inside of nozzle. And the outside of SPT nozzle is washed by purified water (system water) at D-position where the purified water is spouted out from the side hole.

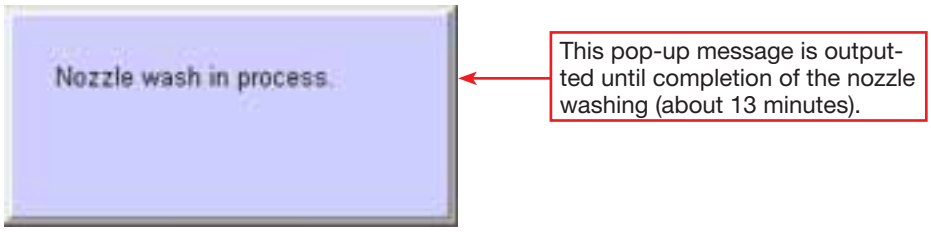
(2) S.P.T. (S): SPT nozzle wash with solution

This function is for SPT nozzle wash by using the wash solution (dilution ratio of C-1: 1/100). Generally, this function is used for SPT to keep clean condition for the next measurement before going to the sleep mode.

When click on the Start button, the following message is popped up at the lower part of screen to urge setting of the cup that is contained wash solution with about 500µl to ASP slot number 18.



Click on the OK button after setting the wash solution to ASP slot number 18. While washing the SPT, the following message is popped up. Of course, when you do not want to perform this function, is possible to click on the Cancel button at the previous popped up window.



The sequence of SPT nozzle washing is as below;

1. SPT moves to ASP slot #18.
2. SPT descends into the cup at the ASP.
3. SPT aspirates 240 µL of wash solution from the cup and ascends to the upper limit.
4. SPT moves to D-position of SPT trough.
5. SPT stays there for 10 minutes without any movement.
6. PT descends 27.5 mm to downward and discharges 240 µL of wash solution and 75 mL of purified water.
7. SPT ascends to the upper limit.

(3) R.P.T. (W): RPT nozzle wash with purified water

By clicking on the Start button, RPT is moved to D-position of RPT trough and discharges the purified water. And RPT is moved to R-position where the purified water is spouted out. Thus, the outside of nozzle is washed by purified water. At the same time, aspirates 1mL of the water spouted out and RPT is moved to D-position and discharges 1mL of water to rinse the inside of nozzle.

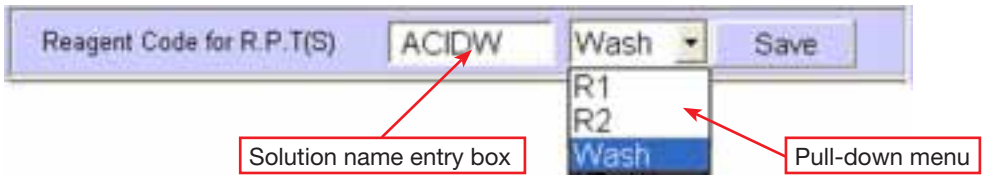
(4) R.P.T.(C) : RPT nozzle wash with solution

The RPT nozzle is washed with wash solution in the RPT trough by clicking on the Start button.

(5) RPT (S) : RPT nozzle wash with solution

This function is for RPT nozzle wash by using wash solution. Generally, this function is used for RPT to keep clean condition for the next measurement as necessary.

Beforehand to perform this function, type of wash solution should be selected at the “Reagent Code for R.P.T(S)” field as below picture.



1. Select one of “R1”, “R2”, or “Wash” from the pull-down menu as the wash solution.
2. Move the cursor onto the solution name entry box and press the [SPACE] key.

Since the name list of wash solution is popped up, select the one of solution name from the list by using cursor and press the [Enter] key.

3. Click on the Save button to determine the solution type.

4. Click on the Start button to perform the RPT nozzle wash.

(6) S.P.T./R.P.T.(W) : SPT & RPT nozzle wash with purified water

Each pipette nozzle is washed by purified water in the respective trough by clicking on the Start button.

(7) S.P.T./R.P.T.(C)

The RPT nozzle is washed with wash solution in the RPT trough and SPT nozzle is washed with pure water in the SPT trough by clicking on the Start button.

(8) Tubing wash

All tubing line and the waste chamber box are cleaned by achievement of this function.

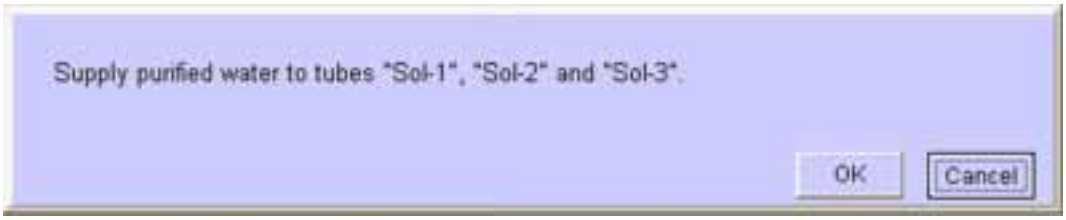
The procedure is shown below.

1. Click on the Start button as below picture.

2. The following message is popped up.

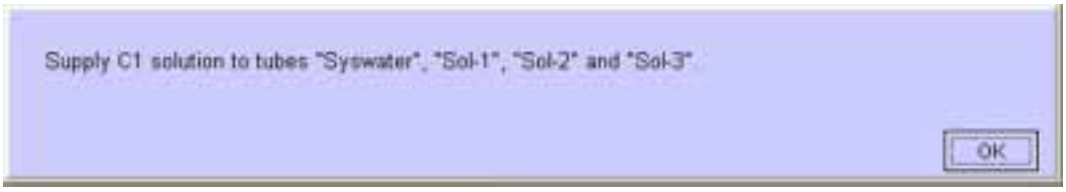
Tubes of Sol-1, Sol-2 and Sol-3 are inserted into the purified water tank.

And click on the OK button, then the priming sequence is performed 5 times in order to supply the purified water into all tubing lines.



3. After execution of priming, the following message is popped up.

Insert the tubes of Systemwater, Sol-1, Sol-2 and Sol-3 into the diluted C1 solution tank which has been prepared in advance. And click on the OK button, then the priming sequence is performed 3 times.

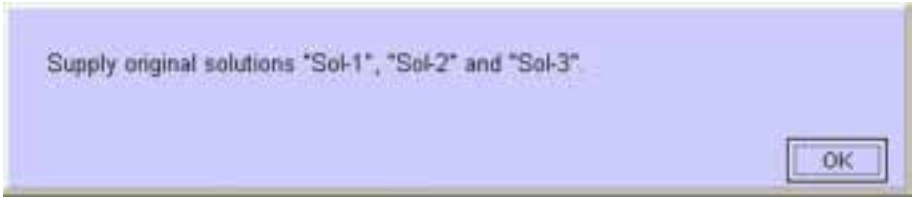


4. To rinse the tubes and waste chamber box in C1 solution, it takes for about 12 minutes.

5. To rinse out the C1 solution, the following message is popped up.
Insert the tubes of Systemwater, Sol-1, Sol-2 and Sol-3 into the purified water tank.
And clicked on the OK button, then the priming sequence is performed 5 times.

6. To rinse the tubes and waste chamber box in the purified water, it takes for about 12 minutes.

7. After rinsing with purified water, the following message is popped up.
Return the all tubes to the original tanks. The tube of Systemwater is inserted into the purified water tank, and the tubes of Sol-1, Sol-2 and Sol-3 are inserted into the tanks of their original solutions. And click on the OK button, then the priming sequence is performed 3 times.

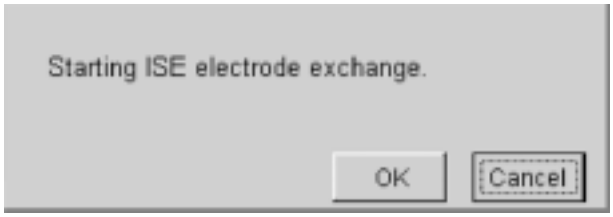


8. At last, the following message is popped up to show the finishing of tubing wash.
After clicking on the OK button, the popped up window is closed.

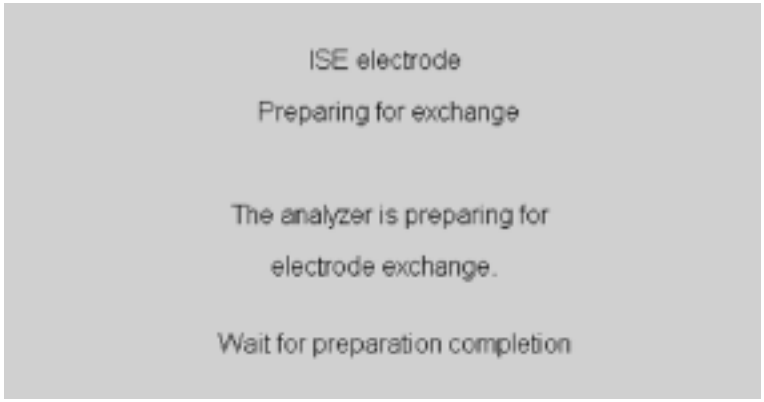
4.7.3 Exchange of ISE Electrode

Exchange of the ISE electrode is carried out in accordance with the following procedures referring to the function menu [Wash (F10)] page 1/2 picture of the job menu [Maintenance].

1. The following message is indicated by clicking on the Start button.



2. After OK button is clicked on, following message is popped up in the centre of screen, and the preparation process is started.



3. When the preparation process has been completed and the analyzer has become ready for exchange of electrode, the following message appears.

When Shut down button is clicked on, Analyzer starts the shut down process.

After completion of the shut down process, the main switch of the analyzer is turned off so that the work of the electrode exchange is started.

For details, see “4.9.4 Procedure for ISE Electrode exchange".

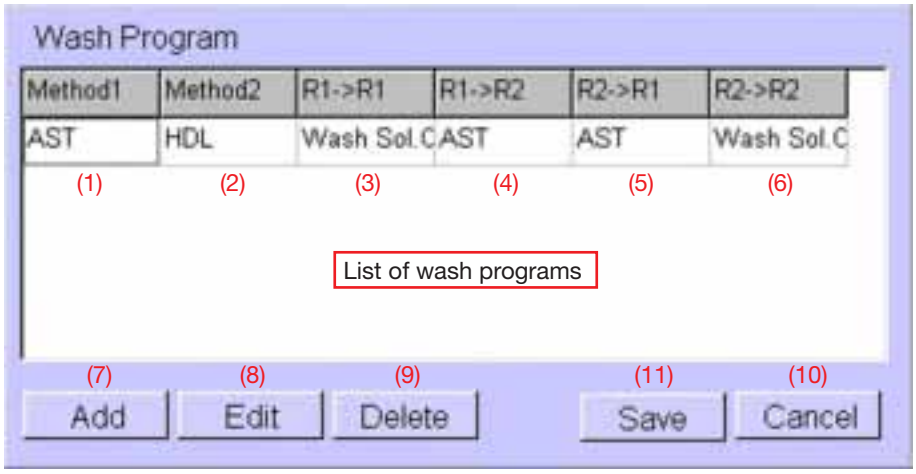
4. After the exchange work has been completed, turn the power switch on and reactivate the analyzer.

4.7.4 Method-to-Method wash (Wash Program)

This function is to structure the wash program of RPT nozzle.

The RPT nozzle is washed in the RPT trough to prevent the reagent for Method 2 from being contaminated by the reagent for Method 1.

The wash program is structured in the [Wash (F10)] page 1/2 picture of the job menu [Maintenance] (See “4.7.2 Nozzle Wash [Wash (F10)] Page 1/2").



(1) Method Name 1

Method name 1 is the method, which is carried out before the RPT wash program is run.

The wildcard "*" as the method name means all methods.

(2) Method Name2

Method number 2 is the method which is carried out immediately after the RPT wash program has been run. The wildcard "*" as the method name means all methods.

(3) R1 → R1

This means that the R1 reagent for the method 2 is dispensed after the R1 reagent for method 1 was dispensed.

The wash solution name for the nozzle wash carried out after dispensation of R1 for method 1 is indicated.

The blank column means pure water wash.

(4) R1 → R2

This means that the R2 reagent for the method 2 is dispensed after the R1 reagent for method 1 was dispensed.

The wash solution name for the nozzle wash carried out after dispensation of R1 for method 1 is indicated.

The blank column means pure water wash.

(5) R2 → R1

This means that the R1 reagent for the method 2 is dispensed after the R2 reagent for method 1 was dispensed.

The wash solution name for the nozzle wash carried out after dispensation of R2 for method 1 is indicated. The blank column means pure water wash.

(6) R2 → R2

This means that the R2 reagent for the method 2 is dispensed after the R2 reagent for method 1 was dispensed.

The wash solution name for the nozzle wash carried out after dispensation of R2 for method 1 is indicated.

The blank column means pure water wash.

(7) Add (Addition of program)

Click on this button to add the method-to-method wash program of the RPT nozzle.

(8) Edit (Editing of program)

Click on this button to edit the method-to-method wash program in the list of wash programs.

(9) Delete (Deletion of program)

Specify the method-to-method wash program in the list of wash programs and click on this button to delete it.

(10) Cancel

Click on this button to cancel the above addition, edition and deletion.

(11) Save

Click on this button to save above addition, edition and deletion of the method-to-method wash program without fail.

The solution names indicated in the steps (3), (4), (5) and (6) are the ones registered in the [System (F9)] picture of the job menu [System Parameters].

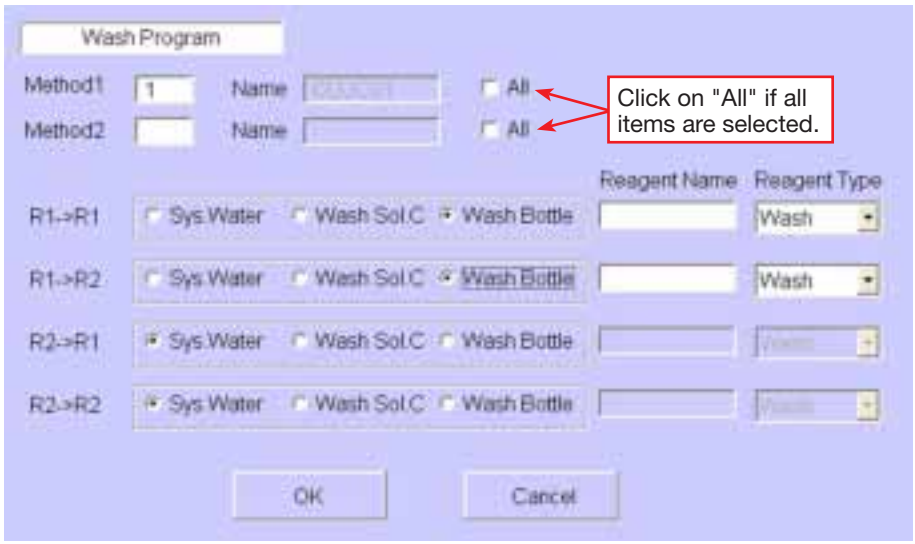
This method-to-method wash has precedence over the "RPT wash" specified in the [Chemistry Prm (F6)] picture.

The detailed procedure for how to structure the method-to-method wash program is shown below.

A) How to program the method-to-method wash program

The method-to-method wash program is structured using Add, Edit, Delete, Save and Cancel buttons.

The following pop-up window appears at the centre of screen by clicking on the Add or Edit button.



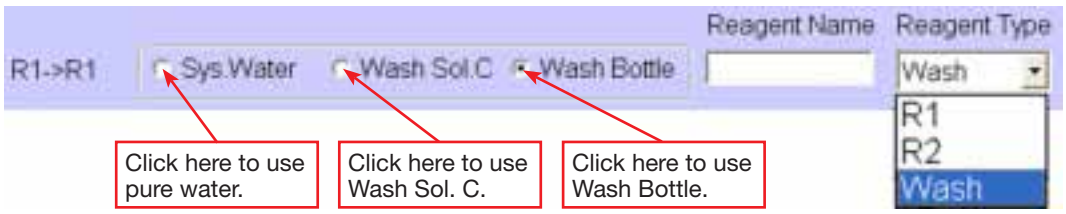
1. Programming of Method1 and Method2

Move the cursor onto the “Method1” or “Method2” box and press the [SPACE] key to indicate the pop-up window of the method list. Select the method by clicking on the applicable method in the list and press the Enter key.

Press the ESC key to close the pop-up window of the method list.

2. Programming of wash [R1 → R1, R1 → R2, R2 → R1, R2 → R2]

Three choices (System Water, Wash Sol. C or Wash Bottle) are provided.



Select one of “Sys. Water”, “Wash Sol.C” or “Wash Bottle” as the wash solution.

Sys Water	System water (purified water) as the wash solution
Wash Sol.C	Wash solution C-1 as the wash solution
Wash Bottle	Wash bottle (R1 or R2 or Wash in RCU) as the wash solution

■ When “Wash Bottle” is selected as the wash solution.

Select one of “R1”, “R2”, or “Wash” from the pull-down menu.

After definition of reagent name, need to specify its bottle name.

Therefore, move the cursor onto the “Reagent Name” box and press the [SPACE] key to indicate the pop-up window of the applicable bottle name list. Select the bottle name by clicking on its name in the list and press the Enter key.

■ When “Sys Water” or “Wash Sol.C” is selected as the wash solution, it is no need of setting of “Reagent Name” and “Reagent Type”.

The structured method-to-method wash program is accepted by clicking on the OK button and cancelled by clicking on the Cancel button.

B) Establishment of the method-to-method wash program

Click on the Save button to save the structured method-to-method wash program.

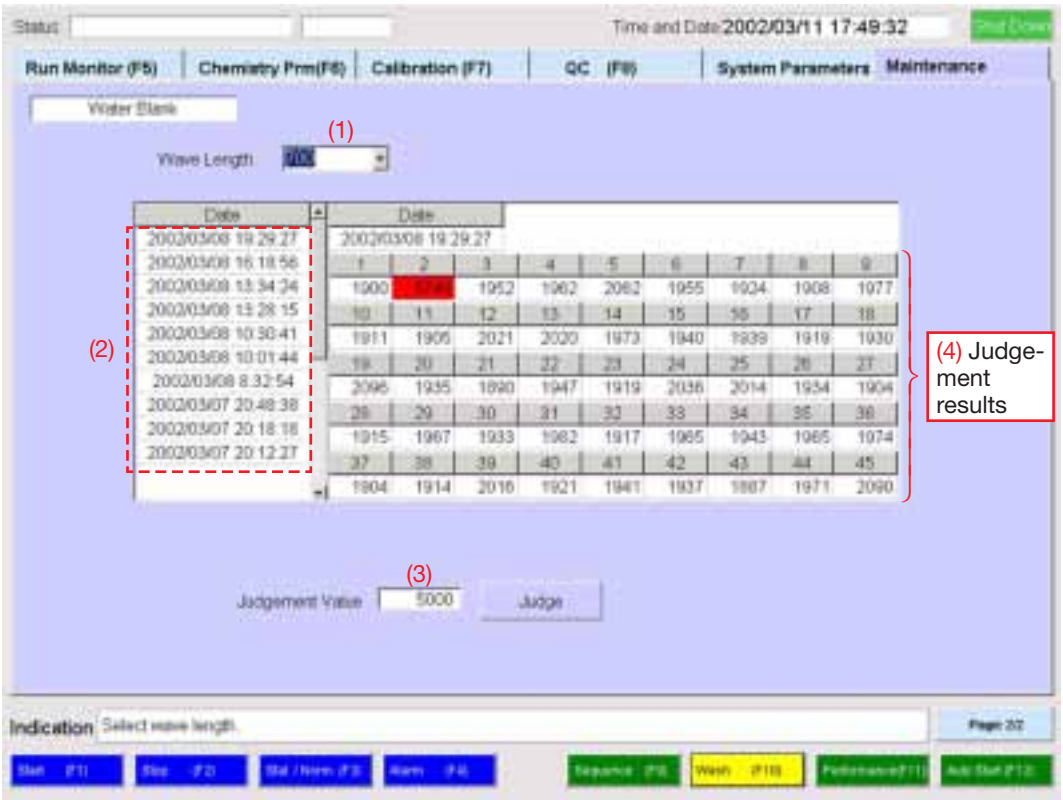
4.7.5 Working hours of expendable parts

The list of working hours of expendable parts which need to be exchanged periodically is indicated in the function menu [Wash (F10)] page 1/2 picture of the job menu [Maintenance]. The exchange timings should be decided referring to the list.

Item	Action	Description
Total Working Hours	None	Total working hours of the analyzer.
Halogen Lamp	Click on the Reset button after the part has been exchanged.	Initial value in parentheses and effective remaining hours at left. When remaining hours become zero, its colour changes to red.
Drain Pump	Click on the Reset button after the part has been exchanged.	Initial value in parentheses and effective remaining hours at left. When remaining hours become zero, its colour changes to red.
Diaphragm Pump (WPP-1 to 7, SPT-Trough, RPT-Trough, MIX1 and MIX2)	Click on the Reset button after the part has been exchanged.	Initial value in parentheses and effective remaining hours at left. When remaining hours become zero, its colour changes to red.
Micro syringe Tip (RPP, SPP and WPP)	Click on the Reset button after the part has been exchanged.	Initial value in parentheses and effective remaining hours at left. When remaining hours become zero, its colour changes to red.
Pump Cassette (For ISE unit)	Click on the Reset button after the part has been exchanged.	Initial value in parentheses and effective remaining hours at left. When remaining hours become zero, its colour changes to red.
Electrodes (For ISE unit)	Click on the Reset button after the part has been exchanged.	Initial value in parentheses and effective remaining hours at left. When remaining hours become zero, its colour changes to red.
Calibrant A (For ISE unit)	Click on the Reset button after the part has been exchanged.	Initial value in parentheses and effective remaining hours at left. When remaining hours become zero, its colour changes to red.

4.7.6 Results of Cuvette Check [Wash (F10)] Page 2/2

The list showing the degree of the stains on the cuvettes in numeric derived from the water blank measurement is displayed in the function menu [Wash (F10)] page 2/2 picture of the job menu [Maintenance]. In this screen, the water blank value for each cuvette can be monitored in real time during measurement.



(1) Wave Length (Selection of wavelength)

Specify the wavelength to display the corresponding water blank measurement results.

(2) Date (Date of measurement)

Move the key-cursor onto the date displayed at the left side on the picture and clicked on the mouse to specify the date on which the water blank measurement value was performed.

And click on the Judge button, the water blank measurement value for each cuvette is outputted at right side as the judgement results.

(3) Judgement Value (Criterion)

The degree of the stains on the cuvette shown in numeric is assessed against this judgement value (criterion).

When this judgment value is changed, its value becomes effective by means of clicking on Judge button.

(4) Data (Judgement result)

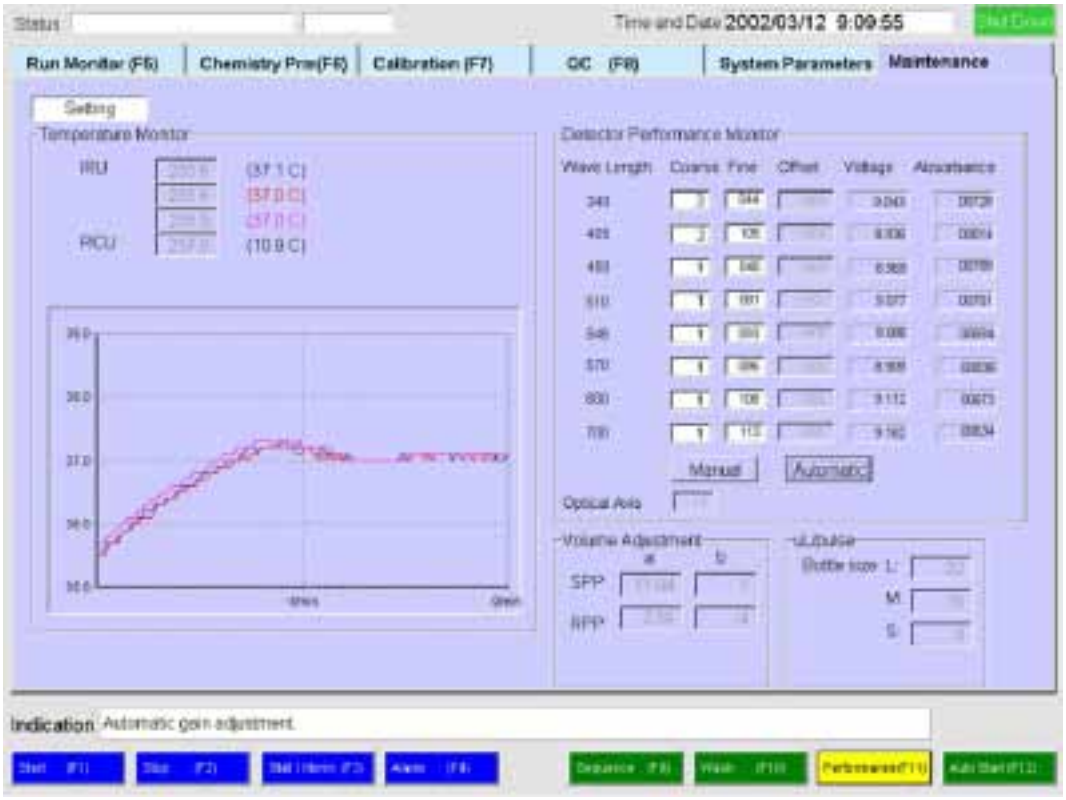
When the water blank measurement values for 8 of wave length exceed the judgement value, its value of cuvette is shown in red, and its cuvette will not be used and skipped at the time of the next measurement.

When the water blank measurement value for 1 of wave length among the 8 of wave length exceeds the judgment value, its value of cuvette is shown in yellow. In this case, its cuvette will be used for next measurement.

The water blank measurement is carried out during the normal measurement and the measured values are stored in the database.

4.7.7 Performance Monitor [Performance (F11)]

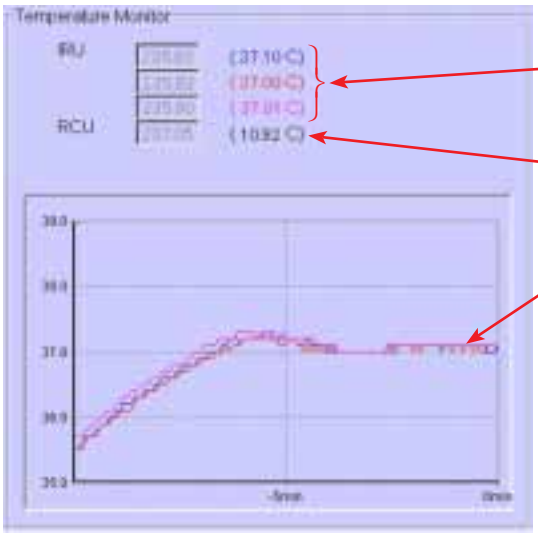
The inside temperatures of IRU and RCU and the detector performance can be checked and monitored in the [Performance (F11)] picture of the job menu [Maintenance]. This performance monitor picture cannot be displayed during measurement.



A) Temperature Monitor

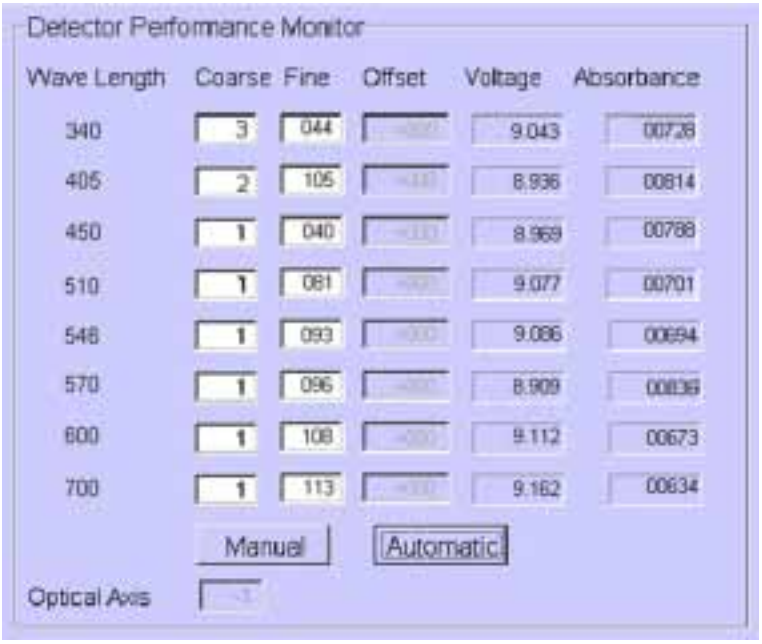
The temperatures of three heaters inside the IRU are shown in numeric (blue, red and yellow) and graphically. The temperature inside the RCU are monitored and shown in numeric (black).

Each temperature is controlled with precision of centesimal degree (0.01 C).



B) Detector Performance Monitor

The functionality of detector auto-gain is checked and monitored.



Title	Description
Wave Length	8 wavelengths
Coarse	Coarse gain adjustment
Fine	Fine gain adjustment
Offset	Not available
Voltage	Gain adjustment voltage (to be adjusted within 9.0 ± 0.5 V)
Absorbance	Absorbance at the above gain voltage.
Manual button	Manual gain adjustment (to be normally used at factory adjustment)
Automatic button	Automatic gain adjustment
Optical Axis	Parameter of DTR optical axis adjustment (factory adjusted before shipment)

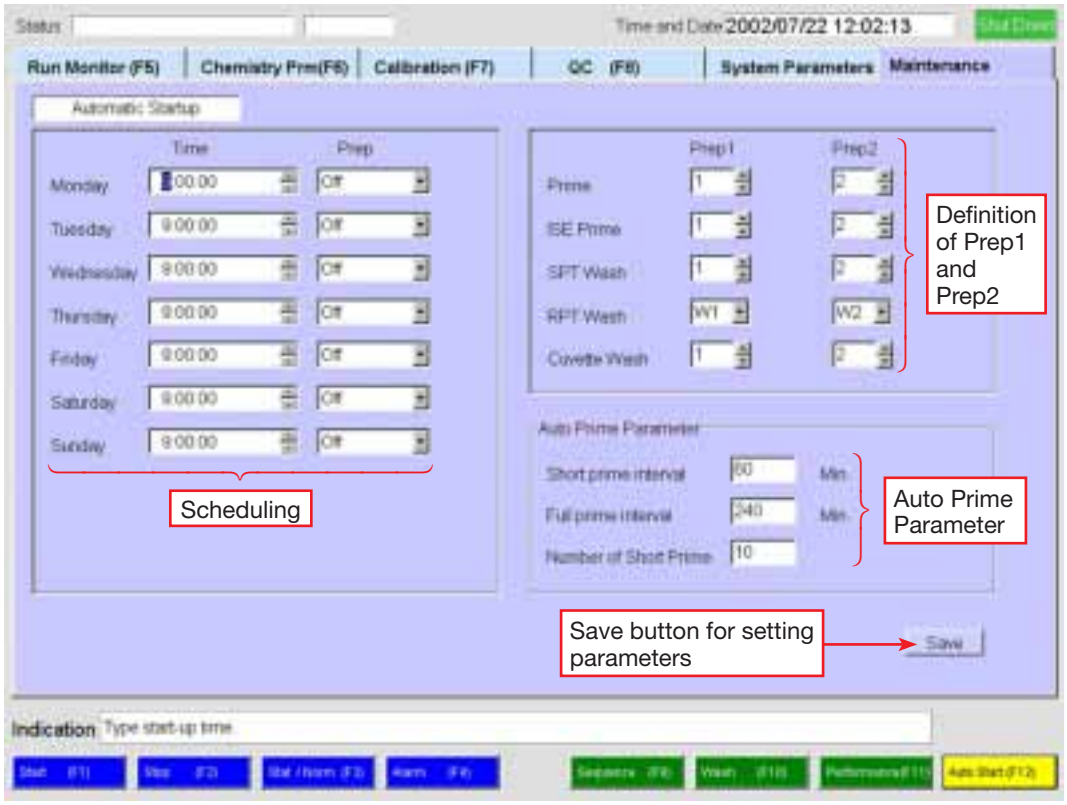
C) Volume Adjustment & µL/pulse

This is a parameter factory adjusted before shipment.

4.7.8 Automatic Start-up [Auto Start (F12)]

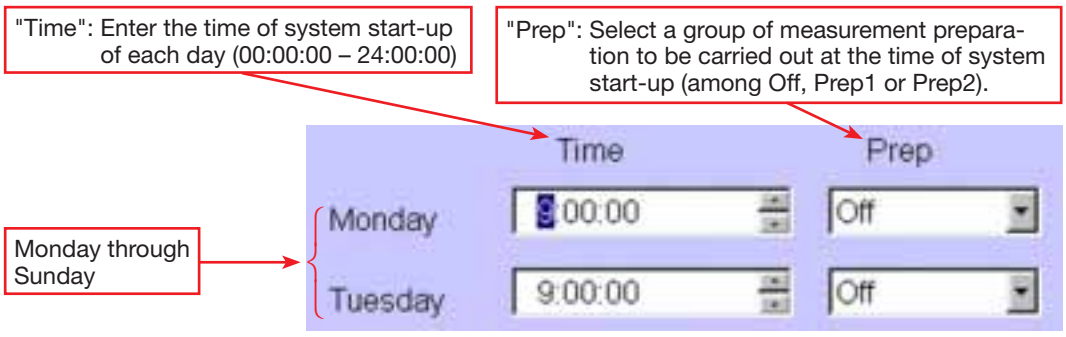
The sequence of measurement preparation at the time of automatic start-up of the system is specified in the function menu [Auto Start (F12)] picture of the job menu [Maintenance].

The analyzer need to be shut down in the "Sleep" mode at the end of its operation in order to enable the sequence of measurement preparation to be executed at the time of the system start-up.



A) Scheduling

The time of system start-up and the sequence of measurement preparation can be specified for a week (Monday through Sunday).



B) Prep1/Prep2

The operational sequence for two selectable types of preparation group (Prep1 and Prep2) is defined.

Actions of measurement preparation

(1) Prime: Selectable from 1 to 5 times (0: Off)

(2) ISE Prime: Selectable from 1 to 5 times (0: Off)

(3) SPT Wash: Selectable from 1 to 5 times (0: Off)

(4) PRT Wash: Selectable from Off, W1 – W5 and C1 – C5
where W2 means 2 times pure water washes and C2 means 2 times wash solution washes.

(5) Cuvette Wash: Selectable from 1 to 5 times (0: Off)

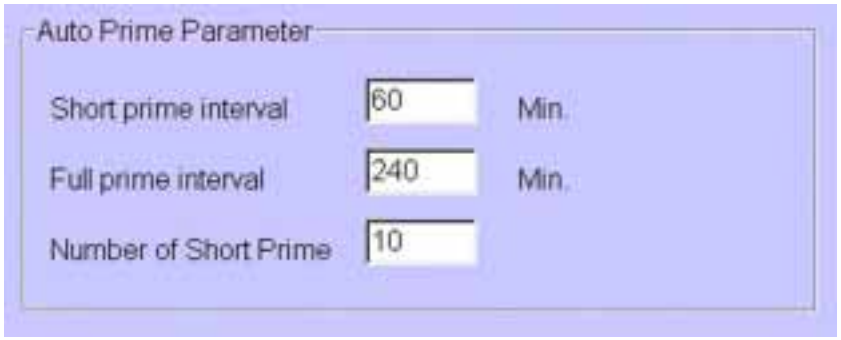
Two types of preparation group

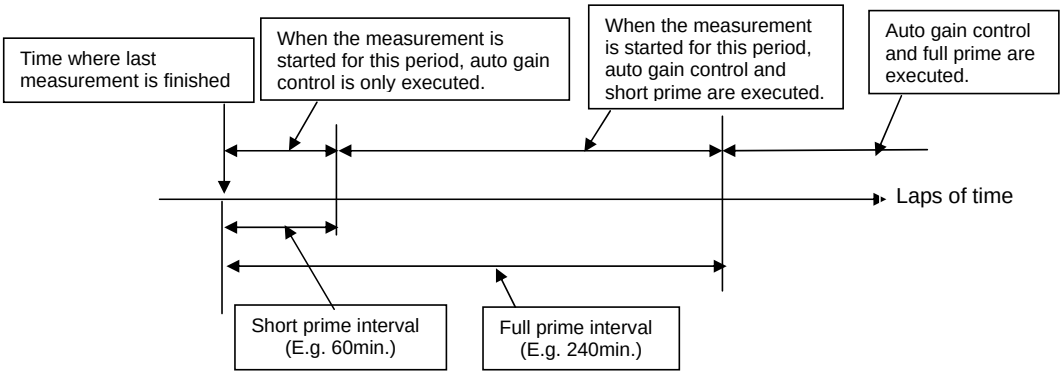
Prep1: No. 1 group

Prep2: No. 2 group

C) Auto prime parameter

When “Auto Prime Mode” is selected in the function menu [Condition (F12)] of the job menu [Run Monitor (F5)], following parameters (Short prime interval, full prime interval and Number of Short Prime) become effective during starting operation of analyzer. (See “2.1.3 Power-on” and “2.5 Setting of Measurement Conditions”)





Time-chart of the "Auto Prime Mode"

In the case of "Auto Prime Mode", when the analyzer is started for the measurement, the movement of preparation (e.g. auto-gain and prime) is performed in accordance with "Auto Prime Parameter".

4.8 Cleaning

This section addresses the cleaning procedures of each tank and unit.

4.8.1 Cleaning of External Tanks

Since the inside of each external tanks are stained with impurities due to long time using, it would be better to clean the inside of each external tanks by purified water at an interval of a month.

Caution: Turn the power switch of the analyzer off without fail before work started.

<Procedure>

(1) Get rid of all liquid or water from each tank. (Sol-1, 2, 3 tank and system water tank)

(2) Clean and wash sufficiently the inside of each tank with purified water.

(3) After cleaning each tanks, take fully away remaining liquid from each tanks.

4.8.2 Cleaning of Pipettes (SPT and RPT)

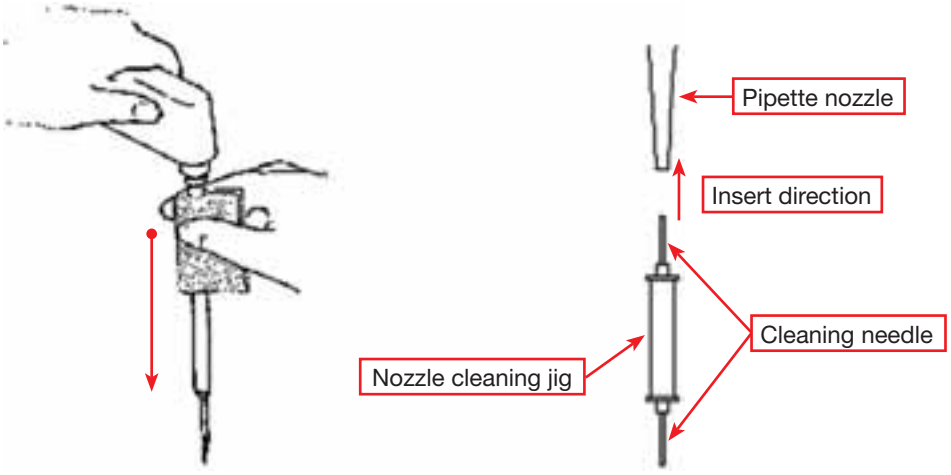
Caution: Turn the power switch of the analyzer off without fail before work started.

In the case of using ethanol, should not be close to fire or high temperature parts/units, because the ethanol is flammable liquid.

<Procedure>

(1) Lift the entire nozzle with one hand.

(2) Wipe the pipette with a gauze or cotton swabs impregnated with ethanol alcohol in the top-to-bottom direction as shown in the following drawing (left-hand side).



Do not apply much pressure to the nozzle when it is lifted and wipe the pipette gently. It is very important for the nozzle to be vertical to the work table in order that the analyzer works properly. If not, this may result in damage of pipette or anomalous measurement results.

(3) If the inside of nozzle is blocked, the nozzle cleaning jig is inserted to the inner nozzle by hand. And take out the stains caused blocking from inner nozzle as shown above mentioned drawing (Right-hand side).

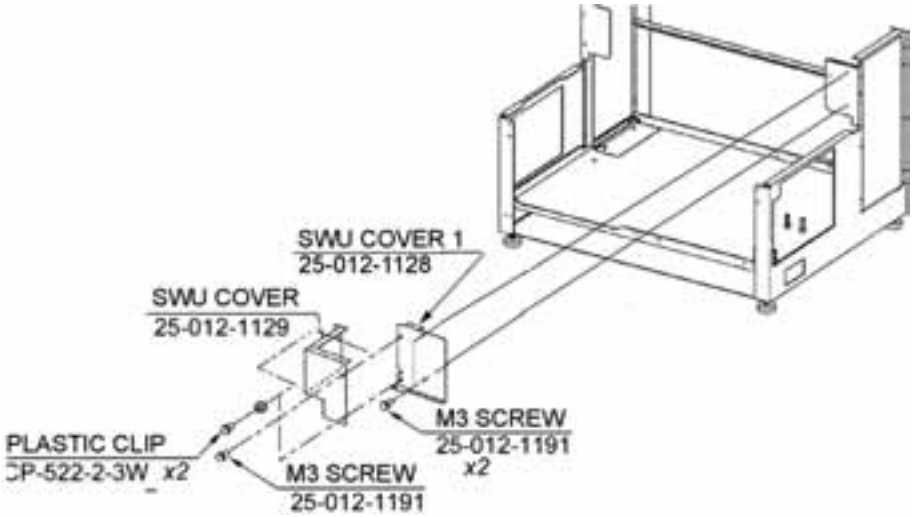
The nozzle cleaning jig has two needles. The fine needle is for SPT and thick one is for RPT/WU.

4.8.3 Cleaning of WU nozzles

Caution: Turn the power switch of the analyzer off without fail before work started. In the case of using ethanol, should not be close to fire or high temperature parts/ units, because the ethanol is flammable liquid.

WU unit has two independent draining nozzles and 6 sets of nozzles that consist of draining nozzle and injection nozzle. Each nozzle should be cleaned with ethanol alcohol.

Before cleaning of WU nozzles, SWU cover is removed as below drawing.



<Procedure>

(1) Lift the entire nozzle with one hand.

(2) Wipe the each nozzle with a gauze or cotton swabs impregnated with ethanol alcohol.

(3) If the inside of nozzle is blocked, the nozzle cleaning jig is inserted to the inner nozzle by hand. And take out the stains caused blocking from inner nozzle in the same way as SPT/RPT nozzle cleaning.

4.8.4 Cleaning of stirrer (MIX-1/MIX-2)

Caution: Turn the power switch of the analyzer off without fail before work started. In the case of using ethanol, should not be close to fire or high temperature parts/ units, because the ethanol is flammable liquid.

The analyzer is provided with two stirrers (MIX-1 and MIX-2).

MIX-1 is located behind the RPT and MIX-2 is located toward the back of the SWU cover behind the ASP. When the MIX-2 is cleaned, first of all, remove the SWU cover.

<Procedure>

(1) Hold the arm cover and lift the entire stirrer with one hand.

(2) Wipe the paddle with a gauze or cotton swabs impregnated with ethanol alcohol carefully.

(3) Furthermore, wipe the paddle with another gauze or cotton swabs impregnated with pure water.

4.8.5 Cleaning of Auto Sampler Unit (ASP)

Caution: Turn the power switch of the analyzer off without fail before work started. In the case of using ethanol, should not be close to fire or high temperature parts/ units, because the ethanol is flammable liquid.

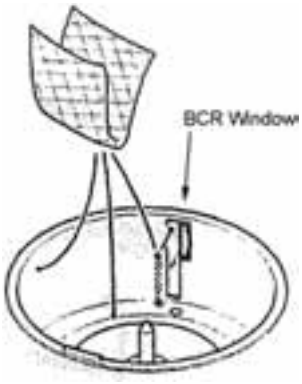
<Procedure>

(1) Make sure that the SPT nozzle is not located over the ASP unit. If so, move it off the ASP with hand.

(2) Remove the lid and take the tray out of the ASP unit.

(3) Wipe the four sides of the aperture for the bar code reader with gauze impregnated with ethanol.

(4) Wipe inside surface of the ASP unit with a gauze or paper towel as shown below. Wipe up water drops completely.



(5) Put back the ASP tray and lid where they were.

4.8.6 Cleaning of Reagent Container Unit (RCU)

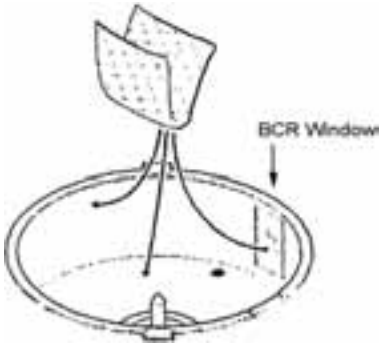
Caution: Turn the power switch of the analyzer off without fail before work started.

<Procedure>

(1) Make sure that the RPT nozzle is not located over the RCU. If so, move it off the RCU with hand

(2) Remove the lid and take the tray out of the RCU.

(3) Wipe the window glass of the aperture for the bar code reader with gauze impregnated with glass cleaner.



(4) Wipe inside surface of the RCU with a gauze or paper towel as shown below. Wipe up water drops completely.

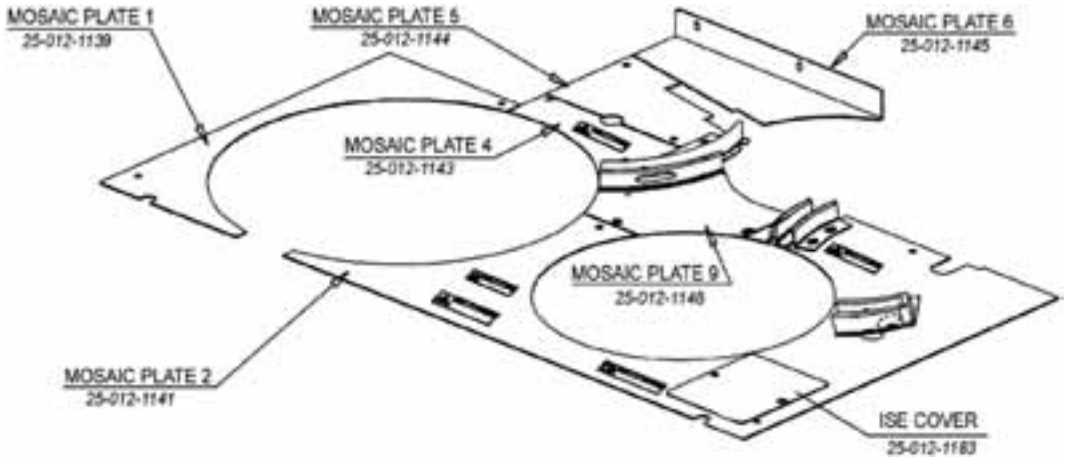
(5) Put back the RCU tray and lid where they were.

4.8.7 Cleaning of work table of the analyzer (mosaic plate)

Caution: Turn the power switch of the analyzer off without fail before work started. In the case of using ethanol, should not be closed to fire or high temperature parts/ units, because the ethanol is flammable liquid.

<Procedure>

(1) Wipe the surfaces of each mosaic plate with a gauze or paper towel impregnated with ethanol.



4.8.8 Cleaning of dust filter

There are two each dust filters provided inside both side covers. Clean the as necessary and replace them with new ones in case that they are smeared by greasy dust or mechanical damaged.

Caution: Turn the power switch of the analyzer off without fail before work started.

4.9 Exchange of parts

At the occasion of the parts exchange, the following special tools, jigs and dies are required.

1. Allen wrench: distances to subtense of 0.9 mm and 6 mm
2. Nozzle height adjustment die (common to both SPT and RPT)
3. Stirrer height adjustment die (common to both Mix-1 and Mix-2)
4. Plunger tip insertion die

4.9.1 Exchange of Syringe Tip

Plunger tips of syringes need to be exchanged every 150 hours of use.

On the assumption that a number of hours worked is 8 hours a day and 5 days a week, they need to be exchanged about every 4 weeks. If a net working rate is higher than the assumption, they must be changed more frequently.

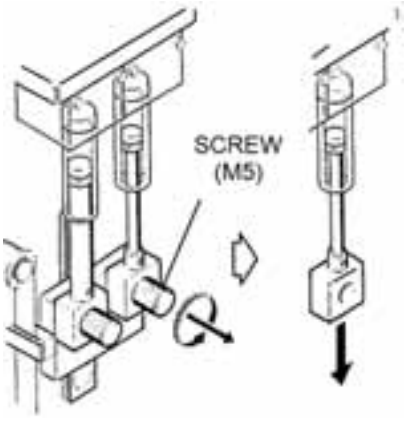
<Procedure>

■ Turn the power switch of the analyzer off without fail before work started.

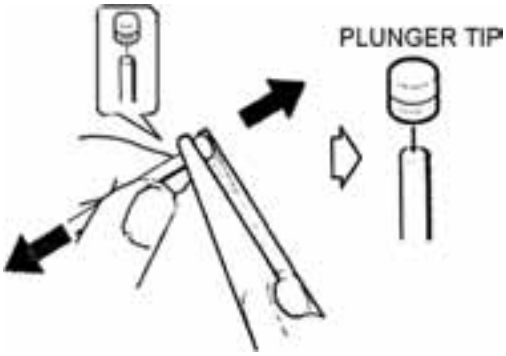
■ Do not fold or bend the tubes connected to each syringe.

■ Put on rubber gloves when syringes are handled in order to prevent them from being polluted or infected.

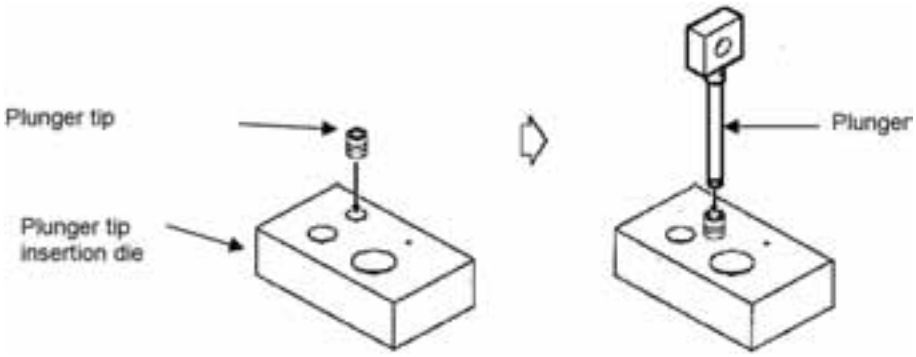
(1) Unfasten a fixing screw (M5) located at the lower portion of the plunger and remove the plunger.



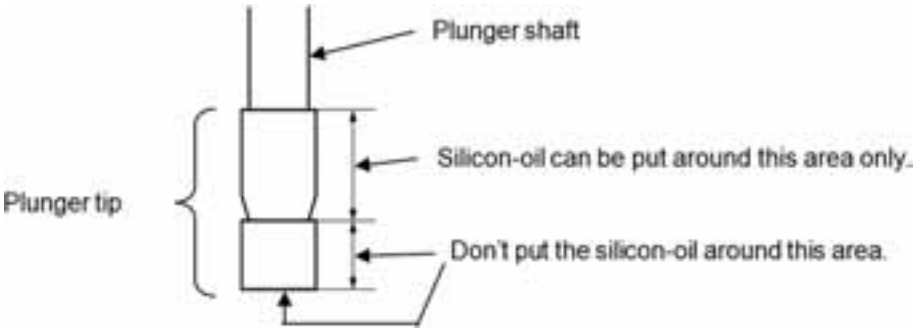
(2) Remove the plunger tip using a pair of long-nose pliers.



(3) Put a new plunger tip into the hole of the plunger tip insertion die.
(4) Hold the plunger vertically and insert it into a hole of the plunger tip.
(5) Insert the tip of the plunger into the syringe slowly and straight up.



(6) Put the silicon-oil (KF-96H-50000CS) thin around plunger tip as below drawing.
Of course, don't put the silicon-oil on the plunger shaft and bottom of the tip.



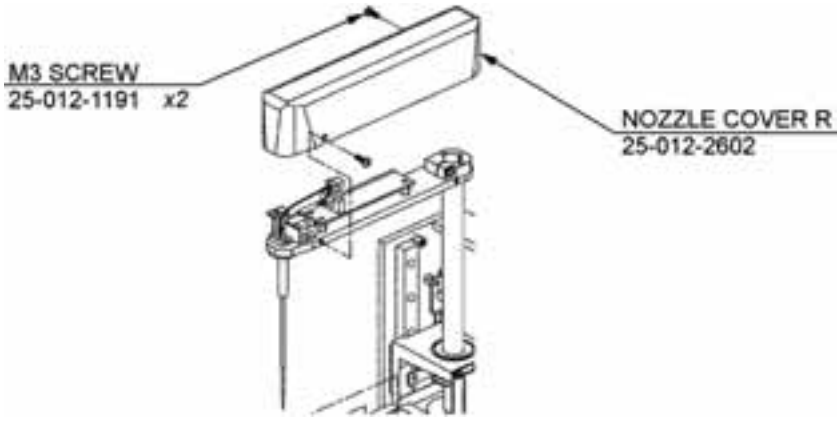
(7) Fasten the fixing screw removed in the step (1).

4.9.2 Exchange of pipette (SPT/RPT)

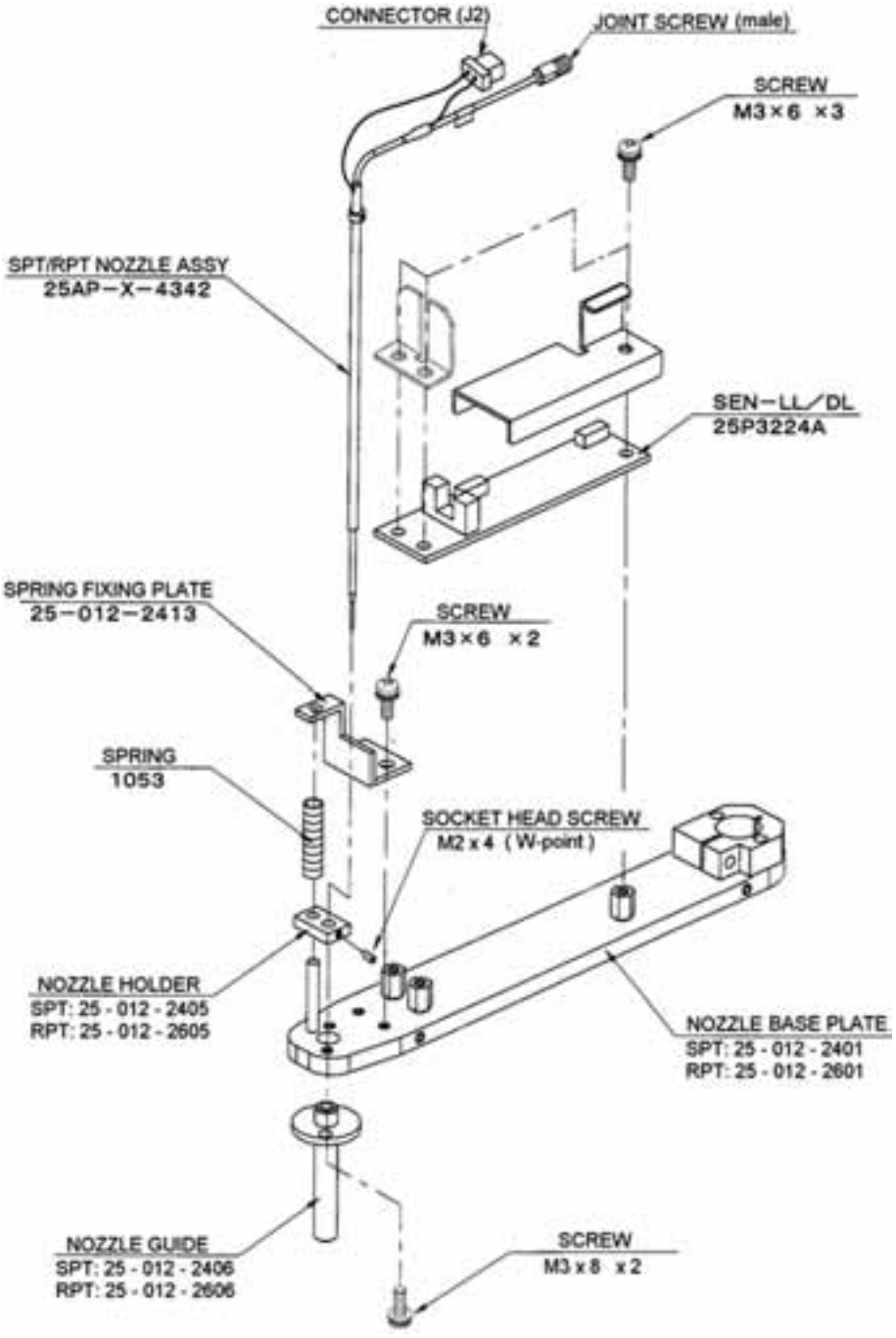
Caution: Turn the power switch of the analyzer off without fail before work started.
Take care not to get hurt while handling nozzle.

<Procedure >

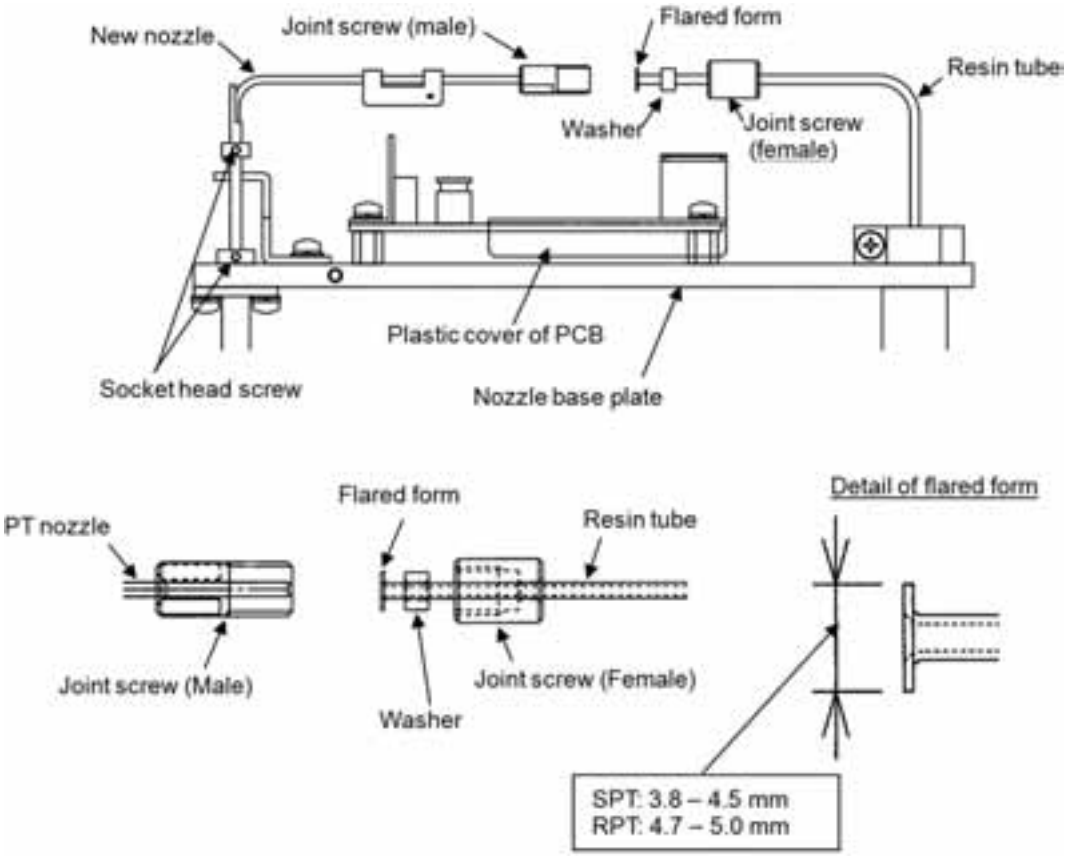
(1) Move the pipette to the position where the work can be carried easily.
(2) Loosen two M3 screws and remove the arm cover.



(3) Disconnect plugs (J2) from the pipette arm.
(4) Remove the tube from the pipette nozzle.
(5) Loosen the socket head screw (W-point, M2x4) of the pipette.
(6) Remove the pipette nozzle from the pipette arm while the nozzle is lifted up.

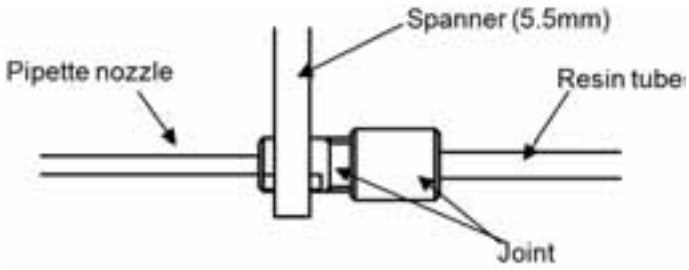


(7) Set the new pipette nozzle with joint screw (male) to the nozzle base plate.

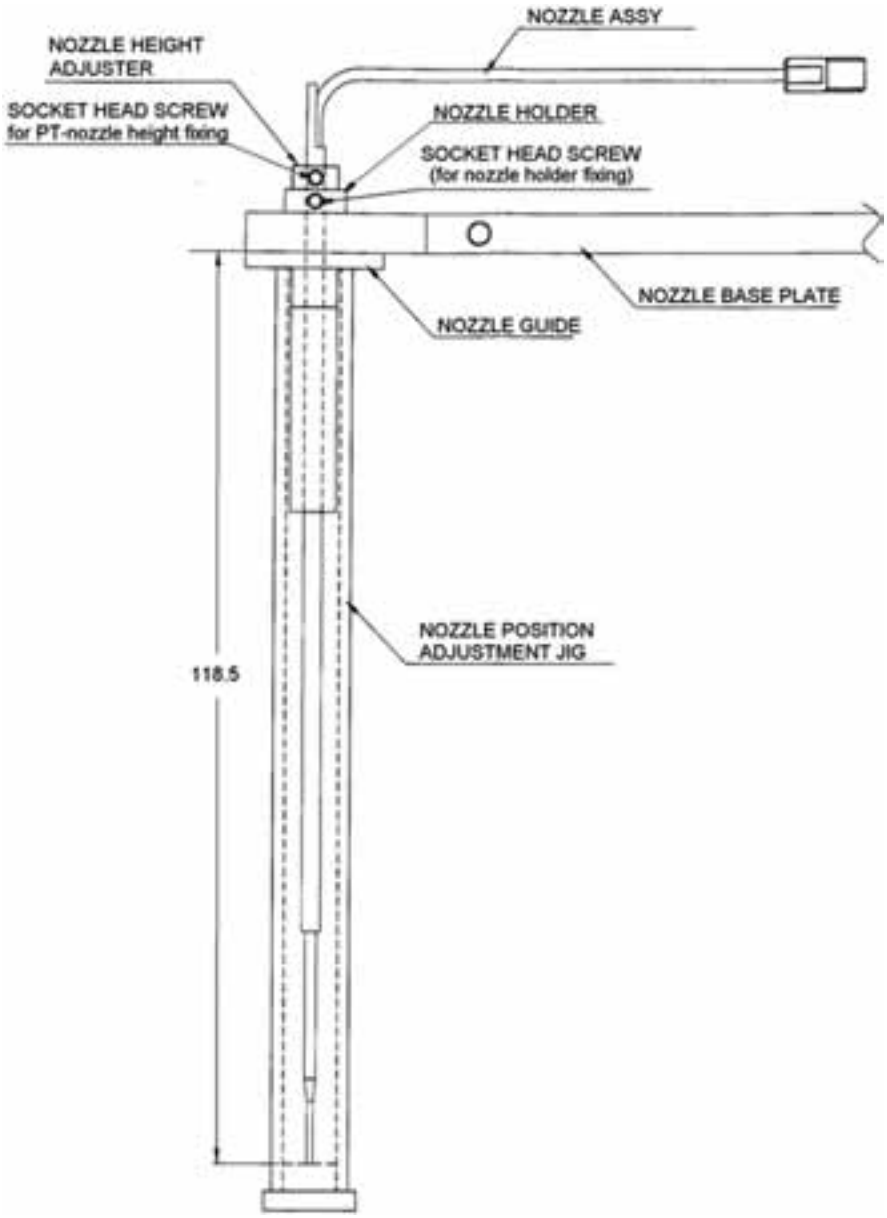


(8) Connect the male joint screw (nozzle) and female joint screw (resin tube) firmly by using spanner (5.5 mm).

Since the pipette nozzle may be twisted by screwing joint, the spanner should be used for prevention such problem.



(9) Adjust nozzle height using the PT nozzle height adjustment jig.
And fix the PT nozzle height position by PT-nozzle height fixing screw.



(10) Connect the connector (J2) to PCB on the nozzle base plate.
(11) Confirm that PT nozzle can move up and down smoothly.
(12) Put the nozzle cover to pipette unit (SPT/RPT).

4.9.3 Exchange of halogen lamp

Halogen lamp needs to be changed every 1000 hours of use.

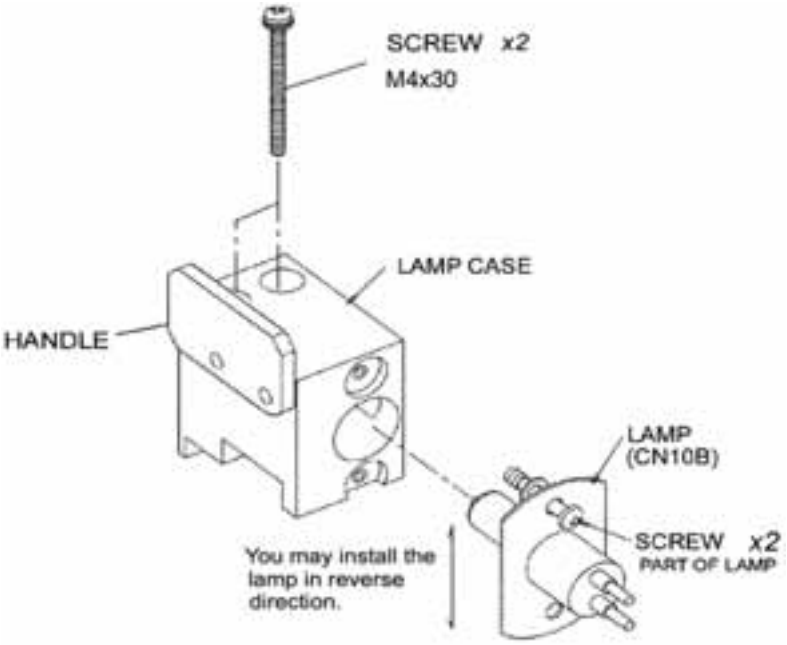
Call up the [Performance [F11]] picture of the job menu [Maintenance] and click on the Automatic button of the "Detector Performance Monitor". When any voltage of each wavelength does not fall within 9.0 ± 0.5 V, the lamp needs to be exchanged.

Follow the procedure shown below to exchange the halogen lamp.

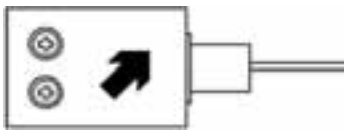
<Procedure>

1. Turn the power switch of the analyzer off without fail before work started.
2. Do not touch the glass part of the lamp.
3. Do not apply force at the joint portion of the lead wire to prevent it from being damaged.

(1) Take off the mosaic plate 9. (See “4.8.7 Cleaning of work table of the analyzer".)
(2) Disconnect the plug (CN10B).
(3) Unscrew off the two screws (M3x30) from the lamp case.
(4) Lift up the lamp case holding its resin handle.
(5) Unscrew the two screws for fixing the lamp to the lamp case and pull out the lamp.



(6) Place a new lamp in its position and fasten two screws while pressing the lamp case in the direction of an arrow as shown below.



(7) Connect the plug (CN10B). Take care that the lamp cable is not contact with the optical filter and motor.

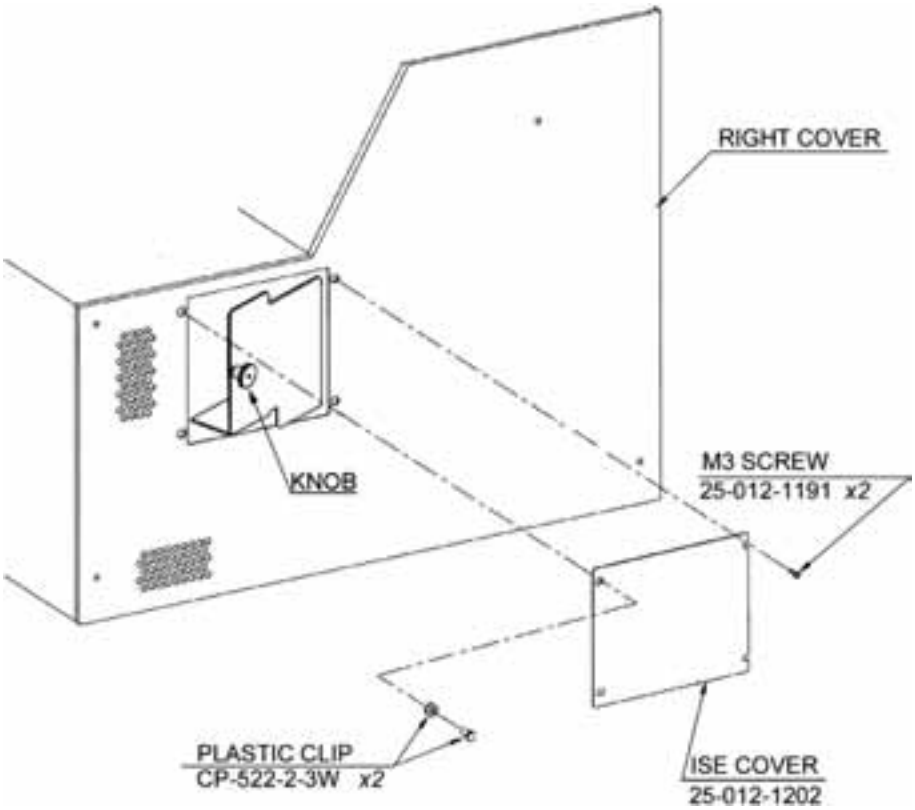
4.9.4 Exchange of ISE Electrodes

The ISE is optionally supplied and the need arises for the analyzer fitted with the ISE unit to exchange the electrode.

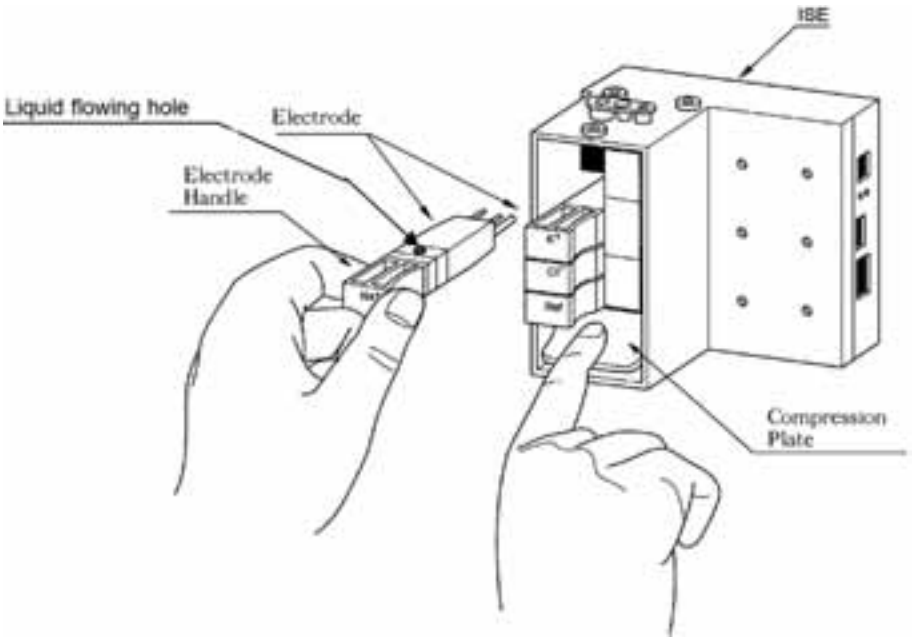
<Procedure>

(1) Where the analyzer is still on, call up the [Wash [F10]] picture of the job menu [Maintenance] and click on the Start button of "Electrode Exchange" (see “4.7.3 Exchange of ISE Electrode").

(2) Turn off the power supply switch of the analyzer.
(3) Take off the ISE cover on the right side panel of the analyzer.



(4) Pull the knob shown in the above drawing so that the electrode becomes visible.
(5) Press down the compression plate to ease removal of the electrode.
(6) Pull out the electrode.
(7) Slip a new electrode into the given position.



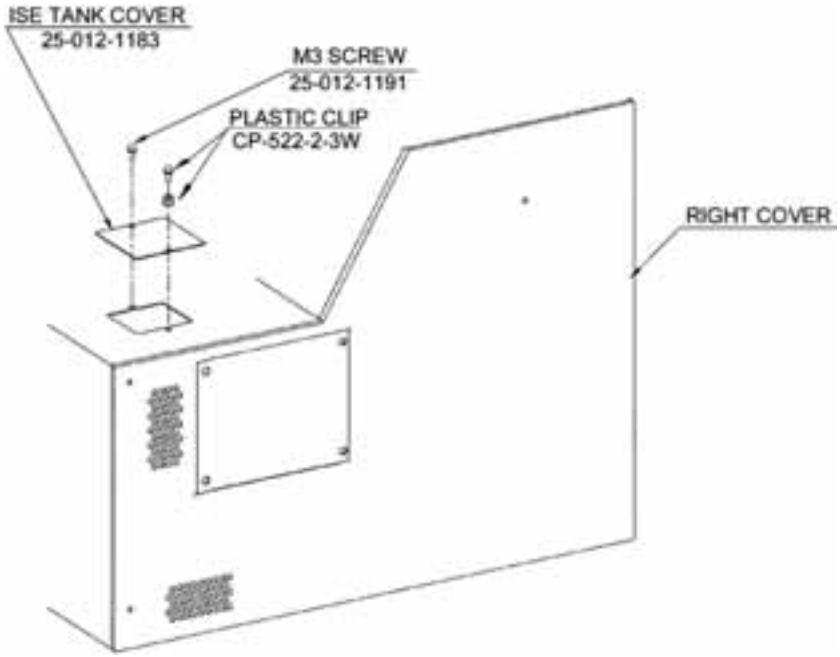
Note: Make sure that the "O"-ring is fitted to the liquid flowing hole of electrode. When the drying protection tube (brown colour) is inserted to the liquid flowing hole of electrode, take away its tube in advance of setting the electrode to the ISE unit.

4.9.5 Exchange of ISE Calibrant-A bottle

Follow the procedure shown below to exchange the ISE Calibrant A bottle.

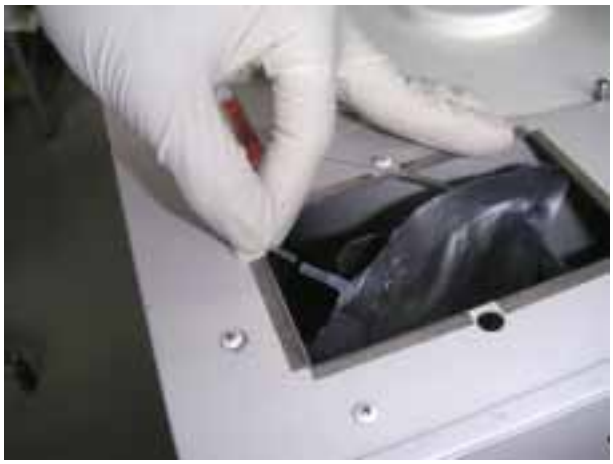
<Procedure for exchange>

(1) Take off the ISE tank cover located on the right side of the upper panel by removing a M3 screw and a latch.



(2) Exchange the Calibrant-A bag with new one. (Refer to the following procedures.)

1 Pull out the liquid supply tube from the short thick tube that is added to the tip of bag.



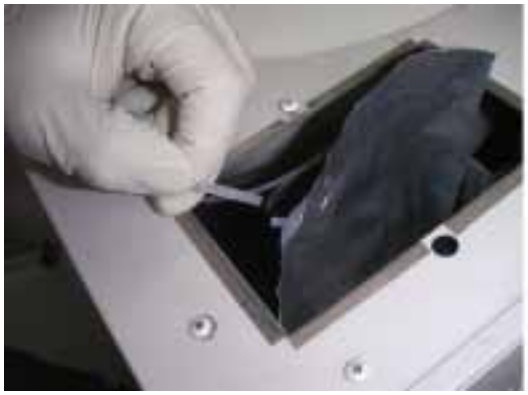
2 Pull out the short thick tube from Calibrant-A case and keep it for reusing.

3 Discard the useless Calibrant-A bag.

4 Prepare the new Calibrant-A bag, and put it into the bag fitting place.

5 Remove the red tube cap from the bag. Take care not to spout the liquid from bag.

6 Reconnect the liquid supply tube and the short thick tube, and plunge it to the Calibrant-A bag.



(3) After exchanging the Calibrant-A, ISE prime should be performed more than 10 times.

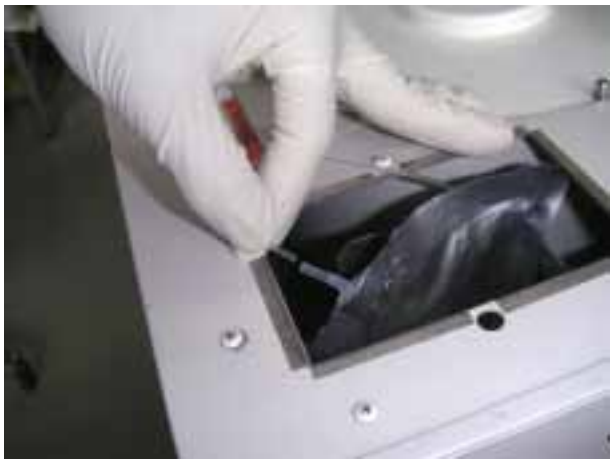
4.9.6 Exchange of ISE Pump Cassettes

Periodical exchanging the pump cassettes are needed to maintain ISE measurement properly.

The working time to know the replacement timing of the pump cassette is shown at the function menu [Wash (F10)] of the job menu [Maintenance].

<Procedure for exchange>

(1) Pull out the liquid supply tube from the short thick tube that is added to the tip of bag and prime ISE more than 5 times to purge the liquid from the flow path.

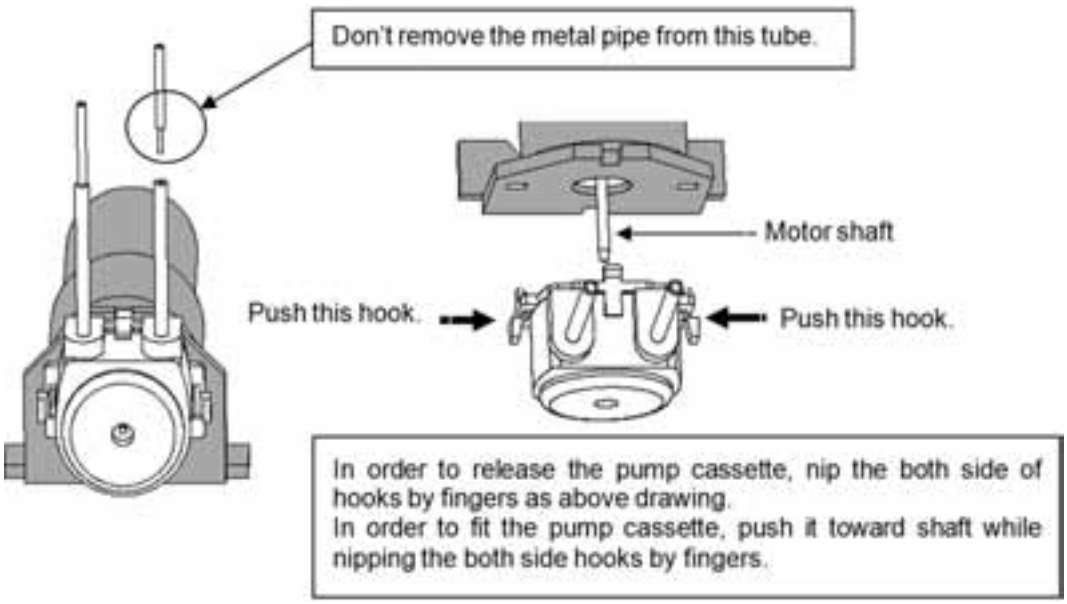


(2) Click on “Shut down” to terminate the analyzers software on PC and then turn the power analyzer off.

(3) Remove the right side cover of analyzer and swing out ISE unit.

(4) Pull out two tubes of pump cassette from the connection parts.

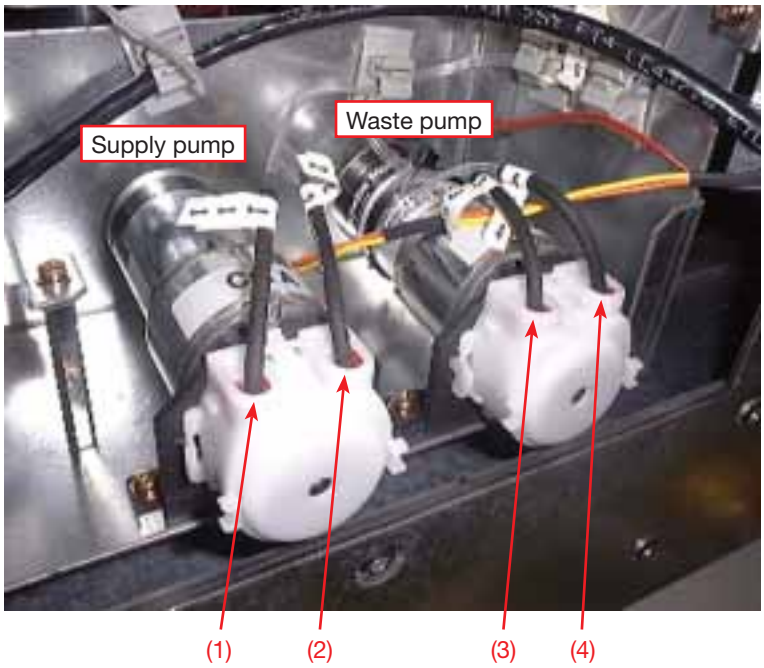
(5) Release the pump cassette from the motor shaft by pressing two hooks at both side of pump cassette with fingers. (See the following drawings.)



(6) Replace the pump cassette.

When replacing, replace both cassettes at the same time.

Beware that there is no markings on the tubes for the cassette. Exchange the cassette carefully not to make wrong tube connection.



Tube marker
(1): Output of the supply pump
(This line is connected to the sample port of ISE unit.)
(2): Input of the supply pump.
(This line is connected to the bottle of Calibrant-A.)
(3): Output of the drain pump.
(This line is connected to the external drain tank.)
(4): Input of the drain pump.
(This line is connected to the termination port of ISE unit.)

(7) Attach the bottle cap for Calibrant-A bottle and turn on the power for analyzer.

Then prime the ISE more than 10 times.

(During the ISE priming, check whether the fluid flows correctly into the each tube and the liquid leaking is not occurred at tube connection.)

After confirming that ISE is properly functioning, attach side covers.

(8) Reset the working hour of pump cassette at function menu [Wash (F10), Page: 1/2] of the job menu [Maintenance].

Chapter 5

Summary of alarm codes

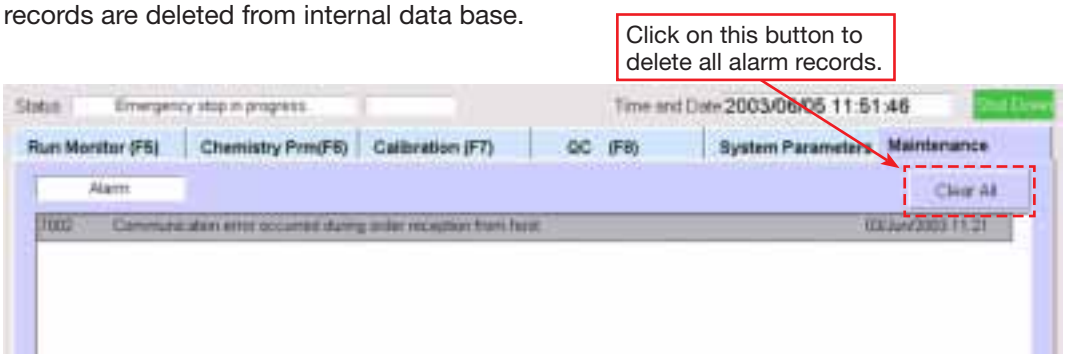
This chapter provides the summary of various alarm codes, which may be generated during the operation of the analyzer. When any error or alarm condition arises, reference should be made to this list and get in touch with our customer service department if necessary.

This chapter consists of:

5.1 Alarm indications and their severity levels

The information about any malfunction that may be mechanical, electrical or detected by software is indicated as an alarm message. In case an error occurs, the Alarm [F4] box at the bottom of the screen flashes in red colour. Press the [F4] key to display "Alarm screen" showing error the relevant code and its detail.

When Clear All Clear All button at right side in the Alarm screen is clicked on, all alarm records are deleted from internal data base.



5.1.1 Types of alarms

Severity level	Type of alarm	Description
1	Emergency stop	This is a critical error and the operation stops immediately.
2	Alarm 1	Sampling is interrupted but for the sample whose sampling operation has been completed, their measurements are carried on.
3	Alarm 2	Only message is displayed and the measurements are carried on.

5.1.2 Place to which alarm message is output

The alarm message is normally output on the display of the analyzer except the judgement flag for the measurement result which is only printed out by the printer.

(See “4.6 Error flags associated with measurement results".)

5.1.3 Numbering system of alarm codes

The alarm code is assigned in the form of the combination of unit and error numbers to each error. Each alarm code has 4-digit numeric and consists of 2-digit each of unit and error number (e.g. 2252).

1. Unit number: 01 – 99
2. Error number: 01 – 99

5.2 Alarm Messages

5.2.1 System Error

Error code	Message	Action
E0075	System file is not recognized.	System file “/home/kogata/sysboot/system/system.txt or khan.txt” can not be found. Contact technical support.
E2875	Sample short. Ordered test not completed.	Check sample level in ASP. If sample level is normal (the cup is not empty). Re-initialize If fault returns, contact technical support.
E6002	Concentration calculation error.	Concentration calculation from measured results not possible. Check the settings in the calibration screen are correct.
E6003	Full calibration failed.	Full calibration has failed. Check the calibration concentration values at the calibration screen. Check the calibrator set in the ASP.
E6004	Full, one point or two point calibration failed.	Full, one point or two point calibration has failed. Check the calibration concentration values at the calibration screen. Check the calibrator set in the ASP.
E6005	Printer output failed.	Check printer cable connections and that the printer is in a ready condition.
E6008	Invalid standard sample found.	Found standard without concentration value. Go to screen “Calibration (F7)” – “Calibration (F9)” and input the concentration value.
E6009	Concentration information not available.	Concentration value is not defined. Check the concentration values for the necessary number of calibrators at the calibration screen.
E6011	Data reception error.	The message received from mechanical control software is longer than maximum allowed data length. Check the software version.
E6012	Software interrupted.	Software interruption occurred at the time of calculation of concentration overflow or division by zero.
E6013	Bcc error occurred during host communication.	Check the communication settings at system parameters.
E6014	Time out error occurred during host communication.	There is no response from the host computer. Check the connection to host.
E6015	Re-transmission error occurred during host communication.	There is no response to the communication of data from the host computer. Check the connection to host.
E6051	Shortage of good cuvettes.	Replace or wash cuvettes until at least 15 are available.

Error code	Message	Action
E6100	There are less than 15 good cuvettes and testing can not begin.	Replace or wash cuvettes until at least 15 are available.
E6101	Not enough reagent inventories to initiate the run.	Check the reagent volume, and exchange it with new bottle, if necessary.
E6120	Standard has been set for “Factor” assay.	Calibration curve type “Factor” does not require calibration. Check for correct standard or calibration curve settings.
E6121	Found calibrators other than S2. As Blank Measurement is set to enable reagent blank as S1, only S2 can be used for calibration.	This is for only warning. Calibration measurement is performed normally. But it would be better to confirm the calibration type and selection of blank measurement in screen “Calibration (F9)” and “Checks (F10)” of job menu Calibration (F7).
E6122	Found series dilution calibration. As Blank Measurement is set to enable reagent blank as S1, only S2 can be used for calibration.	
E6201	RCU bottle #1: Bottle barcode is not usable.	Check label on bottle to ensure it is free from any damage and is clearly in the RCU slot.
E6202	RCU bottle #2: Bottle barcode is not usable.	Check label on bottle to ensure it is free from any damage and is clearly in the RCU slot.
.	.	
.	.	
E6239	RCU bottle #39: Bottle barcode is not usable.	Check label on bottle to ensure it is free from any damage and is clearly in the RCU slot.
E6240	RCU bottle #40: Bottle barcode is not usable.	Check label on bottle to ensure it is free from any damage and is clearly in the RCU slot.
E6301	RCU bottle #1: Bottle barcode has already been assigned.	Barcode has already been used in this analyzer. Use another bottle/barcode.
E6302	RCU bottle #2: Bottle barcode has already been assigned.	Barcode has already been used in this analyzer. Use another bottle/barcode.
.	.	
.	.	
E6339	RCU bottle #39: Bottle barcode has already been assigned.	Barcode has already been used in this analyzer. Use another bottle/barcode.
E6340	RCU bottle #40: Bottle barcode has already been assigned.	Barcode has already been used in this analyzer. Use another bottle/barcode.
E6401	RCU bottle #1: Reagent code is not registered.	Check reagent is registered under system parameters.
E6402	RCU bottle #2: Reagent code is not registered.	Check reagent is registered under system parameters.
.	.	
.	.	
E6439	RCU bottle #39: Reagent code is not registered.	Check reagent is registered under system parameters.

Error code	Message	Action
E6440	RCU bottle #40: Reagent code is not registered.	Check reagent is registered under system parameters.
E6500	The process has been interrupted due to mechanical interference.	Contact technical support.
E6501	Automatic gain adjustment failed.	Check the halogen lamp. Perform automatic gain adjustment. If fault returns, contact technical support.
E6502	Found maintenance parts due exchange.	Check working hour counter for the parts on Wash (F10) screen in Maintenance menu.
E7001	Existing order for a sample has been over written with order from host Sample.	The order received from host for a sample has already been registered. The order for the sample is over written with new order.
E7002	Communication error occurred during order reception from host.	Communication error has occurred while inquiring order to host. Check connection to host then retry order inquiry to host.
E7003	Communication error occurred during result transmission to host.	Communication error has occurred while sending results to host. Check connection to host then retry result transmission to host.
E7004	Received order with short reagent received from host.	Received order from host for tests without enough reagent inventory for the following sample number and method number. Take corrective action and inquire host for the order.
E7005	Sample number with invalid character received from host and discarded it.	Host has ordered tests for sample type other than normal and emergency. The order for the following sample has been deleted. Check at host for proper order.
E7006	Failed to allocate memory for result transmission.	Communication error has occurred while sending results to host to memory allocation error. Check for proper memory capacity and terminate any application running on the PC then retry result transmission to host. If the error repeats, re-booting of PC is required.
E7007	Host transmission retries time over error.	The host communication protocol may not be set correctly. Check the settings at system parameter screen.
E7008	Failed to allocate memory for order acquire.	Communication error has occurred while sending results to host due to memory allocation error. Check for proper memory capacity and terminate any application running on the PC then retry result transmission to host. If the error repeats, re-booting of PC is required.
E7010	Sample number with invalid character received from host and discarded.	Received an order for following sample from host but it has been deleted as the sample was not registered.

Error code	Message	Action
E7011	Failed to allocate memory while acquiring QC data.	
E7030	Failed to read serum indices setting file.	Failed to load serum indices file. The parameter setting file is either missing or corrupted. Contact technical support.
E7051	Received more orders from host than the analyzer can handle.	Received more than allowed maximum (1,000) orders from host. Check with host for order transmission.
E7075	No valid calibration curve for reagent lots on RCU.	The lot number of reagents currently on RCU is different from the ones used to obtain calibration curve. Check lot number of reagents on RCU and perform calibration if necessary.

5.2.2 Unit Error

1) RPT rotation

Error code	Message	Action
E0102	Reagent pipette rotation sensor is on after rotation.	Check RPT is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.
E0103	Reagent pipette rotation sensor is on before rotation. (while not at its origin)	
E0104	Reagent pipette rotation sensor is off after returning to its origin.	
E0106	Reagent pipette up sensor is off at initiation of rotation command.	
E0156	Reagent pipette up sensor is off at initiation of rotation command. (while not at trough or RCU position)	

2) RPT up-and-down movement (origin: RPT upper limit)

Error code	Message	Action
E0201	Reagent pipette, up origin sensor, is off before descent.	Check unit is free to move within its normal operational range. Re-initialize. If fault returns contact technical support.
E0202	Reagent pipette, up origin sensor, is still on after descent.	
E0203	Reagent pipette, ascent to origin sensor, is on before ascent.	
E0204	Reagent pipette origin sensor is off at the initiation of movement command. (from a position other than its origin)	
E0205	Reagent pipette origin sensor is on at the initiation of movement command. (From a position other than its origin.)	
E0206	IRU safety sensor is off at reagent pipette movement command.	
E0207	RPT ascend/descend; RPT safety sensor (RPTR_TS) is off.	
E0251	Reagent pipette up position sensor is off at initiation of reagent pipette downward command.	Check unit is free to move within its normal operational range. Re-initialize. If fault returns contact technical support.
E0253	Reagent pipette up position sensor is on at initiation of reagent pipette upward command.	
E0255	Reagent pipette up sensor is on at initiation of reagent pipette up or down command. (from a position other than its origin)	
E0257	RPT ascend/descend; RPT safety sensor (RPTR_TS) is off. (RCU position)	
E0275	Reagent pipette crash detection sensor is on before reagent pipette has reached the bottom of the RCU.	Clean the pipette with ethanol. Check that reagent pipette detection mechanism is not jammed up (the pipette should move up and down freely). Move the pipette a few mm by hand, while holding the pipette arm. Re-initialize. If fault returns contact technical support.
E0276	Reagent pipette cannot detect RCU liquid level.	Visually check liquid levels within the reagent bottles inside the RCU. Re-initialize the analyzer. If fault persists contact technical support.
E0278	Reagent pipette hardware is functioning abnormally.	
E0279	RPT liquid level detection at RCU; Liquid level is not detected.	
E0280	Not enough wash solution for RPT special wash.	Not enough wash solution left in the reagent bottle. Retry the wash after either adding the wash solution to the bottle or exchange to a new bottle.

3) RPP (origin: upper limit of syringe)

Error code	Message	Action
E0301	Reagent syringe pump origin sensor is off at initiation of aspiration command.	Check unit is free to move its normal operational range. Re-initialize analyzer. If fault returns contact technical support.
E0302	Reagent syringe pu mp origin sensor is still on although syringe has left is origin.	
E0303	Reagent syringe pump origin sensor is on before dispensation command.	
E0304	Reagent syringe pump origin sensor is still off although the reagent syringe has returned its origin.	
E0305	Reagent syringe pump origin sensor is on at initiation of reagent pump movement. (While reagent syringe is not at its origin.)	
E0351	Reagent syringe pump origin sensor is off at initiation of aspiration command.	
E0353	Reagent syringe pump origin sensor is on at initiation of dispensation command.	
E0355	Reagent syringe pump origin sensor is on at initiation of reagent pump movement. (While reagent syringe is at trough or RCU position.)	

4) SPT rotation

Error code	Message	Action
E0402	Sample pipette origin rotation sensor is still on although the pipette has left its origin.	Check unit is free to move its normal operational range. Re-initialize analyzer. If fault returns contact technical support.
E0403	Sample pipette origin rotation sensor is on before rotation to its origin.	
E0404	Sample pipette origin rotation sensor is still off although the pipette has returned to its origin.	
E0406	Sample pipette up origin rotation sensor is off at initiation of pipette rotation command.	
E0456	Sample pipette origin sensor is off at initiation of pipette rotation command.	

5) SPT up-and-down movement

Error code	Message	Action
E0501	Sample pipette up origin sensor is off at initiation of pipette descent from origin command.	Check the unit is free to move within its normal operational range. Re-initialize. If fault returns contact technical support.
E0502	Sample pipette up origin sensor is on after pipette descent.	
E0503	Sample pipette up sensor is on at initiation of pipette return to origin command.	
E0504	SPT ascend to origin; SPTU origin sensor (SPTU_ZERO) is off after ascend. (At initialization)	
E0505	Sample pipette up origin sensor is on at initiation of pipette movement. (The pipette is not at its origin.)	
E0506	The IRU safety sensor is off at initiation of sample pipette movement.	
E0507	SPT ascend/descend; SPT safety sensor (SPTR_TS) is off.	
E0551	Sample pipette origin sensor is off at initiation of pipette downward movement.	
E0553	Sample pipette origin sensor is on at initiation of upward movement.	
E0555	Sample pipette origin sensor is on at initiation of pipette movement. (The pipette is not at its origin.)	
E0557	SPT ascend/ descend; SPT safety sensor (SPTR_TS) is off. (ASP position)	
E0575	Sample pipette crash sensor is on but the pipette is not at the bottom of the ASP.	Clean the pipette with ethanol. Check that reagent pipette detection mechanism is not jammed up (the pipette should move up and down freely). Move the pipette a few mm by hand, while holding the pipette arm. Re-initialize. If fault returns contact technical support.
E0576	Sample pipette cannot detect the liquid level at ASP.	Check sample level in ASP. If sample level is normal (the cup is not empty). Re-initialize. If fault returns contact technical support.

Error code	Message	Action
E0578	Sample pipette crash sensor is on but the pipette has not reached the bottom of the cuvette.	Clean the pipette with ethanol and gently check free vertical movement of pipette. (There should be a few mm of movement up and down.) Re-initialize the instrument. If fault returns contact technical support giving detail.
E0579	Sample pipette cannot detect the liquid level at IRU	Check for liquid in cuvette. Re-initialize if fault persists contact technical support.
E0581	Sample pipette liquid level hardware is abnormal at ASP.	Check the sample levels in ASP if sample levels are normal (the cup is not empty) check for free vertical pipette movement. Clean the pipette with ethanol. Check that reagent pipette detection mechanism is not jammed up (the pipette should move up and down freely). Move the pipette a few mm by hand, while holding the pipette arm. Re-initialize. If fault returns contact technical support.
E0582	Sample pipette liquid level hardware is abnormal at IRU.	Check for liquid in cuvette. Re-initialize if fault persists contact technical support.
E0583	SPT liquid level detection as ASP; Liquid level not detected at duplicate detection.	Check condition of sample in ASP if sample has air bubbles. Remove air bubbles. Re-initialize. If fault returns contact technical support.

6) SPP (origin: upper limit of syringe)

Error code	Message	Action
E0601	Sample syringe origin sensor is off at initiation of aspiration instruction.	Re-initialize analyzer. If fault returns contact technical support.
E0602	Sample syringe origin sensor is still on after the syringe has left its origin.	
E0603	Sample syringe origin sensor is on before initiation of syringe movement to discharge.	
E0604	Sample syringe origin sensor is still off after syringe has returned to its origin.	
E0605	Sample syringe origin sensor is on at initiation of syringe movement command. (The syringe is not at its origin.)	
E0651	Sample syringe origin sensor is off before aspiration. (At trough or ASP position)	
E0653	Sample syringe origin sensor is on before dispensation. (At trough or ASP position)	

7) Mix-1 rotation

Error code	Message	Action
E0706	Mixer 1 origin sensor is on at initiation of stirring paddle rotation.	Check mixer is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.

8) Mix-1 up-and-down movement

Error code	Message	Action
E0801	Mixer 1 up origin sensor is off at initiation of descent command.	Check the mixer is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.
E0802	Mixer 1 up origin sensor is still on although mixer 1 has left its origin.	
E0803	Mixer 1 up origin sensor is on at initiation of return to origin command.	
E0804	Mixer 1 up origin sensor is still off although mixer 1 has returned to its origin.	
E0805	At the initiation of movement the mixer 1 origin sensor is on although the mixer is not at its origin point.	
E0806	IRU safety sensor is off at initiation of mixer 1 up movement.	

9) Mix-2 rotation

Error code	Message	Action
E0906	Mixer 2 origin sensor is on at initiation of stirring paddle rotation command.	Check the mixer is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.

10) Mix-2 up-and-down movement

Error code	Message	Action
E1001	Mixer 2 up origin sensor is off at initiation of descent command.	Check mixer is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.
E1002	Mixer 2 up origin sensor is still on although mixer 2 has left its origin.	
E1003	Mixer 2 up origin sensor is off at initiation of return to origin command.	
E1004	Mixer 2 up origin sensor is still off although mixer has returned to its origin.	
E1005	At the initiation of movement the mixer 2 origin sensor is on although the mixer is not at its origin point.	
E1006	The IRU safety sensor is off at the initiation of mixer 2 movement.	Check mixer and IRU are free to move within their normal operational range. Re-initialize analyzer. If fault returns contact technical support.

11) WU up-and-down movement

Error code	Message	Action
E1101	Wash unit origin sensor is off at initiation of descent command.	Check wash unit is free to move within its normal operational range. (Remove wash unit cover behind sample pipette.) Re-initialize analyzer. If fault returns contact technical support.
E1102	Wash unit origin sensor is still on although the wash unit has left its origin.	
E1103	Wash unit origin sensor is on at initiation of wash unit return to origin command.	
E1104	Wash unit origin sensor is still off although the wash unit has returned to its origin.	
E1105	At the initiation of movement the mixer 2 origin sensor is on although the mixer is not at its origin point.	
E1106	The IRU safety sensor is off at initiation of wash unit movement command.	

12) WPP (origin: upper limit of syringe)

Error code	Message	Action
E1201	WPP aspiration; WPP origin sensor (WPP_ZERO) is off before aspiration.	Re-initialize analyzer. If fault returns contact technical support.
E1202	Wash pump syringe origin sensor is still on although the wash pump has left its origin.	
E1203	Wash pump syringe origin sensor is on before initiation of wash pump movement command. (from fully dispensed position)	
E1204	Wash pump syringe origin sensor is on at initiation of wash pump movement although the unit is not at its origin.	
E1205	WPP aspiration/dispensation at off-origin; WPP origin sensor (WPP_ZERO) is on.	
E1206	WU over flow (WU_OVER=1) (During Prime)	
E1256	WU overflow during run.	
E1276	WU over flow (WU_OVER=1)	

13) IRU

Error code	Message	Action
E1302	IRU origin sensor is still on although the IRU has left its origin.	Re-initialize analyzer. If fault returns contact technical support.
E1304	IRU origin sensor is still on although the IRU has returned its origin.	
E1306	Sample pipette rotation origin sensor is on at initiation of IRU rotation command.	Check sample pipette is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.
E1307	Reagent pipette rotation origin sensor is on at initiation of IRU rotation command.	
E1308	Wash unit origin sensor is off at initiation of IRU rotation command.	Check wash unit is free to move within its normal operational range. (Remove wash unit cover behind sample pipette.) Re-initialize analyzer. If fault returns contact technical support.
E1309	Reagent pipette vertical origin sensor is off at initiation of IRU rotation command.	Check reagent pipette is free to move within its normal operational range. (Remove wash unit cover behind sample pipette.) Re-initialize analyzer. If fault returns contact technical support.

Error code	Message	Action
E1310	Sample pipette vertical origin sensor is off at initiation of IRU rotation command.	Check sample pipette is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.

14) RCU

Error code	Message	Action
E1402	RCU sensor is on although the RCU has left its origin.	Check RCU is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.
E1404	RCU origin sensor is on at initiation of return to origin command.	
E1406	Reagent pipette up origin sensor is off at initiation of RCU rotation command.	
E1454	RCU origin sensor is still off although the RCU has returned to its origin.	

15) FLT

Error code	Message	Action
E1502	Filter wheel origin sensor is on although the filter wheel has left its origin.	Re-initialize analyzer. If fault returns contact technical support.
E1504	Filter wheel origin sensor is off although the filter wheel has returned to its origin.	
E1508	Automatic gain settings are abnormal.	Perform a manual DTR gain check at the maintenance performance screen. Re-initialize the analyzer. If fault continues contact technical support giving details as found at detector performance monitor on maintenance performance screen.

16) ASP

Error code	Message	Action
E1602	ASP rotation origin sensor is on although the ASP has left its origin.	Check ASP is free to move within its normal operational range. Re-initialize analyzer. If fault returns contact technical support.
E1604	ASP rotation origin sensor is off although the ASP has returned to its origin.	
E1606	Sample pipette up origin sensor is off at initiation of ASP rotation command.	
E1654	ASP origin sensor is off although the ASP has returned to its origin.	

18) ISE

Error code	Message	Action
E1775	ISE serum sample error	Refer to “ISE Module Error Code”.
E1776	ISE urine sample error	Refer to “ISE Module Error Code”.
E1777	ISE result measurement data is not available.	Refer to “ISE Module Error Code”.
E1780	No acknowledge from ISE module for “Electrode Exchange” command.	Possible broken communication or poor contact at connectors. If fault returns contact technical support.
E1781	No acknowledge from ISE module for “Prime” command.	
E1782	No acknowledge from ISE module for “Cleaning” command.	

18) Tank (During prime operation)

Error code	Message	Action
E2605	Wash solution 3 is low.	Refill tank and prime analyzer.
E2606	Purified water supply is low.	
E2607	Wash solution 1 is low.	
E2608	Wash solution 2 is low.	
E2609	Waste tank 1 is full to capacity.	Empty tank 1.
E2610	Waste tank 2 is full to capacity.	Empty tank 2.

19) Tank (During running operation)

Error code	Message	Action
E2675	Wash solution 3 is low.	Refill tank and prime analyzer.
E2676	Purified water supply is low.	
E2677	Wash solution 1 is low.	
E2678	Wash solution 2 is low.	
E2679	Waste tank 1 is full to capacity.	Empty tank 1.
E2680	Waste tank 2 is full to capacity.	Empty tank 2.

20) Cover and Waste liquid chamber

Error code	Message	Action
E2701	ASP lid is open.	Secure ASP lid.
E2702	RCU lid is open.	Secure ASP lid.
E2703	Waste chamber over flow	Check liquid and waste levels. Perform prime function twice. If fault returns check the waste pump performance at maintenance sequence screen. Contact technical support with detail.
E2753	Waste chamber over flow	

21) IRU and RCU

Error code	Message	Action
E3051	IRU temperatures lower than 37 - 2 degree.	Temperature of incubator (IRU) is watched during measurement if the temperature is within 35 to 39 degree. When the temperature is out of range, this error is issued and sampling is terminated. Watch the indication of temperature of incubator in the monitor screen during run. Contact technical support with detail.
E3052	IRU temperature higher than 37 + 2 degree.	
E3053	RCU temperature higher than 15 degree.	During measurement, temperature of RCU is watched and when RCU temperature is higher than 15 degree, this error is issued and sampling is terminated. Take care to treat the reagent bottles in RCU. Contact technical support.

22) Barcode reader

Error code	Message	Action
E5001	Reagent barcode reader; Initialization error.	Clean barcode window with ethanol and re-scan. If fault returns contact technical support.
E5002	Sample barcode reader; Initialization error.	Clean barcode window with ethanol and re-scan. If fault returns contact technical support.
E5075	Sample barcode could not be read to character out of specification.	Check for barcode label.

5.3 ISE Module Error Codes

Serum, Plasma and Urine							
		Byte 1	Byte 2	Byte 3	Byte 4	Byte 4	
		Noise or Air for Sample/ Cal B	Noise or Air for Cal A	Drift in Cal A	Out of Range for Sample/ Cal B and Urine	Out of Range and/or Na Error for Urine Only	
	No error	0	0	0	0		
Noise, Drift or out of range	Na	1	1	1	1		
	K	2	2	2	2		
	Na, K	3	3	3	3		
	Cl	4	4	4	4		
	Na, Cl	5	5	5	5		
	K, Cl	6	6	6	6		
	Na, K, Cl	7	7	7	7		
Air		S	A	-	-		S: Sample A/B: Cal-A/B
		B	-	-	-		
SPT liquid detection error.		9	9	9	7		
SPT movement is wrong.		9	9	9	8		
Communication error occurs between ISE and analyzer.		9	9	9	9		
Urine Only							
		Byte 1	Byte 2	Byte 3	Byte 4	Byte 4	
	No error	0	0	0	0	K	Na urine error only, no out of range error
Noise, Drift of out of range	Na	1	1	1	1	L	Na Urine error and out of range error
	K	2	2	2	2	M	
	Na, K	3	3	3	3	N	
	Cl	4	4	4	4	O	
	Na, Cl	5	5	5	5	P	
	K, Cl	6	6	6	6	Q	
	Na, K, Cl	7	7	7	7	R	
SPT liquid detection error.		9	9	9	7		
SPT movement is wrong.		9	9	9	8		
Communication error occurs between ISE and analyzer.		9	9	9	9		

E9997: SPT liquid detection error. E9997 will appear when error is detected at ASP. When this error occurs, the global menu button [Alarm (F4)] at the bottom of the screen flashes in the red colour. The following error/errors can be find when the [F4] key is pressed.		
E-code	Alarm message	Meaning
E0575	Sample pipette crash sensor is on but the pipette is not at the bottom of ASP.	If there is no remaining sample when sample cup is used, this error will appear.
E0576	Sample pipette cannot detect the liquid level at ASP.	If there is no remaining sample when sample cup is not used, this error will appear.
E0581	Sample pipette liquid level hardware is abnormal at ASP.	It is not detected not only liquid level but also sample pipette crash sensing after moving down the sample pipette (SPT).
E0583	SPT liquid level detection at ASP; Liquid level not detected at duplicate detection.	It shows the remaining sample volume in the cup or tube may be shortage.

E9998: SPT movement is wrong. E9998 will appear at the time when error is detected at SPT trough or ASP or ISE sample port. When this error occurs, the global menu button [Alarm (F4)] at the bottom of the screen flashes in the red colour. The following error/errors can be find when the [F4] key is pressed.		
ISE sample is not diluted.		
E-code	Alarm message	Meaning
E0456	Sample pipette origin sensor is off at initiation of pipette rotation command.	SPT cannot start the rotating because sample pipette is not at upper limit position.
E0507	SPT ascend/descend; SPT safety sensor (SPYR_TS) is off.	SPT cannot start the descending at ASP because sample pipette is not at the proper position.
E0501	Sample pipette up origin sensor is off at initiation of pipette descent from origin command.	SPT cannot start the descending at ASP because sample pipette is not at upper limit position.
E0503	Sample pipette up sensor is on at initiation of pipette return to origin command.	Since SPT upper origin sensor shows its position at the origin, sample pipette cannot return to upper origin.
ISE sample is diluted.		
E-code	Alarm message	Meaning
E0456	Sample pipette origin sensor is off at initiation of pipette rotation command.	SPT cannot start the rotating because sample pipette is not at upper limit position.
E0403	Sample pipette origin rotation sensor is on before rotation to its origin.	Since SPT rotation sensor shows its position at the origin, SPT cannot start the rotating to the cuvette at IRU (SPTR origin position).
E0507	SPT ascend/descend; SPT safety sensor (SPYR_TS) is off.	SPT cannot start the descending at ISE sample port because sample pipette is not at proper position.

E0501	Sample pipette up origin sensor is off at initiation of pipette descent from origin command.	SPT cannot start the descending into the cuvette at IRU because sample pipette is not at upper limit position.
		SPT cannot start the descending at ASP because sample pipette is not at upper limit position.
E0503	Sample pipette up sensor is on at initiation of pipette return to origin command.	Since SPT upper origin sensor shows its position at the origin, sample pipette cannot return to upper origin. (At IRU or ISE sample port)

E9999: Communication error between ISE and analyzer. The analyzer did not receive the acknowledgment from ISE module within the time.

5.3.1 Troubleshooting of ISE

Symptom	Problem	Action
Calibration value is low; Na or K < 45 Cl < 35 or Calibration value is high; Na or K > 63 Cl > 60	Misalignment of Electrode	Check the electrode. Remove and replace electrode to re-seat.
	Deterioration of calibrator solutions	Replace Cali-B first and retest, if still low, replace Cal-A and retest.
	Deterioration of Electrode	Replace problem electrode and test.
	Air bubble on Reference electrode membrane	Remove electrode, tap to dislodge bubble, replace, and recalibrate.
	Deterioration of Reference electrode	Replace reference electrode and retest.
	Interaction between sensing Electrodes	Replace Cl electrode only and retest.
Noise error flag; Single electrode	Deterioration of sensing Electrode	Replace problem sensor (electrode) and test.
	Electrical noise spike from environmental source	a) Check for electrical noise coincident with activation. b) Component failure on module board. Replace board.
Noise error flag; Multiple electrodes	Deterioration of sensing Electrode	Replace reference electrode and retest.
	Electrical noise spike from environmental source	a) Check for electrical noise coincident with activation. b) Component failure on module board. Replace board.
Drift error flag; Single electrode	Deterioration of sensing Electrode	Replace problem sensor (electrode) and test.
	Occur when new sensor (electrode) or new bottle of Cal- A is installed on system.	Purge the Cal-A (ISE Prime) and recalibrate the module. If the sensor (electrode) is new it may initially drift as it dehydrates over the course of 15 minutes.

Symptom	Problem	Action
Drift error flag; Multiple electrode	Deterioration of Reference Electrode	Replace reference electrode and retest.
	Electrical noise spike from environmental source	a) Check for electrical noise coincident with activation. b) Component failure on module board. Replace board.
	Occur when new sensor (electrode) or new bottle of Cal- A is installed on system.	Purge the Cal-A (ISE Prime) and recalibrate the module.
Air flag; Sample/Cal-B	Insufficient sample/Cal-B pipetted into ISE sample port.	Operator must place sufficient sample/Cal-B in sample cup to account for all test programmed.
	Sample/Cal-B not run properly to the electrode	a) Pumps not operated normally. b) Pump tubing obstructed or tubing length is excessive.
Air flag; Cal-A	Cal-A bottle is empty.	Replace Cal-A bottle with a new one, purge (ISE Prime) and recalibrate.
	Tubing of Cal-A is disconnected.	Reconnect tubing.
	Cal-A pump is not working properly.	a) Check electrical connectors. b) Replace pump cassette. c) Replace motor.
	Tubing is plugged, split or crimped.	Replace tubing.
Air in Cal-B and Air in Cal-A	Cal-B and Cal-A are segmented with air.	a) Sensors (electrodes) are not properly compressed. Check compression plate, spring and seal. b) Ensure that all sensors and O-rings are in place.
Error code - 9999 (It has been impossible to make communication between ISE and Analyzer.)	RS232 cable is disconnected or damaged.	Reconnect or replace cable.
	Module connector has been damaged.	Replace board.
	Component failure on board.	Replace board.

Appendix

Consists of:

Appendix A PC software upgrading procedure

Appendix B Supplement ISE

Appendix A

PC Software Upgrading Procedure

PC software upgrading procedure for the Clinical Chemistry Analyzer unit is explained here.

1. Backup of System Parameters

As for the backup procedure, refer to “Operator’s Manual” (3.6.3 Backup Operation).

(1) Start the analyzer system.

(2) Click on [System Parameters] of the job menu.

(3) Click on [Backup (F10)] of the function menu.

(4) Insert the floppy disk into the drive.
If the inserted floppy disk is unformatted, click on the Format button of “Format FD”.

(5) Click on the Save button of “Save mechanical Values to FD”.

(6) Click on the Save button of “Save user parameters to FD”.

(7) Click on the Save button of “Save Data” at the data backup block.

2. Terminate all programs on the PC.

For the User-interface Program, terminate it as follows:

(1) While holding down the [Ctrl] key, press the [.](Period) key. Soon the following buttons are displayed:

"Sleep”
“Power Off”
“Cancel”

(2) Click on the [Power Off] button and wait until the Windows desktop reappears.

3. User-interface Software Upgrade (on Windows XP)

A. Deinstallation of Old User-interface Program

(1) On the Windows desktop, start "ADD/REMOVE PROGRAMS" as follows:
1 Click on the [Start] button.
2 Select "Setting".
3 Click on "Control Panel".
4 Double-click on "Add/Remove Programs", and soon its window opens.

(2) Click on “Analyzer” on the selection box, and then click on the [Add/Remove] button. In a while the installer/uninstaller "Install Shield Wizard" starts up.

(3) Click on the [Next>] button, and the "Program Maintenance" screen appears.

(4) Select the "Remove" radio button, then click on the [Next>] button. Soon, the "Remove the Program" screen appears.

(5) Click on the [Remove] button. After a bar graph is displayed, "Install Shield Wizard Completed" is displayed.

(6) Click on the [Finish] button, and the Windows desktop reappears.

(7) Proceed to B (1) below.

B. Installation of New User-interface Program

(1) Insert the New Software CD into the drive, and soon the following message reads automatically:
"Welcome to the Install Shield Wizard …"

(2) Click on the [Next>] button, and the "Customer Information" screen appears.

(3) Fill out the blanks as follows:
User Name: Analyzer
Organization: FEC

NOTE: Type "Analyzer" and "FEC" as shown above. Do not change the case of letters.

---

(4) Click on the [Next>] button, and "Destination Folder" appears.

(5) Click on the [Next>] button, and "Ready to Install the Program" appears.

(6) Click on the [Install] button, and a bar graph is displayed. Wait until "Install Shield Wizard Completed" appears.

(7) Click on the [Finish] button, and the Windows NT desktop reappears.

(8) Proceed to C (1) below.

C. Restoration of System Parameters

(1) Start the newly-installed User-interface Program.
([Start] -> "Programs" -> "analyzer" -> "analyzer“)

(2) Click on the [System Parameters] tab of the job menu, and the "System Parameters" screen appears.

(3) Click on the [Backup (F10)] tab of the function menu.

(4) Insert the saved floppy disk (you made this in "1. Backup of System Parameters") into the drive.

(5) Click on the Load button of “Load Parameters.
The saved mechanical parameters and user parameters are reloaded into the current suitable areas.

(6) Click on the Load button of “Load Data” at the data backup block.
All data saved into the HD are reloaded to the current suitable areas.

Note: this function becomes valid when data have been saved by the one previous version’s software of PC or this new version’s software.

---

(7) Terminate the User-interface Program as follows:

1 While holding down the [Ctrl] key, press the [.](Period) key. Soon the following buttons are displayed:
“Sleep”
“Power Off”
“Cancel”

2 Click on the [Power Off] button and wait until the Windows desktop reappears.

(8) Proceed to D (1) below.

D. Final Check

(1) Perform the power shut-down procedure on the PC and main analyzer.

(2) Turn on the Clinical Chemistry Analyzer.

(3) Turn the PC on again, and start the Windows.

(4) Start the User-interface Program.
([Start] -> "Programs" -> "analyzer" -> "analyzer“)

(5) Click on the [System Parameters] tab of job menu, and then click on the [System (F9)] button of function menu.

(6) make sure that the new PC version number (printed on the CD label) is displayed on the upper-right portion of the screen as shown in the following example:

Program Version
Main: 25501641xx
Sub: 25501651xx
PC: 25501631xx

<PC PROGRAM VERSION NUMBER PRESENTATION>

NOTE: 2-digit number “xx” indicates a program version number.

(7) Click on the [Maintenance] tab of job menu.

(8) Click on the [Sequence (F9)] button of function menu, and the "Mechanical Maintenance" screen appears.

(9) Click on the Start button for "Initialization", and make sure that the operation is performed properly.

Appendix-B

Supplement of ISE unit

Table of Contents

General notation of ISE

1. Electrodes are marked with an “INSTALL BY date”.

   If the electrode is installed in the ISE unit by that day, the electrode is warranted on a prorated basis for up to 10,000 samples or 6 months, whichever comes first.

2. Electrodes require Calibrant-A to be flushed at 30 minutes interval for stable measurement. Therefore, the analyzer should be kept to “Sleep” mode even if the analyzer is not in use.

3. When turning off the power of the analyzer, perform purge at the procedure described below. Leaving the fluid in the path with power turned off results in potassium measurement drift. Perform the purge by using “Electrode Exchange” command in [Wash (F10), Page 1/2] at [Maintenance] menu.

4. It is recommended to perform 2-point calibration of the ISE module is required at least once a day prior to running the first sample of the day.

   Also, at the end of the day when running more than 50 samples a day, ISE cleaning is required.

5. It is expected to perform the ISE cleaning at the end of the day when the ISE unit performs more than 50 samples per day by using wash solution to prevent protein build-up.

   But do not over clean the electrode as certain amount of protein on electrode contributes to stable measurement. Please be aware that wash solution effects electrode performance and may require several hours to recover. Therefore, it is recommended to perform the wash at the end of the day and leave the analyzer at “Sleep” mode.

6. Swirl Calibrant-A bottle daily to prevent growth of dewdrop in the bottle.

7. When only sodium (Na) value at ISE calibration is high, probably a bubble in the fluid has effected the measurement.

   Perform “ISE Prime” three times from [Sequence (F9)] at [Maintenance] menu to take away the bubbles. Perform calibration and prime three more times if symptom stays.

8. The acceptable variation of calibration results between two consecutive calibration measurements is within 2.0.

9. Calibrant-A, B and cleaning solution should be stored in a dark and cool place at room temperature.

1. General Description

ISE (Electrolyte Measurement System) is placed at right side of the chemistry analyzer, and it measures the concentration of Na, K and Cl of serum, plasma or diluted urine with the ion electrodes.

The ISE unit consists of ISE module, ion electrode and two pumps, for supply and waste.

ISE module	This module consists of electrodes (Na, K, Cl and Reference) and pumps. Measurement of concentration is done at electrodes and rinses/calibrates after every measurement. Communication to the analyzer is carried out through RS232C.
Ion electrode	This unit consists of Na, K, Cl and Reference electrodes.
Supply pump	This pump supplies Calibrant-A into ISE module.
Waste pump	This pump drains liquid in ISE module.

All waste liquid are discharged into the external tank for high concentration waste liquid.

1-1 Parts Location

1-2 Solutions

Calibrant-A: Used as wash solution and single point calibrator.

The single point calibration is carried out at the same time when Calibrant-A is dispensed to wash the electrodes every time the sample measurement is performed.

120µL of Calibrant-A are automatically dispensed into the ISU unit every 30 minutes to prevent the electrodes from drying.

Calibrant-A is pumped into the sample port by supply pump.

The dedicated bottle for Calibrant-A is placed beside the ISE unit.

Calibrant-B: Used as the two-point calibrator.

Calibrant-B is aspirated from a sample cup on the ASP (Slot #18) at least once a day or every 8 hours. The cup with a volume of 500µL is placed at No.18 position of ASP just before use to prevent a change in values from evaporation.

(See the section “2 ISE Calibration”.)

Cleaning solution: Should be run once a day to prevent protein build-up or at 8 hours intervals if the ISE measurement is performed greater than 50 samples per day and when measurement of control is effected.

Cleaning solution is aspirated from sample cup with 600 µL that is placed at No.18 position of ASP.

After cleaning processing, the analyzer should be left at standby for 30 minutes before any measurement to stabilize the membrane of electrode. While at standby, perform prime more than 5 times.

The cleaning can be done at, [Sequence (F9)] - [Maintenance].

(See the section “3 ISE Cleaning” for detail.)

Urine Diluent: This is used to dilute urine sample. Urine sample must be diluted by a factor of 10 to perform urine measurement.

Put a reagent bottle with urine diluent in RCU. A volume of 315µL is necessary for diluting one sample. The dilution is carried out using a cuvette in IRU. Therefore one cycle for analysis sequence is allocated to the process.

The code of diluent should be pre-registered in the [System (F9)] - [System Parameters].

1-3 Solution life: Storage life and Use life

A reagent shelf life is defined by the expiration date printed on the solution label and the solutions should not be used after the date. The shelf life is good in an unopened bottle. Once the bottle is opened, use them within short period and do not attempt to store opened bottle. Discard the contents when the expiration date is due. Using a solution past expiration date will result in poor measurement performance.

1-4 Storage and Usage of the Reagents

(1) Store all solutions in a dark and cool place at room temperature.
Don't preserve the reagents such as Calibrant-B or cleaning solution once they are dispensed to sample cup.

(2) Don't use the expired solution.

(3) When opening new bottle for a solution, don't mix remaining solution from the previous bottle.

(4) Calibrant-A has one month of on board stability.
Having the bottle more than one month requires swirling the bottle every day to assure homogeneity of the solution.

(5) Dispense Calibrant-B into a sample cup just before ISE calibration to avoid evaporation.

1-5 When turning off the power

As Calibrant-A is automatically dispensed into ISE unit every 30 minutes to prevent electrodes from drying out; it is not recommended to turn off the power of analyzer. After using the analyzer for the day, put it to sleep. This will keep the above function activated.

When Calibrant-A remains in fluid path for over two hours without flowing, the Na ion from reference electrode can reach Na electrode and saturate the membrane resulting in effected Na measurement.

When the power to the analyzer needs to be turned off for a reason such as maintenance, follow the procedure below to purge Calibrant solution in the path. Also refer to the procedure when turning off the power for more than several hours, as it requires storage of the electrodes.

1-6 Shutdown Procedure: Preparing the ISE module for storage

(1) Unscrew the bottle cap for Calibrant-A.

(2) Prime ISE more than 10 times.

(Function menu [Sequence (F9)] of job menu [maintenance])

(3) Remove all electrodes from ISE unit. (See “1-8 Procedure for exchanging the electrode”.)
(a) Na, Cl electrodes
Place the Reference, Na and Cl electrodes into individual sealed bags.
(b) K electrode
Inject Calibrant-A into the lumen of K electrode until fluid fills the lumen.
Cover both ends of the lumen (both side of the K electrode) with cellophane tape to hold the Calibrant-A in place. Insert the K electrode into a sealed bag.

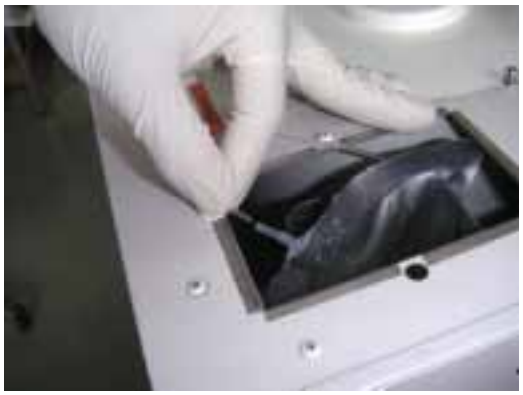
(4) Remove the Calibrant-A from the analyzer and discard it.

1-7 Exchanging Calibrant-A

Follow the procedure below to exchange the Calibrant-A bottle.

(1) Remove ISE cover on the upper-right side of the analyzer by loosening a M3 screw and pulling the plastic clip.

(2) Pull out the liquid supply tube from the short thick tube that is added to the tip of bag.



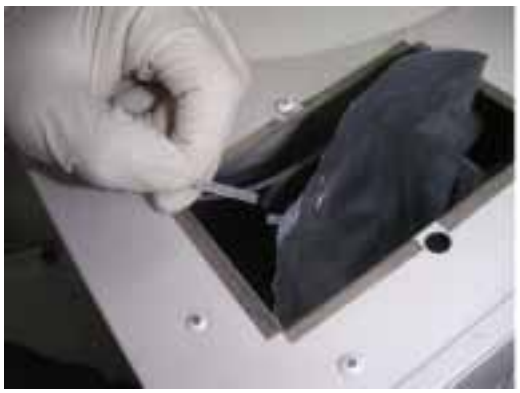
(3) Pull out the short thick tube from Calibrant-A case and keep it for reusing.

(4) Discard the useless Calibrant-A bag.

(5) Prepare the new Calibrant-A bag, and put it into the bag fitting place.

(6) Remove the red tube cap from the bag. Take care not to spout the liquid from bag.

(7) Reconnect the liquid supply tube and the short thick tube, and plunge it to the Calibrant-A bag.



(8) Reset the working hour counter for Calibrant-A at the function menu [Wash (F10), Page: 1/2] of the job menu [Maintenance].

Note: Don't mix Calibrant-A solution from old bottle with the new bottle.
After exchanging Calibrant-A, perform ISE priming more than 10 times.
If any water drop is found in the back of Calibrant-A bottle cap, wiped out with clean gauze.

1-8 Exchanging electrodes

Electrodes are marked with an “Install-by date”. If the electrode is installed in ISE unit by that date, the electrodes can be used for up to 10,000 samples or 180 days (6 months), whichever occurs first.

Follow the procedure below to exchange electrodes.

(1) Before removing electrodes, it is necessary to perform “Electrode Exchange” in order to purge all fluid from the fluid path.

Select the function menu [Wash (F10), Page: 1/2] from [Maintenance].

Click on the Start button at the following pup-up screen.

(2) Click on the OK button at the following pop-up screen.

(3) The following pop-up screen is displayed until the analyzer is ready for electrode exchange.

(4) The following pop-up screen is displayed when the analyzer is ready for electrode exchange.

(3) Clicked on the Shut down button.

When PC has been shut down, turn off the power to the analyzer.

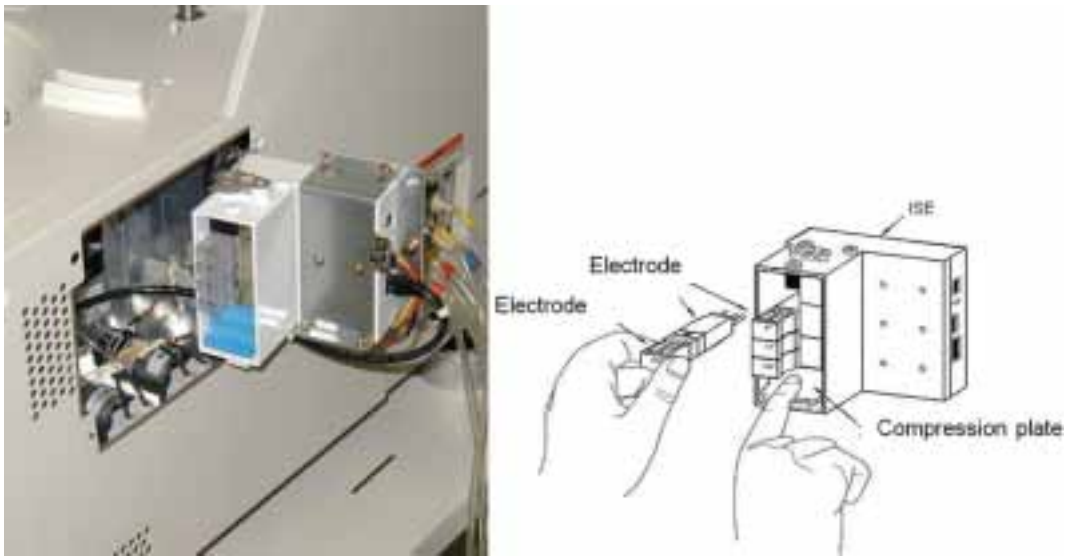
(4) Exchange the electrodes.

a) Remove ISE cover by loosing the two screws (M3) and pulling two plastic clips at the right side of analyzer.

b) Pull the knob at ISE unit and swing out to gain access to the electrodes.

c) Press down and hold the compression plate (blue resign) while pulling the electrode handle out with your fingers to release the electrode.

d) Insert the new electrode in position while pressing down the compression plate.



(5) Turn on the power of analyzer and PC.

(6) When the electrodes are exchanged to new ones, reset the working hour counter of the electrodes at function menu [Wash (F10), Page: 1/2] of the job menu [Maintenance].

(7) Perform “ISE Prime” more than 10 times from the function menu [Sequence (F9)] of the job menu [Maintenance]. Leave the analyzer for 15 minutes or more to settle the solution in each electrode before measurement.

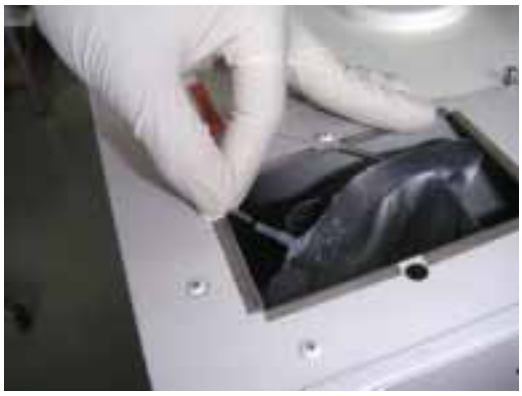
Note: Confirm that “O” ling is fitted firmly between each electrode.
Remove a brown tube stuck in electrode, if it exists.
Prime the ISE several times when a measurement result could not be obtained properly after installing new electrodes.

1-9 Exchanging Pump Cassettes

Periodical exchanging the pump cassettes are needed to maintain ISE measurement properly.

The working time to know the replacement timing of the pump cassette is shown at the function menu [Wash (F10)] of the job menu [Maintenance].

(1) Detach bottle cap of Calibrant-A and prime ISE more than 5 times to purge the liquid from the flow path.

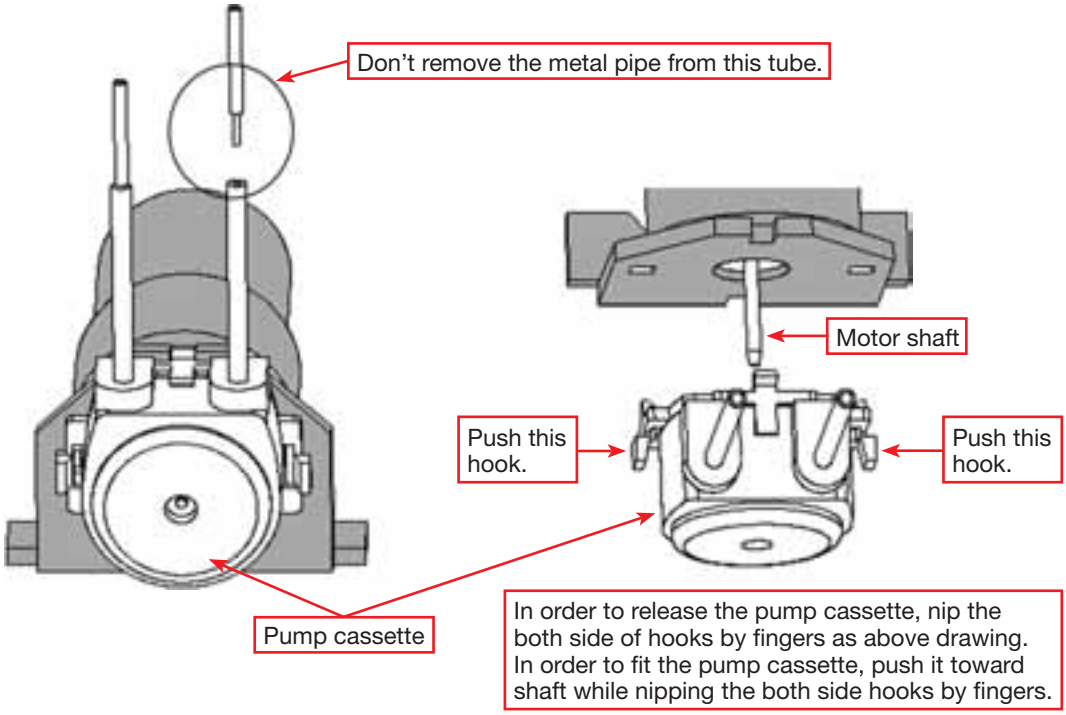


(2) Click on “Shut down” to terminate the analyzers software on PC and then turn the power analyzer off.

(3) Remove the right side cover of analyzer and swing out ISE unit.

(4) Pull out two tubes of pump cassette from the connection parts.

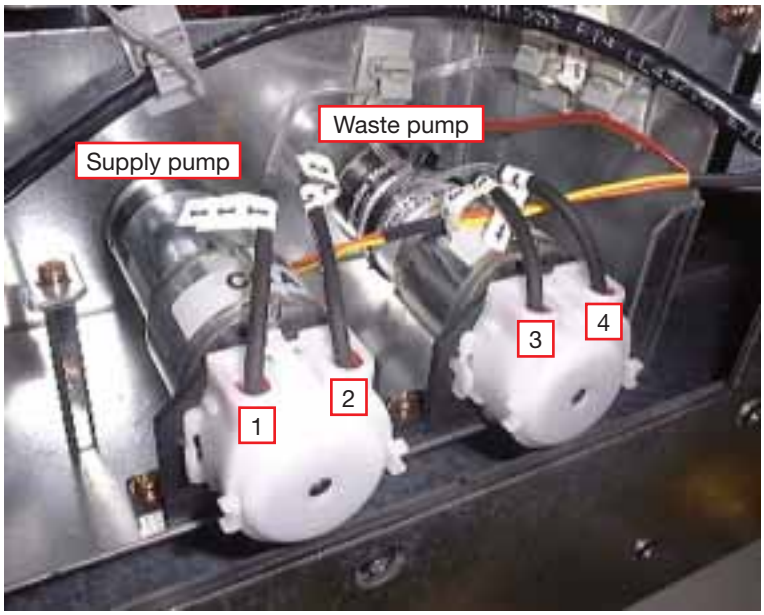
(5) Release the pump cassette from the motor shaft by pressing two hooks at both side of pump cassette with fingers. (See the following drawings.)



(6) Replace the pump cassette.

When replacing, replace both cassettes at the same time.

Beware that there is no markings on the tubes for the cassette. Exchange the cassette carefully not to make wrong tube connection.



Tube marker

1: Output of the supply pump
(This line is connected to the sample port of ISE unit.)

2: Input of the supply pump.
(This line is connected to the bottle of Calibrant-A.)

3: Output of the drain pump.
(This line is connected to the external drain tank.)

4: Input of the drain pump.
(This line is connected to the termination port of ISE unit.)

(7) Attach the bottle cap for Calibrant-A bottle and turn on the power for analyzer.

Then prime the ISE more than 10 times.

(During the ISE priming, check whether the fluid flows correctly into the each tube and the liquid leaking is not occurred at tube connection.)

After confirming that ISE is properly functioning, attach side covers.

(8) Reset the working hour of pump cassette at function menu [Wash (F10), Page: 1/2] of the job menu [Maintenance].

2. ISE Calibration

It is mandatory to perform calibration (two points) before ISE measurement. It is recommended to make it a routine operation to run calibration before running first sample of the day.

One point calibration is automatically performed at each sample processing by Calibrant-A and Calibrant-B is used for two-point calibration.

The calibration is required at the following cases;

(1) The power switch of analyzer is turned off.

(2) Eight hours have passed since the last ISE calibration.

(3) Environmental temperature has changed more than 4 degrees C since the last ISE calibration.

2-1 Procedure for ISE calibration

Perform the ISE calibration from function menu [Sequence (F9)] at the job menu [Maintenance].

(1) Prime the analyzer at least once, twice preferable prior to ISE calibration.

(2) Prime ISE more than 3 times.

(3) Put 500 µL of Calibrant-B into a sample cup, and place it at ASP position 18.

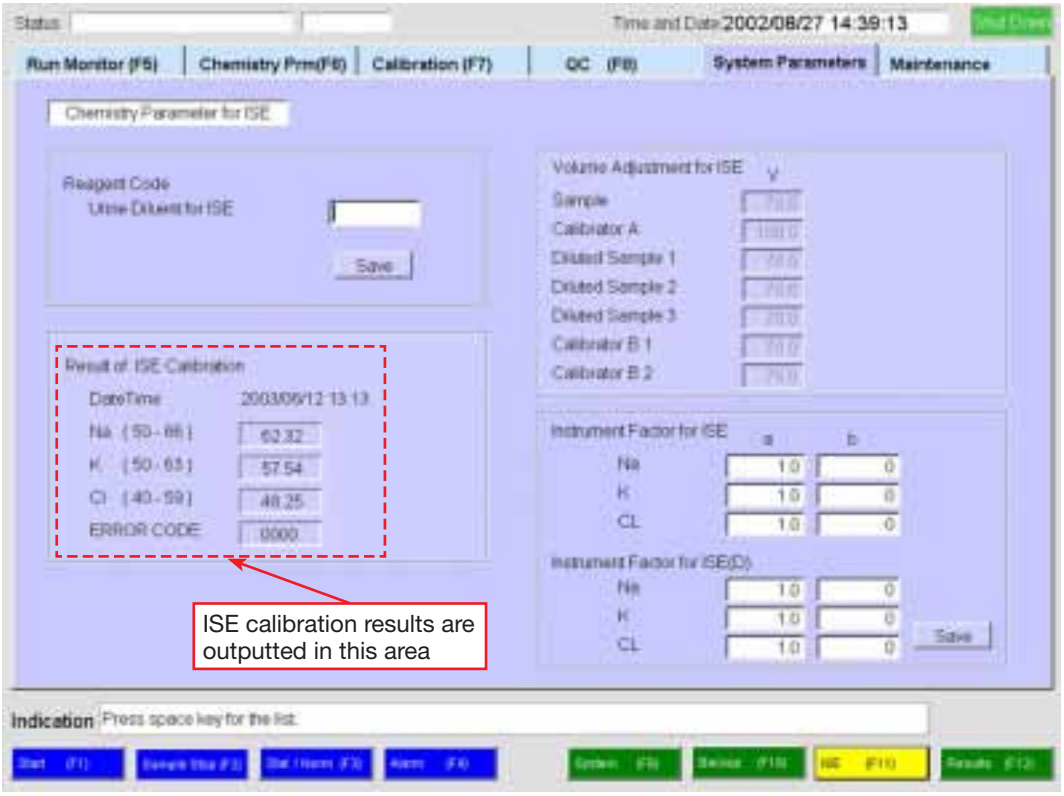
Click on the Start button at the pop-up screen shown below.

(4) Click on the OK button at the pop-up screen shown below.

(5) The following at the pop-up screen will be displayed while ISE calibration is made.

(6) At completing of ISE calibration, the above message window will be closed.

The result of calibration will be shown on the function menu [ISE (F10)] of the job menu [System Parameters] and ISE calibration results will be printed when printer output is set to “Enable”.



Once the calibration results are with in the acceptance limit as shown below, repeat the steps (3) to (6) again. Check the calibration results stays within 2.0 in the two consecutive measurements.

If not, prime ISE unit twice and run calibration again then compare the calibration results. Repeat as necessary.

Acceptable limits of ISE calibration results

Na 50-66
K 50-63
Cl 40-59

3. ISE Cleaning

Use ISE cleaning solution for ISE cleaning and it should be performed once a day to prevent protein build-up or at 8 hours intervals if the ISE unit performs greater than 50 samples per day and measurement of standards are affected.

The cleaning solution effects electrode performance and it takes about 30 minutes for it to be recovered. After the cleaning, it is required to perform ISE priming more than 5 times and wait 30 minutes or more to ensure the measurement performance. It is recommended to perform ISE cleaning at the end of the day in order to minimize protein build-up in the fluid line and to save analyzer from down time.

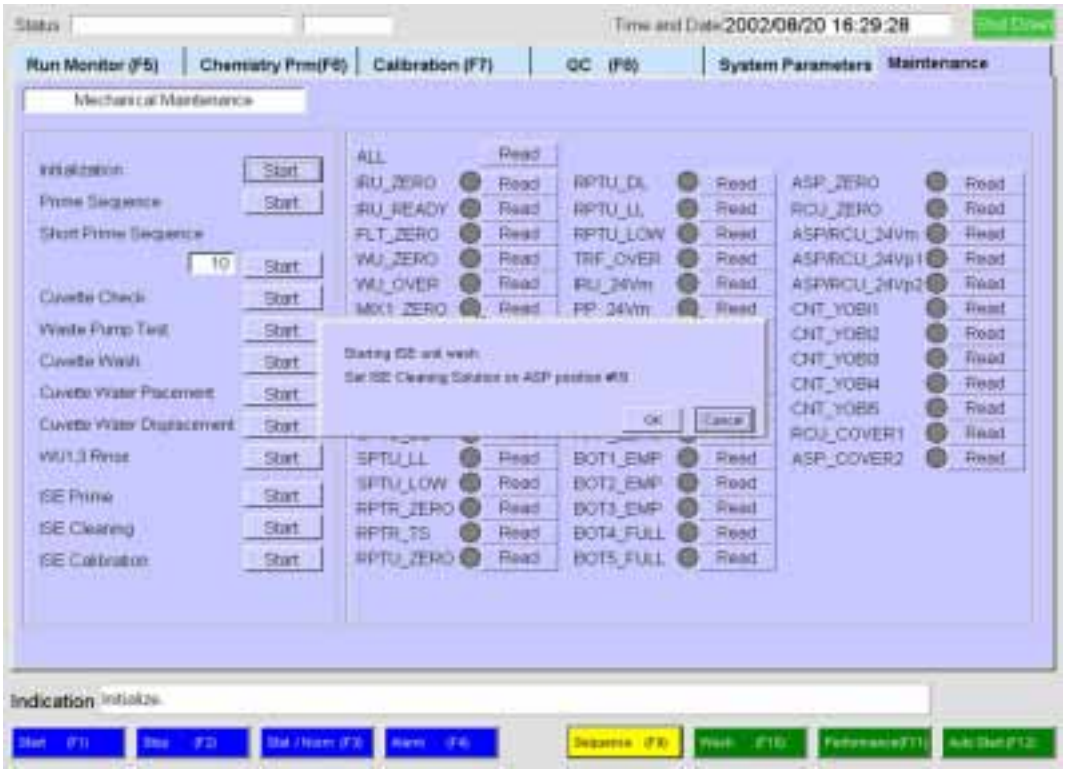
3-1 Procedure for the ISE cleaning

(1) Put 600 µL of the cleaning solution into the sample cup, and place it at ASP position #19.

Click on the ISE Cleaning button as shown below.

(2) Pop-up window confirming the cleaning will be displayed as below.

Click on the OK button to start cleaning.



(3) The following at the pop-up screen will be displayed while ISE cleaning is made.

(4) At completing of ISE cleaning, the above message window will be closed.

4. Error flag

Cause	Measure-ment Item	Byte1	Byte2	Byte3	Byte4	Byte4	
		Noise or Air for Sample or Cali-brant-B	Noise or Air for Cali-brant-A	Drift in Cali-brant-A	Out of Range for Sample of Calibrant-B or Urine		
Noise, Drift or Out of Range	No error	0	0	0	0		
	Na	1	1	1	1		
	K	2	2	2	2		
	Na, K	3	3	3	3		
	Cl	4	4	4	4		
	Na, Cl	5	5	5	5		
	K, CL	6	6	6	6		
	Na, K, Cl	7	7	7	7		
Air		S or B (Note-1)	A (Note-1)	–	–		
Noise, Drift or Out of Range (Urine)	No error	0	0	0	0	K	No out of range error
	Na	1	1	1	1	L	Out of range error
	K	2	2	2	2	M	
	Na, K	3	3	3	3	N	
	Cl	4	4	4	4	O	
	Na, Cl	5	5	5	5	P	
	K, CL	6	6	6	6	Q	
	Na, K, Cl	7	7	7	7	R	
SPT liquid detection error		9	9	9	7		
SPT malfunction		9	9	9	8		
Communication error		9	9	9	9		

Note-1: "S" means sample.
"A" means Calibrant-A.
"B" means Calibrant-B

Note-2: When there is only a Na urine error and no out of range error, the error code is "K".

5. Trouble shooting

Error	Cause	Action
Out of range	Stability of Calibrant-A	Swirl Calibrant-A bottle to assure homogeneity of the solution. The onboard stability of Calibrant-A is one month. When the Calibrant-A is on the analyzer for more than one month, it requires swirling.
	Stability and storage of Calibrant-B	Calibrant-B must be kept in a dark and cool place at room temperature. If the Calibrant-B is expired, it should be replaced with new one. Calibrant-B should be pipette into a sample cup on the analyzer just before the performing of calibration to avoid the evaporation.
	Validity of Electrode	Check that the Electrodes are within expiry date and total measurement count is less than 10,000 samples. If they are expired, the Electrodes must be replaced with new ones.
	Fitting of Electrode	Check that the Electrodes are properly installed into the ISE module without any fluid leaking from tubing connectors and between electrodes.
	Environment temperature	Check that the environmental temperature is within 15 to 30 degrees centigrade.
	Cleaning	After ISE cleaning, it requires about 30 minutes for electrodes to recover to stable measuring condition.
Noise	Validity of Electrode	Check that Electrodes are not expired and total measurement count is less than 10,000 samples. If they are expired, the Electrodes must be replaced with new ones.
	Fitting of Electrode	Check that the Electrodes are properly installed into the ISE module without any fluid leaking from tubing connectors and between electrodes. Also check for crystallization in the path.
	Surrounding equipments	Check that the electrical noise spike from environmental source (such as refrigerator and centrifuge) is not affected. Check for ground condition. The power source should be separated from other equipments.
Drift	Just after electrode exchange	Prime ISE several times. Leave the analyzer for 15 minutes or more without any operation until settling the solution in each electrode.
	Caused by cleaning	After ISE cleaning, it requires about 30 minutes for electrodes to recover to stable measuring condition.
	Validity of Electrode	Check that Electrodes are not expired and total measurement count is less than 10,000 samples. If they are expired, the Electrodes must be replaced with new ones.
	Fitting of Electrode	Check that the Electrodes are properly installed into the ISE module without any fluid leaking from tubing connectors and between electrodes. Also check for crystallization in the path.

Error	Cause	Action
	Exchanging Calibrant-A bottle	Prime ISE to purge the remaining air in the fluid path.
	Glutinous of Sample.	Check for viscosity of sample. When the viscosity of sample is abnormally high such as hyperproteinemia sample, the “Drift error” may occur.
	Caused by Fibrin.	When the sample tube is not anti-coagulator (heparin) type, the measurement should be performed after leaving the sample for 30 minutes to settle the fibrin down. Measurement can be interfered when fibrin is pipette into ISE unit.
	Tubing	Check for the bent, twisted and loose connection of ISE unit tubing. Correct if any.
Air	Caused by air in the SPT.	Prime the analyzer and try ISE measurement again. When air exists in the sampling line, it can be introduced to ISE unit resulting in measurement error.
	Shortage of Calibrant-A. Or the tip of supply tube is placed above the liquid level.	Exchange Calibrant-A bottle to a new one. Check for tubing condition. Prime ISE more than 10 times, and try measurement again.
	Shortage of Calibrant-B.	Pour 500 uL of Calibrant-B in a fresh sample cup and run calibration again.
	Air bubbles in Calibrant-B.	Pour 500 uL of Calibrant-B in a fresh sample cup and run calibration again.
	Shortage of Sample	Add sample to a sample cup and try again the measurement.
	Air bubbles in a sample.	Get rid of air from the sample.
	Abnormal movement of pump (Supply or Waste pump.)	Check for the working hour counter on the job menu [Maintenance]. When the working hour of pump cassette exceeds the use period (180 days), exchange the supply and drain pump with new pumps.
	Tubing	Check for the bent, twisted and loose connection of ISE unit tubing. Correct if any.
	Poor connection of Electrode	Check that the Electrodes are properly installed into the ISE module without any fluid leaking from tubing connectors and between electrodes. Also check for crystallization in the path. Check for displaced compression plate spring.
	Bad of “O”-ling of Electrode	Check for proper fitting of “O”-ring between electrodes. When “O”-ring has some defect or is deformed, exchanged with new “O”-ring.
9999 or others	Occurring ISE communication error between analyzer and ISE module.	Check for misalignment of Electrodes, movement of supply or waste pump and tubing connection. Check for a dirty of sample port at the top of ISE unit. Prime ISE and prime analyzer. When above does not solve the situation, call for service.

Trouble shooting guidance of ISE

Category	Symptom	Possible Cause	Measures	Remarks
Calibration	Drift (Multi analytes); The calibration slopes for all analytes shift little by little and finally one of them shifts out of the normal range. In many cases, the slopes for sodium and chloride shift in the same direction but the slope for potassium shifts in the opposite direction from sodium and chloride.	Misalignment of electrodes.	Take out all of electrodes and reinstall them to the proper position.	
		Cal-A concentrated due to evaporation.	Replace Cal-A.	Cal-A container will be changed from tank to bag type.
		Cal-B concentrated due to evaporation.	Replace Cal-B.	
		Defective reference electrode.	Replace reference electrode.	
		Contaminated electrode.	Perform the cleaning procedure using specified cleaning solution.	
		Poor grounding.	Improve grounding	
	Unstable calibration (Single analyte); All of the slopes move suddenly and one of the slopes becomes out of range. (Associated error code 00X0 or 000X.) Other slopes are often in the range. In many cases, the slopes for sodium and chloride shift in the same direction but the slope for potassium shifts in the opposite direction from sodium and chloride.	Dirt on the sample port.	Wipe out the dirt with moist paper or cotton swab.	
		Cal-B left on ASP tray too long.	Put Cal-B on ASP tray just before calibration.	
		Insufficient flow rate for Cal-A or waste pump.	Replace pump unit with enough flow rate	Minimum flow rate for Cal-A pump: 140µL/sec
		Liquid leakage to the bubble detector.	Replace bubble detector.	
		Expiration of the pump cassette for Cal-A or waste pumps.	Replace pump cassette.	Minimum flow rate for Cal-A pump: 140µL/sec
		Use of not recommended solution.	Use only recommended cleaning solution.	
		Misalignment of electrode.	Detach all electrodes and align them to the proper position.	
		Defective reference electrode.	Replace reference electrode.	
		Contaminated electrode.	Perform the cleaning procedure with cleaning solution.	
		Poor grounding.	Improve grounding	
		Insufficient priming for ISE.	Perform additional ISE priming.	
		Leakey SPP syringe tip.	Replace SPP syringe tip.	
	Drift & unstable calibration (Single analyte); One slope moves sharply and the others are stable.	Defective electrode.	Replace electrode.	
		Expired electrode.	Replace electrode.	

Category	Symptom	Possible Cause	Measures	Remarks
QC & Sample measurement	Shifting of result; The measurement results of control or specimen shift from criterion range or separate reference value that has been measured by other analyzer. All of the results become low value, but there is little chance to find out the result of shifting for potassium in the many cases.	Sample diluted in SPT.	Apply a correction equation.	
		Dirty inside surface of SPT.	Perform cleaning procedure using C1 solution.	
		Cleaning too often.	Control the frequency of cleaning. Or perform the cleaning with specimen.	
		Cal-A concentrated due to evaporation.	Replace Cal-A.	Cal-A container will be changed to a bag type.
		Insufficient priming of ISE.	Perform additional ISE priming.	
		Leakey SPP syringe tip.	Replace SPP syringe tip.	
	Unstable measurement (Multi analyte); In the measurement of control material, the measurement result of every item is not stable, and in any of the item, result becomes out of criterion range. As for other electrode, even if the result is within criterion range, the tendency of result is toward same in case of out of criterion range, in many cases.	Dirt on the sample port.	Wipe out the dirt by using moist paper or cotton swab.	
		Insufficient flow rate for Cal-A or waste pump.	Replace pump unit.	Minimum flow rate for Cal-A pump: 140µL/Sec
		Liquid leakage to the bubble detector.	Replace bubble detector.	
		Expired pump cassette on Cal-A or waste pump.	Replace pump cassette.	Minimum flow rate for Cal-A pump: 140µL/Sec
		Use of not recommended solution.	Use only recommended solutions.	
		Misalignment of electrode fixing.	Detach all electrodes and align them to the proper position.	
		Defective reference electrode.	Replace reference electrode.	
		Contaminated electrode.	Perform cleaning procedure by solution.	
		Poor grounding.	Improve grounding	
		Insufficient priming for ISE.	Perform additional ISE priming.	
		Leakey SPP syringe tip.	Replace SPP syringe tip.	
QC & Sample measurement	Unstableness (Single analyte); Only single item whose measurement result becomes out of criterion range. Good results are obtained on others items.	Defective electrode.	Replace electrode.	
		Expired electrode.	Replace electrode.	