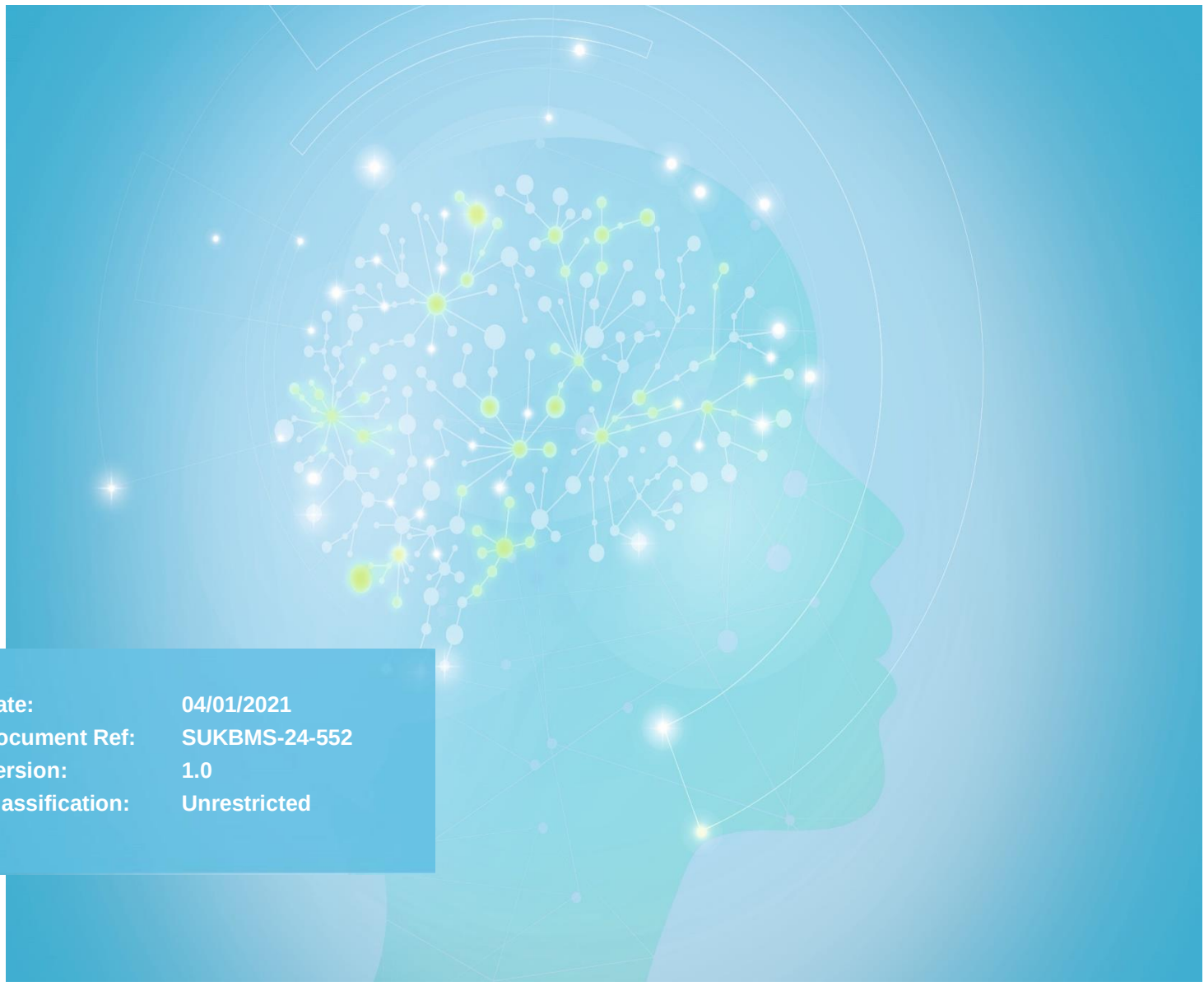
Routine Use Training Workbook

XP-300



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Disclaimer

Please note the information in this presentation, workbook or training session provided by Sysmex should not be used as an alternative to your sites Standard Operating Procedure (SOP)/Contract. If you have any particular questions regarding any site specific use of reagents, consumables and/or equipment please contact your management team.

Analyser Components

Outside the XP-300

1. **Front cover –** The front cover is opened to replace lyse bottles or to check or clean the interior of the measuring unit.

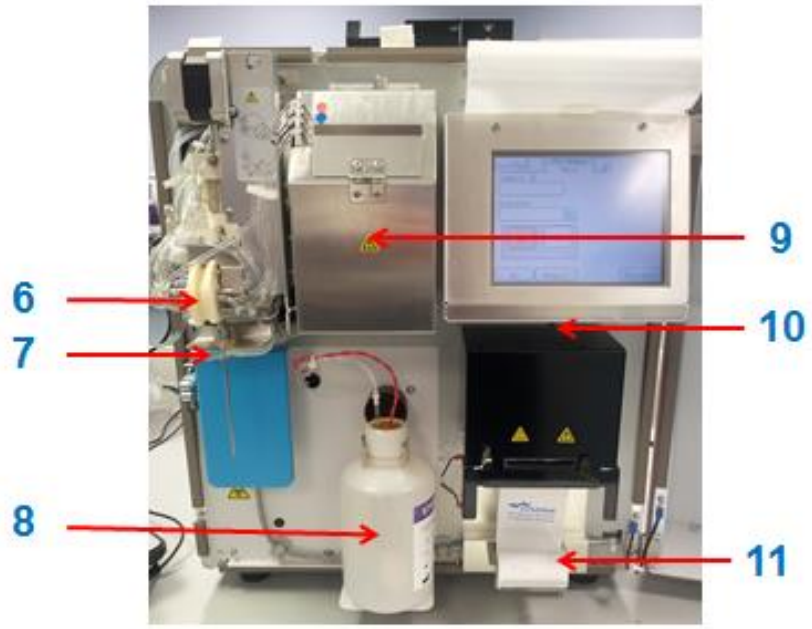
2. **Sample probe –** The sample probe is used to aspirate the samples in both whole blood and pre-diluted modes.

3. **Start switch –** Pressed to initiate sample analysis.

4. **LCD screen –** The user interface that displays the sample ID number, analysis results, instrument status, error messages and various other menus.

5. **Main power switch –** Used to turn the XP-300 analyzer on/off.

Inside the XP-300



6. **Sample Rotation Valve (SRV**) – Splits the aspirated sample.
7. **Rinse cup –** Cleans the sample probe following use.
8. **WBC/haemoglobin lyse reagent (Stromatolyser-WH) –** For the measurement of WBC and haemoglobin.
9. **Detector block –** Detector block containing RBC transducer, WBC transducer and haemoglobin flow cell.
10. **Contrast adjuster –** Used to adjust the contrast of the LCD screen.
11. **Internal printer –** For printing analysis results, error logs etc…..

Reagents on board the XP-300

The XP-300 requires 2 reagents for the analysis of a full blood count, along with a cleaning fluid and quality control material. A summary of these can be found below describing the reagents name, function (how it reacts with the blood) and the parameters produced.

CellPack

CellPack is a diluent used to dilute the aspirated analysis samples in order to measure a RBC count, WBC count, haemoglobin concentration and a platelet count.

Stromatolyser-WH

This reagent is used to lyse RBCs in the analysis samples in order to measure a WBC count and the haemoglobin concentration.

Cell Clean

Cell Clean is a strong alkaline detergent used to remove lyse reagents, cellular residuals and blood proteins remaining inside the XP-300.

Eightcheck-3WP

Eightcheck-3WP is a control blood used for measuring the precision and accuracy of the XP-300 analyzer.

Reagent Table

The table below gives a more concise version of the reagent information also including the number of cycles per pack and the volume available for each reagent.

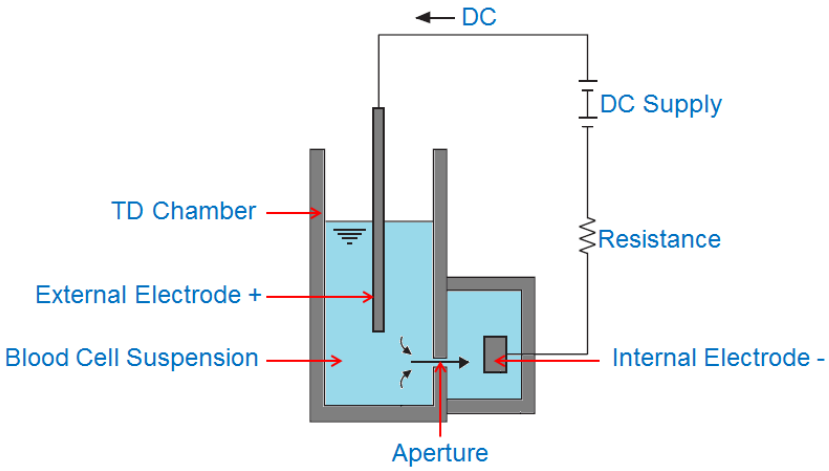
Reagent Name	Container Volume (ml)	Volume Per Cycle (ml)	Cycles Per Container (approx.)	On board Stability (Days)
Cell Pack (10L)	10,000	30	300	60
Cell Pack (20L)	20,000	30	600	60
Stromatolyser-WH	500	1	470	90

Principles of Analysis

The XP-300 performs an FBC by utilising 2 analysis principles:

Direct Current Detection Method

Following aspiration of a pre-determined volume of blood (50□l), it is diluted and sent into each transducer chamber (WBC, RBC/PLT). The transducer chamber contains an aperture with an electrode on either side, between which a direct current flows. As the cells flow through the aperture they cause direct current resistance changes, which allows the size of the cells to be determined as the height of the peak of resistance is directly proportional to the size of the cell. These peaks are counted and a histogram of blood cell sizes are plotted allowing various data to be obtained.



Non-cyanide Haemoglobin Analysis Method

Following the lysing of the RBCs and shrinkage of platelets the haemoglobin is released from the cells and converted into methaemoglobin (red coloured), the sample is then analysed using spectrophotometric analysis at 555nm in the HGB flow cell. The concentration of the sample is measured as an absorbance and compared with that of the diluent (CellPack) alone (this is measured before the addition of the sample), thus allowing the calculation of the haemoglobin value.

Calculation of RBC Parameters

By using the measured parameters, RBC, HGB and HCT the following additional RBC parameters can be determined:

Mean Cell Volume (MCV)

$$\text{MCV (fL)} = \frac{\text{HCT (\%)}}{\text{RBC } (\times 10^6/\mu\text{L})} \times 10$$

Mean Cell Haemoglobin (MCH)

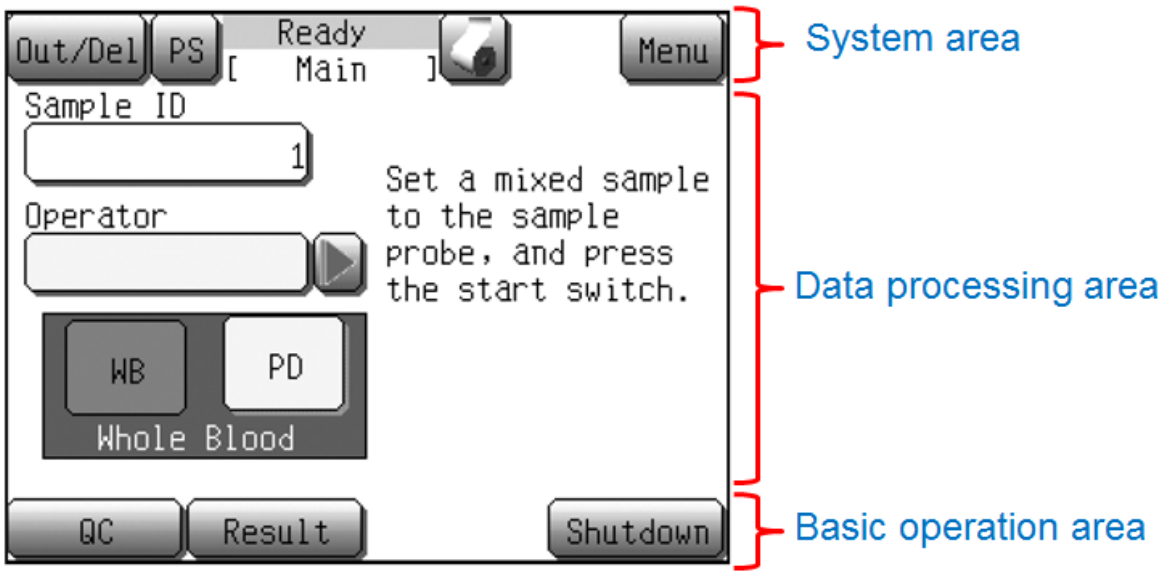
$$\text{MCH (pg)} = \frac{\text{HGB (g/dL)}}{\text{RBC } (\times 10^6/\mu\text{L})} \times 10$$

Mean Cell Haemoglobin Concentration (MCHC)

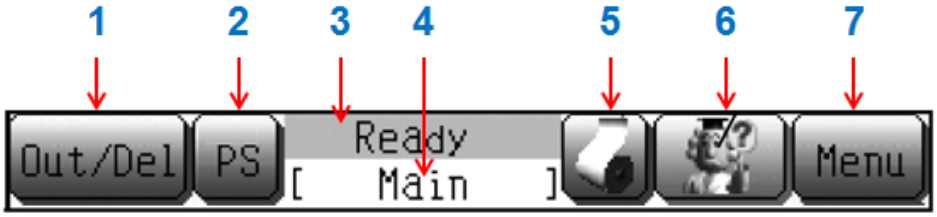
$$\text{MCHC (g/dL)} = \frac{\text{HGB (g/dL)}}{\text{HCT (\%)}} \times 100$$

Quick Guide to Using XP-300

Main Screen



System Area



1. **Out/Del –** Print, output or delete the displayed data. This button also gives access to the menu screen for the SNCS function (see page 27).

2. **PS –** The 'Print Screen' button is used to save a screen image (BMP format) for the SNCS function.

3. **Instrument status –** Displays the current analyzer status (Ready/Aspirating /Running/Not Ready/PU (Pneumatic Unit) Sleep).

4. **Screen name –** Displays the current screen shown in the 'Data Processing Area'.

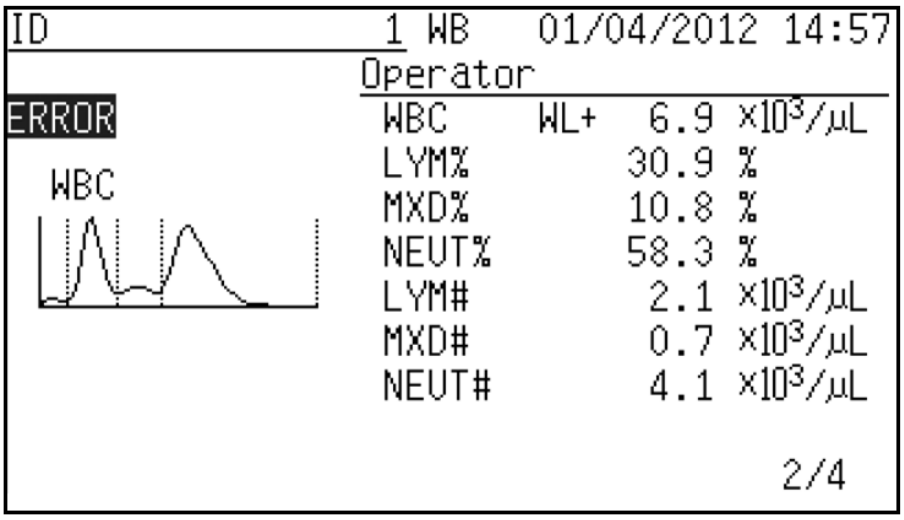
5. **Paper feed –** Press to initiate paper feed in the internal printer.

6. **Help (only visible following an error) –** Displays the 'Action Message' screen following an error, if more than one error occurs simultaneously then the 'Error list' will appear.

7. **Menu/Top/Back –** When in the 'Main screen' the 'Menu' button will be visible to access the XP-300 menus. When in any other screen either 'Top' or 'Back' will be displayed.

Data Processing Area

The 'Data Processing Area' is used to display various display options.

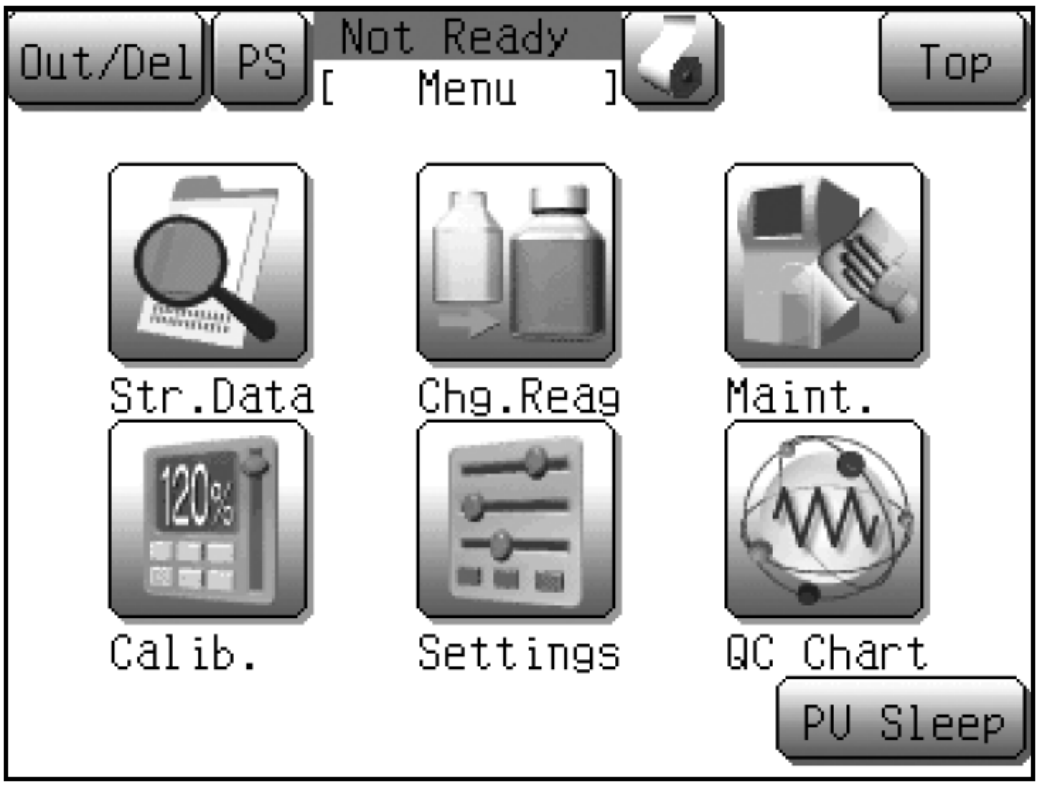


Basic Operation Area

1. **QC –** Press to access the quality control screen and run the QC material.
2. **Result –** Press to access the results screen (last result to be processed).
3. **Shutdown –** Press to initiate the shutdown procedure.

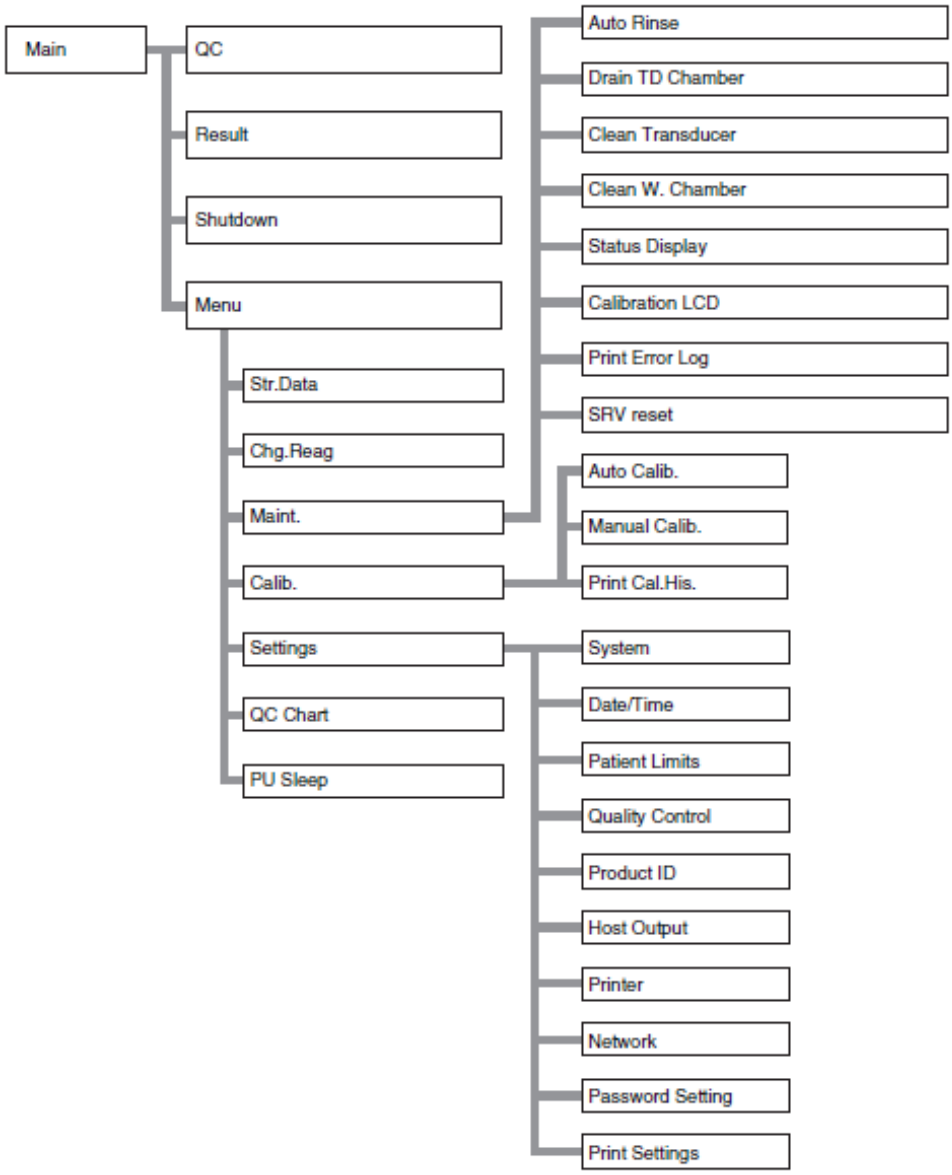
Menu Screen

Press ‘Menu’ to access the menu screen to gain access to various user options.



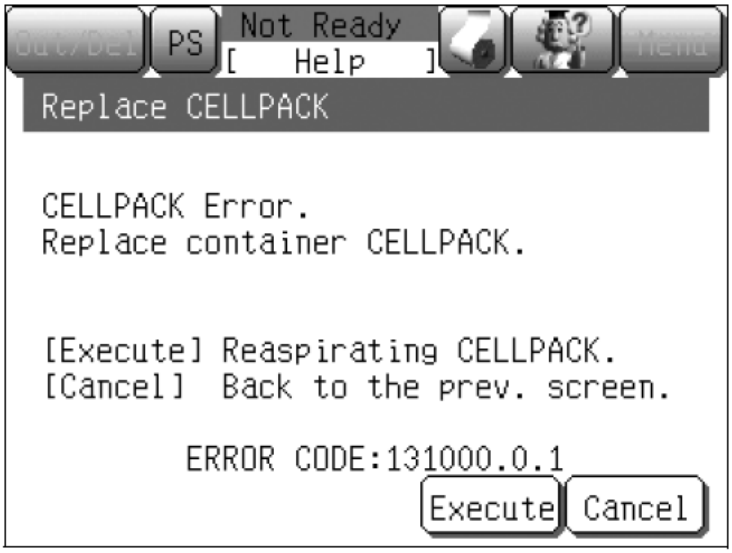
- **Str. Data –** Access the archive of the last 40,000 sample results.
- **Chg. Reag –** Press to enter the reagent screen, new reagent information can then be entered.
- **Maint. –** Access various maintenance options.
- **Calib. –** Access to calibration information.
- **Settings –** Access various setting options.
- **QC Chart –** Displays the QC results in chart form (Levy-Jennings).
- **PU Sleep –** The ‘PU Sleep’ button will stop the pneumatic unit which prevents the hydraulic line from becoming dry, saves power consumption and extends component service life. The pneumatic unit of the XP-300 will automatically stop following 15 minutes of inactivity. To resume operation press the start switch.

The full XP-300 menu tree is shown below:



Action Message (Help) Screen

Press  to access the ‘Action message’ screen and follow the instructions to execute the recovery process.



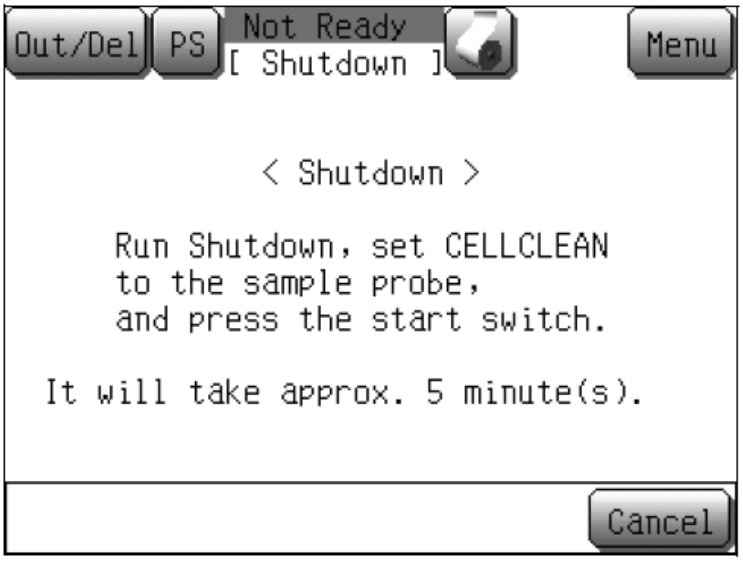
Maintenance

Daily Maintenance

Shutdown Procedure (recommended as daily maintenance)

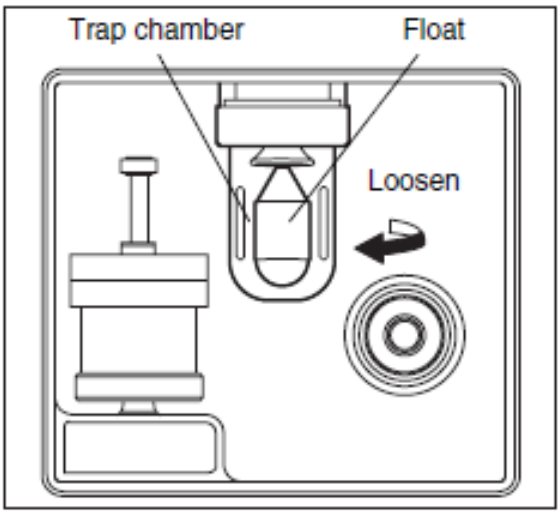
Before the XP-300 is shutdown at the end of the day the shutdown procedure should be initiated (must be performed every 24 hours).

To begin this procedure from the main screen press the 'Shutdown' button and follow the instructions by setting Cell Clean to the sample probe and pressing the start switch. When complete turn off the power by pressing the main power switch (or press 'Restart' if the XP-300 is required immediately).



Check Trap Chamber

Every day the trap chamber must be checked for fluid, if fluid is seen in the trap this may indicate failure of the hydraulic system. Contact a Sysmex technical representative if this occurs. The trap chamber has an alarm system that will sound if this trap becomes full at any point during the day.



Start-up Procedure

Turn on the power of the XP-300 using the switch on the right hand side of the analyzer.

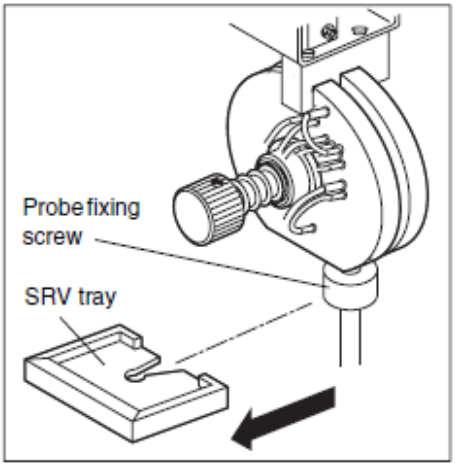
The Sysmex logo will appear then the XP-300 will go through its start-up process, the self-check takes approximately 2 minutes and this is followed by an auto-rinse (clean) and background check (blank). If the background check fails it is repeated up to 3 times before the message 'Blank Error' is displayed and the alarm sounds. If a 'Blank Error' occurs repeat the procedure.

When complete the main screen will appear.

Weekly Maintenance

Clean the SRV Tray

The SRV tray should be removed and cleaned using tap water on a weekly basis. Dry off the tray before replacing it back into position.

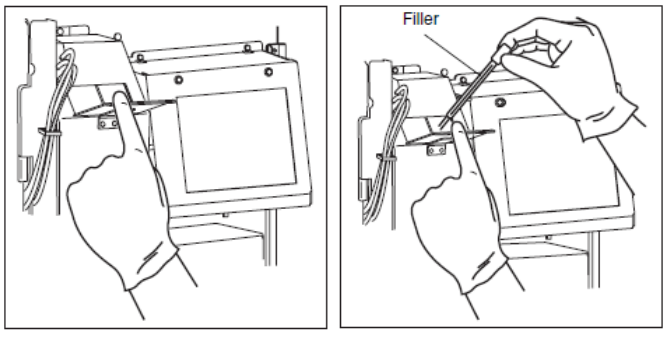


Monthly Maintenance

Clean TD

On a monthly basis (or following 1,500 cycles) a message will appear instructing the user to clean the transducer. From the main menu select 'Maint.' followed by 'Clean Transducer'.

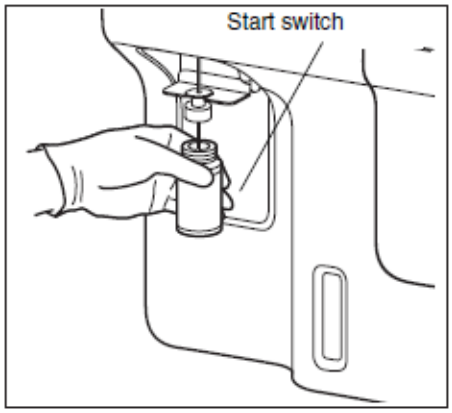
Open the front cover of the main unit and open the transducer cover. Using the filling tool provided add 1ml of Cell Clean into both the WBC and RBC transducers. Close the transducer cover and the front cover of the main unit.



Following this press the start switch and the transducer will be cleaned, a process that takes approximately 7 minutes. An auto rinse and background check will be performed following the clean then the main screen will appear, indicating the process is complete.

Clean Waste Chamber

On a monthly basis (or following 1,500 cycles) a message will appear instructing the user to clean the waste chamber. From the main menu select ‘Maint.’ followed by ‘Clean W. Chamber’.



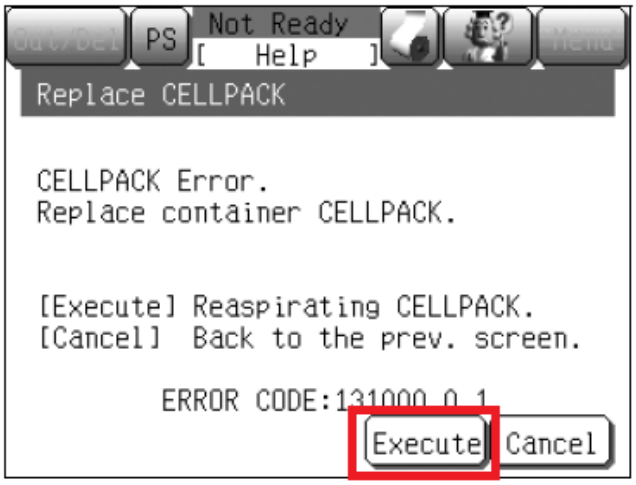
Following the on screen instructions set Cell Clean to the sample probe and press the start switch, hold the Cell Clean in position as long as the analyzer status is displayed as ‘Aspirating’ and the beeping stops. An auto rinse and background check will be performed following the clean then the main screen will appear, indicating the process is complete.

Replacing Reagents

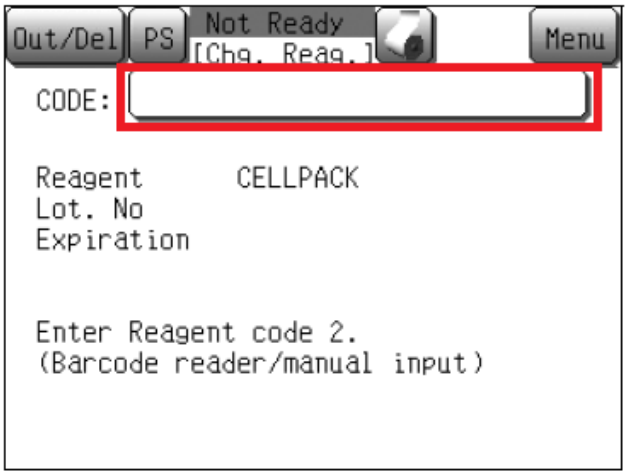
When a reagent needs replacing the analyzer will stop and an error dialog box will appear informing the user which reagent needs to be replaced (CellPack or Stromatolyser-WH).

Prepare the new reagent by removing the cap and placing it next to the analyzer, then remove the cap/spout from the empty reagent and place it straight into the new reagent, ensuring the cap is tightened.

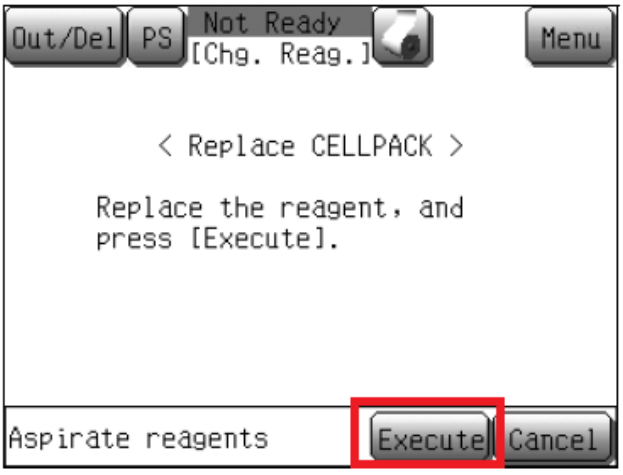
To complete the procedure either press ‘Execute’ from the ‘Action Message (Help) Screen’ or from the menu select ‘Chg. Reag’:



In the reagent screen select the reagent to be replaced, then in the reagent barcode entry screen either scan in the barcode with the hand held barcode reader or manually enter the number using the on screen keypad.



When the new reagent lot information appears on the screen, press 'OK' to confirm the information, then 'Execute' to prime the new reagent through the system.



Reagent Log

The XP-300 holds the information on the last 100 reagents to have been used on the system. This can be accessed from the 'Chg. Reag' screen by selecting 'Reag. Log'.

Quality Control

Running QC

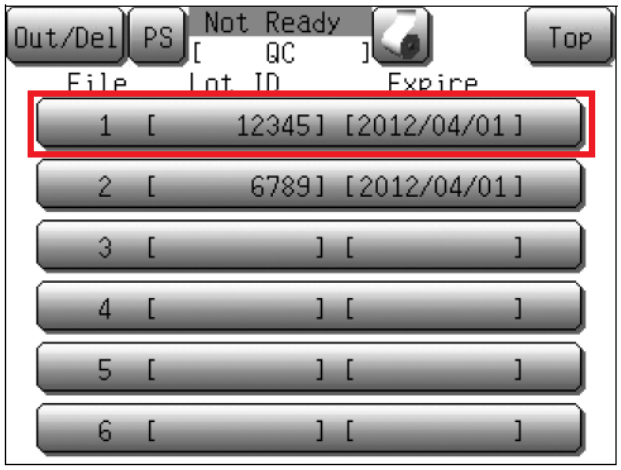
The XP-300 uses QC material known as Eightcheck-3WP, which comes in 3 levels, normal(-N), low(-L) and high(-H).

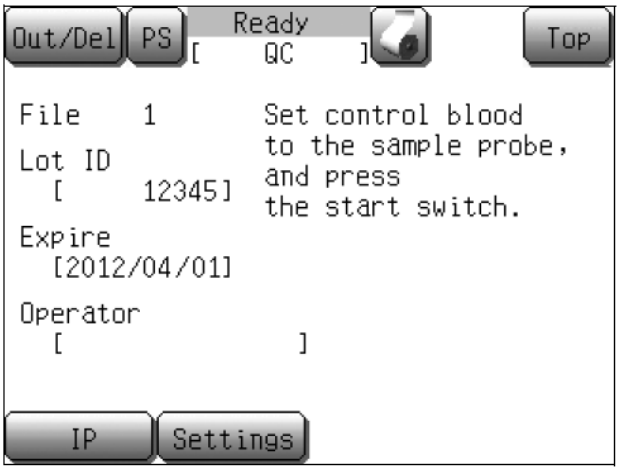
Prior to the performance of the QC analysis it is important that the Eightcheck-3WP control material is allowed to equilibrate to room temperature for 15 minutes and that it is thoroughly mixed. The open vial stability of Eightcheck-3WP is 7 days.

The following procedure can then be followed:

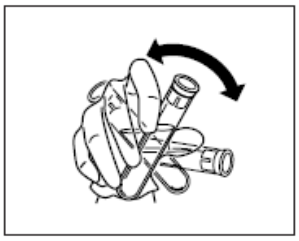
1. Set the analysis mode to 'WB' (WB (Whole Blood) mode is the default mode for analysis, to change this press 'WB' (turns red), if PD (Pre Dilution) mode is required press 'PD' (turns yellow)).

2. Enter the QC ID by selecting the 'QC' box and select the relevant QC lot number from the file selection screen. Following this the message 'Set control blood to the sample probe and press the start switch' will appear and the analyzer status will show 'Ready'.



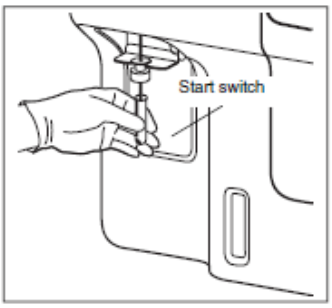


3. **IMPORTANT** - Mix the QC material thoroughly.



4. Carefully remove the cap from the tube.

5. Set the tube to the sample probe and press the start switch.

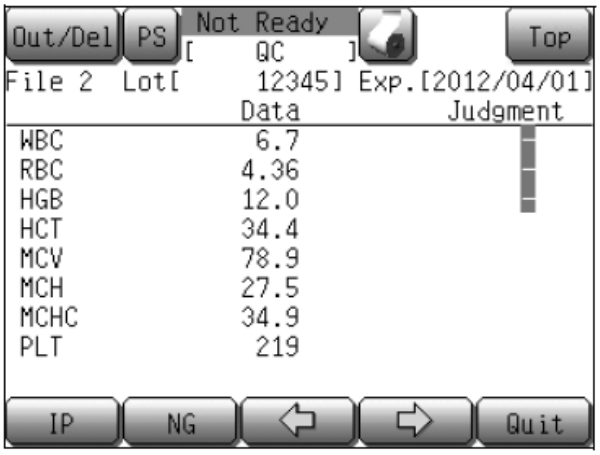


6. During the analysis the analyzer status will firstly display ‘Aspirating’, when this changes to ‘Running’ the sample can be safely removed.

7. Following approximately 60 seconds the quality control results are displayed. Press ‘→’ to view the remaining results. Any results that are out of range will be indicated by a ‘+’ or ‘-‘in the ‘Judgment’ column, the alarm will sound and the QC error message will be displayed (‘Data is out of QC limits’).

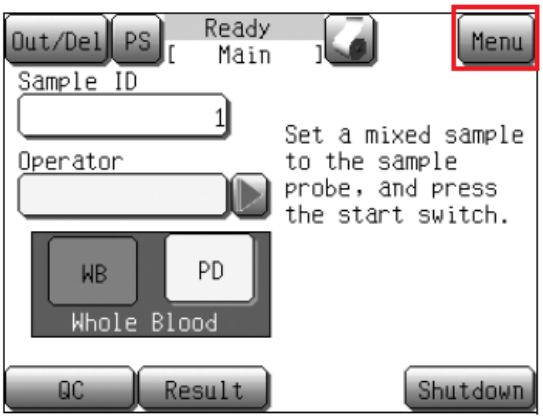
8. The following options are then available:

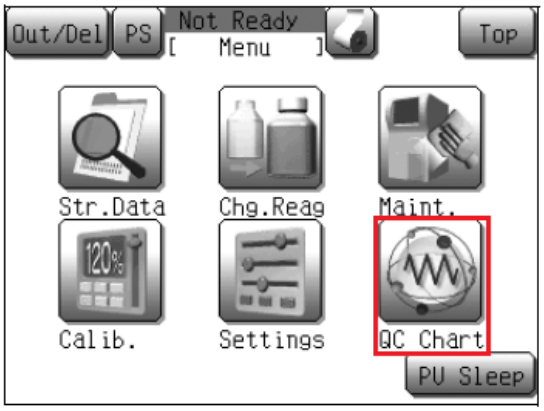
IP – Select to print using the Internal Printer.
NG – Press to repeat the analysis if the results are outside the acceptable limits.
→ - Select the next set of parameters.
← - Select the previous set of parameters.
Quit – Quit the QC screen and accept the results.



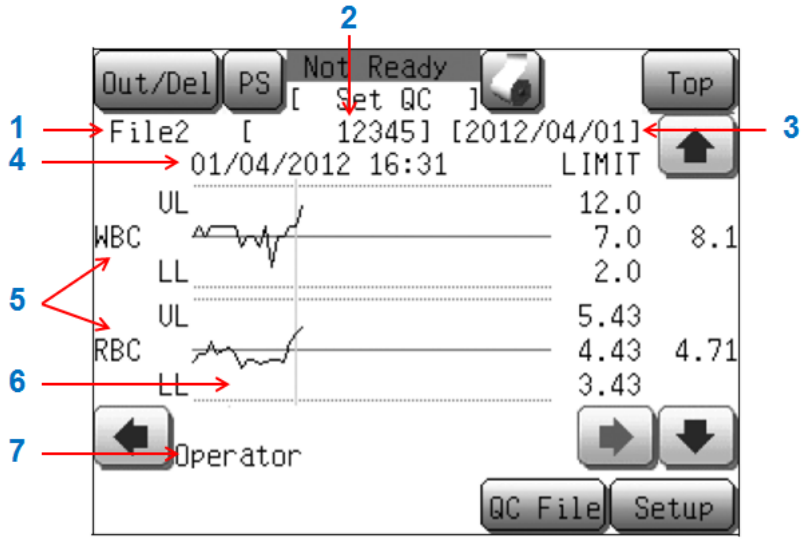
Checking QC Results

On the main menu select ‘Menu’ followed by ‘QC Chart’.





The following screen will then be displayed:



1. **File No -** Displays the file for the last QC result to be performed, to view alternative files, press 'QC File' and select the desired file.

2. **Lot ID –** Displays the lot ID associated with the current file.

3. **Expiration Date –** Displays the expiration date of the selected QC material.

4. **Date and time of analysis –** Displays the date and time of the selected QC result.

5. **Item/Parameter –** Displays which parameter charts are currently being displayed. Press '↓' or '↑' to toggle between the various parameters.

6. **Chart –** Displays the Levy-Jennings plot for the cumulative data for the selected lot number of QC material. By pressing '←' and '→' the previous/next QC results can be selected, this will then display the results on the right hand side of the chart and the time and date of analysis for the selected result above. A maximum of 60 data points can be stored on each QC plot.

7. **Operator ID –** Displays the operator for the currently selected QC point on the chart.

Running Patient Samples

For sample analysis 1ml of blood is required in an adult sample tube or 0.5ml in a micro tube to guarantee accurate analysis (the aspirated sample volume is 50µl).

The following procedure can then be followed:

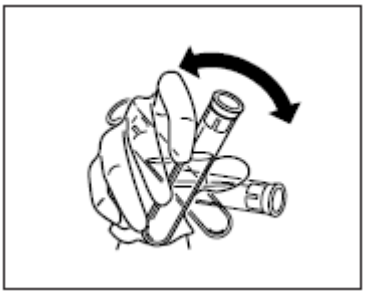
1. Set the analysis mode (WB (Whole Blood) mode is the default mode for analysis, to change this press 'WB' (turns red), if PD (Pre Dilution) mode is required press 'PD' (turns yellow)). **NOTE: If Pre Dilution (PD) mode is selected a 1:26 dilution is required by diluting 20µl of the sample in 500µl CellPack, the following procedure can then be followed.**

2. Enter the sample ID by selecting the 'Sample ID' box and either scanning the sample barcode using the handheld scanner or typing in the ID number using the dialog box that appears (press 'C' to delete and 'Ent.' to confirm). The analyzer status will then change to 'Ready'.

3. Register the Operator ID (up to 6 operator IDs can be set on the XP-300 if required) by selecting the 'Operator' box, then either scanning the operator ID barcode using the handheld scanner or typing in the operator ID number using the dialog box that appears (press 'C' to delete and 'Ent.' To confirm. The analyzer status will then change to 'Ready'.

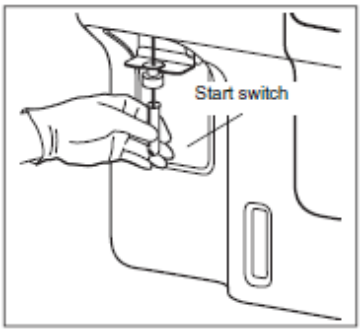
   Alternatively press  and select the operator ID from the list (press 'More' if the desired operator is not visible).

4. **IMPORTANT** - Mix the blood sample thoroughly.



5. Carefully remove the cap form the sample tube.

6. Set the tube to the sample probe and press the start switch.



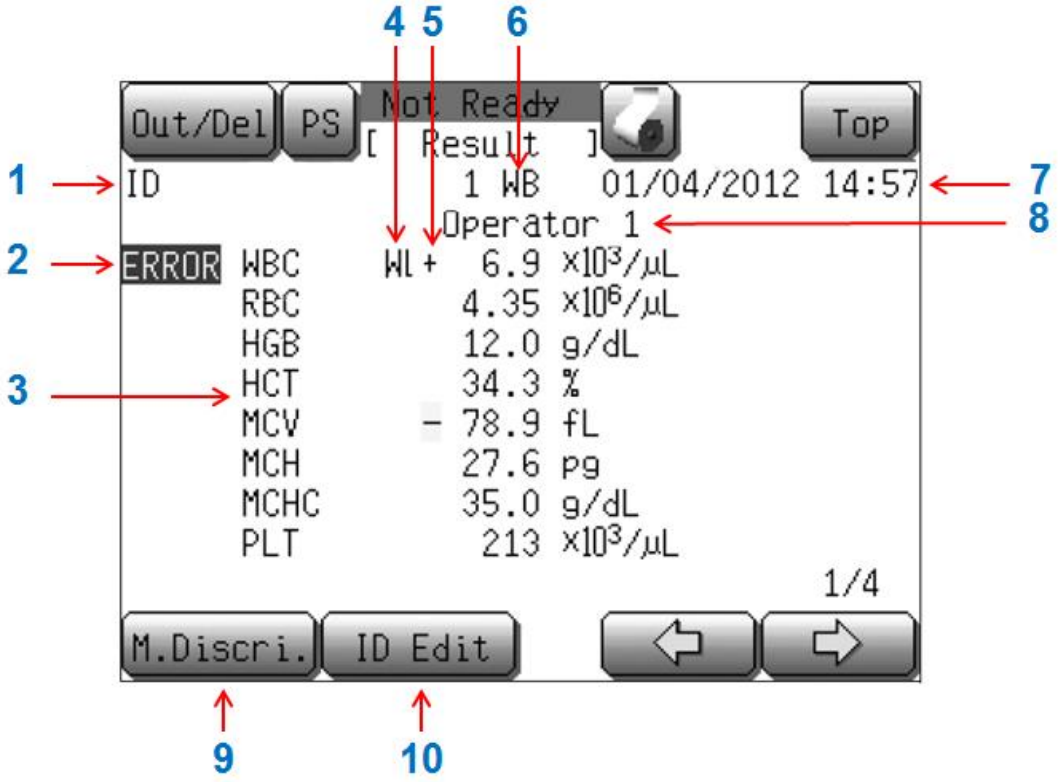
7. During the sample analysis the analyzer status will firstly display 'Aspirating', when this changes to 'Running' the sample can be safely removed.

8. Following approximately 60 seconds the sample results are displayed

Checking Patient Sample Results

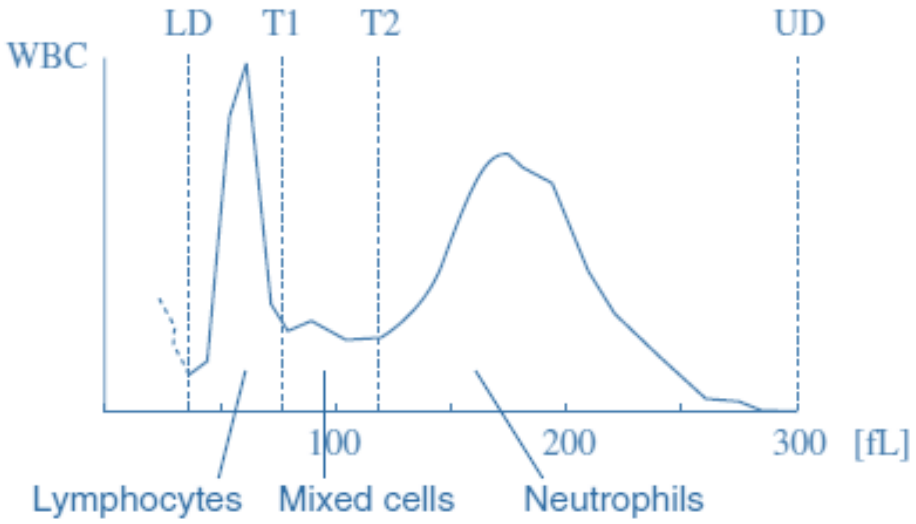
Analysis Results Screen

Following sample analysis the results will appear automatically on the screen (from the main screen the last result can also be viewed by pressing 'Result' on the main screen).



1. **Sample ID -** Displays the sample ID number that was input prior to analysis.
2. **Instrument Error Flag –** Displays if an error has occurred during sample analysis.
3. **Analysis Data –** Displays the parameters, numeric results and units of the analysis.
4. **Histogram Error Flag* –** If an error has occurred, the error flag displayed here give further information regarding this error:

WL	WBC lower discriminator has exceeded the range
WU	WBC upper discriminator has exceeded the range
T1	T1 discriminator position cannot be determined
T2	T1 discriminator position cannot be determined
F1	T1 discriminator (frequency) has exceeded the range
F2	T1 or T2 discriminator (frequency) has exceeded the range
F3	T2 discriminator (frequency) has exceeded the range



RL	RBC lower discriminator has exceeded the range
RU	RBC upper discriminator has exceeded the range
DW	Distribution width cannot be calculated
MP	Multiple peaks present
PL	PLT lower discriminator has exceeded the range
PU	PLT upper discriminator has exceeded the range
AG	The particle count ≤ WBC-LD has exceeded the range

*See the operator's manual for more information regarding histogram error flags.

5. **Numeric Value Abnormal Flag –** Symbols to show information regarding the result of the specific parameters, these may be:

   ! Outside of linearity
   + The result exceeds the upper patient limit
   The result exceeds the lower patient limit
   The result is unreliable

6. **Analysis Mode –** Displays the analysis mode for the selected sample (WB/PD).

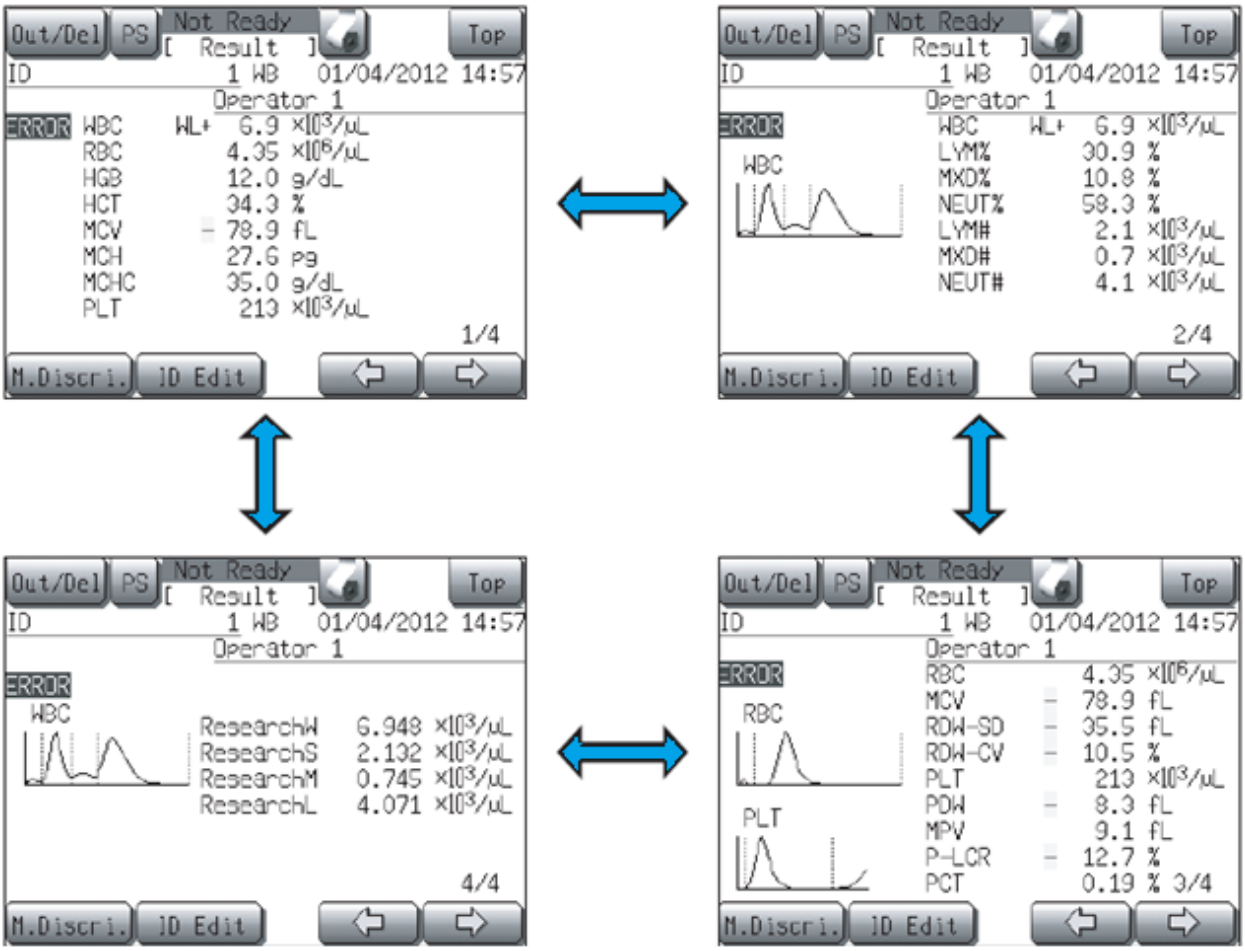
7. **Date and Time of Analysis –** Displays the date and time the analysis was performed.

8. **Operator ID –** Displays the operator that performed the analysis.

9. **M.Discri. –** Relocates the particle distribution discrimination in the histogram and recalculates the data (see manual for further information).

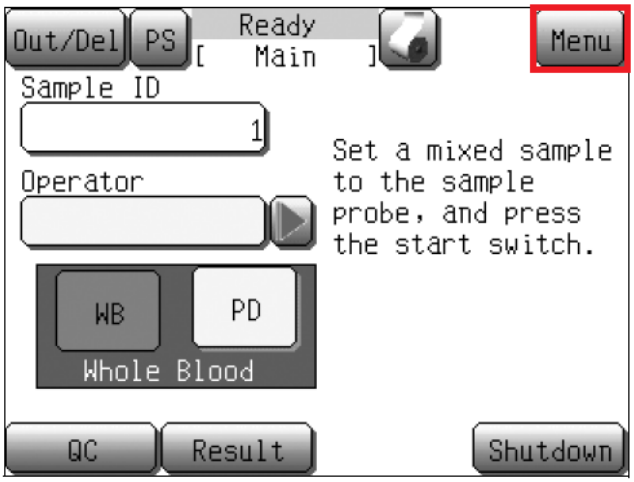
10. **ID Edit –** Allows the user to edit the sample ID if required.

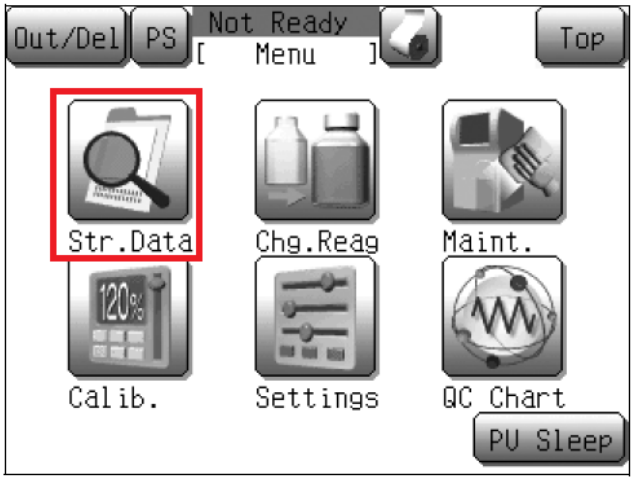
To see all of the parameters of the result it is necessary to toggle through 4 pages by using pressing '←' and '→', the 4 screens are shown below:



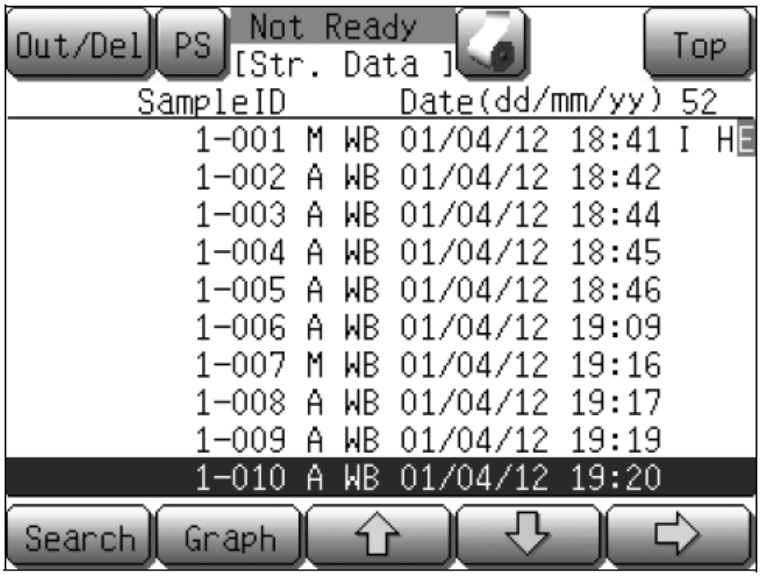
Stored Data

To view previous analyzed sample data form the main screen press ‘Menu’ followed by ‘Str. Data’.

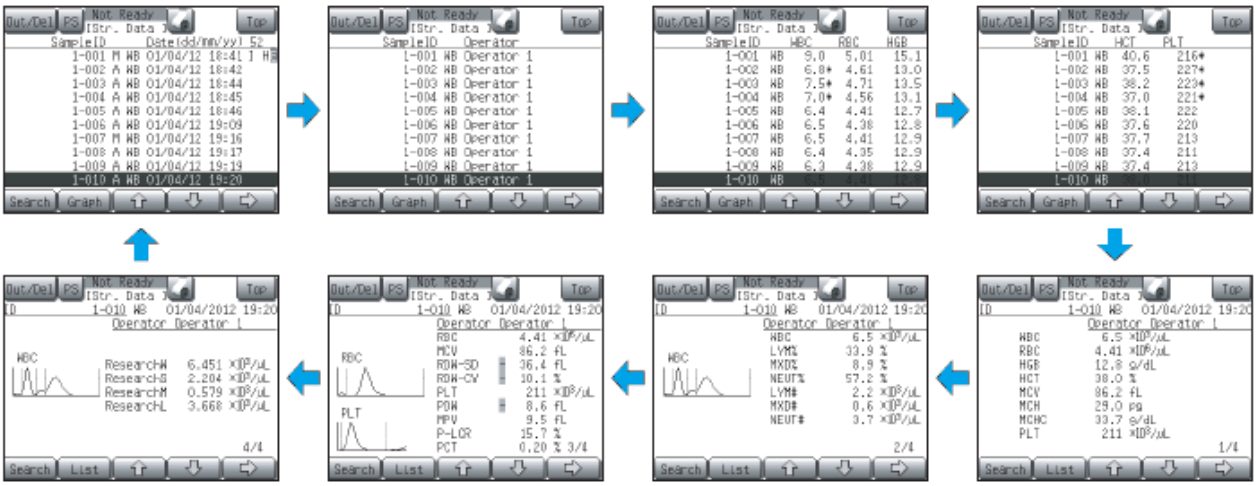




This will display the archive of the last 40,000 sample results.

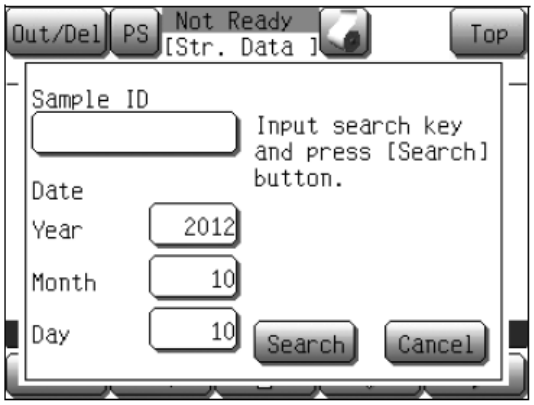


There are 8 screens in total that can be toggled through by using pressing ‘←’ and ‘→’.



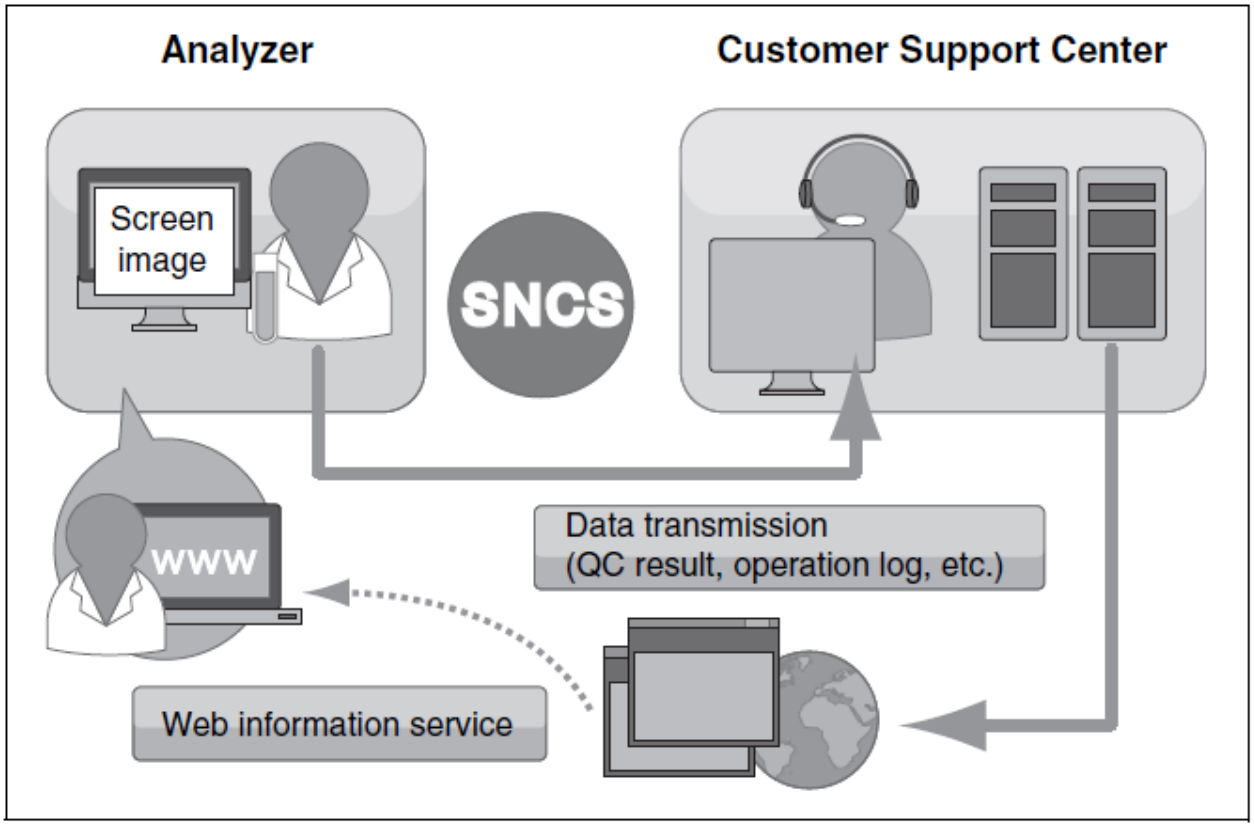
To select an individual result, either scroll up or down using the '↑' or '↓' keys (or press 'Search' and enter the sample ID or date of analysis), then press 'Graph' to enter the result detail screens (last 4 screen shown above – see 'Analysis Results Screen on page 20 for more details).

From any of the result detail screens press 'List' to return to the stored data list.



SNCS (Sysmex Network Communication Systems)

The SNCS function allows the XP-300 to connect to the Sysmex Customer Support Centre and internet for the online provision of remote instrument maintenance and support; this consists of online QC support and maintenance/error reporting.



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