XN-9100 Training Manual (Part II)

Revision November 2019

XN-9100 Series Training Manual (Part II)

Revision 2: November 2019

Roche Diagnostics Training and Support

Roche Diagnostics Pty Australia Ltd

2 Julius Avenue,

North Ryde NSW 2113

Tech Support Hotline: 1800 645 619

www.rochediagnostics.com.au

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Purpose and Scope of the Manual

The XN training manual has been prepared to provide a basic understanding of the XN analysers, the technologies and methodologies employed by the systems, as well as general operations and maintenance. It is NOT intended to replace the Sysmex XN Instruction for use or Operator manual.

New operators are advised to read the Operators and Instructions For Use manuals before use, and to take particular notice of all Warnings and Safety Information notices.

Section 1: Introduction

Introduction

The Sysmex XN-9100 is an integrated Haematology system which includes automation of full blood count analysers with slide maker staining capabilities using Sysmex transportation.

The Sysmex XN analysers enable the analysis of tangible components of blood and body fluid by means of electrical impedance, laser light scattering, and dye bonding.
The XN provides a full 6-part differential, with extended diff parameters (NRBC, and Immature Granulocytes)

Data is stored and displayed on the Information Processing Unit (IPU).

Throughput:

XN-9100: maximum of 900 “CBC+ DIFF+ NRBC”, samples per hour (without any SP)

SP-10: maximum of 120 samples per hour

SP-50: maximum of 75 samples per hour (high speed model)

Note! *Only human blood, human body fluids or control blood should be run. Any other use is regarded as non-specified.*
Use only the reagents and cleaning fluids mentioned in this manual.

Instrument Overview

The XN-9100 series haematology system consists of the components and options below, which are used in a suitable combination.

- Analyser (XN-10/20)
- IPU
- Pneumatic unit
- Printer
- SP-10/SP-50
- XN-9100 Supply parts
- Transportation units

System Configuration

The XN-9100 System includes up to 9 XN full blood count analysers (XN-10/XN-20) and 1 or more SP-10 or SP-50 automated haematology slide preparation unit, connected via a transportation system.

This system can include a combination of conveyors for single (CV-50) or twin wagon (CV-55) XN as well as one or multiple SP-10 (CV-60) or SP-50 (CV-65) but not a mixture of both SP's on the same line.

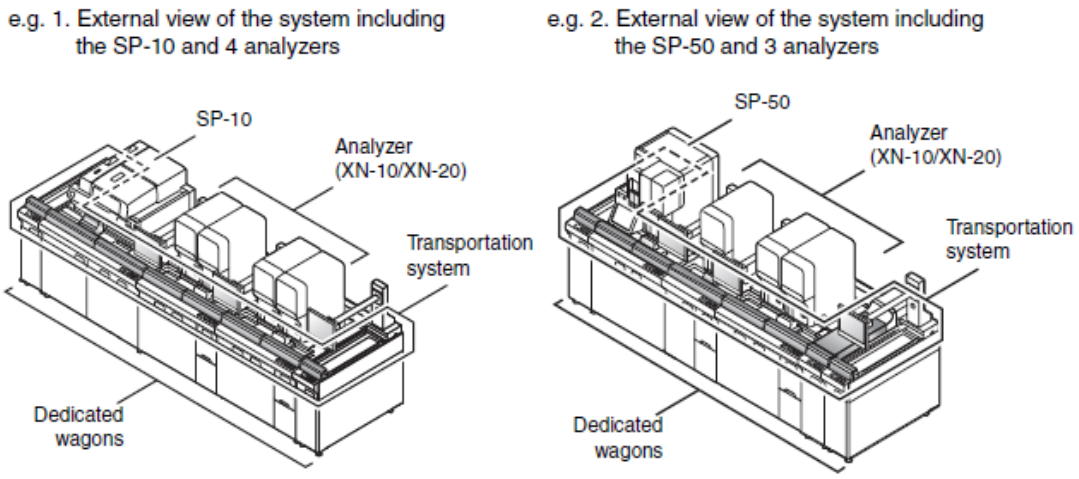
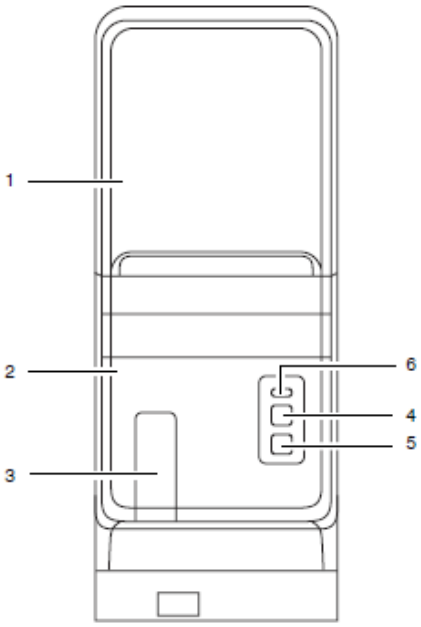


Figure 1: External view of the XN-9100

Overview of XN-9100 Parts Names and Functions

Analyser (XN-10 or XN-20)

Analyses patient and Quality control samples



1 Front top cover
Opens upward. Open this cover to inspect the interior of the analyzer, or to perform cleaning or maintenance tasks.

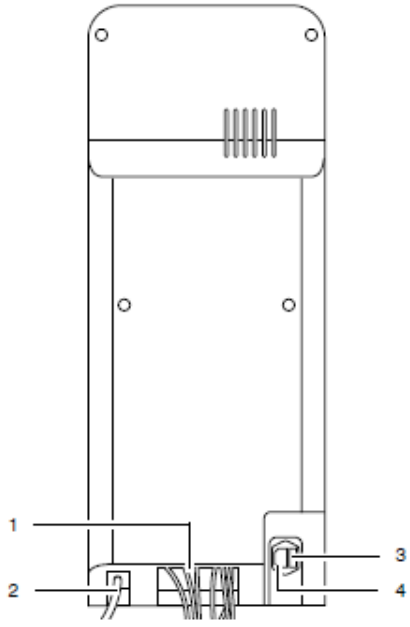
2 Front bottom cover
This is a protective cover. Open this cover to inspect the interior of the analyzer, or to perform cleaning or maintenance tasks.

3 Tube holder
Used to load the sample tubes for manual analysis.

4 Start switch
Press to start manual analysis.

5 Mode switch
Press to switch between manual analysis and sampler analysis. Pressing it opens and closes the tube holder.
When the tube holder is open: Manual analysis
When the tube holder is closed: Sampler analysis

Figure 2: Analyser Front View



1 Various tubes/cables
Hydraulic tubes and electrical cables to be connected to the different devices.
The tubes and cables will be connected by Sysmex service representative.

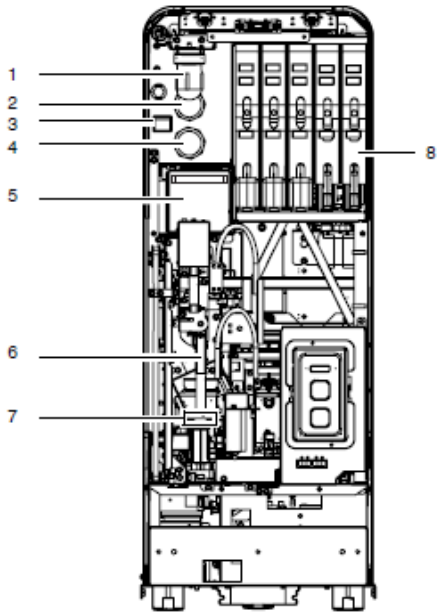
2 Waste Fluid Outlet Nipple
Waste fluid is discharged via this nipple. Connect this to the drain or the waste container.

3 Fuse holder
Use a 250V 10A (Time Lag low breaking capacity) fuse.

4 AC power inlet
Supplies power using the provided power cable.

Figure 3: Analyser Rear View

Figure 4: Analyser Front Interior



1 Pneumatic trap chamber
Prevents the reagent from flowing back into the pneumatic unit, when the instrument malfunctions.

2 0.16 MPa regulator
Regulates the pressure at 0.16 MPa.

3 Main power switch

4 0.07 MPa regulator
Regulates the pressure at 0.07 MPa.

5 RBC/PLT detector section
Equipped with a RBC/PLT detector.

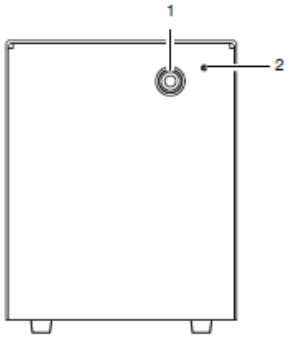
6 Tube grabber
Removes the sample tube from the rack and mixes it. Then after the analysis is complete, places the sample tube back in the rack.

7 Tube rotation mechanism
Rotates the sample tube to read its barcode label.

8 Dye cartridge holder
Holds the dye reagent.

Pneumatic unit

Supplies vacuum and pressure to the device

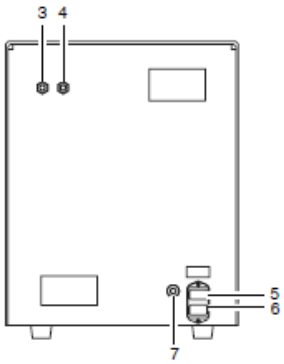


1 0.25 MPa regulator
Regulates the pressure supplied to the analyzer at 0.25 MPa.

2 Pilot lamp
Lights up when the pneumatic unit's power is ON.

Figure 5: Front View

Figure 6: Rear View



3 Pressure outlet nipple
Pressure is supplied to the analyzer from this nipple. Connect this nipple with the pressure supply nipple on the analyzer.

4 Vacuum outlet nipple
Vacuum is supplied to the analyzer from this nipple. Connect this nipple with the vacuum supply nipple on the analyzer.

5 Fuse
Use only with fuses of the specified type and current rating.
100 -117 VAC: Fuse 250V 4A (Time Lag)
220 - 240 VAC: Fuse 250V 3.15A (Time Lag)

6 Power connector
Supplies power using the provided power cable.

7 Pneumatic control input connector
An input connector for turning the pneumatic unit ON/OFF. Connect this to the pneumatic control output connector on the analyzer.

IPU (Information Processing Unit)

The Sysmex XN-9100 IPU (Information Processing Unit) serves as the graphical user interface for the XN-9100. It can store up to 100,000 sample records, including histograms, and displays detailed information on the analysis results.

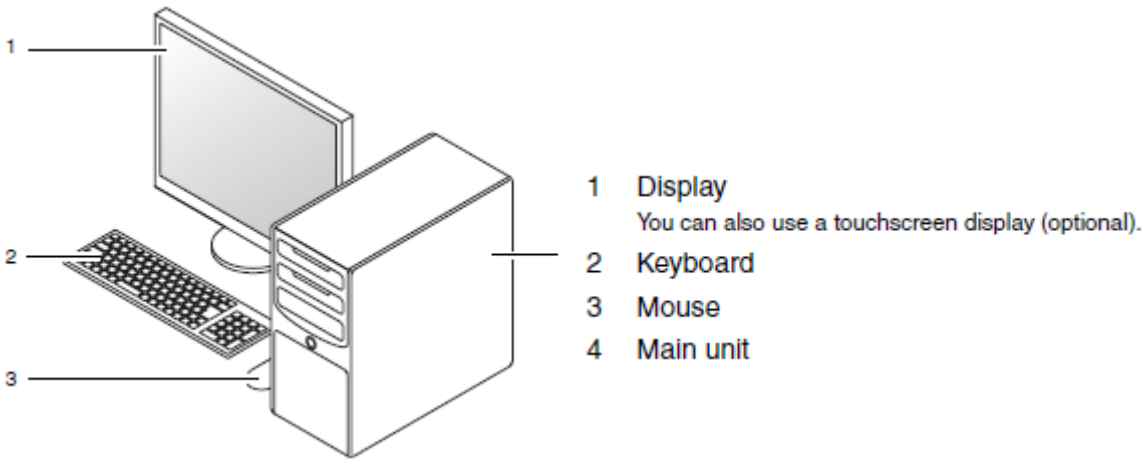
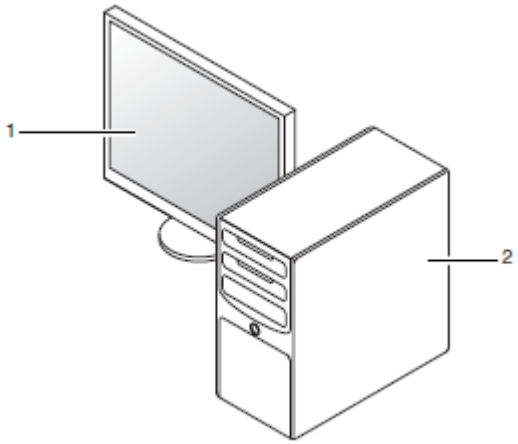


Figure 7: Information Processing Unit (IPU)

Transportation controller (CT-90)

Instructs rack transportation and manages order information.

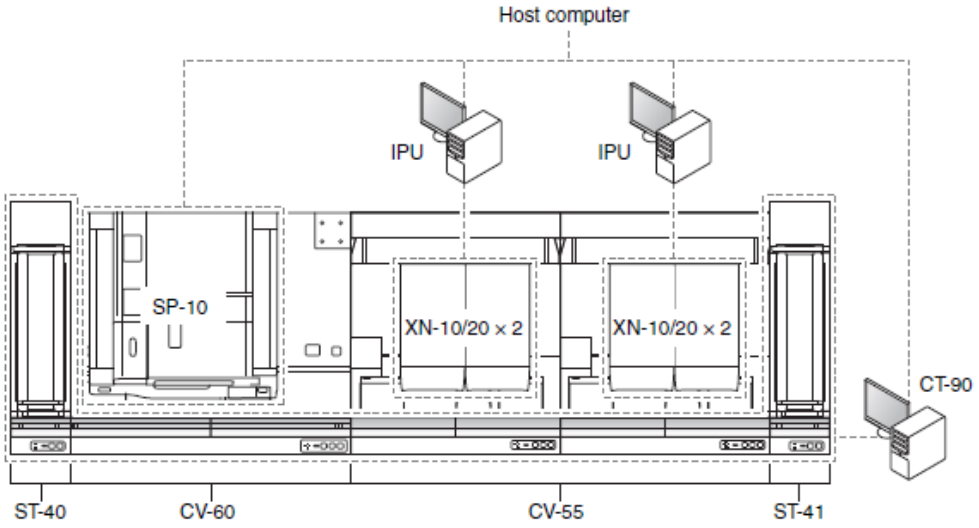


1. Touchscreen display
   An LCD display with touchscreen operation support.
2. Main unit

XN-9100 Transportation unit

The transportation system automatically supplies samples to each analyser.

The basic configuration of the transportation system is as follows.
Other configurations are also possible to work with your environment.



e.g. 2. External view of the system including the SP-50 and 3 analyzers

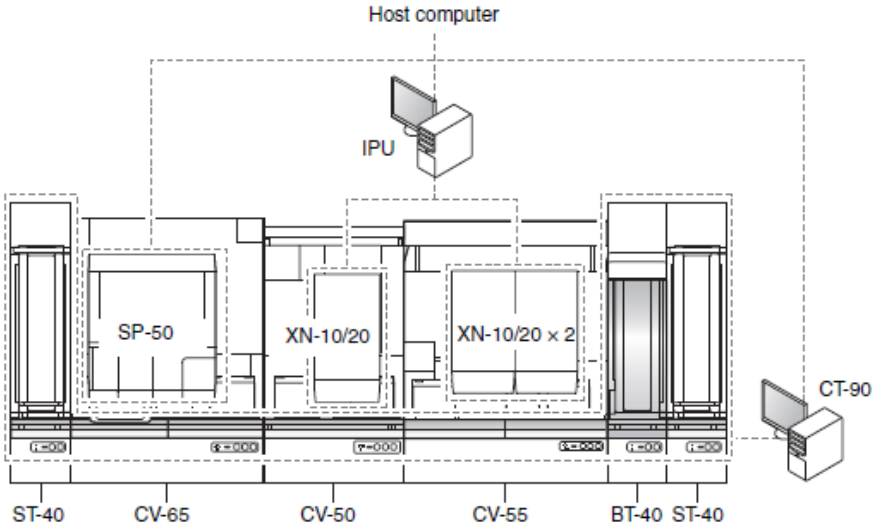


Figure 8: XN-9100 Transportation Top View

Start yard/Stock yard

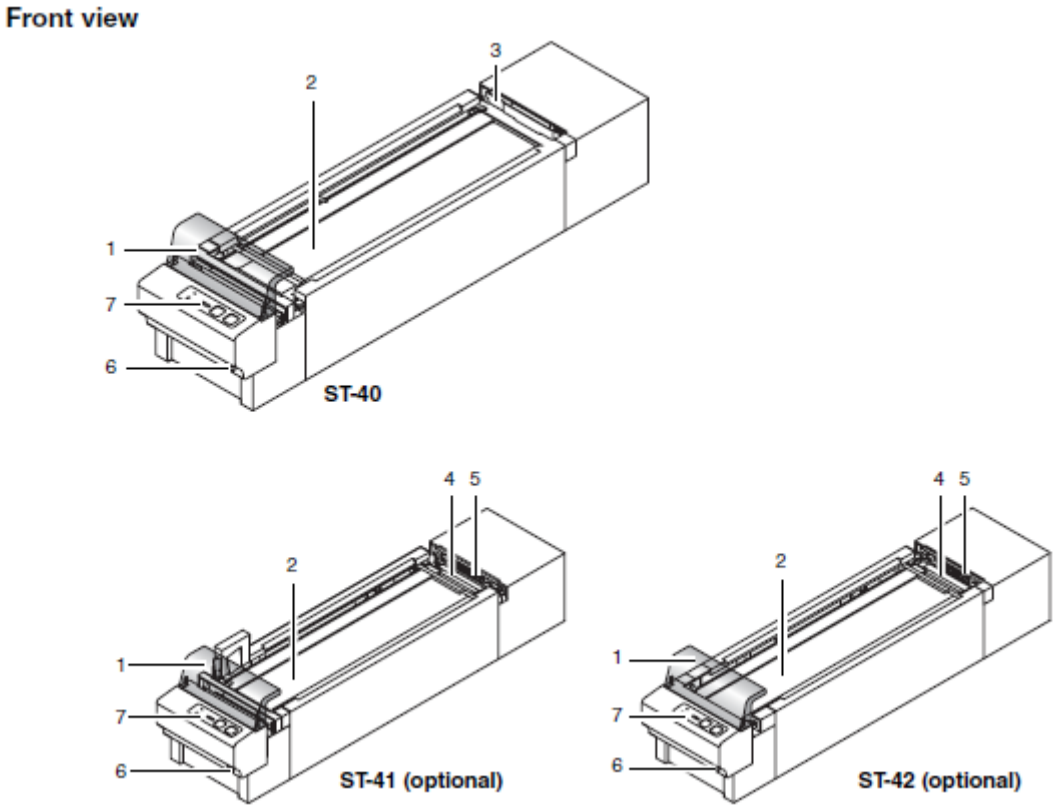


Figure 9: Start yard/ Stock yard

1. Protective cover

A cover to protect the rack from contact with any object during transit. Open the cover when performing inspection.

2. Rack table

A maximum of 25 racks can be stocked.
Depending on your configuration the instrument, it can be used as a feeder section, q collection section, or a conveyor route.

3. Sweep line

Feeds the rack to the next connected conveyor device.

4. Receiving line

Receives the rack from the conveyor device connected in front of it.

5. Rack feed-out lever

Feeds the rack that has reached the receiving line out to the rack table.

6. Start-up switch

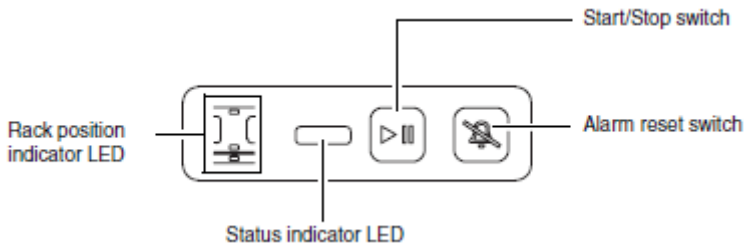
Turns the power of the device ON/OFF.

ST-40

ST-41 (optional) ST-42 (optional)

7. Control panel

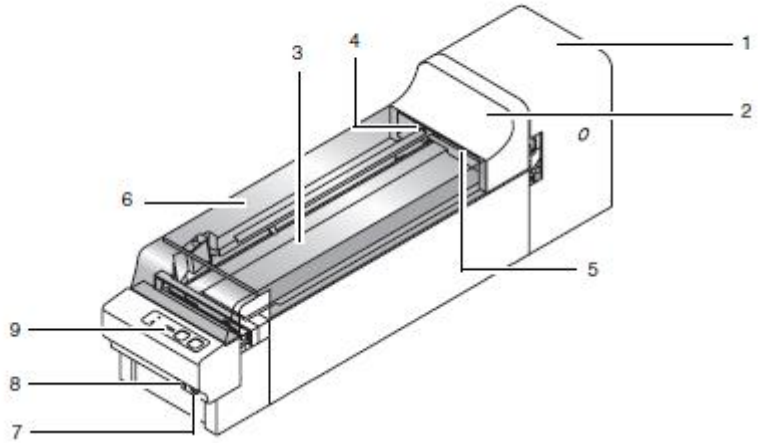
Used to operate the start yard/stock yard. Also displays the status of the device as well as the position of the rack.



Barcode terminal (BT-40)

Reads the rack number barcode and sample number barcode. This is installed on the dedicated wagon (WG-40).

Front view



1. Sample barcode reader section

Reads the barcode labels on the rack or the sample tubes in the rack.

2. The barcode reader cover

The barcode reader cover can be opened when performing inspections. When opening this cover, you must remove the protective cover. Cover open/close is detected by a sensor. When the cover is open, instrument operation stops.

3. Rack table

A maximum of 25 racks can be stocked.

4. Rack feed-out lever

Feeds the rack that has reached the feeder line out to the rack table.

5. Receiving line

Receives the rack from the conveyor device connected in front of it.

6. Protective cover

A cover to protect the rack from contact with any object during transit. Open the cover when performing inspection.

7. Start-up switch

Turns BT ON/OFF.

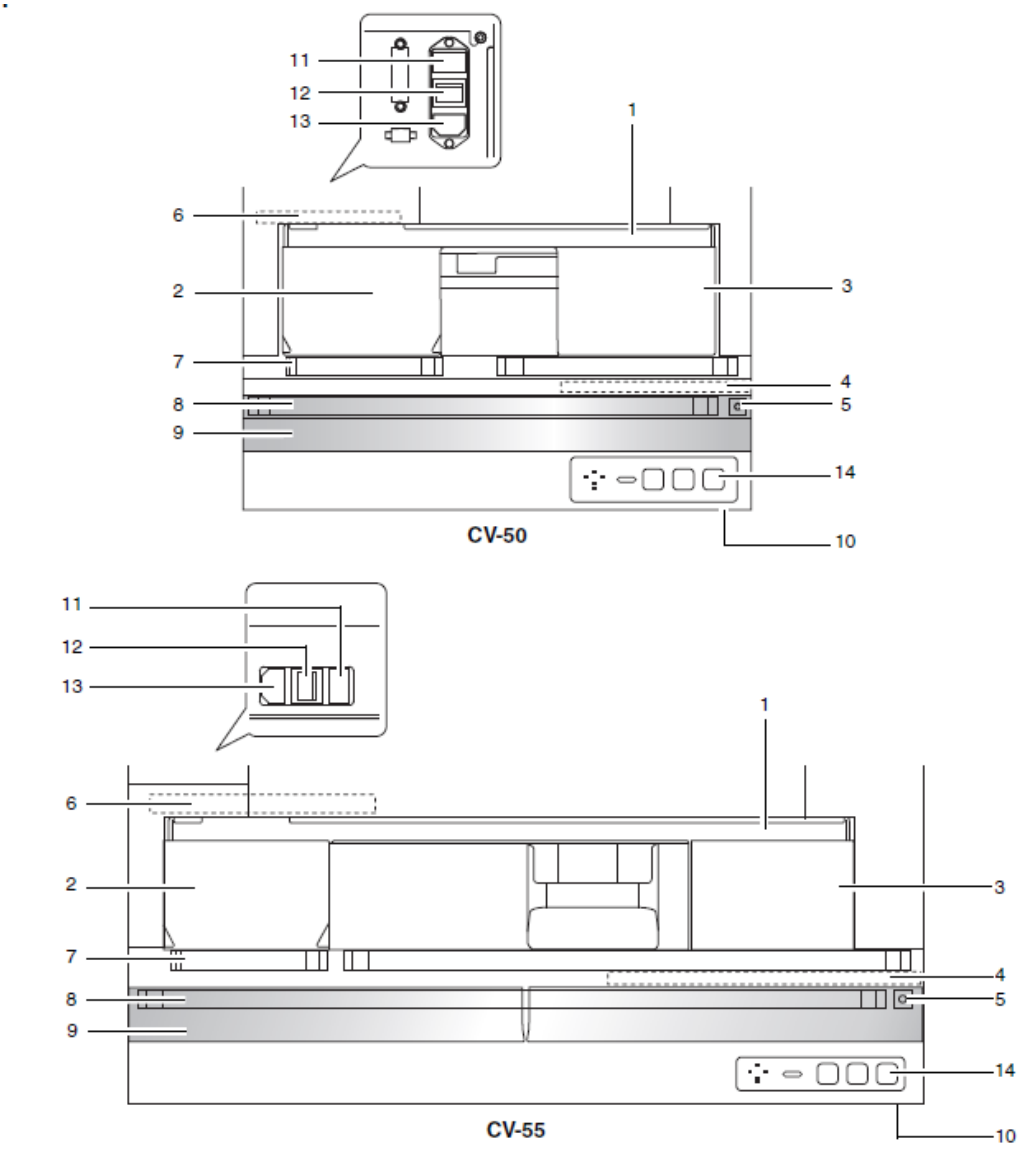
8. Master start-up switch

Turns ON the power of the entire instrument at once. In addition, you can press this to turns OFF all transportation units.

9. Control panel

Same as the control panel for the start yard/stock yard.

XN conveyor (CV-50/CV-55)



Automatically supplies the samples to the analyser. This is installed on the dedicated wagon (WG-50/WG-55).

1. Analysis line
The racks are transported laterally. In this line, the racks are checked for existence of any sample tube, and the samples are mixed and aspirated.

2. Left conveyor pool
Feeds the racks from the analysis line to the feeder line and the collection line.
When performing an off-line analysis (sampler analysis), the finished rack gets transported here.

3. Right conveyor pool
Takes the rack that was transported via the feeder line and feeds it to the analysis line.
Place the rack here when performing a off-line analysis (sampler analysis).

4. Rack feeder lever
Feeds the rack to the right conveyor pool.

5. Rack stopper
Stops the rack that was transported to the collection line.

6. Rack feed-out lever
Feeds the finished racks from the analysis line to the left conveyor pool.

7. Feeder line
Pulls in the rack from the conveyor device connected to its right side.
Also pushes the rack out to the conveyor device on its left.

8. Collection line
Collects finished racks that have been analysed. In some transportation system configurations, racks are conveyed from the start yard.

9. Protective cover
A cover to protect the rack from contact with any object during transit. Open the cover when performing inspection.

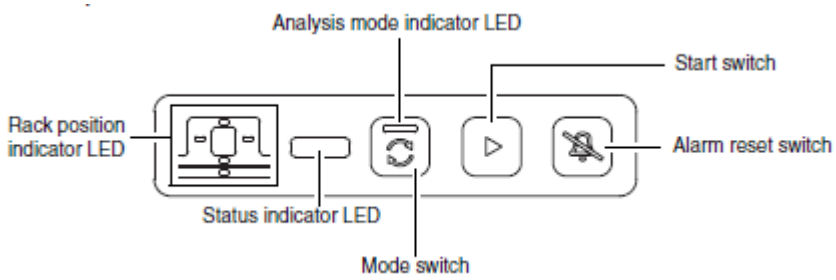
10. Start-up switch
Turns the power of the device ON/OFF.

11. Fuse holder
Use a 250V 3.15A (Time Lag) fuse.

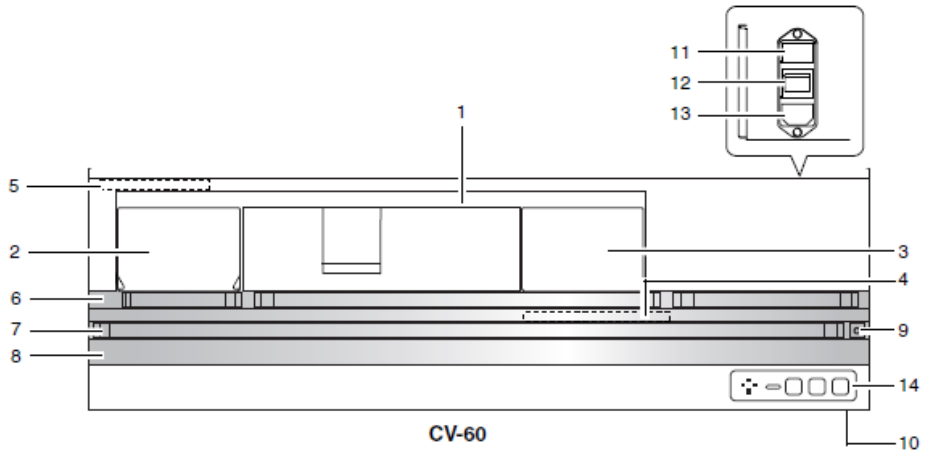
12. Main power switch
Turns the main power of the device ON/OFF.

13. AC power inlet
Supplies power using the provided power cable.

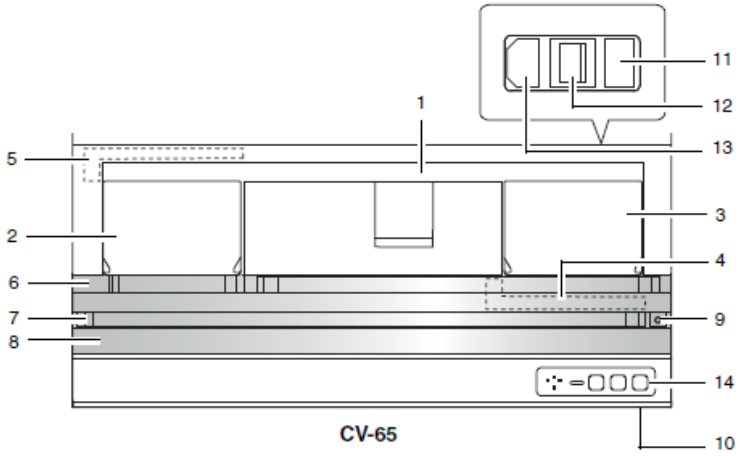
14. Control panel



SP conveyor (CV-60/CV-65)



CV-60



CV-65

Automatically supplies the samples to the SP-10/SP-50. This is installed on the dedicated wagon (WG-60/WG-65).

1. Analysis line

The racks are transported laterally. In this line, the racks are checked for existence of any sample tube, and the samples are mixed and aspirated.

2. Left conveyor pool

Feeds the racks from the analysis line to the feeder line and the collection line.
When performing an off-line analysis (sampler analysis), the finished rack gets transported here.

3. Right conveyor pool

Takes the rack that was transported via the feeder line and feeds it to the analysis line.
Place the rack here when performing an off-line analysis (sampler analysis).

4. Rack feeder lever

Feeds the rack to the right conveyor pool.

5. Rack feed-out lever
Feeds the finished racks from the analysis line to the left conveyor pool.

6. Feeder line Pulls in the rack from the conveyor device connected to its right side.
Also pushes the rack out to the conveyor device on its left.

7. Collection line
Collects finished racks that have been analysed. In some transportation system configurations, racks are conveyed from the start yard.

8. Protective cover
A cover to protect the rack from contact with any object during transit. Open the cover when performing inspection.

9. Rack stopper
Stops the rack that was transported to the collection line.

10. Startup switch
Turns the power of the device ON/OFF.

11. Fuse holder
Use a 250V 3.15A (Time Lag) fuse.

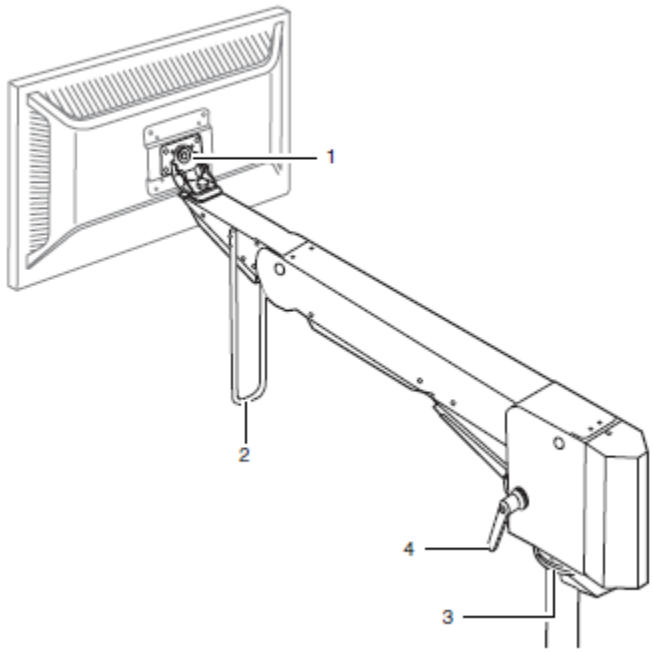
12. Main power switch
Turns the main power of the device ON/OFF.

13. AC power inlet
Supplies power using the provided power cable.

14. Control panel
Same as XN conveyor (CV-50/CV-55).

Monitor arm (DA-10)

Rear view



Option that allows the touch panel display to be operated close at hand.

1. Display mounting part
   The touch panel display is mounted on this part.
   There are 3 axes of movement. The panel can be adjusted up and down, left and right, and the angle can be adjusted.

2. Handle
   Use when moving the arm.

3. Monitor arm rotation mechanism
   Rotates the monitor arm left and right.

4. Adjustment lever
   The tightness of the monitor arm rotation mechanism can be adjusted.

Section 2: Supported Sample Types and Modes of Analysis

Supported Sample Types

Regular Sample Tubes

Following tubes have been verified for proper operation on XN-9100 system:

- VENOJECT II (Terumo)* * Reusable caps cannot be used
- Hemoguard (BD)
- VACUETTE (griener)
- Monovette (SARSTEDT)

Micro Collection Sample Tubes

Following tubes have been verified for proper operation on XN-9100 system:

- CAPIJECT (Terumo)
- Microtainer 365974 (BD)

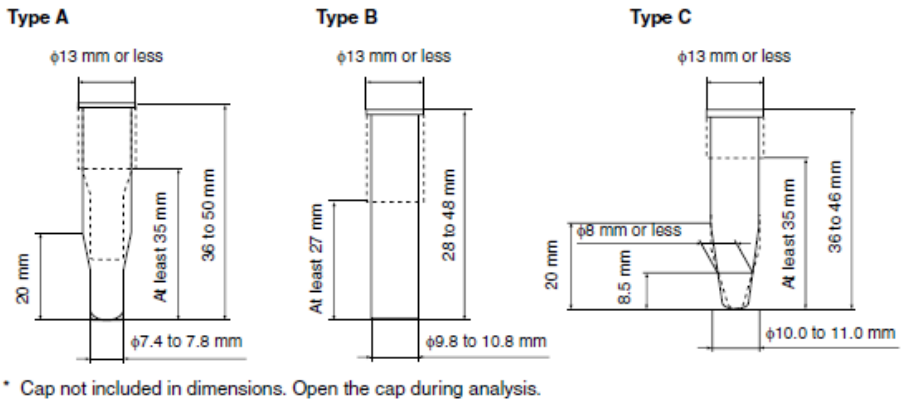


Figure 10: Micro Collection Sample Tube Dimensions

Modes of Analysis

Manual analysis (Aspirated volume of 88 µL)
In this mode the operator is required to manually introduce the sample to the instrument for sample aspiration after mixing. Use this analysis for STAT sample analysis, or for analysing special samples.

Micro analysis (Aspirated volume 88 µL)
This is a type of manual analysis. This mode is used for micro tubes and requires the operator to mix the sample prior to introducing it to the analyser. The analysis is performed without a cap on the sample tube. The conditions for micro analysis are as follows:

- When [Cap Open] is turned ON in the Manual Analysis menu
- When an analysis is performed in [Pre-Dilution] mode **(Aspirated volume 70 µL)**
- When a micro collection tube is used

Pre-diluted analysis (Aspirated volume 70 µL)
Whole blood is diluted by an operator to a 1 in 7 with CELLPACK DCL, and analysed as in Manual Mode. CBC parameters are automatically re-calculated. DIFF parameters are not obtainable in this mode.

Body fluid analysis (Aspirated volume 88 µL)
This is a type of manual analysis. Use this analysis to measure body fluid.
* The body fluid analysis can only be performed if the instrument offers the body fluid analysis mode.

RBT Manual analysis (Aspirated volume of 88 µL)
In this analysis, the operator loads RBT (Paediatric MAP tubes only) sample tubes individually by hand. The operator also mixes the samples by hand. Use this mode for RBT sample analysis.

System analysis (sampler analysis) (Aspirated volume 88 µL)
In this analysis, the operator is required to mix the samples prior to loading the sample tubes into a rack, which is then automatically transported and analysed by the instrument. You can place up to 200 samples at a time.

Off-line analysis (sampler analysis) (Aspirated volume 88 µL)
In this analysis, the operator separates an analyser from the system's transport line, in order to perform a separate analysis of a rack. Use this analysis for samples of greater urgency.

RBT sampler analysis (Aspirated volume of 88 µL)
In this analysis, the operator loads RBT (Paediatric MAP tubes only) sample tubes on to special RBT rack.
Note: RBT rack barcode must be applied to the sample racks used. This will ensure application of correct aspiration steps.

Section 3: XN-9100 Software (IPU)

The Information Processing Unit (IPU)

The Sysmex XN IPU (Information Processing Unit) serves as the graphical user interface for the XN. IPU processes and displays data generated by the XN analyser.
It can store up to 100,000 sample records, including histograms, and displays detailed information on the analysis results.

The IPU is connected to the main unit by a Local Area Network (LAN) connection, and contains all of the calibration files, flagging data limits, and operating limits for the analyser. It can be bi-directionally interfaced to the host Laboratory Information Systems (LIS) via TCP / IP, or ASTM connection protocols.

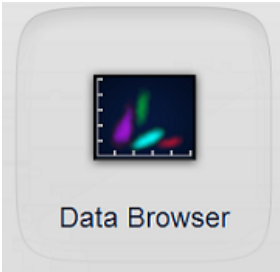
Main Screen layout

The main screen consists of those icons that are used most regularly and is user definable.

Figure 11- Main Screen

The icons of the Main Screen

Sample Explorer - the result database of up to 100,000 results displayed in numerical form.

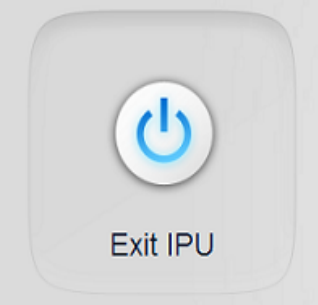


Data Browser –the result database displayed in graphical form.

QC File - used to access all QC functions, such as file data input, data review, and statistics.

Instruction for Use- This manual explains how to operate the instrument, focusing primarily on routine work.

LOGOFF- Used to switch between users.



Exit IPU- Used to close XN IPU program.

History- The items in the history list change depending on which tab is selected. Tabs include operation, Error, Reagent and maintenance.

Version Information- Information about current version of IPU program.

Control Menu

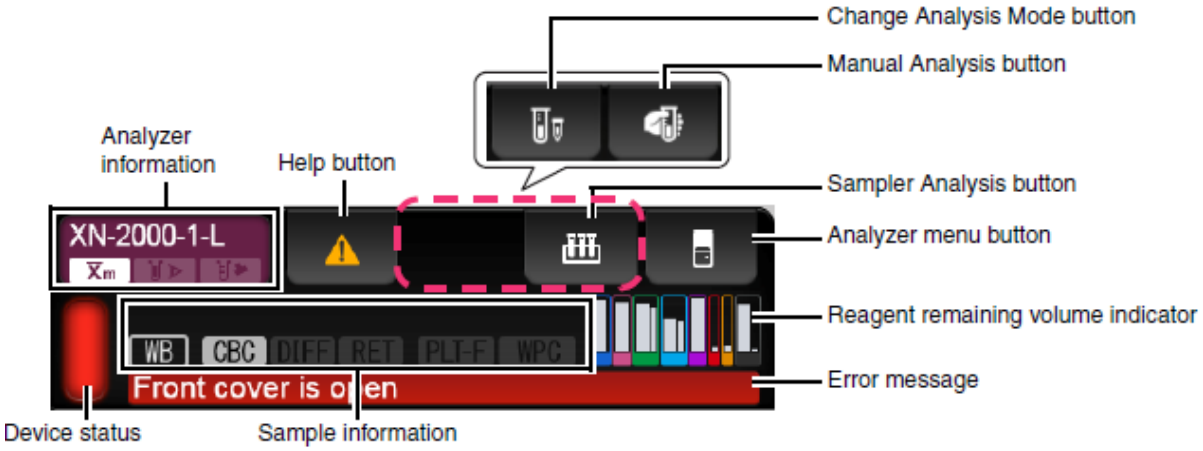
Located on the bottom left of the IPU menu. Layout of the control menu is as follows:

Control Menu

Analyser Area	Displays information about the analyser
Sampler Area	Displays information about the sampler
RU area	Displayed when the RU-20 is connected
Printer Area	Displayed when the printer is connected
Host Computer Area	Displayed when the IPU is connected to a host computer

Analyser Area

Layout of the analyser area menu is as follows:



Analyser Area Menu

Analyser Information Displays mane of the analyser and its settings.
Meaning of each icon is as follows:

: This is displayed when the X-barM function is ON.
: This is displayed when the blood aspiration sensor is ON.
: This is displayed when [Cap Open] is ON.

Help Button — Displayed when an error occurs, click to display the Help dialog box

Change Analysis Mode — Displayed when performing manual analysis, click to select an analysis mode

Manual Analysis Button — Displayed when performing manual analysis.
Click to define settings as follows:


: This is displayed when [Cap Open] is OFF.
: Blinks when [Cap Open] is ON.

Sampler Analysis Button — Displayed when performing sampler analysis. Click to define settings for the sample, as well as if clicked during sample analysis, a dialog box for aborting the sample analysis is displayed.

Analyser Menu Button — Allows operators access to analyser menus and maintenance functions.

Reagent Remaining Indicator — Displays visually how much reagent is remaining
Colours indicate the colour of each reagent's pack. Reagents from left to right are as follows:
DCL, SLS, WNR, WDF, DFL, RET, PLT and WPC
Thick bars indicate dilution/ haemolytic agent and the thin bars indicated dye

Clicking on the reagent level display to open the reagent replacement dialog

Error Message — Displays highest priority error among all current errors

Device Status — Indicated status of the analyser

Sample Information — Displays information about the sample to be analysed
Sample number: displays sample number
Analysis mode: WB, LW, PD, BF, HPC
Discrete: Displays selected discrete test, not displayed for BF or HPC

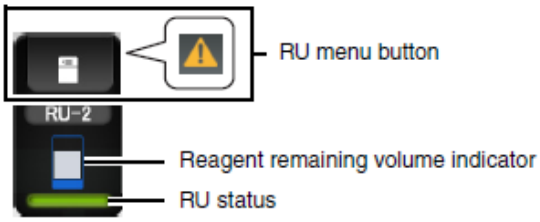
Sampler area

Showing information about the XN analysers only (this doesn't include SP-50)

Device status: Status of the sampler
Error message: Displays highest priority error among all current errors

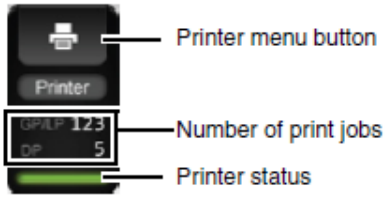
RU Area*

RU menu button, opens and closes the RU help dialog
Reagent remaining volume indicator, displays visually how much reagent is remaining in the RU-20
RU status, Indicates status of the RU-20 unit

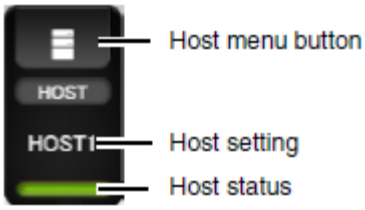


***RU-20 is optional**

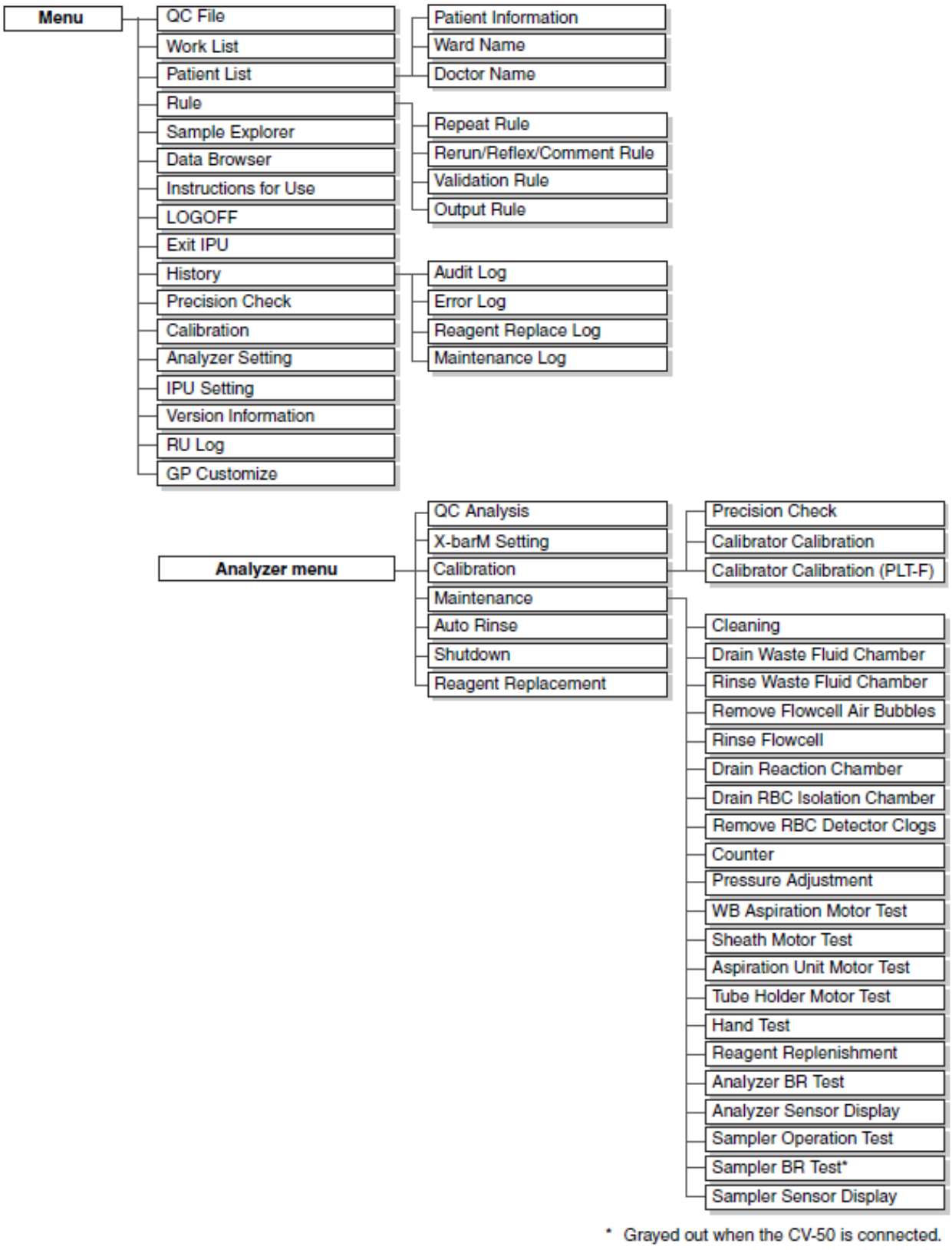
Printer Area



Host Computer Area



IPU Menu

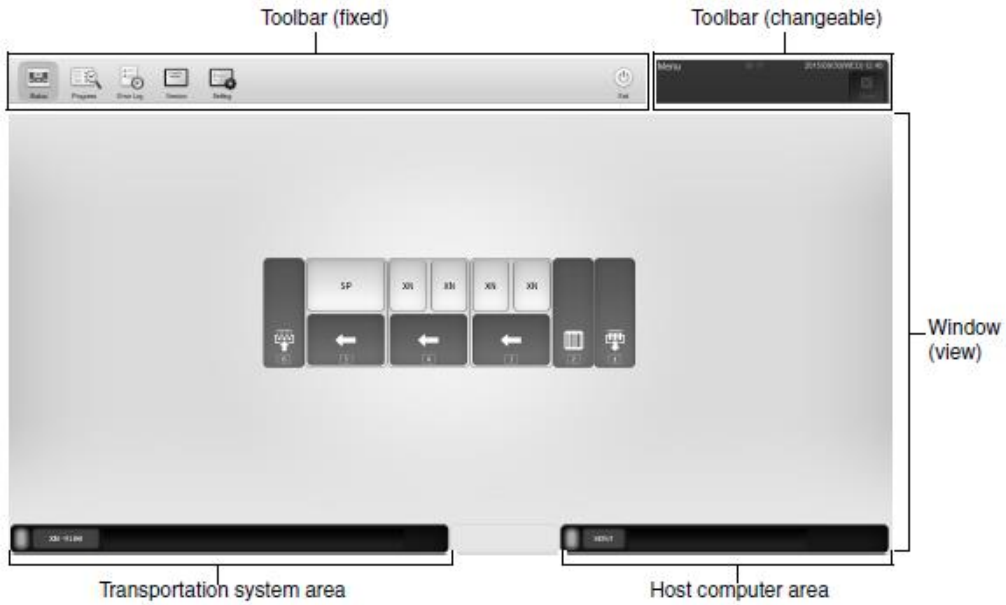


* Grayed out when the CV-50 is connected.

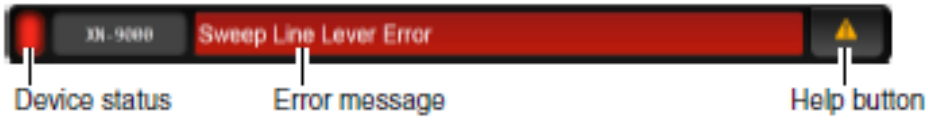
Operation of the transportation controller (CT-90)

The Transportation controller is a device for operating and configuring the transportation system.

Main screen layout

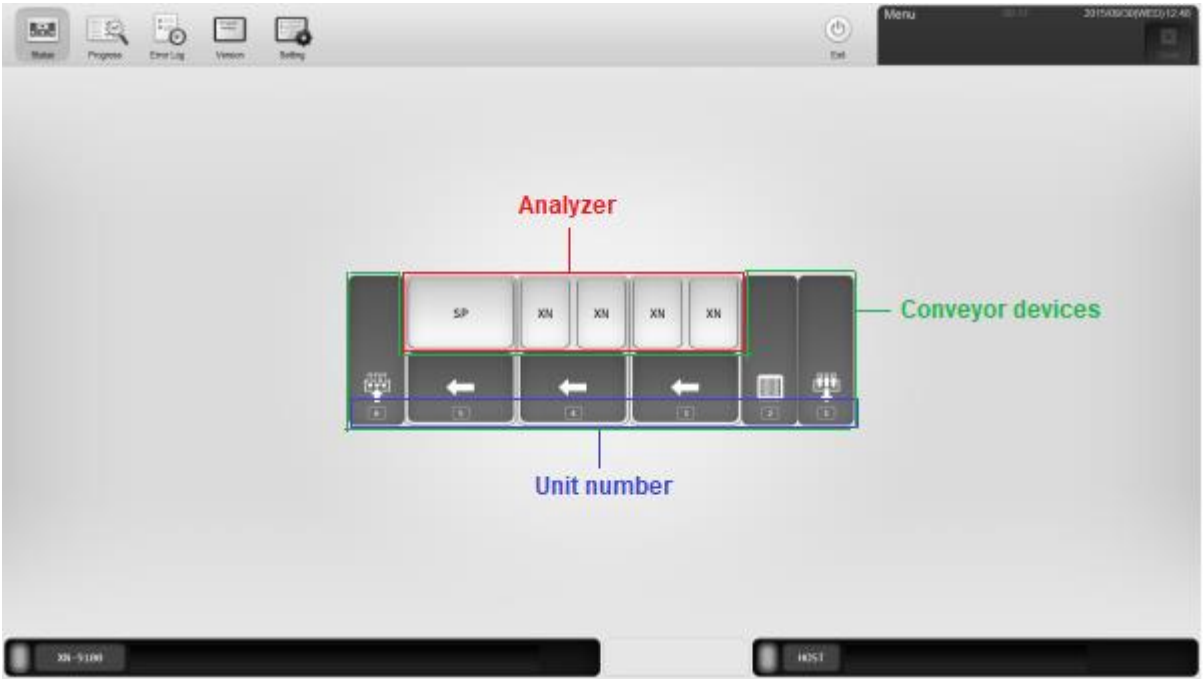


Transportation system area



Host computer area

Check system status



Conveyor devices	Displays the status of the conveyor devices.	
Categories of conveyor devices	:	Feeder section
	:	Collection section
	:	Buffer section (Used to expand the conveyor system line.)
	:	Barcode terminal section
	:	Conveyor section
	:	Turn unit section
Conveyor device status	Gray:	Not connected
	Green:	System analysis mode
	Orange:	Off-line analysis mode
	Red:	Error in progress

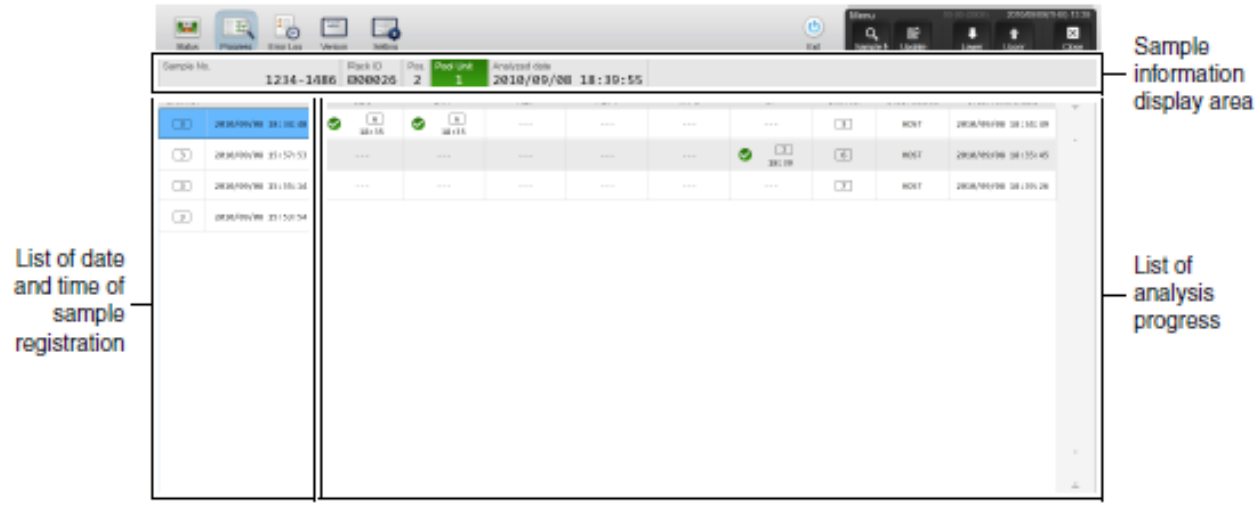
Unit number
Numbers are assigned in order starting from the right side of the instrument.
These numbers are used to distinguish the devices when checking progress, etc.

Analyser
Identifies the analysers connected to the transportation system. The XN series are displayed as [XN], and the SP-10/SP-50 is displayed as [SP].

The meaning of each displayed colour is as follows:

Grey: Not connected
White: Normal
Orange: Starting, maintenance in progress, manual analysis in progress
Red: Error in progress

[Progress] screen



[Progress] screen

List of Analysis Progress

Progress display	Displays the progress information for each parameter. 6 — Device from which the result was output 18:35 — Time at which the result was output Indicates the status of the order. The meaning of each icon is as follows:
---	No order
	Order registration
	Analysis complete
	Analysis error
NB	Inadequate sample
	Cancel order
	Transition order
	Unknown analysis result
	Pending

Section 4: XN-9100 Instrument Setup

Instrument Setup - Settings

The instrument settings consist of [Analyser Setting] for the specific analyser type, and [IPU Setting] for configuring IPU application settings.

Analyser Settings

The analyser settings are used to configure analyser settings, sampler system settings, and flag settings.

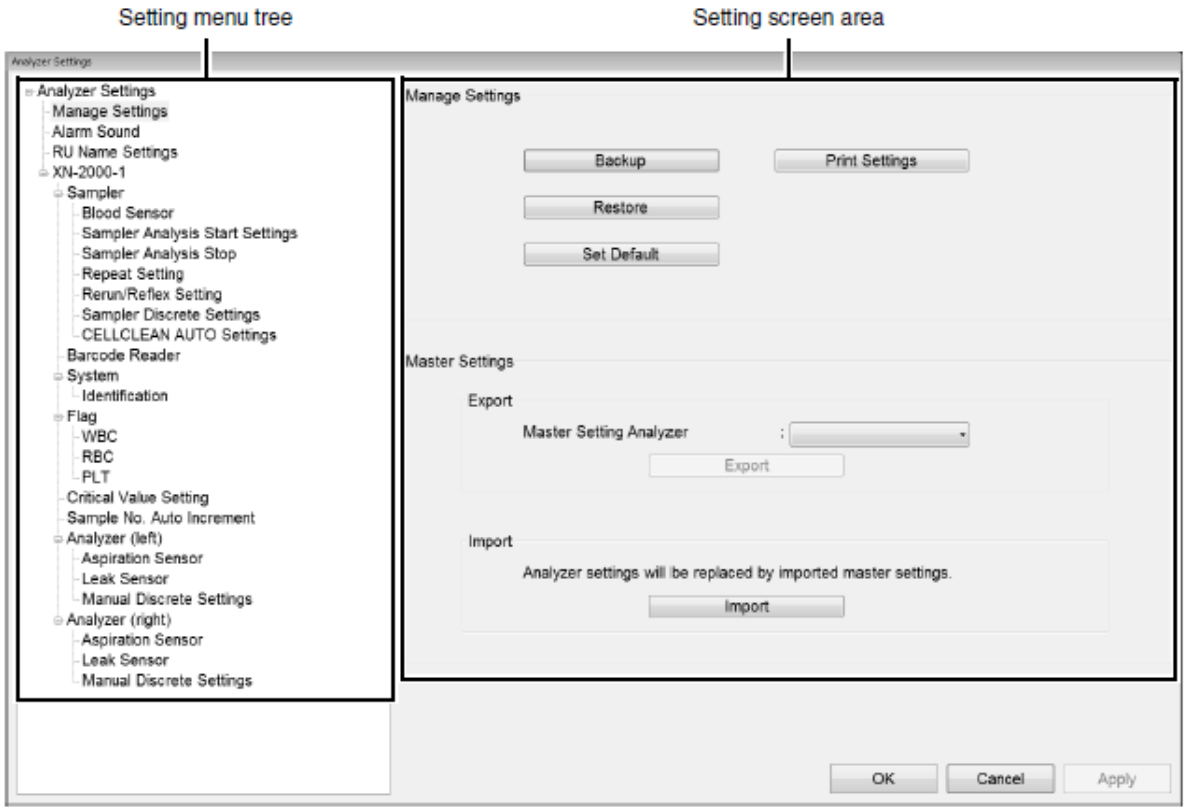
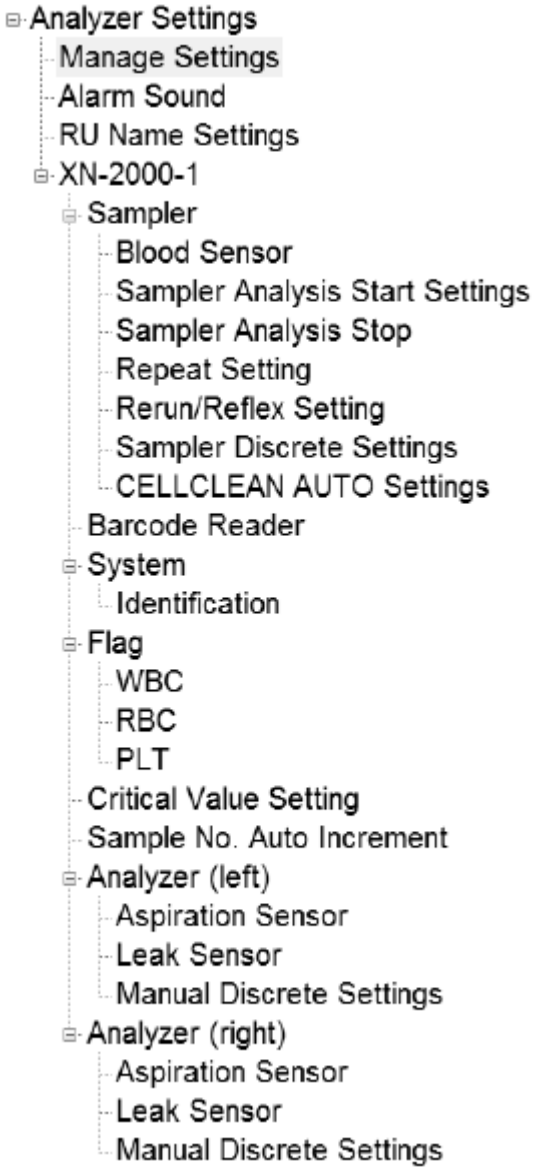


Figure 12- Analyser Setting Dialog Box

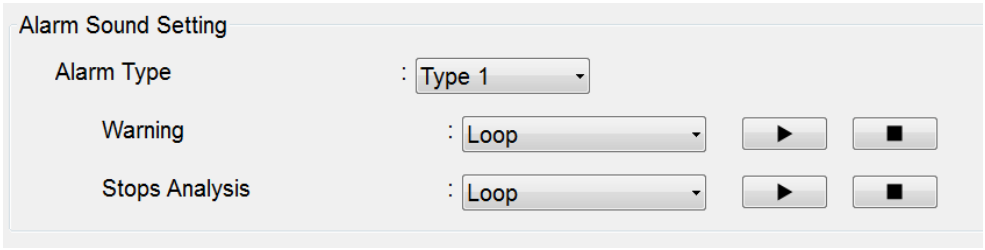
The items shown below, which appear in the setting menu tree of the [Analyser Setting] dialog box, can be configured.



Note:

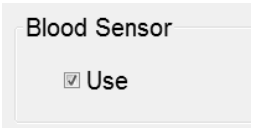
- *For the XN-9000/9100, when multiple analysers are connected to the IPU, the name of each analyser appears.*
  e.g: [XN-9100-2] and [XN-9100-3]
- *For XN-9100 where the analysers are connected to CV-55, right and left is in indicated in [Analyser].*
  e.g: [Analyser (right)] and [Analyser (left)] in the illustration at right.
- *For XN-9100 where the analysers are connected to CV-50, only [Analyser] appears.*

Alarm Sound

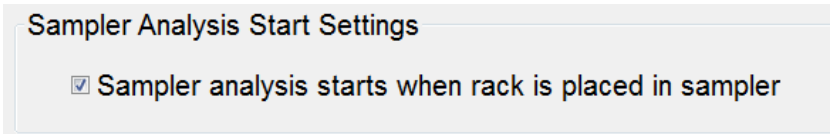


Sampler settings

[Blood Sensor] Specify whether or not the [Blood Sensor] is used. When used, the sensor detects whether or not there is blood in the sample tube. **[USE]**

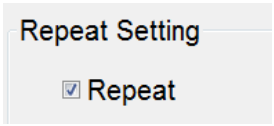


[Sampler Analysis Start Settings] Specify whether or not analysis is started automatically. **[USE]**

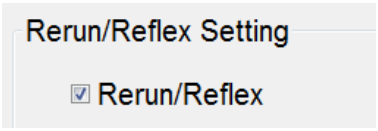


[Sampler Analysis Stop] Set the conditions for stopping analysis. **[UNTICK ALL]**

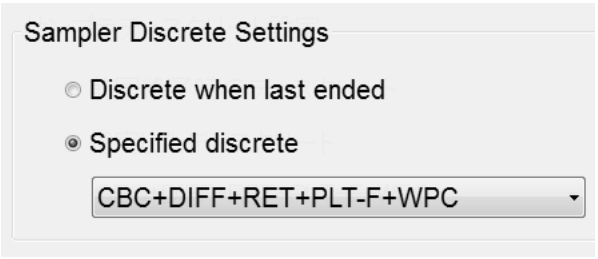
[Repeat Setting] Specify whether [Repeat] analysis is performed. **[USE]**



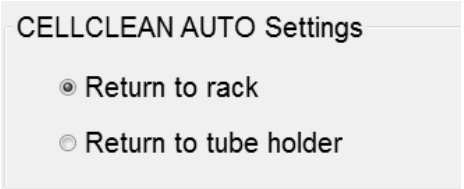
[Rerun/Reflex Setting] Specify whether or not [Rerun] analysis / [Reflex] analysis are performed. **[USE]**



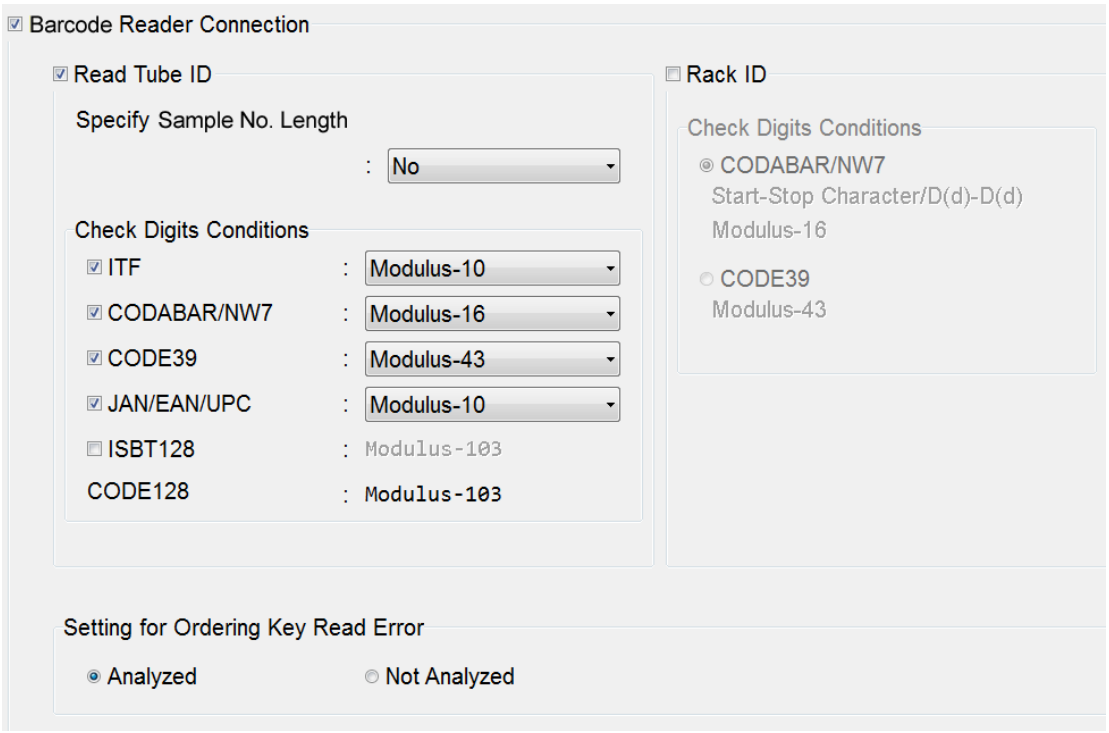
[Sampler Discrete Settings] Set the discrete used for sampler analysis. This is the startup default. **[DISCRETE: CBC+DIFF]**



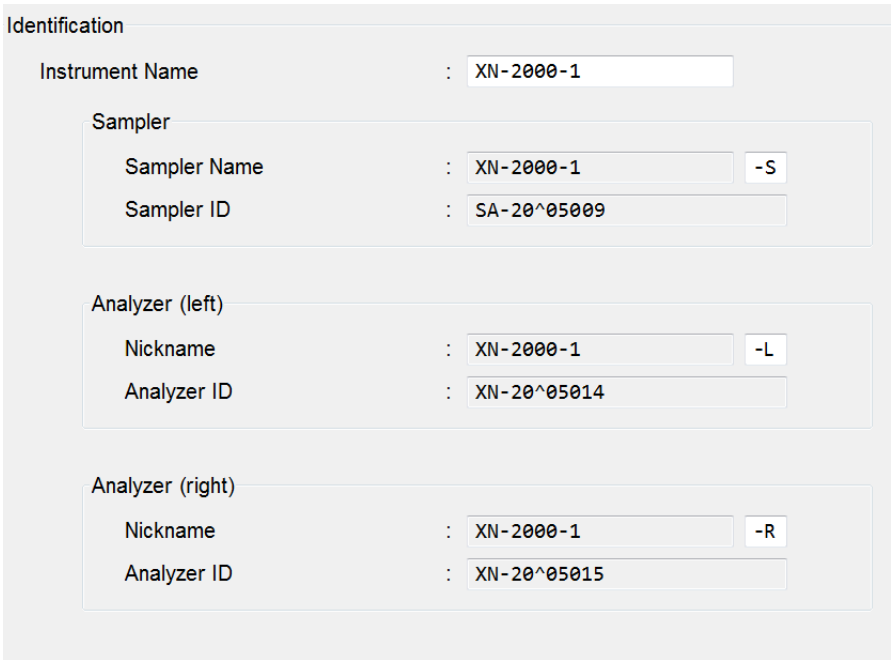
[CELLCLEAN AUTO Settings] Specify whether CELLCLEAN AUTO tube returns to rack or tube holder after aspiration. **[RETURN TO RACK]**



Barcode Reader



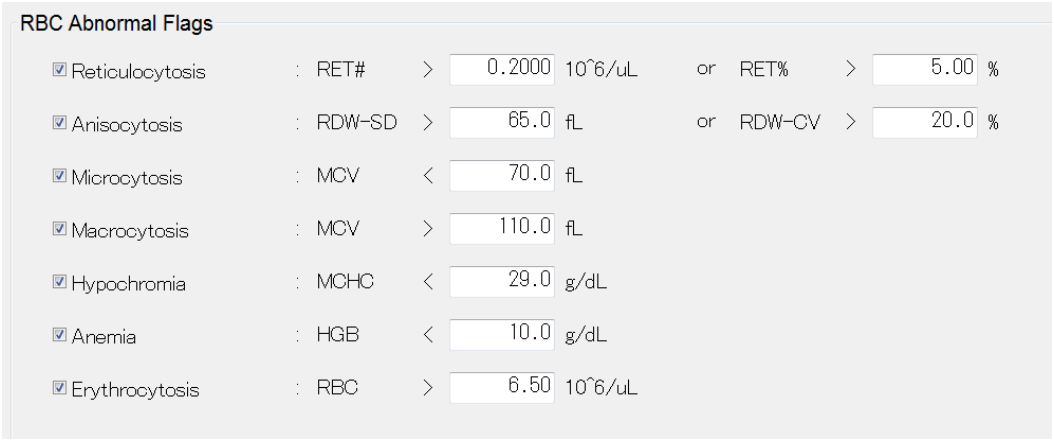
System



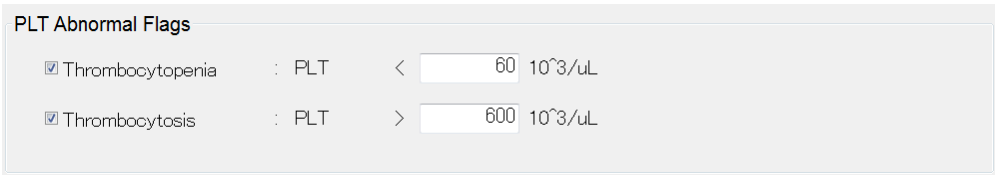
Flag

[WBC flag settings]

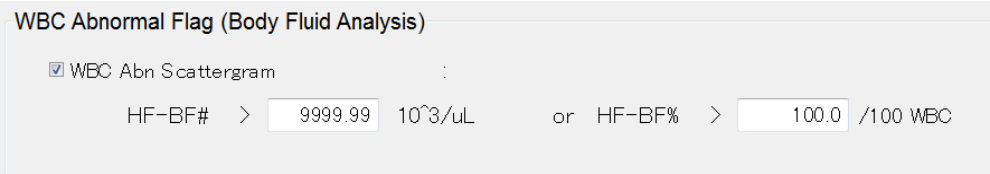
[RBC flag settings]



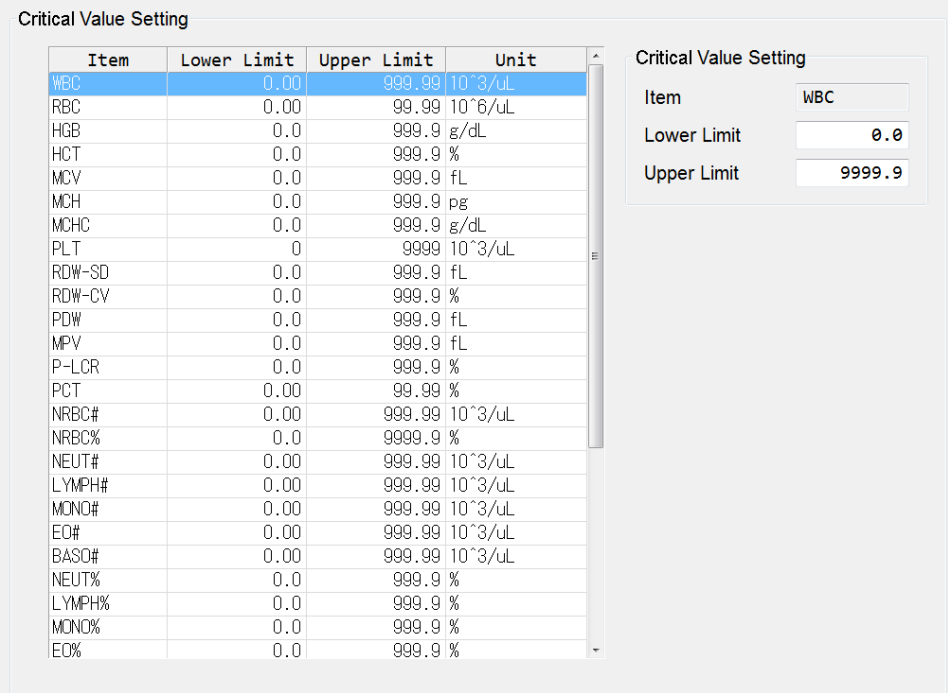
[PLT flag settings]



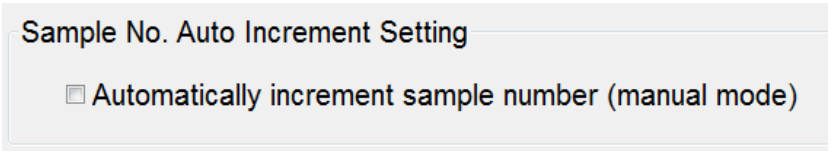
[WBC flag settings (body fluid)]



Critical Values setting

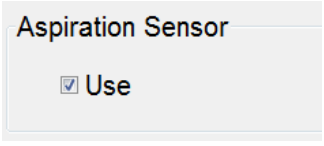


Sample number auto increment setting [OFF]



Analyser Settings

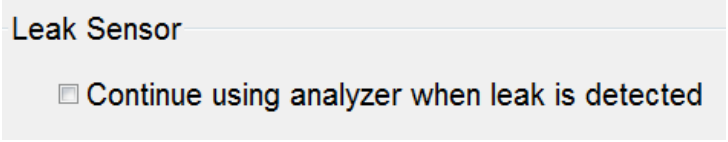
[Aspiration Sensor] Specify whether or not the Blood aspiration sensor is used. **[USE]**



Note:

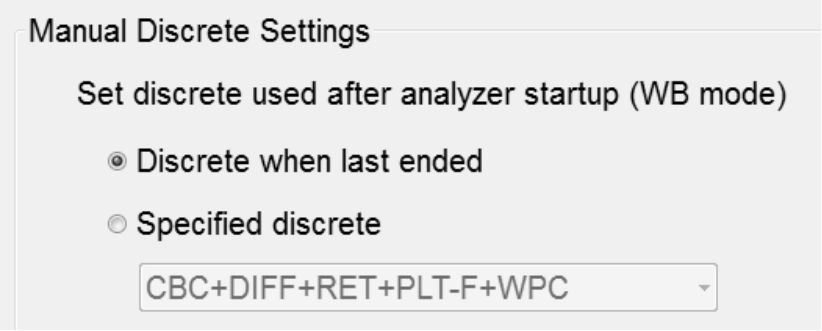
- *During [Pre-Dilution] mode, [Body Fluid] mode, [HPC] mode analysis, the blood aspiration sensor is always off, regardless of the setting.*
- *Not using the [Aspiration Sensor] may affect test results. For [Whole Blood] mode analysis, select [Use].*
- *If you know in advance that a blood sample will be very thin (such as that of a dialysis patient), deactivate the [Aspiration Sensor].*

[Leak Sensor] Specify whether use of the analyser is continued when a weak leak is detected. **[OFF]**

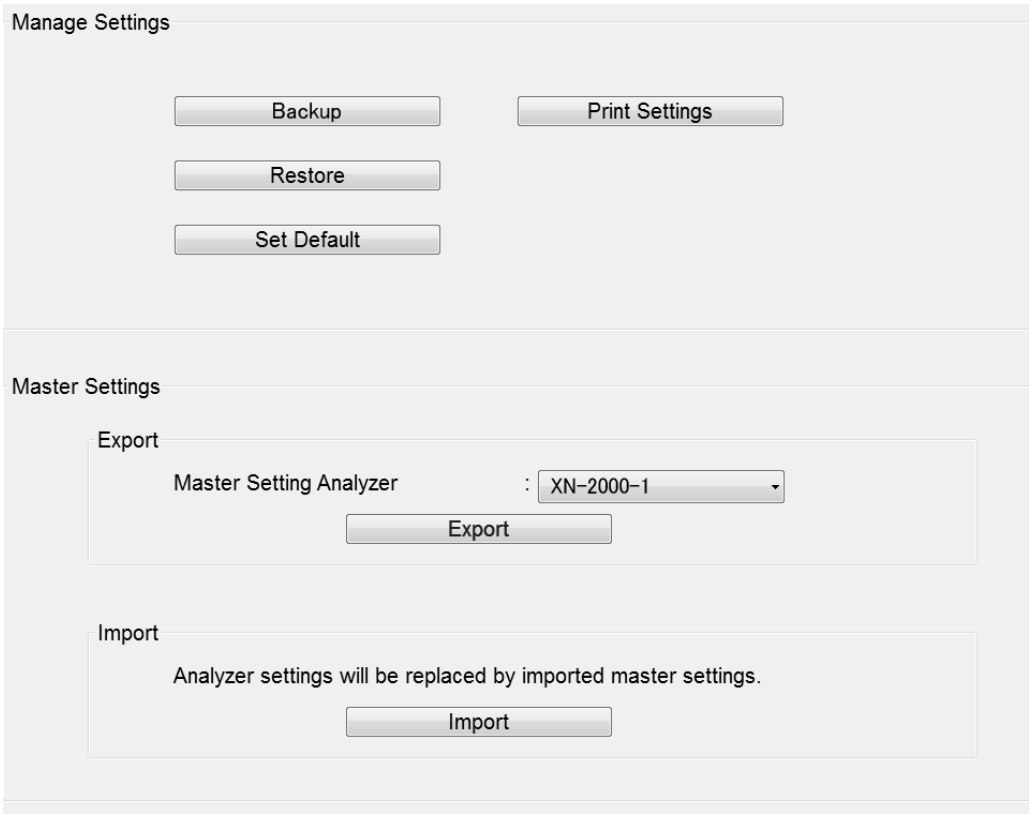


Caution!
Unless otherwise directed by your local RDA representative, keep the setting set to OFF.
If use is continued with the setting set to ON, the instrument and other devices may be damaged if leakage occurs.

[Manual Discrete Settings] Set the discrete used for manual analysis. This is the startup default setting. **[DISCRETE: CDC+DIFF]**



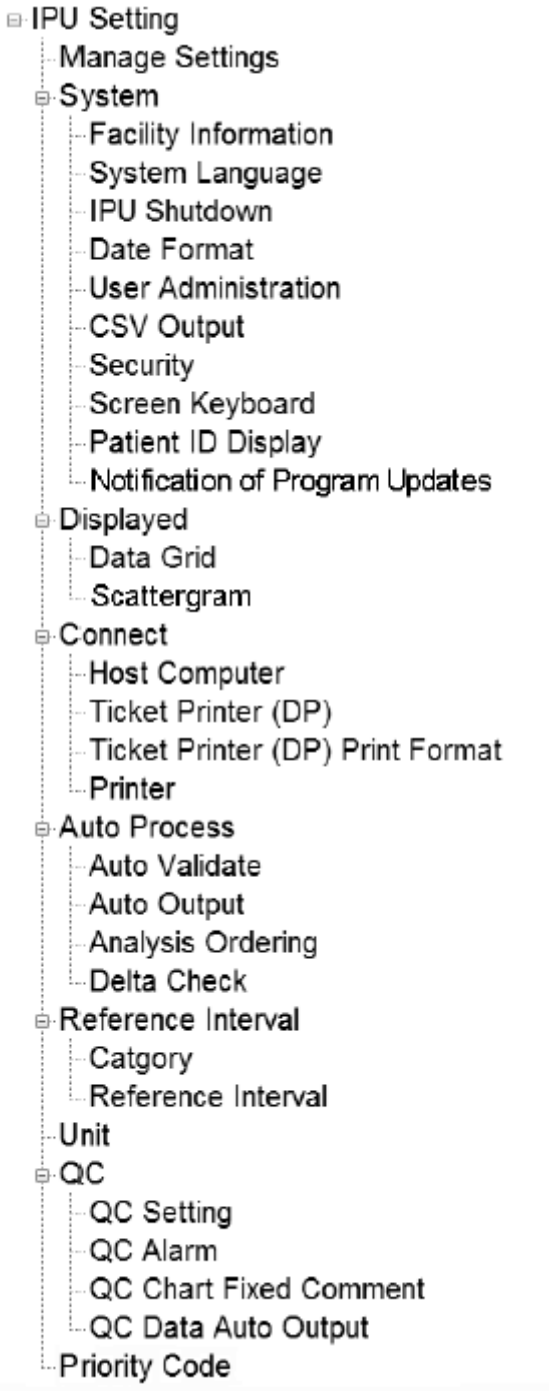
Manage settings



IPU Settings

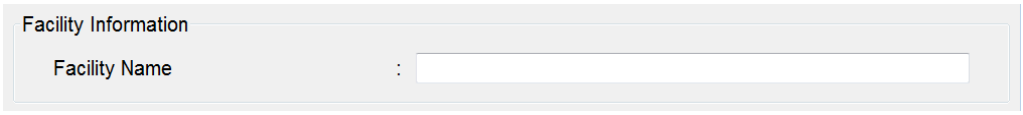
The system settings of the IPU, external device connection settings, and automatic processing settings can be configured in the IPU settings.

The items shown below, which appear in the setting menu tree of the [IPU Setting] dialog box, can be configured.

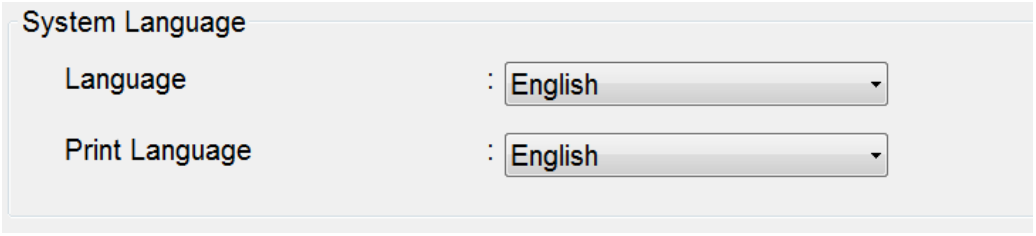


System settings

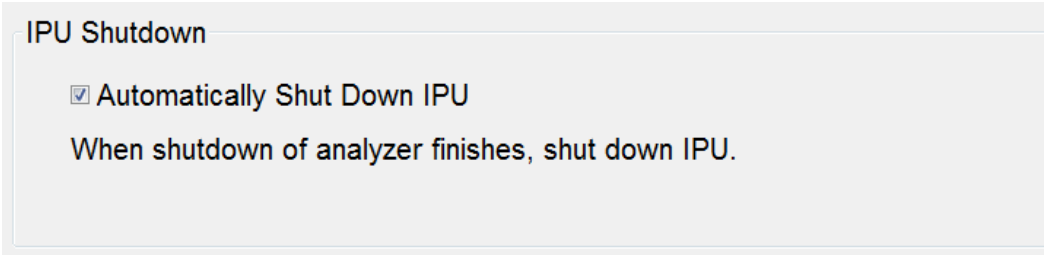
[Facility Information] Displays laboratory name on top of the GP printout reports.



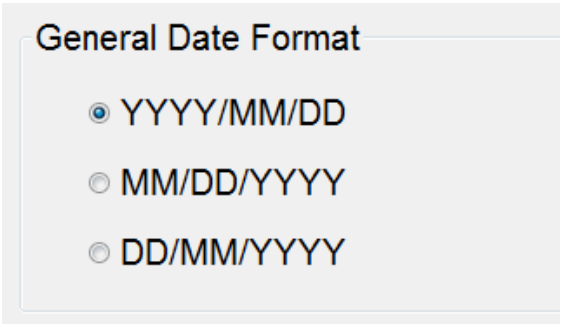
[System Language]



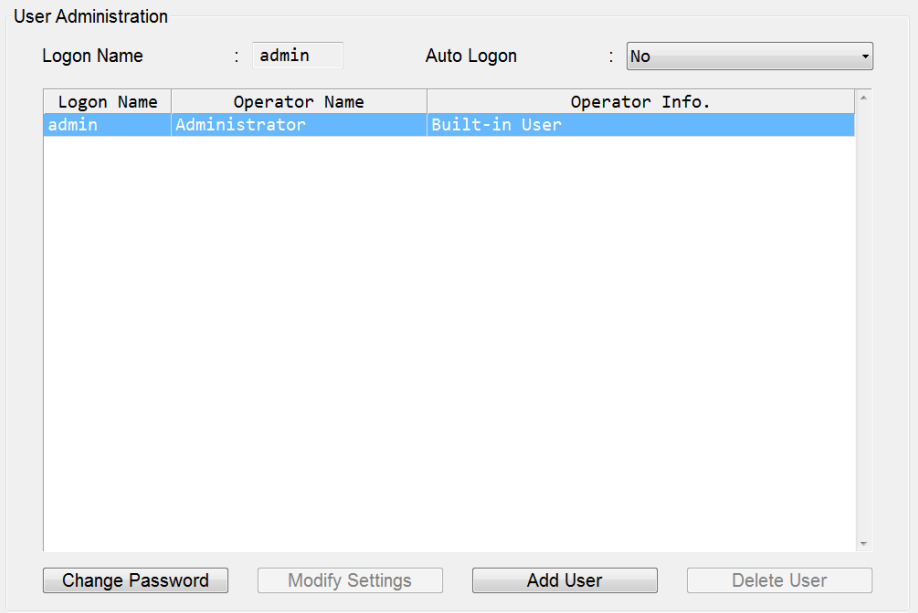
[IPU Shutdown] Specifies whether the IPU automatically shut down after the CellClean Auto Shutdown procedure **[USE]**

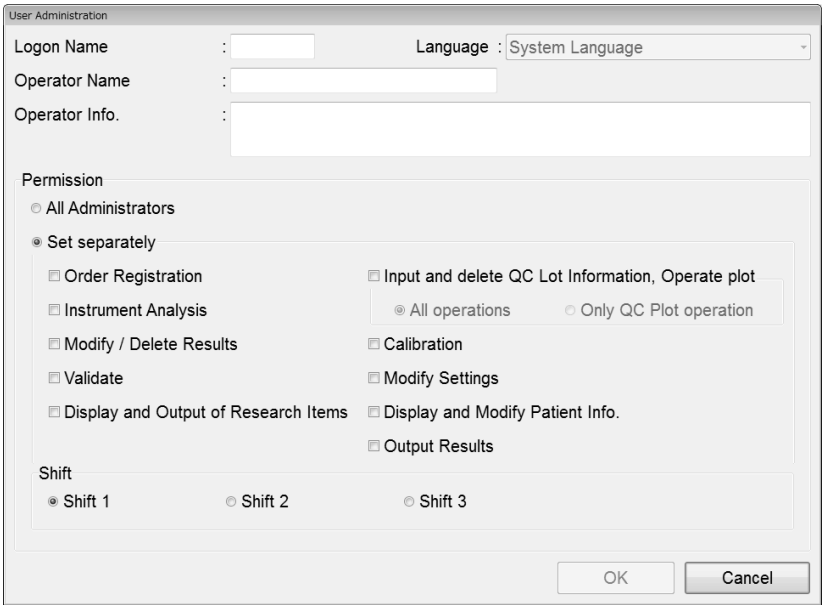


[General Date Format] **[DD/MM/YYYY]**

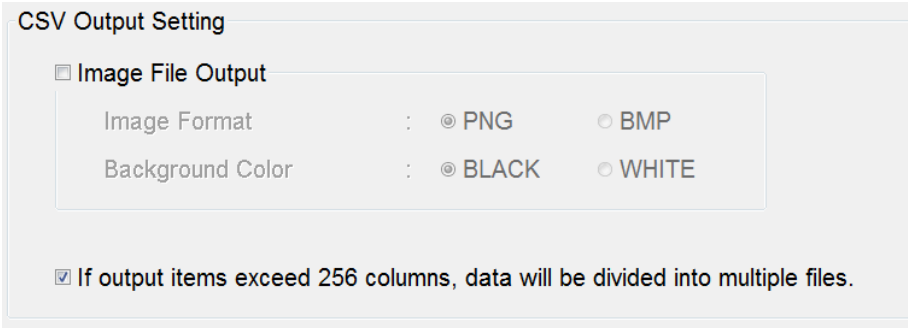


[User Administration]

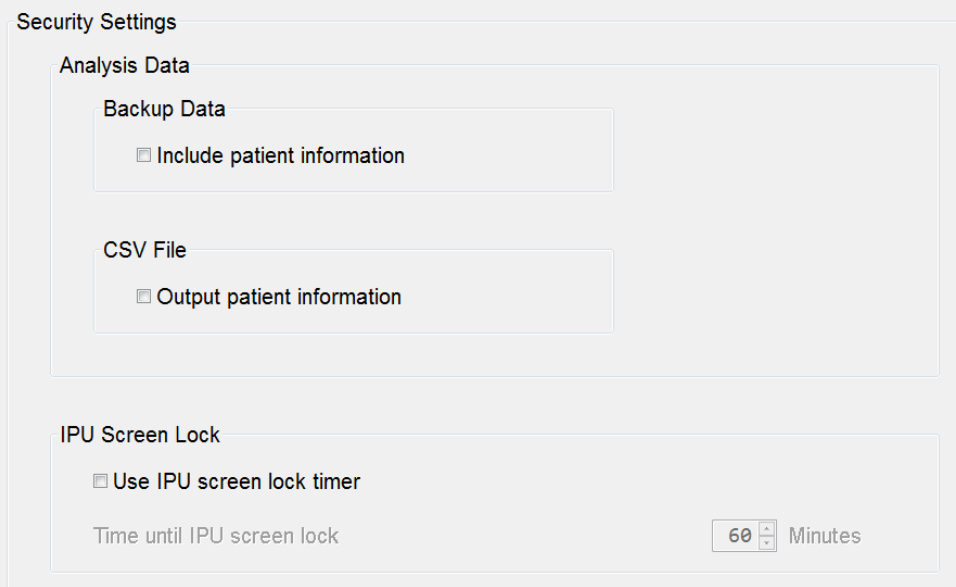




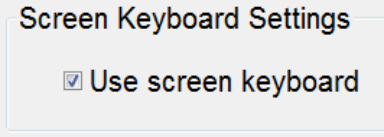
[CSV Output Setting] Specifies whether the scattergram/histogram images are output with csv backups and if multiple csv files is used. **[UNTICK ALL]**



[Security Settings] Specifies whether patient information is displayed when performing smp or csv backups and if IPU screen lock timer is used. **[UNTICK ALL]**

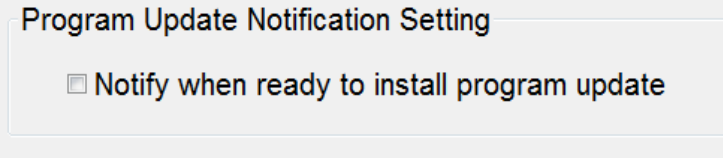


[Screen Keyboard Settings] Specifies whether the onscreen keyboard is used when an input field is selected. **[USE]**



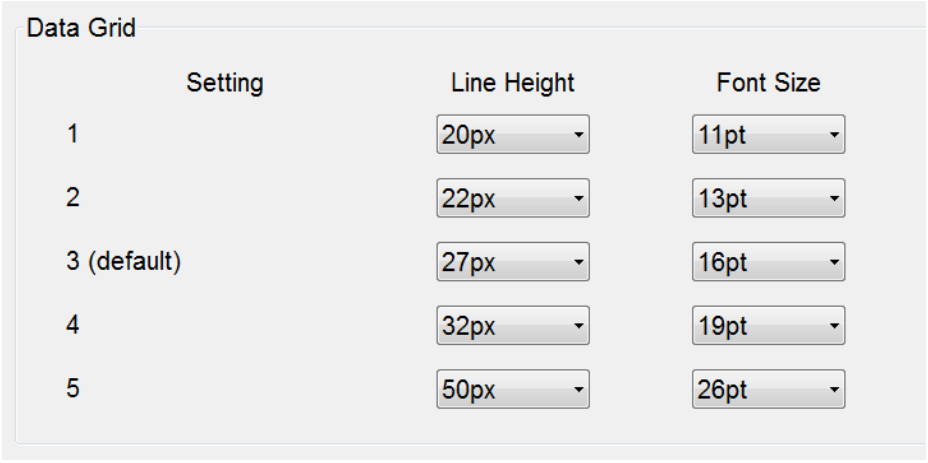
[Patient ID Display Settings] The patient ID displayed in the patient information area is always left-justified, regardless of the setting.

[Program Update Notification Setting] This function is not available. **[OFF]**

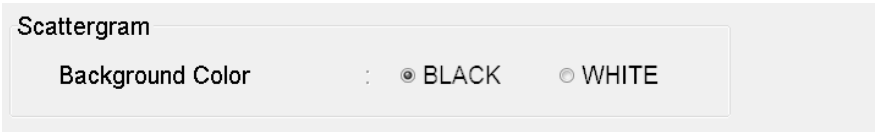


Display settings

[Data Grid] **[USE DEFAULT]**

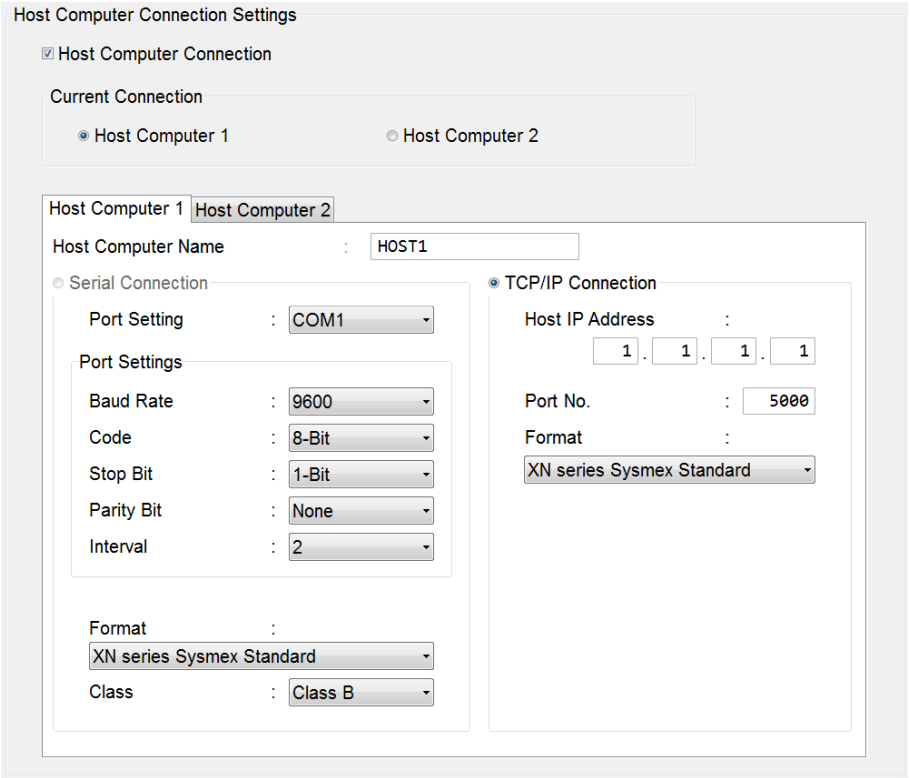


[Scattergram] A black or white background colour for the scattergram can be selected. **[BLACK]**

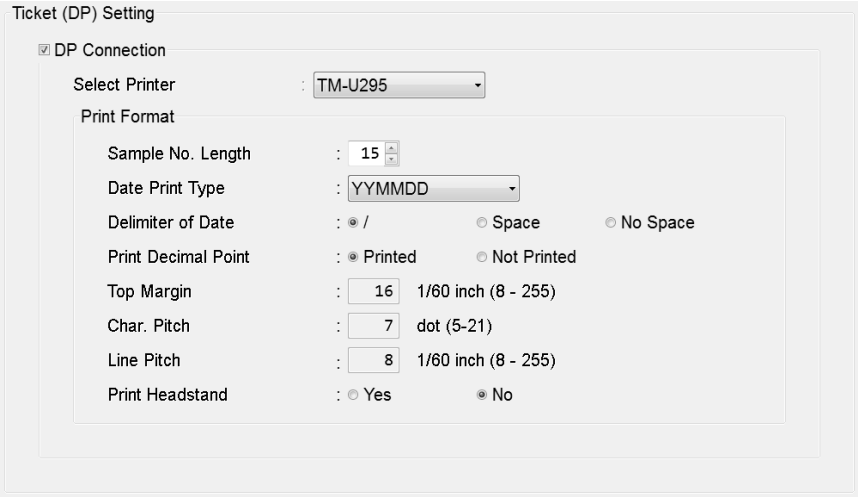


Connection settings

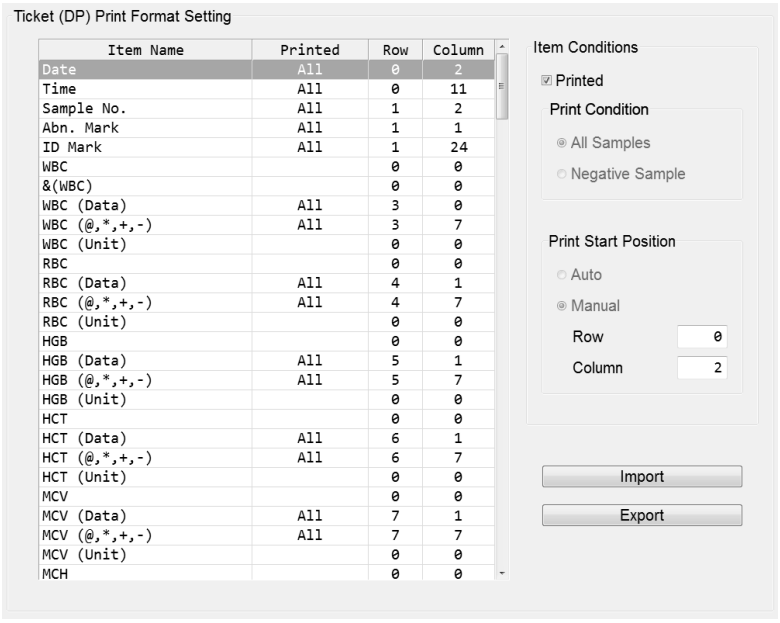
[Host Computer]



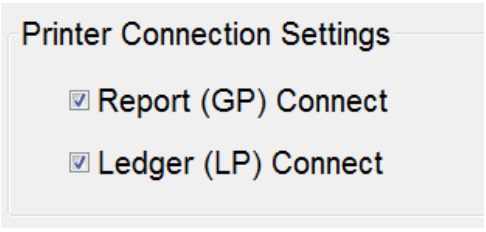
[Ticket Printer (DP)] **[UNTICKED]**



[Ticket Printer (DP) Print Format] **[SET DEFAULT]**



[Printer Connection Settings] Specifies connection to a graphic printer (GP) and list printer (LP). **[USE BOTH]**

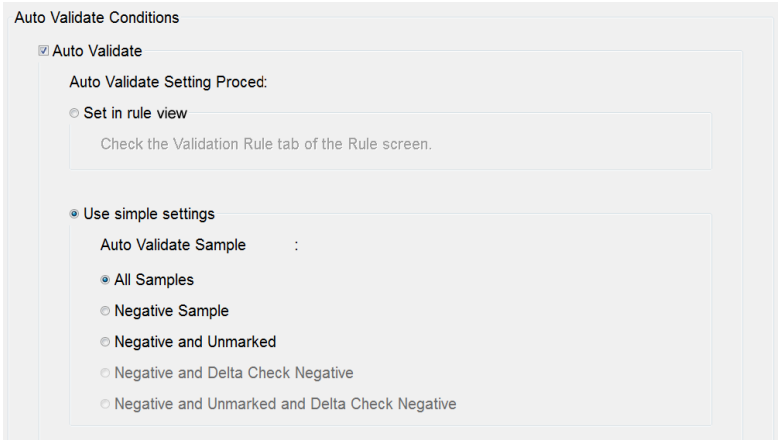


Automatic processing settings

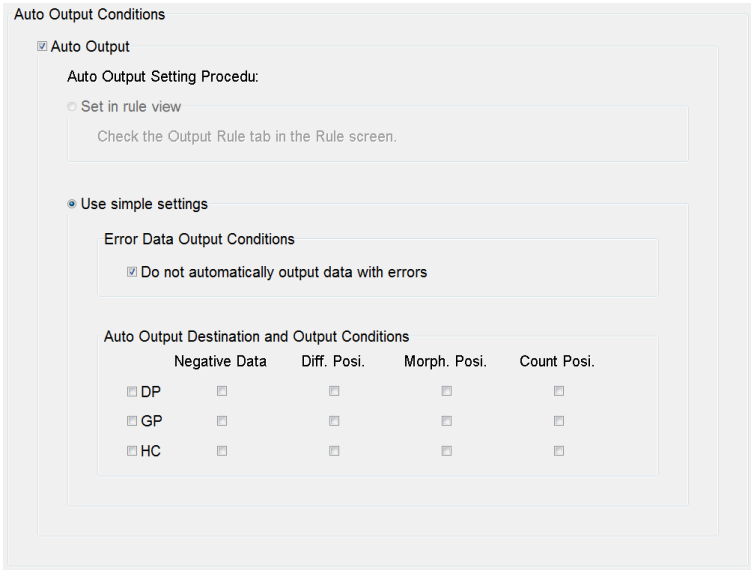
Note!

- *Only when setting the delta check, the items including "Delta Check Negative" are displayed.*
- *When auto validated samples are [All Samples], samples are validated regardless of the analysis mode.*

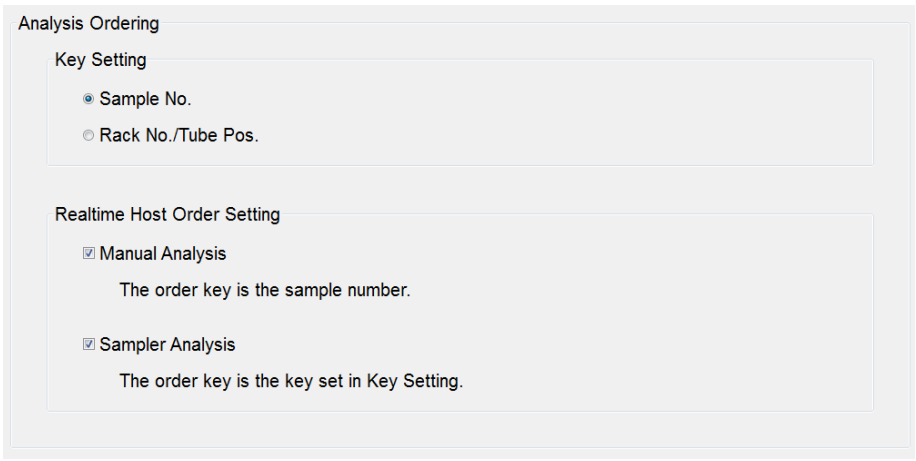
[Auto Validate] Specifies which results are validated in the Sample Explorer screen. **[TICK Auto Validate > Use simple settings > All Samples]**



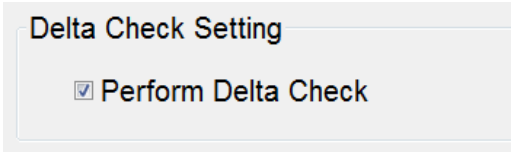
[Auto Output] Specifies the conditions and destination of results. **[TICK Auto Output > Use simple settings > TICK Do not auto output data with errors > TICK all HC boxes and GP boxes if printing]**



[Analysis Ordering] Specifies whether the Host is bidirectional and requests patient information and test orders when running in Manual or Sampler mode.

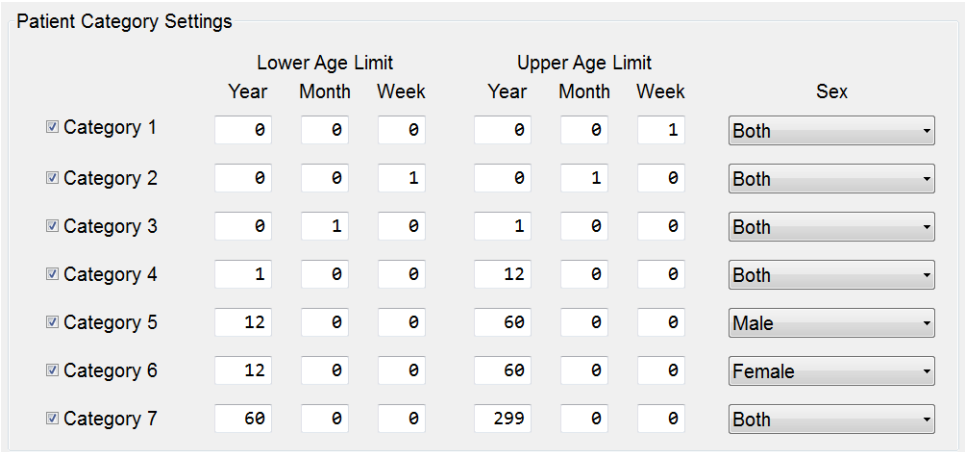


[Delta Check] Uses the patient ID as the keyword to compare recent analysis data with previous analysis data stored on board the IPU.

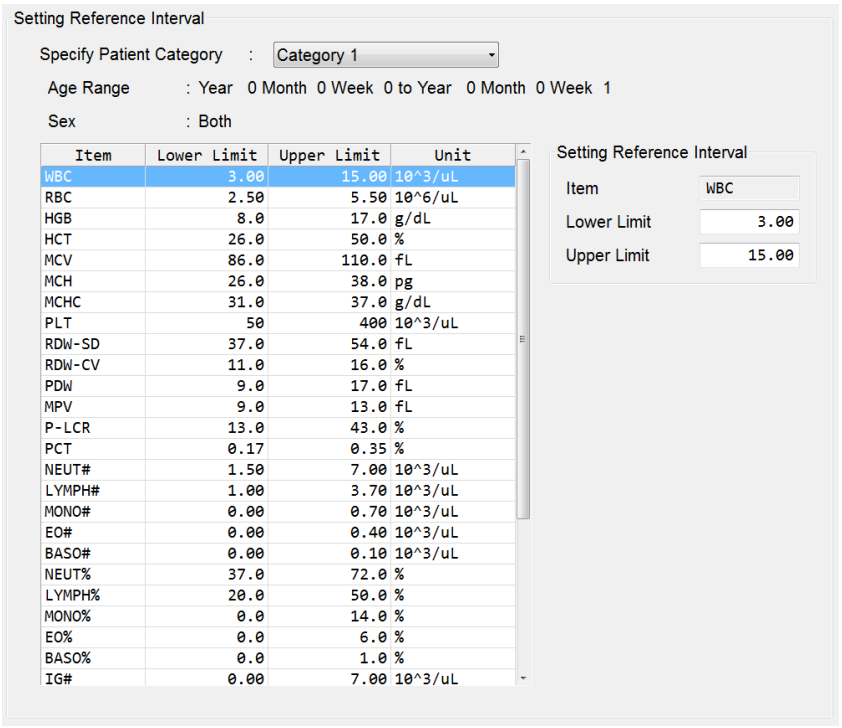


Reference interval settings

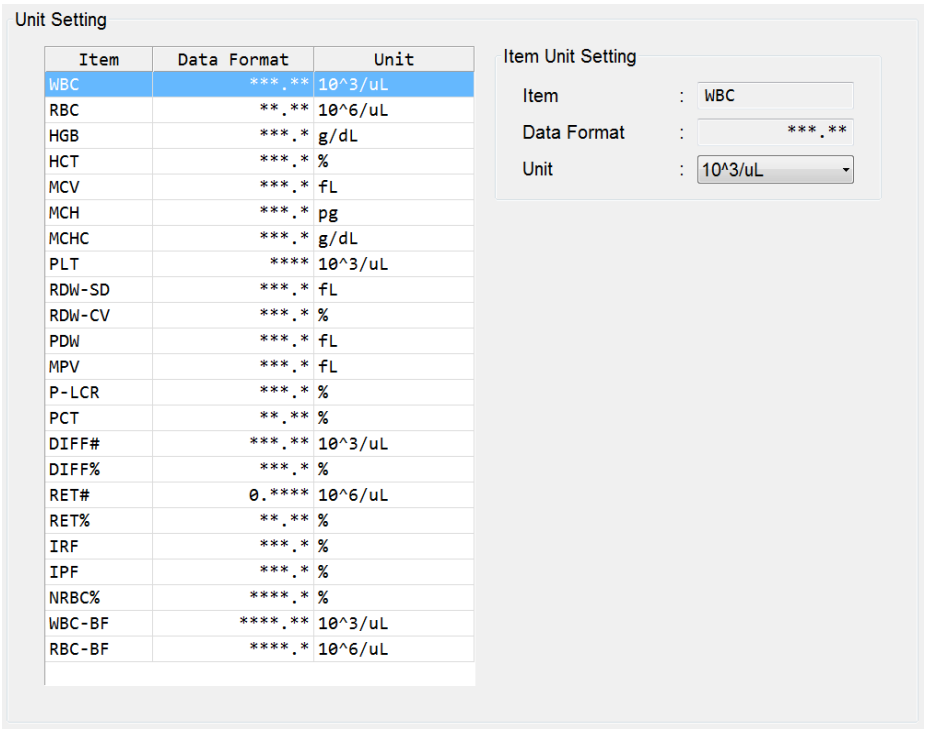
[Patient Category settings] Specify reference interval groups based on age and sex. **[UNTICK ALL]**



[Reference Interval] When the analysis data of an item exceeds the upper or lower limit, "+" or "-" will appear to the right of the data. **[SET UNIVERSAL]**

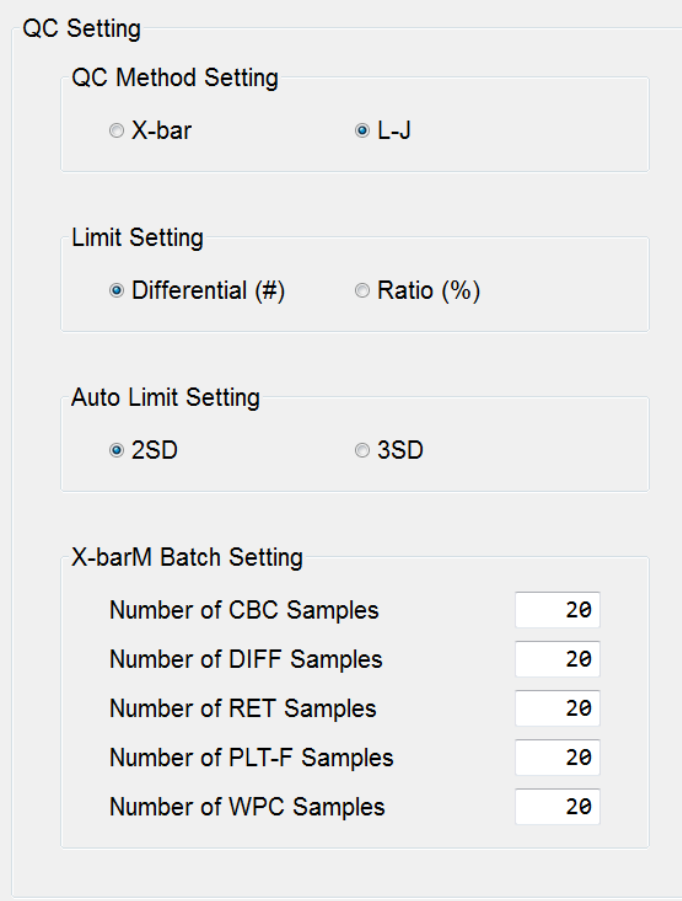


Unit settings (Unit)



QC settings

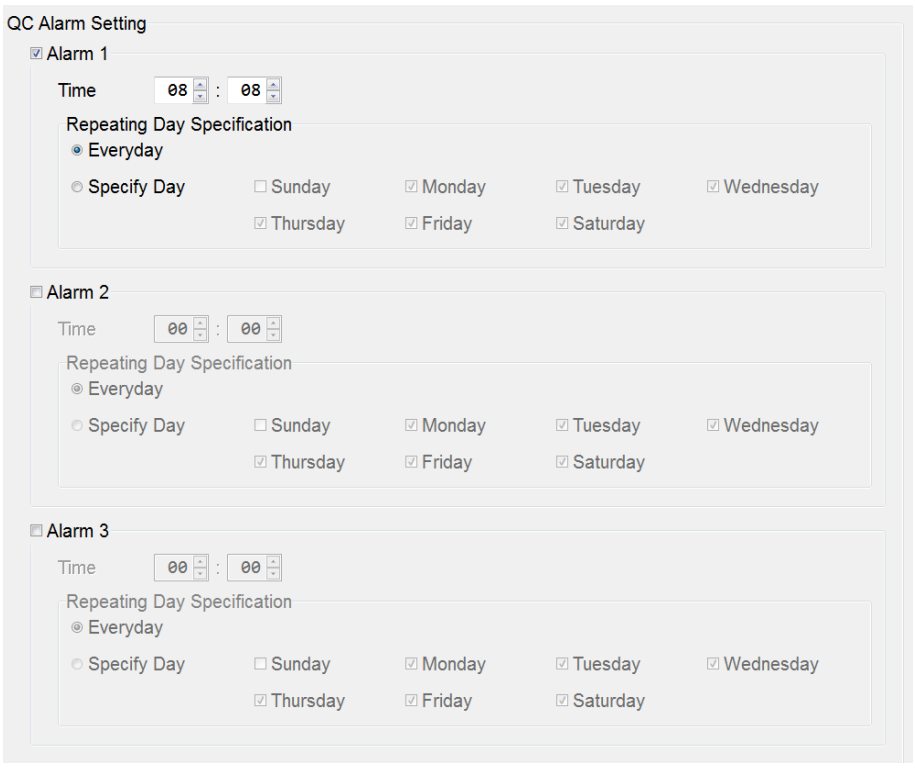
[QC]



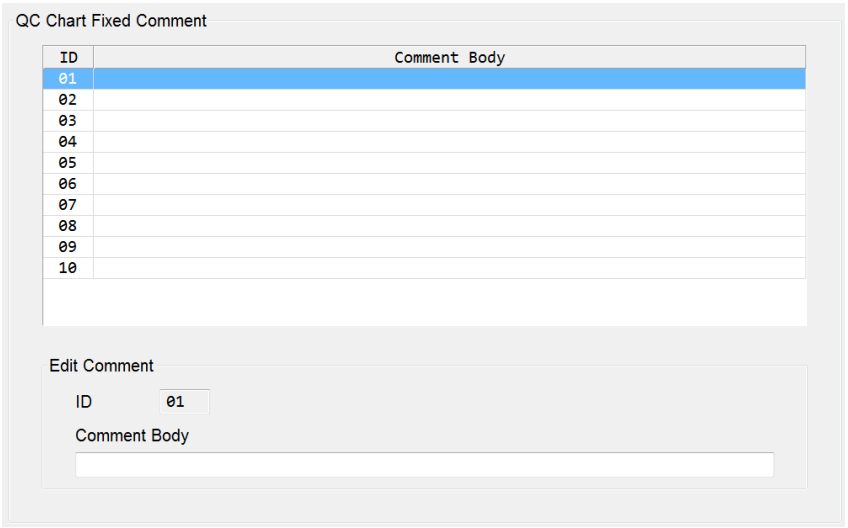
[USE L-J]

[USE DIFFERENTIAL (#)]

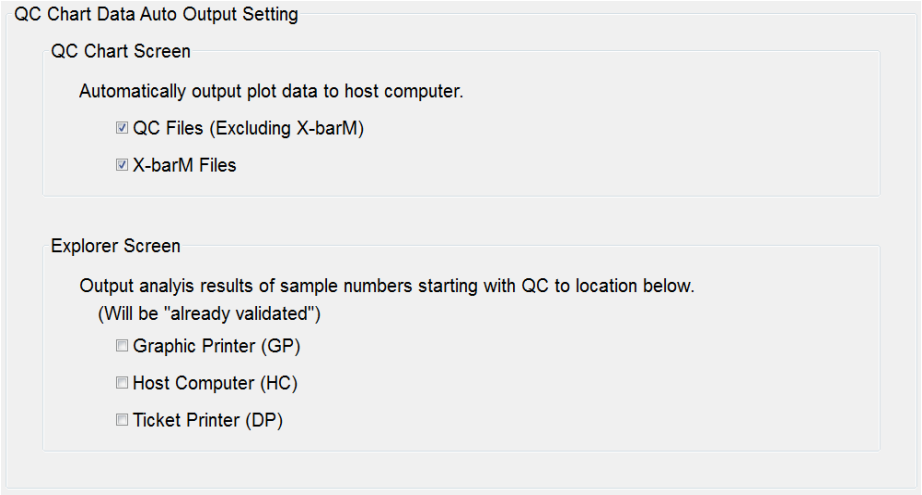
[QC Alarm]



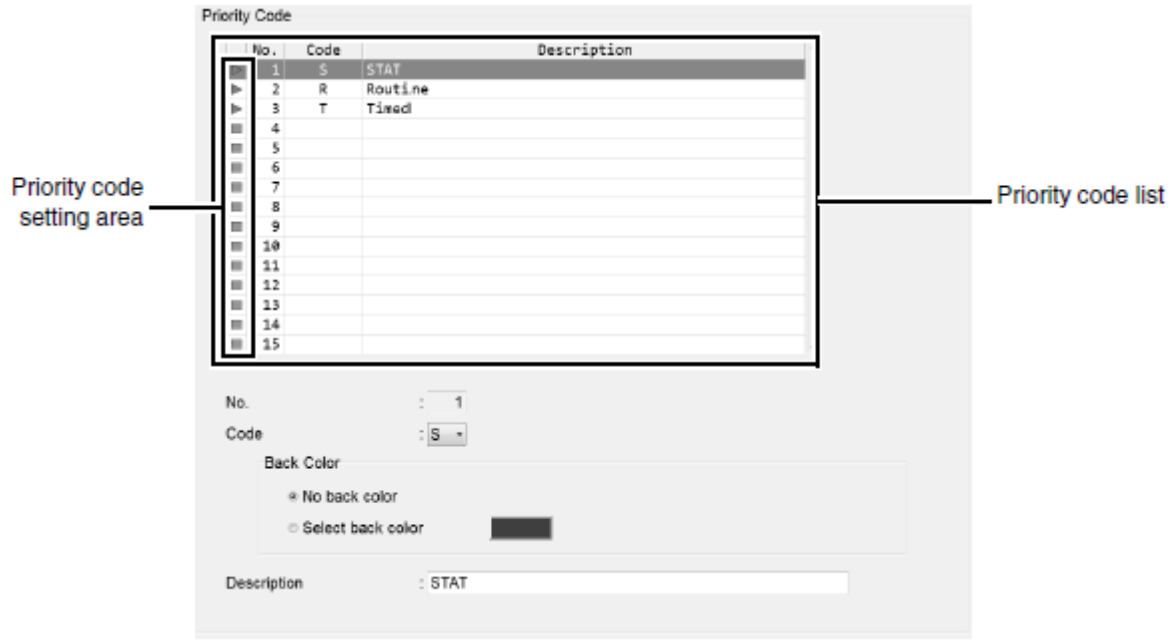
[**QC Chart Fixed Comment]** Create comments to display against the QC data points.



[QC Data Auto Output] Specifies whether the QC or X-barM files are automatically outputted to the host computer or validated for GP or HC output.



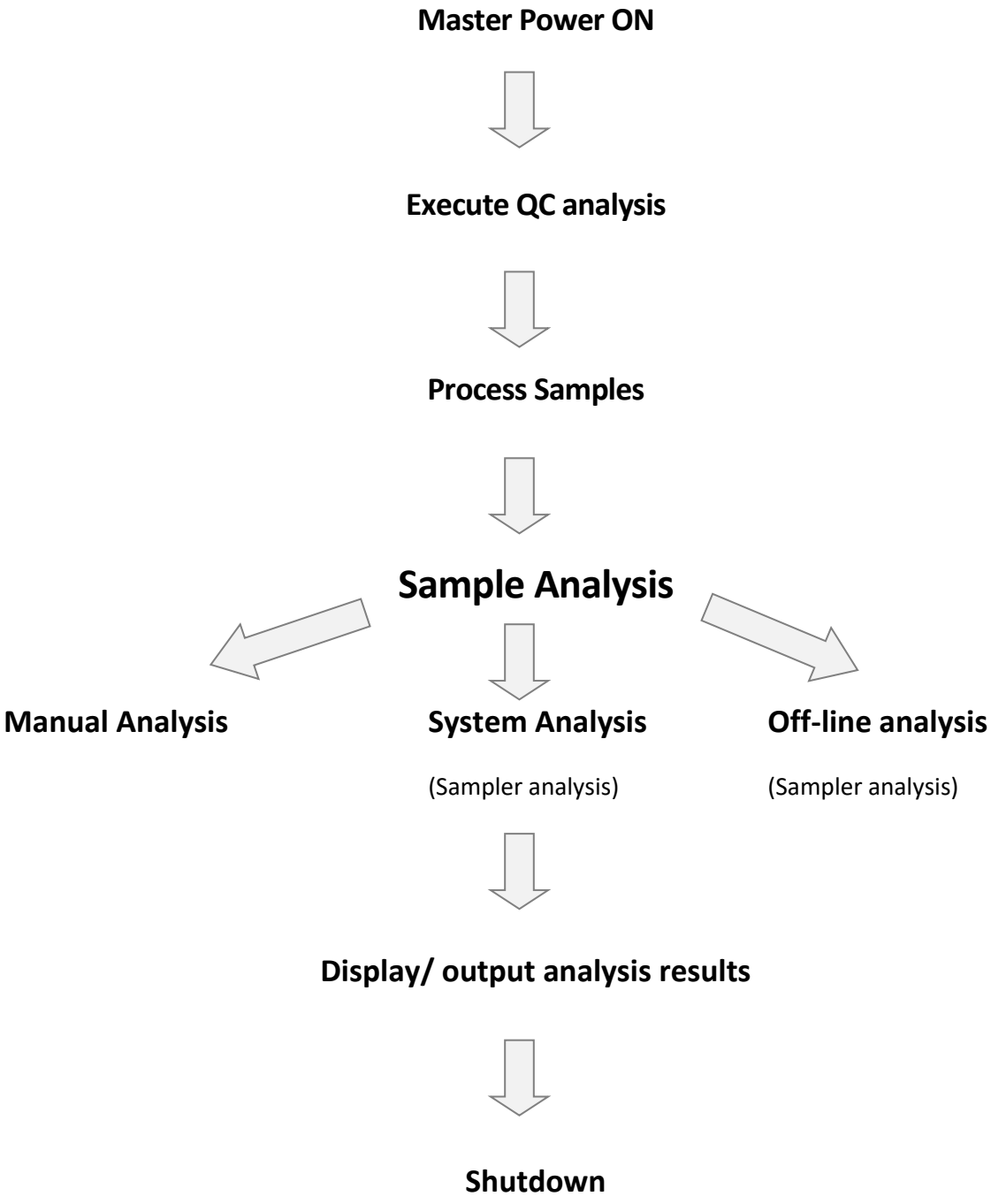
Priority Code



Manage settings

Section 5: XN-9100 Basic Operation

XN Overall flow of Operation



XN Start up

Before turning ON the instrument's power, check the following.

Instrument inspection

- Check the connection of tubes and cables.
- Check for any misplaced racks.
- Discard any waste fluid in the waste container (if applicable).
- Check if enough reagents are available for the daily routine analyses.

There are two types of Start-up;

Turning On entire system
Turning on power for specific analysers

Turning On Entire System

1. Verify that power switches on the individual conveyors, instruments and devices on the XN-9100 system are in the "ON" position.

   Leaving power switches to these systems in "ON" position will allow master start up switch on **BT or ST device** to control power to these devices.

2. Press master start up switch to turn on entire system and connected instruments and devices.

   Press the switch (green) in the position shown at right. The power for the entire instrument turns ON.

   Check the status of the device in the [Status] screen of the

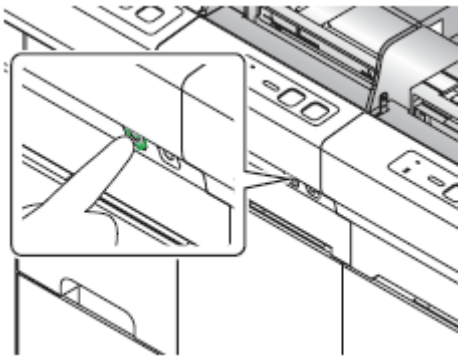


Figure 13- Master Start-up switch

The power for the connected devices is controlled by the Master start-up switch on the BT device. This allows you to keep the main power switches in the ON position at all times. Press the sampler switch (green) for entire system start-up.

Turning On Power for Specific Analyser

Power On can be specific to just the XN analysers when performing manual analysis only.

1. Verify that the main power switch of XN conveyor (CV-50/CV-55) is ON.

2. Turn on the IPU computer.

3. The power to the instrument turns ON, and the analyser runs a self-check. Wait until the test is finished, Logon to the IPU using the dialog box.

Log on to the IPU

When turning ON the instrument's power, the following logon dialog box appears in the IPU. Enter the required information and then click [OK] to log on to the instrument.

If you click [Abort], logon is not performed, and the IPU program exits.

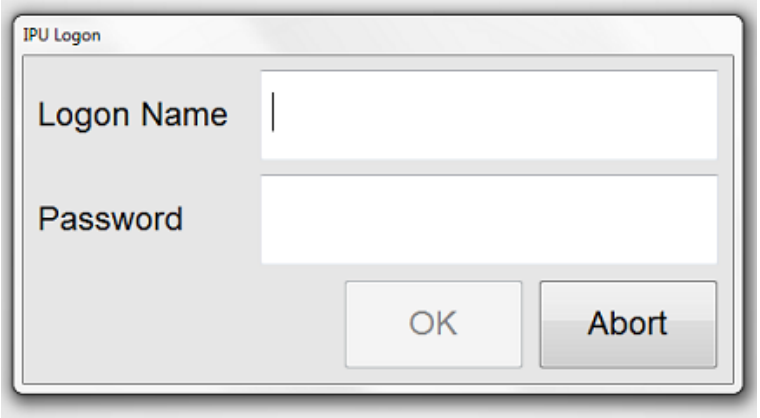


Figure 14- IPU Logon

XN Execution of analyser self-check

Self-check runs automatically once the system is powered ON

- Self-check runs for 10 minutes
- Self-check consists of the following:
    - Initialization of the mechanical parts
        - Homing of the mechanical parts and check of the hydraulic parts
    - Rinse
        - Rinse of the analyser, up to three rinse will automatically take place
    - Waiting for temperature stabilization
        - System will wait until the temperatures are stable
    - Background check
        - Performs analysis of a sample without aspirating samples
        - This is to verify the effects of the auto- rinse
        - can be repeated up to 3 times
        - Any results falling out side of allowable limits will be marked with (!)

XN Analysing Samples

XN-9100 supports the following sample types.

- **Whole blood**
- **Pre- diluted**
- **Body fluid analysis**
- **HPC**

Sample Volume

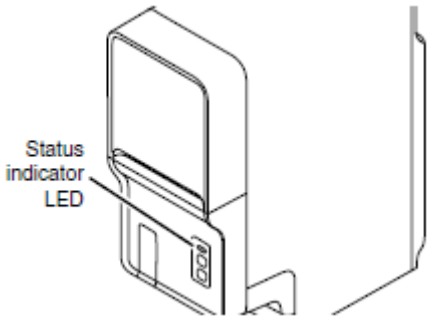
Type of analysis	Specimen	Tube type	Sample setting posittion	Manual analysis menu (Cap Open)	Aspirated volume	Minimum sample volume
Sampler	WB	Closed tube	Sample rack	***	88µL	1mL
Manual	WB	Closed tube	Normal tube holder	OFF	88µL	1mL
		Open tube	Normal tube holder	ON	88µL	300µL
		Open micro tube	Micro tube holder	***	88µL	160µL
Manual	PD	Open tube	Normal tube holder	ON	70µL	300µL
		Open micro tube	Micro tube holder	***	70µL	160µL
Manual	BF	Open tube	Normal tube holder	ON	88µL	300µL
		Open micro tube	Micro tube holder	***	88µL	160µL
Manual	WB(HPC)	Open tube	Normal tube holder	ON	190µL	400µL
		Open micro tube	Micro tube holder	***	190µL	260µL
Manual	"hsA"	Open tube	Normal tube holder	ON	200µL	400µL
		Open micro tube	Micro tube holder	***	200µL	260µL

Executing Sample Analysis (XN)

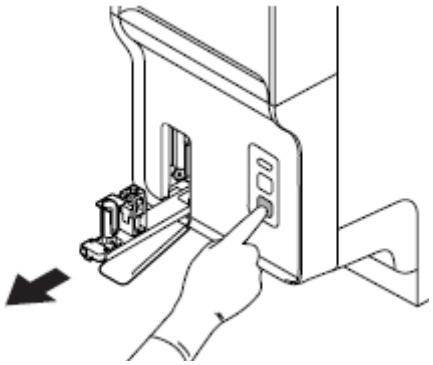
XN Manual analysis

Follow the steps below to perform manual mode analysis on whole blood, diluted blood and STAT samples.

1. Check the Status indicator LED on the analyser is green.



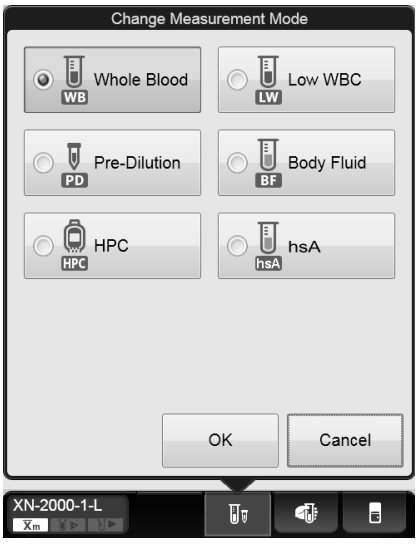
2. If the tube holder has not ejected out, press the Grey mode switch.



3. Click the Change Analysis Mode button on the control menu.

   - specifying the analysis mode:

   [Whole blood]
   [Low WBC]
   [Pre-Dilution] Select this when using 1:7 diluted samples
   [Body Fluid]



4. Click [OK].

5. Click on the Manual Analysis button on the control menu.

6. Use the hand-held barcode reader to input the sample number.
   If checkbox [Read ID] is selected, [Sample No.] input is not necessary

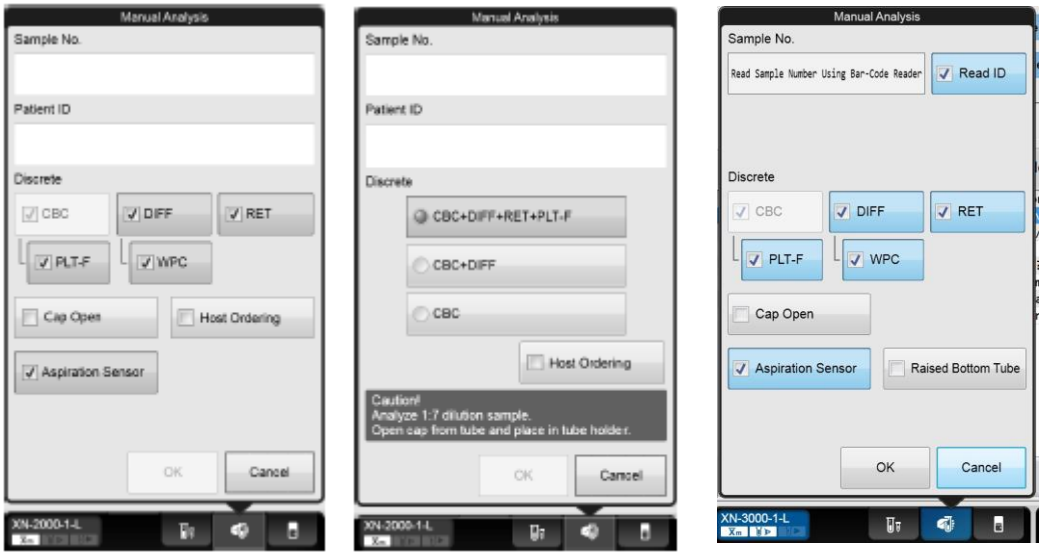
7. Select the [Discrete] check marks for the discrete tests to be performed

8. Select the [Cap Open] check mark to perform a micro blood. This enables you to minimize dead volume

9. [Query to Host] This only appears if real-time query is set to ON

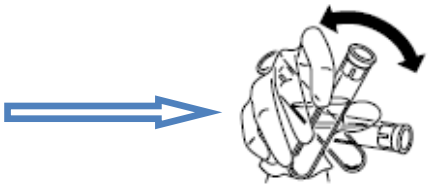
10. [Aspiration Sensor] Enables/disables the Blood Aspiration Sensor.

11. Select “Raised Bottom Tube” (RBT) option if, sample was collected in Microtube MAP.



12. Click [OK].

13. Mix the sample tube as shown.



e.g. Normal sample tube

14. Place the sample tube in the tube holder.

There are 2 sample tube holders;

(1) Normal sample and RBT tube holder
(2) Micro collection tube holder

When performing micro analysis place the sample tubes after removing the cap. When inserting a micro collection tube, insert the tube all the way in so that the bottom of the tube contacts the base of the holder.

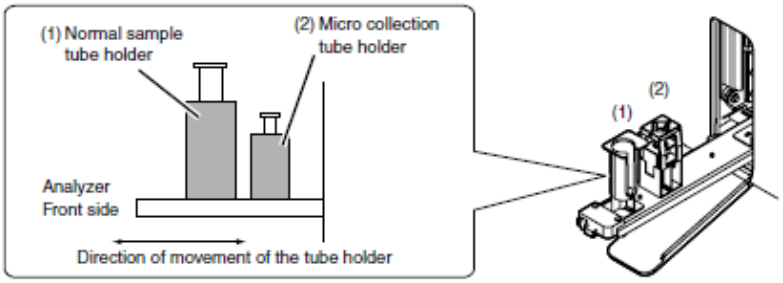
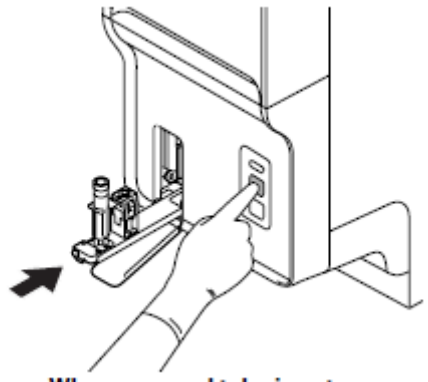


Figure 16- Sample tube Holder

15. Press the start switch on the analyser.



e.g. When a normal tube is set

16. Remove the sample after analysis is finished and sample tube is ejected.

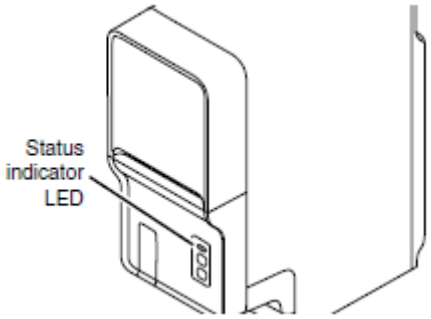
The instrument is equipped with a Blood Aspiration Sensor. However, there is a possibility that correct results may not be obtained if the sample volume is low and the sensor could not detect a "Short Sample" or "Sample Not Asp Error".

XN Body fluid analysis

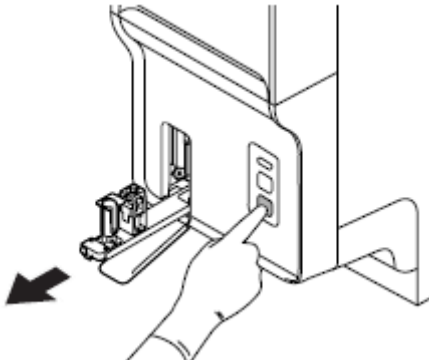
The body fluid analysis can only be performed if the instrument has BF analysis capabilities.

Follow the steps below to perform body fluid analysis.

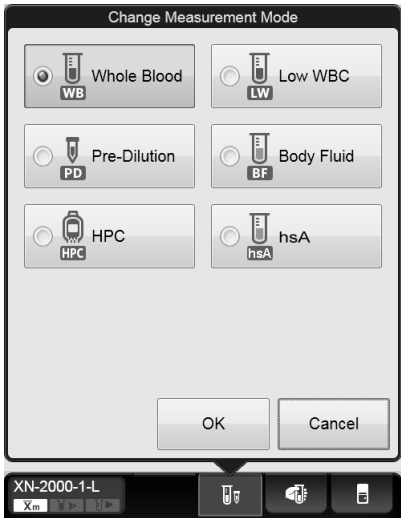
1. Check the Status indicator LED on the analyser is green.



2. If the tube holder has not ejected out, press the Grey mode switch.



3. Click the Change Analysis Mode button on the control menu.

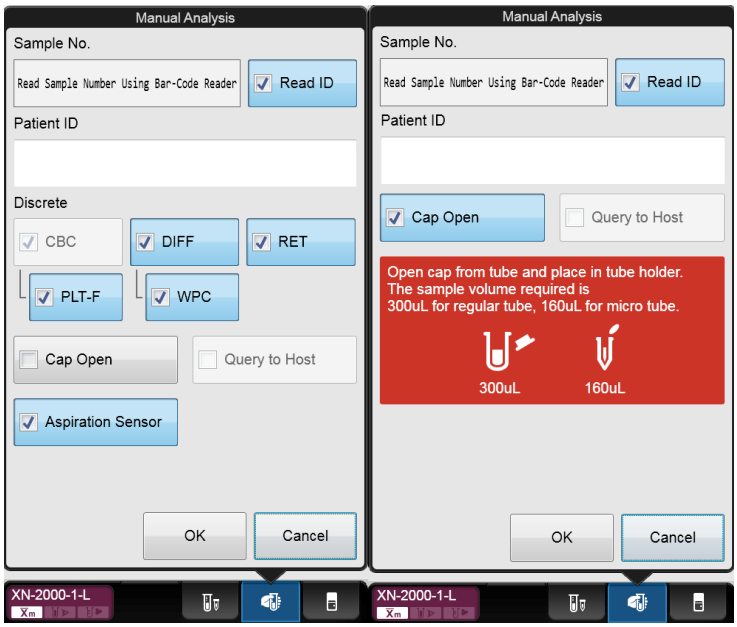


4. Click [Body Fluid].

5. Click [OK].

The instrument will automatically perform a background check after body fluid analysis is selected. If the background values that result from the background check are under the allowable values, the Status indicator LED lights green and the analyser enters the body fluid analysis preparation done state.

6. Click on the Manual Analysis button on the control menu.



7. Input [Sample No.] either by manually entering the sample, or it is not necessary if the [Read ID] checkbox is selected.

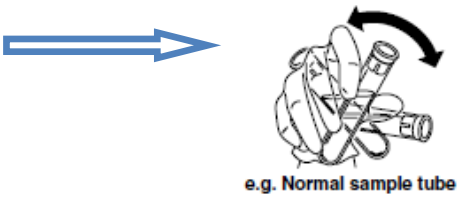
8. Select the [Discrete] check marks for the discrete tests to be performed

9. Select the [Cap Open] check mark to perform a micro blood. This enables you to minimize dead volume

10. [Aspiration Sensor] Enables/disables the Blood Aspiration Sensor.

11. Click [OK]

12. Mix the sample tube as shown.



13. Place the sample tube in the tube holder.
There are 2 sample tube holders;
(1) Normal sample tube holder
(2) Micro collection tube holder

When performing micro analysis place the sample tubes after removing the cap. When inserting a micro collection tube, insert the tube all the way in so that the bottom of the adaptor.

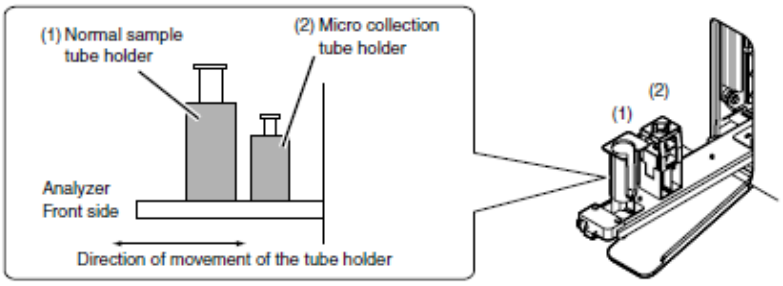
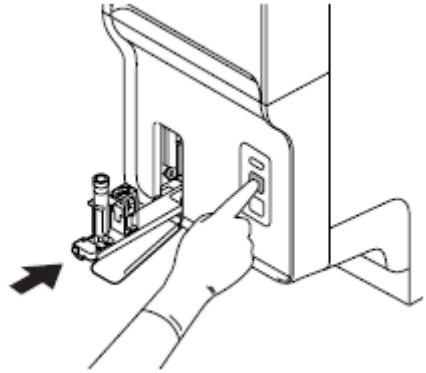


Figure 15- Sample tube Holder

14. Press the start switch on the analyser.

The tube holder slides in, and the aspiration of the sample begins.



e.g. When a normal tube is set

15. Once the analysis finishes, the tube holder slides out. Remove the sample.

16. Press the mode switch.

Allowable limits for Background check performed prior to Body Fluid mode analysis:

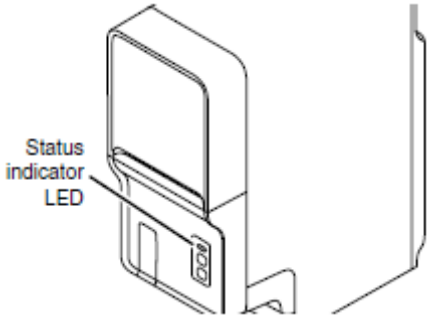
WBC-BF	*0.001×10^9 / L*
RBC-BF	*0.003×10^{12} / L*

XN HPC analysis

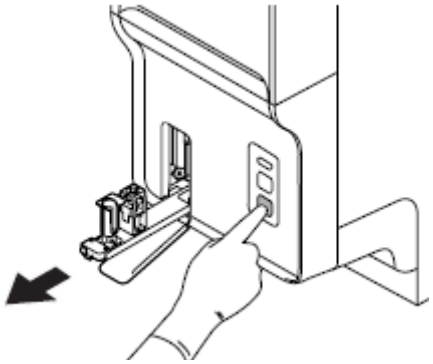
The HPC analysis can only be performed if the instrument has HPC analysis capabilities.

Follow the steps below to perform body fluid analysis.

1. Check the Status indicator LED on the analyser is green.



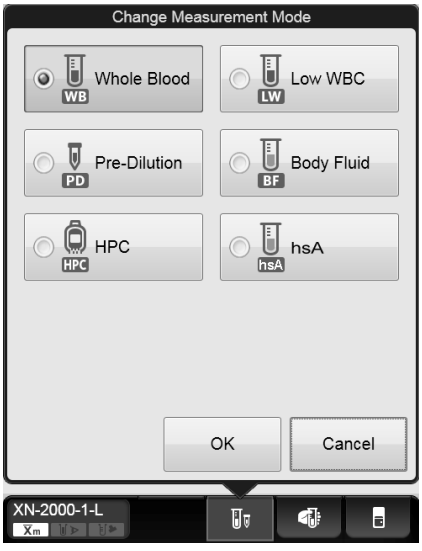
2. If the tube holder has not ejected out, press the Grey mode switch.



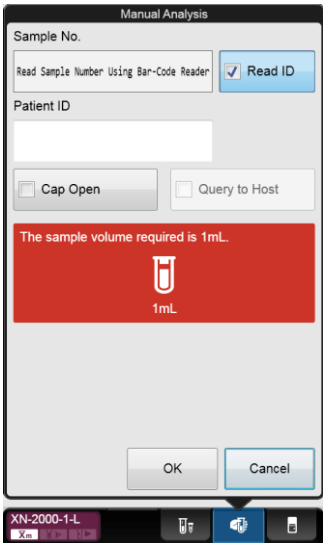
3. Click the Change Analysis Mode button on the control menu.

4. Click [HPC].

5. Click [OK].



6. Click on the Manual Analysis button on the control menu.

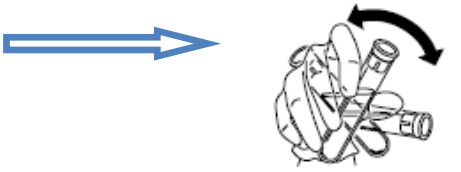


7. Input [Sample No.] either by manually entering the sample, or it is not necessary if the [Read ID] checkbox is selected.

8. Select the [Cap Open] check mark to perform a micro blood. This enables you to minimize dead volume

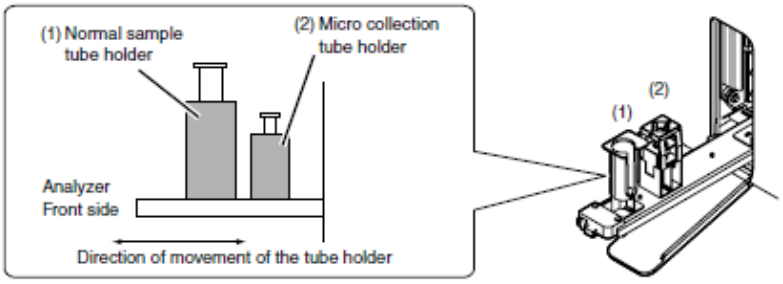
9. Click [OK]

10. Mix the sample tube as shown.



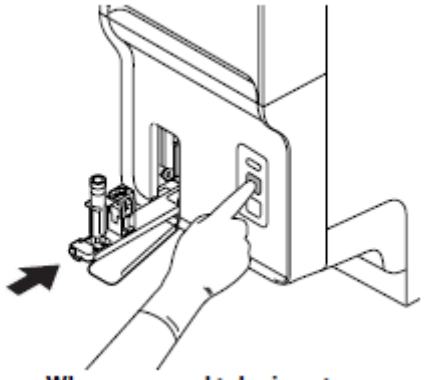
11. Place the sample tube in the tube holder.
There are 2 sample tube holders;
(1) Normal sample tube holder
(2) Micro collection tube holder

When performing micro analysis place the sample tubes after removing the cap. When inserting a micro collection tube, insert the tube all the way in so that the bottom of the adaptor.



12. Press the start switch on the analyser.

The tube holder slides in, and the aspiration of the sample begins.



e.g. When a normal tube is set

13. Once the analysis finishes, the tube holder slides out. Remove the sample.

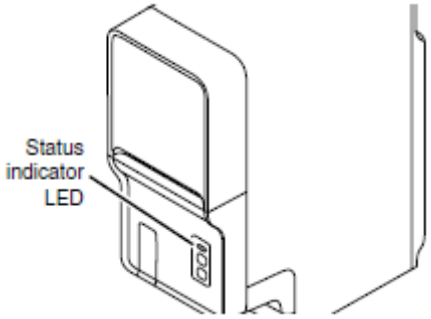
14. Press the mode switch.

XN hSA analysis

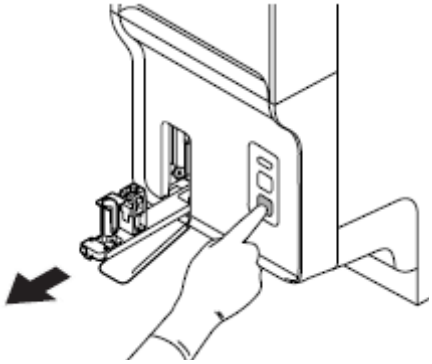
The highly sensitive analysis (hSA) can only be performed if the instrument has BF and RET analysis capabilities.

Follow the steps below to perform body fluid analysis.

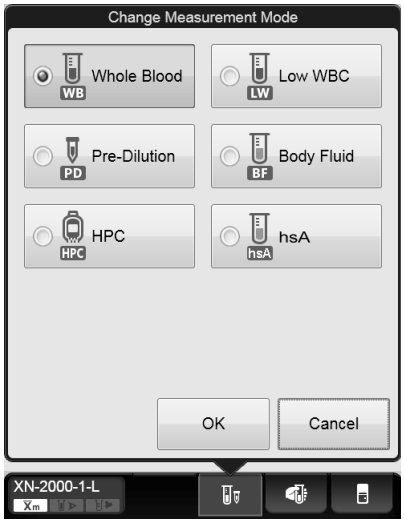
1. Check the Status indicator LED on the analyser is green.



2. If the tube holder has not ejected out, press the Grey mode switch.



3. Click the Change Analysis Mode button on the control menu.

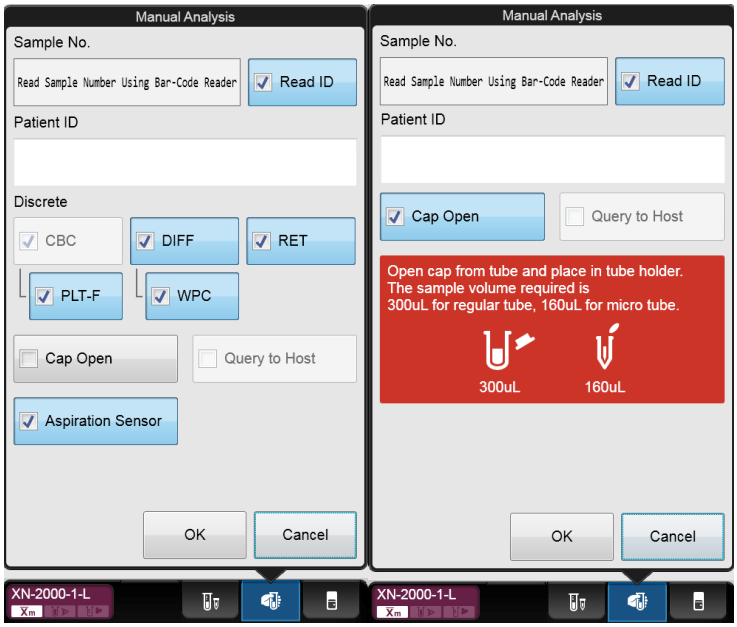


4. Click [hSA].

5. Click [OK].

The instrument will automatically perform a background check after hSA analysis is selected. If the background values that result from the background check are under the allowable values, the Status indicator LED lights green and the analyser enters the body fluid analysis preparation done state.

6. Click on the Manual Analysis button on the control menu.



7. Input [Sample No.] either by manually entering the sample, or it is not necessary if the [Read ID] checkbox is selected.

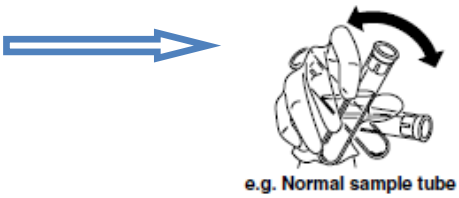
8. Select the [Discrete] check marks for the discrete tests to be performed

9. Select the [Cap Open] check mark to perform a micro blood. This enables you to minimize dead volume

10. [Aspiration Sensor] Enables/disables the Blood Aspiration Sensor.

11. Click [OK]

12. Mix the sample tube as shown.



13. Place the sample tube in the tube holder.
    There are 2 sample tube holders;
    (1) Normal sample tube holder
    (2) Micro collection tube holder

When performing micro analysis place the sample tubes after removing the cap. When inserting a micro collection tube, insert the tube all the way in so that the bottom of the adaptor.

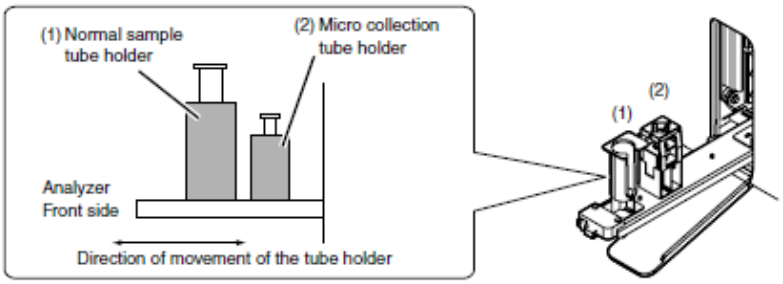
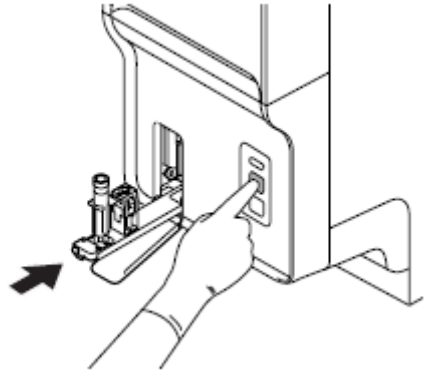


Figure 15- Sample tube Holder

14. Press the start switch on the analyser.

The tube holder slides in, and the aspiration of the sample begins.



e.g. When a normal tube is set

15. Once the analysis finishes, the tube holder slides out. Remove the sample.

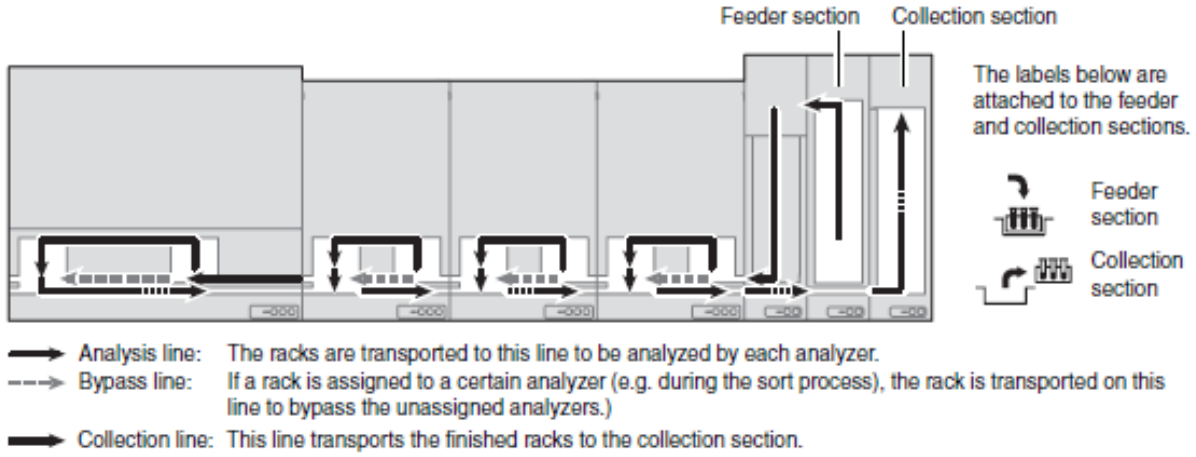
16. Press the mode switch.

Allowable limits for Background check performed prior to hSA mode analysis:

WBC	*0.0010 x 10^9 / L*
RBC-I	*0.0030 x 10^{12} / L*
RBC-O	*0.000100 x 10^{12} / L*

System rack flow

The following section will concentrate on standard configurations of an XN-9100 system, minor variations may exist where a non-standard configuration has been installed.

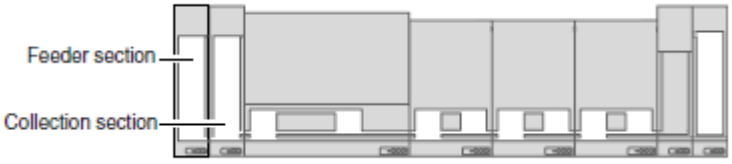


Note:

The locations of the feeder section and collection section vary depending on the instrument combination.

Take care not to place a rack in the wrong position.

e.g. 1. A configuration with the feeder and collection sections on the left side.



e.g. 2. A configuration with the feeder section on the right side and the collection section on the left side.

XN Sampler analysis

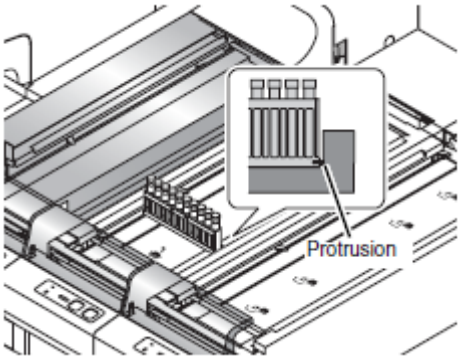
Follow the steps below to perform a system analysis (sampler analysis).

1. Check the status of the transportation units.
   In the [Status] screen of the transportation controller, make sure that there are no transportation units that are unconnected (grey) or in an error state (red)

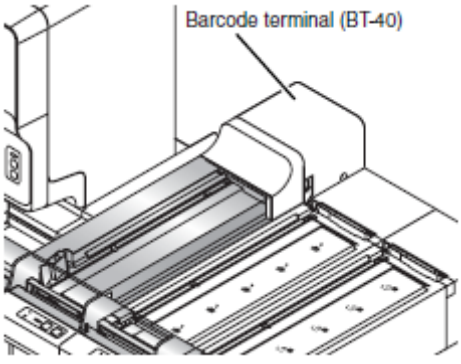
2. Verify that the start yard (ST) is in READY state.

3. Rack loading:
   Load sample racks into the feeder section of the Start yard (ST). Verify that rack is properly seated in the feeder; the groove on the bottom of the rack should fit into the guide in the feeder section. See figure on the right.

   The system will recognize the rack and automatically proceed to transport to the next module. Rack process can be stopped by pressing the Start/Stop switch on the feeder section of ST.



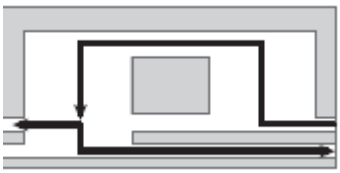
4. The barcode terminal (BT-40) or ST-41 (with RB-10) reads the barcode label.
   It queries the host computer for the sample number to verify the analysis order.



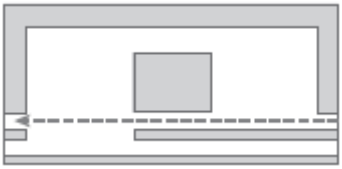
5. The rack is transported to the appropriate analyser.

Racks will be automatically transported to the haematology analysers on the system. When there are multiple analysers, the system will manage the workload and use systems equally, based on the test requests on the tubes and available test menu on the analysers.

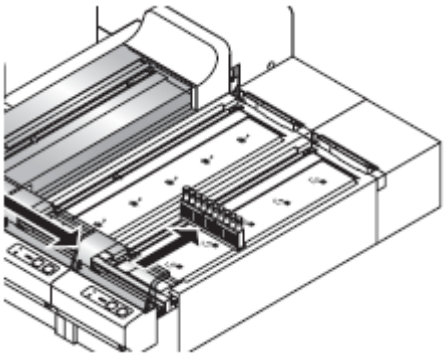
- Rack flows through the analysers or device as shown in the diagram here:
  The rack moves to the analysis line, and is analysed by the analyser.



- If Rack is not assigned to the analyser or device, then it will by-pass the module, as shown in the diagram here:
  The rack travels through the bypass line.



6. The rack is pooled in the stock yard (ST).
   Racks, containing completed samples will travel and pool at the collection line stock yard (ST).

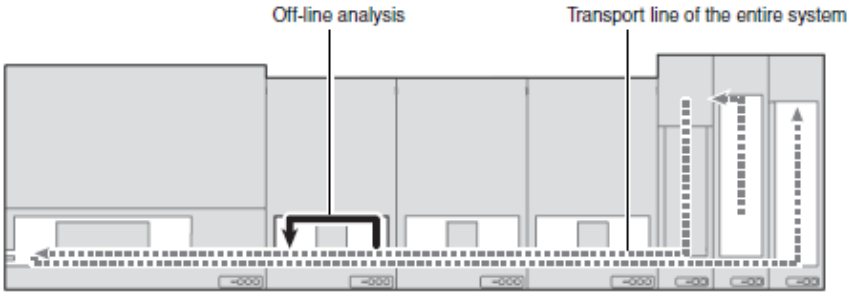


7. Remove the rack after the analysis is finished.

Off-line Sampler analysis

This is not a routine mode of analysis. Off-line analysis mode is when a module (CVR) is setup so that racks will not automatically enter for analysis or processing.

During this mode of operation, the rest of the analysers or devices on the XN-9100 will continue to process samples and racks in automated fashion.

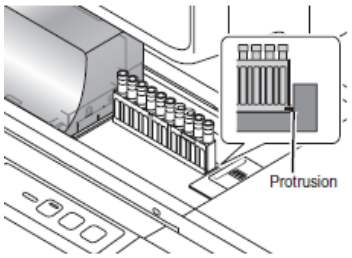


e.g. Transport line when off-line analysis (sampler analysis) is performed on CV-50.

1. Press the mode switch on the conveyor.

2. Verify that the conveyor is in READY state.
   If you press the mode switch while system analysis is in progress, the switching of modes takes place after all the racks on the conveyor has completed analysis and has been discharged.
   Please wait until all the racks on the conveyor have been discharged, and the LED is lit in orange.

3. Place the rack on the right pool of the conveyor.
   Slide the groove on the rack into the protrusion on the right side (when you face the analyser).
   Once the rack is set, the transport of the rack begins automatically.
   A maximum of 2 racks can be placed at a time.



e.g. Setting the racks on CV-50

4. Remove the rack after the analysis is finished.
   After the analysis has finished, the rack is discharged to the left conveyor pool, and the rack position indicator LED turns ON.

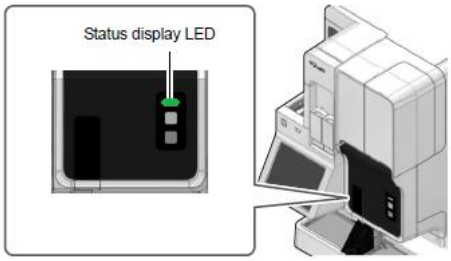
5. Press the mode switch on the conveyor.
   The analysis mode indicator lights green and the mode switch to system analysis.

Executing Sample Analysis (SP-50)

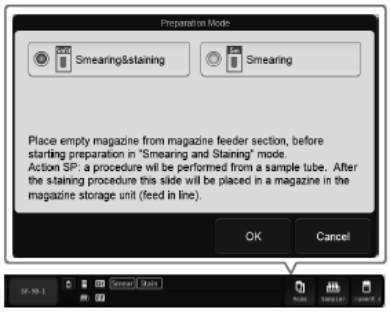
Preparing a smear sample in sampler mode (SP-50)

Minimum sample volume required: 500µL (regular tube), 250µL (RBT)
Aspirated sample volume: 70µL

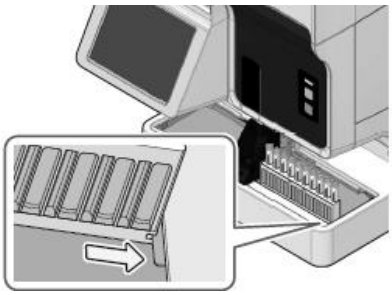
Follow the steps below to perform manual analysis with SP-50.



1. Isolate the SP-50 from the XN-9100 track.
2. Make sure that the instrument is in the ready state. The status display LED should be lit green.
3. Make sure the sample holder is retracted into the main unit.



4. To change the slide preparation mode, touch [Mode] in the status area.
5. Touch [Smearing&staining] or [Smearing].
6. Touch [OK].



7. Place the sample rack containing the samples in the right sampler pool.

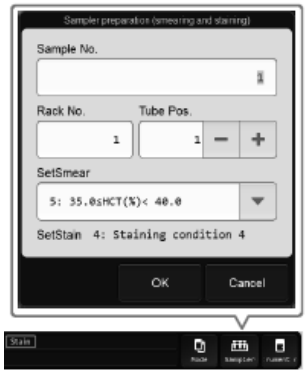
   Slide the groove on the sample rack onto the protrusion on the right side.
   A maximum of 5 sample racks can be placed.

Note:
Raised Bottom Tube and RBT rack can be used only when the instrument is connected to XN series. These cannot be used for SP-50 standalone sampler preparation due to special rack barcodes used to identify the RBT tube type. These rack barcodes can only be read by the BT-40 (RB-10) or ST-40 (RB-10).

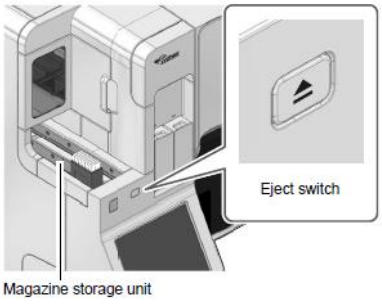
8. Touch [Sampler] in the status area.
   Set smear preparation condition.

9. Touch [OK].

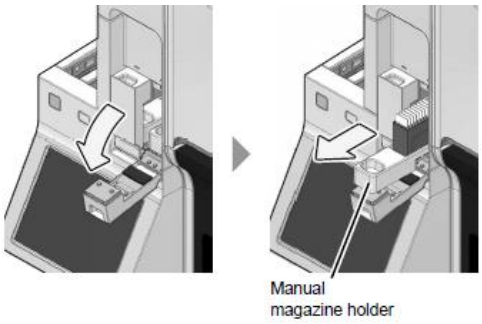
10. Remove the sample rack whose samples have been aspiration.



11. In [Smearing&staining] mode, remove the prepared and stained smears by taking the magazine from the magazine storage unit.



12. In [Smearing] mode, remove the prepared smears by taking the magazine in the manual magazine holder.

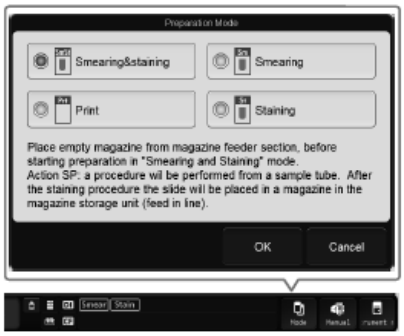


Preparing a smear sample in manual mode (SP-50)

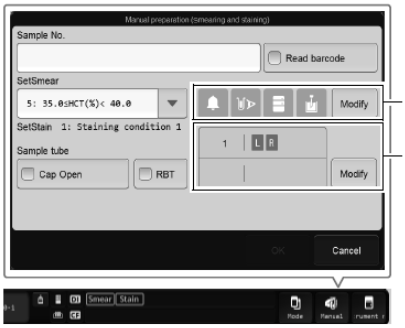
Minimum sample volume required: 500µL (regular with cap), 300µL (without cap), 250µL (RBT), 110µL (Micro tube – 1 slide), 140 µL (Micro tube – 2 slides)
Aspirated sample volume: 38µL (without cap/micro - 1 slide), 70µL (with cap, without cap/micro – 2 slides, RBT)

Follow the steps below to perform manual analysis with SP-50.

1. Press the [Mode] switch on the main unit front side to eject the sample holder.

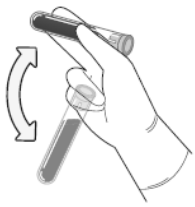


2. Touch [Mode] in the status area.
3. Touch [Smearing&staining] or [Smearing].
4. Touch [OK].



[Manual Preparation] dialog box ([Smearing&staining]/[Smearing] mode)

5. Input the Sample No. or use Read barcode, set the smear preparation conditions and sample tube in the Manual Preparation dialog box.
6. Touch [OK].
7. Mix the sample tube as shown.



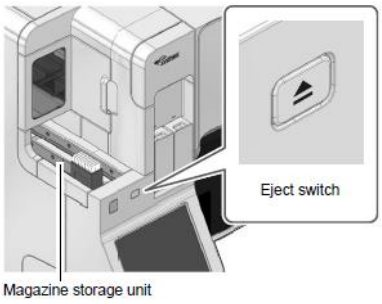
e.g. Regular sample tube

8. If [Cap Open] is selected or the smear will be prepared from a micro collection sample tube open the sample tube cap.
9. Set the sample tube in the sample holder in the correct position.
10. Press the start switch on the main unit front side.

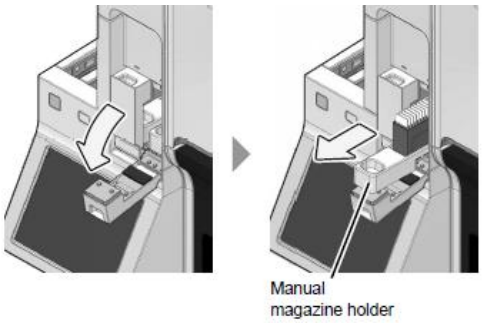
e.g. When a regular sample tube is set

11. Remove the sample tube from the sampler holder and press the [Mode] switch on the main unit front side to retract the sample holder.

12. In [Smearing&staining] mode, remove the prepared and stained smears by taking the magazine from the magazine storage unit.



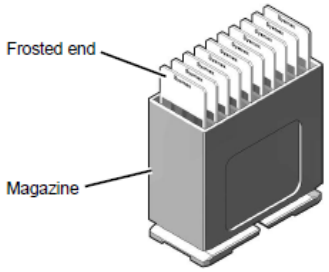
13. In [Smearing] mode, remove the prepared smears by taking the magazine in the manual magazine holder.



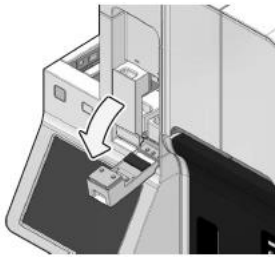
Staining manually prepared smears in manual mode (SP-50)

Follow the steps below to perform manual Stain analysis with SP-50.

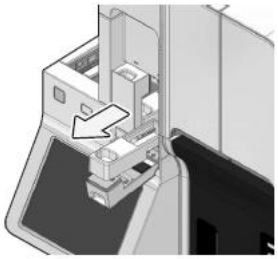
1. Load smeared slide glassed into the magazine.
   Ensure the frosted end of the slide faces to the front, the slide is successively stained from the front.



2. Open the manual magazine holder cover.
   The staining process will start regardless of which of the right and left manual magazine holders were loaded, the left magazine will be processed first.

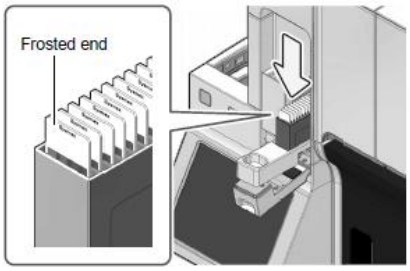


3. Pull out the manual magazine holder.

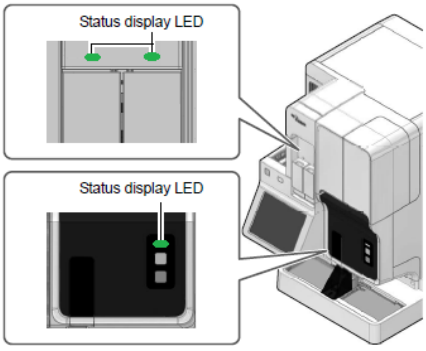


4. Load the magazine that holds the slide glass in the manual magazine holder. Load slide glasses so that the frosted ends face forward.

5. Push in the manual magazine holder and close the manual magazine holder cover.



6. Check the instrument and status display LED of manual magazine holder is lit green.

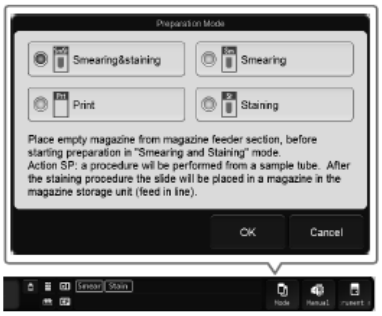


7. If the sample holder has not been ejected out, press the [Mode] switch main unit front side.

8. Touch [Mode] in the status area.

9. Touch [Staining].

10. Touch [OK].

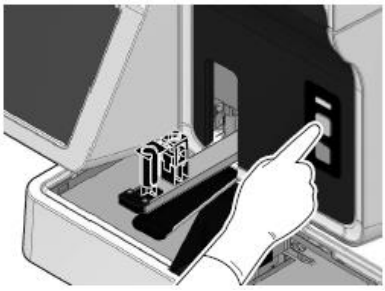


11. To change the Staining conditions, touch [Manual] in the status area.

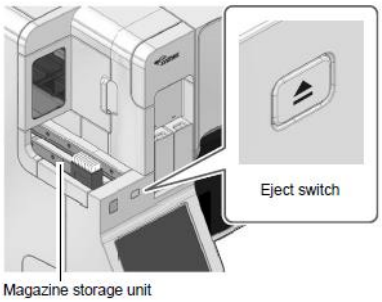
12. Touch [OK].

13. Press the [Start] switch on the main unit front side to start staining.

14. Press the [Mode] switch on the main unit front side to retract the sample holder.



15. Remove the stained smears by taking the magazine from the magazine storage unit.



Executing Sample Analysis (SP-10)

Preparing a smear sample in manual mode (SP-10) – Regular or RBT

Minimum sample volume required: 600µL (regular tube), 360µL (RBT)
Aspirated sample volume: Approx. 200µL

Follow the steps below to perform manual analysis with SP-10.

1. Prepare for analysis by SP-10.

2. Touch [Conv.int.] in SP-10's main menu screen.

3. Touch [Interrupt].

4. Touch [Return].

5. Touch [Manual] in main menu screen.
Enter the necessary information.

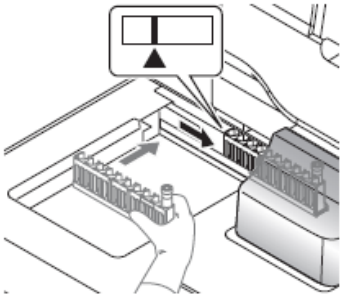
Note:
If the power to the transportation units is OFF, the step for interrupting the transport is not necessary. Carry out the operations in steps 5 through 10.

6. Mix the sample tube as shown.


e.g. Normal sample tube

7. Set the sample in the SP conveyor (CV-60).
To set the sample in [Closed] mode:
   - Insert the sample tube you want analysed into the 10th position of the rack.
   - Set the rack so that its left end fits the label shown on the right.

To place the sample in [Micro] or [Stain] mode:
See Chapter 6 of the SP-10 Instructions for Use.



8. Touch [Start] in the manual screen.
Wait until the preparation of the smear sample finishes and the sample tube is returned to the rack.

9. Remove the rack.
Slide the rack to left on analysis line, and then remove it.

10. Touch [Return] in the manual screen.

11. Touch [Conv.int.] in the main menu screen.

12. Touch [Stop int.].

Preparing a smear sample in manual mode (SP-10) – Micro tubes

Minimum sample volume required: 300 µL (micro tube)
Aspirated sample volume: Approx. 60µL

Follow the steps below to perform manual analysis with SP-10.

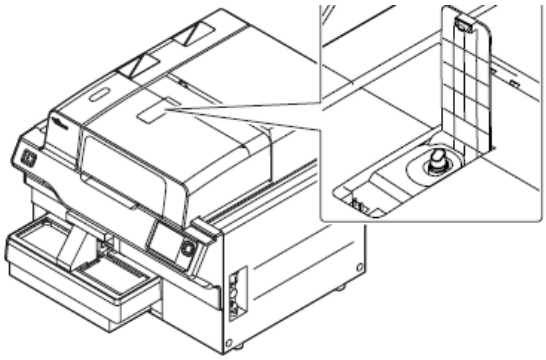
1. Prepare for analysis by SP-10.
2. Touch [Conv.int.] in SP-10's main menu screen.
3. Touch [Interrupt].
4. Touch [Return].
5. Touch [Manual] in main menu screen.
   Enter the necessary information.

Note:
If the power to the transportation units is OFF, the step for interrupting the transport is not necessary. Carry out the operations in steps 5 through 10.

6. Mix the sample tube as shown.


e.g. Normal sample tube

7. Remove the cap from the sample tube, open the micro collection sample tube holder cover, and place the tube in the manual open sample holder.



8. Touch [Start] in the manual screen.
   Wait until the preparation of the smear sample finishes.
9. Remove the sample and replace the sample cap.
10. Touch [Return] in the manual screen.
11. Touch [Conv.int.] in the main menu screen.
12. Touch [Stop int.].

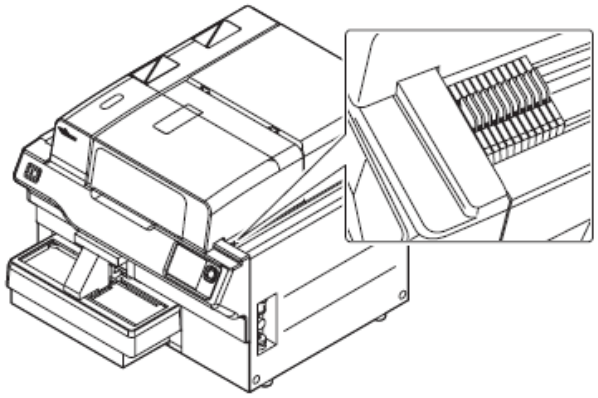
Staining manually prepared smears in manual mode (SP-10)

Follow the steps below to perform manual Stain analysis with SP-10.

1. Touch [Conv.int.] in SP-10's main menu screen.
2. Touch [Interrupt].
3. Touch [Return].
4. Touch [Manual] in main menu screen.
   Enter the necessary information.

Note:
If the power to the transportation units is OFF, the step for interrupting the transport is not necessary. Carry out the operations in steps 5 through 10.

5. Put the smears in the single cassettes and place them in the front of the cassette supply table.



6. Touch [Start] in the manual mode screen.
Manual operation starts.

Note:
Single cassettes loaded with slides are automatically fed to the staining process until no more cassettes remain. The feeder will automatically stop when no single cassettes remain or a single cassette without a slide is fed.

If there are many single cassettes ahead of the single cassette that you want to stain when you place it on the cassette supply table, it will take a long time to complete the slide. To shorten the time, remove as many of the other single cassettes as possible from the cassette

Sample Explorer and Data Browser (Sample results overview)

The two most commonly displayed screens are those of Data Browser and Sample Explorer. The Sample explorer screen displays stored data in numerical form up to 100,000 results.

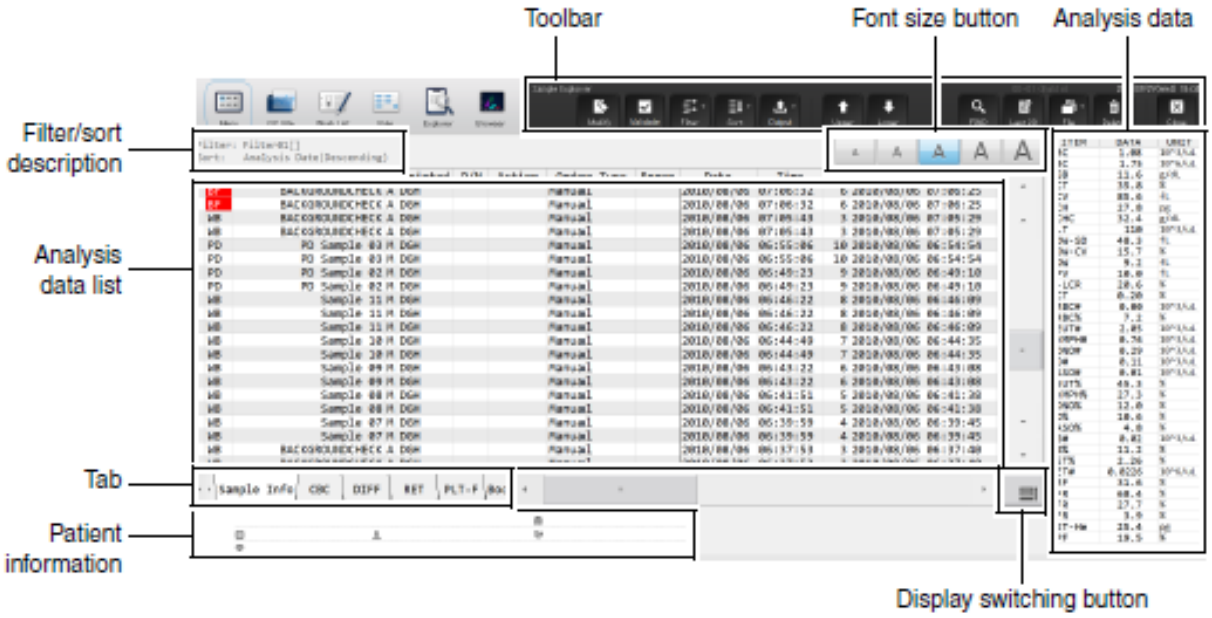


Figure 16- Sample Explorer

The Data browser shows the detailed graphical representation of the same data, scatterplots, histograms, flags, service data, as one result at a time.

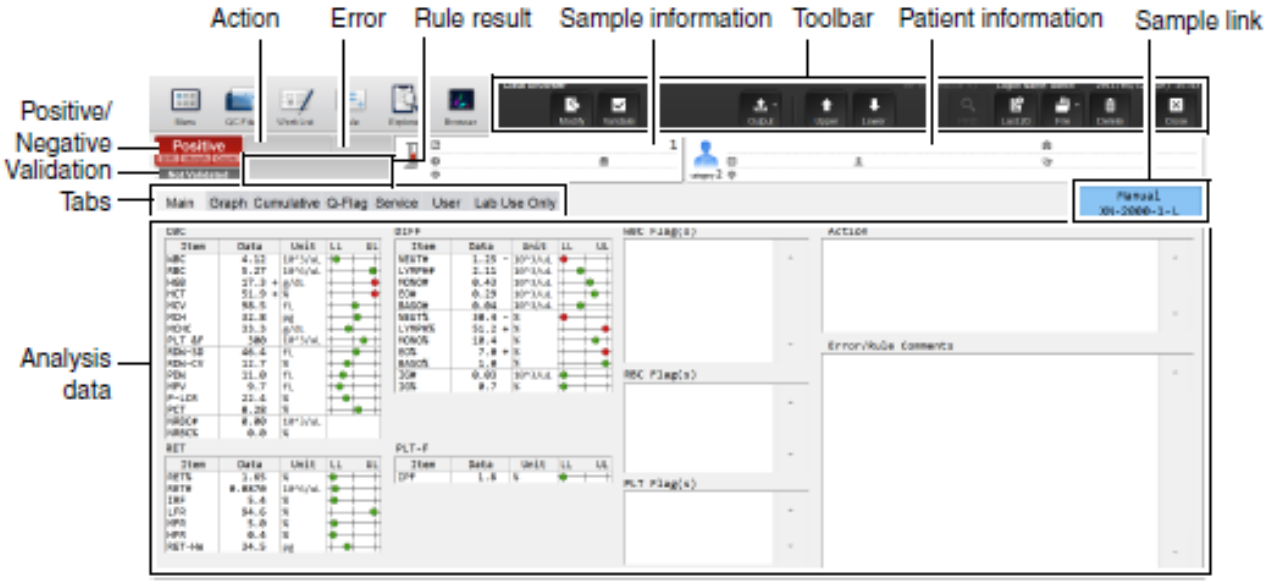


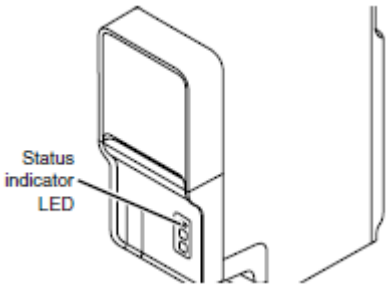
Figure 17- Data Browser

Shutdown

Performing daily shutdown on the XN-9100 is required after finishing analysis for the day; this includes the XN and SP-10/SP-50 instruments. Performing manual shutdown of the XN and SP-10/ SP-50 is described here.

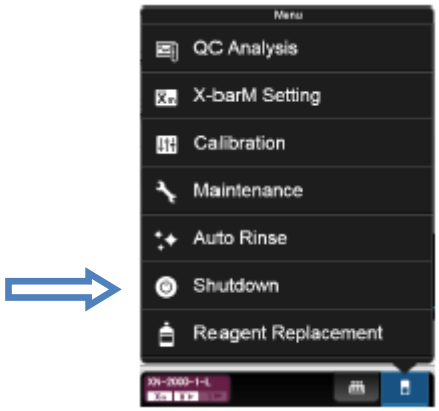
XN shutdown

1. Check the Status indicator LED is green.



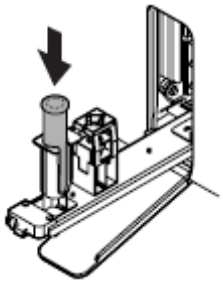
If the Status indicator LED is not lit green, wait until it does.

2. Click the Analyser menu button on the control menu.
The menu on the right appears.

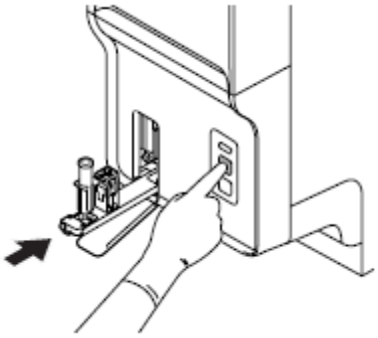


3. Click [Shutdown].
The shutdown window dialog appears. If retracted, the manual tube holder slides out.

4. Decant 4 mL of CELLCLEAN in to a new EDTA tube, or Set CELLCLEAN AUTO into each instruments tube holder.
Set it into the front holder, when you face the analyser.



5. Press the [Start] switch on the analyser.
   The tube holder retracts into the analyser and aspiration begins. When aspiration finishes, the tube holder automatically eject out.



XN-9100 shutdown process will take 15 minutes. Progress is shown in a progress bar on the screen. IPU will shutdown automatically after all analysers connected to the IPU have shutdown.
When shutdown finishes, the tube holder automatically retracts into XN analyser. If the CELLCLEAN is not removed before shutdown finishes, a notice indicating that a sample tube remains in the tube holder will appear at the next start-up. Each XN instrument requires dedicated tube with 4mL of CELLCLEAN.

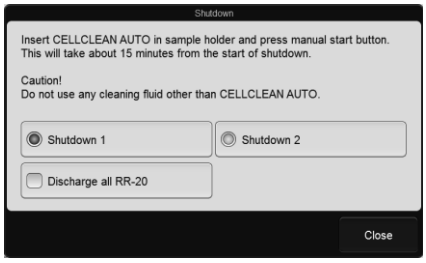
SP-50 shutdown – Manual mode

Perform the preparations for shutting down the SP-50. (For details, see the Instructions for Use for SP-50 Basic Operation.)

1. Touch [Menu] on the toolbar.

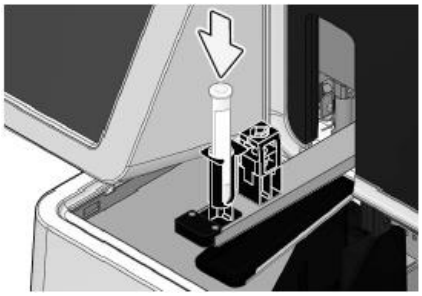
2. Touch [Shutdown].
   [Discharge all RR-20] is displayed only when the instrument is connected to the RR-20.

3. Set [Shutdown 1] daily or [Shutdown 2] weekly.



4. Set CELLCLEAN AUTO in the sample holder.

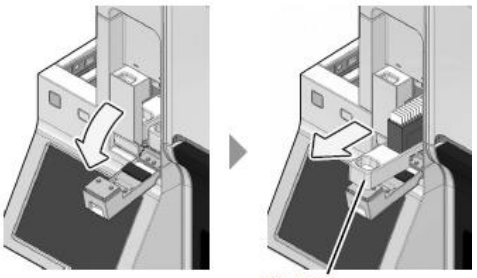
5. Press the [Start] switch on the main unit front side.



6. Shutdown is automatically performed.
   Shutdown takes approximately 15-20 minutes after CELLCLEAN AUTO aspiration starts.
   Remove and discard CELLCLEANAUTO tube once the sample holder ejects the empty tube.

   When all operations are finished, the sample holder automatically retracts into the main unit, and the instrument power turns OFF.

7. Remove the slide glass used for cleaning.
   The cleaned slide glass will be stored in the magazine in the manual magazine holder.

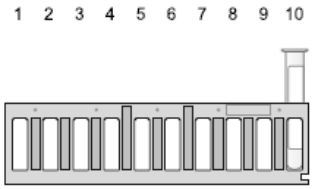


Note:
If the CELLCLEAN AUTO is not removed before shutdown finishes, a notification that a sample tube remains in the sample holder will appear at the next startup.

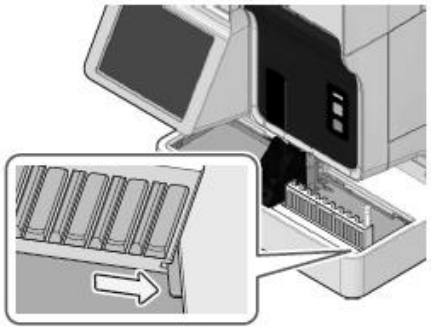
SP-50 shutdown – Sampler mode

A sample rack can be used to perform a shutdown.

1. Place CELLCLEAN AUTO in the sample rack in position 10.



2. Place the sample rack in the right sampler pool.

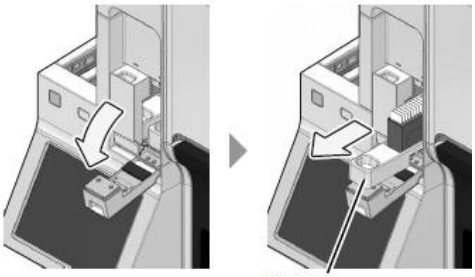


CV-65 of SP-50

3. Touch [Sampler] in the status area.
4. Touch [OK].

   Once the CELLCLEAN AUTO barcode is read, the instrument enters the shutdown ready state.

5. Remove the sample rack whose CELLCLEAN AUTO has been aspirated.
6. Shutdown is automatically performed.
   Shutdown takes approximately 15 minutes after CELLCLEAN AUTO aspiration starts.
7. Remove the slide glass used for cleaning. The cleaned slide glass will be stored in the magazine in the manual magazine holder.



Note:
[Shutdown 2] is selected in the following cases.

- *The instrument was started on the day of the week set in [Shutdown 2 settings]*
- *More than 40 days has elapsed since the last time [Shutdown 2] was performed*

SP-10 shutdown

Perform the preparations for shutting down the SP-10. (For details, see the Instructions for Use for SP-10.)

If the power to the transportation system is OFF, the step for interrupting the transport is not necessary. Carry out the operations in steps 5 through 8, otherwise start with step 1.

1. Touch [Conv.int.] in SP-10's main menu screen.

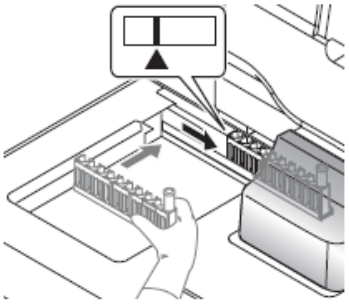
2. Touch [Interrupt].

3. Touch [Return].

4. Touch [Shutdown] in main menu screen.
The Shutdown screen appears.

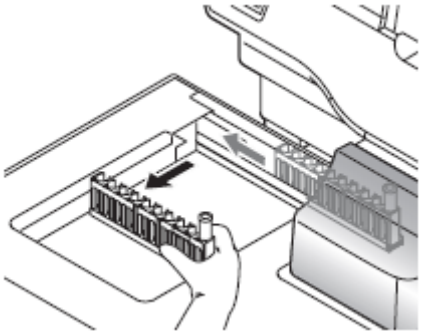
5. Aliquant 4mL of CELLCLEAN and set the tube on the sampler (SP-10 side).

    1. Place CELLCLEAN in the 10th position of the rack.
    2. Place the rack so that its left end fits the label shown here



6. Touch [Shutdown1 (Daily)] or [Shutdown2 (Weekly)] in SP-10's Shutdown screen.
The progress will be displayed in a progress bar on the screen. Wait until the preparation of the smear sample finishes and the sample tube is returned to the rack.

7. Remove the rack at the end of shutdown process.
Slide the rack to the left on analysis line, and then remove it.

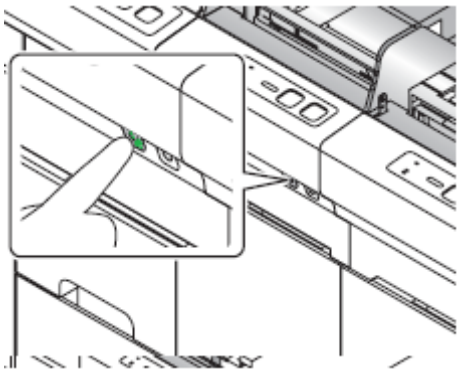


Turning OFF the transportation system manually

If needed, you can turn OFF only the power of the transportation system.

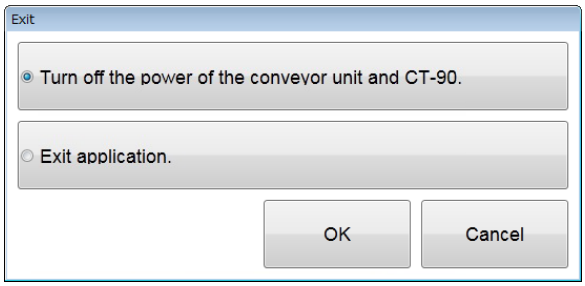
1. Make sure that all transportation units are in the READY state.
   If the status LED is not lit green, wait until it does.

2. Hold down the [Master start up] switch on the barcode terminal (BT-40) for at least 2 seconds.
   - Press the switch (green) in the position shown at below.



   - Or, execute the procedure below.
     a) Touch the [Exit] button on the toolbar in Transportation controller (CT-90).

     b) Touch [Turn off the power of the conveyor unit and CT-90.]



     c) Touch [OK].

3. The entire transportation system's power is turned OFF.

Shutting down the XN IPU manually

1. Click [Exit IPU] in the XN menu screen.
   A dialog box appears.

2. Click [Yes].
   The IPU shuts down.

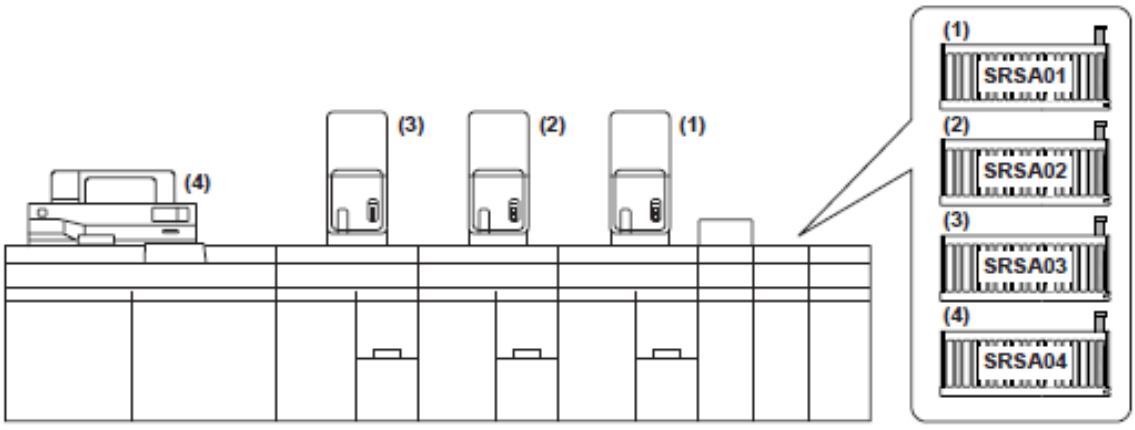
3. Shutdown Windows.
   Your computer shuts down.

Automatically shutting down the entire system

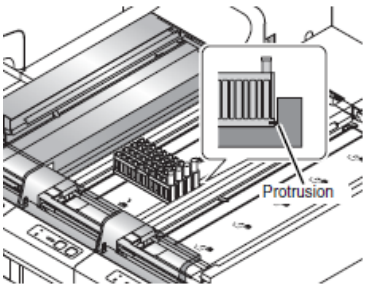
The power of the entire system can be turned off automatically by placing a rack with CELLCLEAN AUTO.
Use the special racks for shutdown. The racks for shutdown have a green label for identification. In the procedure below, a rack with a barcode label beginning with "SRSA" is used as an example.

1. **Make sure each instrument is in the READY state.**
   - If the status LED is not lit green, wait until it does.
   - If an error has occurred on one of the instruments or an instrument is performing standalone analysis, that instrument will not be shut down.
   - It takes about 20 minutes for the SP-10/SP-50 to enter the READY state after the final analysis.

2. **Place CELLCLEAN AUTO in the rack.**
   - Place CELLCLEAN AUTO in the racks with numbers corresponding to each analyser as shown below (Recommended).
   - This procedure uses the basic configuration (4 analysers) as an example. Prepare a number of racks equal to the number of analysers you are using.



3. **Place the rack in the feeder.**
   - Slide the groove on the rack into the protrusion on the right side (when you face the analyser). Conveying automatically starts when the rack is placed.



XN-9100 track

4. **Shutdown is performed automatically.**
   - CELLCLEAN AUTO is aspirated in each analyser and rinsing begins sequentially.
   - After the racks are sent to the collection section, the power of the transportation system turns OFF.
   - When shutdown is finished, the power of each instrument turns OFF.

Note:
You can shut down a particular analyser by placing only the rack for that analyser. Shutdown of only that analyser and the entire transportation system will take place.

Shutdown of analysers for which racks are not placed will not be performed.

Shutdown can also be performed by placing a number of CELLCLEAN AUTO vials equal to the number of instruments in the rack with the barcode label "SRSA00".
In this case, the placement positions in the rack correspond to the instruments as follows:
- *7th: 4th connected analyser*
- *8th: 3rd connected analyser*
- *9th: 2nd connected analyser*
- *10th: 1st connected analyser*

Section 6: XN-9100 Quality Control

Quality control

Quality control is performed in order to monitor instrument's performance over time.
Sysmex XN CHECK is the quality control material used to monitor the performance of all assayed whole blood parameters on the XN analyser. For systems with optional body fluid mode there is also XN-Check BF available. Quality control should be run according to your laboratory protocols.

XN-Check

3 levels Level 1, 2, 3

Volume: 3.0 ml / 8 vials in single pack size

Stability: Closed Vial Stability (CVS) – 8 weeks

Open Vial Stability (OVS) – 7 days

XN-check will control all whole blood assay parameters including:

8 CBC parameters (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT)

RDW-SD/CV, PDW, PCT, MPV, P-LCR

WBC-D, WBC-P, 5-DIFF#/%, IG#/%, NRBC#/%

PLT-F, IPF

Ret#/%, LFR/MFR/HFR, IRF, Ret-He, RBC-O, PLT-O

XN-Check Body Fluid

2 levels Level 1 & 2

Volume: 3.0 ml / 3 vials of Level 1 and 3 of Level 2 in a single pack size

Stability: Closed Vial Stability (CVS) – 8 weeks

Open Vial Stability (OVS) – 30 days

XN-check BF will control body fluid assay parameters including:

WBC- BF, MN#/%, PMN#/%, TC-BF#

RBC-BF

XN-9100 QC methods using control material includes:

- X-bar Control: The control blood is analysed twice in succession, and the average of the 2 results is used as the control data.
- L-J Control: Takes the data from a single analysis of control blood and uses it as the control data.
- QC using normal samples
    - X-barM Control: This program calculates a weighted average of batches of normal patient samples (usually 20) and plots the resulting value as control data. The number of samples can be set to any number.

To execute the quality control using an external QC sample or a residual sample (pooled blood), set the [Material] to [Other].

QC Menu Screen

QC file menu can be accessed via IPU main menu screen or toolbar options.

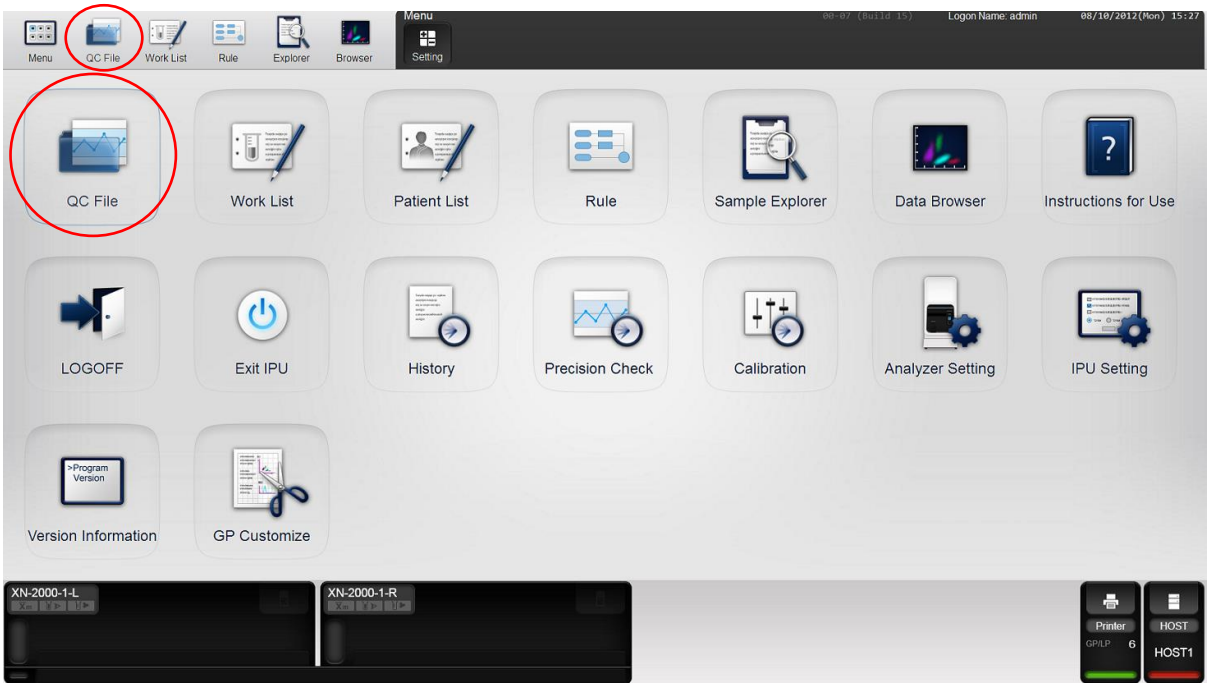


Figure 18- IPU Main Menu

Click the [QC File] button on the toolbar or the [QC File] icon on the Menu screen to display below screen.

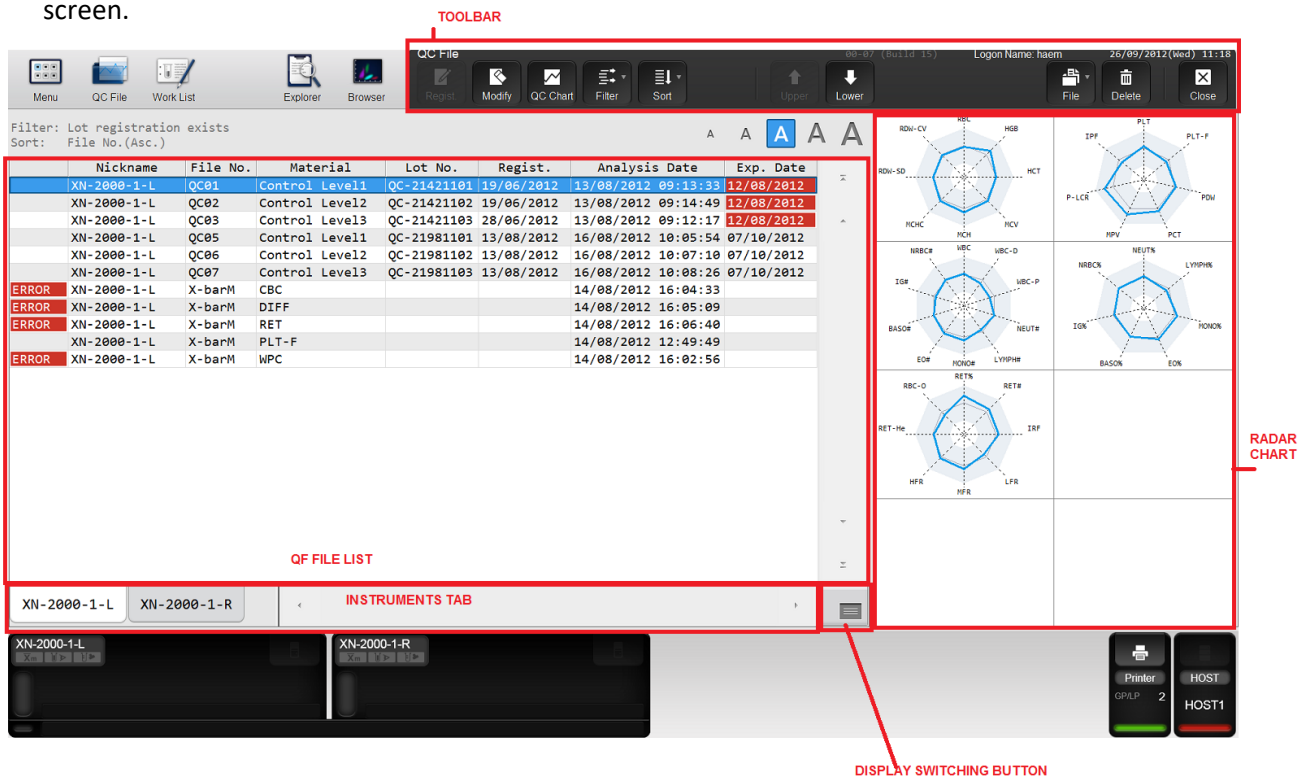


Figure 19- QC File

Radar Chart

This chart will display the latest plot data from the selected QC file on the radar charts. If there is not a single plot in the selected QC file, only the frame and the item name are displayed.

Any point exceeding the upper or lower limit is marked with a red "X"

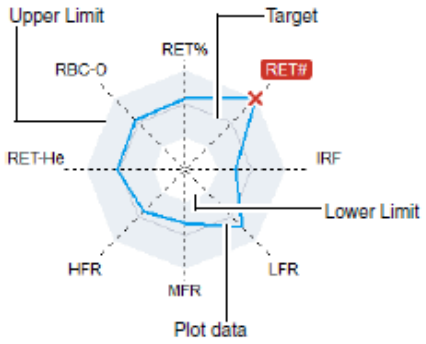


Figure 20- Radar Chart

QC Chart Screen

The [QC Chart] screen allows you to view detailed graph data of the QC file.

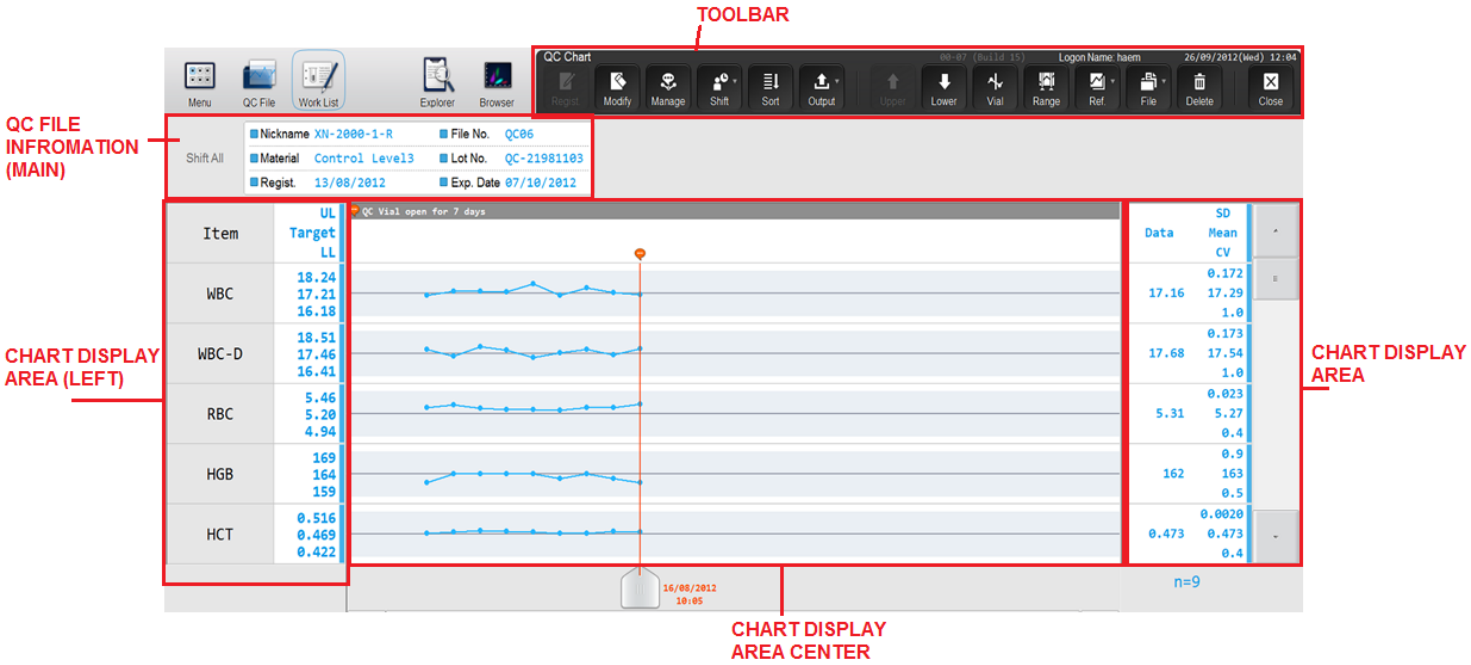


Figure 21- QC Chart Screen

QC Registration

To perform quality control tasks, QC files must be registered (lot information input). You can register up to 94 QC files per analyser.

Register lot information using one of the methods below.

- Manual lot registration
- Automatic lot registration
- Modifying lot information

Performing lot registration automatically

1. Insert the QC Assay CD-ROM in to the IPU driver

2. Load the rack with the three vials of controls in the sampler.

3. Once the barcode is read, all target and limits along with lot information will be registered and added to the first three available QC files.

Performing lot registration manually

1. Insert the QC Assay CD-ROM in to the IPU driver

2. Click the [QC File] icon in the Menu screen.
The [QC File] screen appears.

3. Click a tab and select an analyser.
QC files are managed for each analyser. Select the analyser that you want to register.

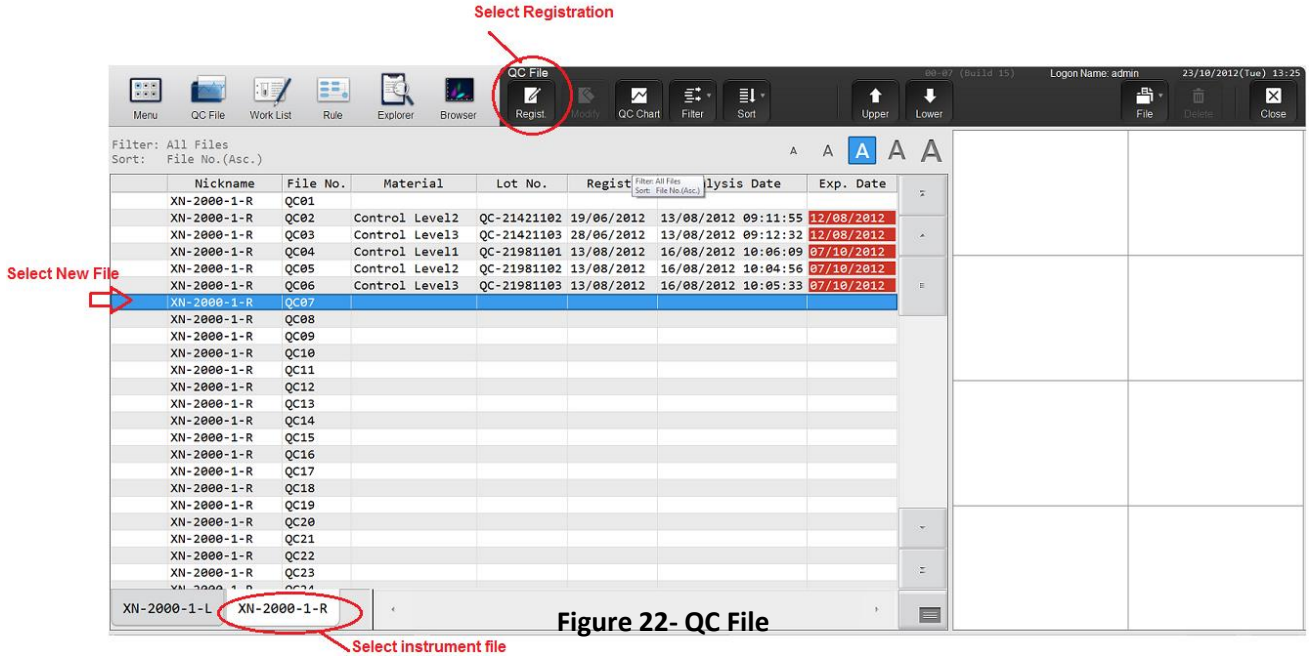


Figure 22- QC File

4. Select empty QC file Click the [Regist.] button on the toolbar.
The following dialog appears.

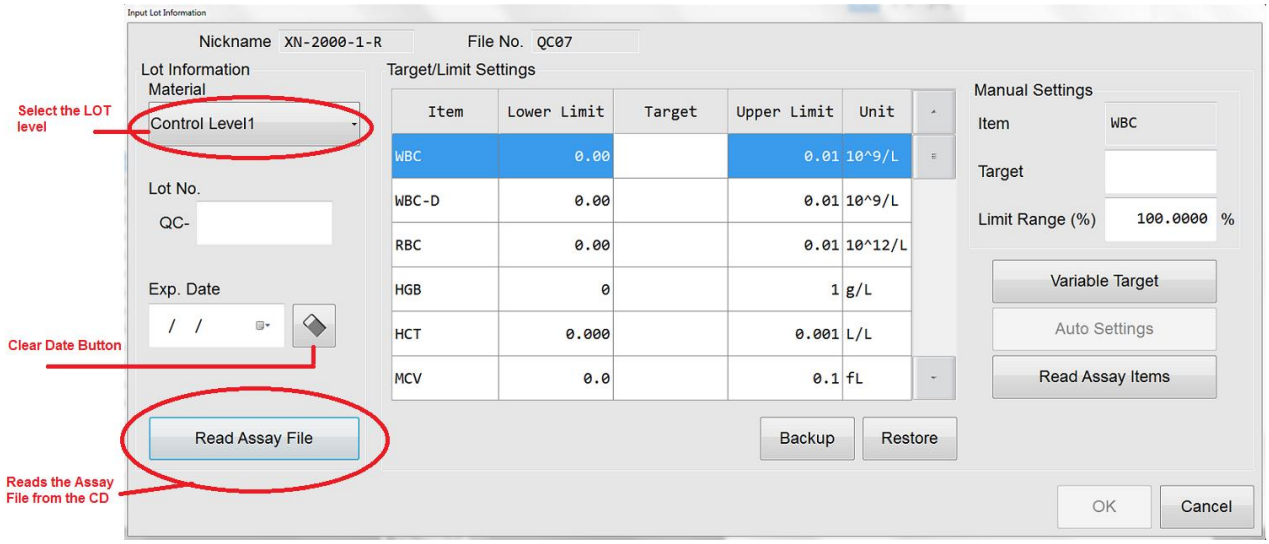


Figure 23- QC Registration File

5. Enter lot information.

- [Lot Information]

  [Material] Select the type of control blood. (Level 1, Level 2, Level 3, Other)

- Select [Read Assay File] button

  Selecting this will read the lot information from the CD-ROM that came with the control blood.
  Click the [Read Assay File] option.

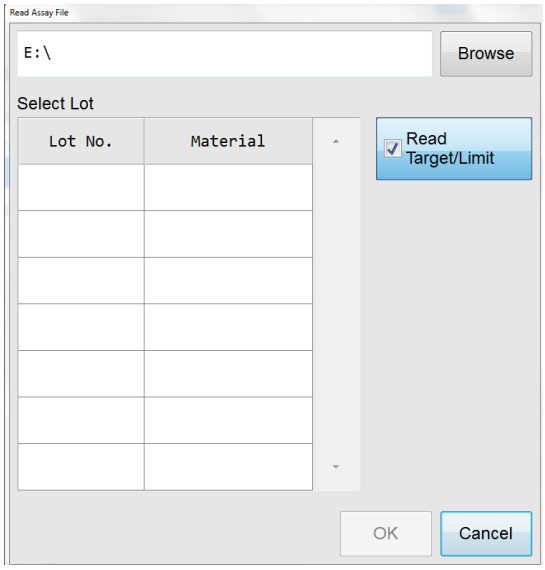


Figure 24- Read Assay File

[Browse] Click to display the dialog box for specifying the folder.
[Select Lot] Displays the list of files on the CD-ROM. Select the file that you want to register.
[Read Target / Limit] Select this check box if you want to read the target / limit of the selected QC item.

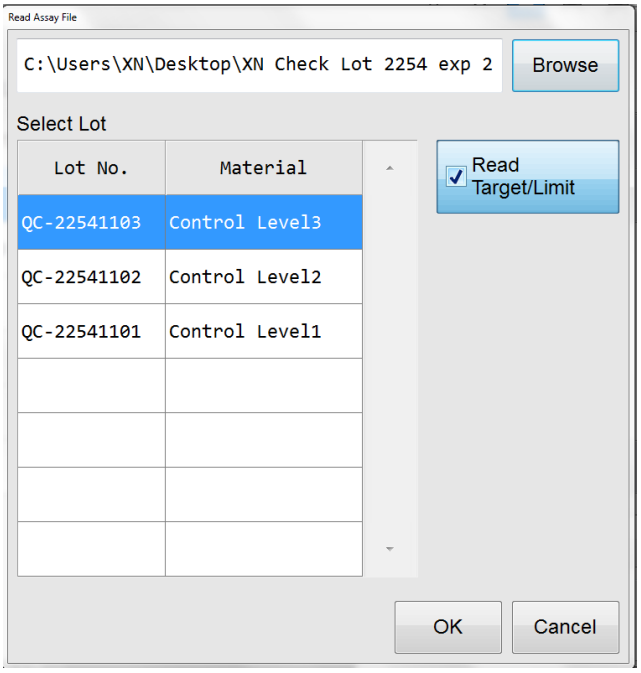


Figure 25-Assay File: select Lot No and check box Target/ Limit

6. Select [OK].
   All target and limits along with lot information will be registered.

7. Repeat this process for other 2 levels until all 3 QC lots have been registered

NOTE: If the check box is not checked, the target/limit values are reset to their default values which are shown when the dialog box is opened.

Note:
The lot number is registered as shown below in the assay file.*

- *XN CHECK Level1: QC-XXXX1101*
- *XN CHECK Level2: QC-XXXX1102*
- *XN CHECK Level3: QC-XXXX1103*

QC File Management

This section explains how to modify, delete, save and restore QC files.

1. Click the [QC File] icon menu.

2. Select the QC function you want to perform.

Modify
Click the [Modify] button on the toolbar to display the [Input Lot Information] dialog box.

Delete
Click the [Delete] button on the toolbar to delete the selected file.

Save QC file data
Click the [File] button - [Backup] on the toolbar to display the dialog box for confirming the file name and save directory.

Restoring saved data
Click the [File] button - [Restore] on the toolbar to display the dialog box for specifying the file to read.

Output

Print GP (LJ plot of the accumulated QC points selected)
Print LP (Ledger print of numerical data for selected QC points)
Send to the host

Each laboratory must establish internal protocols for management of their QC data. QC files can be Saved, Restored, printed and deleted. Follow the IFU manual on the how to guide to perform QC File Management.

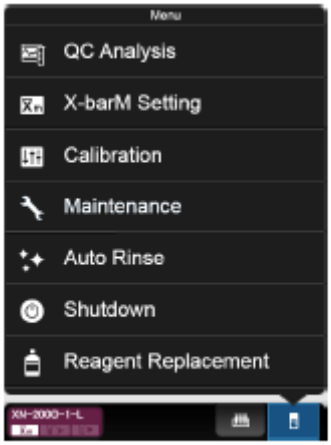
X-barM Control

Activating / deactivating

X-bar M control: calculates the summation average of batches of patient samples (usually 20) using Bull's algorithm, and plots the resulting value as a control data point.
X-bar M control is a good indicator for analyser drift, and for the detection of pre-analytical problems, or when a fault is occurring intermittently that is not discovered by the daily QC or drift control analyses alone

X-barM control is executed each time the analyser is started. Follow the steps below to configure X-barM control settings:

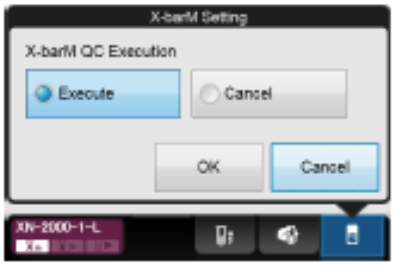
1. Click the Analyser menu button on the control menu.



2.

3. Click [X-barM Setting].

The dialog box on the right appears.



4. Click [Execute] to perform X-barM Control, or [Cancel] to cancel X-barM Control.

5. Click [OK].

X-barM Setup

Once the X-barM is activated results will accumulate in the appropriate files. Depending on the system used up to 5 X-barM files are monitored, these include:

CBC, DIFF, RET, PLT-F and WPC

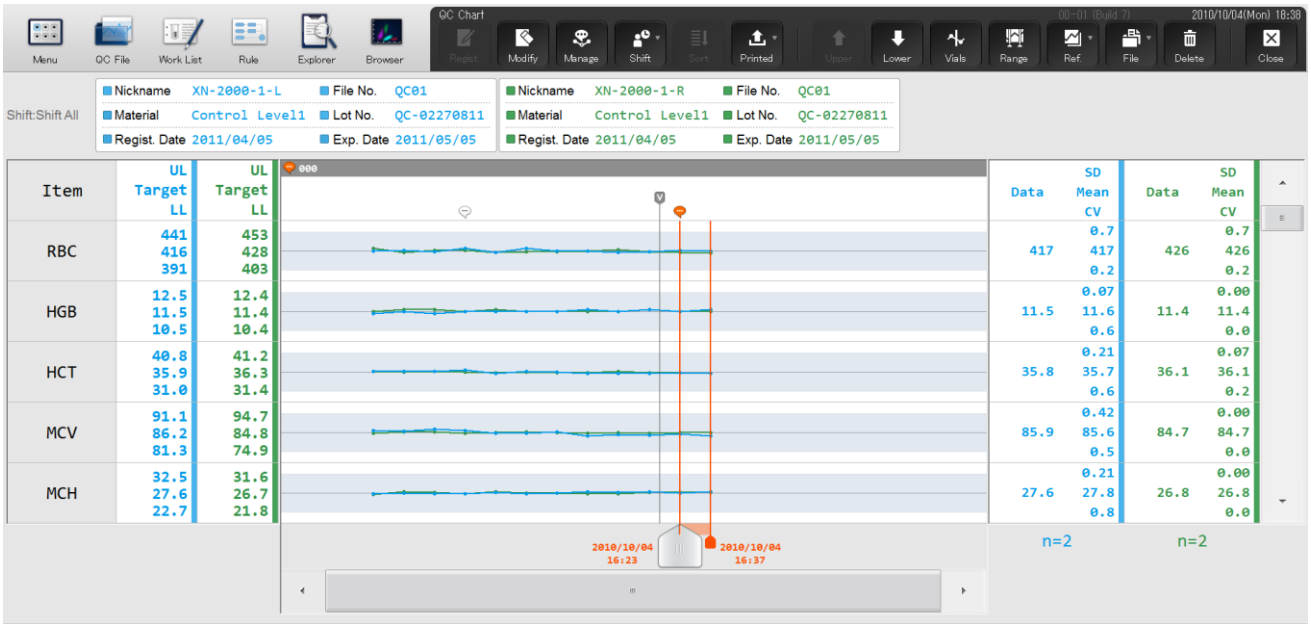
Manual Setting of target values for X-barM

Limit Range for the X-barM will be assigned at the time of system installation. Setup of Target is setup after accumulation of at least 5 points.

Note: *It may be necessary to setup X-barM targets over time; generally X-barM Targets are reset over 3 cycles of XN-check.*

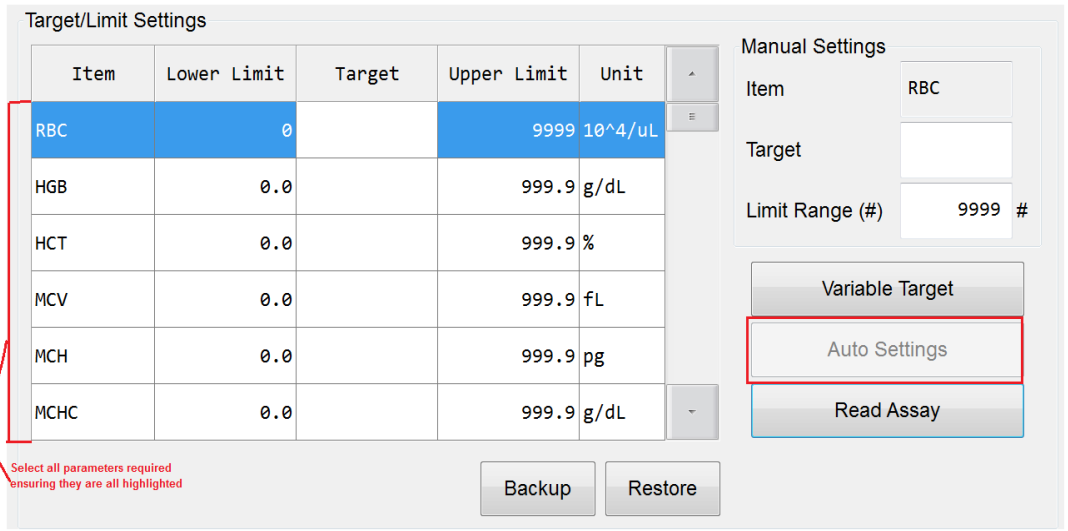
1. Select the CBC X-barM file from the QC file

2. Using the Range option select all results accumulated.

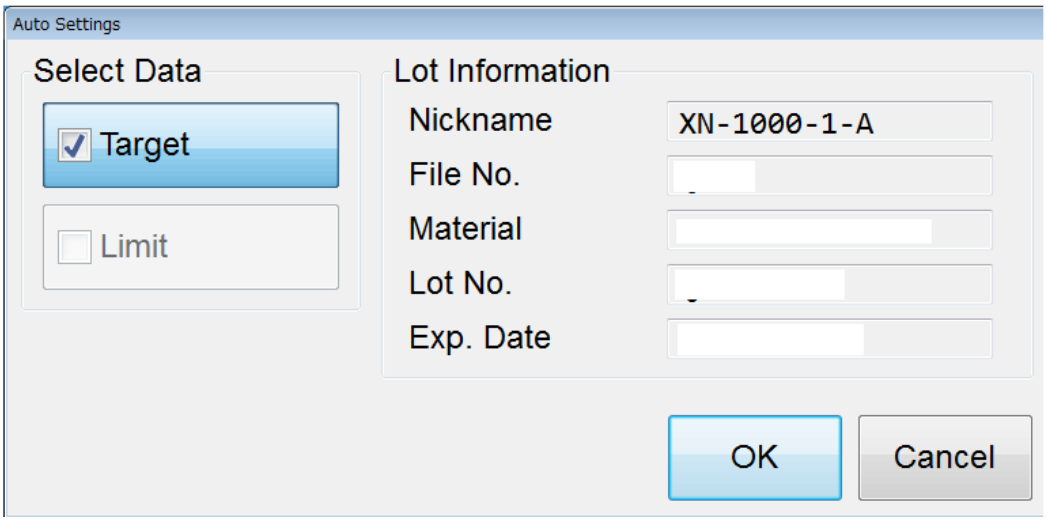


3. Select Modify to access targets and limits

4. Select all parameter on the target/ Limit setting box



5. Select Auto Settings and ensure only the Target box is nominated



6. Select OK

Repeat this process for any other X-BarM files required

Performing QC analysis

Performing QC analysis using sampler analysis

When using control blood XN-Check, you can perform L-J Control by sampler analysis.
Follow the steps below to perform QC analysis using sampler analysis.

1. Place the vial containing control blood.

2. Analyse the sample using sampler analysis.

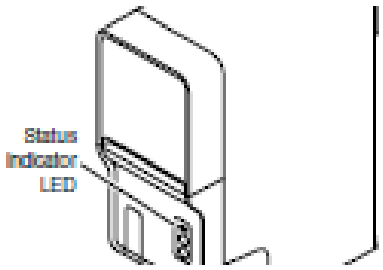
   Once the analysis is finished, the QC results are displayed on the IPU's screen.

Performing QC analysis using manual analysis

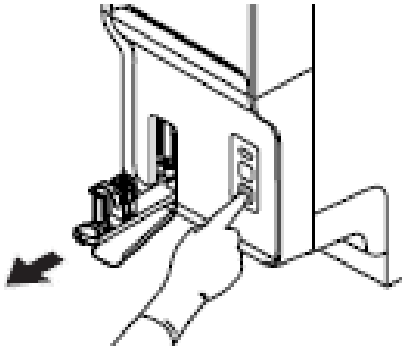
To perform body fluid QC XN-BF, non-Sysmex QC material using an external QC (RCPA QAP) sample or remaining sample (pooled blood), perform manual analysis.

To perform QC on above mentioned materials, set [Material] to [Other] and follow the procedure below to perform analysis

1. Check the Status indicator LED on the analyser.
   If the Status indicator LED is not lit green, wait until it does.



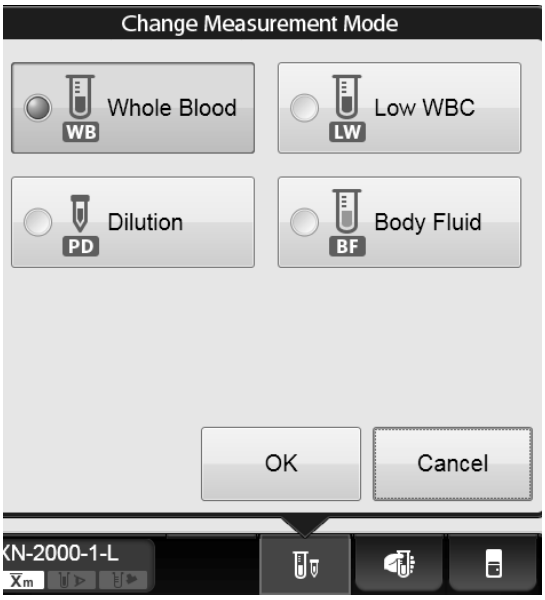
2. If the tube holder has not ejected out, press the mode switch.
   The tube holder slides out forward.



3. Click the Change Analysis Mode button on the control menu.

   If the sample is whole blood, select [Whole Blood] mode.

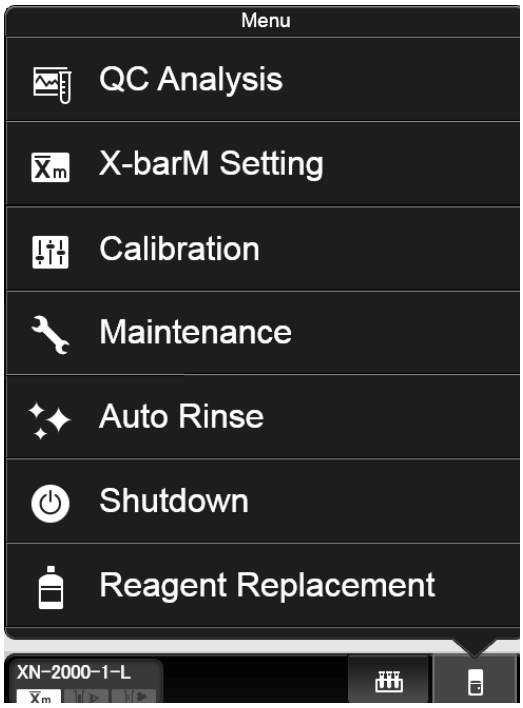
   For body fluid, select [Body Fluid] mode.



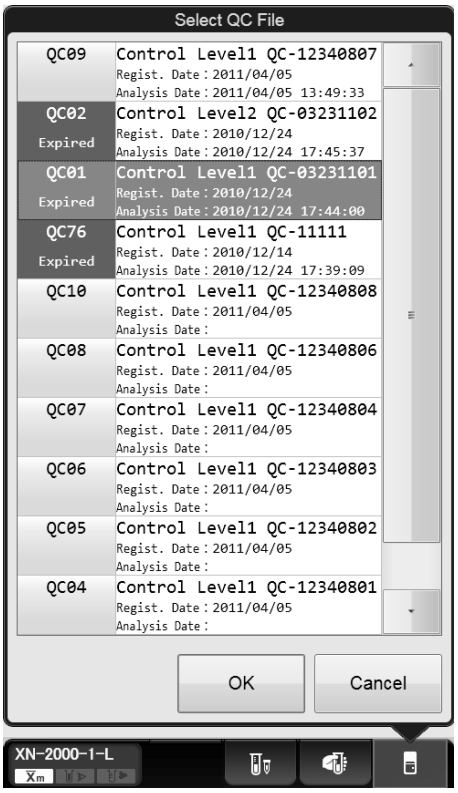
4. Click [OK].

   The dialog box closes.

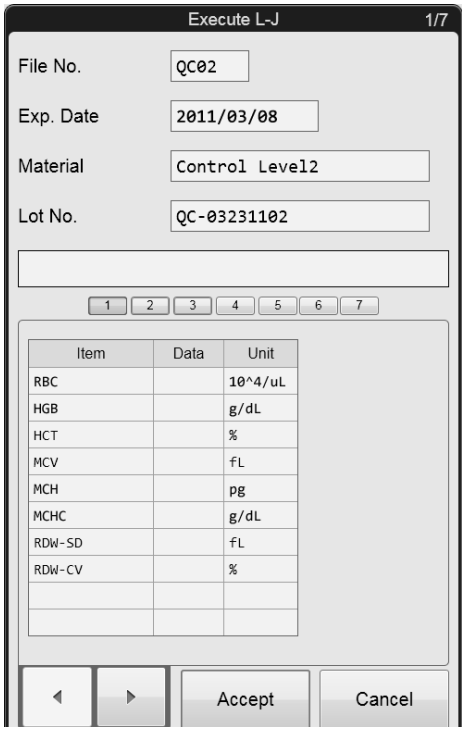
5. Click the Analyser menu button on the control menu.



6. Click [QC Analysis].

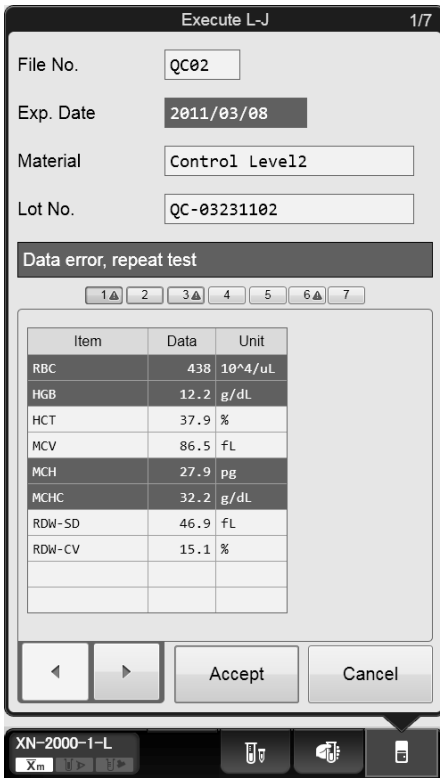


7. From the list of QC files, click the file you want to analyse.



8. Analyse the sample using manual analysis.

9. Check the analysis results.
When the analysis finishes, the analysis results are displayed in the [Execute L-J] dialog box.



10. Accept results or cancel.

Section 7: XN Reagent Management

XN Reagent Replacement

If a reagent runs out during an analysis, the analysis is paused, and an error message appears in the analyser area of the Control menu, followed by an audible alarm. Display the [Reagent Replacement] dialog box to replace the reagent.

The [Reagent Replacement] dialog box allows you to check the remaining volume for reagents and replace them.

Note:
Even when an error message does not appear, the steps below can be used to open the [Reagent Replacement] dialog box.

- *Click the analyser menu button in the control menu, and click [Reagent Replacement].*
- *Click the reagent level display in the control menu.*

1. Click the help button on the control menu.

Help dialog box appears.
Replace the empty reagent and Click Accept

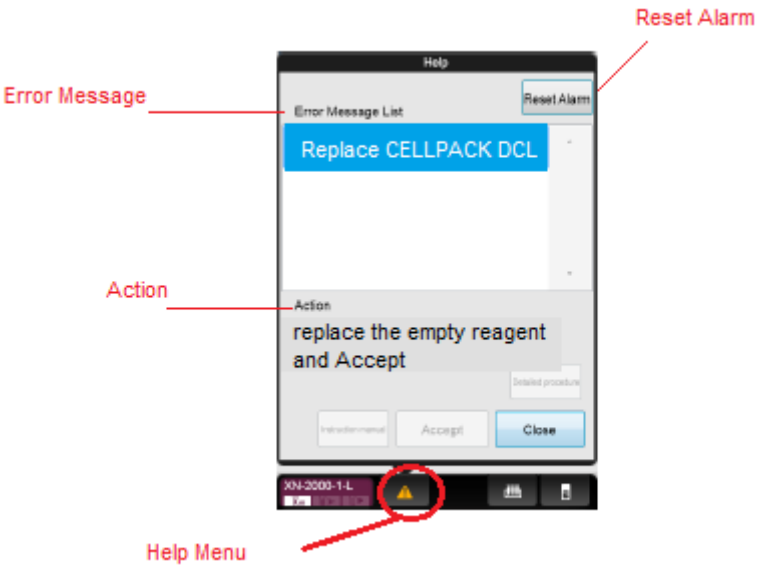


Figure 26– Help Menu

2. Click [Execute].

The following dialog box appears, and the reagent remaining volume indicator appears.

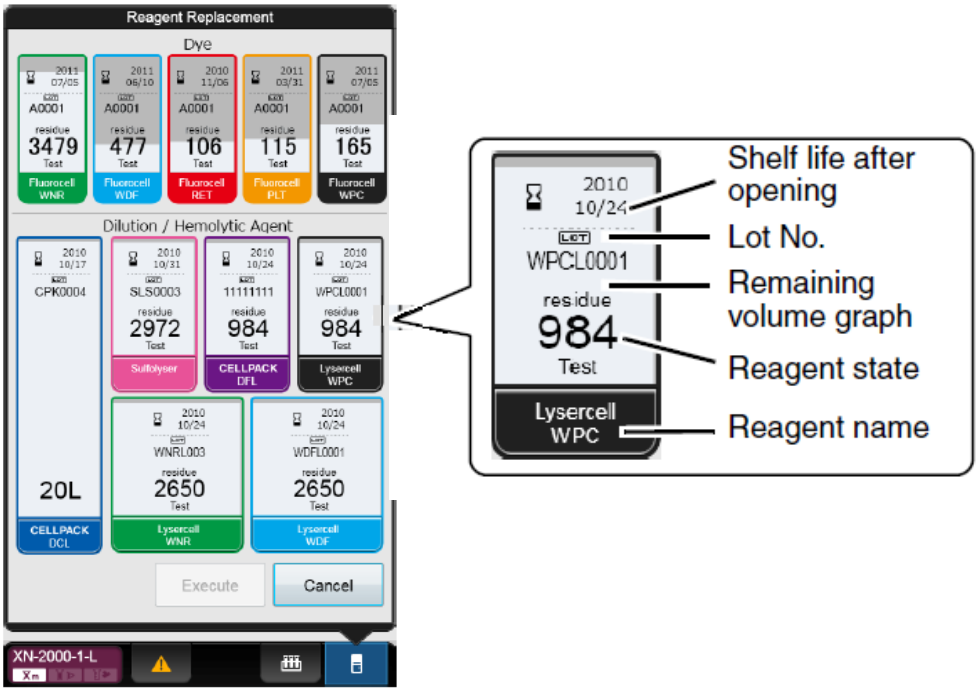


Figure 27 – Reagent Replacement Box

Shelf life after opening; display the shelf life of the reagent after opening. This is not displayed if the reagent has not been registered. When the shelf life after opening has expired, it displayed in white letter on a red background.

Lot No; displays the lot number of the reagent.

Remaining volume graph; displays the remaining volume of the reagent as a graph. This is not displayed if the reagent has not been registered, or if the reagent has run out

Reagent state; displays the remaining number of tests for the reagent. (Only the remaining level of [CELLPACK DCL] reagent will be displayed.)

Reagent name; displays the reagent name.

Note:

The remaining number of tests is only an approximation. It can change with use conditions. This is not displayed if the reagent has not been registered.

When a reagent runs low, the background becomes yellow.

During diluent or haemolytic agent replacement, progress is indicated as "0 to 100%".

Section 8: Sysmex SP-50

SP-50 Introduction and Overview

The SP-50 is a fully automated slide preparation and staining unit. By means of ID scanning, mixing and the wedge method, the SP-50 can make a smear from a sample that has been judged abnormal by the haematology analyser connected.

The SP-50 receives the necessary information from the host computer or the conveyor system and makes smears based on the smearing conditions set on the SP-50 main unit.

In order to make blood films that are uniform and suitable for microscopy, staining solution is dispensed to each smeared slide one at a time.

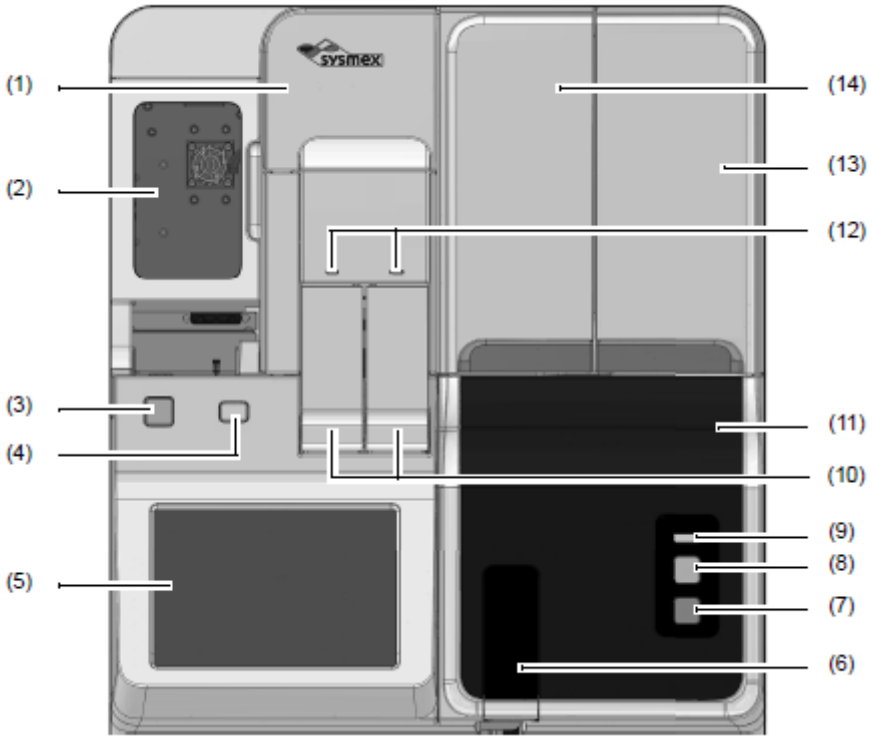


Figure 28– SP-50 front view

(1) Main power switch cover
Opens upward. Open this cover to turn the main power switch ON/OFF, and to regulates the pressure.

(2) Stain unit cover
Opens to the left. Open this cover to inspect the interior of the main unit, or to perform cleaning or maintenance tasks.

(3) Power switch
Press to turn ON the instrument power.

(4) Eject switch
Press to forcibly feed out a magazine.

(5) Touchscreen
Used to check the instrument status and perform operations.

(6) Sample holder

Used to set sample tubes for manual preparation.

(7) Mode switch

Press to switch between manual preparation and sampler preparation. Pressing it opens and closes the sample holder.

- When the sample holder is open: Manual preparation
- When the sample holder is closed: Sampler preparation

(8) Start switch

Press to start manual preparation.

(9) Status display LED (main unit front)

Instrument status is represented by the LED on/flashing pattern.

Color	Status
Green	Ready (for blood smear preparation) status/Waiting to execute maintenance
Flashing green	Starting up/Preparing a slide (sampler preparation)/ Aspirating sample (manual preparation)/Switching the slide preparation mode/ Shutting down/Sleeping/Maintenance in progress
Orange*	Ready (for blood smear preparation) status
Flashing orange*	Starting up/Preparing a slide/Switching the slide preparation mode/ Shutting down/Sleeping
Red	Error (without alarm)/Initializing system/Error stop/Stopped
Flashing red	Error (with alarm)
Not lit	Powered OFF

* An error has occurred, but the instrument is still operational.

(10) Manual magazine holder (right/left)

This is used for the following purposes in each slide preparation mode.

- [Smearing]/[Print] mode:
  The prepared slide glass is loaded into the magazine in the manual magazine holder.
- [Staining] mode:
  Load the magazine that holds the slide glass to be stained in this holder.

(11) Front-lower cover

This is a protective cover. Open this cover to inspect the interior of the main unit, or to perform cleaning or maintenance tasks.

(12) Status display LED (manual magazine holder)

The status of the manual magazine holder is indicated by the LED on/flashing pattern. The magazine cannot be loaded or removed while the LED is flashing.

Color	Status
Green	With a magazine
Red	Error
Not lit	Powered OFF/Without a magazine

(13) Slide set unit cover

Opens upward. Open to load a slide glass.

(14) Smear unit cover

Opens upward. Open this cover to inspect the interior of the main unit, or to perform cleaning or maintenance tasks. The smear unit cover and the slide set cover are one piece. To open the smear unit cover, remove the slide supply cassette first.

SP-50 Software Overview

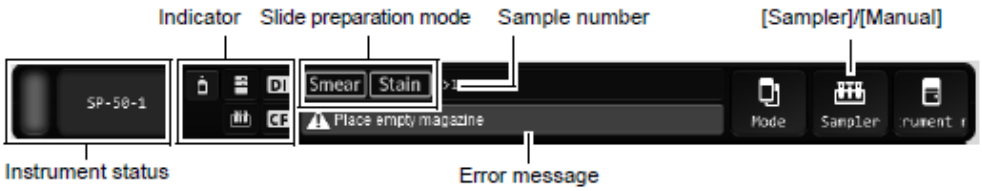
The SP-50 is operated via a 10.4-inch touch panel colour LCD display.

Main Menu area

Figure 29 – SP-50 Screen

Status area

The status area layout is as follows:



Status area

Instrument status

A message is shown as indicated below, depending on the status of the instrument.

Message	Status
[Start Up]	Starting up
[Shutdown]	Shutdown in progress
[Maintenance]	Maintenance in progress

The status area layout is as follows:

Color	Status
Green	Ready (for blood smear preparation) status/Waiting to execute maintenance
Flashing green	Starting up/Preparing a slide/Switching the slide preparation mode/Shutting down/Sleeping/ Maintenance in progress
Orange*	Ready (for blood smear preparation) status
Flashing orange*	Starting up/Preparing a slide/Switching the slide preparation mode/Shutting down/Sleeping
Red	Error (without alarm)/Initializing system/ Error stop/Stopped
Flashing red	Error (with alarm)
Not lit	Powered OFF

* An error has occurred, but the instrument is still operational.

Indicator	The statuses of the instrument, connected reagents and peripheral devices are displayed by icons. If a reagent or device is not connected, an icon does not appear.
Reagent status	Changes to yellow the remaining reagent volume is low. Changes to red when one of the connected reagents runs out (reagent level 0). Touch to display the [Reagent Replacement] dialog box.
Host computer status	When a host computer is connected, this changes to red if a connection error occurs.
DI status	When the DI-60 is connected, this changes to red if an error occurs on the DI-60.
RU status	When the RU-20 is connected, this changes to red if an error occurs on the RU-20.
Sampler status	Changes to red if a sampler error occurs.
CF status	When the CF-70 is connected, this changes to red if an error occurs on the CF-70.
Slide preparation mode	Displays a selected slide preparation mode. (➤P.58 "Chapter 3: 3.2.2 Slide preparation mode")
Sample number	Displays a sample number. [>] at the beginning of the sample number indicates that the instrument is ready to aspirate the next sample. If the sample number is not read, or if it has not been entered manually, a message is displayed to prompt the input of the number.
Error message	Displays the highest priority error among all current errors. The displayed error is categorized as one of the following error types: Color: Orange background/Black text — Status: Caution Color: Red background/White text — Status: Warning Non-urgent information such as notices appears in white text.
[Mode]	Touch to select the slide preparation mode. (➤P.58 "Chapter 3: 3.2.2 Slide preparation mode")

[Sampler]/[Manual]

Touch to register sample information and slide preparation conditions.
Touch to display the [Manual Preparation] dialog box or [Sampler Preparation] dialog box.
The icon displayed varies depending on the selected slide preparation method and settings.

Display	Types of slide preparation	Setting
	Sampler preparation	—
	Manual preparation	[Cap Open] is OFF
		[Cap Open] is ON
		[RBT] is ON

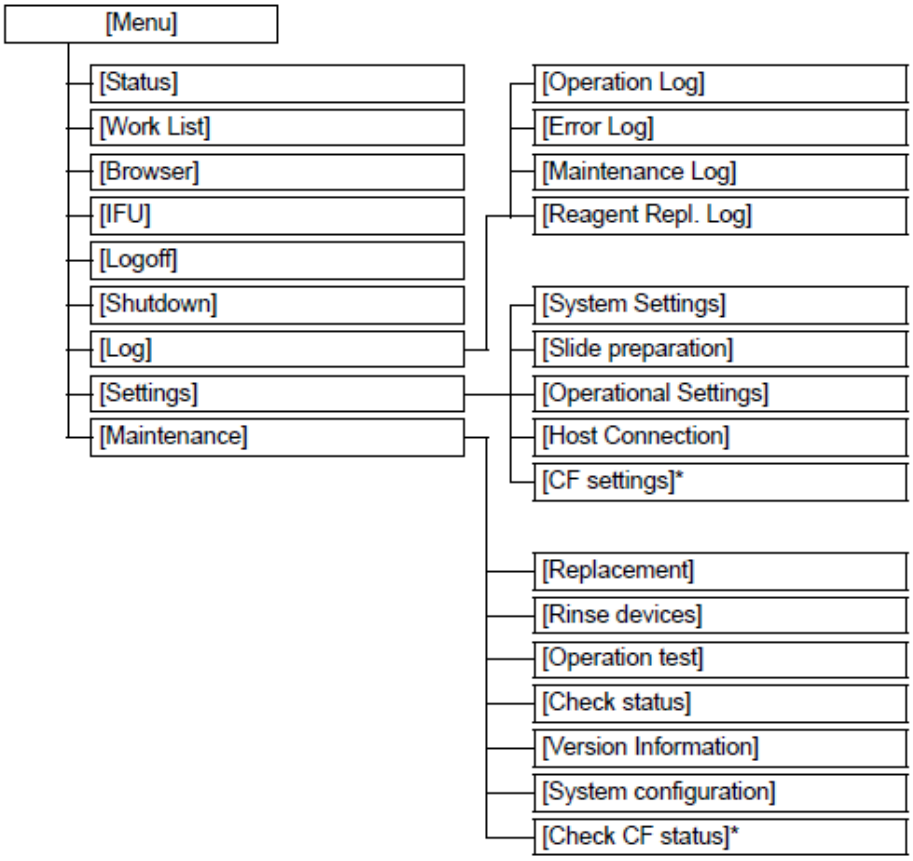
[Menu]

Touch to display a submenu, which allows you to execute the following functions.

[Shutdown]: Touch to display the [Shutdown] dialog box.
[Reagent Replacement]: Touch to display the [Reagent Replacement] dialog box.
[Spreader glass rinsing]: Touch to display the [Spreader glass rinsing] dialog box.
[Emergency stop]: Touch to execute instrument emergency stop.

SP-50 Menu

The menu structure is shown below.

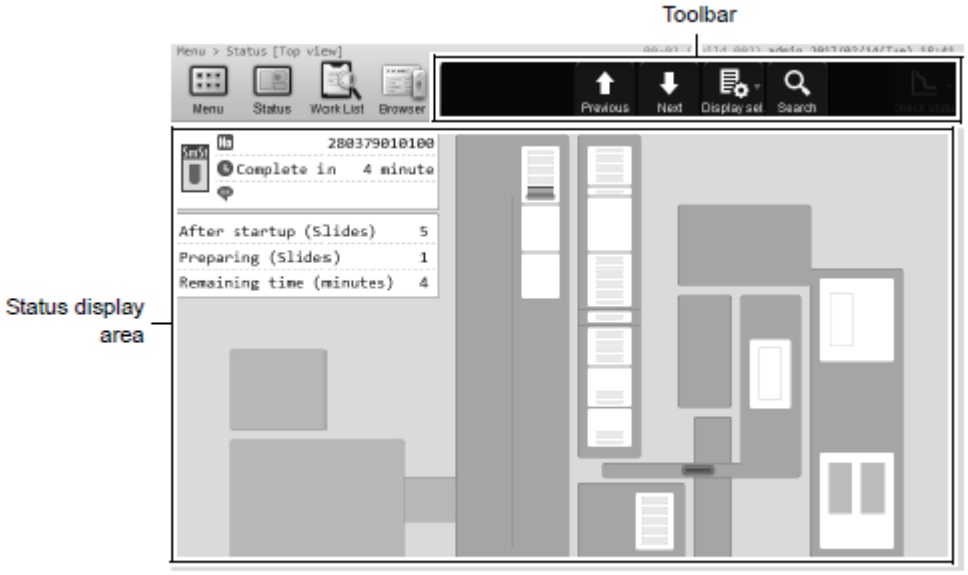


* Displayed only when the instrument is connected to the DI-60.

Status Screen

When [Status] is selected on the menu screen, the status display screen appears.

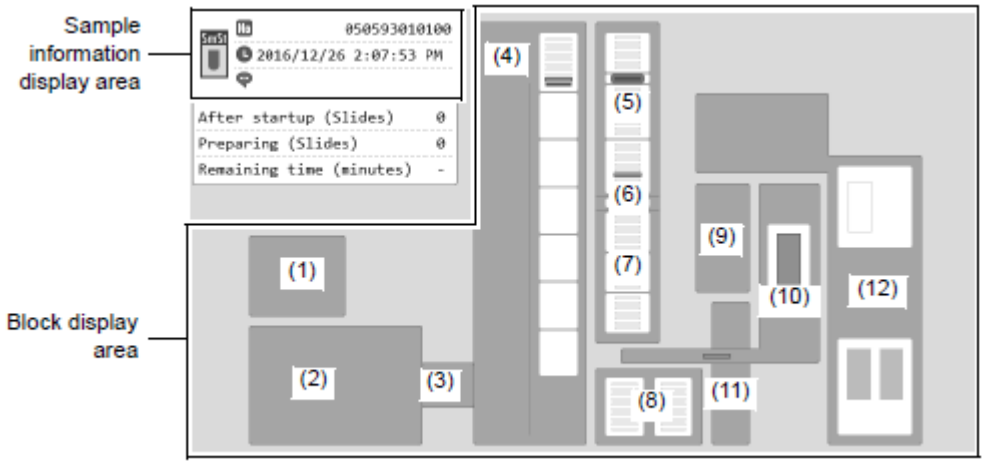
In the [Status] screen, you can check the status of smear preparation and whether an error has occurred on the instrument.



[Status] screen
e.g. Top view

Display Top view

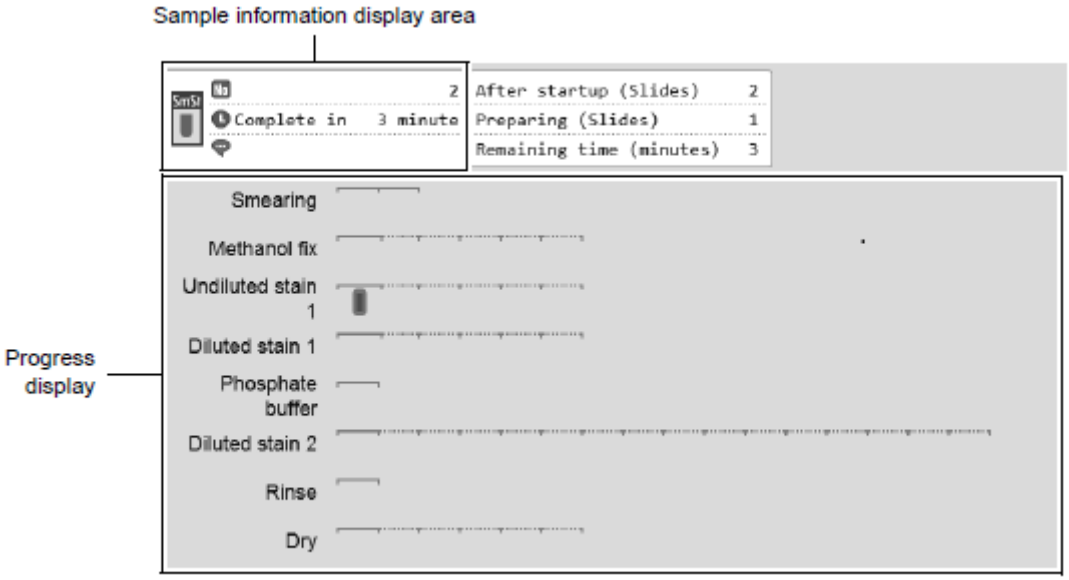
Displays the instrument status, current smear position, and other information by block in top view.



[Status] screen (top view)

Display Process view

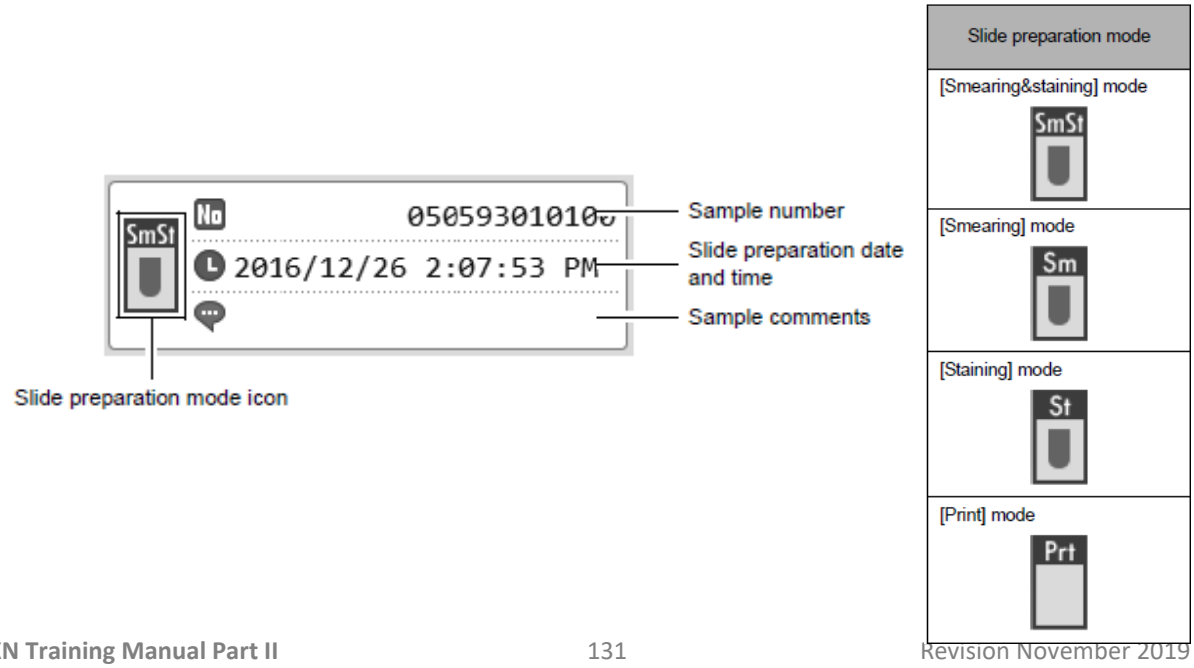
This shows the progress of smear preparation in each process.



[Status] screen (process view)

Sample information display area

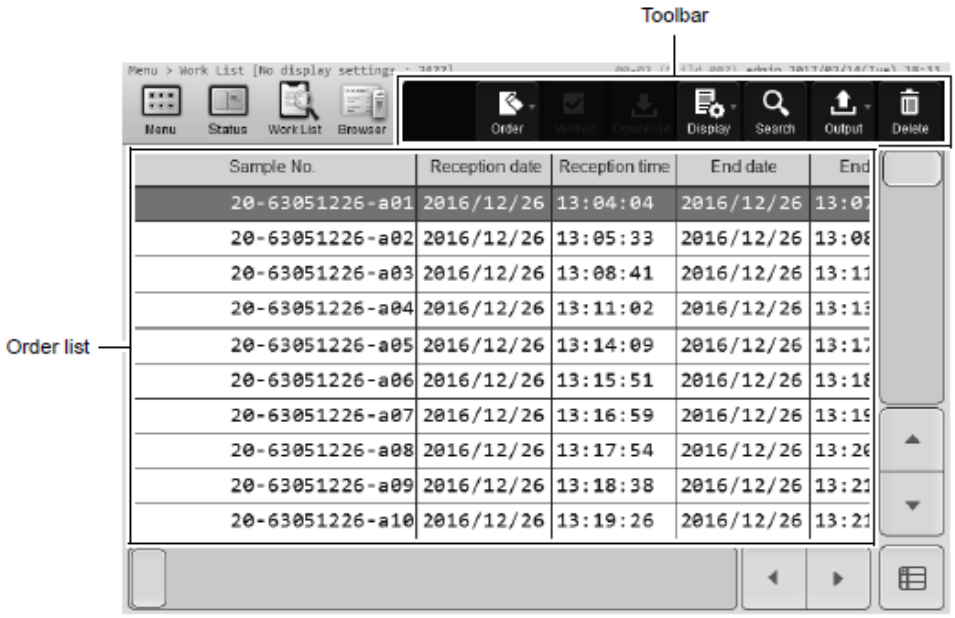
Displays the order selected in the [Work List] screen and the information of the order corresponding to the sample selected in the status display area of the [Status] screen. Blank when the [Status] of the selected order is [Not prepared] or there is no slide being prepared.



Worklist Screen

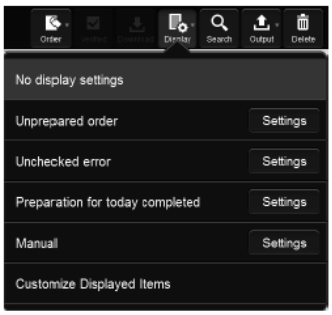
When [Worklist] is selected on the menu screen, the worklist screen appears.

In the [Worklist] screen, you can download, register, edit, delete, search and manage slide preparation orders.



[Work List] screen

Display settings



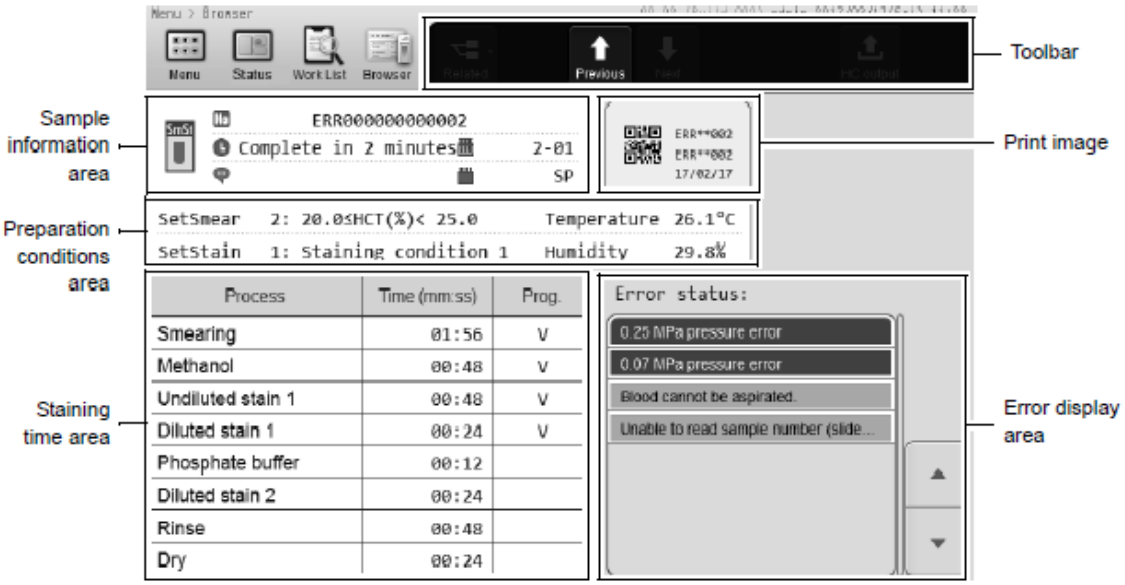
The order of display can be changed and filtered to match specified conditions.

[No display settings]	Touch to cancel the sort and filter settings and show all slide preparation orders in the order of registration.
[Unprepared order]	Touch to display only unprepared orders by [Sample No.] in ascending order.
[Unchecked error]	Touch to display only completed orders that have unconfirmed errors by [End date] and [End time] in descending order.
[Preparation for today completed]	Touch to display only completed orders that were prepared that day, by [End time] in ascending order.
[Manual]	Touch to display only completed orders that were prepared manually, by [End date] and [End time] in ascending order.
[Settings]	Touch this to configure display sorting and filtering conditions. (➤P.52 "●Changing display settings (sort/filter)")
[Customize Displayed Items]	Touch to display a dialog box, which allows you to change the items displayed on the order list. (➤P.55 "2.6.2 Changing the items displayed in the order list")

Browser Screen

When [Browser] is selected on the menu screen, the browser screen appears.

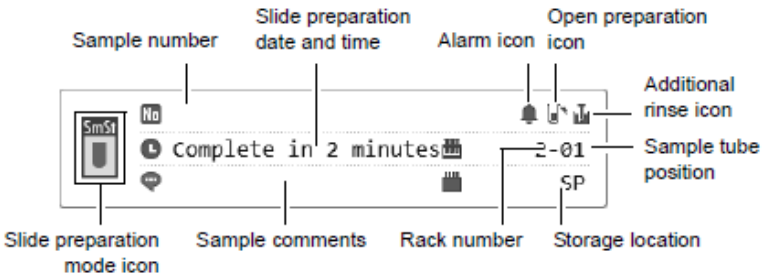
In the [Browser] screen, you can view detailed slide preparation information such as preparation condition used, staining time, printed information and error display.



[Browser] screen (data for users)

Sample information area

Displays the following information.



Log Screen

When [Log] is selected on the menu screen, the log screen appears.

The following logs can be viewed (data capacity of 5000 entries).

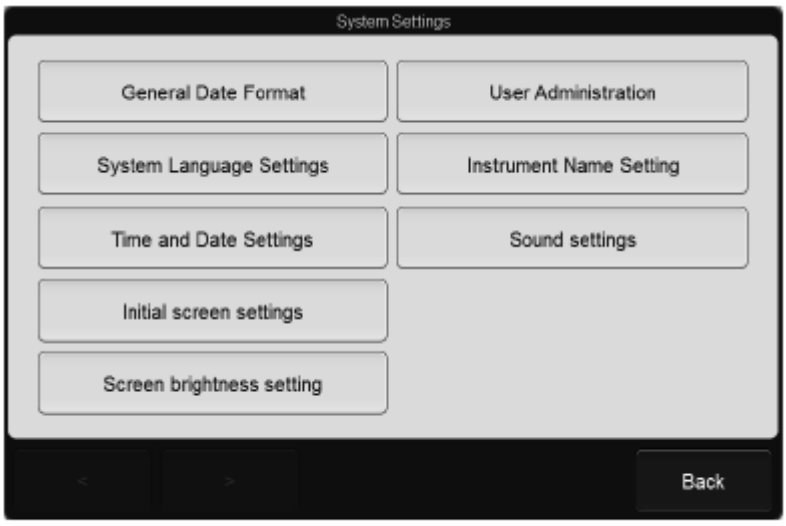
- **Operation log:** Displays a log of operations.
- **Error log:** Displays a log of errors that occurred, and information at the time of occurrence and clearance.
- **Maintenance log:** Displays a log of maintenance tasks executed, and information at the time of execution.
- **Reagent replacement log**: Displays a log of reagent replacement, and any information that was entered at the time of replacement.

[Log] menu screen

Settings Screen

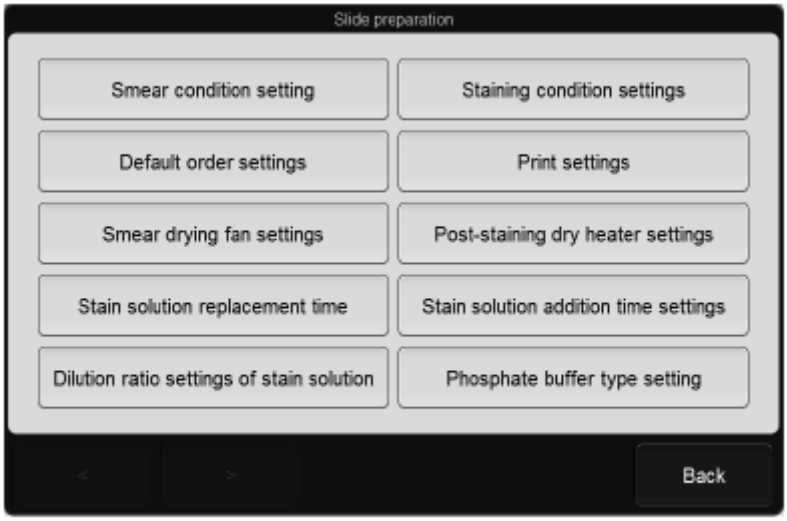
[Settings] menu screen

System Settings



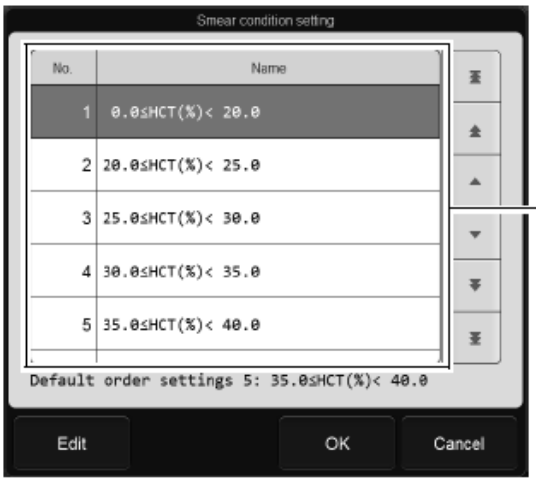
[System Settings] dialog box

Slide Preparation Settings



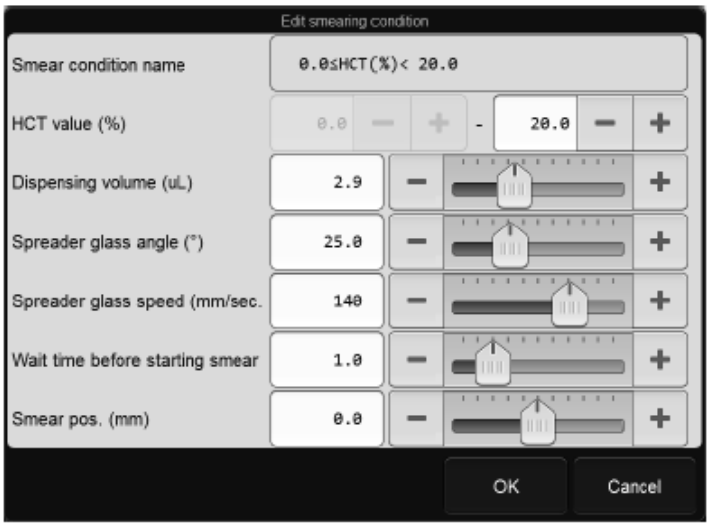
[Slide preparation] dialog box

Smearing Condition setting



Smear conditions list

[Smear condition setting] dialog box



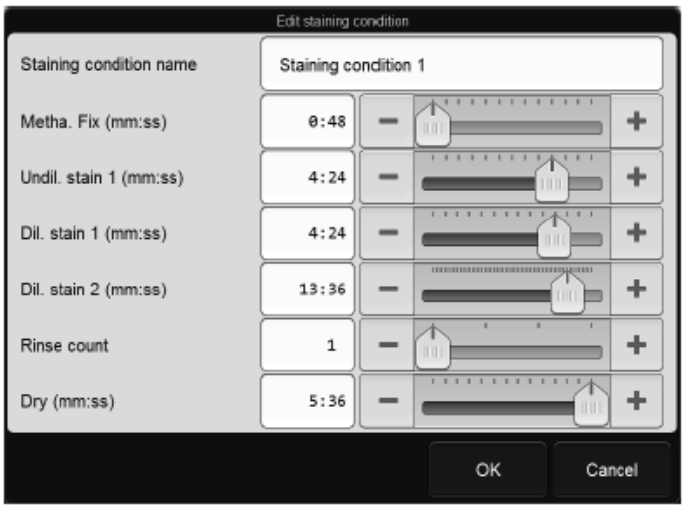
Touch [Edit] in the [Smear condition setting] dialog box to display the following dialog box.

Touch an item to change the settings.

Staining Condition settings

Staining conditions list

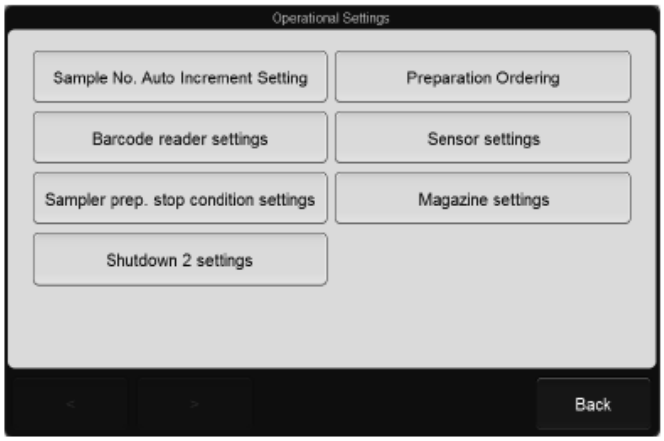
[Staining condition settings] dialog box



Touch [Edit] in the [Staining condition settings] dialog box to display the following dialog box. The displayed contents differ depending on the staining method.

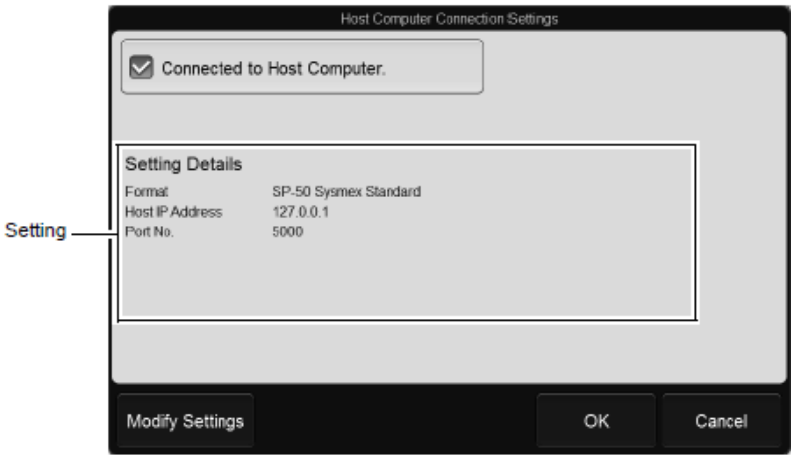
Touch an item to change the settings.

Operational Settings



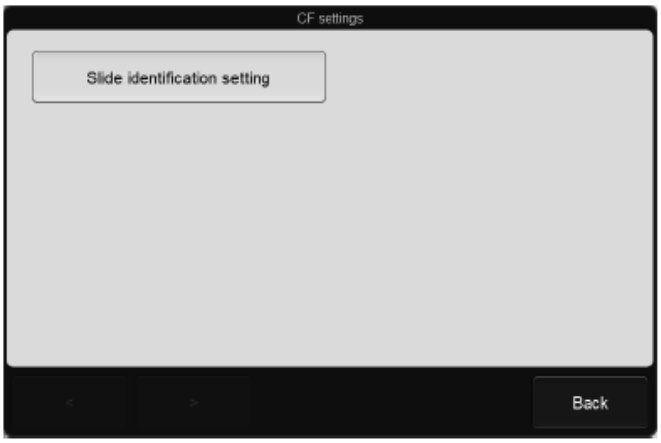
[Operational Settings] dialog box

Host Computer Connection Settings



[Host Computer Connection Settings] dialog box

CF Settings (DI-60 connection)



[CF settings] dialog box

SP-50 Reagent

The following stains, buffers and rinsing agents are recommended for use on the SP-50:

- May-Grünwald stain
- Wright's stain
- Giemsa stain
- Phosphate buffer
- Concentrated phosphate buffer for SP (pH 6.6/pH 6.8/pH 7.0/pH 7.2)
- Rinse water

CELLPACK DCL (diluted) or CELLPACK DST (concentrated)

Rinse solution used to rinse the whole blood aspiration line. The on-board stability of CELLPACK is 60 days.

CELLCLEAN AUTO

CELLCLEAN AUTO is a strong alkaline detergent that is used to remove residual reagent, cellular residuals and blood proteins remaining in the hydraulic system of the automated haematology slide preparation unit.

Store in a dark place and do not allow exposure to direct sunlight. Excessive exposure to direct sunlight will cause the chlorine component to degrade, resulting in a loss of detergent strength. Open vial stability is 60 days.

CONCENTRATED PHOSPHATE BUFFER FOR SP (pH 6.6/pH 6.8/pH 7.0/pH 7.2)

Concentrated phosphate buffer for SP is diluted appropriately in the SP-50 automated haematology slide preparation unit using RO water from the RR-20 unit and then used as a reagent for preparation of smears.

May-Grünwald stain (procured locally)
Stain used to stain blood smears.

Wright's stain (procured locally)
Stain used to stain blood smears.

Giemsa stain (procured locally)
Stain used to stain blood smears.

Phosphate buffer (procured locally)
Buffer used for the preparation of blood smears.

Rinse water (procured locally)
Detergent used when preparing smears.
Use ion-exchanged water or an equivalent detergent with no fluctuations of pH.

SP-50 Reagent Consumption

Start-up Reagent volumes

Startup			
Staining method	Reagent name	Standard specifications	High-speed specifications
Double staining	CELLPACK DCL	Approx. 48 mL	Approx. 48 mL
	Stain solution 1	Approx. 73 mL	Approx. 117 mL
	Stain solution 2	Approx. 26 mL	Approx. 32 mL
	Concentrated phosphate buffer	Approx. 7.5 mL	Approx. 9.9 mL
	Rinse water*1	Approx. 439 mL	Approx. 581 mL
	Methanol*2	Approx. 70 mL	Approx. 95 mL
Single staining	CELLPACK DCL	Approx. 70 mL	Approx. 48 mL
	Stain solution 1	Approx. 99 mL	Approx. 138 mL
	Concentrated phosphate buffer	Approx. 4.5 mL	Approx. 6.8 mL
	Rinse water*1	Approx. 266 mL	Approx. 399 mL
	Methanol*2	Approx. 70 mL	Approx. 95 mL
Startup after [Shutdown 2] is performed			
Staining method	Reagent name	Standard specifications	High-speed specifications
Double staining	CELLPACK DCL	Approx. 48 mL	Approx. 48 mL
	Stain solution 1	Approx. 226 mL	Approx. 274 mL
	Stain solution 2	Approx. 158 mL	Approx. 166 mL
	Concentrated phosphate buffer	Approx. 7.5 mL	Approx. 9.4 mL
	Rinse water*1	Approx. 439 mL	Approx. 439 mL
	Methanol*2	Approx. 70 mL	Approx. 110 mL
Single staining	CELLPACK DCL	Approx. 70 mL	Approx. 70 mL
	Stain solution 1	Approx. 378 mL	Approx. 400 mL
	Concentrated phosphate buffer	Approx. 4.5 mL	Approx. 7.1 mL
	Rinse water*1	Approx. 266 mL	Approx. 414 mL
	Methanol*2	Approx. 70 mL	Approx. 110 mL

*1 Rinse water consumption volume includes the volume used for dilution of concentrated phosphate buffer.
*2 Methanol is not required when methanol prefixing is not used.

Reagent volumes used to prepare one smear

Slide preparation*1			
Staining method	Reagent name	Standard specifications	High-speed specifications
Double staining	CELLPACK DCL	Approx. 21 mL	Approx. 21 mL
	Stain solution 1	Approx. 2.15 mL	Approx. 0.54 mL
	Stain solution 2	Approx. 0.90 mL	Approx. 0.45 mL
	Concentrated phosphate buffer	Approx. 1.15 mL	Approx. 0.57 mL
	Rinse water*2	Approx. 107 mL	Approx. 77 mL
	Methanol*3	Approx. 1.30 mL	Approx. 0.45 mL
Single staining	CELLPACK DCL	Approx. 21 mL	Approx. 21 mL
	Stain solution 1	Approx. 3.45 mL	Approx. 1.45 mL
	Concentrated phosphate buffer	Approx. 0.65 mL	Approx. 0.47 mL
	Rinse water*2	Approx. 82 mL	Approx. 70 mL
	Methanol*3	Approx. 1.30 mL	Approx. 0.45 mL

*1 Volume consumed per slide when prepared using the conditions below.
Standard specifications: 30 slides prepared per day
High-speed specifications: 75 slides prepared per day
*2 Rinse water consumption volume includes the volume used for dilution of concentrated phosphate buffer.
*3 Methanol is not required when methanol prefixing is not used.

Reagent volumes used at Shutdown 1

[Shutdown 1]			
Staining method	Reagent name	Standard specifications	High-speed specifications
Double staining	CELLPACK DCL	Approx. 149 mL	Approx. 149 mL
	Concentrated phosphate buffer	Approx. 3.5 mL	Approx. 4.6 mL
	Rinse water*1	Approx. 180 mL	Approx. 268 mL
	CELLCLEAN AUTO	Approx. 4 mL (1 vial)	Approx. 4 mL (1 vial)
	Methanol*2	Approx. 420 mL	Approx. 475 mL
	Ethanol*2	Approx. 420 mL	Approx. 475 mL
Single staining	CELLPACK DCL	Approx. 149 mL	Approx. 149 mL
	Concentrated phosphate buffer	Approx. 3.5 mL	Approx. 3.5 mL
	Rinse water*1	Approx. 180 mL	Approx. 207 mL
	CELLCLEAN AUTO	Approx. 4 mL (1 vial)	Approx. 4 mL (1 vial)
	Methanol*2	Approx. 420 mL	Approx. 475 mL
	Ethanol*2	Approx. 420 mL	Approx. 475 mL

*1 Rinse water consumption volume includes the volume used for dilution of concentrated phosphate buffer.
*2 If methanol is used for prefixing, refer to the methanol consumption volume. If methanol is not used for prefixing, you can select whether methanol or ethanol is used as the rinsing reagent.

Reagent volumes used at Shutdown 2

[Shutdown 2]			
Staining method	Reagent name	Standard specifications	High-speed specifications
Double staining	CELLPACK DCL	Approx. 149 mL	Approx. 149 mL
	Concentrated phosphate buffer	Approx. 3.5 mL	Approx. 4.3 mL
	Rinse water*1	Approx. 180 mL	Approx. 250 mL
	CELLCLEAN AUTO	Approx. 4 mL (1 vial)	Approx. 4 mL (1 vial)
	Methanol*2	Approx. 694 mL	Approx. 848 mL
	Ethanol*2	Approx. 694 mL	Approx. 848 mL
Single staining	CELLPACK DCL	Approx. 149 mL	Approx. 149 mL
	Concentrated phosphate buffer	Approx. 3.5 mL	Approx. 3.5 mL
	Rinse water*1	Approx. 180 mL	Approx. 180 mL
	CELLCLEAN AUTO	Approx. 4 mL (1 vial)	Approx. 4 mL (1 vial)
	Methanol*2	Approx. 588 mL	Approx. 743 mL
	Ethanol*2	Approx. 588 mL	Approx. 743 mL

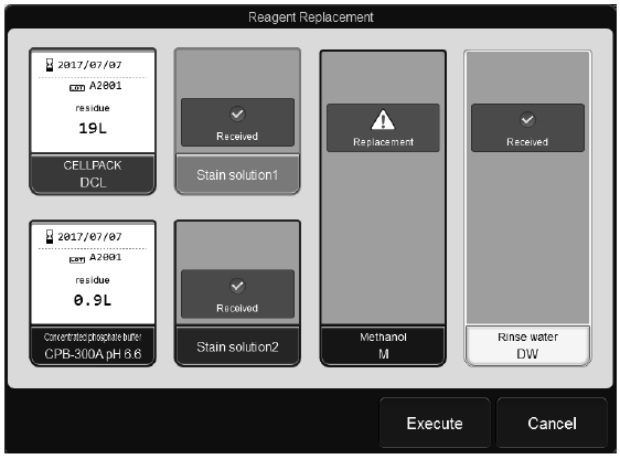
*1 Rinse water consumption volume includes the volume used for dilution of concentrated phosphate buffer.
*2 If methanol is used for prefixing, refer to the methanol consumption volume. If methanol is not used for prefixing, you can select whether methanol or ethanol is used as the rinsing reagent.

SP-50 Registering and Replacing Reagent

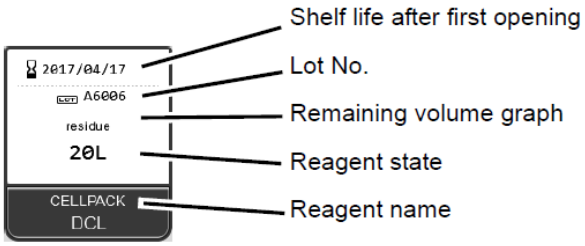
Replacing CELLPACK DCL, Phosphate Buffer, Stain 1, Stain 2, Methanol and Rinse water

1. From the menu screen, touch [Maintenance], touch [Replacement] and touch [Reagent Replacement].

   The dialog box displays the reagent information and reagent remaining volume.



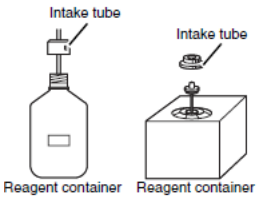
[Reagent Replacement] dialog box



   If the following messages appears, follow the steps below.
   [Out of stain 1 solution], [Out of stain 2 solution], [Out of concentrated phosphate buffer], [Out of CELLPACK DCL], [RU-20 Out of CELLPACK DST]

2. Prepare the new reagent and confirm that its expiration date has not passed.

3. Remove the cap from the new reagent container.



4. Remove the cap from the empty reagent container, and pull the intake tube straight up.

5. Insert the intake tube into the new reagent container and tighten the cap.

6. Input the reagent information of the new reagent.
   Input by barcode scanning for: Cellpack DCL, Cellpack DST or Concentrated phosphate buffer.

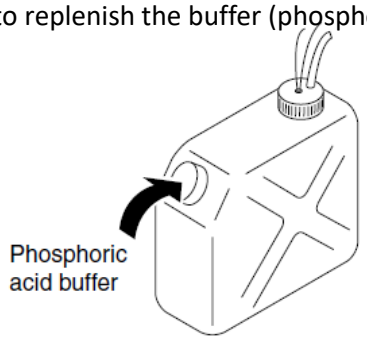
   When the Reagent information is input, [Received] appears on the reagent in the dialog box
   The lot number and the expiration date of the new reagent are shown.

7. When reagent information registration is completed, touch [Execute].
   The new reagent is aspirated and the reagent is replaced.

Replenishing the phosphate buffer (pre-diluted)

If [Out of phosphate buffer] appears, follow the steps below to replenish the buffer (phosphoric acid buffer).

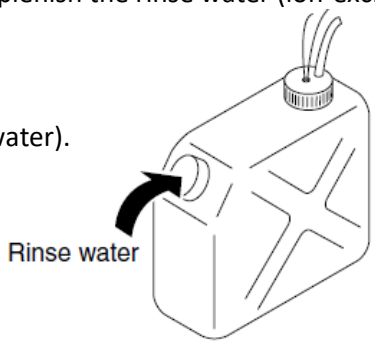
1. Remove the cap from the container.
2. Fill the container with phosphoric acid buffer. container holds about 20 L.
3. Cap the container.



Replenishing rinse water

If [Out of rinse water] appears, follow the steps below to replenish the rinse water (ion-exchanged water).

1. Remove the cap from the container.
2. Fill the container with rinse water (ion-exchanged water). container holds about 20 L.
3. Cap the container.

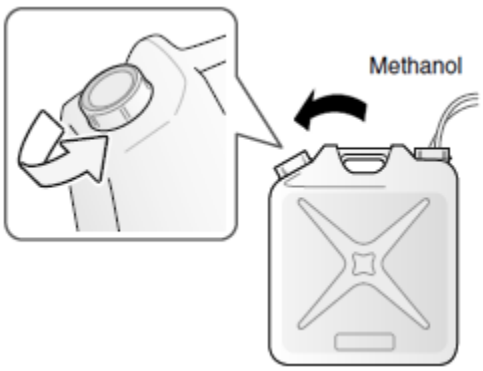


Caution!
When replenishing rinse water and/or phosphoric acid buffer do not remove the float switch.

Replenishing the methanol

If [Out of methanol] appears, follow the steps below to replenish the methanol.

1. Remove the cap from the container.
2. Fill the container with methanol. container holds about 10 L.
3. Cap the container.



SP-50 Temporarily use CELLPACK DCL (if using RU-20)

When the RU-20 cannot be used due to a failure or other problem, you can temporarily use CELLPACK DCL.

1. Remove the DCL adaptor from the RU-20 supply tank.
2. Attach the DCL adaptor that you removed from the RU-20 supply tank to the CELLPACK DCL.
3. Touch [Maintenance] in the menu screen.
4. Touch [Replacement].
5. Touch [RU<->DCL] and select [RU->DCL].
6. Touch [OK].
7. Display the [Reagent Replacement] dialog box.
8. Register the CELLPACK DCL.
9. Perform XN tri-level QC check.
10. Instruments connected are ready for use.

[RU<->DCL] dialog box

SP-50 End temporarily use CELLPACK DCL (if using RU-20)

To reset the RU-20, end temporary use of CELLPACK DCL.

1. Remove the DCL adaptor from the CELLPACK DCL keg.
2. Attach the DCL adaptor that you removed from the CELLPACK DCL to the RU-20 supply tank.
3. Touch [Maintenance] in the menu screen.
4. Touch [Replacement].
5. Touch [RU<->DCL] and select [DCL->RU].
6. Touch [OK].
   The dialog box closes and the alarm sounds briefly.
   End temporary use of CELLPACK DCL, and use RU-20.
7. Touch [Back] in the [Replacement] dialog box.
8. Perform XN tri-level QC check.
9. Instruments connected are ready for use.

[RU<->DCL] dialog box

Section 9: Sysmex SP-10

SP-10 Introduction and Overview

The SP-10 is a fully automated slide preparation and staining unit. By means of ID scanning, mixing and the wedge method, the SP-50 can make a smear from a sample that has been judged abnormal by the haematology analyser connected.

The SP-10 receives the necessary information from the host computer or the conveyor system and makes smears based on the smearing conditions set on the SP-10 main unit.

In order to make blood films that are uniform and suitable for microscopy, staining solution is dispensed to each smeared slide one at a time.

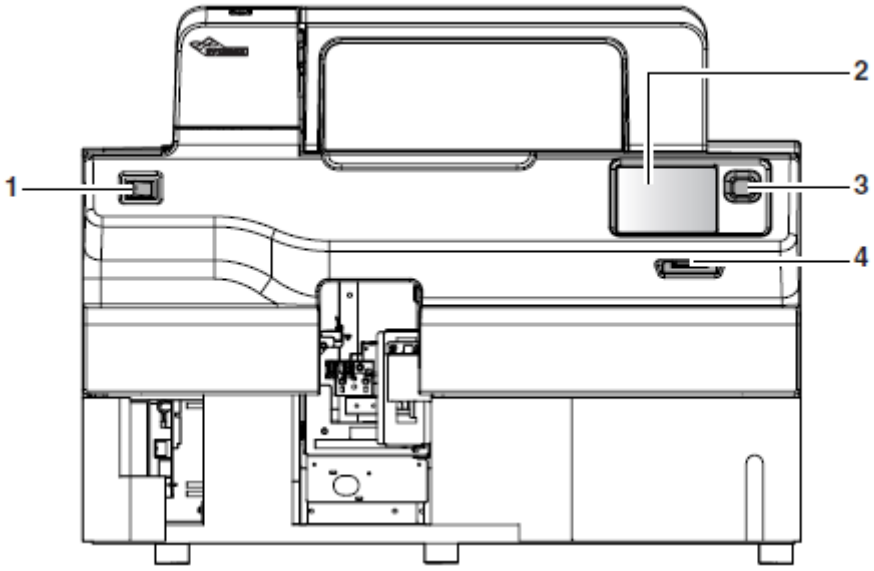


Figure 28– SP-10 front view

1 Main power switch

Turns the main power on and off.

2 Display

This is a 5.7-inch touch panel color LCD.
The display shows the device status, operation menus, and other information. The touch panel can be used to operate the device.

3 Startup switch

Starts up the device.

4 Brightness adjustment lever

Adjusts the brightness of the LCD screen.
To adjust the brightness of the LCD screen, move the lever to the left or right.

SP-10 Software Overview

The SP-10 is operated via a 5.7-inch touch panel colour LCD.

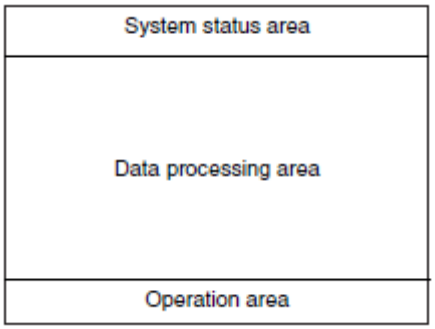
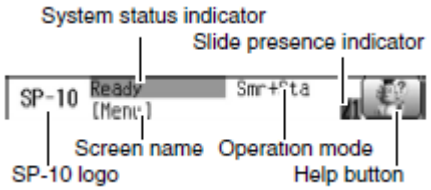


Figure 29 – SP-10 Screen

System status area

Displays the screen name, system status indicator, and Help button.

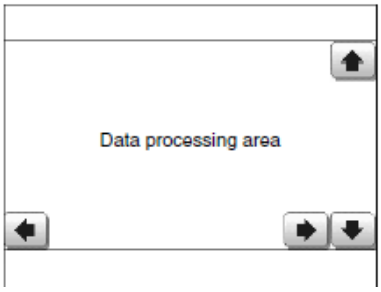


Data processing area

Displays the data of each screen, data can be viewed and input. Vertical and horizontal cursor buttons are displayed as necessary.

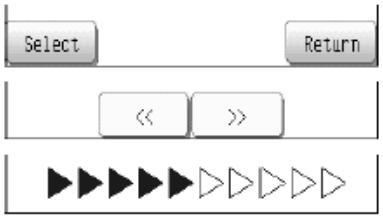
These enable the following operations to be performed:

- Move the cursor.
- Scroll through a list.
- Switch to other screens.



Operation area

Displays messages and buttons for the screen displayed in the data processing area.



SP-10 Menu

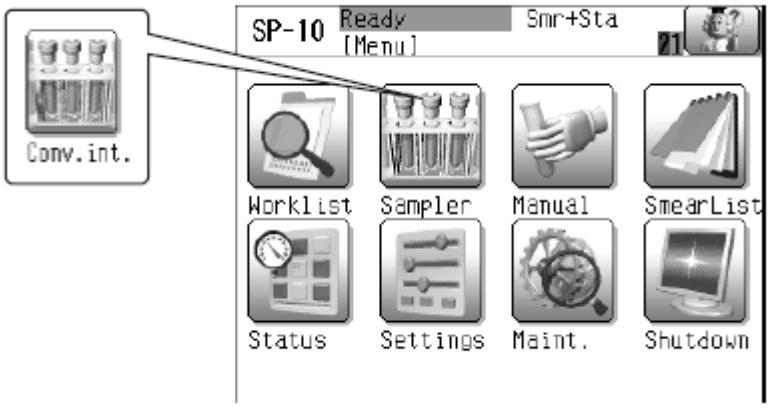


Figure 30 – SP-50 Menu Screen

Note:

If SP-10 is part of an XN-3100 or XN-9100 system, refer to the relevant IFU manual for information regarding functionality and operation.

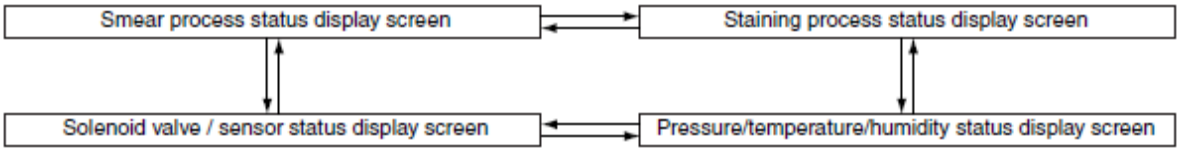
For integrated systems, Sampler key on the SP-10 Menu screen is not functional . Sampler mode will be controlled by system sampler.

Status Display Screen

When [Status] is selected on the menu screen, the status display screen appears.

This consists of four screens that show the status of the smear preparation process.

To switch through the screens, touch [<<] or [>>].



To exit status display and return to the menu screen, touch [Return].

Smear Process Status Display Screen

Provides up-to-date information about status of all completed and in progress smears.

Figure 31 – SP-10 Smear Process Status Display Screens

Staining Process Status Display Screen

The items shown will vary depending on the staining mode (single staining or double staining), and user defined staining conditions which have been set.

Figure 32 – SP-10 Staining Process Status Display Screens

Pressure/Temperature/Humidity Status Display Screen

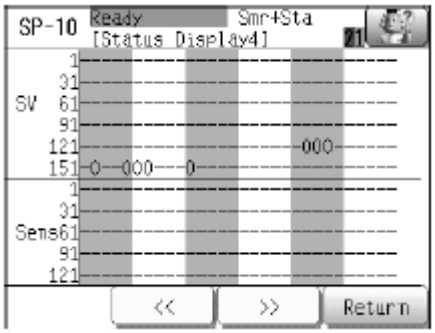


Figure 33 – SP-10 Pressure, Temperature and Humidity Status Display Screens

Solenoid Valve/Sensor Status Display Screen

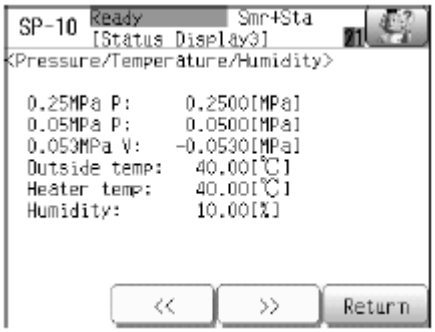


Figure 34– SP-10 Solenoid Valve/ Sensor Status Display Screen

SP-10 Discharge Timer information

Discharge timer 1:

Discharge timer is a timer to set for replacing diluted stain solution between mixing chamber and pipette 2. Diluted stain solution may deteriorate after a period of time; it is a countermeasure for degradation of staining properties.

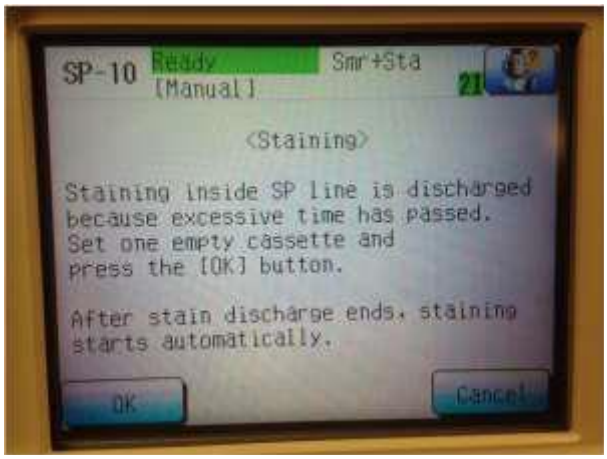
Depending on staining profile selected this process can be initiated automatically every 15, 30, 60, 90 or 120 minutes following the last smear/staining.

During discharge timer 1, one empty cassette will be needed. This empty cassette will go through one cycle of the whole staining process. During this time, diluted stain solution between mix chamber and pipette 2 will be dispensed into the cassette and discard.

How to enable Discharge timer 1:

Service mode > Select > Settings > System 1 > StainMode > Discharge Timer 1

When instrument is running in manual mode, this action message will be shown.



Operator will need to press [OK] to activate the process; however the process will carry out automatically when running in sampler mode.

Discharge timer 2:

Discharge timer 2 function is to rinse stain line between mixing chamber and pipettes with methanol and replace diluted stain solution after this rinsing sequence. The main purpose of this discharge timer is to prevent the crystallization or precipitation of stain which causing the poor staining quality.

Depending on staining profile selected this process can be initiated automatically:

20min/1.0h

Stain discharge is performed after 20 minutes from the previous smear/ staining operation or 1.0 hour from the previous rinsing with methanol (previous discharge 2)

20min/2.0h

Stain discharge is performed after 30 minutes from the previous smear/ staining operation or 2.0 hour from the previous rinsing with methanol (previous discharge 2)

20min/3.0h

Stain discharge is performed after 60 minutes from the previous smear/ staining operation or 3.0 hour from the previous rinsing with methanol (previous discharge 2)

20min/4.0h

Stain discharge is performed after 90 minutes from the previous smear/ staining operation or 4.0 hour from the previous rinsing with methanol (previous discharge 2)

10min/1.0h

Stain discharge is performed after 120 minutes from the previous smear/staining operation or 1.0 hour from the previous rinsing with methanol (previous discharge 2)

10min/2.0h

Stain discharge is performed after 120 minutes from the previous smear/staining operation or 2.0 hour from the previous rinsing with methanol (previous discharge 2)

10min/3.0h

Stain discharge is performed after 120 minutes from the previous smear/staining operation or 3.0 hour from the previous rinsing with methanol (previous discharge 2)

10min/4.0h

Stain discharge is performed after 120 minutes from the previous smear/staining operation or 4.0 hour from the previous rinsing with methanol (previous discharge 2)

During discharge timer 2, 6 cassettes will be used. This process consists of:

- Step 1: discharging the diluted stain solution between the mix chamber and pipette 2
- Step 2: rinsing the mix chamber with methanol and
- Step 3: priming the new diluted stain solution to fill up between mix chamber and pipette 2.

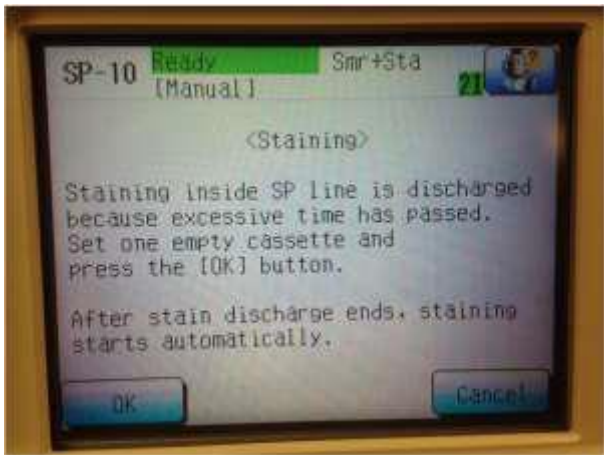
Approximate reagent quantity (discharge timer 2):

- Methanol : approx. 15mL
- Stain 1 : approx. 20mL (for replenishing new stain diluted solution)

How to enable Discharge timer 2:

Service mode > Select > Settings > System 1 > StainMode > Discharge Timer 2

When instrument is running in manual mode, this action message will be shown.



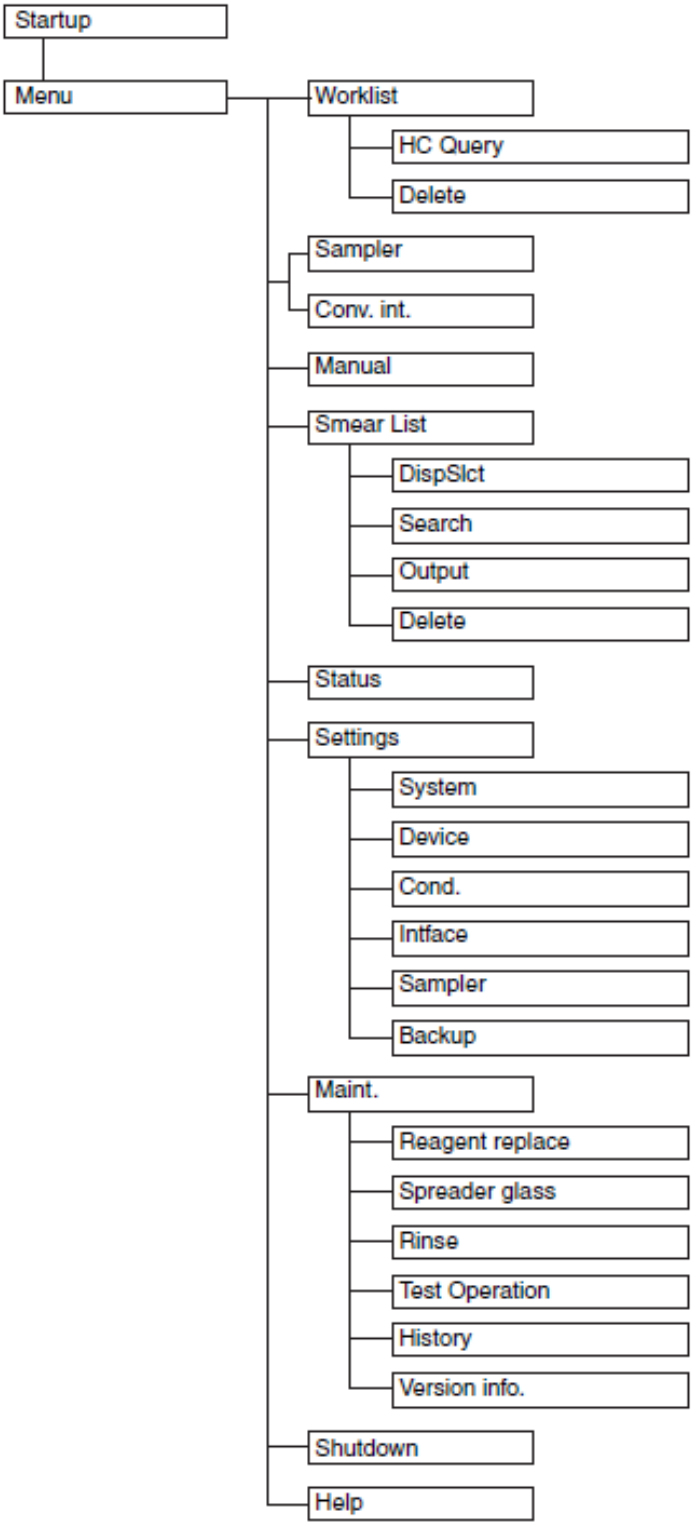
Operator will need to press [OK] to activate the process; however the process will carry out automatically when running in sampler mode.

Final note:

Generally discharge timer 1 or 2 will only take about 5 minutes (all cassettes utilised for discharge must reach stain 1 pipette) before instrument is made available and start to process on sample racks.

The cassettes which are taken on board during discharge however, will continue along the stain station and reach the end as per operator s normal stain protocol.

SP-10 Menu


Startup
Menu
Worklist
HC Query
Delete
Sampler
Conv. int.
Manual
Smear List
DispSlct
Search
Output
Delete
Status
Settings
System
Device
Cond.
Intface
Sampler
Backup
Maint.
Reagent replace
Spreader glass
Rinse
Test Operation
History
Version info.
Shutdown
Help

SP-10 Reagent

The following stains, buffers and rinsing agents are recommended for use on the SP-50:

- May-Grünwald stain
- Wright's stain
- Giemsa stain
- Phosphate buffer
- Rinse water

CELLPACK DCL (diluted) or CELLPACK DST (concentrated)

Rinse solution used to rinse the whole blood aspiration line. The on-board stability of CELLPACK is 60 days.

CELLCLEAN AUTO

CELLCLEAN AUTO is a strong alkaline detergent that is used to remove residual reagent, cellular residuals and blood proteins remaining in the hydraulic system of the automated haematology slide preparation unit.

Store in a dark place and do not allow exposure to direct sunlight. Excessive exposure to direct sunlight will cause the chlorine component to degrade, resulting in a loss of detergent strength. Open vial stability is 60 days.

Rinse water (procured locally)
Detergent used when preparing smears.
Use ion-exchanged water or an equivalent detergent with no fluctuations of pH.

May-Grünwald stain (procured locally)
Stain used to stain blood smears.

Wright's stain (procured locally)
Stain used to stain blood smears.

Giemsa stain (procured locally)
Stain used to stain blood smears.

Phosphate buffer (procured locally)
Buffer used for the preparation of blood smears.

SP-10 Consumption

Start-up Reagent volumes

Startup after shutdown by [Shutdown1]

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 48 mL	
Stain 1	Approx. 45 mL	Approx. 46 mL
Stain 2	Approx. 6 mL	
Phosphate buffer	Approx. 60 mL	Approx. 66 mL
Rinse water	Approx. 28 mL	

Startup after shutdown by [Shutdown2]

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 48 mL	
Stain 1	Approx. 220 mL	Approx. 221 mL
Stain 2	Approx. 83 mL	
Phosphate buffer	Approx. 186 mL	Approx. 192 mL
Rinse water	Approx. 28 mL	

Single staining

Startup after shutdown by [Shutdown1]

Reagent name	Reagent volume
CELLPACK DCL	Approx. 48 mL
Stain 1	Approx. 46 mL
Phosphate buffer	Approx. 30 mL
Rinse water	Approx. 67 mL

Startup after shutdown by [Shutdown2]

Reagent name	Reagent volume
CELLPACK DCL	Approx. 48 mL
Stain 1	Approx. 221 mL
Phosphate buffer	Approx. 75 mL
Rinse water	Approx. 66 mL

When Methanol prefix is performed

Startup after shutdown by [Shutdown1]

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 48 mL	
Stain 1	Approx. 45 mL	Approx. 46 mL
Stain 2	Approx. 6 mL	
Phosphate buffer	Approx. 60 mL	Approx. 66 mL
Rinse water	Approx. 28 mL	
Methanol	Approx. 24 mL	

Startup after shutdown by [Shutdown2]

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 48 mL	
Stain 1	Approx. 204 mL	Approx. 205 mL
Stain 2	Approx. 42 mL	
Phosphate buffer	Approx. 186 mL	Approx. 192 mL
Rinse water	Approx. 28 mL	
Methanol	Approx. 24 mL	

Single staining
Startup after shutdown by [Shutdown1]

Reagent name	Reagent volume
CELLPACK DCL	Approx. 48 mL
Stain 1	Approx. 46 mL
Phosphate buffer	Approx. 30 mL
Rinse water	Approx. 67 mL
Methanol	Approx. 24 mL

Startup after shutdown by [Shutdown2]

Reagent name	Reagent volume
CELLPACK DCL	Approx. 48 mL
Stain 1	Approx. 221 mL
Phosphate buffer	Approx. 75 mL
Rinse water	Approx. 66 mL
Methanol	Approx. 24 mL

Reagent volumes used to prepare one smear

Double staining (when phosphate buffer is used to rinse samples stained with stain 1)

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 21 mL	
Stain 1	Approx. 6 mL	Approx. 6.65 mL
Stain 2	Approx. 0.25 mL	
Phosphate buffer	Approx. 12 mL	Approx. 18 mL
Rinse water	Approx. 27 mL	

Double staining (when rinse water is used to rinse samples stained with stain 1)

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 21 mL	
Stain 1	Approx. 6 mL	Approx. 6.65 mL
Stain 2	Approx. 0.25 mL	
Phosphate buffer	Approx. 6 mL	Approx. 12 mL
Rinse water	Approx. 33 mL	

Single staining

Reagent name	Reagent volume
CELLPACK DCL	Approx. 21 mL
Stain 1	Approx. 6.65 mL
Phosphate buffer	Approx. 6 mL
Rinse water	Approx. 27 mL

When Methanol prefix is performed

Double staining (when phosphate buffer is used to rinse samples stained with stain 1)

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 21 mL	
Stain 1	Approx. 6 mL	Approx. 6.65 mL
Stain 2	Approx. 0.25 mL	
Phosphate buffer	Approx. 12 mL	Approx. 18 mL
Rinse water	Approx. 27 mL	
Methanol	Approx. 6 mL	

Double staining (when rinse water is used to rinse samples stained with stain 1)

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 21 mL	
Stain 1	Approx. 6 mL	Approx. 6.65 mL
Stain 2	Approx. 0.25 mL	
Phosphate buffer	Approx. 6 mL	Approx. 12 mL
Rinse water	Approx. 33 mL	
Methanol	Approx. 6 mL	

Single staining

Reagent name	Reagent volume
CELLPACK DCL	Approx. 21 mL
Stain 1	Approx. 6.65 mL
Phosphate buffer	Approx. 6 mL
Rinse water	Approx. 27 mL
Methanol	Approx. 6 mL

Reagent volumes used at Shutdown 1

Double staining

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 149 mL	
Stain 1	Not used	
Stain 2	Not used	
Phosphate buffer	Not used	
Rinse water	Approx. 67 mL	
CELLCLEAN AUTO	Approx. 4 mL (1 vial)	
Methanol	Approx. 190 mL	

Single staining

Reagent name	Reagent volume
CELLPACK DCL	Approx. 149 mL
Stain 1	Not used
Phosphate buffer	Not used
Rinse water	Approx. 67 mL
CELLCLEAN AUTO	Approx. 4 mL (1 vial)
Methanol	Approx. 130 mL

Reagent volumes used at Shutdown 2

Double staining

Reagent name	Stain 1 (without dilution)	Stain 1 (with dilution)
CELLPACK DCL	Approx. 149 mL	
Stain 1	Not used	
Stain 2	Not used	
Phosphate buffer	Not used	
Rinse water	Approx. 28 mL	
CELLCLEAN AUTO	Approx. 4 mL (1 vial)	
Methanol	Approx. 445 mL	

Single staining

Reagent name	Reagent volume
CELLPACK DCL	Approx. 149 mL
Stain 1	Not used
Phosphate buffer	Not used
Rinse water	Approx. 48 mL
CELLCLEAN AUTO	Approx. 4 mL (1 vial)
Methanol	Approx. 315 mL

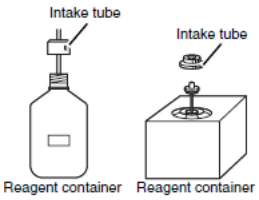
SP-10 Registering and Replacing Reagent

Note: If system has run out of reagent audible alarm will be generated. Use the Help menu to access reagent replacement replenish and register the reagent replaced.

If reagent is replaced before system has run out of reagent, use the maintenance menu to access the reagent replacement option.

Replacing CELLPACK DCL, Stain 1, and Stain 2 using the Help menu

1. Prepare the new reagent and confirm that its expiration date has not passed.
2. Remove the cap from the new reagent container.



3. Remove the cap from the empty reagent container, and pull the intake tube straight up.
4. Insert the intake tube into the new reagent container and tighten the cap.
5. Touch [Regist] in the action message.
   This screen appears.

6. Enter the Reagent Code.
Touch [Manual] to display the Reagent Code screen and enter the Reagent Code manually. Once the Reagent Code is entered, the reagent information is displayed automatically and [Exchange] becomes enabled.

7. When reagent information registration is completed, touch [Return].
The screen returns to the action message.

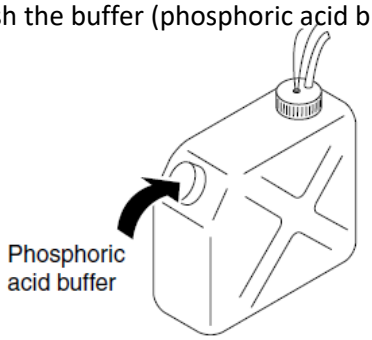
8. Touch [OK] in the action message.
The new reagent is aspirated and the reagent is replaced.

Note:
• The reagent information of methanol cannot be registered. Only replacement is possible.
• To register reagent information with the hand-held barcode reader, open the Reagent Registration screen and scan the EAN-128 barcode that is affixed to the outer case of the reagent.

Replenishing the phosphoric acid buffer

If [Replace buffer] appears, follow the steps below to replenish the buffer (phosphoric acid buffer).

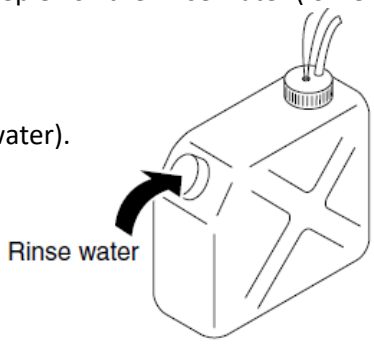
4. Remove the cap from the container.
5. Fill the container with phosphoric acid buffer.
   container holds about 20 L.
6. Cap the container.



Replenishing rinse water

If [Replace rinse water] appears, follow the steps below to replenish the rinse water (ion-exchanged water).

4. Remove the cap from the container.
5. Fill the container with rinse water (ion-exchanged water).
   container holds about 20 L.
6. Cap the container.

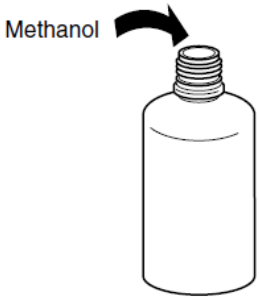


Caution!
When replenishing rinse water and/ or phosphoric acid buffer do not remove the float switch.

Replenishing the methanol

If [Methanol not filled in chamber1.] or [Methanol not filled in chamber2.] appears, follow the steps below to replenish the methanol.

10. Remove the cap from the container.
11. Fill the container with methanol.
    container holds about 5 L.
12. Cap the container.

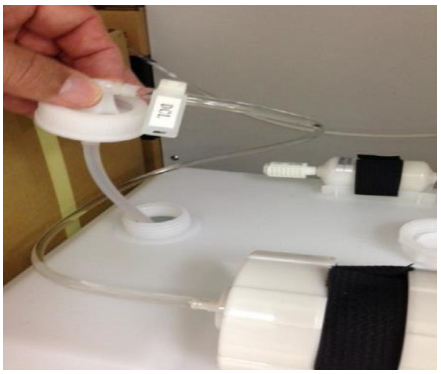


SP-10 Temporarily use CELLPACK DCL (if using RU-20)

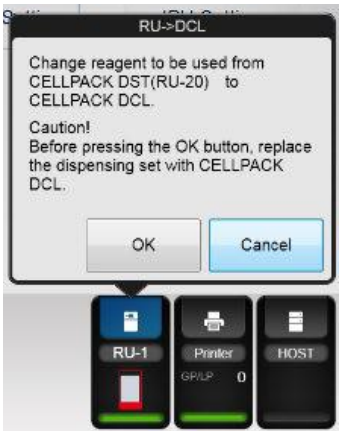
When the RU-20 cannot be used due to a failure or other problem, you can temporarily use CELLPACK DCL.

1. Select Menu from RU icon on IPU and then [RU→DCL].

2. Open the XN wagon where CELLPACK DST and Supply tank are housed, remove the DCL adapter from RU-20 supply tank as indicated in photo below, transfer into a new box of CELLPACK DCL then press [OK].

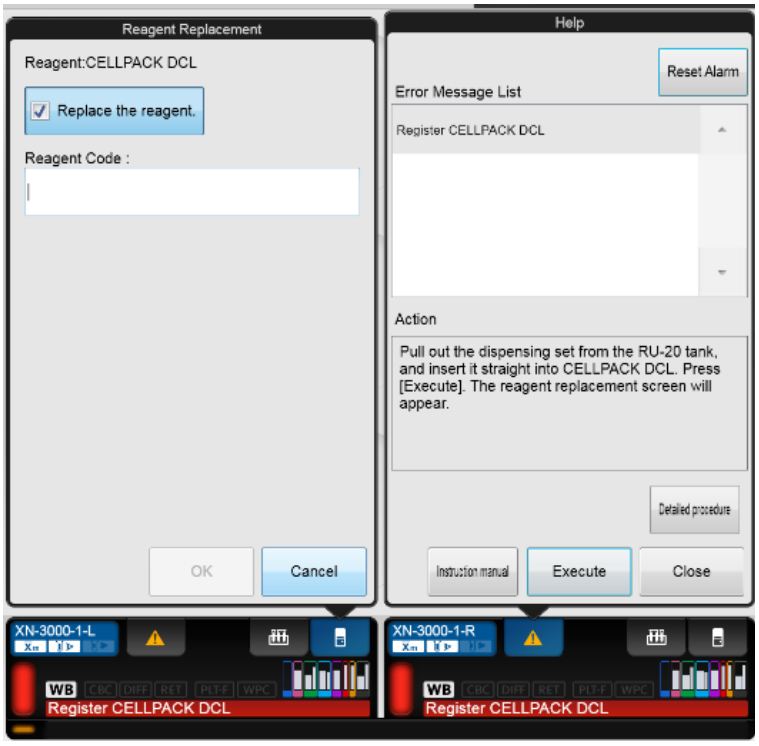


3. Once the DCL tubing has been secured into the CELLPACK DCL keg, press [OK] on the pop-up message.

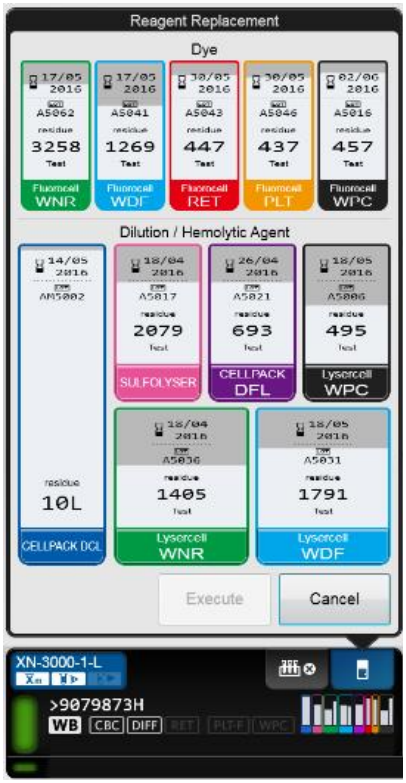


4. Once performed, an error alarm “reagent replacement CELLPACK DCL” will be triggered.

5. Follow the reagent replacement instructions to register CELLPACK DCL.



6. Once completed reagent replacement menu will display the CELLPACK DCL information.



7. Perform XN tri-level QC check.

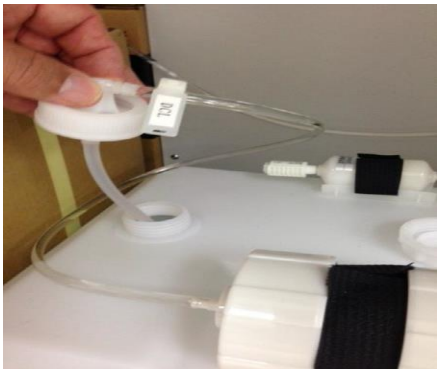
8. Instruments connected are ready for use.

SP-10 End temporarily use CELLPACK DCL (if using RU-20)

To reset the RU-20, end temporary use of CELLPACK DCL.

1. Remove the dispensing set from the CELLPACK DCL keg.

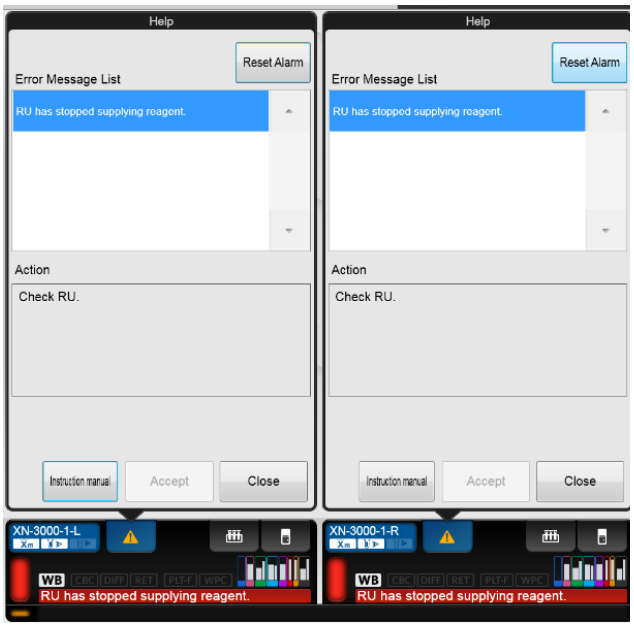
2. Attach the dispensing set that you removed from the CELLPACK DCL to the RU-20 supply tank.



3. From the main IPU menu select and press on the RU-1 icon.

4. From the RU-1 help menu Select [DCL→RU-20].
Popup message “DCL-> RU” will appear.

5. Press [OK]. The RU help menu will appear.



6. Reset Alarm (instrument will resume reagent preparation shortly).

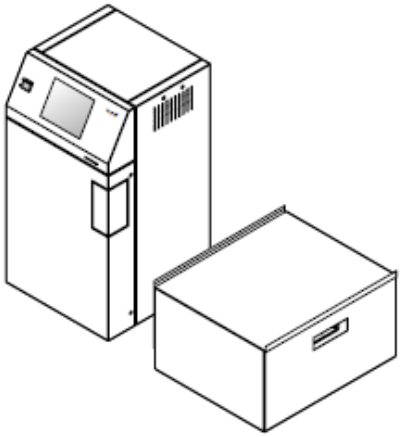
7. Perform XN tri-level QC check.

8. Instruments connected are ready for use.

Section 10: RU-20

RU-20 Introduction and Overview

The RU-20 is a reagent unit preparation which is responsible for diluting Concentrated reagent CELLPACK DST using Reverse Osmosis water to the required concentration and supplying the reconstituted product to multiple XN and SP-10/SP-50 analysers.
This instrument is installed as a peripheral device for haematology analysers XN and SP-10/SP-50.



* Pneumatic unit is omitted in this figure.

External view of RU-20

Front view

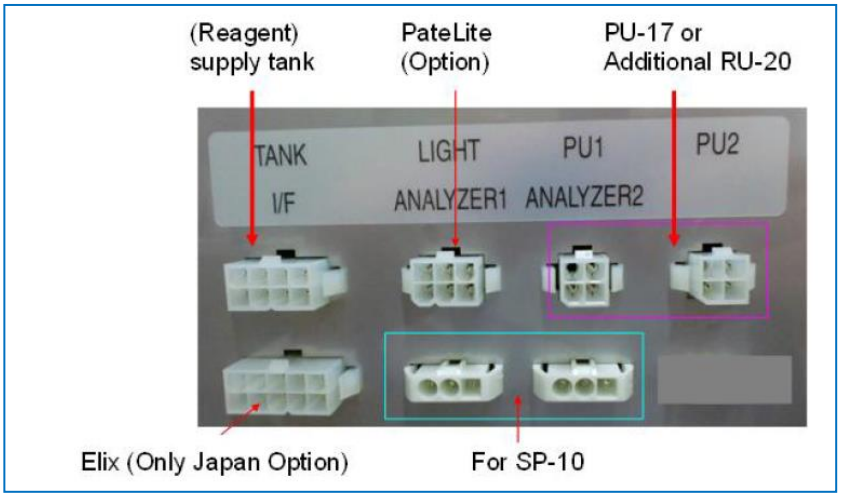
1. Main switch; Turns the main power of the instrument on and off.

2. LCD display (touch panel); Shows the status of the instrument. The touch panel is used to operate the instrument.

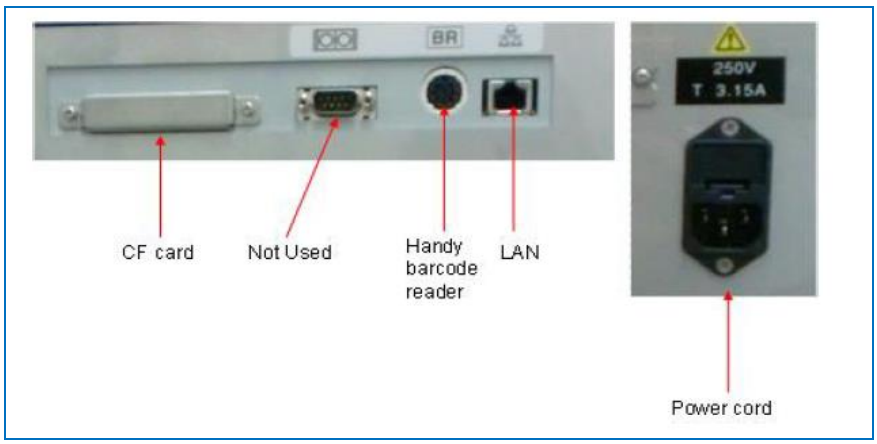
3. Contrast adjustment lever; adjusts the contrast of the LCD display.

4. Door for pneumatic pressure adjustment; Open the door and adjust the 0.07 MPa pressure.

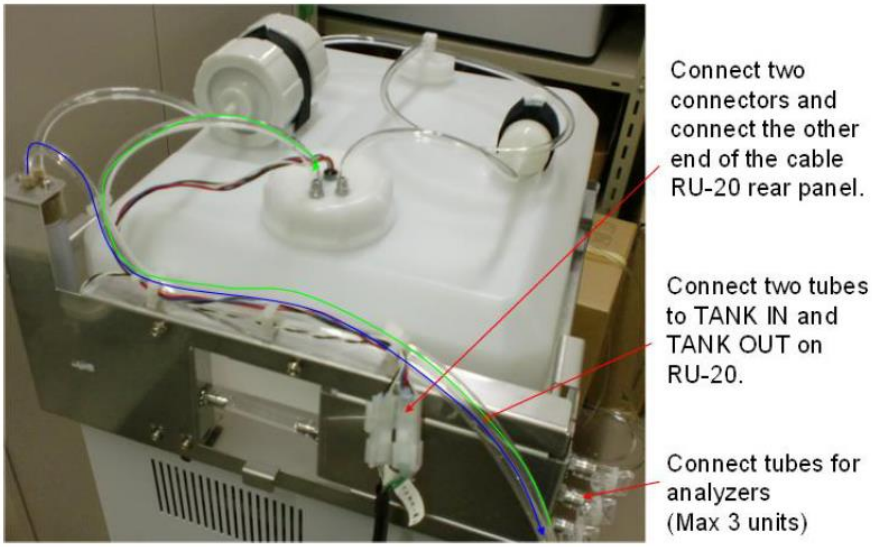
Fluid and pneumatic connections



Electric cord connections

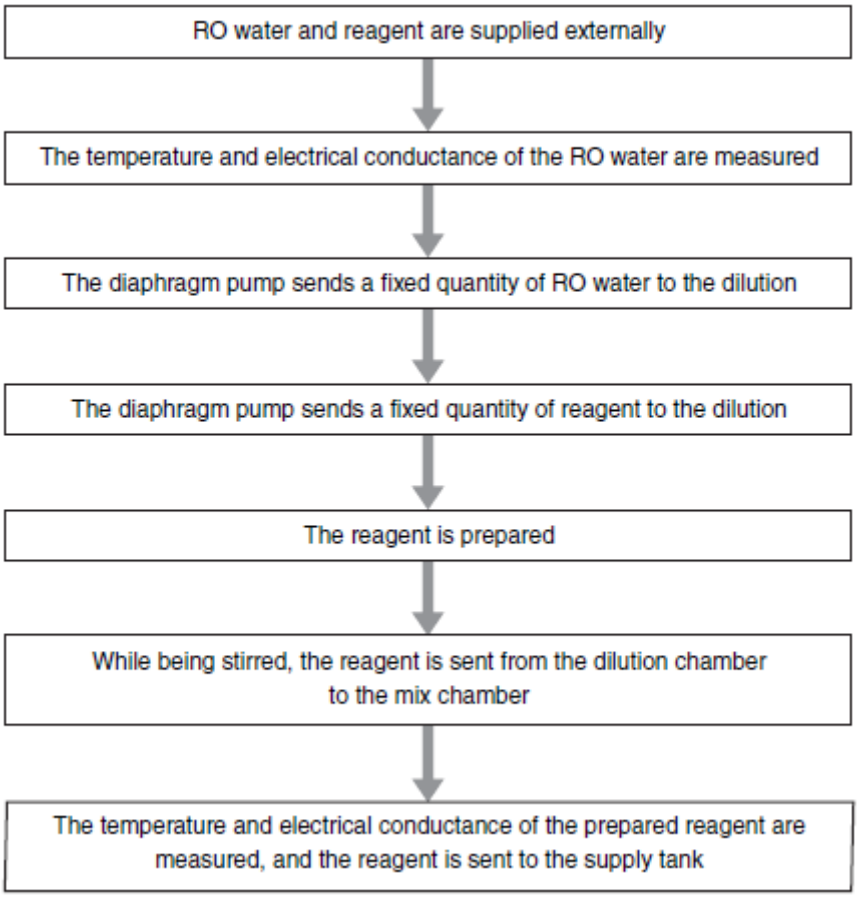


Computer connections



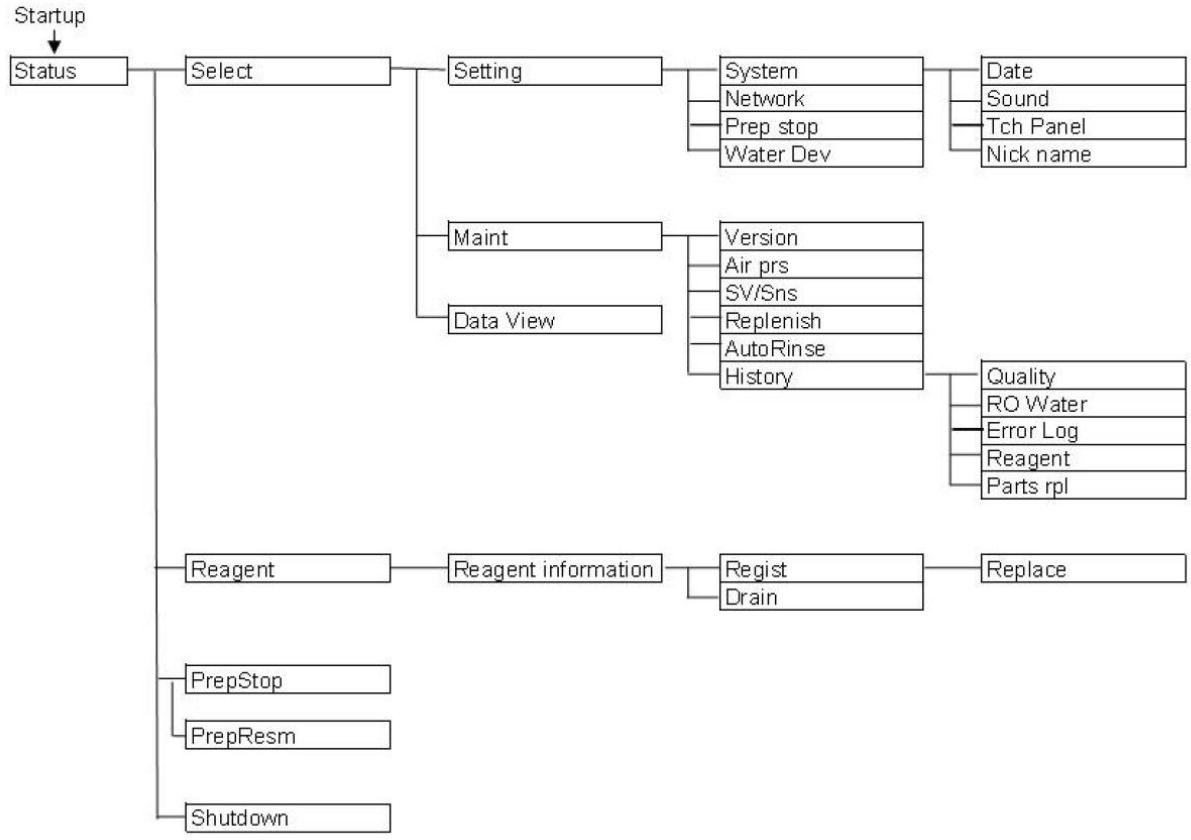
Supply tank connections

RU-20 Overall flow of Operation

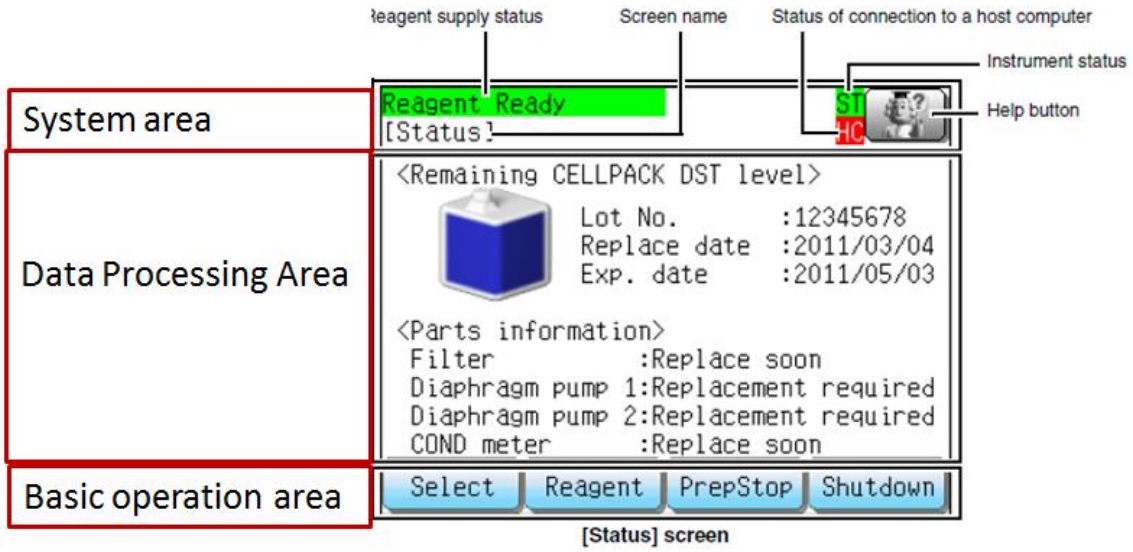


RU-20 Operation

User Menu Tree



Status screen



[Status] screen

Start up

1. Press the power on switch on the main unit

2. Turn on the analyser which connect to RU-20

* If the analyser turns on before RU-20, notification of the diluted reagent level cannot reach and error may occur on the analyser

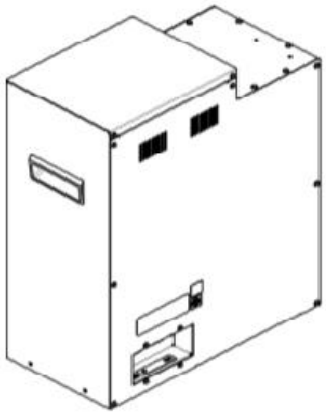
Shutdown

Refer to page 174 of this manual or page 4-7 of RU-20 IFU manual.

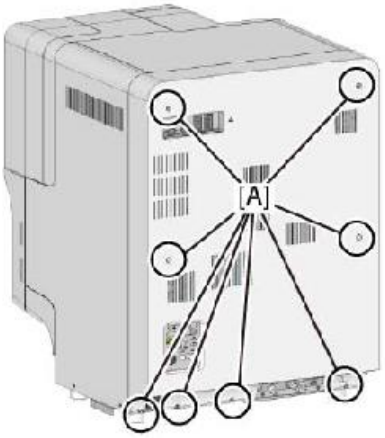
Section 11: RR-20

RR-20 Introduction and Overview

The RR-20 is a reservoir tank which holds RO water generated by a RO water generator and supplies the RO water to the SP-50 instrument. This instrument is installed as a peripheral device for haematology analysers SP-50.



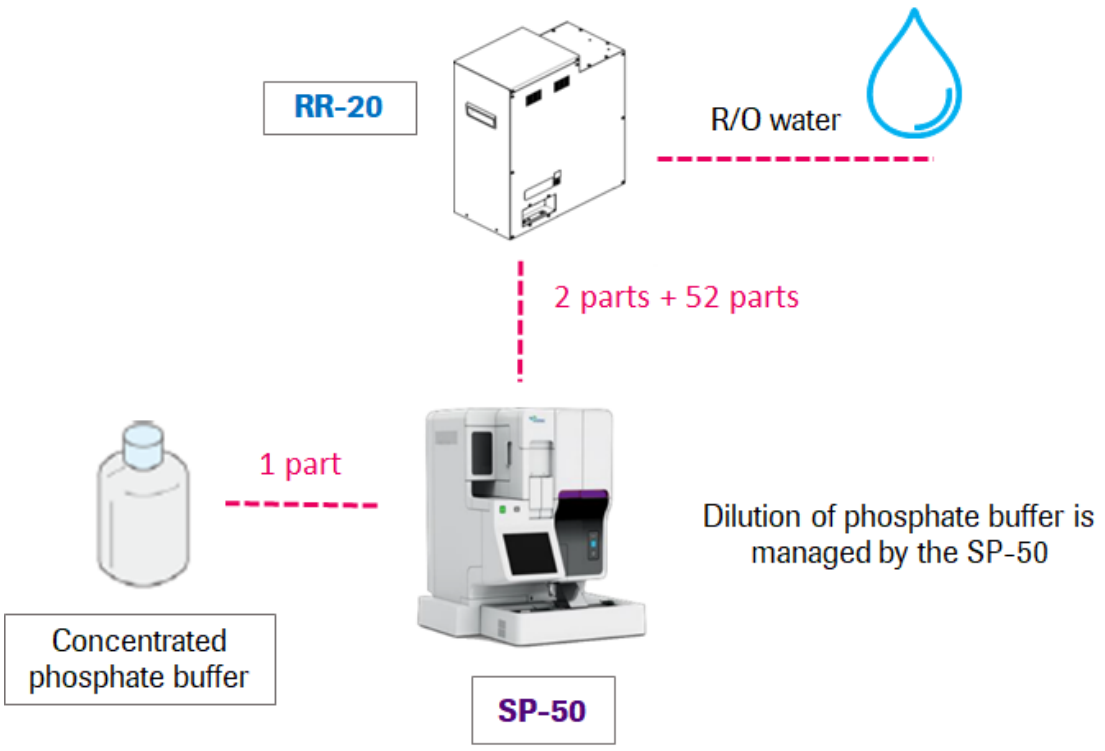
External view of RR-20



Rear view of RR-20

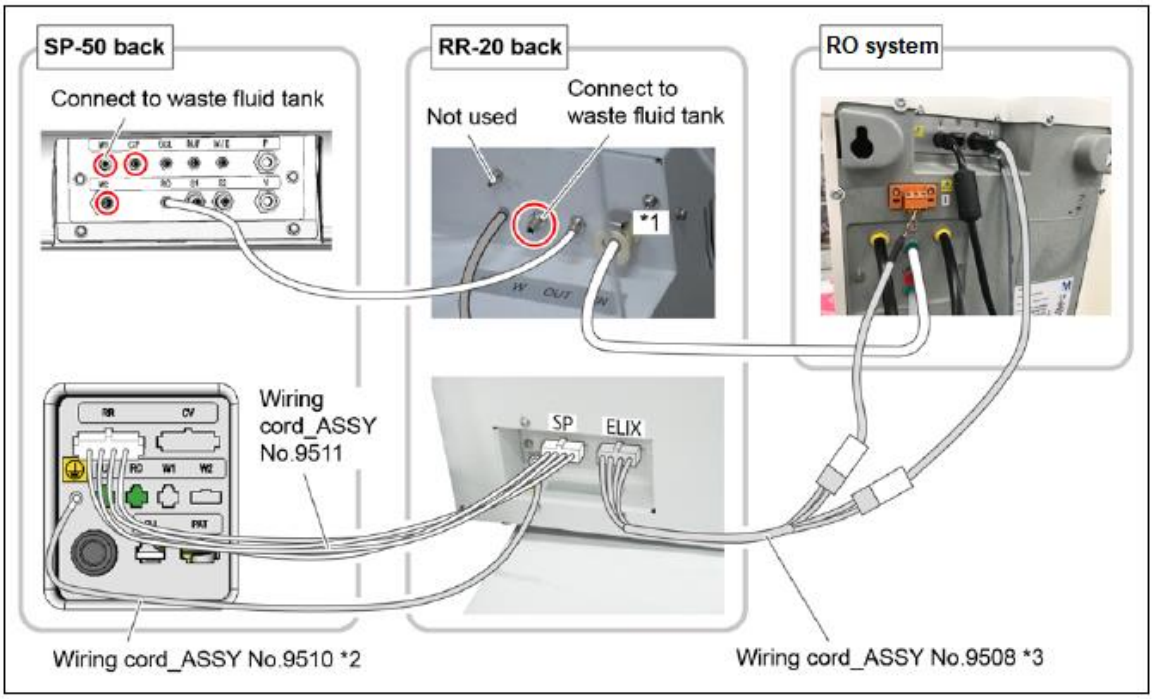
Dilution of Concentrate phosphate buffer for SP-50

The SP-50 aspirates RO water from the RR-20 to dilute the concentrated phosphate buffer (pH 6.6/pH 6.8/pH 7.0/pH 7.2) connected to the SP-50. Concentrated buffer is diluted in 1:55 ratio, 2 parts RO water + 1 part concentrated buffer + 52 parts RO water.



Reagent placement in WG-65 (SP-50 wagon with RU-20)

Tube and cables connection to the RR-20



Section 12: XN-9100 Maintenance

I. XN Maintenance

Regular maintenance of the analysers is necessary to keep the instrument at optimal condition. Maintenance is further described in chapter 13 of XN-9100 IFU.

To perform maintenance, the analyser and the sampler must be in READY state.

Daily maintenance

- Shutdown (please refer to page 97)

As-Needed maintenance

- Automatic rinsing
- Cleaning
- Remove an RBC detector clog
- Draining the Waste chamber
- Rinsing the Waste chamber
- Removing Flowcell air bubbles
- Rinsing Flowcell
- Draining Reaction chamber
- Draining RBC isolation chamber
- Adjusting the Pressure (0.25 MPa), (0.16 MPa) and (0.07 MPa)
- Draining the Pneumatic trap chamber

Supply and Reagent replacement

- Replacing a new dilution/haemolytic agent
- Replacing a new dye
- Replenishing reagents
- Draining the reagent

Health and Safety

Please ensure that proper precautions are followed with regard to Health and Safety.

Risk of infection

The operator is advised to wear the appropriate protective equipment and clothing whilst carrying out any maintenance procedure on the analyser.

Please read the entire chapter before attempting any maintenance or replacement procedures, and take not of the CAUTION and WARNING notices herein

When working with the front cover opened, be sure to set the stop bar in advance, to avoid injury

XN Maintenance Menu

You can perform specific maintenance tasks, operation checks, and operation test, using the Maintenance menu.

Follow the steps below to display the Maintenance menu.

1. Click the Analyser menu button on the control menu.

   Analyser Menu appears.

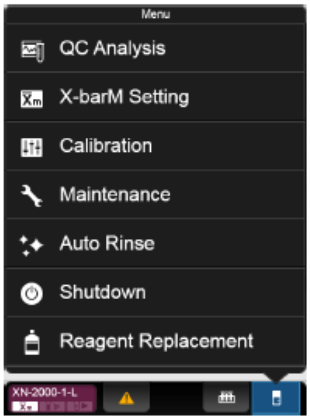


Figure 35– XN Analyser Menu

2. Click [Maintenance].
   The submenu appears.

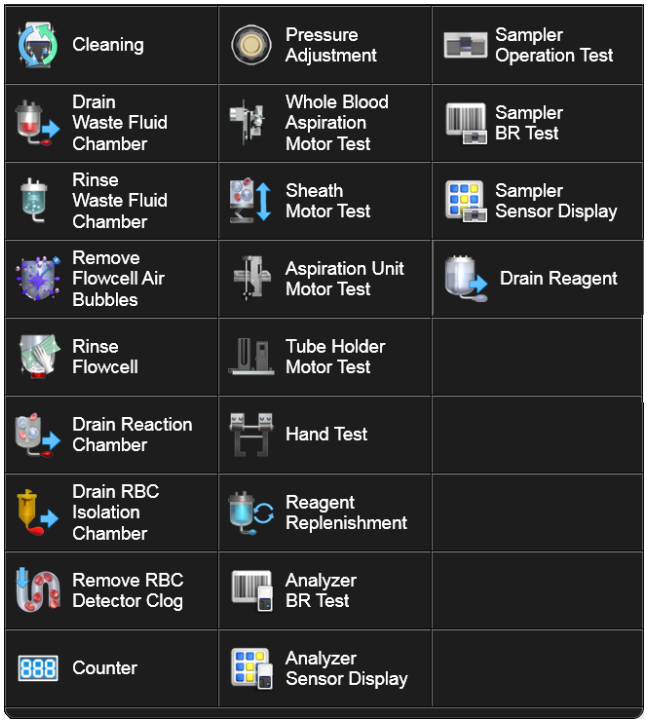


Figure 36– XN Maintenance Menu (update screen – no replace piercer option)

XN Daily Maintenance

Shutdown (please refer to page 97)
Check pneumatic trap chambers for presence of liquid.

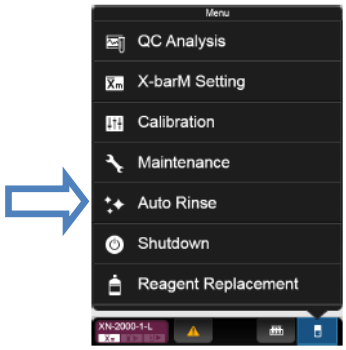
XN As-Needed Maintenance

1. Auto rinsing

You can automatically perform rinsing of the analyser and the post-rinse background check.

If a background check error occurs, a help dialog will appear on the IPU screen.
Follow the procedure below to perform Auto Rinse.

1. Click the Analyser menu button on the control menu.



2. Click [Auto Rinse].

The menu automatically closes, [Auto Rinse] appears in the control menu and auto rinse starts.
Progress is shown as a progress bar in the control menu. Wait until it is complete.
Once complete, [Auto Rinse] disappears and the background check begins.

2. Cleaning

If the error is not cleared after Auto Rinse is performed, perform Cleaning.

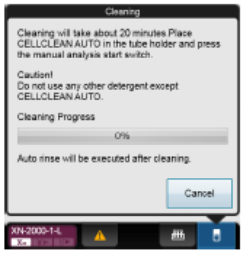
Note: *this process will take approximately 20 Minutes. Progress is shown as a progress bar on the screen. Wait until this process is finished.*

Once cleaning is complete, auto rinse starts automatically. Wait until it is complete.

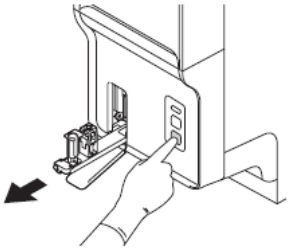
Follow the steps below to perform cleaning:

1. Check the Status indicator LED on the analyser.
2. Display the Maintenance menu.

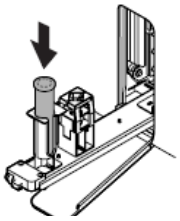
3. Click [Cleaning].



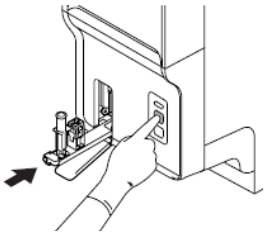
4. If the tube holder is not ejected, press the mode switch to allow manual mode access.



5. Place the CELLCLEAN AUTO in the sample tube holder.



6. Press the start switch on the analyser.



7. Remove the CELLCLEAN AUTO.

8. Press the mode switch, to restore analyser back to sampler mode.

3. Remove RBC Detector Clog

If the RBC detector is clogged or air bubbles have formed, a help dialog will appear on the IPU screen.

Follow the procedure below to remove the clog from the RBC detector:

1. Display the Maintenance menu.
2. Click [Remove RBC Detector Clog].

The window appears, and the removal of the clog starts. Progress is shown as a progress bar on the screen. Wait until it is complete. When it is complete, the window closes automatically.

4. Clean RBC Detector Aperture

If the removing the clog from the RBC detector does not remove all the clog or clear the error, rinse the RBC detector aperture.

Warning!
Never touch the detector when the power of the Main Unit is turned ON. An electrical shock could occur.

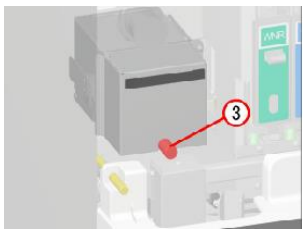
Caution!
Be sure to use CELLCLEAN AUTO only.
When closing the detector cover, take care not to kink the tube. Otherwise, it may lead to incorrect analysis.
When rinsing the detector aperture, use the supplied unclogging brush and lightly tap on the detector aperture. Excessive force will damage the detector aperture.

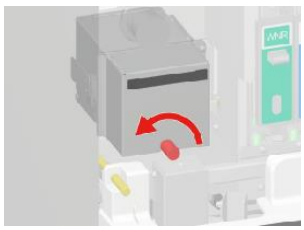
Follow the steps below to rinse the RBC detector aperture:

1. Shutting down analyser for maintenance.
   Shutdown the instrument and switch off the main power switch.

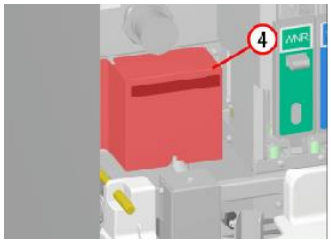
2. Open the top front cover.

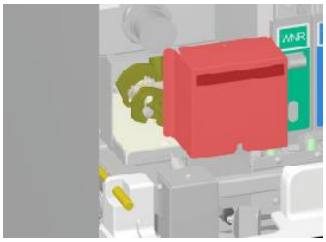
3. Loosen the screw that is holding the detector cover in place.





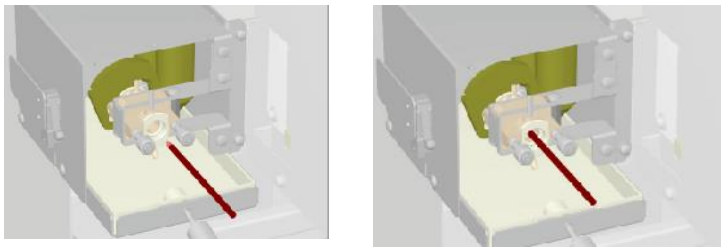
4. Remove the detector cover.
   Lift it temporarily, and pull it out toward you.



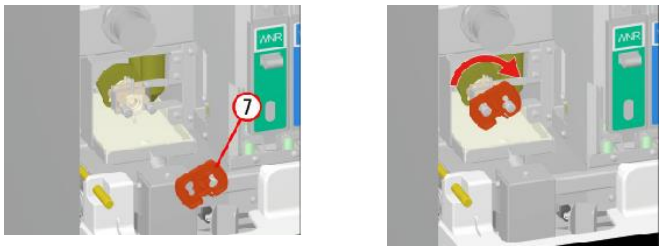


5. Pull out the lid of the detector chamber by turning it in the direction of the arrow.

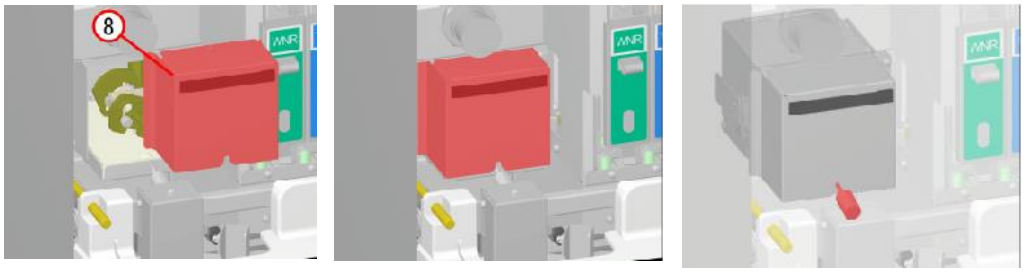
6. Soak the supplied unclogging brush in CELLCLEAN AUTO, and wash the detector aperture by lightly tapping it. Ensure the black o-ring is still in place.



7. Insert the detector chamber cap straight in, and turn in the opposite direction as step 5 to secure.



8. Attach the detector cover and secure with the screw.



9. Close the top front cover.

10. Turn ON the analyser's power.

5. Drain the Waste Fluid Chamber

If the waste tube from the waste chamber is clogged, a help dialog will appear on the IPU screen.

Follow the procedure below to drain waste fluid that has collected in the waste chamber:

1. Display the Maintenance menu.

2. Click [Drain Waste Fluid Chamber].
The menu closes automatically, [Drain Waste Fluid Chamber] appears in the control menu, and draining begins.

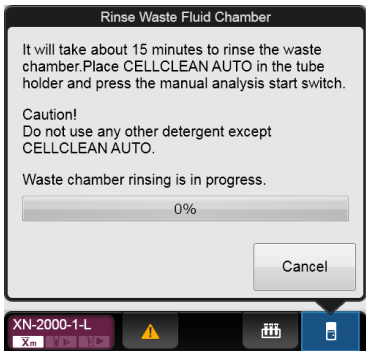
6. Rinse Waste Fluid Chamber

If the error is not cleared after waste fluid is drained from the waste chamber, rinse the waste chamber. You can clean the waste chamber with CELLCLEAN AUTO.

Follow the steps below to rinse the inside of the waste chamber:

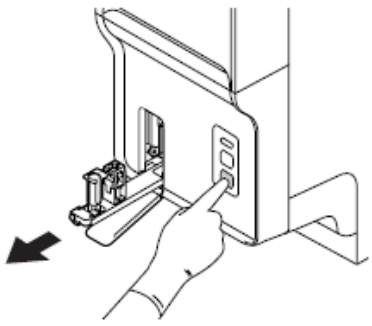
1. Check the Status indicator LED on the analyser.

2. Display the Maintenance menu.

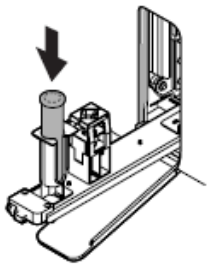


3. Click [Rinse Waste Fluid Chamber].

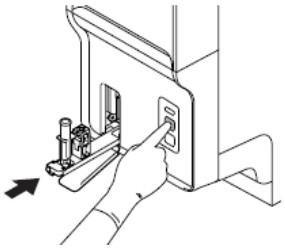
4. If the tube holder is not ejected, press the mode switch on the analyser.
The tube holder slides out forward.



5. Place the CELLCLEAN AUTO in the sample tube holder.
   Set it into the front holder, when you face the analyser.



6. Press the start switch on the analyser.
   The tube holder retracts into the analyser and rinsing starts.



7. Remove the CELLCLEAN AUTO.

8. Press the mode switch.
   The tube holder slides into the analyser.

Note! *Rinsing Waste Fluid Chamber takes approximately 15 minutes. Progress is shown as a progress bar on the screen. Wait until this process is finished. When the process ends, the tube holder is ejected.*

7. Remove Flowcell Air Bubbles

If air bubbles have formed in the Flowcell, a help dialog will appear on the IPU screen.

Follow the procedure below to remove the air bubbles from the inside of the Flowcell:

1. Display the Maintenance menu.

2. Click [Remove Flowcell Air Bubbles].
   The window appears, and the removal of air bubbles starts. Wait until it is complete. Progress is shown as a progress bar on the screen. Once complete, the window closes automatically.

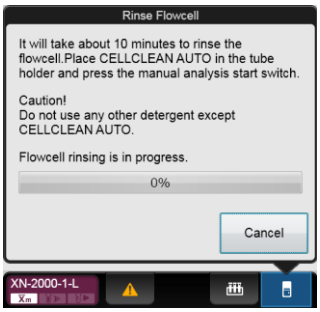
8. Rinse Flowcell

If the Flowcell is clogged or dirty, a help dialog will appear on the IPU screen.

Follow the procedure below to rinse the inside of the Flowcell:

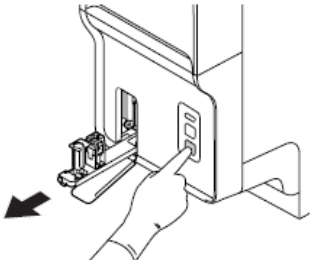
1. Check the Status indicator LED on the analyser.

2. Display the Maintenance menu.

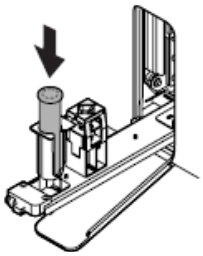


3. Click [Rinse Flowcell].

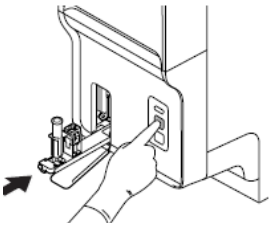
4. If the tube holder is not ejected, press the mode switch on the analyser.
The tube holder slides out forward.



5. Place the CELLCLEAN AUTO in the sample tube holder.
Set it into the front holder, when you face the analyser.



6. Press the start switch on the analyser.
The tube holder retracts into the analyser and rinsing starts.



7. Remove the CELLCLEAN AUTO.

8. Press the mode switch.
The tube holder slides into the analyser.

Note! Rinse Flowcell takes approximately 10 minutes. Progress is shown as a progress bar *on the screen. Wait until this process is finished. When the process ends, the tube holder is ejected.*

9. Drain Reaction Chamber

If the drain tubing in the RBC/HGB reaction chamber is clogged, the help dialog box appears in the IPU screen.

Follow the procedure below to drain reagent that has collected in the reaction chamber:

1. Display the Maintenance menu.
2. Click [Drain Reaction Chamber].

The window appears, and draining starts. Wait until it is complete. When it is complete, the window closes automatically.

10. Drain RBC isolation chamber

If the density of the reagent is inconsistent, [PLT sampling error] appears on a help dialog of the IPU screen. If the error appears after clear it, drain the reagent from the RBC isolation chamber.

Follow the steps below to drain the reagents that have accumulated in the RBC isolation chamber:

1. Display the Maintenance menu.
2. Click [Drain RBC Isolation Chamber].

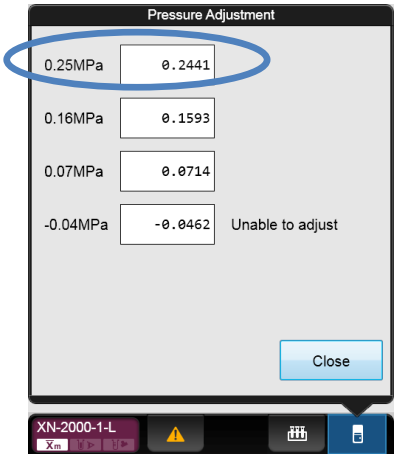
The window appears, and draining starts. Wait until it is complete. Progress is shown as a progress bar on the screen. When it is complete, the window closes automatically.

11. Pressure Adjustment (0.25 MPa)

A 0.25 MPa pressure is applied to operate the master valves.

If an error message for pressure abnormality is displayed, first check the tubes to see if there is any air leakage. If there is no abnormality in the tube, display the [Pressure Adjustment] window and adjust the pressure by checking the numeric values.

Follow the steps below to adjust the 0.25 MPa pressure. The adjustment is done in the pneumatic unit:



1. Display the Maintenance menu.

2. Click [Pressure Adjustment].

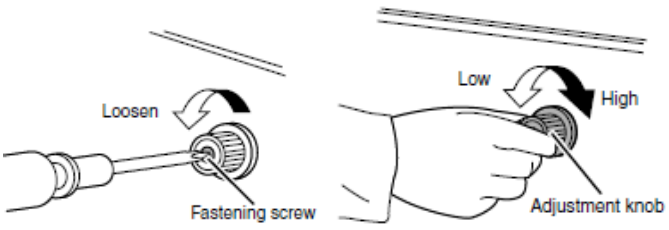
If the pressure is too high, first decrease it below the specified value, and then increase to adjust it.

3. Loosen the fastening screw for the 0.25 MPa regulator on the front of the pneumatic unit.

4. Adjust the pressure by turning the knob on the 0.25 MPa regulator.
While checking the pressure displayed in the [Pressure Adjustment] window, adjust the pressure to the specified value (0.25 ± 0.04 MPa). Turn the knob clockwise to increase the pressure, and counter-clockwise to decrease the pressure.

5. Tighten the fastening screw of the 0.25 MPa regulator, without turning the adjustment knob.

6. Click [Close] in the [Pressure Adjustment] window.



12. Pressure Adjustment (0.16 MPa)

A 0.16 MPa pressure is applied to the optical detection block to supply the sheath fluid.

If an error message for pressure abnormality is displayed, first check the tubes to see if there is any air leakage. If there is no abnormality in the tube, display the [Pressure Adjustment] window and adjust the pressure by checking the numeric values.

Follow the steps below to adjust the 0.16 MPa pressure. The adjustment is done in the main unit:

1. Display the Maintenance menu.

2. Click [Pressure Adjustment].
The [Pressure Adjustment] window appears.

3. Open the top front cover.
Open to the highest point. It may move down.

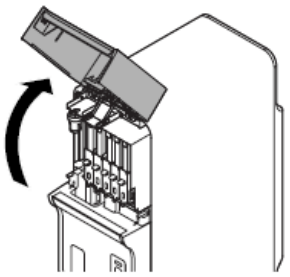
4. Pull out the adjustment knob on the 0.16 MPa regulator to unlock it.

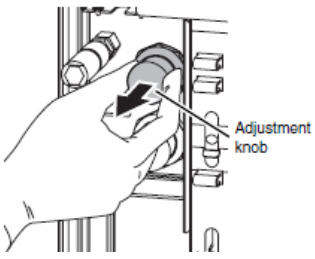
5. Adjust the pressure by turning the knob on the 0.16 MPa regulator.
While checking the pressure displayed in the [Pressure Adjustment] window, adjust the pressure to the specified value (0.16 ± 0.016 MPa). Turn the knob clockwise to increase the pressure, and counter-clockwise to decrease the pressure.

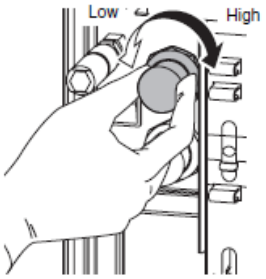
6. Push the adjustment knob on the 0.16 MPa regulator to lock it.

7. Close the top front cover.

8. Click [Close] in the [Pressure Adjustment] window.







13. Pressure Adjustment (0.07 MPa)

A 0.07 MPa pressure is applied to drain waste and mix the samples.

If an error message for pressure abnormality is displayed, first check the tubes to see if there is any air leakage. If there is no abnormality in the tube, display the [Pressure Adjustment] window and adjust the pressure by checking the numeric values.

Follow the steps below to adjust the 0.07 MPa pressure. The adjustment is done in the main unit:

1. Display the Maintenance menu.

2. Click [Pressure Adjustment].
   The [Pressure Adjustment] window appears.

3. Open the top front cover.
   Open to the highest point. It may move down.

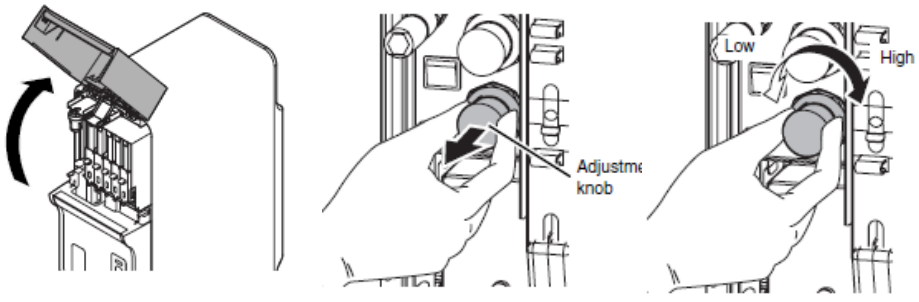
4. Pull out the adjustment knob on the 0.07 MPa regulator to unlock it.

5. Adjust the pressure by turning the knob on the 0.07 MPa regulator.
   While checking the pressure displayed in the [Pressure Adjustment] window, adjust the pressure to the specified value (0.07 ± 0.01 MPa). Turn the knob clockwise to increase the pressure, and counter-clockwise to decrease the pressure.

6. Push the adjustment knob on the 0.07 MPa regulator to lock it.

7. Close the top front cover.

8. Click [Close] in the [Pressure Adjustment] window.

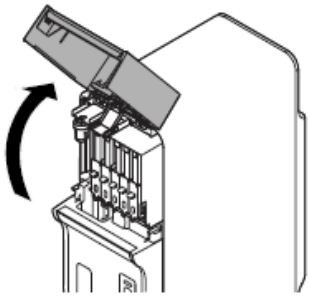


14. Draining the pneumatic trap chamber

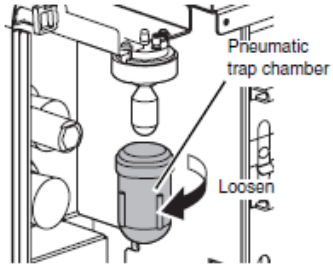
If the pneumatic trap chamber becomes full of water, a help dialog will appear on the IPU screen. Check if the trap chamber is full of water, and drain as needed.

Follow the steps below to drain the pneumatic trap chamber:

1. Open the top front cover.
   Open to the highest point. It may move down.

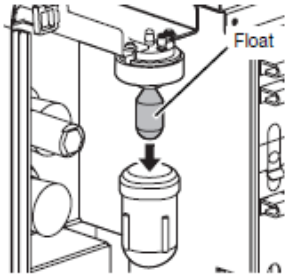


2. Remove the pneumatic trap chamber by rotating it in the direction of the arrow.



3. Discard water that has collected in the chamber.

4. Remove the float, and place it in the pneumatic trap chamber.
   Hold the removed float in the same orientation and put it straight into the pneumatic trap chamber.



5. Attach the pneumatic trap chamber by turning it in the direction that is opposite to step 2.

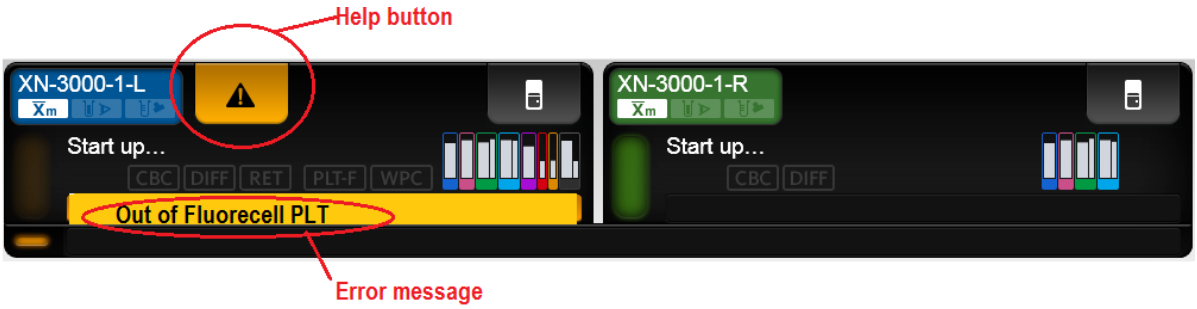
6. Close the top front cover.

XN Supply and Reagent replacement

1. Replacing a new dilution/haemolytic agent

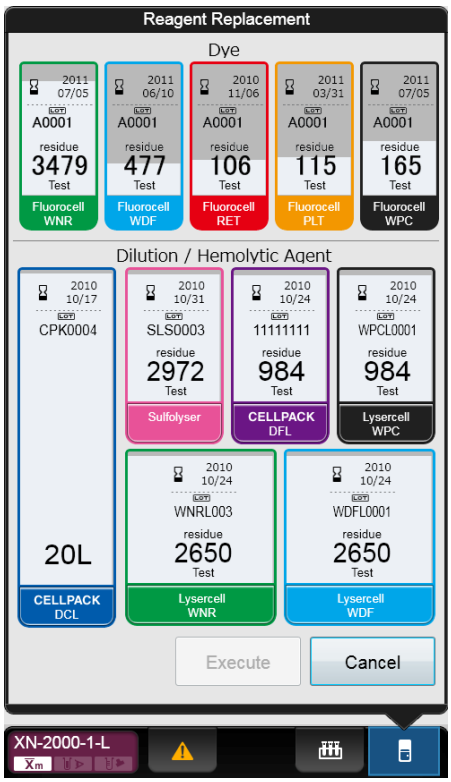
The [Reagent Replacement] dialog box allows you to check the remaining volume for reagents and replace them.

If a reagent runs out during an analysis, the analysis is paused, and an audible alarm is generated. Following an error message will appear in the analyser area of the Control menu on the XN IPU.



1. **Click the help button on the control menu**

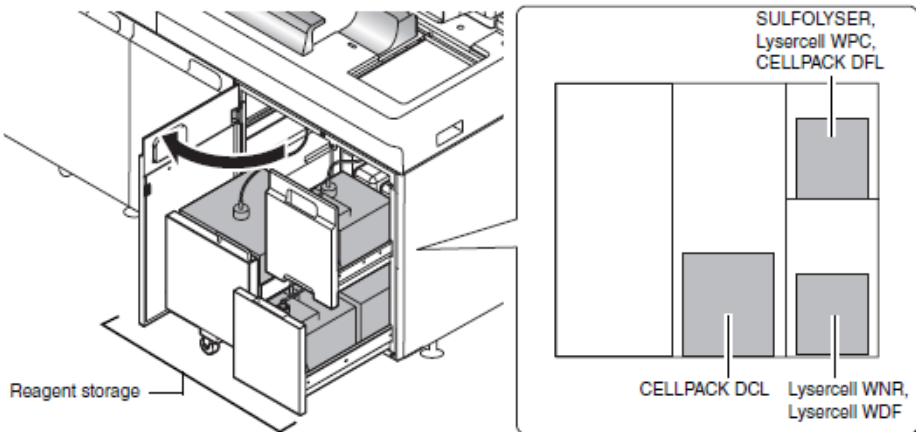
2. **Click [Execute].**
Display the [Reagent Replacement] dialog box to replace the reagent.



This section explains how to replace the following reagents.

- CELLPACK DCL, CELLPACK DFL
- SULFOLYSER
- Lysercell WNR, Lysercell WDF, Lysercell WPC

If a dedicated wagon is used, the reagent for the analyser is stored in the area below. When replacing the reagent pull out the reagent storage slowly.

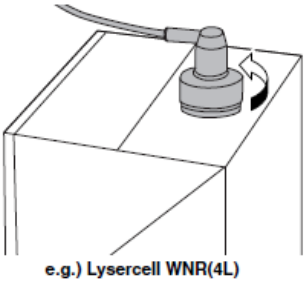


Note! *If you are sharing 1 reagent with multiple analysers, replacing the reagent in 1 analyser automatically replaces it in the other analysers.*

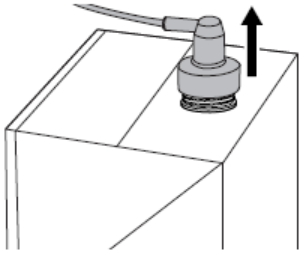
1. Remove the cap from the new reagent container.
   Check that the reagent has not expired.

2. Scan the reagent code (barcode) with the hand-held barcode reader.
   Manual input: Click the name of the reagent to be replaced in the [Reagent Replacement] dialog box. Enter the reagent code (barcode) and click [OK].

3. Remove the cap from the old reagent container.



4. Pull out the dispensing set in the upward direction.



5. Insert the dispensing set straight into the new reagent container.

6. Close the cap.

7. Click [Execute].
   The replacement of the reagent starts. Wait until it is complete. When it is complete, the dialog box closes automatically.

Note! The time guidelines for replacement of the reagent are as shown below.

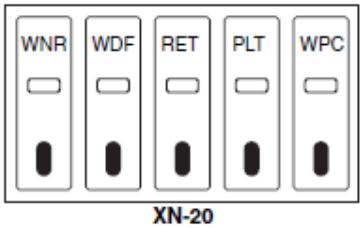
Reagent name	Time
CELLPACK DCL	About 1 and a half minutes
SULFOLYSER	About 2 minutes
CELLPACK DFL	About 3 minutes
Lysercell WPC	
Lysercell WDF	
Lysercell WNR	

2. Replacing Fluorocell Reagent Cartridge

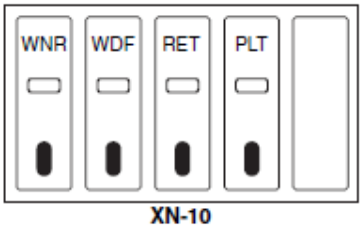
This section explains how to replace the following reagents.

- Fluorocell WNR
- Fluorocell WDF
- Fluorocell WPC
- Fluorocell RET
- Fluorocell PLT

Install the dye cartridge in its corresponding dye cartridge holder. The dye cartridge holder that can be installed will vary depending on the analyser types. The position of each dye cartridge holder is shown below.



XN-20

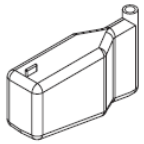


XN-10

Follow the steps below to replace the reagent:

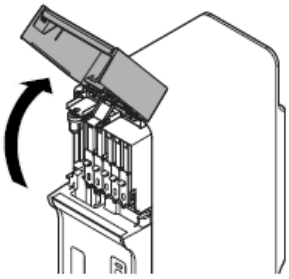
1. Display the [Reagent Replacement] dialog box.

2. Prepare the new reagent cartridge; Check that the reagent has not expired.

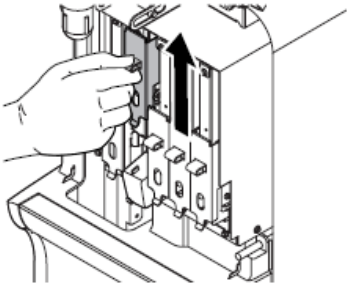

e.g.) Fluorocell WDF

3. Open the top front cover.

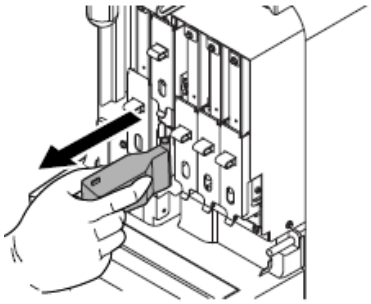
Open to the highest point, and ensure that it is securely in place.



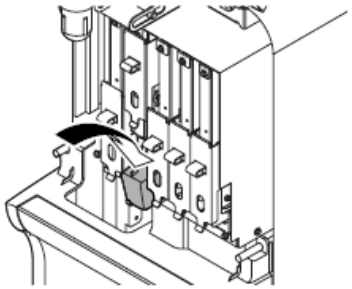
4. Pull up the cover from the reagent that is to be replaced, as far as possible to reveal reagent slot.


e.g.) XN-20

5. Remove the old reagent cartridge from its holder.



6. Install the new reagent cartridge into the holder.
   Ensure the colour of the label on the new reagent cartridge matches the colour of the dye cover.
   Insert the new Flurocell cartridge so that RFID is towards the front of anlayser and on the left hadside, with the reagent lable facing forward.



7. The analyser beeps.

The ID of the new reagent is read automatically, and the information is registered.

8. Pull down the cover on the reagent until “click” sound is heard.

9. Close the top front cover.

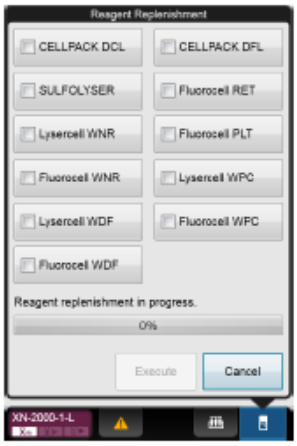
The replacement of the reagent starts. Wait until it is complete. When it is complete, the window closes automatically.

3. Replenishing reagents

If you encounter an error with the dye solution, or if you set the wrong reagent, you cannot replenish the reagent.

Follow the steps below to replenish the reagent:

1. Ensure the reagent you want to replace is connected.
2. Display the Maintenance menu.
3. Click [Reagent Replenishment].



4. Click the name of the reagent to replenish, and click [Execute].
   The replenishing of the reagent begins. Progress is shown as a progress bar on the screen. Wait until it is complete. When it is complete, the dialog box closes automatically.

4. Draining the reagent (RU-20 only)

If the reservoir tank is being used, reagent can be drained and the reservoir tank automatically cleaned in the event that the reagent in the tank has expired or the wrong reagent was taken in.

Follow the procedure below to drain the reagent:

1. Ensure the reagent you want to reconnect is connected.
2. Display the Maintenance menu.
3. Click [Drain Reagent].
4. Click the name of the reagent that you wish to drain and click [Execute].
   Draining starts. Progress is shown as a progress bar on the screen. Wait until it is complete. When it is complete, the dialog box closes automatically.

II. SP-50 Maintenance

Regular maintenance of the analysers is necessary to keep the instrument in optimal condition. Please refer to chapter 2 of SP-50 Troubleshooting manual.

To perform some maintenance tasks, the analyser and the sampler must be in READY state. Otherwise, maintenance cannot be performed. In addition, analysis is not possible during maintenance.

When working with the top cover open, secure it in a position where it is stable. Otherwise, the cover may fall and injure your head or other part of your body.

Fragments of glass may occasionally fall into the device. When inserting your hand into the device, be alert for fragments of glass.

Note:
The times required for the maintenance sequences are indicated below.

- *[Shutdown1]: About 15 minutes*
- *[Shutdown2]: About 20 minutes*
- *Cleaning the smear/stain unit: About 50 minutes*
- *Cleaning smear unit: About 15 minutes*

SP-50 Maintenance

Daily maintenance

- Performing [Shutdown1] (rinsing of hydraulic system)

Weekly maintenance

- Wiping dirt off the spreader glass

Monthly maintenance

- Performing [Shutdown2] (rinsing of hydraulic system and cleaning stain chamber with methanol)

As-Needed maintenance

- Cleaning the staining pool
- Cleaning the smear/stain unit
- Wiping the printer
- Discharge all RR-20 (drains all RO water in chambers of RR-20)
- Adjusting the air pressure
- Replacing the waste fluid tank (if installed)

Supply and Reagent replacement

- Loading the slide glasses
- Replacing the reagent
- Replacing the spreader glass
- Replacing the ink ribbon
- Replacing the fuse
- Replenishing the reagent

SP-50 Maintenance Screen

The [Maintenance] screen displays specific maintenance tasks, operation checks, and operation tests.

Follow the steps below to display the Maintenance menu.

1. Click the [Maintenance] icon.

[Maintenance] screen

SP-50 Daily Maintenance

Performing [Shutdown1]

Perform [Shutdown 1] at the end of the routine day or after 24 hours.
[Shutdown 1] cleans the hydraulic line.

For Shutdown 1 procedure, please refer to page 99-100.

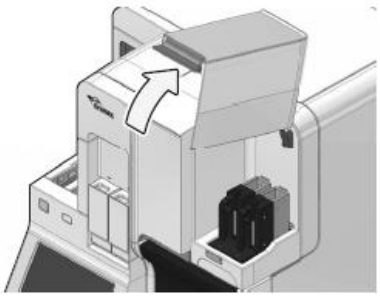
SP-50 Weekly Maintenance

Wiping dirt off the spreader glass

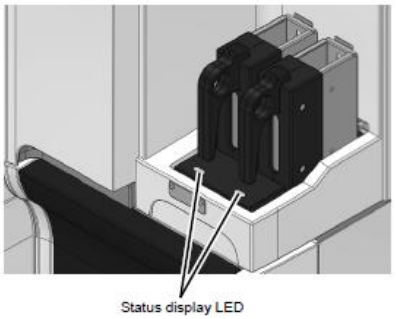
To maintain smear quality for a longer period, the instrument cleans the spreader glass with CELLCLEAN AUTO each time shutdown is performed. However, spreader glass dirt should be manually wiped off once a week. Dirty spreader glass reduces smear quality.

Replace the spreader glass when smear quality does not improve after wiping off the spreader glass dirt or when the spreader glass is damaged or cracked.

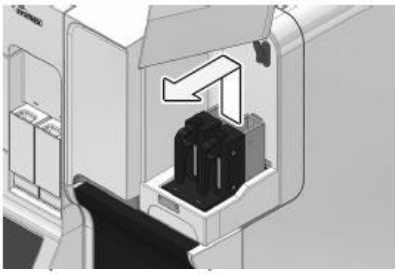
1. Touch [Maintenance] in the menu screen.
2. Touch [Rinse devices].
3. Touch [Spreader glass rinsing].
4. Make sure that the smear unit cover is closed.
5. Touch [OK].
   The smear unit moves to the position at which the spreader glass can be wiped. Wait until the smear unit cover unlocks once the smear unit stops moving.
6. Open the slide set unit cover.
   Lift the cover until it locks into place.



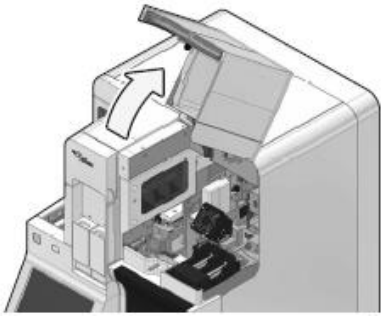
7. Make sure that the status display LED on the slide set unit lights in green or red.



8. Remove the slide supply cassette from the slide set unit.
   Remove both the left and right slide supply cassettes.

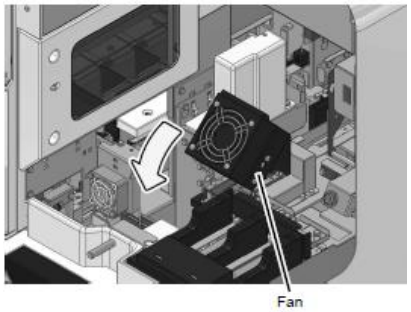


9. Close the slide set unit cover.
   Lightly press the cover to unlock and then close the cover.



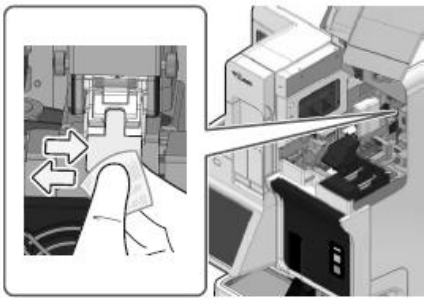
10. Open the smear unit cover.
    Lift the cover until it locks into place.

11. Rotate the fan forward and down.



12. Wipe the surface of the spreader glass with gauze moistened with ethanol.
    Sandwich the spreader glass between the gauze and wipe from left to right.

13. To remove stubborn dirt, wipe with gauze moistened with CELLCLEAN AUTO.



14. Replace the fan in its original position.

15. Close the smear unit cover.

16. Open the slide set unit cover, install the slide supply cassette and close the slide set unit cover.

17. Touch [OK].

> ! *If CELLCLEAN AUTO is used, make sure to rinse off the CELLCLEAN with rinse water as the final step.*

SP-50 Monthly Maintenance

Performing [Shutdown2]

Perform [Shutdown 2] once a month or when instrument will not be used for 1 week or more after the day's work.
[Shutdown 2] cleans the hydraulic line, and cleans the stain chamber with methanol or ethanol.
[Shutdown 2] ends by filling the stain chamber with methanol or ethanol, and fills the chamber with stain the next time the power is turned on.

For Shutdown 2 procedure, please refer to page 99-100.

Note:
[Shutdown 2] is selected in the following cases.

- *The instrument was started on the day of the week set in [Shutdown 2 settings]*
- *More than 40 days has elapsed since the last time [Shutdown 2] was performed*

The day of the week on which [Shutdown 2] is executed can be set in [Shutdown 2 settings].
When the instrument is started on the set day, a message will appear prompting you to execute [Shutdown 2], and [Shutdown 2] will be executed automatically when shutdown takes place. If you want to change the shutdown type, touch [Shutdown] in the [Menu] screen and change the setting.

If the [Shutdown 2] process was performed, wait at least 2 hours after the instrument has shutdown before starting it again.

The instrument may not be sufficiently clean if restarted immediately after shutdown.

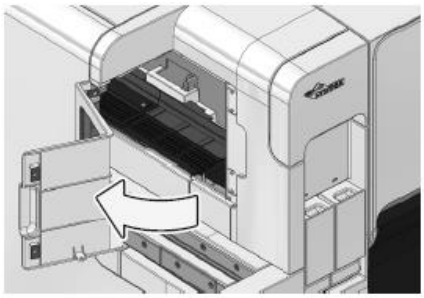
SP-50 As-Needed Maintenance

1. Cleaning the staining pool

When there is a dirt on the staining pool, remove the staining pool for cleaning. Methanol, ethanol, and lukewarm water can be used as the rinse fluid. Lukewarm water is not as effective as other rinse fluids. Use methanol or ethanol for the rinse process when the staining pool is noticeably dirty.

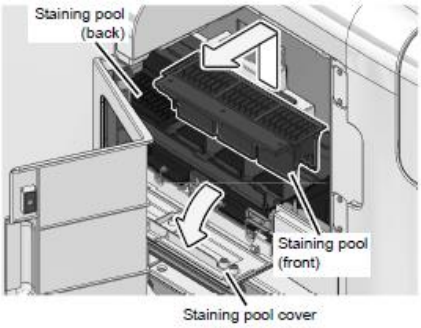
1. Prepare a container to use for the cleaning process.
   Select a container made from material, such as glass, stainless steel, fluororesin, etc., that has suitable chemical resistance to the chemicals used as rinse fluid.

2. Shutdown the instrument.



3. Open the stain unit cover.

4. Open the staining pool cover forward and down, and lift and remove the staining pools.
   There are 2 staining pools. Remove both pools.



5. Insert the staining pool into the cleaning container.

6. Add rinse fluid to the container.
   Add enough rinse fluid so that the staining pool is completely submerged.

7. Clean the staining pool in the container.
   Wear protective gloves and lightly stir to clean.

8. Dry the staining pool.
   Allow the staining pool to dry naturally.
   If you need to wipe off moisture, use a non-woven cloth or other cloth that will not leave fibers. Make sure that the staining pool is completely dry before mounting it back into the instrument.

9. Install the staining pool.

10. Replace the staining pool cover and close the stain unit cover.

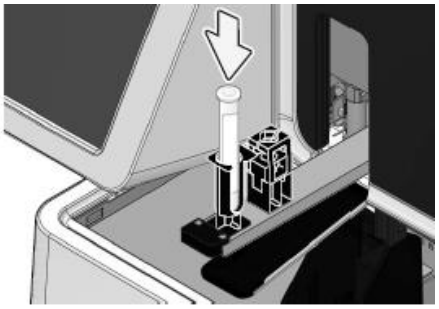
2. Cleaning the smear/stain unit

Use CELLCLEAN AUTO to clean the smear unit and stain unit, or the smear unit only.

1. Touch [Maintenance] in the menu screen.
2. Touch [Rinse devices].
3. Touch [Cleaning].
   The [Cleaning] dialog box appears, and the sample holder slides out forward.

[Cleaning] dialog box

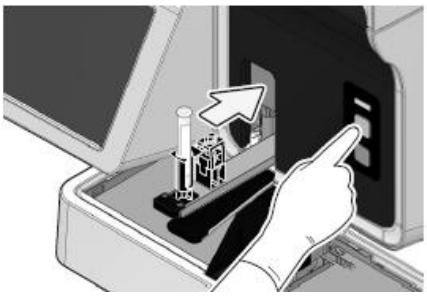
4. Select the part that you want to clean.
5. Set CELLCLEAN AUTO in the sample holder.
   Set the CELLCLEAN AUTO in the regular sample tube holder, which is at the main unit front side.



6. Press the [Start] switch on the main unit front side.
   The sample holder retracts and aspiration begins.
   When the aspiration is finished, the sample holder is ejected out forward.
   The time for cleaning is as shown below.

   [Smear unit/Stain unit]: About 50 minutes
   [Smear unit]: About 15 minutes

   When the cleaning is finished, the dialog box closes.

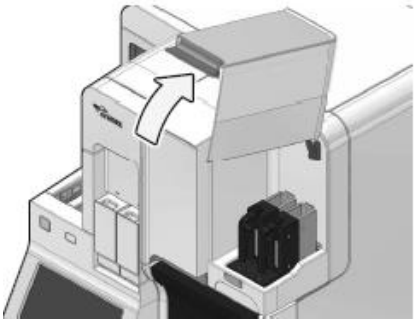


7. Remove the CELLCLEAN AUTO.
8. Press the mode switch on the main unit front side.
   The sample holder retracted into the instrument.

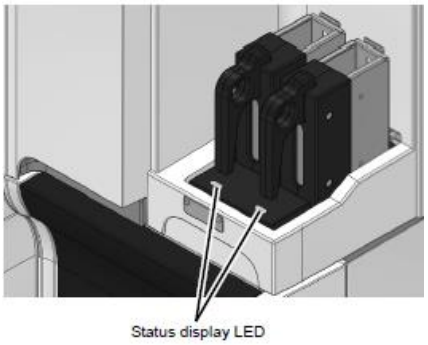
3. Wiping the printer

If the printing on the slide is faint, or when replacing the ink ribbon, wipe off any dirt on the ribbon roller and the printer head. Use ethanol to wipe off.

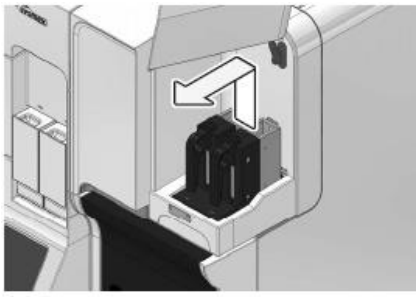
1. Open the slide set unit cover.
   Lift the cover up until it locks into place.



2. Make sure that the status display LED on the slide set unit lights in green or red.

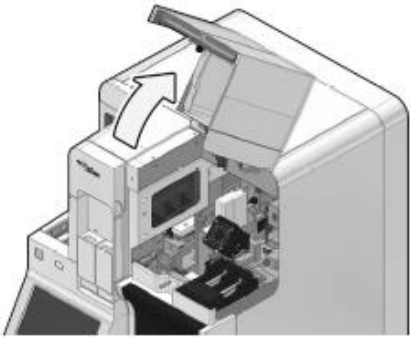


3. Remove the slide supply cassette from the slide set unit.
   Remove both the left and right slide supply cassettes.

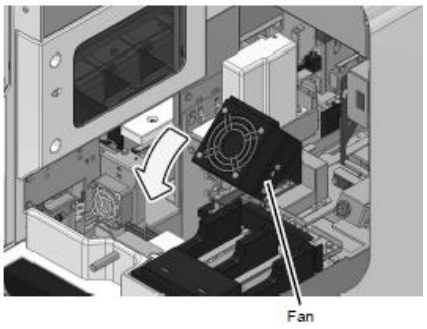


4. Close the slide set unit cover.
   Lightly press the cover to unlock and then close the cover.
   If sample preparation is in progress, wait until the smear unit cover unlocks after all samples have been fed into the stain unit.

5. Open the smear unit cover.
   Lift the cover up until it locks into place.

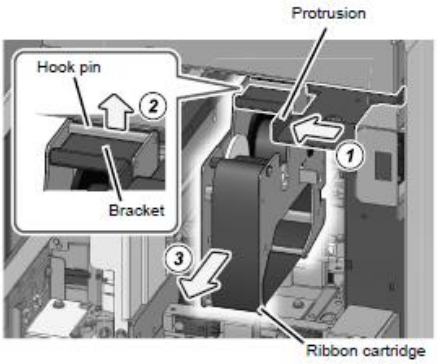


6. Rotate the fan forward and down.

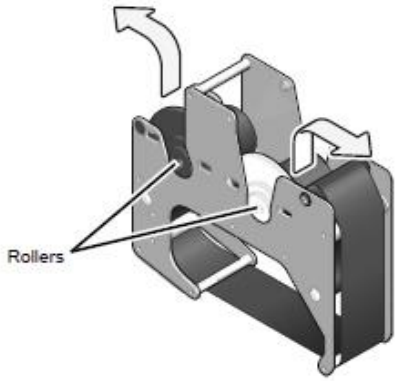


7. Remove the ribbon cartridge.

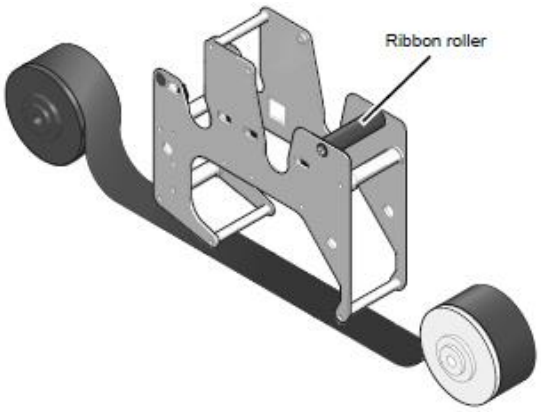
   a) Grasp the protrusion, slide the bracket to the left, and move the ribbon cartridge to the removal position.
   b) Lift the ribbon cartridge and remove the hook pin from the bracket.
   c) Remove the ribbon cartridge.

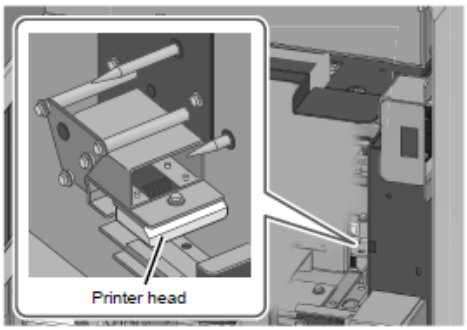


8. Lift both rollers of the ink ribbon and remove the used ink ribbon.

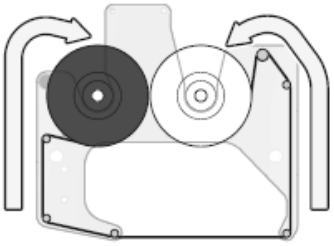


9. Clean the ribbon roller and printer.
   Wipe the ribbon roller and slide printer head with a cotton swab, absorbent cotton, or non-woven fabric moistened with disinfecting ethanol.

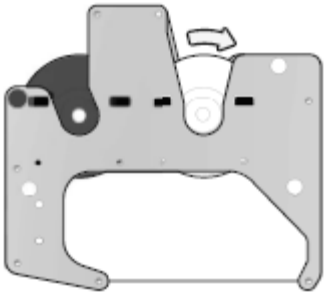




10. Mount the ink ribbon into the ribbon cartridge.

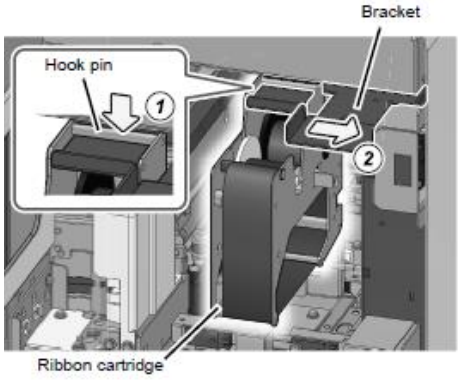


11. Remove the slack in the ribbon.
    Turn the white roller in the direction of the arrow illustrated in the figure.



12. Install the ribbon cartridge.

    a) Catch the ribbon cartridge hook pin on the bracket.
    b) Slide the bracket to the right and mount the ribbon cartridge.



13. Replace the fan in its original position.

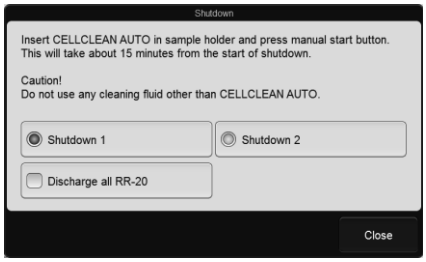
14. Close the smear unit cover.
    Lightly press the cover to unlock and then close the cover.

15. Open the slide set unit cover, install the slide supply cassette and close the slide set unit cover.

4. Discharge all RR-20 (drains all RO water in chamber of RR-20)

[Discharge all RR-20] is displayed only when the instrument is connected to the RR-20.
Select this checkbox to have all the RO water drained from the reserve tank (RR-20) chamber during shutdown.

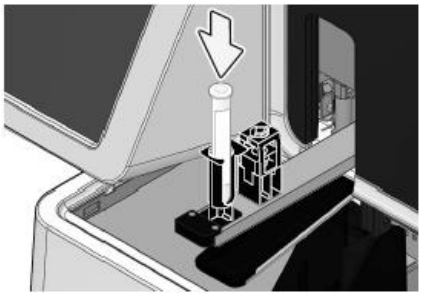
1. Touch [Menu] on the toolbar.



2. Touch [Shutdown].

3. Set [Shutdown 1] daily or [Shutdown 2] weekly.

4. Tick [Discharge all RR-20].



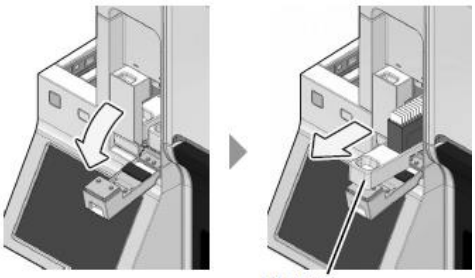
5. Set CELLCLEAN AUTO in the sample holder.

6. Press the [Start] switch on the main unit front side.

7. Shutdown is automatically performed.
   Shutdown takes approximately 15-20 minutes after CELLCLEAN AUTO aspiration starts.
   Remove and discard CELLCLEANAUTO tube once the sample holder ejects the empty tube.

   When all operations are finished, the sample holder automatically retracts into the main unit, and the instrument power turns OFF.

8. Remove the slide glass used for cleaning.
   The cleaned slide glass will be stored in the magazine in the manual magazine holder.



Note:
[Discharge all RR-20] can be selected in the following case.
- *When instrument will not be used for long-term after the working day*

5. Adjusting the air pressure

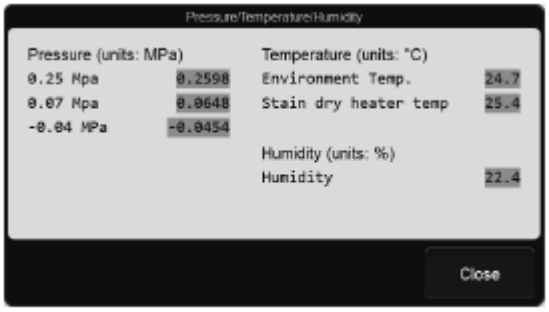
The pressure and vacuum supplied from the pneumatic unit and SP-50 are 0.25 MPa, 0.07 MPa and -0.04 MPa. These pressures are monitored by pressure sensors, and an error message will appear if there is any abnormality.

If an error message indicating an abnormal pressure is displayed, check if there is any leakage from the tube connections. If everything appears to be normal, display the pressure readings in the pressure/temperature/humidity status display screen and adjust each pressure.

Follow the steps below to adjust the pressure.

1. Touch [Maintenance] in the menu screen.

2. Touch [Check status] to display the pressure/temperature/humidity status display screen.



[Pressure/Temperature/Humidity] dialog box

3. Touch [Close].

Information
Always adjust the pressure to the required level by increasing the pressure. If the pressure is too high, lower it below the required level and then increase it to the required level.

6. Replacing the waste fluid tank

This work is necessary when a waste fluid tank is used. When the waste fluid tank becomes full, replace it. If the waste fluid tank becomes full, the [Help] dialog box shows [Waste container 1 is full] and [Waste container 2 is full].

Replace the waste fluid tank after setting the instrument in ready state.

Follow the steps described in SP-50 Troubleshooting manual chapter 2:
(Replacing the waste fluid tank, page 125)

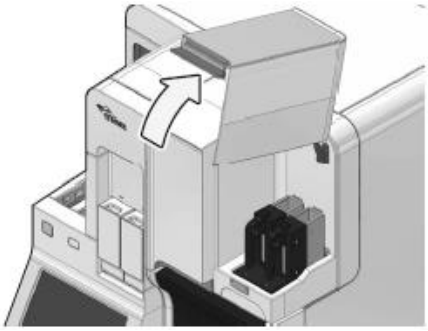
Be sure to wear adequate personal protective equipment, such as protective gloves, a protective mask, protective eyewear, and a lab coat when working. Wash your hands with antiseptic solution after completing the task.
There is a risk of infection.

SP-50 Supply and Reagent replacement

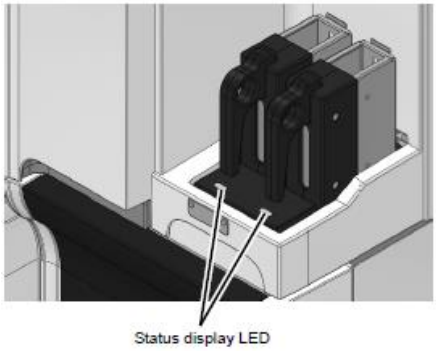
1. Loading the slide glass

Follow the steps below to load slide glass.

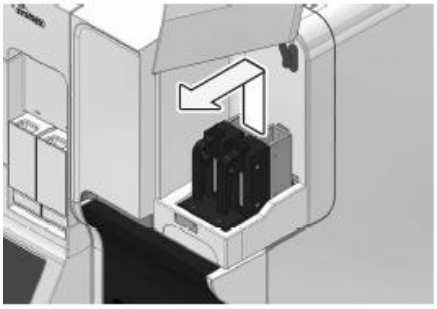
1. Open the slide set unit cover.
   Lift the cover up until it locks into place.



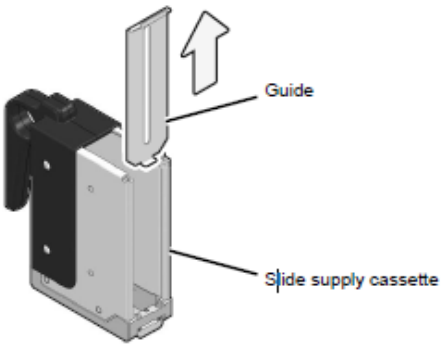
2. Make sure that the status display LED on the slide set unit lights in green or red.



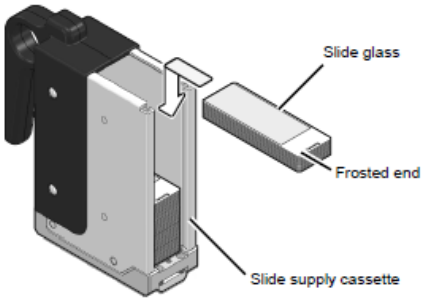
3. Remove the slide supply cassette from the slide set unit.
   The slide set unit has left and right holders, allowing separation of the slide glasses to meet your laboratory's needs.



4. Remove the slide supply cassette guide.



5. Load the new slide glass.
   As illustrated in the figure below, load the slide glass so that the frosted end faces upwards in the slide supply cassette.



6. Install the slide supply cassette guide.

7. Install the slide supply cassette.

8. Close the slide set unit cover.
   Lightly press the cover to unlock and then close the cover.

2. Replacing the reagent

Replacing the reagent (please refer to page 143)

3. Replacing the spreader glass

When the error message [Replace spreader glass] appears, the spreader glass must be replaced.

1. Touch [Maintenance] in the menu screen.

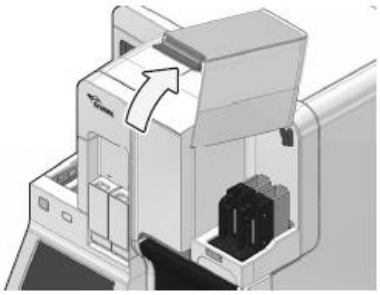
2. Touch [Replacement].

3. Touch [Replace spreader glass].

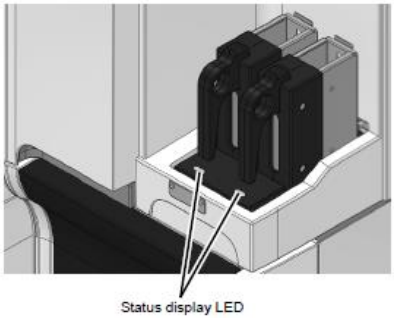
4. Make sure that the smear unit cover is closed.

5. Touch [OK].
   The smear unit moves to the position at which the spreader glass can be wiped. Wait until the smear unit cover unlocks once the smear unit stops moving.

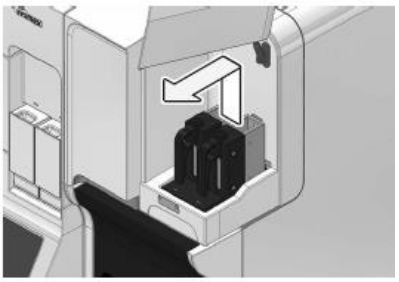
6. Open the slide set unit cover.
   Lift the cover until it locks into place.



7. Make sure that the status display LED on the slide set unit lights in green or red.

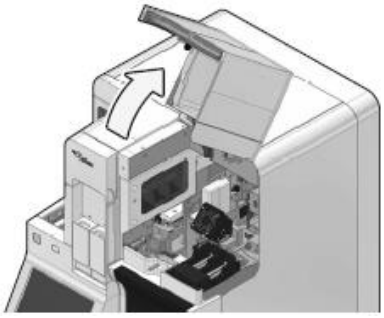


8. Remove the slide supply cassette from the slide set unit.
   Remove both the left and right slide supply cassettes.

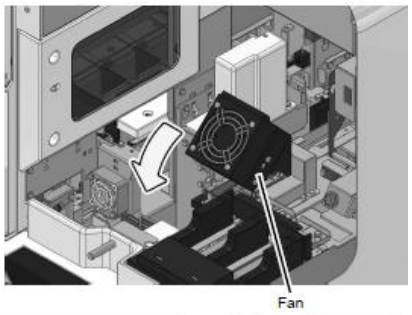


9. Close the slide set unit cover.
   Lightly press the cover to unlock and then close the cover.

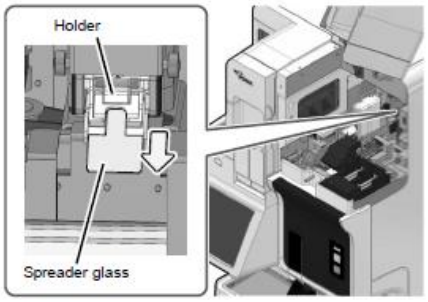
10. Open the smear unit cover.
    Lift the cover until it locks into place.



11. Rotate the fan forward and down.



12. Remove the spreader glass from the holder.
    To remove, grasp the spreader glass and pull it forward.



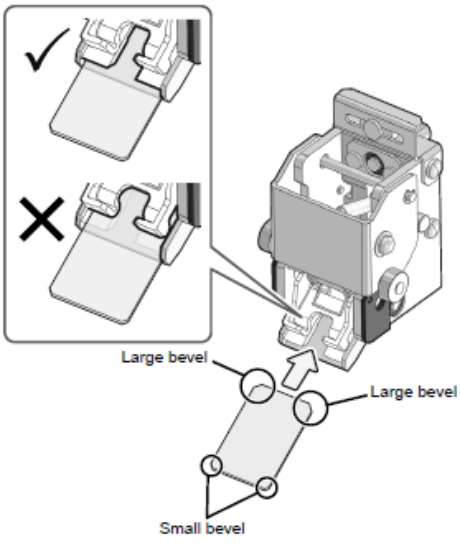
13. Set the new spreader glass in the holder.
    Set the spreader glass so that the edge with the smaller chamfer faces forward.
    Insert the spreader glass all the way into the spreader glass holder until it stops.

14. Replace the fan in its original position.

15. Close the smear unit cover.

16. Open the slide set unit cover, install the slide supply cassette and close the slide set unit cover.

17. Touch [OK] twice.
    The spreader glass operation count is reset after replacing the spreader glass.

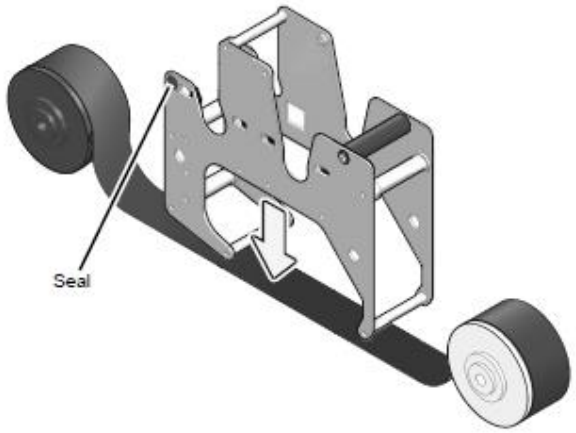


4. Replacing the ink ribbon

When the error message [No Ink ribbon] appears, replace the ink ribbon. When replacing ink ribbon, wipe off dirt on the printer.

1. Follow the procedure for “Wiping the printer” page 200-201, from steps 1 to 9.

2. Insert the new ink ribbon down into the ribbon cartridge.
   Make sure the ink side of the ink ribbon faces downward. Place the blue shaft on the side with the seal, and the white shaft on the opposite side.



3. Continue to follow the procedure for “Wiping the printer” page 202, from steps 10 to 15.

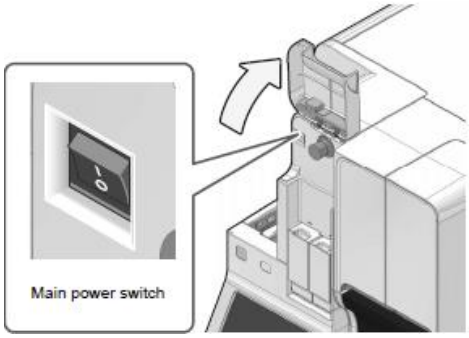
5. Replacing the fuse

Over-current protection fuses are used in the main unit and pneumatic unit. If a fuse blows, replace the fuse immediately.

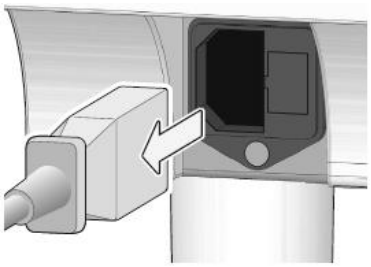
Fuse used in the main unit

Product code	Item name	Rating	Type	Number used
26677681	Fuse 50T100H	250 V 10 A	Time Lag	2

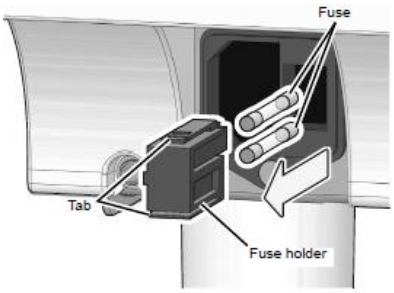
1. Shutdown the instrument.
2. Open the main power switch cover, and turn OFF the main power switch.



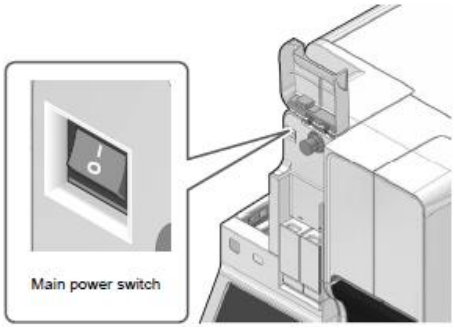
3. Unplug the power cable from the rear side of the main unit.



4. Remove the old fuse.
   a) On the rear of the unit, pinch the tabs of the fuse holder and pull out forward.
   b) Remove the old fuse from the fuse holder.



5. Set a new fuse into the fuse holder, and insert it into the unit.
6. Plug in the power cable.
7. Turn ON the main power switch.
8. Close the main power switch cover.
9. Turn ON the power to the instrument.



6. Replenishing the reagent

If you encounter an error related to reagents, or if you set the wrong reagent, you can replenish the reagent in a flow path.

10. Make sure that the reagent you want to use is connected.

11. Touch [Maintenance] in the menu screen.

12. Touch [Rinse devices].

13. Touch [Reagent Replenishment].
    The [Reagent Replenishment] dialog box appears. The items displayed depend on your instrument configuration.

[Reagent Replenishment] dialog box

14. Select a checkbox of the reagent you want to replenish.
    Multiple selections can be made.

15. Touch [OK].
    A progress dialog box appears and reagent replenishment begins. When the replenishment is finished, the dialog box closes.

Note:
Prolonged use will cause the vacuum to gradually decrease. When this occurs, the vacuum pump may need to be repaired or replaced. Contact your local RDA representative.

III. SP-10 Maintenance

Regular maintenance of the analysers is necessary to keep the instrument in optimal condition. Please refer to chapter 9 of SP-10 IFU.

To perform some maintenance tasks, the analyser and the sampler must be in READY state. Otherwise, maintenance cannot be performed. In addition, analysis is not possible during maintenance.

When working with the top cover open, secure it in a position where it is stable. Otherwise, the cover may fall and injure your head or other part of your body.

When closing the top cover, release the stopper.

Fragments of glass may occasionally fall into the device. When inserting your hand into the device, be alert for fragments of glass.

Note:
The times required for the maintenance sequences are indicated below.

- *[Shutdown1]: About 15 minutes*
- *[Shutdown2]: About 20 minutes*
- *Whole line cleaning: About 40 minutes*
- *Stain line cleaning: About 40 minutes*

SP-10 Maintenance

Daily maintenance

- Performing [Shutdown1] (clean the hydraulic line)
- Cleaning the spreader glass
- Checking the water level in the trap chamber and discarding the water
- Cleaning single cassettes
- Replacing the staining solutions in the stain chambers

Weekly maintenance

- Cleaning the whole line (clean both smearing and staining line)
- Performing [Shutdown2] (clean the hydraulic line and staining chamber)

Monthly maintenance

- Cleaning the racks, right and left sampler rack pools, and measurement line

As-Needed maintenance

- Cleaning the smearing line
- Cleaning the staining line
- Adjusting the air pressure
- Replacing the waste container (if installed)

Supply and Reagent replacement

- Replacing the hand gripper
- Replacing rubber plate No. 39
- Replacing the fuses
- Replacing the spreader glass
- Replacing the ink ribbon

For full list of maintenance and the detailed instructions on how to perform these please refer to supplied SP-10 Instruction For Use manual; CHAPTER 9- Performing maintenance of device and replacing supply parts.

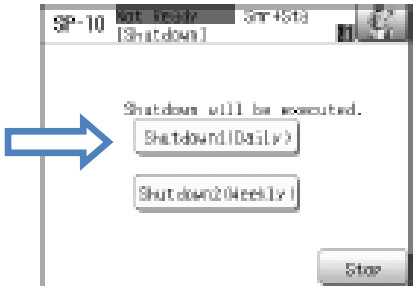
SP-10 Daily Maintenance

1. Performing [Shutdown1]

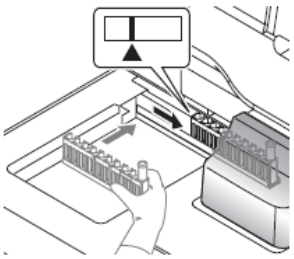
Perform [Shutdown 1] at the end of the routine day or after 24 hours. [Shutdown 1] cleans the hydraulic line.

> ***Note:***
> *When 24 hours have elapsed since the device was started, the message [It has been over 24 hour, since power was turned on. [Execute shutdown1.] Appears before the device returns to the ready state.*

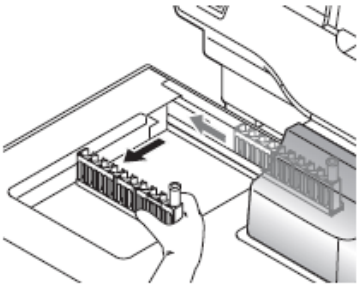
1. Ensure analyser is 'ready'
2. Verify the following:
   - There are at least 12 single cassettes on the cassette supply table.
   - There is at least 450 mL of methanol in the methanol bottle.
3. Select [Conv.int.] in SP-10's main menu screen.
4. Select [Interrupt].
5. Select [Return].



6. Select [Shutdown] in main menu screen, and select [Shutdown1 (Daily)].
7. Set the CELLCLEAN AUTO tube in position 10 on the rack.
8. Place the rack so that its left end fits the label shown here
9. Touch [OK], shutdown will commence.
   When the shutdown is complete, the device power automatically turns off.



10. Remove the rack at the end of shutdown process.
    Slide the rack to the left on analysis line, and then remove it.



2. Cleaning the spreader glass

The spreader glass should be cleaned once every 24 hours. Replace when smear quality does not improve (even after cleaning) or glass is damaged or cracked upon visual inspection.

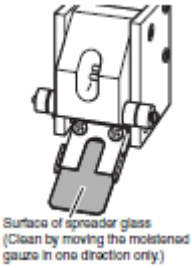
18. Select [Maint.] in the menu screen.
    The main maintenance screen appears.

19. Select [Spreader glass].

20. Select [OK].

The smear unit moves to the front. While the smear unit moves, the

21. When you are prompted to replace the spreader glass, open the top cover.



22. Clean the surface of the spreader glass with gauze moistened
    With ion-exchanged water (or purified water).

23. Close the top cover and touch [OK].
    The smear unit returns to its home position. While the smear unit moves, a message indicating that it is moving appears.

24. Touch [Cancel].
    The spreader glass counter is not reset, and the screen returns to the main maintenance screen.

Risk of infection

When cleaning the spreader glass, always wear gloves. After finishing work, wash your hands with a disinfectant. Risk of infection by pathogens if there is blood contamination.

CELLCLEAN is a strong alkaline detergent. Avoid contact with skin, eyes, and clothing. In case of contact, flush with copious amounts of water.

Information
Do not use detergents other than CELLCLEAN. The spreader glass is resistant to corrosion by CELLCLEAN, but other device parts are not. To prevent problems, thoroughly wipe off any parts that come in contact with CELLCLEAN.

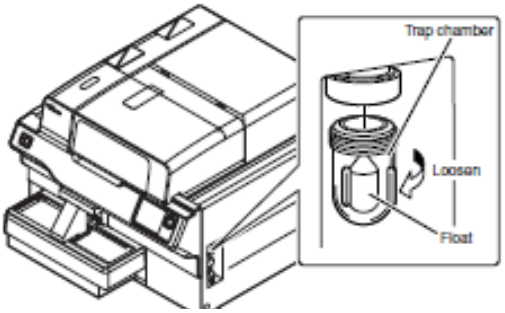
3. Checking the water level in the trap chamber and discarding the water

When the day's work is finished, check the water level in the trap chamber. If water has collected, follow the steps below to discard it.

Unplug the power cord from the electrical outlet before performing the work.

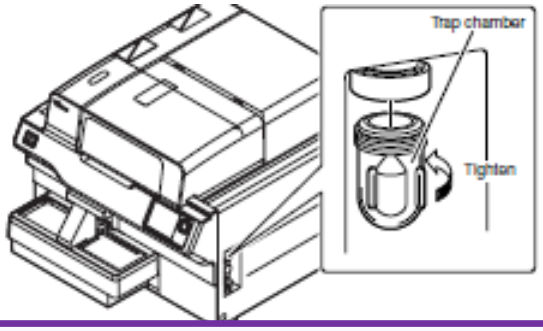
9. Shut down the device and wait for one minute.

10. Remove the trap chamber from the right side of the device by unscrewing it in the direction of the arrow.



11. Discard the water that has collected in the trap chamber.

12. Replace the trap chamber by screwing it in in the direction of the arrow.



If water collects persistently each day, there may be a problem in the device. Contact your local RDA representative.

When discarding trap chamber water, always wear gloves. When finished, wash your hands with a disinfectant.

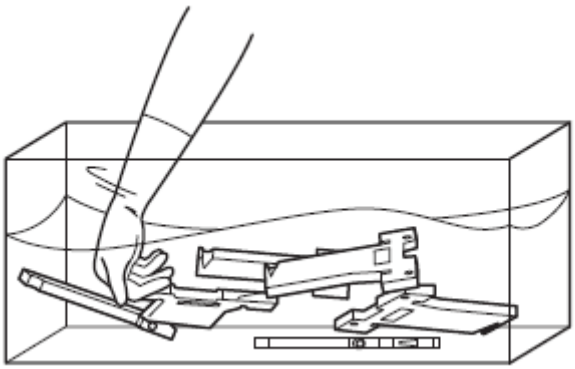
4. Cleaning single cassettes

Clean single cassettes once a day. Methanol, ethanol (70%), or warm water can be used for the rinsing solution. Warm water is not as effective for removing dirt as the other rinsing solutions. If warm water is used, clean the cassettes with methanol or ethanol once a week, or when dirt becomes noticeable.

1. Place the single cassettes in the cleaning container.

2. Fill the container with rinsing solution (e.g. methanol, ethanol, warm water). Pour enough solution to immerse the cassettes.

3. Clean the single cassette in the container. Clean by stirring the solution around gently with your hands (wearing rubber gloves) as per image figure below.



4. Drain the solution from the cassette and dry completely. Before using the single cassette, make sure that the cassette is completely dry.

If any methanol remains inside a single cassette, haemolysis may occur in the smeared sample inside the single cassette, preventing accurate microscopy. Make sure that single cassettes are dried thoroughly and no methanol remains.

Warning!
When using hot air to dry single cassettes, set the temperature to 50°C or lower. Too high a temperature may deform single cassettes and cause them to become unusable.

Do not allow methanol to remain in cassettes for a prolonged period of time (longer than 30 minutes) as this may cause material to deteriorate and affect shape of cassette.

5. Replacing the staining solutions in the stain chambers

Due to bacteria growth and other reasons, the staining solution cannot be left in the stain chamber over 48 hours. The device will automatically add or replace the staining solutions in the situations indicated below. However, if none of these situations occur within 48 hours, follow the steps described in SP-10 Instruction For Use manual chapter 9:
(Replace the staining solutions in the stain chambers 9-11)

SP-10 Weekly Maintenance

1. Cleaning the whole line (smear and stain lines)

Perform [Cleaning the whole line] to clean both the smear and stain lines.
Follow the steps described in SP-10 Instruction For Use manual chapter 9: Clean the smear and stain lines 9-19.

2. Performing [Shutdown2]

Perform [Shutdown2] to clean the hydraulic line and stain chambers. Shutdown 2 ends with the stain chambers filled with methanol. The chambers will be filled with the staining solutions the next time the power is turned on.

Follow the steps described in SP-10 Instruction For Use manual chapter 9:
(Run [Shutdown2] clean the hydraulic line and staining chamber) 9-17)

Note:
When one week elapses after [Shutdown2] is last performed, the message [Execute shutdown 2] appears before the device returns to the ready state.

SP-10 Monthly Maintenance

Cleaning the racks, right and left sampler rack pools, and measurement line

If the right or left pools of the sampler, the measurement line, or racks are dirty, wipe clean with a damp cloth.

SP-10 As-Needed Maintenance

1. Cleaning the smearing line

If an error such as [Waste chamber1 not draining] occurs, indicating that the waste chamber may be dirty, follow the steps below to clean the smearing line.

When smearing line cleaning is performed, waste chamber 1 is automatically cleaned together with the hydraulic line through which waste fluid flows.

Follow the steps described in SP-10 Instruction For Use manual chapter 9:
(Clean smearing line 9-22).

2. Cleaning the staining line

If [Shutdown2] is not performed, follow the steps below to clean the staining line once a week.
When staining line cleaning is performed, the hydraulic system through which the staining solutions run is automatically cleaned and the staining solutions are replaced.

Follow the steps described in SP-10 Instruction For Use manual chapter 9:
(Clean staining line 9-13)

3. Adjusting the air pressure

The pressure and vacuum supplied from the pneumatic unit are adjusted 0.25 MPa, 0.05 MPa and -0.053 MPa in the pneumatic unit and in the SP-50. These pressures are monitored by pressure sensors, and an error message will appear if there is any abnormality.

If an error message indicating an abnormal pressure is displayed, check if there is any leakage from the tube connections. If everything appears to be normal, display the pressure readings in the pressure/temperature/ humidity status display screen and adjust each pressure.

Adjusting the pressure to 0.25 MPa

This pressure is used to drive the air cylinders and master valves.

Follow the steps below to adjust the pressure.

1. Touch [Status] in the menu screen.
2. Touch [<<] or [>>] to display the pressure/temperature/humidity status display screen.

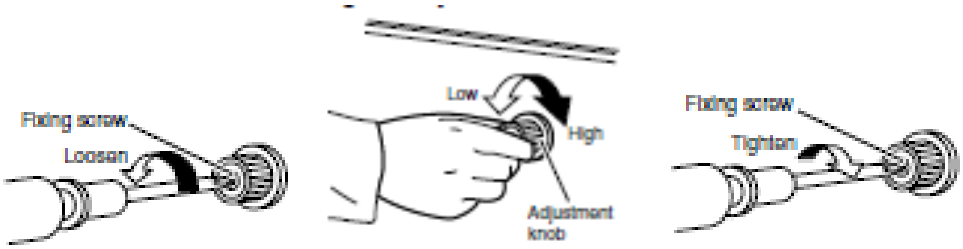
3. Loosen the fixing screw for the 0.25 MPa regulator on the pneumatic unit.

4. While viewing the pressure display in the pressure/temperature/humidity status display screen, adjust the pressure by turning the adjustment knob.

To increase the pressure, turn the adjustment knob clockwise.

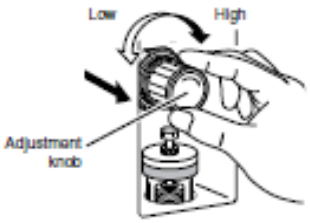
5. Make sure that the pressure displayed in the pressure/temperature/ humidity status display screen is at the required level.

6. Tighten the fixing screw, being careful that the adjustment knob does not rotate.



Information
Always adjust the pressure to the required level by increasing the pressure. If the pressure is too high, lower it below the required level and then increase it to the required level.

Adjusting the pressure to 0.05 MPa



This pressure is used to discharge waste fluid.

Follow the steps below to adjust the pressure.

1. Touch [Status] in the menu screen.

2. Touch [<<] or [>>] to display the pressure/temperature/humidity status display screen.

3. Loosen the fixing screw for the 0.05 MPa regulator on the pneumatic unit.

4. While viewing the pressure display in the pressure/temperature/humidity status display screen, adjust the pressure by turning the adjustment knob.

To increase the pressure, turn the adjustment knob clockwise.

5. Make sure that the pressure displayed in the pressure/temperature/ humidity status display screen is at the required level.

6. Push in the 0.05 Mpa regulator adjustment knob to lock it.

Pneumatic unit vacuum -0.053 MPa

This vacuum pressure is used to move fluids between the chambers.

Note:
Check if the tubing between the main unit and the pneumatic unit or the tubing inside the pneumatic unit has become disconnected
If disconnected, reconnect the tubing.
If the tubing has not become disconnected, contact your local RDA representative.

Follow the steps below to adjust the pressure:

1. Touch [Status] in the menu screen.

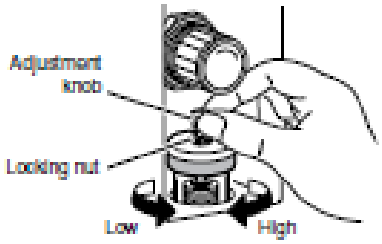
2. Touch [<<] or [>>] to display the pressure/temperature/humidity status display screen.

3. Loosen the bellows adjuster locking nut.

4. While viewing the pressure display in the pressure/temperature/humidity status display screen, adjust the pressure by turning the adjustment knob.
   To increase the pressure, turn the knob clockwise.

5. Make sure that the pressure displayed in the pressure/temperature/ humidity status display screen is at the required level.

6. Tighten the locking nut, being careful that the adjustment knob does not rotate.



Note:
Prolonged use will cause the vacuum to gradually decrease. When this occurs, the vacuum pump may need to be repaired or replaced. Contact your local RDA representative.

4. Replacing the waste container (if installed)

When the waste fluid monitoring sensor (optional) is installed

Follow the steps described in SP-50 Instruction For Use manual chapter 9:
(Replace the waste container (if installed) 9-28)

When [OK] becomes active in the action message, start work. Waste fluid may scatter, creating a risk of infection by pathogens.

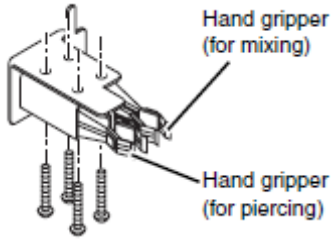
SP-10 Supply and Reagent Replacement

1. Replacing the hand gripper

If the hand grippers are deformed and no longer able to hold sample tubes, follow the steps below to replace them.

When replacing the hand grippers, always wear gloves. When finished, wash your hands with a disinfectant. Risk of infection by pathogens if there is blood contamination.

1. Run shutdown to shut down the device, and switch off the main power switch.
2. Open the CP cover.
3. Remove the hand gripper fixing screws (2 each for piercing and for mixing), and remove the hand grippers.



4. Install the new hand grippers with the fixing screws (2 each for piercing and for mixing).
5. Close the CP cover.

Note:

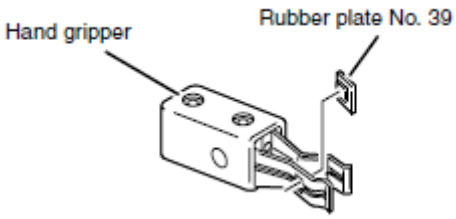
- *When the XN-3100 or XN-9100 is connected, there is no special hand gripper for mixing.*
- *The hand gripper for mixing has a tube holder part. If this part is removed, the hand gripper will be the same as the hand gripper for piercing.*

2. Replacing rubber plate No. 39

If a hand gripper becomes slippery and is no longer able to hold a sample tube, follow the steps below to replace anti-slip rubber plate No. 39.

When replacing rubber plate No. 39, always wear gloves. When finished, wash your hands with a disinfectant. Risk of infection by pathogens if there is blood contamination.

1. Run shutdown to shut down the device, and switch off the main power switch.
2. Open the CP cover.
3. Remove the hand gripper fixing screws (2 each for piercing and for mixing), and remove the hand grippers.
4. Remove rubber plate No. 39 from the hand gripper.



5. Attach the new rubber plate No. 39 to the hand gripper.
6. Reinstall the hand grippers.
7. Close the CP cover.

3. Replacing the fuses

Over-current protection fuses are used in the main unit and pneumatic unit. If a fuse blows, follow the steps below described in SP-50 Instruction For Use manual chapter 9:
(Replace fuses 9-43)

Use a fuse of the specified type and rating. Risk of smoke emission.

Fuse used in main unit

Specification	Part Number	Model name	Type
100 VAC - 240 VAC	266-7767-7	Fuse 250 V 8 A 50T080H	Time lag

Fuse used in pneumatic unit

Specification	Part Number	Model name	Type
100 VAC - 117 VAC	266-5011-3	Fuse 250 V 4 A ST4-4A-N1	Time lag
117 VAC - 240 VAC	266-5293-0	Fuse 250 V 3.15 A No. 19195	Time lag

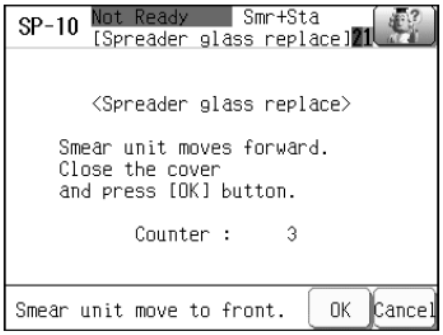
4. Replacing the spreader glass

When the spreader glass usage has exceeded factory usage cycle limit, [Replace spreader glass] message will appear prior to completion of start-up sequence.

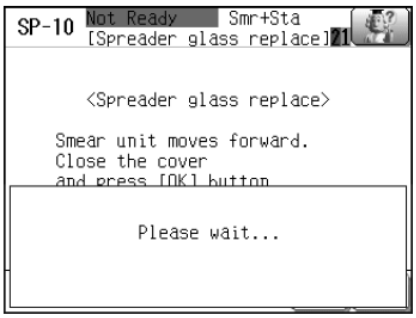
If this message appears, follow the steps below to replace the spreader glass.

1. Select [Maint.] in the menu screen.
   The main maintenance screen appears.

2. select [Spreader glass].



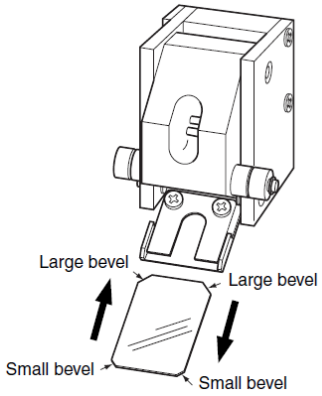
3. Touch [OK].
The smear unit moves to the front. While the smear unit moves.



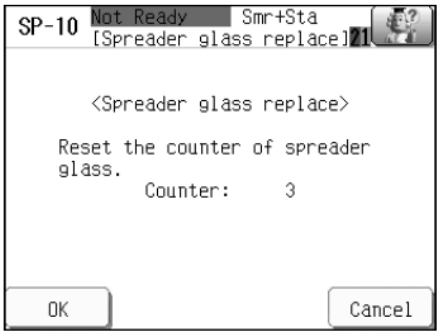
4. When you are prompted to replace the spreader glass, open the top cover.

5. Remove the spreader glass from the spreader glass holder.
To remove, grasp the spreader glass and pull it towards you.

6. With the smaller bevelled corners toward you, insert the new spreader glass into the spreader glass holder.
Insert the spreader glass all the way into the spreader glass holder until it stops.



7. Close the top cover and touch [OK].
The smear unit returns to its home position. While the smear unit moves, a message indicating that it is moving appears.



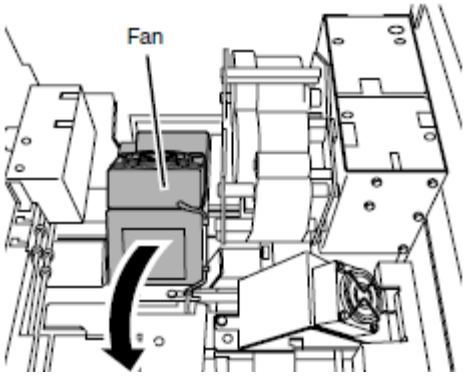
8. Touch [OK].
The spreader glass operation count is reset, and the screen returns to the main maintenance screen.

5. Replacing the ink ribbon

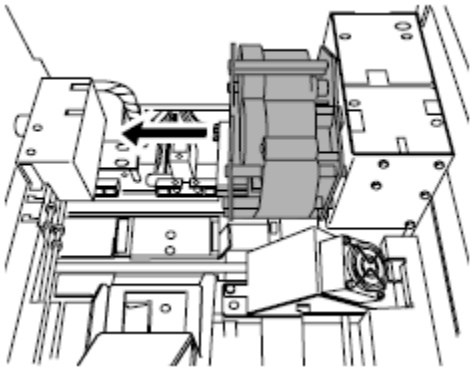
If [Replace ink ribbon] or [No Ink ribbon] is displayed, follow the procedure below to replace the ink ribbon.

1. After the top cover lock is released, open the top cover.

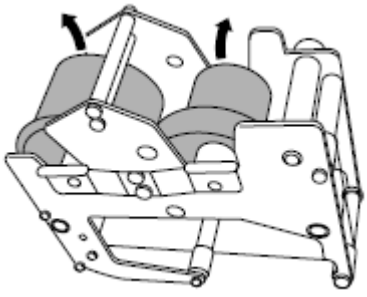
2. Rotate the fan toward you and down.



3. Pull the ribbon cartridge to the left and remove it from the device.



4. Lift both ink ribbon spindles and remove the used ink ribbon from the ribbon cartridge.

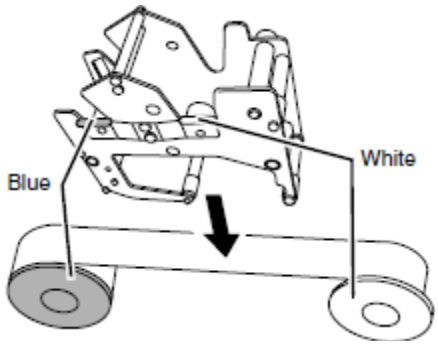


Follow the steps below to load the new ink ribbon in the ribbon cartridge.

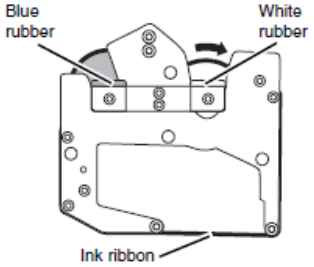
- Place the ink ribbon on a flat surface with the ribbon up, and pull out a length of about 20 cm of ribbon from the spindle.

- Place the ribbon cartridge on the ribbon.

- Lift the ink ribbon spindles and place in the ribbon cartridge.

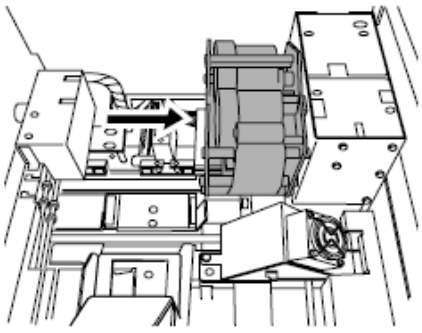


5. Turn the white spindle in the direction of the arrow so that the ribbon is taut.

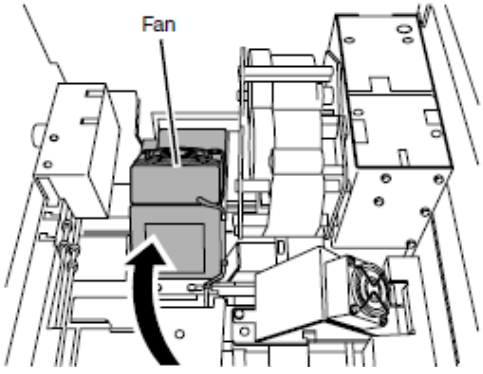


Information
White and blue rubber is attached to the ribbon cartridge. When placing the spindle, place in the part with the rubber that is the same colour as the spindle.

6. Insert the ink cartridge to the right and into the device.



7. Return the fan to its original position.



8. Close the top cover.
When closing the top cover, release the stopper

9. Touch [OK].
When the error is cleared, the ribbon will rewind.

Information
When the ribbon cartridge is removed from the sample printer, [Ink ribbon was loaded incorrectly.] will appear. Touch [OK] in the error dialog and continue replacement.

IV. RU-20 Maintenance

Regular maintenance of the analysers is necessary to keep the instrument in optimal condition. Please refer to chapter 6 of RU-20 IFU and chapter 13 of XN-9100 IFU.

To perform some maintenance tasks, connected analysers must be switched off or supplied with Cellpack DCL.

Note:
The times required for the maintenance sequences are indicated below.

- *Shutdown: About 1 minute*
- *Auto rinse: About 45 minutes*
- *Reagent replenishment: About 4-6 hours*

  (Note only RDA service representative should perform this maintenance)

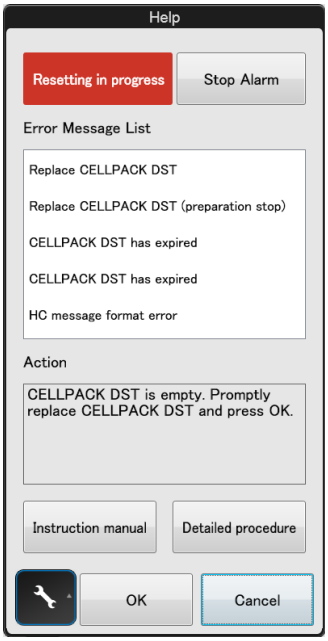
As-Needed maintenance

- Replacement the reagent
- Shutdown
- Performing automatic RU-20 rinse
- Replenishing the reagent (performed by RDA service representative)
- Replacing a fuse
- Replacing a maintenance part (performed by RDA service representative)
- Adjusting the air pressure

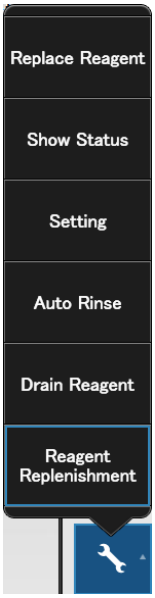
For full list of maintenance and the detailed instructions on how to perform these please refer to supplied RU-20 Instruction For Use manual; CHAPTER 6- Performing maintenance of device and replacing supply parts.

When the RU-20 is used, special maintenance and settings can be performed in the “RU-20 Maintenance Menu” which is available on board the XN IPU.

1. Click the RU menu button on the control menu.
   Following dialog box will appear.



2. Click the submenu button.
   Following submenu appears.



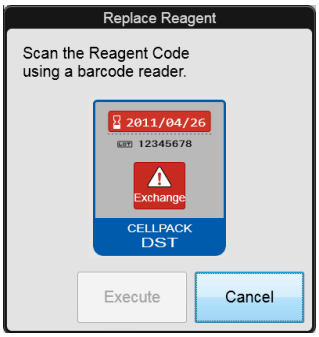
RU-20 As-Needed Maintenance

1. Replacing the reagent

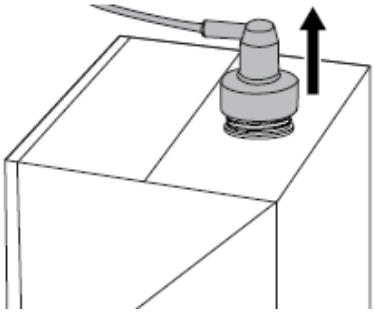
When the reagent has run out or expired, it must be replaced.

Follow the procedure below to perform reagent replacement.

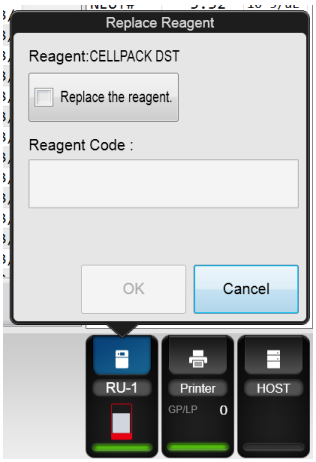
1. Display the RU-20 Maintenance menu.
2. Select [Replace Reagent].



3. Replace the old reagent container with the new reagent container and insert the dispensing set.



4. Register new reagent information.



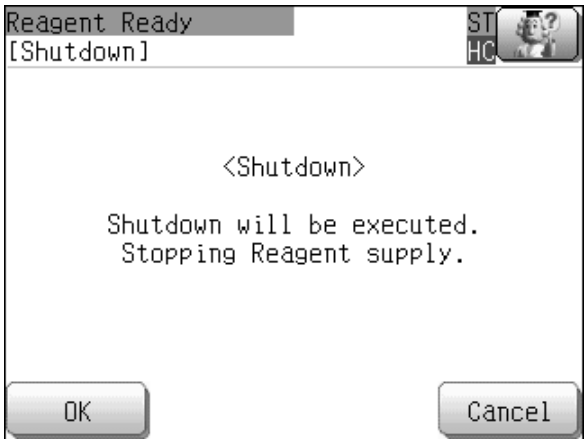
5. Select [OK].

2. Shutdown

Shutdown is performed as needed.

Following system error and during troubleshooting operator can perform shutdown as follows:

1. Turn off the power of the analyser(s) connected to the instrument.
2. Touch [Shutdown].



3. Touch [OK]. The shutdown completion screen appears.
4. Press the power switch off the main unit.

Note:

The system cannot be shutdown when the instrument is in the [Not ready] state.

If operation of connected analysers is required, switching the system to use of Cellpack DCL before shutdown of RU-20.

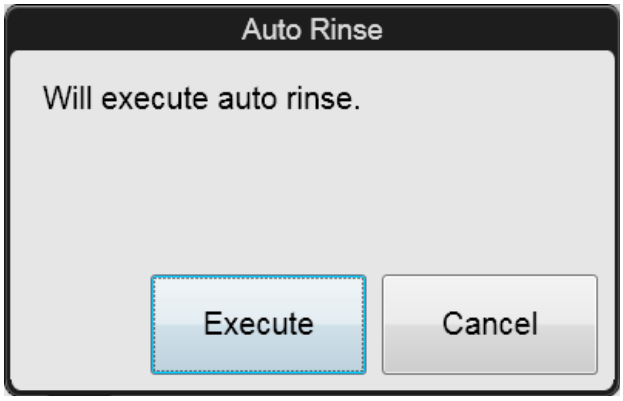
3. Performing Automatic RU-20 rinse

Note:
When using the RU-20, follow the steps below to perform automatic rinsing. In the event that a reagent preparation problem occurs, the partially prepared reagent can be drained and the interior of the RU-20 automatically rinsed.
When automatic rinsing is performed, the prepared reagent in the supply tank is not drained.

Follow the procedure below to perform automatic rinsing.

1. Display the RU-20 Maintenance menu.

2. Click [Auto Rinse].



3. Click [Execute].
   The dialog box automatically closes, [Maintenance in progress] appears in the operation status display area of the help dialog box, and automatic rinsing begins.
   Wait until it is complete.

4. Click [Cancel].
   The dialog box closes.

Note:
Automatic rinse is requested by operator in the event that the background check is not within limits.

This maintenance function, will offer complete rinse of the RU-20 fluidics pathway.

Automatic rinse will approximately take 45 minutes, but depending on the speed of RO water supply this time can vary.

4. Replenishing the reagent

In the event that expired Cellpack DST was utilised during reagent preparation or when quality of prepared reagent is compromised, Cellpack DST reagent in the instrument and the prepared reagent in the supply tank must be drained and replenished with new reagent.

Note:
Reagent Replenishment is performed only by RDA representative.

Reagent Replenishment will take approximately 4-6 hours, during which no reagent supply from the RU-20 is possible.

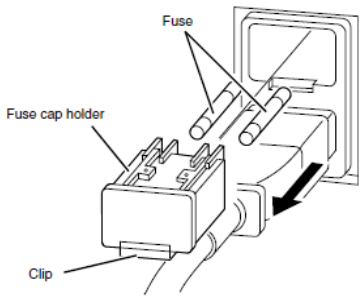
In the event that this maintenance is required please contact your local RDA representative.

5. Replacing a fuse

Over-current protection fuses are used in the main unit and pneumatic unit. If a fuse is blown, it must be replaced.

Follow the steps below to replace the fuse.

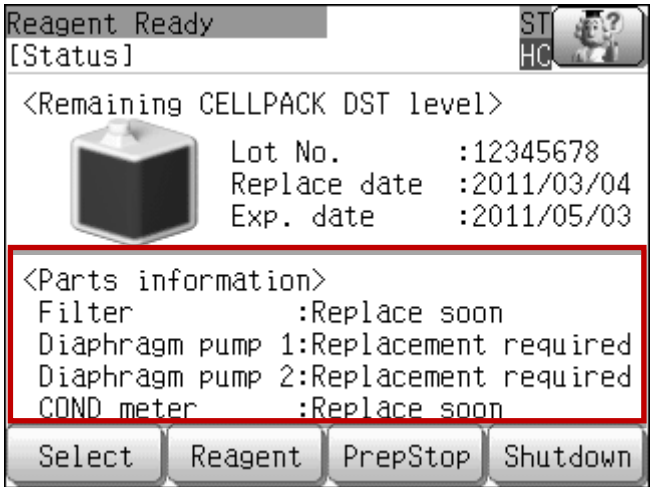
1. Turn off the power of the main unit and the pneumatic unit.
2. Disconnect the power cord of the unit with the fuse to be replaced.
3. Remove the fuse cap holder.
   To remove the fuse cap holder, use a flathead screwdriver or similar tool to press up on the clip.



4. Replace the fuse.
5. Replace the fuse cap holder.
6. Connect the power cord of the unit with the fuse that was replaced.
7. Turn on the power of the main unit and the pneumatic unit.

6. Replacing a maintenance part

If [Replacement required] or [Calibration required] appears in parts information, stop using the instrument and contact local RDA representative.



Note:

- *Filter replacement is performed as part of service every 2 years of following preparation of 72,000L of reagent, whichever comes first.*
- *Diaphragm pump 1 or 2, are replaced every 2 years or following 3 million cycles, whichever comes first.*
- *COND meter is replaced once a year.*

7. Adjusting the air pressure

If a [0.25 MPa pressure error] or [0.07 MPa pressure error] occurs, follow the procedure below to adjust the air pressure (positive pressure).

0.25 MPa pressure error

1. Display the [Air pressure] screen.

2. Loosen the fastening screw for the 0.25 MPa regulator on the front of the pneumatic unit.

3. Adjust the pressure by turning the knob on the 0.25 MPa regulator.
   While viewing the [Air pressure] screen, adjust the pressure to the specified pressure (0.25 ± 0.01 MPa). To increase the pressure, turn the knob clockwise.

4. Tighten the fastening screw of the 0.25 MPa regulator, without turning the adjustment knob.

0.07 MPa pressure error

1. Display the [Air pressure] screen.

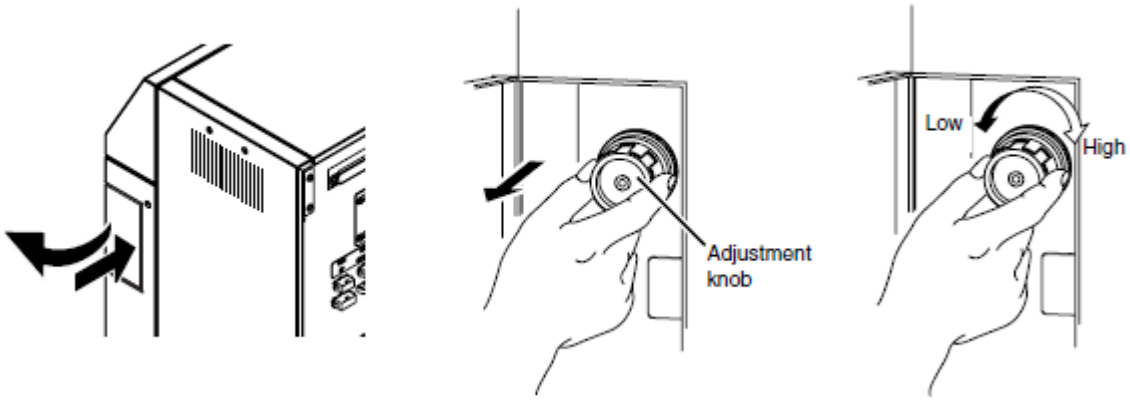
2. Open the door for pneumatic pressure adjustment.

Push the cover located on the right side of the Door for pneumatic pressure adjustment once, so that it pops up. Then open the door.

3. Pull out the adjustment knob on the 0.07 MPa regulator to unlock it.

4. Adjust the pressure by turning the knob on the 0.07 MPa regulator.
   While viewing the [Air pressure] screen, adjust the pressure to the specified pressure (0.07 ± 0.005 MPa).
   To increase the pressure, turn the knob clockwise.

5. Push the adjustment knob on the 0.07 MPa regulator to lock it.



Note:
0.04 MPa vacuum cannot be adjusted.
If a [Vacuum Error] occurs, check if a tube between the main unit and the pneumatic unit has become disconnected. If disconnected, firmly reconnect the tube.

If the tube is properly connected but an error still occurs, please contact your local RDA service representative.

Section 13: Troubleshooting

Help dialog box (XN and RU-20 only)

When a specific error occurs, or a maintenance task or cleaning becomes necessary, the following help dialog box appears on the IPU. Respond to the error message according to the message shown the [Action] field.

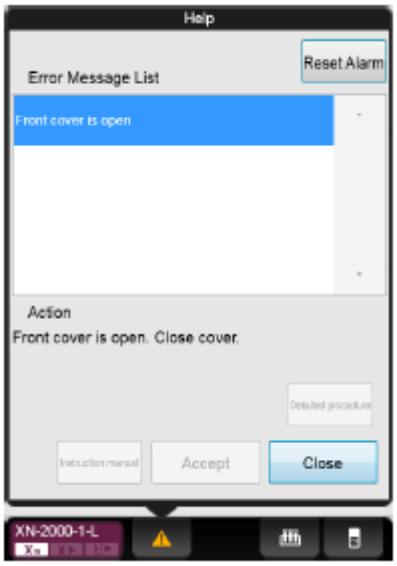


Figure 37: Help Dialog Box

Note:
When there is an error, the help dialog box can be displayed. Click the help button on the control menu.
All alarms sounding on the IPU will stop when you click any button in the Help dialog box or press any key on the keyboard.

Errors related to Transportation Unit (CT-90)

The following types of error statuses are possible in the transportation units. Take the appropriate troubleshooting actions by referring to the [Action Message(s)] field on the help dialog box of the transportation controller.

1. **Barcode label read error**

If an ID read error occurs while a barcode is being read from a sample or a rack, the transportation unit assigns an error barcode number to that sample or rack. The error barcode number is generated according to the following convention:

- Error barcodes for samples: **ERRyyXXXXXXXXXX**
  - **yy**: Unit number of device on which the read error occurred.
  - **XX**: An error number is assigned in the order of occurrence, from 0000000001 to 9999999999. The number resets to 0000000001 when you turn OFF and ON the transportation unit.

- Error barcodes for racks: **EHyyXX**
  - **yy**: Unit number of device on which the read error occurred.
  - **XX**: An error number is assigned in the order of occurrence, from 01 to 99. The number resets to 01 when you turn OFF and ON the transportation unit.

Samples that have been assigned an error barcode are analysed according to the settings in the transportation controller.
If a read error occurs on the first rack ID that was read, the rack is sent to the analysis line regardless of whether an order exists.

2. **Analyser error**

Some types of errors that occur in the analyser during an analysis may also trigger the alarm on the CV-50/CV-55 or CV-60/CV-65.

In such a case, press the alarm reset switch on the transportation unit whose alarm is sounding, and then clear the error according to the Instructions for Use.
After clearing the error, press the start switch on the CV-50/CV-55 or CV-60/CV-65. The samples that encountered an analysis error are automatically re-analysed.

About automatic re-analysis
Once the analysis resumes, re-analysis is performed starting with the samples that encountered an error.
Only one re-analysis is performed automatically per sample.
In off-line analysis (sampler analysis), the analysis does not resume with automatic re-analysis. Instead, it resumes with analysis of unanalysed samples.

3. **Conveyor error**

An alarm will sound at the transportation unit where the error occurred.

If you are using the TU-40, an alarm will sound on the transportation unit connected before or after the TU-40, depending on the nature of the error.

Clear the error and restart analysis. The sample at which the error occurred is automatically re-analysed.

If an error occurred in a transportation unit, reset the rack in the input area and clear the error.

If the error is still not cleared and the rack position LED is not lit, check the error that has occurred in the transportation controller (CT-90) and take the action indicated in the [Action Message(s)].

Follow the steps below to clear the errors:

1. **Press the alarm reset switch.**

The alarm sound stops.

2. **Remove the rack that is in the position indicated by the rack position LED that is lit orange.**

If you are using the TU-40, an error may be occurring on the TU-40 that is connected before or after the transportation unit with the illuminated rack position indicator LED.
If there is a foreign object, remove the foreign object.

3. **Press the Start/Stop switch (ST-40/41/42, BT-40) or the Start switch (CV-50/55, CV-60/65).**

Analysis restarts.

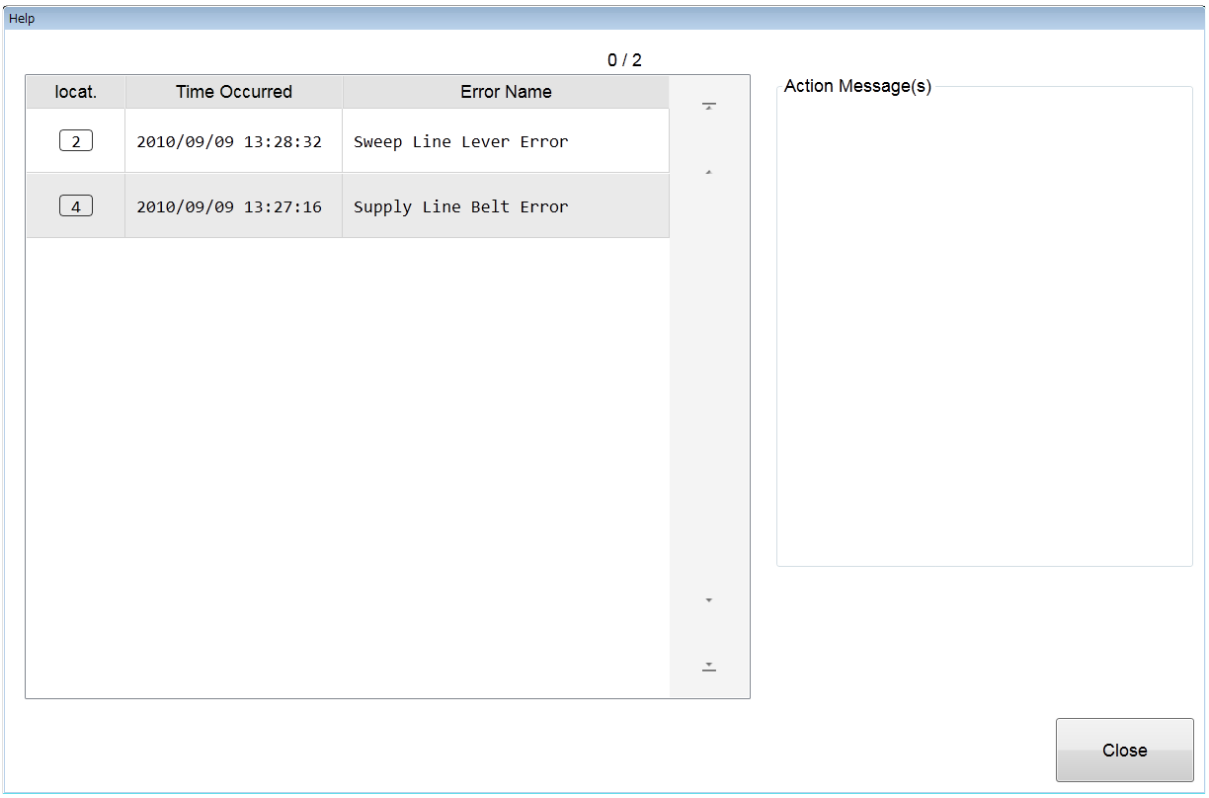
4. **Place the rack that was removed in the input area.**

Fit the slot in the rack onto the protrusion on the right side as viewed from the front.

When an error is displayed in the error display area of the transportation controller, you can check the error that is occurring.

Follow the steps below to check the current errors:

1. Touch the Help button on the transportation system area in the transportation controller.



2. Check the current error.
3. Touch [Close].

[List of error messages] *Displays a list of current errors. If multiple errors exist, errors that have higher priority are displayed at the top.*

[locat.] *Displays the name of the transportation unit where the error occurred.*

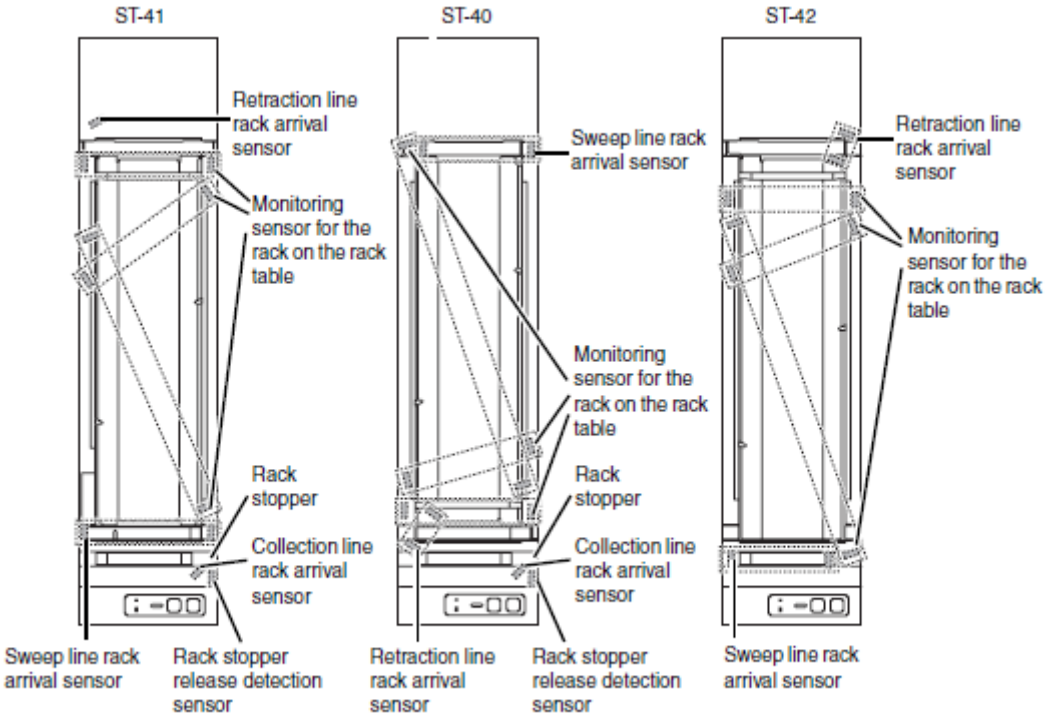
[Time Occurred] *Displays the date and time when the error occurred.*

[Error Name] *Displays the description of the error.*

[Action Message(s)] *Displays the troubleshooting action(s) for the error selected in the error list. Depending on the type of error, this field may be blank.*

Start yard/stock yard (ST-40/ST-41/ST-42)

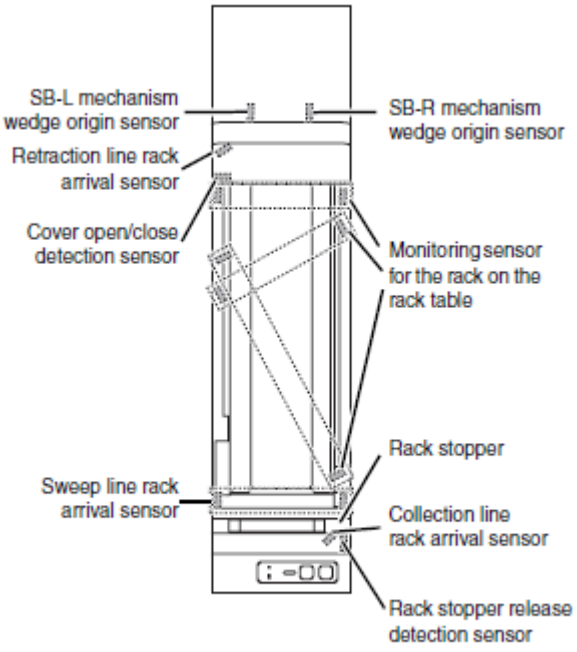
The names and positions of the sensors attached to the ST are shown below.



The structure of ST

Barcode terminal (BT-40)

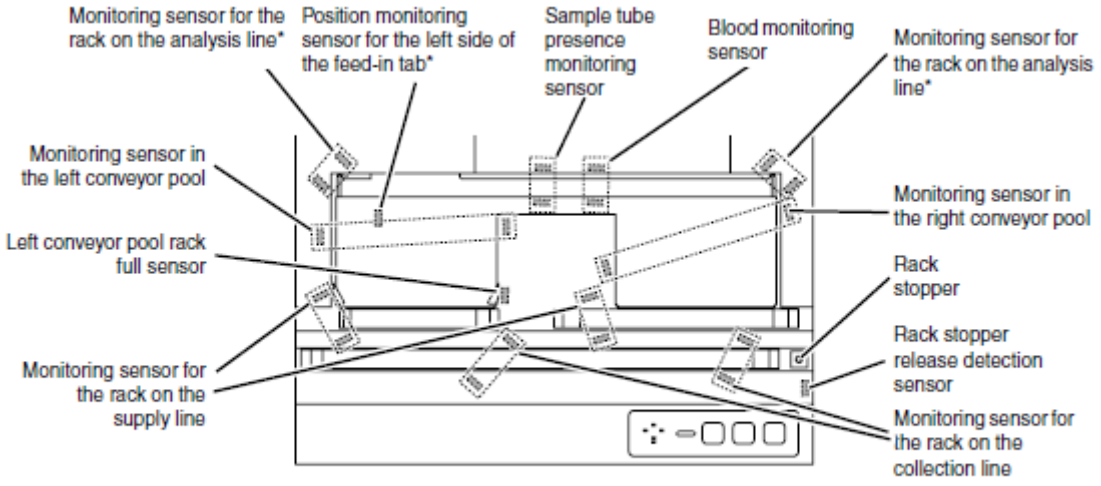
The names and positions of the sensors attached to the BT-40 are shown below.



The structure of BT-40

XN conveyor (CV-50/CV-55)

The names and positions of the sensors attached to the CV-50/CV-55 are shown below.

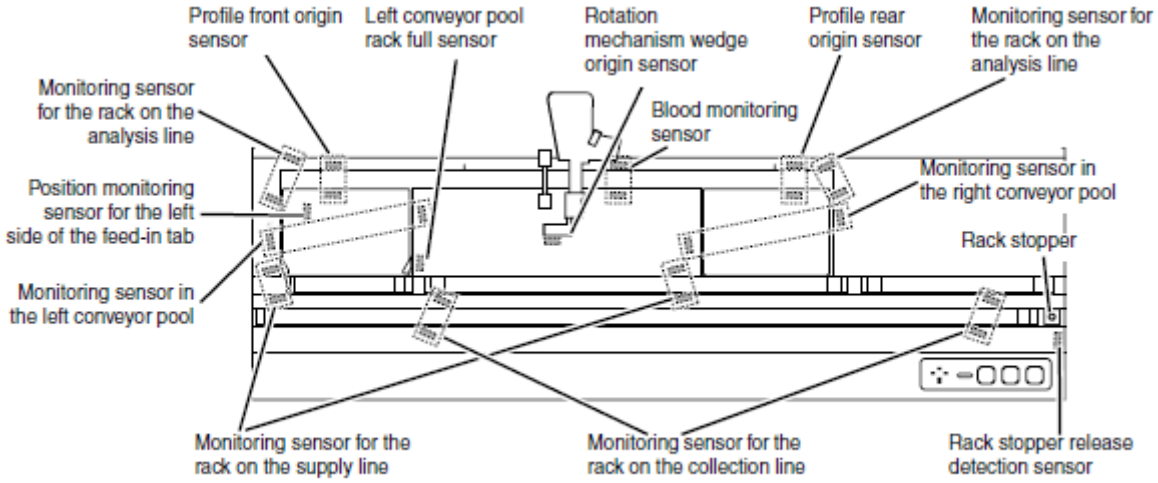


The structure of a CV-50

*Sensor or mechanism monitored by the analyzer.

SP conveyor (CV-60/CV-65)

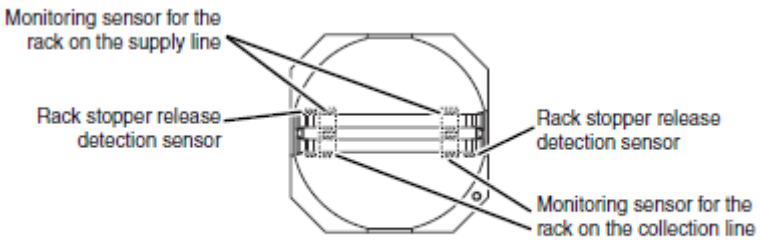
The names and positions of the sensors attached to the CV-60 are shown below.



The structure of a CV-60

Turn unit (TU-40)

The names and positions of the sensors attached to the TU-40 are shown below.



The structure of a TU-40

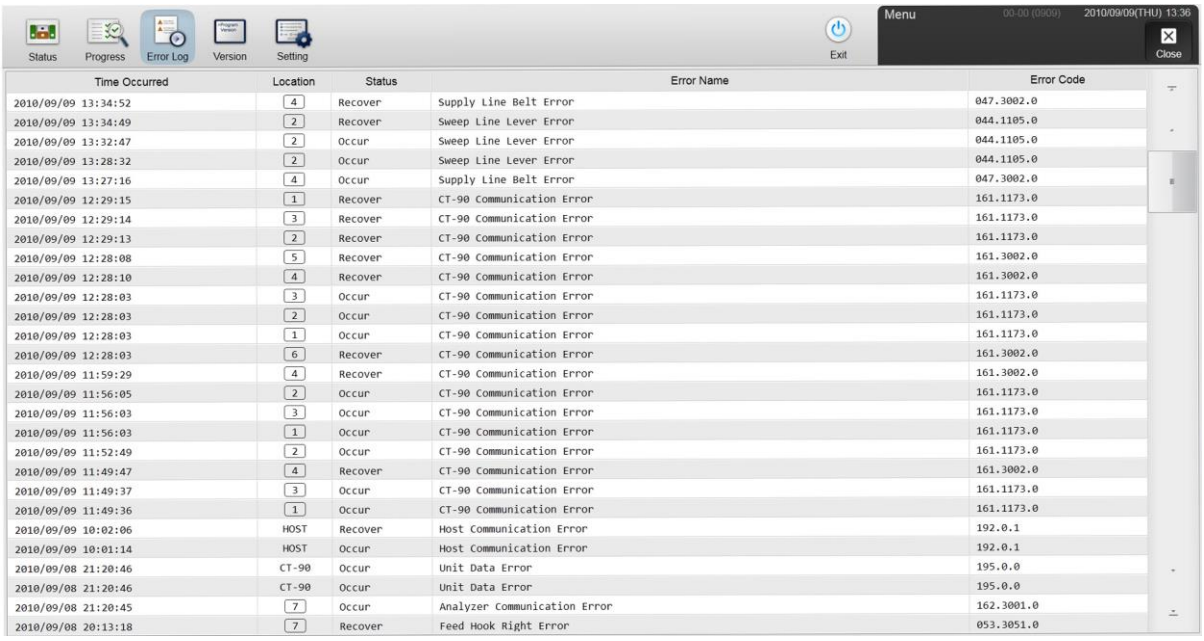
Check the Error Log on CT-90

The history of error occurrences can be viewed.
The log data shows the information regarding the occurrence and the clearing of each error, and comments can be entered.
The log can be printed or output as a file in CSV format.

Check the error log for the transportation units

You can check the system error log for the transportation units in the transportation controller.
Follow the steps below to check the error log for the transportation units.

1. Touch the [Status] button on the toolbar in the transportation controller.



Time Occurred	Location	Status	Error Name	Error Code
2010/09/09 13:34:52	4	Recover	Supply Line Belt Error	047.3002.0
2010/09/09 13:34:49	2	Recover	Sweep Line Lever Error	044.1105.0
2010/09/09 13:32:47	2	Occur	Sweep Line Lever Error	044.1105.0
2010/09/09 13:28:32	2	Occur	Sweep Line Lever Error	044.1105.0
2010/09/09 13:27:16	4	Occur	Supply Line Belt Error	047.3002.0
2010/09/09 12:29:15	1	Recover	CT-90 Communication Error	161.1173.0
2010/09/09 12:29:14	3	Recover	CT-90 Communication Error	161.1173.0
2010/09/09 12:29:13	2	Recover	CT-90 Communication Error	161.1173.0
2010/09/09 12:28:08	5	Recover	CT-90 Communication Error	161.3002.0
2010/09/09 12:28:10	4	Recover	CT-90 Communication Error	161.3002.0
2010/09/09 12:28:03	3	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 12:28:03	2	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 12:28:03	1	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 12:28:03	6	Recover	CT-90 Communication Error	161.3002.0
2010/09/09 11:59:29	4	Recover	CT-90 Communication Error	161.3002.0
2010/09/09 11:56:05	2	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 11:56:03	3	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 11:56:03	1	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 11:52:49	2	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 11:49:47	4	Recover	CT-90 Communication Error	161.3002.0
2010/09/09 11:49:37	3	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 11:49:36	1	Occur	CT-90 Communication Error	161.1173.0
2010/09/09 10:02:06	HOST	Recover	Host Communication Error	192.0.1
2010/09/09 10:01:14	HOST	Occur	Host Communication Error	192.0.1
2010/09/08 21:20:46	CT-90	Occur	Unit Data Error	195.0.0
2010/09/08 21:20:46	CT-90	Occur	Unit Data Error	195.0.0
2010/09/08 21:20:45	7	Occur	Analyzer Communication Error	162.3001.0
2010/09/08 20:13:18	7	Recover	Feed Hook Right Error	053.3051.0

2. Touch the button for the device for which you want to the check the error log.
3. Check the error log.

   [Time Occurred] Displays the date and time when the error occurred.

   [Location] Displays the name of the transportation unit where the error occurred.

   [Status] Displays the status of the error.

   [Error Name] Displays the description of the error.

   [Error Code] Displays the error code.

4. Touch [Close].

History List

XN and SP-50 History list

The items in the history list change depending on which tab is selected:

- **Operation history screen**

Displays a history of operations performed in the device.

A maximum of 5000 entries are stored and displayed in the operation history.

- **Error Log screen**

A history of errors that occurred is displayed with information at the time of occurrence and clearance.

A maximum of 5000 entries are stored and displayed in the error log.

- **Reagent Replacement Log screen**

Displays history of reagent replacement, and all the information which was entered at the time of reagent replacement.

A maximum of 5000 entries are stored and displayed in the reagent replacement log.

- **Maintenance Log screen**

Displays a history of maintenance tasks executed with information at the time of execution.

A maximum of 5000 entries are stored and displayed in the maintenance log. The maintenance log tab is similar to the error log tab.

Note:

Output history to a printer

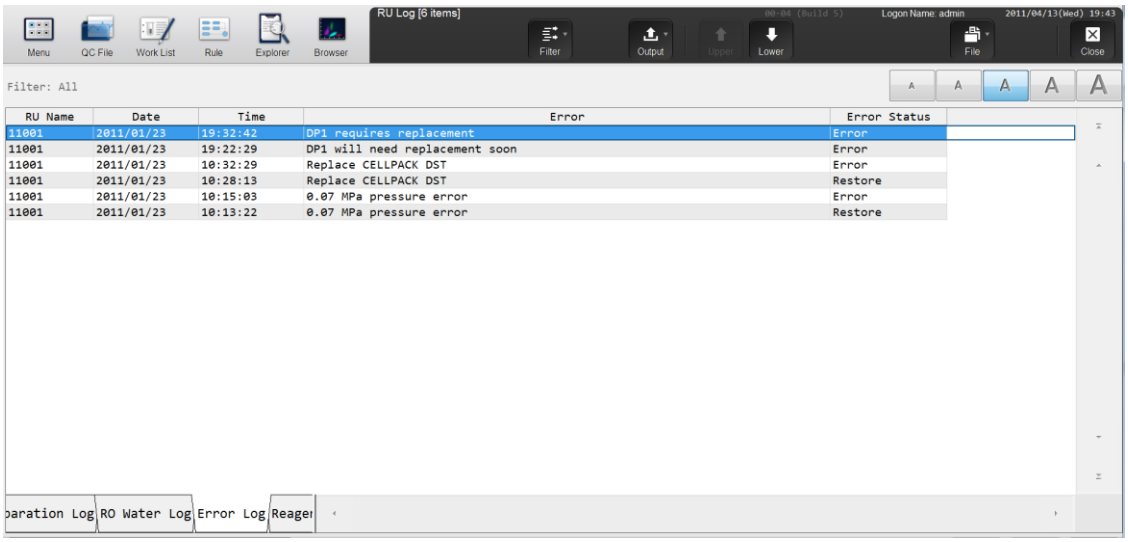
You can output the history list to a connected printer, using Ledger printer.

Save history in CSV format.

You can save the history list as a CSV file.

RU-20 History list

Clicking the [RU history] icon in the Menu screen displays the following screen.



The items in the RU history list change depending on which tab is selected.

Preparation history screen

Displays a history of reagent preparation performed on the RU and related information.
A maximum of 2000 entries are stored and displayed in the preparation history.

RO water history screen

Displays a history of reagent preparation performed on the RU and related information.
A maximum of 2000 entries are stored and displayed in the RO water history.

Error Log screen

A RU history of errors that occurred is displayed with information at the time of occurrence and clearance.
A maximum of 2000 entries are stored and displayed in the error log.

Reagent Replacement Log screen

Displays a history of reagent replacement, and any information that was entered at the time of replacement.
A maximum of 200 entries are stored and displayed in the reagent replacement log.

Part Replacement Log screen

This displays the part replacement log.
A maximum of 200 entries are stored and displayed in the part replacement history.

Note:

Output history to a printer

You can output the history list to a connected printer, using Ledger printer.

Save history in CSV format.

You can save the history list as a CSV file.

Background Limits

WBC	**0.10 x 10^9/L or less**
RBC	**0.02 x 10^{12}/L or less**
HGB	**1 g/L or less**
PLT-I*1	**10 x 10^9/L or less**
PLT-O*2, 4	**10 x 10^9/L or less**
PLT-F*3, 4	**3 x 10^9/L or less**
WBC-BF	**0.001 x 10^9/L or less**
RBC-BF	**0.003 x 10^{12}/L or less**

**1 PLT counted in the RBC/PLT channels (PLT particle size distribution).*
**2 PLT counted in the RET channels.*
**3 PLT counted in the PLT-F channels.*
**4 these items do not appear with all analyser types.*

Analysis Range for Whole Blood Mode

WBC	**0.00 to 440.0 x 10^9/L**
RBC	**0.00 to 8.60 x 10^{12}/L**
HGB	**0.0 to 260.0 g/L**
HCT	**0.0 to 0.750 L/L**
PLT	**0 to 5000 x 10^9/L**
NRBC#	**0.00 to 200.0 x 10^9/L**
NRBC%	**0.0 to 600.0 /100 WBC**
RET%	**0.00 to 300.00 %**
RET#	**0.000 to 72.0 x 10^9/L**

Troubleshooting SP Issues

Staining Issues

Alkaline Stain	
Symptom: RBC's appear blue-ish red. WBC granules & nucleus appear purple/black. Stain in normal inclusions appears abnormal	
Cause	**Resolution**
Prolonged Stain 1 time	Decreased Stain 1 time
Insufficient Stain/Buffer time	Increase Stain 1 dilution time
Alkaline buffer (pH too high)	Use lower pH buffer

Acidic Stain	
Symptom: RBC's orange/pink in colour. WBC granules & nucleus light	
Cause	**Resolution**
Insufficient Stain 1 time	Increase Stain 1 time
Prolonged buffer time	Decrease Stain 1 dilution time
Acidic Buffer	• Check buffer pH. If buffer was used for too long, change buffer & clean 20L bottle with methanol. Replace with fresh buffer • Use buffer with higher pH
Acidic Rinse	Check pH of H_2O. If water has not been changed recently, clean bottle with methanol & replace with fresh distilled water with pH 7.0

Stain Precipitate	
Cause	**Resolution**
Identify source of precipitate. SP or stain product	Stain smear manually using same stain & stain times to simulate SP. Example for SP-10: • 1 cassette: 6 mL undiluted stain • 1 cassette: 1:10 dilution (0.65 stain + 6 mL buffer) • 4 cassettes: 6 mL distilled water
Stain bottle has high precipitate level	Check bottom of stain bottle. Filter stain
Stain build up in stain chambers or in stain lines	Perform replace stain & observe inside of stain chambers when empty. Can you see through glass? Perform rinse stain If severe, attach stain line to methanol. Perform replace stain several times. Then reattach stain line & perform rinse stain.

RBC water artefacts	
Symptoms: Refractile bodies in RBC's. Too many RBC's with "punched hole" in centre of red cell	
Cause	**Resolution**
Stain 1 time too short	Increase stain 1 time to 3-5 minutes
Insufficient methanol in stain	Select a stain product with at least 96-99% methanol
Stain used for too long	Replace stain. Decrease Stain 1 cycle limit (replace stain every 1-2 days)
Water contaminate due to high humidity	Use fresh methanol & perform Rinse Stain If severe use super cleaning procedure
Water contaminate due to wet cassettes	Only use dry cassettes. Set Dryer Heater to USE, 5 min (Settings>Set Stain)
Water left in cassettes at Pipette 4	Pipette 4 should be 1 mm from the bottom of the cassette Realign or call for engineering assistance
Smear problem (carryover or smear not dry)	Check for carryover at Cap piercer, Sample piercer, Smear unit. Is smear dry before it is loaded into a cassette?
Wrong type of methanol	Use anhydrous methanol. Use fresh methanol daily. Do not use Histology grade methanol or isopropyl alcohol.

Suggested Stain times and information

Single stain: Wright's stain Or Wright-Giemsa in single bottle	Stain 1 5 Min With stain pre-Fix 3 Min Slide fix: 5 sec Dry time: 3 sec	• Helps define WBC • Fixes the RBCs and stains PLTs • <3 Mins may effect fixing of RBCs and cause RBC water artefacts
	Stain 1 dilution 7 Min With stain Pre-fix 5 Min	• Brings out colour of WBC (cytoplasm, granules and nucleus)
	Dry time 5 Min	• Smear must be dry. NEVER reuse wet cassettes, water may be added to the stain or haemolyse the smear
Double stain: **<u>Stain 1</u>** Wright's stain Or May gruwald stain	Stain 1 5 Mins	• Helps define WBC • Fixes the RBCs and stain PLTs • <3 Mins may effect fixing of RBCs and cause RBC water artefacts
	Stain 1 option use: 4 Mins	• Brings put colour of WBC (cytoplasm, granules and nucleus)
<u>Stain 2</u> Giemsa stain	Stain 2 10 Mins	• Makes WBCs very dark
	Rinse Option Not used	• Does not appear to show any difference in stained smear
	Dry time 5 Mins	• Smear must be dry. NEVER reuse wet cassettes, water may be added to the stain!

Effects of Buffer and DI water

Buffer pH of 6.6- 6.8	• Makes RBCs red in colour, and WBCs lighter
Buffer pH of 7.0-7.2	• Makes RBCs more blue in colour, and WBCs darker.
DI water ph of 7.0	• Should be neutral pH or it will change the final colour of the slide. May also affect both RBC and WBC colour. Refer to Buffer pH's above for details • If in lab water supply is used, check QC on DI water supply. If the problem continues, consider buying water or rinse

Stain Problems and Resolutions

Problems	Resolution
WBCs to light in colour	• Increase stain 1 and stain 1 dilution time • Check pH of buffer, may need higher pH buffer or water • Replace stain, buffer, and/or DI water
Monos appear washed out	• Decrease stain 1 dilution time • Check pH of buffer, may need higher pH buffer or water • Replace stain, buffer, and/or DI water
RBCs and/or PLTs are too light	• Increase stain 1 time • Check pH of buffer, may need higher pH buffer or water • Replace stain, buffer, and/or DI water
RBCs are too red or blue in colour	• Check pH of buffer • Buffer theory: pH 6.6-6.8 makes red RBCs; 7.0-7.2 makes bluish RBCs (and darker WBCs) • Replace stain, buffer and/or DI water
Too much stain precipitate	• Clean SP-1000 (shutdown 2, rinse stain or clean)
RBC water artifacts	• Clean SP-1000 (shutdown 2, rinse stain or clean)

Daily Maintenance Tasks

Yr. Month

Maintenance task \ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Shutdown																															
Signed																															

Maintenance Tasks to Be Performed as Needed

Maintenance task	M/D Signed	M/D Signed
Auto Rinse		
Cleaning		
Replacing waste container		
Draining waste chamber		
Remove Clog		
RBC detector aperture cleaning		
Rinsing waste chamber		
Remove Air Bubbles		
Rinse Flowcell		
Draining reaction chamber		
Drain RBC isolation chamber		
Adjusting the pressure (0.25 MPa)		
Adjusting the pressure (0.16 MPa)		
Adjusting the pressure (0.07 MPa)		
Draining chamber		

Replacing reagents and supply parts

Maintenance task	M/D Signed	M/D Signed
Replacing reagents (CELLPACK DCL)		
Replacing reagents (CELLPACK DST)		
Replacing reagents (CELLPACK DFL)		
Replacing reagents (SULFOLYSER)		
Replacing reagents (Lysercell WNR)		
Replacing reagents (Lysercell WDF)		
Replacing reagents (Lysercell WPC)		
Replacing reagents (Fluorocell WNR)		
Replacing reagents (Fluorocell WDF)		
Replacing reagents (Fluorocell WPC)		
Replacing reagents (Fluorocell RET)		
Replacing reagents (Fluorocell PLT)		
Draining the reagent		
Replacing piercer		
Replace fuses		

Daily maintenance task

Year Month

Day / Maintenance task	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Shutdown																															
Signed																															

Weekly maintenance task

Maintenance task	M/D Signed	M/D Signed
Wipe dirt off spreader glass		

Monthly maintenance task

Maintenance task	M/D Signed	M/D Signed
Performing [Shutdown 2]		

As-needed maintenance

Maintenance task	M/D Signed	M/D Signed
Loading slide glasses		
Replenishing rinse water		
Replacing the reagent		
Cleaning the staining pool		
Cleaning the smear/stain unit		
Wiping the printer		
Replacing the waste fluid tank		

Reagents and supply parts replacement

Maintenance task	M/D Signed	M/D Signed
Replenishing the reagent (CELLPACK DCL)		
Replenishing the reagent (Stain solution 1, Stain solution 2)		
Replenishing the reagent (Phosphate buffer)		
Replenishing methanol/ethanol		
Replacing the fuse		
Replacing the ink ribbon		
Replacing the spreader glass		

* We recommend that our customers prepare a checklist that suits their operating environment.

Daily Maintenance

Year: Month:

Maintenance task \ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Run Shutdown 1																															
Clean spreader glass																															
Check trap chamber																															
Clean single cassettes																															
Signature																															

Weekly Maintenance

Maintenance task	mm/dd, signature	mm/dd, signature	mm/dd, signature	mm/dd, signature
Clean staining line				
Run Shutdown 2				

As-Needed Maintenance

Maintenance task	mm/dd, signature	mm/dd, signature
Cleaning smearing and staining line		
Clean smearing line		
Adjust air pressure		
Replace waste container		
Replace Stain Solution		

Monthly Maintenance

Maintenance task	mm/dd, signature
Clean racks, right and left sampler rack pools, and measurement line	

Supply Replacement

Maintenance task	mm/dd, signature	mm/dd, signature
Replace reagents		
Replace hand gripper		
Replace rubber plate No. 39		
Replace fuses		
Replace spreader glass		
Replace ink ribbon		

Section 14: Practical Assessments

Knowledge Review XN

Practical Session 1

- Startup the analyser form shutdown ☐
- Logon to the IPU ☐

Explorer Operations ☐

- Ensure “Last 20” option is turned off
- Sort the data base using the 1st key option of the “sort” in ascending order ☐
- Use the filter toolbar to apply filter where only “validated” results are be displayed ☐
- Use the filter toolbar to apply filter where “Discrete RET” results are only displayed ☐
- Use the filter toolbar to apply filter where only “Host- not output” sample results are displayed ☐
- Find sample number ROCHE1 ☐
- Print a GP copy of the ROCHE1 ☐
- Backup results for sample number ROCHE1 ☐
- Delete the results from sample Explorer ☐
- Restore the results for sample ROCHE1 to sample explorer file ☐

- Edit the lab number from ROCHE1 to ROCHE2 ☐

- Print GP report copy of the edited sample ☐

- Randomly select analysis data from the Explorer screen save the results using CSV format ☐

Trainers Signature…… Date ……

Trainee Signature…… Date ……

Practical Session 2

Settings

Using Analyser Settings setup the following

- Sampler setting Blood sensor to: ☐

  USE

- Sampler setting Analysis start to: ☐

  Sample analysis start when rack is placed in the sampler

- Following sampler stop conditions on: ☐

  Aspiration Error

  Inadequate Sample

  L-J Limit Error

- Setup following flag settings: ☐

Lymphopenia to	LYMPH # < 1.0
NRBC present to	NRBC % > 2.5
Anemia	HGB < 85.0 g/L
Thrombocytosis	PLT >500 10^9 /L

- Set analyser leak sensor to: ☐

  Don't continue using analyser when leak is detected (OFF)

- Backup changes made using Manage Settings option: ☐

  Create folder Analyser setting with the file name:

  Analyser setting and date created (on the desktop)

  E.g. Analyser setting 02-10-11

Using IPU Settings setup the following

- Set the date to: ☐

  dd/mm/yyyy

- Setup automatic IPU shutdown ☐

- Create a new user called “Haem” with following settings: ☐

  Permission; Instrument Analysis, Accept results, Output results

- Connect HOST, LP and GP printers ☐

- Setup following Auto output criteria’s: ☐

  HC: Negative

- Auto validate to: ☐

  All samples

- Setup Delta Check setting to: ☐

  Perform

- Setup following reference intervals for Universal settings: ☐

  RBC Lower Limit to 2.00 10^12 /L

  PLT upper limit to 600 10^9/L

  HGB upper limit to 170 g/L

- Setup following Units: ☐

  WBC to 10^ 9 /L

  MCV to fL

- Setup following QC settings: ☐

  QC method to L-J

  Auto Limit settings to 2SD

- Create following fixed comments ☐

  QC vial used after 7 day onboard expiry

  QC vial used before RT temperature equilibrium reached

- Backup changes made using Manage Settings option: ☐

  Create folder IPU setting with the file name:

  IPU setting and date created (on the desktop)

  E.g. IPU setting 02-10-11

Trainers Signature…… Date ……

Trainee Signature…… Date ……

Practical Session 3

Quality Control

- XN-check QC material is used to monitor the performance of..... Parameters ☐

- How many QC files are available per XN instrument?..... ☐

- Register and load new QC file ☐

- Manage QC file as follows: ☐

  Backup old QC files

  Print LJ of Old QC file

  Delete old QC file

  Restore QC file deleted

- Run QC on board the sampler ☐

- Run QC using QC analysis option on the instrument menu ☐

- Review both QC runs on the LJ chats ☐

- Insert below comment for QC Analysed using Instrument menu ☐

"QC used after 7 days on board expiry"

- Insert pre assigned comment “QC vial used before RT temperature equilibrium reached “ ☐

- Activate Xbarm setting using Instrument Control Menu ☐

- Setup X-barM QC file for WDF channel ☐

- Review and print X-barM file WNR for the points accumulated ☐

Trainers Signature…… Date ……

Trainee Signature…… Date ……

Practical Session 4

Maintenance

- When is maintenance task cleaning performed? ☐

……

- When is Rinse the waste chamber performed? ☐

……

- When is Rinse Flowcell performed? And what reagent is used to clean the system: ☐

……

- When is RBC isolation chamber drained? ☐

……

- A 0.25Mpa is applied to control …… ☐

- ***Perform with the analyser switched ON:*** ☐

RBC Clog removal

Drain the waste chamber

Remove Flowcell air bubble

Drain reaction chamber

Replace Fluorocell: RETIC

Replace Cellpack DCL

Replenish Cellpack DFL

- ***Perform with the analyser switched OFF:*** ☐

  Draining the pneumatic trap chamber

- Perform daily shutdown ☐

Trainers Signature…… Date ……

Trainee Signature…… Date ……

Practical Session 5

SP-10/SP-50 Knowledge review

- Shutdown 1 is performed to? …….. ☐
- SP-10 Single Cassettes should be cleaned at least once every ?…….. hours ☐
- SP-50 Magazines should be cleaned at least once every ?…….. ☐
- Shutdown 2 is performed to?..... ☐
- When is the Spreader glass clean performed?..... ☐

SP-10/SP-50 Operations

- Change the Operation Mode to SMEAR only ☐
- Set the machine to make 2 slides per sample ☐
- Set the Smear level to Level 5 ☐
- Exit and save settings ☐

SP-10/SP-50 Maintenance

- Perform the spreader clean operation and reset counter ☐
- Re-set the spreader counter at the prompt ☐

Trainers Signature…… Date ……

Trainee Signature…… Date ……