XE-2100

Automated Haematology Analyser

Instructions for use

CE

Sysmex

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Distributed by:

- The contents of the screens illustrated in this manual may differ from the actual screens displayed on the instrument.
- We reserve the right of continuous product enhancement. This may result in deviation of actual product properties against the properties stated in this manual.
- The names of patients and doctors used in this manual are fictitious only and are solely used for illustrative purposes.

This instrument carries the CE Mark according the directive 98/79/EC on in vitro diagnostic medical devices.

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1. Introduction

The XE-2100 is an automated haematology analyser for in vitro diagnostic use in clinical laboratories.

By using the Sampler a large number of samples can be mixed automatically and supplied to the Main Unit. For single samples (“emergency analysis”) or diluted samples an aspiration pipette is provided.

In the Main Unit the samples are analysed.

Both whole blood samples and prediluted samples can be measured. For this reason the XE-2100 can also be used with low sample volumes (min. 40 µL).

The XE-2100 performs a reliable analysis of a sample within 60 seconds. Up to 32 analysis parameters and 6 research parameters are provided.

The analysis results are displayed on the Main Unit's LCD screen.

The “Information Processing Unit” (IPU) consists of a PC and software. Here the results produced by the main unit are stored, further parameters calculated and the data managed. Different types of representation (e.g. histograms, scattergrams, etc.) can be referred to. Values that are outside the limits are indicated, so they can be checked and verified by further analysis.

Analysis results and diagrams can be printed on any of the connected printers.

The accuracy of the results is ensured by an internal quality control. Possible variations are detected quickly and can be eliminated.

The XE-2100 is equipped with a rinse cup – after aspiration of a sample or control blood the aspiration pipette is automatically cleaned. It is no longer necessary to wipe the aspiration pipette.

Sysmex has been trying hard to keep the noise generation as low as possible. For non-operating periods the compressor can be switched off.

By individual settings the user can adapt the instrument to his needs or existing laboratory conditions, respectively.

Carefully read the instructions before starting work on the XE-2100. Pay special attention to the safety information. Keep this manual for future reference.

For further information please contact the Sysmex representative in your country.

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Manufacturer

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Ordering of Supplies and Replacement Parts

If you need to order supplies or replacement parts, please contact your local Sysmex representative.

Service and Maintenance

Please contact the Service Department of your local Sysmex representative.

Training courses

For further information please contact the Sysmex representative in your country.

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1.1 Danger information in this manual

Warning!

High risk. Ignoring this warning could result in personal injury to the operator.

Risk of electric shock!

High risk. Ignoring this warning could result in personal injury to the operator.

Dangerous Laser radiation!

High risk. The laser beam may injure your eyes.

Caution!

Average risk. Ignoring this warning could cause incorrect measuring results or property damage.

Important!

Minor risk. Facts which should be observed when operating this instrument.

Note:

Background information and practical tips.

1.2 Protected names

- Sysmex® is a registered trademark of SYSMEX CORPORATION, Japan.
- CELLSHEATH, CELLPACK, CELLCLEAN, STROMATOLYSER-FB, -4DL, -4DS, -NR, -IM, SULFOLYSER and RET-SHEATH (II) are trademarks of SYSMEX CORPORATION.
- Windows NT und Windows 2000 are registered trademarks of Microsoft Corporation.
- Cubitainer is a registered trademark of Hedwin Corporation.

The fact that a trademark is not explicitly mentioned in this manual does not authorize its use.

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1.3 Abbreviations used throughout this manual

General abbreviations

ABN	abnormal
ACAS	Adaptive Cluster Analysing System
CBC	Complete Blood Count
DC	Direct current
D, Diff	Differential blood count
dL	decilitre (0.1 litre)
DP	Data printer
FCM	Flow cytometry
fL	femtolitre (10^{-15} litre)
FSC	Forward scatter light for size/volume of the cell
G-CSF	Granulocyte-colony stimulating factor
HF, RF	High frequency/Radio frequency
HPC	Stem cells (human progenitor cells)
I	Current
IMI	Immature myeloid information
LD	lower discriminator
LL	lower limit
µL	microlitre (10^{-6} litre)
PBSCH	Peripheral stem cell pheresis
PBSCT	Peripheral stem cell transplantation
PD	pre-diluted mode
SRV	Sample Rotor Valve
pg	Picograms (10^{-12} gram)
PH	Pulse height
QC	Quality Control
R	Resistance
SD	Standard deviation
SFL	Cell (side) fluorescence intensity
SI	System International (for parameter units)
SLS	Sodium Lauryl Sulfate
SCMP	Stem cell monitoring program
SRD	Standard
SSC	Side scatterlight = internal cell structure
U	Voltage
UD	upper discriminator
UL	upper limit
V	Volume

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Abbreviations XE-2100

Data Browser	Graphical representation of samples
Explorer	Stored data
GP	Sending of data to graphics printer
HC	Sending of data to host computer
H-Copy	Hardcopy, printout of the current screen page
HF/RF	High frequency/Radio frequency
HPC	Human Progenitor Cells
IMI	Immature myeloid information (channel for immature cells)
IPU	Information Processing Unit
Last 20	Display of the last 20 samples
LP	Sending of data to line printer (text print)
QC	Quality control program
Q-Flag	Quantified flag representation

Analysis Parameters

The XE-2100 provides results for the following parameters:

WBC	Number of all leucocytes
RBC	Number of all erythrocytes
HGB	Haemoglobin concentration
HCT	Haematocrit value: Erythrocytes ratio of total blood volume
MCV	Mean erythrocyte volume in total sample
MCH	Mean haemoglobin volume per RBC
MCHC	Mean haemoglobin concentration of erythrocytes
PLT	Total number of platelets
NEUT%	Neutrophils quota in percent
LYMPH%	Lymphocytes quota in percent
MONO%	Monocytes quota in percent
EO%	Eosinophils quota in percent
BASO%	Basophils quota in percent
NRBC%	Quota of nucleated erythrocytes in percent
NEUT#	Neutrophils count, absolute
LYMPH#	Lymphocytes count, absolute
MONO#	Monocytes count, absolute
EO#	Eosinophils count, absolute
BASO#	Basophils count, absolute
NRBC#	nucleated erythrocytes count, absolute

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RDW-SD	Calculated distribution width of erythrocytes, standard deviation
RDW-CV	Calculated distribution width of erythrocytes, coefficient of variation
PDW	Calculated distribution width of platelets
MPV	Mean platelet volume
P-LCR	Ratio of large platelets (volume exceeding 12 fL) to the total number of platelets
PCT	Platelets quota of the total volume
RET%	Reticulocytes quota in percent
RET#	Reticulocytes count, absolute
IRF	Fraction of immature reticulocytes
LFR	Reticulocytes with low fluorescence quota
MFR	Reticulocytes with medium fluorescence quota
HFR	Reticulocytes with high fluorescence quota

Research parameters

The following additional parameters are detemined for research purposes only:

IG%	Quota of immature granulocytes in percent
IG#	Quota of immature granulocytes, absolute
HPC%	Quota of Human Progenitor cells in percent
HPC#	Quota of Human Progenitor cells, absolute
Other%	Quota of highly fluorescent cells such as atypical lymphocytes in percent
Other#	Quota of highly fluorescent cells such as atypical lymphocytes, absolute

Flag information

IMI	Immature cells

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2. Safety information

2.1 Specified conditions of use

The XE-2100 shall only be used for in vitro analysis of human blood or artificial control blood. Any other use is regarded as non-specified.

Only the reagents and cleaning solutions mentioned in this manual may be used.

The specified conditions of use also entail the observance of the laid-down cleaning and maintenance rates.

2.2 General information

- Read the instructions before operating the instrument. Observe all cautionary markings in the manual and on the instrument. Keep this manual for future reference.
- This instrument must only be opened as instructed in this manual.
- Keep long hair, fingers and clothing away from rotating parts.
- Should the instrument emit unusual odours or smoke, turn the main switch OFF immediately and unplug the power cable. Using the instrument any further bears the risk of fire, electric shock or personal injury. Contact the Sysmex service representative.
- Do not spill blood samples or reagents onto the instrument. Also take care not to allow any objects to fall into the instrument. This could cause a short-circuit. If this happens, turn the main switch OFF immediately and unplug the power cable. Contact the Sysmex service representative.
- Do not touch the electric circuits inside the instrument. Especially with wet hands, as there is a risk of electric shock.
- This instrument must be connected to a power outlet of correct voltage. Please note that the instrument must be earthed.
- Avoid damage to the power cable. Do not place any appliances on the power cable. Do not pull on the power cable.
- Switch the power supply to the instrument OFF before connecting any additional devices (host computer, printer etc.).
- Use the check-digit as much as possible. If the check-digit cannot be used, the potential of the incorrect reading of the barcode label may be increased.

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2.3 Installation

- The instrument must be installed in a dry and dust-free location.
- It must be protected against splash water.
- Do not expose the instrument to excessive temperature fluctuation and direct sunlight.
- Avoid shocks and vibrations.
- The place of installation must be well ventilated.
- Avoid installation near devices causing interference, such as radios, centrifugal machine, or similar.
- Installation of this instrument in places where chemicals are stored or gas develops is not permitted.

2.4 Electro-magnetic compatibility (EMC)

This instrument complies with the following IEC (EN) standards:

- IEC 61326-1:97 + A1:98 (EN61326:97+A1)
  Electrical equipment for measurement, control and laboratory use - EMC requirements
- EME (electromagnetic emission (= interference radiation))
  Class A requirements are met.
- EMI (electromagnetic immunity (= resistance to jamming))
  The minimum test requirements concerning immunity are met.

2.5 Avoidance of infections

- In principle, all parts and surfaces of the XE-2100 must be regarded as potentially infective.
- Always wear rubber gloves when carrying out work on or with the XE-2100. After completion of work, wash hands with disinfectant.
- Never touch waste, or parts having been in contact with waste, with bare hands.
- Should you inadvertently have come in contact with potentially infective materials or surfaces, immediately rinse skin thoroughly with water, then follow the antiseptic regulations of your laboratory.
- Even control blood must be regarded as potentially infective. Wear rubber gloves when performing quality controls.

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2.6 Handling of reagents

- Observe the labelling of the reagent packages as well as the information given on the package insert.
- Avoid direct contact with reagents. Reagents can cause irritation of the eyes, skin and mucous membranes.
- Should you inadvertently have come in contact with reagent, rinse skin immediately with plenty of water.
- At eye contact, rinse at once with plenty of water. See a doctor without delay. Observe the material data safety sheet.
- If reagent has inadvertently been swallowed consult a physician immediately!
- Avoid contact of dust, dirt or bacteria with the reagent.
- Reagents must not be used after their expiration date.
- Handle reagents gently to avoid bubbling. Do not shake! Do not use directly after transportation.
- Reagents must not be spilled. If it happens nevertheless, wipe up with a damp cloth.
- The CELLPACK diluent is a good conductor. If diluent was spilled inadvertently near electrical cables or appliances, there is a risk of electric shock. Switch the instrument off, unplug and remove the liquid.
- CELLCLEAN is a strong alkaline cleaning material. It should not come in contact with skin or clothing. If it happens nevertheless, rinse skin or clothing with plenty of water to avoid injury or damage, respectively.
- The CELLCLEAN cleaning material contains sodium hypochlorite. If CELLCLEAN makes contact with the instrument's surfaces, it will affect the surface finish. Danger of corrosion. Immediately wipe up CELLCLEAN with a damp cloth.
- RET-SEARCH (II) and STROMATOLYSER-4DS are detrimental to health. Keep the containers tightly closed.

2.7 Control blood

- Do not inject or ingest.
- Control blood must always be stored in an upright position – irrespective of whether the vial has been opened or is still closed.

2.8 Laser

- In order to carry out specific measuring methods the XE-2100 is equipped with a class 2a semiconductor laser. The metal box screening off the laser must never be

removed. The emitted laser radiation can cause damage to the eyes.

2.9 Maintenance

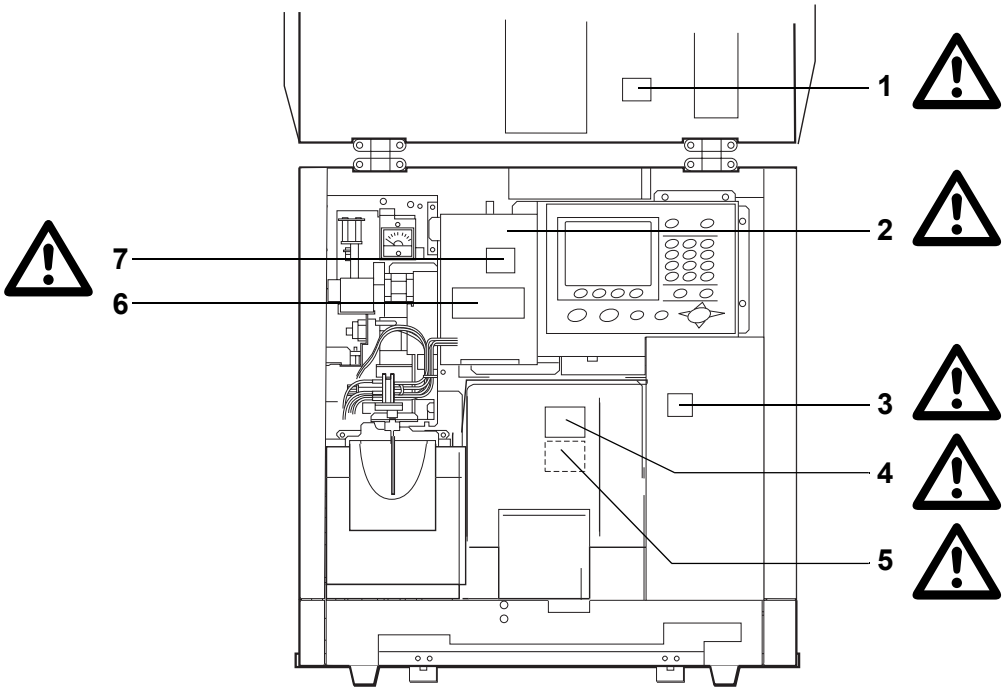
- To avoid the risk of infections, electric shock or burns, wear rubber gloves for all service or maintenance work. After completion of work, wash hands with disinfectant.
- When carrying out maintenance work, use only the tools expressly provided for such work.
- Install only such spare or replacement parts expressly intended for the XE-2100.

2.10 Disposal of materials

- Disposal procedures for residual reagents, detergent and all waste must meet the requirements of all applicable local regulations.

2.11 Markings on the instrument

Front side, front door open



1	**Warning!** When working with the front cover open, make sure that the stop bar is in place.

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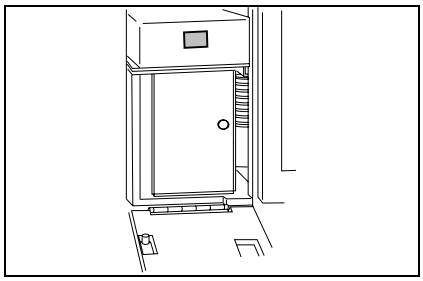
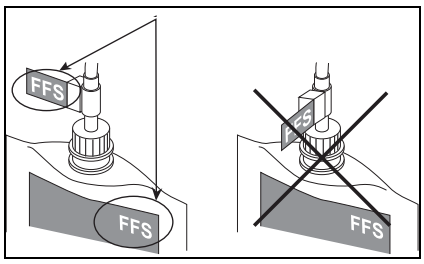
2	**Warning!** Switch up during service adjustment. Switch down during normal operation. The label is behind the cover of the IMI detector block. 
3	**Warning!** Do not touch the transducer when the power in ON to avoid electric shock.
4	**Warning!** Never open the cap piercer cover if the instrument is turned on.
5	**Warning!** Do not put your finger inside to avoid being injured. The lable is on the inside.
6	**Note:** When replacing the FFS reagent bag, make sure that the two FFS labels face to the same direction to avoid sensor malfunction. 

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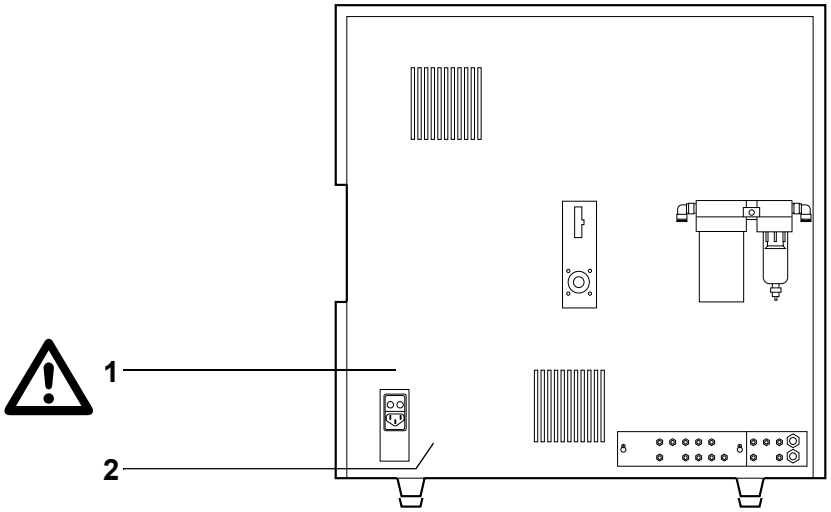
7	**Warning!** Do not touch the transducer when the power in ON to avoid electric shock.

Rear side



1	**Warning!** To avoid electrical shock, disconnect supply before servicing. For the continued protection against risk of fire, replace only with fuse of the specified type and current ratings.
2	**Type plate** SN Serial number Date of manufacture Manufacturer IVD In Vitro Diagnostic Medical Device

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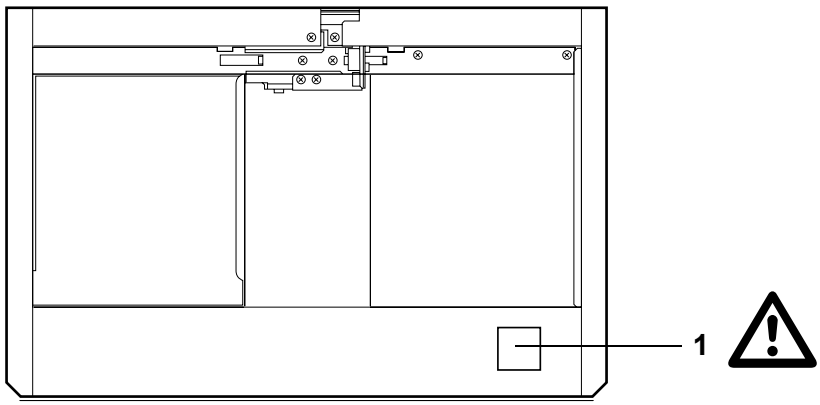
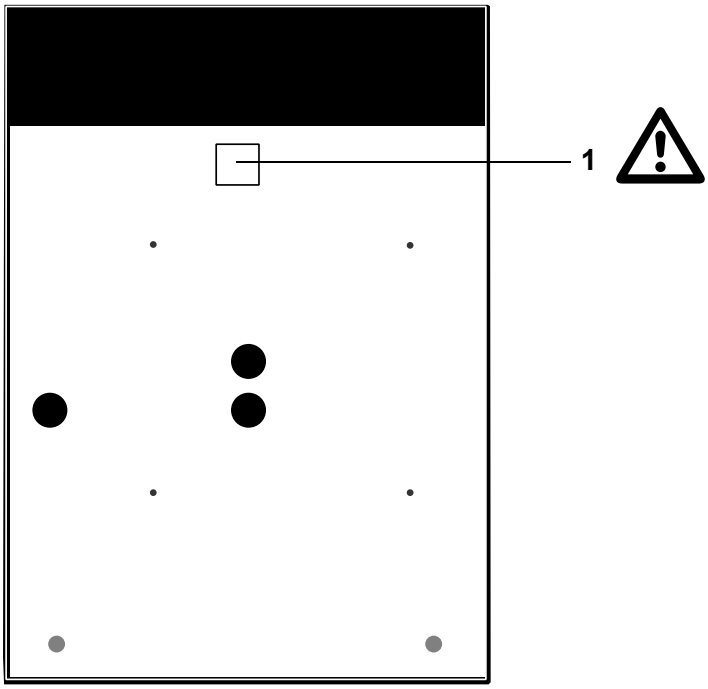
Sampler



1	**Caution!** The sample tubes must move easily in the rack. If not, replace the label. The sample tubes must be capped tightly. The sample tubes must be inserted fully to the bottom of the rack, otherwise the blood volume sensor will not recognize the blood sample.

Pneumatic Unit, Rear



1	**Caution!** Do not close the outlet on the rear of Pneumatic Unit.

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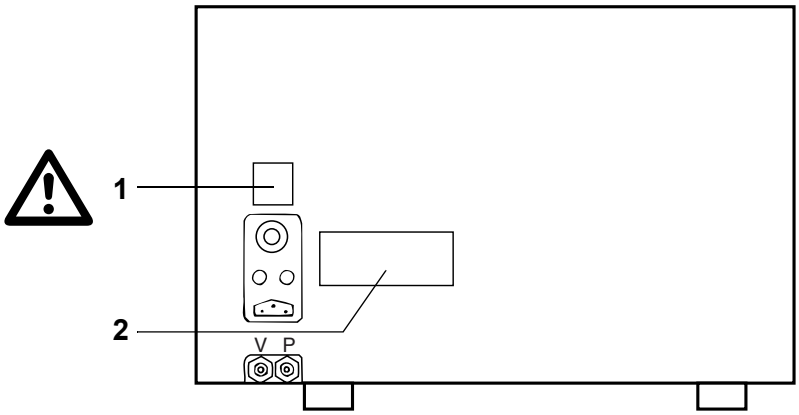
Pneumatic Unit, Right Side



1	**Warning!** The instrument must be earthed.
2	**Type plate** SN Serial number Date of manufacture Manufacturer IVD In Vitro Diagnostic Medical Device

2.12 Personnel

- This instrument may only be operated by sufficiently trained personnel having been instructed in its operation.
- Any maintenance and repair work shall only be carried out by persons having the required specialised knowledge.

2.13 Interpretative messages (Flags)

The overall goal of any automated differential cell counter is to screen and report normal specimens and to alert the technologist to the presence of abnormalities. Specimens that do not meet software defined decision factors or criteria established by the laboratory are flagged.

Results of sensitivity and specificity studies may heavily vary by the proportion of abnormal or normal specimens in the total number of specimens tested and institutional review criteria (e.g. Q-Flag settings).

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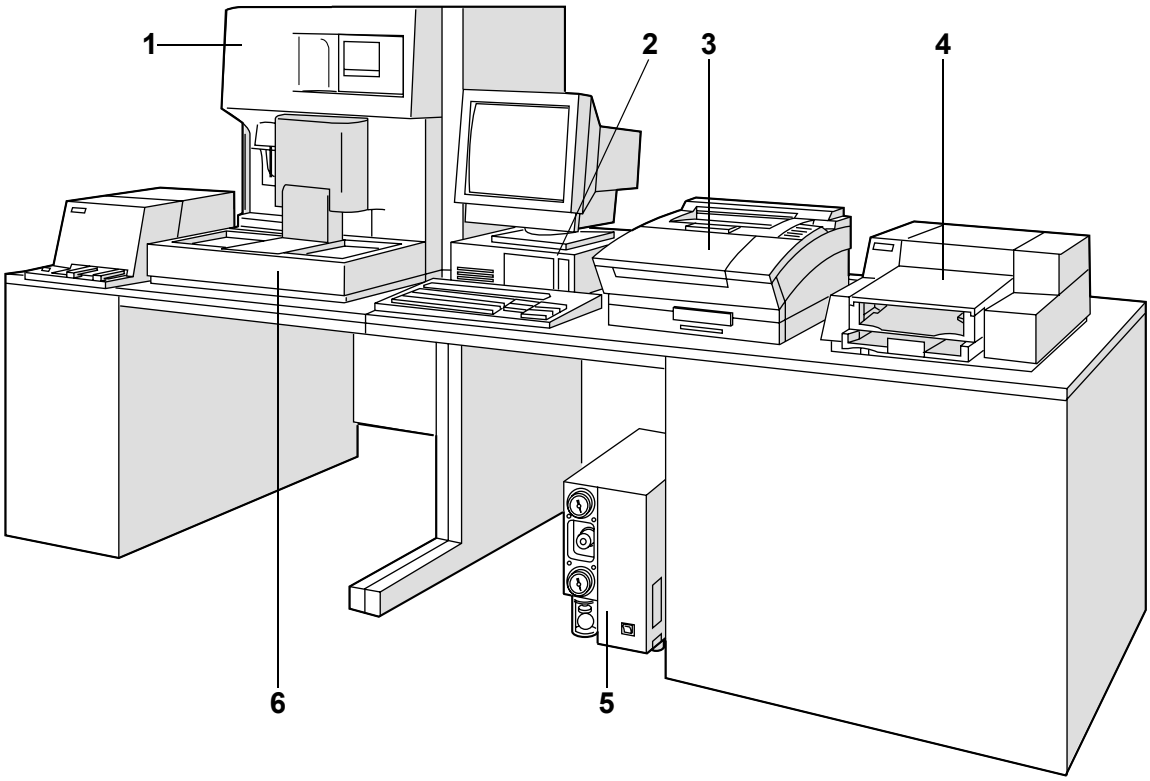
3. Design and Function

3.1 Overview

The XE-2100 consists of four basic components and two printers.



1 Main Unit
In the Main Unit the samples are analysed.

2 IPU (Information Processing Unit)
The IPU consists of a PC and the software belonging to it. In the IPU the data supplied by the Main Unit are stored, further parameters calculated and the data processed.

3 Data printer
Prints the analysis results on commercially available tickets

4 Colour graphics printer/line printer
Colour graphics printer prints analysis data, histograms, scattergrams, etc.
Line printer prints listings of sample information or results.

5 Compressor
Provides pressure and vacuum for the Main Unit

6 Sampler
The Sampler feeds the samples automatically to the Main Unit.

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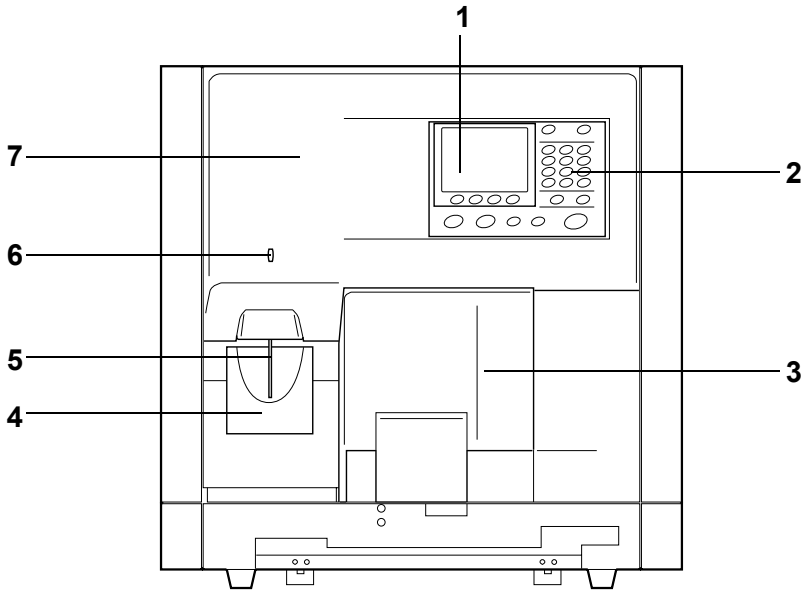
3.2 Main Unit

Front view



1 LCD screen
Shows the Main Unit's operating status, sample ID and analysis data of the latest sample, etc.

2 Panel keyboard

3 Piercer unit cover

4 START switch
Starts the analysis in Manual, Capillary or Closed mode

5 Aspiration pipette
To aspirate the sample in Manual mode or Capillary mode

6 Ready indicator
Is on when the Main Unit is ready to operate

7 Front cover
May be opened and swung up

Caution! Risk of personal injury!

Secure the opened front cover with the stop bar.

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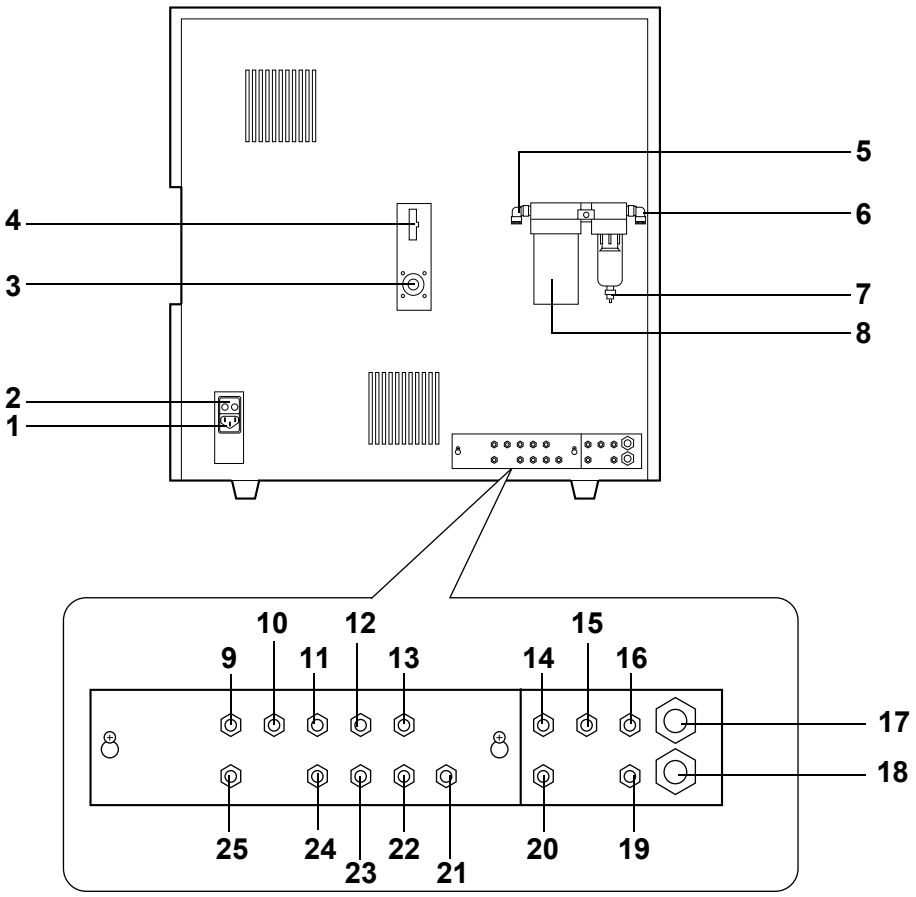
Rear view



1 Power cable socket

2 Fuse holder

3 Power supply socket for compressor
Using this socket to supply power to the compressor, the compressor does not need to be switched On and OFF separately. Is connected to the corresponding socket at the rear of the compressor.

4 Connector for float switch

5 Air dryer outlet
Supplies compressed air cleaned and dryed by the air dryer.
Is connected to the compressed air inlet (19).

6 Air dryer inlet

7 Air dryer condensate drain cock

8 Air dryer
Removes impurities or moisture from the compressed air supplied by the compressor

9 FBA: Connector for STROMATOLYSER-FB

10 FFD: Connector for STROMATOLYSER-4DL

11 SLS: Connector for SULFOLYSER

12 SIM(1): Connector for STROMATOLYSER-IM

13 ESE(1): Connector for CELLSHEATH

14 EPK(1): Connector for CELLPACK

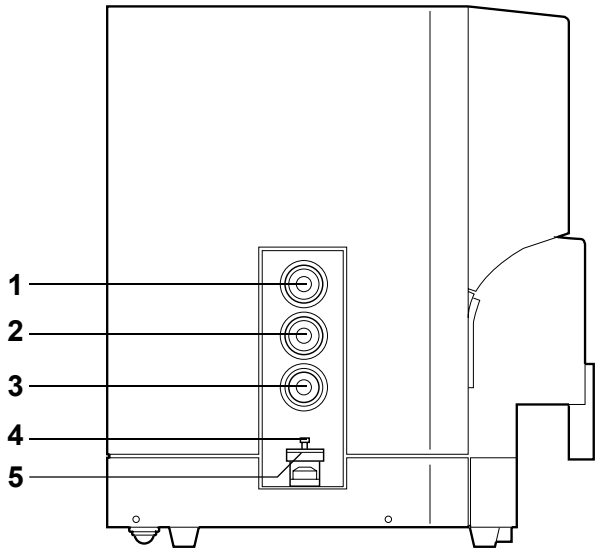
15 W: Waste connector
Condensation from the air dryer is transferred to the waste fluid

16 V: Vacuum connector

17 P2: Connector for waste level indicator P2

18 P1: Connector for waste level indicator P1
19 P: Air inlet nipple
20 D: Drain outlet nipple
21 EPK(2): Drain outlet nipple for air bubbles from the CELLPACK float switch
22 ESE(2): Drain outlet nipple for air bubbles from the CELLSHEATH float switch
23 SIM(2): Drain outlet nipple for air bubbles from the STROMATOLYSER- IM float switch
24 RED: Connector for RET-SEARCH (II) diluent
25 SNR: Connector for STROMATOLYSER-NR lysing reagent

View of left-hand side



1 Pressure regulator 0.16 MPa
At this pressure the Sheath reagent is carried to the measuring chambers.

2 Pressure regulator 0.07 MPa
At this pressure the waste fluid is carried to the waste chamber.

3 Pressure regulator 0.03 MPa
This pressure is required for the RBC-PLT Sheath detector.

4 Vacuum regulator
Keeps the vacuum at 0.04 MPa. At this vacuum the fluids are transported between the chambers.

5 Air filter
Prevents dust from entering the vacuum regulator

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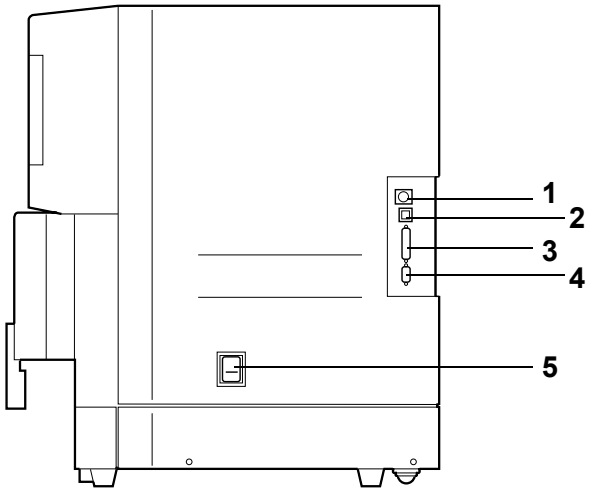
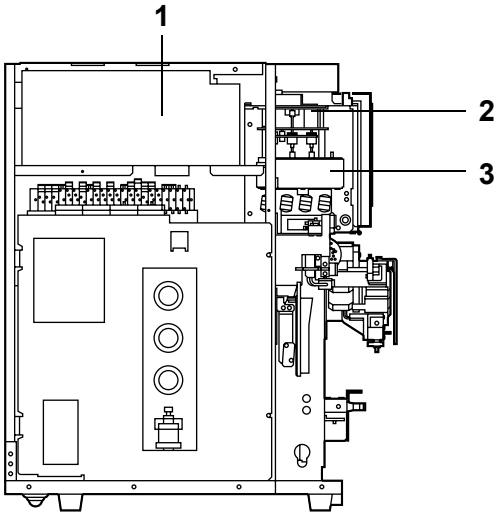
View of right-hand side



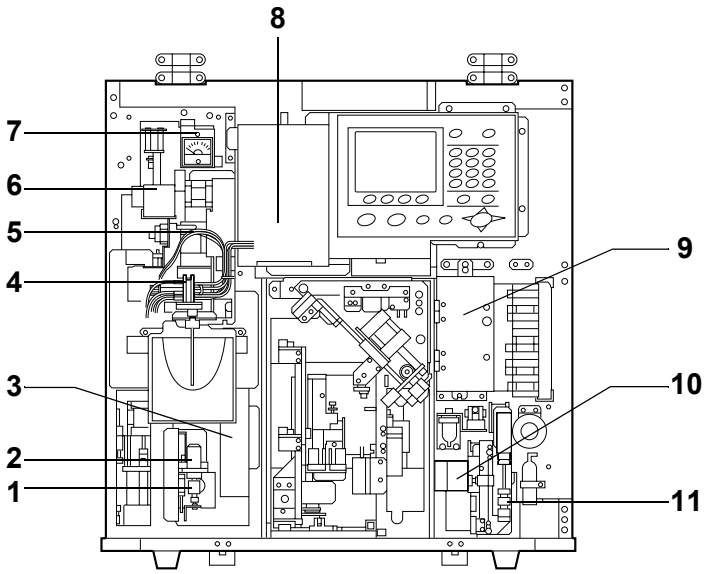
1	BR	Barcode reader	Socket for manual barcode reader
2		LAN	Communications port for IPU
3		DP	Parallel port for graphics printer
4		RS232C	Serial port for one printer
5			Main Unit mains switch

Inside view, left-hand side



1 WBC detector block
2 Reaction chamber mixing motor
3 Reaction chamber

Inside view, front



1 Motor blood aspiration pump

2 Blood aspiration pump
Aspirates whole blood samples

3 HGB detector block

4 Sample Rotor Valve (SRV)

5 Blood aspiration sensor
Monitors the aspiration of whole blood in Sampler mode and Closed mode

6 Reaction chamber

7 High frequency metre
Indicates the status of the IMI detector's high frequency voltage

8 IMI detector block

9 RBC detector block

10 Syringe motor

11 Syringe
Supplies a specific quantity of the diluted sample to the RBC detector

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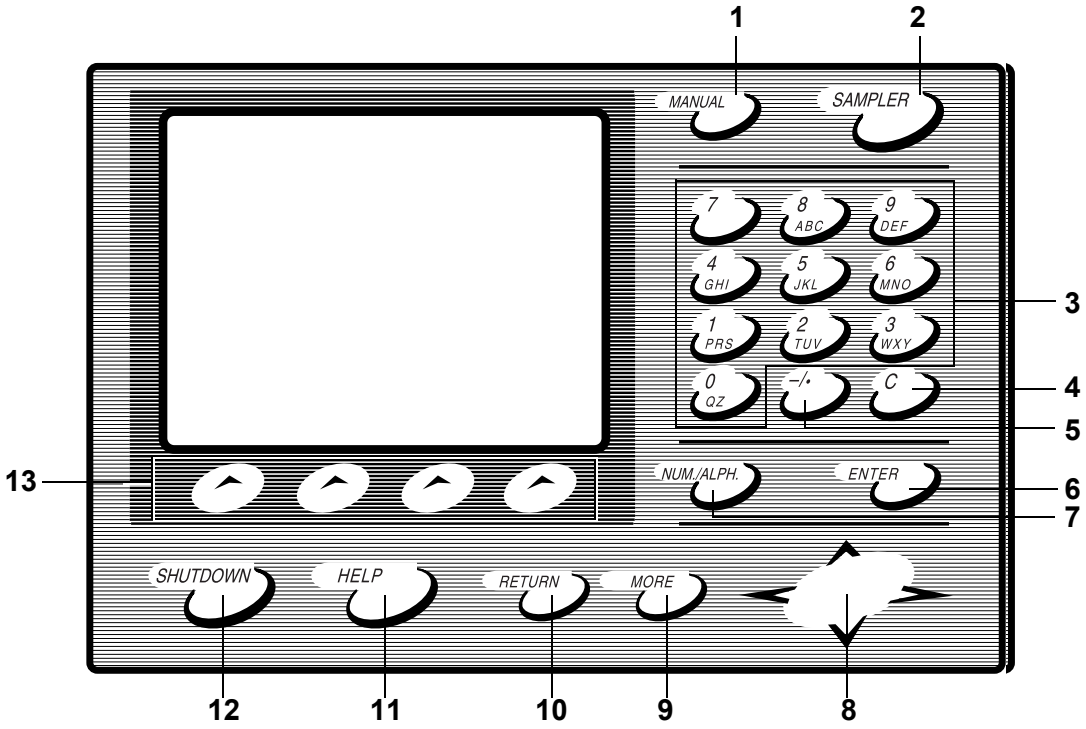
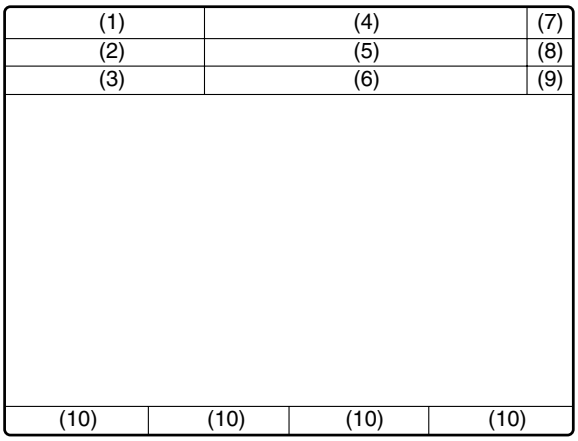
Panel keyboard



1	MANUAL Input of a sample ID or QC file number (Manual mode/Closed mode/Capillary mode)
2	SAMPLER To start or stop the Sampler analysis
3	Alphanumeric keys 0/QZ – 9/DEF For entering sample IDs, numerical values (limits, etc.) and text (patient names, etc.); selection of submenus
4	C (Clear) Deletes the character to the left of the cursor in entry mode; turns the alarm buzzer off
5	-/. Decimal point when entering numerical values; hyphen when entering sample numbers
6	ENTER Used to confirm input
7	NUM./ALPH. Change-over between the entry modes of the alphanumeric keys
8	Cursor keys To scroll through the display, move cursor to desired parameter
9	MORE To scroll through function menu screens if more than 5 functions available
10	RETURN To abort the execution of a menu. The systems returns to the screen active before the menu was called up
11	HELP Invokes further information if an error has occurred.
12	SHUTDOWN Used to shut the XE-2100 down
13	Selection keys To select functions displayed on the screen directly above; depending on the active menu

Main Unit LCD screen



1 Display of analysis mode for the next sample

Manual:	Manual mode
Capillary:	Capillary mode
Sampler:	Sampler mode
Closed:	Closed mode

2 Display of analysis profile for the next sample

C:	CBC
C N:	CBC + NRBC
C D:	CBC + DIFF
C D R:	CBC + DIFF + RET
C R:	CBC + RET
C D N:	CBC + DIFF + NRBC
C D N R:	CBC + DIFF + NRBC + RET

3 Display of analysis status in the Main Unit

Ready	Ready
Not Ready	Not Ready
Running	Instrument is running
S-Ready	Sampler is ready
Stat	Emergency analysis
S-Not Ready	Sampler is not ready

4 Display of sample ID for the next analysis

5 Display of sample ID for the data printer

6 Display of the current error message of highest priority
Once the cause for the error displayed is removed, the error having the next highest priority will be displayed.

7 Display of entry mode of the alphanumeric keys

Num	Numbers
Alp	Upper case letters
alp	Lower case letters

To change over between the modes, press the **NUM./ALP.** key.

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8 Display of data printer connection

DP	Data printer is connected, no error has occurred
No display	Data printer is not connected
DP (highlighted)	Data printer is connected, but an error has occurred

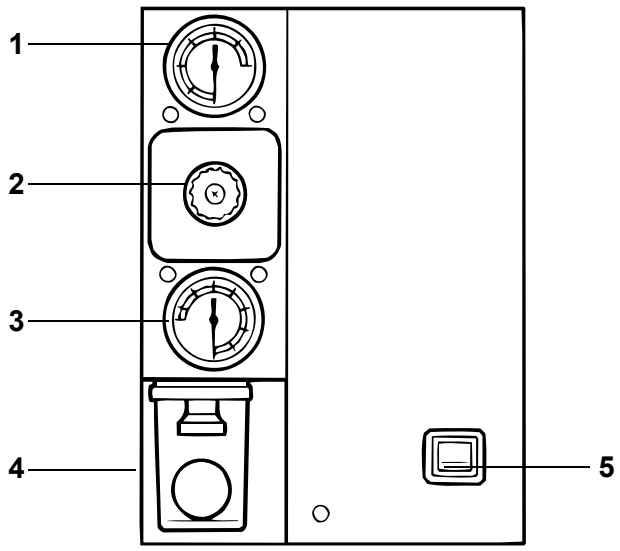
9 Display of the XbarM control

Xm	XbarM control enabled
No display	XbarM control disabled

10 Display of the functions available by the selection keys

3.3 Pneumatic Unit

Front view



1 Pressure gauge 0.23 to 0.27 MPa
Indicates the pressure at the Main Unit
At this pressure the main valves and the Sample Rotor Valve of the XE-2100 are operated.

2 Pressure regulator 0.25 MPa
Regulates the pressure supplied to the Main Unit

3 Vacuum gauge
Indicates the vacuum at the Main Unit

4 Trap chamber

5 Compressor mains switch

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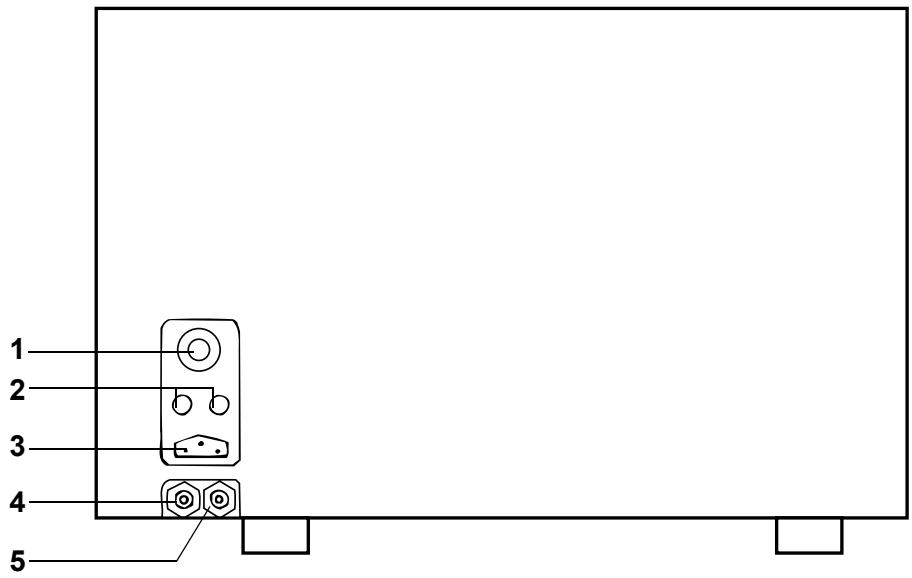
View of right-hand side



1 Socket for power supply from Main Unit
Can be connected to connector (3) of the Main Unit
If the power to the compressor is supplied by the Main Unit, the compressor does not need to be turned ON or OFF separately.

2 Fuse

3 Power cable socket

4 Vacuum port
Is connected to the vacuum inlet at the Main Unit (16); provides vacuum to the Main Unit.

5 Compressed air port
Is connected to the air dryer at the Main Unit (8); provides pressurized air to the Main Unit.

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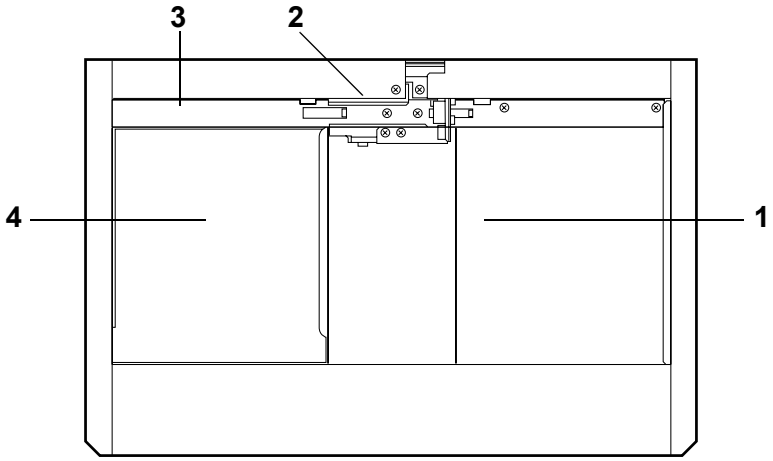
3.4 Sampler



1 Rack infeed
The racks are placed into the right-hand side of the Sampler. They are moved automatically towards the analysis line.

2 Blood volume sensor
Monitors the blood volume in the sample tube

3 Analysis line

4 Rack outfeed
The racks are moved out of the analysis line and parked here.

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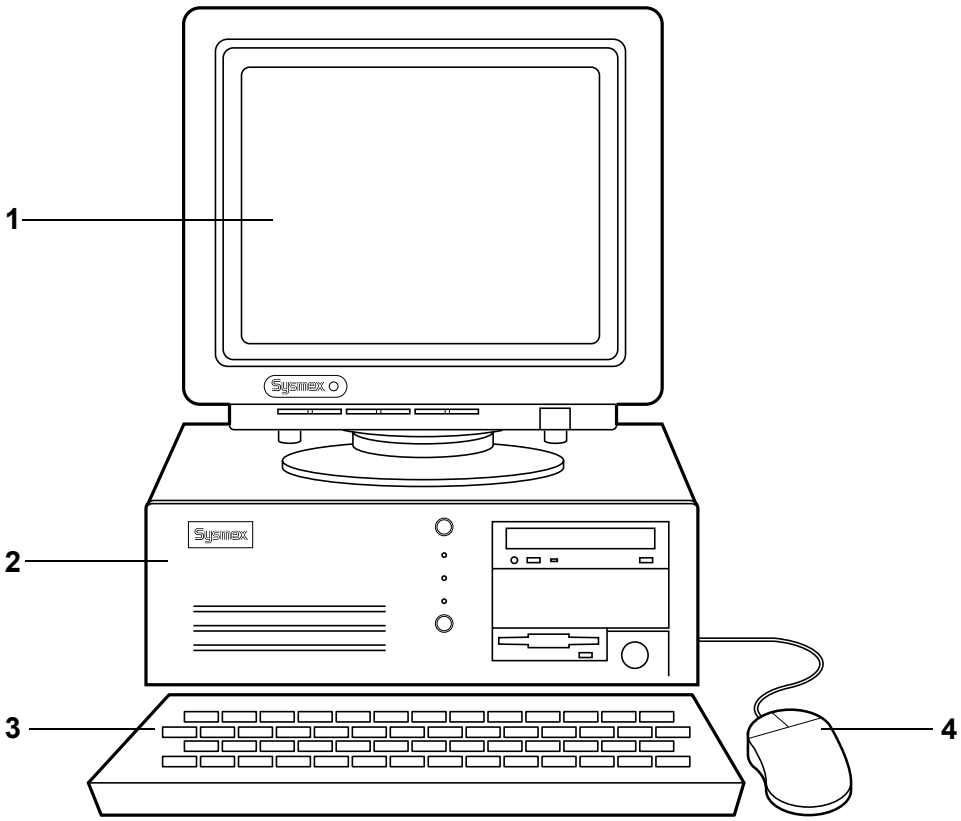
3.5 Information Processing Unit (IPU)

Front view



1 SVGA compatible colour monitor

2 Computer

Important!

The computer shall **solely** be used for XE-2100 data processing. Running applications or programs other than described in this manual may cause malfunction of the instrument. Doing so will also invalidate the warranty.

3 Standard keyboard
For data input

4 Mouse
For controlling various functions

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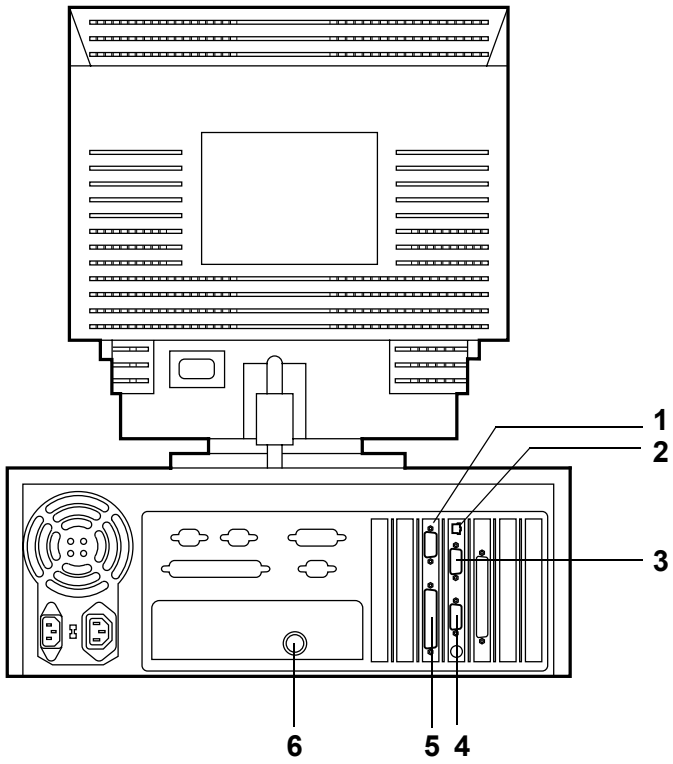
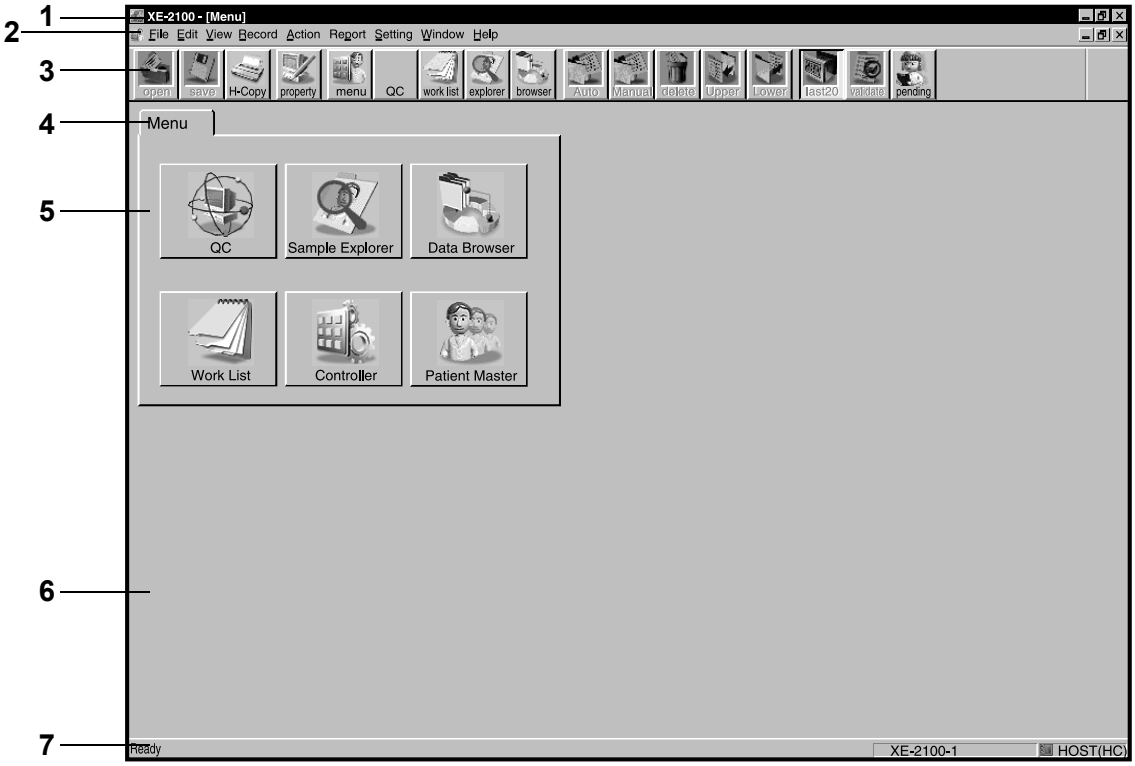
Rear view



1 COM 1: Line printer port
2 Main Unit connector
3 COM 2: Host computer port
4 Graphics printer port
5 Mouse port
6 Keyboard port

Main screen of the IPU's user interface



1 Window Title bar
Here the instrument name, name of the current function or view, number of saved or displayed data, respectively, etc. are displayed

2 Menu bar
Left-click on any of the menu items, to open the pull-down menu containing submenus and/or functions.

3 Icon bar
Frequently used functions are also available as buttons on the icon bar. By clicking on a button the underlying function is executed or view opened. Icons that are greyed out are not available in the current view.

4 Tab
Using tabs different views (tabs) can be opened.

5 Tab with buttons

6 Window display area
In this area different windows can be displayed simultaneously, to watch multiple operations and processes at the same time.

7 Status bar
Here the status of the Main Unit and the connection to the host computer are displayed.

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3.6 Functional description

Starting

After switching ON the instrument, the XE-2100 performs a Self-Check. During this check the internal service counters are checked.

If the Self-Check establishes the need for maintenance, an alarm is sounded and a respective message will appear on the LCD screen.

Background check

After the Self-Check, tubes and measuring chambers are rinsed and a Background Check performed to see if there still is any contamination present.

Logging on

You must log on to both IPU (Information Processing Unit) and Main Unit with user name and password. This will ensure that only authorized persons can work with the instrument, change settings and view the saved data.

Sample aspiration

The samples are in sample tubes.

When working with the Sampler, a large number of samples can be supplied automatically. As soon as the rack containing the sample tubes is in the analysis line, each sample tube is taken out and mixed. In the next step the piercer pierces through the cap and aspirates the sample. The analyse process is started.

Single or prediluted samples are held under the aspiration pipette. By pressing the start switch the sample is aspirated and the analysis is started.

Analysis

In the Sample Rotor Valve precise amounts of the sample are measured and, together with a defined amount of the relevant reagents (lyse and/or dye) transferred into the measuring chambers.

In the RBC measuring chamber, size and number of the erythrocytes and platelets are determined by the resistance measuring method.

In the haemoglobin measuring chamber, the aliquote of sample is converted into SLS haemoglobin and the haemoglobin concentration is measured by photometric determination.

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In the optical detector block the absolute number of leucocytes and the percentage of basophils are determined.

In the Diff measuring chamber the erythrocytes are dissolved by the influence of the lysis and the leucocytes are dyed. In the optical detector block a laser beam is directed at the blood cells. Scattered light and fluorescence properties are measured and allow for drawing conclusions as to the physiological and chemical properties of the cell.

In the IMI detector the erythrocytes are haemolysed and the cell plasma of all leucocytes (except immature granulocytes) is released or dissolved. The granulocyte count is performed by resistance measuring.

In the NRBC reaction chamber the erythrocytes are haemolysed and the leucocytes as well as nucleated erythrocytes are dyed. In the optical detector block the groups of nucleated erythrocytes are classified and analysed.

In the reaction chamber of the reticulocytes the diluted sample is dyed. In the optical detector block the groups of reticulocytes and platelets are classified and analysed.

Parameter calculation

Based on the measured values, the microprocessor calculates the remaining parameters.

Display

After the analysis is completed the data are saved in the Main Unit and also transmitted to the IPU.

The analysis results of the latest sample are display on five screen pages on the Main Unit's LCD screen.

At the IPU it is possible, in addition to the lists, to call up different display formats of the analysis results: histograms, scattergrams, pie charts, etc.

Output

Analysis results can be printed on any of the connected printers or transmitted to the host computer. An automatic output for samples having specific properties can be configured.

Preparations for the Next Analysis

The sample flow system is rinsed. The sample ID number will be automatically incremented by 1, if no bar code is used or another sample ID number entered. The instrument is then ready to perform the next analysis.

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3.7 Analysis mode

The XE-2100 provides four analysis modes.

Sampler mode

In Sampler mode the samples are automatically supplied, mixed, aspirated and analysed. The sample tube does not need to be opened. The required quantity of sample blood is 1 mL minimum.

Note:

The Sampler mode can be interrupted for urgent “emergency samples”.

Manual mode

The Manual mode is used to analyse individual samples. For example, it is used for “emergency samples” during operation in Sampler mode. The sample needs to be mixed manually. The uncapped sample tube is held under the aspiration pipette. The required quantity of sample blood is 1 mL.

Capillary mode

The Capillary mode is used for small sample volumes. The required quantity of sample blood is 40 µL. Before the sample is aspirated by the instrument, it needs to be diluted by a ratio of 1:5. Further proceeding is the same as in Manual mode.

Closed mode

The Closed mode is used to analyse individual capped samples. There must be no racks in the Sampler. The sample needs to be mixed manually. The sample tube needs not to be opened. The required minimum sample blood quantity is 1 mL.

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4. Reagents

4.1 General information

Important!

Follow the information pertaining to the handling of reagents given in chapter 2.6.

Additional special equipment

The below mentioned reagents are intended solely for use in Sysmex analysers.

If other reagents are used the product performance of Sysmex instruments can not be guaranteed.

Reagent consumption

Reagent	Abbreviation	Number of cycles possible per container	Container size
CELLPACK	PK	approx. 660 cycles	20 L
CELLSHEATH	SE	approx. 9.500 cycles	20 L
STROMATOLYSER-FB	FBA	approx. 2.750 cycles	5 L
STROMATOLYSER-4DL	FFD	approx. 2.750 cycles	5 L
STROMATOLYSER-4DS	FFS	approx. 6.000 cycles	42 mL
STROMATOLYSER-NR (lysing reagent)	SNR	approx. 550 cycles	1 L
STROMATOLYSER-NR (dye)			12 mL
SULFOLYSER	SLS	approx. 10.000 cycles	5 L
STROMATOLYSER-IM	SIM	approx. 3.700 cycles	10 L
RET SEARCH (II) (diluent)	RED	approx. 550 cycles	1 L
RET SEARCH (II) (dye)			12 mL

Note:

These figures apply to cycles run in CBC+DIFF+RET+NRBC analysis mode. Depending on the analysis profile the number varies.

The amount of reagent, which is needed for switch-on, mode change, shutdown and rinsing is not contained.

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Note:

STROMATOLYSER-4DS is only available as a pack of three containers of 42 ml each.

STROMATOLYSER-NR lysis agent and dye are available as package only.

RET SEARCH (II) diluent and dye are available as package only.

4.2 CELLPACK

Intended use

Diluent for use in haematology analysers.

Storage and shelf life after first opening

Store CELLPACK at 5-30 °C.

If unopened, CELLPACK is stable up to the expiry date shown.

Once opened (connected to the instrument), product stability in the cubitainer is max. 60 days.

Methodology

CELLPACK is a ready-made diluent for analysing blood by resistance measuring or photometric processes.

Composition of active constituents

Sodium Chloride	6,4 g/L
Boric Acid	1,0 g/L
Sodium Tetraborate	0,2 g/L
EDTA-2K	0,2 g/L

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4.3 CELLSHEATH

Intended use

Sheath solution for use in laboratory analyzers.

Storage and shelf life after first opening

Store CELLSHEATH at 5-30 °C.

If unopened, CELLSHEATH is stable up to the expiry date shown.

Once opened (connected to the instrument), product stability in the cubitainer is max. 60 days.

Methodology

CELLSHEATH is a ready-made solution for focussing the sample flow in sheath flow detectors.

Composition of active constituents

Sodium chloride	7.1 g/L
Tris buffer	2.0 g/L
EDTA-2K	0.2 g/L
Surfactant	0.8 g/L

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4.4 STROMATOLYSER-FB

Intended use

Diluent for use in Sysmex haematology analysers.

Storage and shelf life after first opening

Store STROMATOLYSER-FB at 5-30 °C.

If the container is unopened, STROMATOLYSER-FB can be used up to the expiry date shown on the container.

Once opened (connected to the instrument), product stability in the cubitainer is max. 60 days.

Methodology

STROMATOLYSER-FB is a ready-made lysing reagent to analyse leucocytes and the basophilic granulocytes of a whole blood sample by means of resistance measuring and photoelectric methods.

Composition of active constituents

Nonionic surfactant	4.0 g/L

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4.5 STROMATOLYSER-4DL

Intended use

Diluent for use in haematology analysers.

Storage and shelf life after first opening

Store STROMATOLYSER-4DL at 2-35 °C.

Do not use reagent once frozen.

If the container is unopened, STROMATOLYSER-4DL can be used up to the expiry date shown on the container.

Once opened (connected to the instrument), product stability in the cubitainer is max. 60 days.

Replace STROMATOLYSER-4DL showing signs of contamination or instability, as indicated by cloudiness or colour change.

Methodology

STROMATOLYSER-4DL is a ready-made diluent for analysing blood by resistance measuring or photometric processes.

Composition of active constituents

Nonionic surfactant	1.8 g/L
Organic quaternary Ammoniumsalt	0.8 g/L

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4.6 STROMATOLYSER-4DS

Intended use

STROMATOLYSER-4DS is to be used to stain the leucocytes in diluted and lysed blood samples. It serves for the determination of the 4-part differential count with selected Sysmex haematology analysers.

Storage and shelf life after first opening

Store STROMATOLYSER-4DS in a dark place at 2-35 °C.

Do not use reagent once frozen.

If unopened, STROMATOLYSER-4DS is stable up to the expiry date stated on the container.

Once opened (connected to the instrument), product stability is max. 60 days.

Replace STROMATOLYSER-4DS displaying signs of contamination or instability, such as cloudiness or colour change.

Methodology

The following steps are automatically performed by the analyser: after sample aspiration a part of the whole blood sample is diluted 1:50 with lysing reagent STROMATOLYSER-4DL, lysed and then STROMATOLYSER-4DS dye is added. After a predefined incubation time the stained sample is introduced into the sheath flow detector, where forward light scatter and fluorescent emission are measured. From this the four leucocyte populations neutrophil count (NEUT#), the lymphocyte count (LYMPH#), the monocyte count (MONO#), the eosinophil count (EO#), the neutrophil percent (NEUT%), the lymphocyte percent (LYMPH%), the monocyte percent (MONO%) and the eosinophil percent (EO%) are computed.

Composition of active constituents

Polymethine Dye	0.02 g/L
Methanol	30.0 g/L
Ethylene Glycol	969.0 g/L

Warnings and precautions

Consult the labelling on the package and the package insert of the reagent.

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4.7 STROMATOLYSER-NR LYSING REAGENT STROMATOLYSER-NR DYE

Intended use

STROMATOLYSER-NR is used for the assay of the concentration of nucleated red blood cells in blood samples with Sysmex haematology analysers.

STROMATOLYSER-NR is a pre-packaged reagent kit consisting of STROMATOLYSER-NR LYSING REAGENT buffer and STROMATOLYSER-NR DYE.

Storage and shelf life after first opening

Store STROMATOLYSER-NR at 2-35 °C in a dark place.

Do not use reagent once frozen.

If unopened, STROMATOLYSER-NR is stable up to the stated expiration date.

Once opened (connected to the instrument), product stability is max. 60 days.

Replace STROMATOLYSER-NR displaying signs of contamination or instability, as indicated by cloudiness or colour change.

Methodology

The following steps are automatically performed by the analyser:

After aspiration a portion of the whole blood sample is diluted into a 1:50 dilution with STROMATOLYSER-NR LYSING REAGENT, haemolysed and then stained with STROMATOLYSER-NR DYE.

After a predefined incubation time the stained sample is introduced into the sheath flow detector, where forward light scatter and fluorescent emission are measured. From this the NBRC count (NRBC#) and the NRBC percent (NRBC%) are computed.

Composition of active constituents

Stromatolyser-NR Diluent

Sodium Salicylate	1.6 g/L

Stromatolyser-NR Dye

Polymethine Dye	0.1 g/L
Ethylene Glycol	999.0 g/L

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Warnings and precautions

Consult the labelling on the package and the package insert of the reagent.

4.8 SULFOLYSER

Intended use

SULFOLYSER is a reagent for the automated determination of hemoglobin concentration of blood with Sysmex haematology analysers.

Storage and shelf life after first opening

Store SULFOLYSER at 1-30 °C in a dark place.

If unopened, SULFOLYSER is stable up to the stated expiration date.

Once opened (connected to the instrument), product stability is max. 90 days.

Replace SULFOLYSER displaying signs of contamination or instability, as indicated by cloudiness or colour change.

Methodology

The anionic surfactant contained in SULFOLYSER lyses the red blood cell membrane and combines with the released hemoglobin to form a stable haemichrome. The concentration of haemoglobin is then quantified by photometry.

Composition of active constituents

Sodium Lauryl Sulphate	1.7 g/L

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4.9 STROMATOLYSER-IM

Intended use

Reagent for the determination of immature leucocyte pre-stages with SYSMEX haematology analysers.

Storage and shelf life after first opening

Store STROMATOLYSER-IM at 5-30 °C.

If the container is unopened, STROMATOLYSER-IM can be used up to the expiry date shown on the container.

Once opened (connected to the instrument), product stability in the cubitainer is max. 60 days.

Methodology

STROMATOLYSER-IM is a ready-made reagent for analysing blood by means of resistance measuring and photometric processes.

Composition of active constituents

Sodium Hydroxide	0.3 g/L
Nonionic surfactant	24.0 g/L
Sodium Chloride	4.1 g/L

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4.10 RET-SEARCH(II) DILUENT (RED-300) RET-SEARCH(II) DYE (RED-800)

Intended use

RET-SEARCH(II) is intended to dilute the sample while simultaneously staining the reticulocytes for the assay of reticulocyte concentration in blood with Sysmex haematology analysers.

Storage and shelf life after first opening

Store RET-SEARCH(II) at 2-35 °C.

Do not use reagent once frozen.

If unopened, RET-SEARCH(II) is stable up to the stated expiration date.

Once opened (connected to the instrument), product stability is max. 60 days.

Replace RET-SEARCH(II) displaying signs of contamination or instability, as indicated by cloudiness or colour change.

Methodology

A sample volume of a whole blood specimen is introduced into the analyzer where a portion of it is automatically diluted with RET-SEARCH(II) DILUENT. RET-SEARCH(II) DYE is then added and reticulocytes present in the sample are stained. The stained sample is then introduced into the sheath flow detector where forward light scatter and side fluorescent emission are measured.

Composition of active constituents

RET-SEARCH(II) Diluent

Tricine Buffer	1.8 g/L

RET-SEARCH(II) Dye

Polymethine Dye	0.3 g/L
Methanol	71.0 g/L
Ethylene Glycol	928.0 g/L

Warnings and precautions

Consult the labelling on the package and the package insert of the reagent.

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4.11 CELLCLEAN

Intended use

Strong alkaline detergent for use in Sysmex analyzers.

Storage and shelf life after first opening

Store CELLCLEAN in a dark place at 15-30 °C.

Avoid exposing to direct sunlight, or the chlorine component is deformed and the effectiveness of this detergent will be lost, depending on the period of exposure.

Once opened, this reagent should be used within 60 days.

Methodology

CELLCLEAN is a detergent to clean the instrument, to remove residuals of reagents, cellular deposits and proteins from the hydraulic system, measuring chambers, sample aspiration tube and where applicable the Hgb flowcell, flow cell and sample rotor valve.

Composition of active constituents

Sodium hypochlorite (available concentration 5.0 %)

Warnings and precautions

Consult the labelling on the package and the package insert of the reagent.

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4.12 Symbols used on the label

IVD	In Vitro Diagnostic Medical Device
	Consult Instructions for Use
LOT	Batch code
	Use By …
	Temperature limitation
CE	CE conformity sign as per directive 98/79/EG
 Xn	Danger symbol
	Manufacturer
EC REP	Authorised Representative in the European Community

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5. Initial Operation

5.1 Delivery, Storage Until Installation

- Make sure the instrument is transported with due care.

Important!

In case of any damage of the packing, inform the local Sysmex representative immediately.

- Store the instrument in its packing in a dry location until installation. It must be stored in an upright position.

Important!

The initial installation of the instrument is made by a Sysmex service engineer. If the instrument is to be moved to a different location at a later time, contact your local Sysmex representative.

5.2 Preparation

- The XE-2100 must be installed in a dry a dust-free location.
- Take note of the required space by the instrument (see “16. Technical Information”).

Important!

To ensure the space required for servicing is available, the IPU should be placed to the right of the Main Unit.

- Due to the heat radiation the distance of side, rear and top panels to walls should be at least 50 cm. Sufficient space for carrying out maintenance or service work must be provided for.
- Avoid installation of the instrument near devices that cause signal noise, such as radios, centrifugal machines, etc.
- The power supply cable is approx. 2.50 m long. Ensure there is a suitable outlet within reach.
- Means for waste collection or the discharge of waste must be available.
- When air conditioning is used, a minimum cooling capacity of 800 W (2730 btu/h; 688 kcal/h) is required to offset the heat generated by the instrument.

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5.3 Peripheral devices

Important!

For each connected device a separate individual outlet must be available. Commercially available power boards must not be used.

Caution!

When connecting peripheral devices, the XE-2100 must be switched off.

The following peripheral devices can be connected to the XE-2100.

Graphics printer (optional)

With a graphics printer analysis data are printed out on DIN A4 or US letter size paper.

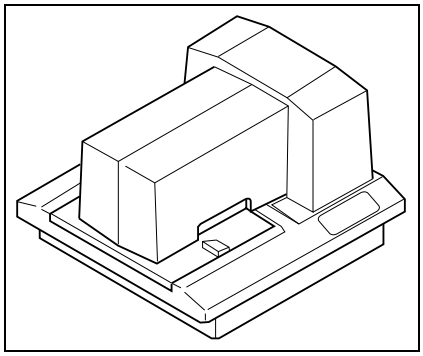
Important!

The graphics printer is not standard delivery.

Refer to the printer manual for detailed information on the installation of the graphics printer.

How the graphics printer is enabled is detailed in chapter “10. Output”.

Data printer (optional)



With a data printer the analysis data can be printed out in a “ticket size” format. The “ticket size” format is standard for the tickets usually printed in laboratories, printed on special printers.

Important!

The data printer is not standard delivery.

Refer to the printer manual for detailed information on the installation of the data printer.

How the data printer is enabled is detailed in chapter “10. Output”.

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Line printer (optional)

On a line printer lists with sample information and analysis data can be printed.

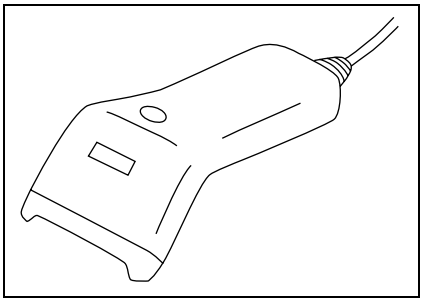
Important!

The line printer is not standard delivery.

Refer to the line printer manual for detailed information on the installation of the line printer.

How the line printer is enabled is detailed in chapter „10. Output“.

Barcode reader (optional)



A barcode reader scans the barcode on the sample tube and automatically inputs the sample number.

Important!

The barcode reader is not standard delivery.

Refer to the barcode reader manual for detailed information on the installation of the barcode reader.

See chapter “10. Output” on how to activate the barcode reader.

5.4 Additional components

The following additional components can assist in making the operation of the XE-2100 still more efficient:

Waste sensor

If a waste sensor is fitted, the user is notified by an error message if the waste tank is full.

Important!

The waste sensor is not standard delivery.

Uninterruptible power supply (UPS)

If an UPS is installed the power supply of the IPU is ensured in case of a power failure for up to 5 minutes.

Also the IPU's hard disk drive will be protected from damage by lightning (surge voltage).

Important!

To prevent data loss it is strongly recommended to have an USP installed.

The USP is not standard delivery.

Twin Connection Manager

Allows for the connection of two main units to one IPU. With this extension the analysis data of both instruments can be managed.

Important!

The Twin Connection Manager is not standard delivery.

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5.5 Basic instrument settings

Note:

In this chapter only the settings relevant for initial operation are described. For detailed information on all possible settings refer to chapter “13. Settings”.

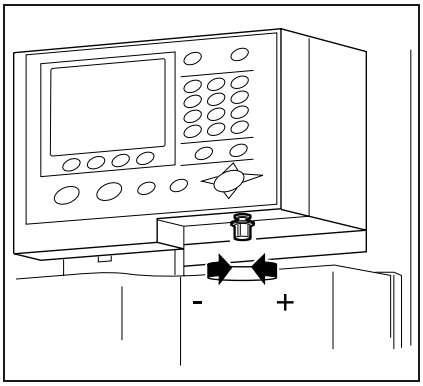
Date and Time

In order to have an analysis properly marked, it is important to have date and time set correctly. These are set in the computer's system settings.

Note:

When time changes to summer or winter time, respectively, the clock must be corrected accordingly.

Setting the display brightness



To adapt the display brightness to the lighting in your laboratory, proceed as follows:

1. Open the front cover of the XE-2100.
2. With the adjustment knob under the panel keyboard the LCD display's brightness can be adjusted as desired:
   Turning clockwise: darker (-)
   Turning counter-clockwise: brighter (+)
3. Close the front cover.

Note:

If no key is pressed for 10 minutes, the LCD display is dimmed. Press any key to return to a normally illuminated LCD display.

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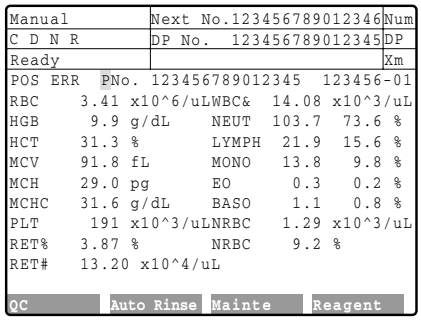
6. Operation

6.1 General information about Main Unit operation

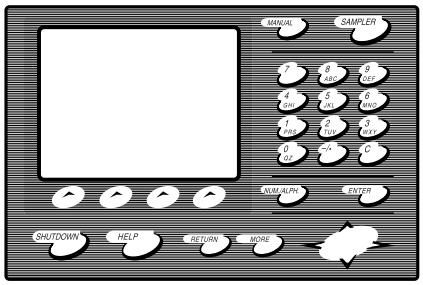
To a large extent the instrument is operated by a menu-driven control. The LCD screen shows which functions or submenus are available. Also the instrument's operating status and the progress of a measurement, respectively, are displayed.

Main menu

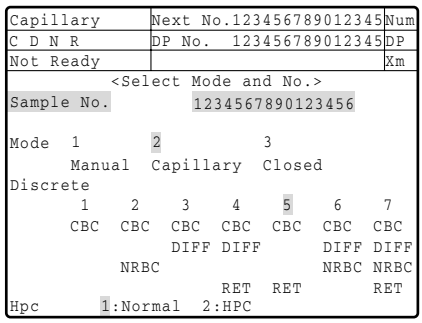


The items of the Main menu are shown on the last line of the Analysis screen.

– To display the additional menu items on the Main menu's second screen page press **MORE**.
– To choose a function press the corresponding selection key below the LCD screen.
– To open the Main menu from any of the screens, press - multiple times, if necessary - the **RETURN** key.



Selecting submenus/options



In the LCD screen's footer is shown which submenu or functions, respectively, are available.

Note:

There are two options:

– Press the corresponding selection key below the LCD screen.

or:

– Press the relevant numeric key.

Input of numbers and letters

Sample IDs, patient names, etc. are entered using the alpha-numeric keypad.

Pressing the **NUM./ALPH.** keys changes over between input of numbers and input of upper case or lower case letters, respectively.

– To enter a number, press the corresponding number key.

– To enter a letter, press – multiple times, if necessary – the corresponding number key.

– To delete a character press the **C** key.

– To conclude the input press **ENTER**.

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6.2 Menu tree


QC
Exec. QC
Xm STT/STP
AutoRinse
Mainte.
1: Drain IMI
2: Air Bubble Removal
3: Clog Removal
4: Rinse Flowcell
5: Drain Waste
Reagent
Logoff
Cal.
1: Manual
2: HGB/HCT
Test
Status
1: Senser 1
2: Senser 2
3: Counter
4: Pump
Sampler
1: Rack Feed In
2: Rack Shift
3: Rack Feed Out
CP
Barcode
Motor
1: WB. Asp. Motor
2: RBC Sheath Injector
3: FCM Sheath Injector
4: Spits Motor
5: Mixing Motor
SRV
Replenish
1: FFD
2: FFS
3: SNR
4: RED
5: FBA
6: EPK
7: ESE
8: SLS
9: SIM
DP

6.3 General information about IPU operation

The IPU consists of a PC and the software belonging to it.

Important!

The computer shall **solely** be used for XE-2100 data processing. Running applications or programs other than described in this manual may cause malfunction of the instrument. It will also invalidate the warranty.

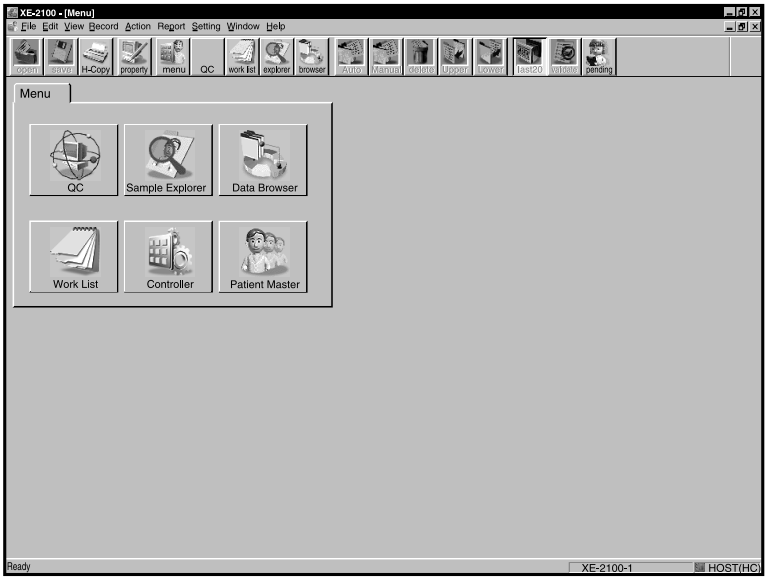
Preconditions

It is assumed that the user is familiar with the basic principles of operation of a Windows PC:

- use of the mouse, clicking, double-clicking
- left mouse button to choose an option;
  right mouse button to open context menus
- menus, pull-down menus, window closing/minimising/ restoring
- boot up procedure, logging on, shut down

Main menu

After turning on the XE-2100 the Main menu will be displayed on the IPU's screen.



Note:

Upon initial operation the system is configured to individual preferences. This is why the screenshots shown in this manual may deviate from the screens your instrument may display.

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If, at a later date, you wish to change the number style and order style of icons and tabs, see chapter “13. Settings” for detailed information.

Selecting a menu or function

There are three ways to select a menu or function:

– Click on the corresponding button on the Icon bar.

– On the Menu bar, open the **View** pull-down menu and on the menu choose the desired submenu or function.

– On a tab, click on the corresponding button.

 **Note:**

Greyed out icons or menu items are not enabled in the current view and can not be selected.

Window

To move a window area currently not visible to the area visible on the screen, move the scroll bar(s) or click on the arrow.

 **Note:**

Window layout, style and size can be adapted to individual preferences, see chapter “13. Settings”.

Tabs

Within the menus different views can be displayed by means of the tabs.

– To display a view simply click on the corresponding tab.

Buttons

With buttons

- additional views can be displayed,
- input dialogue boxes are opened, or
- functions are executed.

– Left-click on the button. The assigned function will be executed immediately.

Input

Many windows require input of values or data.

– Place the cursor in the desired entry box and enter the values or data on the keyboard.

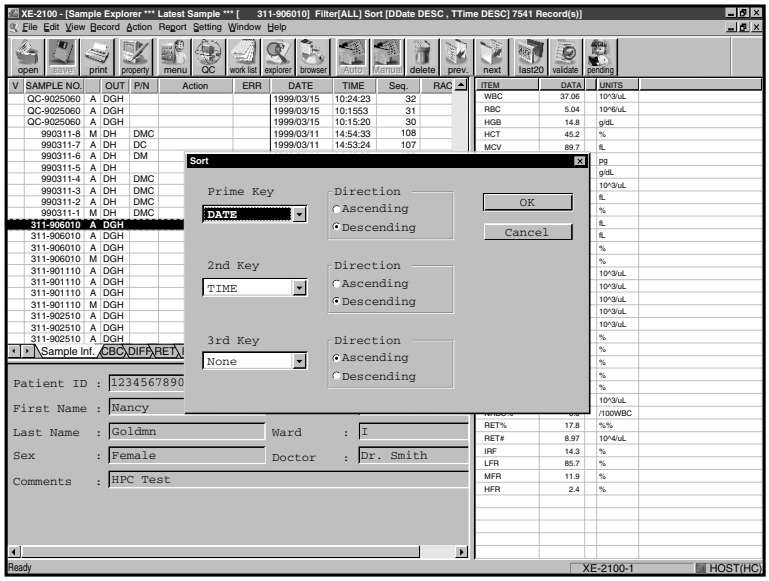
Note:

If there are multiple entry boxes press the Tab-key to go to the next box.

Selecting options

For some entry boxes several default values are available to choose from.

– Right-click on the arrow to open the pull-down list, then left-click on the desired value.



Context menu

There is the option to call up a so-called “context menu”. On the menu – depending on which submenu or function is currently active – various functions can be directly called up.

– Right-click to open the context menu, then left-click on the desired menu item.

IPU menu tree

Menu	Submenu	Menu Function
File	Open	Open data record (from within Explorer only)
	Close	Close data record
	Save	Save data record
	Print	Print screen, hardcopy
	Logoff	Logging off from the XE-2100 (Log on dialogue)
	Exit	Exiting application (Exit Program dialogue)
Edit	Select All	Select all data records
	Find	Open Find dialogue
	Property	Changing sample information
View	Tool Bar	Display/hide Icon bar
	Status Bar	Display/hide Status bar
	Menu	Start “Menu” view
	QC	Start “QC” view
	Work List	Start “Work List” view
	Sample Explorer	Start “Sample Explorer” view
	Data Browser	Start “Data Browser” view
Record	Sort	Sort data records displayed (sort key dialogue box)
	Filter	Select data records displayed (filter key dialogue box)
	Auto add	Add new data record (only for list input)
	Manual add	Add new data record (only for list input)
	Delete	Delete selected data record
	Backup	Save selected data record to floppy disk
	Restore	Read information saved on floppy disk into memory
	Download	Receive data from host computer
	First	Go to first data record
	Previous	Go to previous data record
	Next	Go to next data record
	Last	Go to last data record
Action	Validate	Validate sample displayed
	PendingList	Display pending Work List
	Last20	Display last 20 samples

Menu	Submenu	Menu Function
Report	Host (HC)	Transmit selected data records to host computer
	Ticket (DP)	Print selected data records on data printer (DP)
	Report (GP)	Print selected data records on graphics printer (GP)
	Ledger (LP)	Print selected data records to line printer (LP)
Setting	Date Format	Selection of default date format
	Auto Validate	Selection of condition for automatic validation
	Auto Output	Selection of parameters and output device for automatic output
	Discrete	Parameter selection
	Analysis Ordering	Setting the criteria for analysis registration
	User Administration	User administration, setting of user profiles
	Host (HC) Setting	Settings for host computer connection
	Report (GP) Setting	Settings for graphics printer connection
	Ledger (LP) Setting	Settings for line printer connection
	Categories	Settings of categories
	Reference Interval	Setting of upper and lower parameter limits, assignment to categories
	Units	Setting of data format and parameter units
	Sampler Stop Limit Setting	Setting of upper and lower parameter limits for stopping the sampler
Window	Cascade	All open windows are displayed staggered, partly overlapping
	Tile	All open windows are reduced, but displayed without overlapping
	Arrange Icons	Arrange icons of reduced windows
	Split	Split window display
Help	About XE-2100	Display software version number (Version dialogue box)

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6.4 Signal tones

The XE-2100 indicates different situations by distinct signal tones:

Key tone:
With each depression of a key a brief beep sounds.

Input errors:
If a wrong key is pressed, a long beep sounds.

Analysis error:
A permanent alarm sounds if an error has occurred in the instrument.

Important!

To stop the alarm press **C**. Then press **HELP** on the Main Unit to call up the Help menu. All other keys are disabled during an alarm.

Aspiration of a sample:
When the start switch is pressed a single beep is sounded. When aspiration is completed, two consecutive beeps are sounded.

In pre-diluted mode or for sample number “0” beeps are sounded from the time the start switch is pressed until aspiration of the sample is completed.

6.5 Checks prior to operation

Perform the following checks before switching the instrument ON:

Reagents

- Check to see that the reagent quantity is enough for daily consumption.
- If there is insufficient reagent during operation, an alarm will sound – the analysis is not started.
- Place fresh reagents at disposal, if necessary. How to replenish reagents is detailed in chapter “14.15 Replacing reagents”.

Cables and tubing

- Check to see that all cables and tubing are properly connected. The power cable must be plugged into an outlet.
- All cables and tubing must not show any indication of damage. Replace if necessary, or contact the Sysmex service representative.

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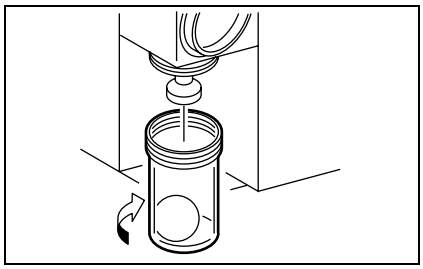
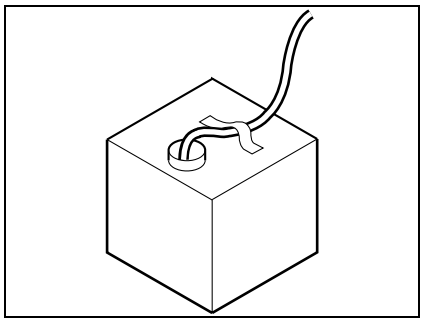
Trap chamber



- Check to see if any fluid has accumulated in the trap chamber at the compressor – drain if necessary (see chapter “14.4 Trap chamber checking and draining”).

Waste tank



- Check the level in the waste tank – replace if necessary (see chapter “14.14 Waste tank replacement”).

Note:

If a waste sensor is fitted an error message will be displayed if the waste tank is full.

Sampler

- Ensure there are no racks in the analysis line or Sampler – remove if necessary.

Printer

- Check to see that there is sufficient paper in the printer to last for the day – replenish paper if necessary.

Important!

Observe the instructions of the relevant device.

6.6 Starting

After completion of all checks the instrument can be switched on.

Important!

You must carry out the steps in the prescribed sequence, otherwise the communication between IPU and Main Unit will not work.

1. First turn PC and monitor on.
2. Then press the **Ctrl**, **Alt** and **Del** key simultaneously, to log on to Windows NT/2000.

   The system will boot.

Important!

Should there be more than one operating system installed, select Windows NT Version 4.0 or Windows 2000.

3. Wait until the IPU is ready to operate. Only then set the main switch of the Main Unit to position **I ON**.

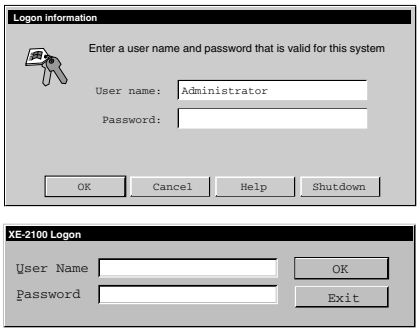
   The LCD screen will be illuminated. The program version is displayed briefly.
4. Start the compressor.

Important!

Normally the compressor does not need to be started, since the power is supplied from the Main Unit.

5. Finally, switch the printers and other connected peripheral devices on.

Logging on to the IPU



1. Enter your user name and password. Confirm with **OK**.

   The XE-2100 application software is started automatically.

2. Log on to the XE-2100 application software

Note:

Contact your administrator should you have any questions regarding your password and user rights.

Self-check

After switching ON, the instrument performs a Self-Check. The micro-processor tests the system and the memory.

If an error is detected during the system check, an error message appears on the LCD screen.

Note:

Make a note of the error message.

– Turn the XE-2100 OFF. Wait at least 10 seconds, then turn ON again.

Important!

If the error occurs again contact the Sysmex service representative.

Temperature and pressure test

After the micro-processor check temperature and pressure in the reaction chambers are checked.

– Check the indication of pressure and vacuum at the compressor. The values must be within the following limits:

Pressure	2.5 ± 0.3 kg/cm^2; 0.2452 MPa ± 0.0294 MPa
Vacuum	minimum 400 mm Hg; -0.533 MPa

Note:

In case the pressure value at the compressor is out of tolerance follow the instructions given in chapter “14.19 Adjustment of pressure and vacuum”.

If the vacuum is out of tolerance observe the information given in chapter “14.19 Adjustment of pressure and vacuum”.

Mechanical component check

Finally the mechanical components are checked:

- Sample Rotor Valve
- Motors
- Aspiration and rinsing device

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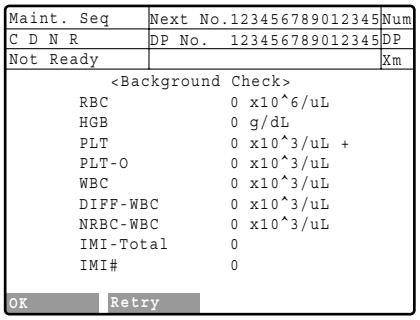
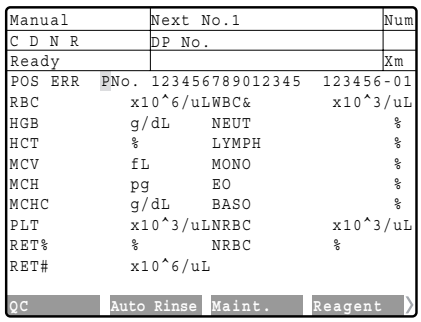
Background check



After a successful system check three automatic rinse cycles are performed. After the third rinse cycle a background check is performed.

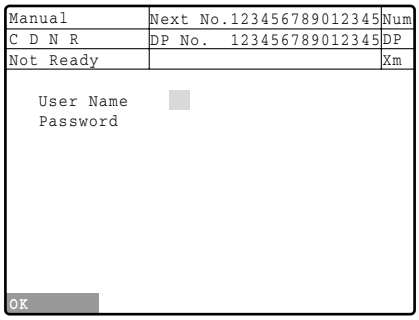
Should any of the values be out of tolerance (see “16.1 Performance characteristics/specifications”), two additional rinse cycles are performed. If afterwards a value is still out of tolerance, a continuous alarm is sounded and the message “Background error” displayed on the LCD screen.

- Press **HELP** to stop the alarm and to call the Help menu.
- Carry out the measures suggested in the online help.



If the background check revealed no errors, the XE-2100 is operational. A brief beep is sounded and the status display shows “Ready”.

6.7 Logging on to the Main Unit



When the background check is completed, the Logon screen for logging on to the Main Unit will be displayed.

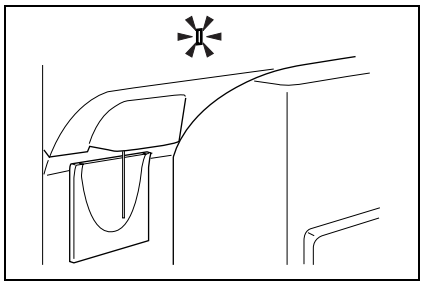
Important!

You must log on using the same user name and password you use for the IPU.

Note:

By this login you will have access to specific functions. Should you have no access to important functions contact your administrator.

1. Make sure that at the upper right of the Main Unit's screen **alp** (for input of letters in lower case) or **Alp** (for input of letters in upper case) is displayed. If necessary, press the **NUM./ALP.** key on the Main Unit's panel keyboard to change over.
2. Enter your user name with the alphanumeric keys.
3. Press ▼ to move the cursor to the next line.
4. Enter your password in the second line.
5. Press the left selection key to confirm with **OK**.



Afterwards the instrument is ready for analysing samples. Ensure that the screen displays “Ready”.

6.8 Automatic validation

If you wish specific analysis results (e.g. all negative samples) to be automatically validated, you can enable the automatic validation. For detailed information refer to chapter “13. Settings”.

6.9 Automatic output

If you wish specific analysis results (e.g. all negative samples) to be output automatically, you can enable the automatic output. For detailed information refer to chapter “13. Settings”.

Important!

Only validated samples can be output.

6.10 Quality Control

Important!

Always perform a Quality Control prior to operation – before samples are analysed – as described in chapter “11. Quality Control”.

6.11 Sample requirements

Sample type

For whole blood mode analysing venous blood, for capillary blood mode analysing capillary blood should be used. Capillary blood samples can be taken from the ear lobe or the fingertip of adults (preferred) or from the heel of infants. Ideally, large drops of blood should exude slowly but spontaneously, and only gentle squeezing is permissible. If it is necessary to squeeze firmly to obtain blood, the results are unreliable.

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Conditions of collection

Venous blood should be mixed with EDTA anticoagulant (K_2-EDTA or K_3-EDTA) and analysed within 4 hours after the sample was taken. In case samples cannot be analysed within 4 hours, they should be kept refrigerated to 2 - 8 °C until they can be analysed. Prior to analysing the refrigerated samples should be allowed to warm up to room temperature (for a minimum of 15 minutes), than mixed for at least 2 minutes.

Capillary blood samples may be diluted directly into the diluent without utilisation of anticoagulant, or may be collected into micro-collection devices with EDTA anticoagulant for dilution at a later time.

Stability of whole blood samples

When samples are stored without cooling for more than 4 hours, the blood cells undergo changes which may cause incorrect results of clinical significance. Erythrocytes will swell, MCV and RDW-SD increase. Likewise the platelets will swell, with MPV and P-LCR increasing. The concentration of leukocytes and the reliability of the automated leukocyte differentiation may decrease. The degree of the change depends on the sample itself and the storage temperature. These changes are prevented to a large degree by refrigerating the sample to 2 - 8 °C.

6.12 Analysis mode

The proper analysis mode must be choosen for particular circumstances:

- A large number of samples should be processed in **Sampler mode**.

  In Sampler mode only whole blood samples can be analysed.
- If the XE-2100 is working in Sampler mode, the routine processing can be interrupted to perform an “emergency analysis”. This is done in **Manual mode**.
- If only a minor sample volume (minimum 40 µL blood) is available, choose the **Capillary mode**.
- If a single sample is to be analysed in the rack choose **Closed mode**.

  In Closed mode only whole blood samples can be analysed. In this mode the sample is not mixed.

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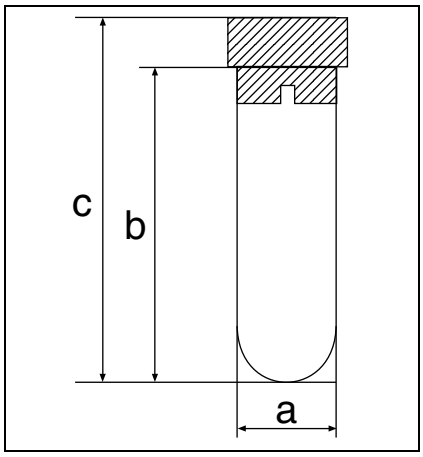
6.13 Preparations for sample analysing

Sample

- The blood sample should be collected by venepuncture.
- As a minimum 1 mL whole blood is required; for Capillary mode a minimum of 40 µL capillary blood is required.

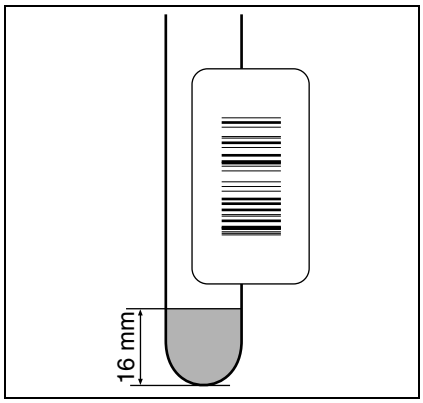
Sample tube



- Observe the sample tube dimensions:

Diameter **a**	between 12 and 15 mm
Height **b**	maximum 75 mm
Total height **c** (including cap)	maximum 82 mm

Sticking on a bar code label



It is recommended to use barcodes whenever possible.

– Stick a label on the tube.

Important!

The label must be at least 16 mm away from the bottom edge, otherwise the blood volume sensor will not work.

Caution!

To ensure a correct sample identification please note the following:

- It is recommended that no more than two labels be placed on the sample tube.
- It is important to assure that the labels are flat and smooth against the tube, without creases or flaring.
- Affix the barcode label so that the bars on the label would become horizontal when the rack is placed on the sampler.

Sample tubes with multiple labels, or labels which are not flat and smooth against the tube, may cause interference with sampling. The sampler is likely to jam, and in extreme circumstances, the sampler may not be able to properly release the tube back into its original rack position.

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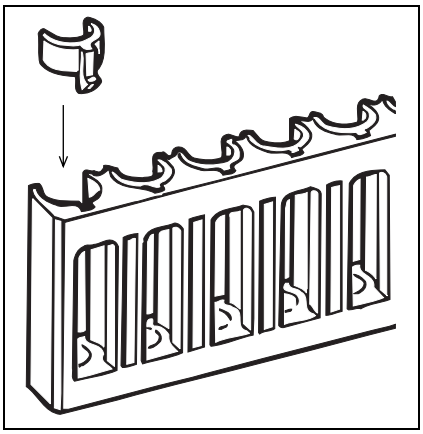
If the barcode label is affixed slanted, the potential of the incorrect reading of the barcode labe will be increased.

Rack preparation (for Sampler mode and Closed mode)



– Set the capped sample tubes in the rack.

If necessary, fit an adaptor:

Outer diameter of sample tube	Adaptor
12 mm	Tube Holder No. 58
13 mm	Tube Holder No. 56

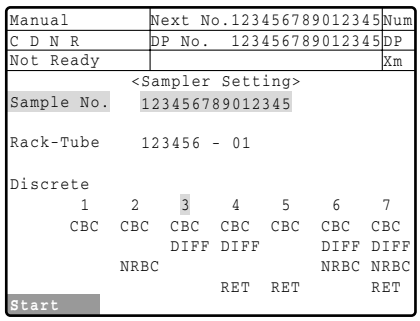
Important!

In order for the instrument to be able to scan the bar code, turn the sample tube so that the entire bar code is visible though the slot.

Entering a sample number

Important!

Only if no barcode reader is enabled (e.g. because there is no host computer existing), the sample ID needs to be manually entered prior to the analysis.



For an exact identification and assignment of samples the following designating numerals are required:

- Sample ID number
- Rack number (Sampler mode only)
- Sample tube position in rack (Sampler mode only)

The sample ID can consist of up to 15 characters (numerals, letters, hyphens). It corresponds with the bar code.

For a new analysis the sample ID is automatically incremented, e.g.:

123	→ 124
999999999999999	→ 1
12-3	→ 12-4
12-999	→ 12-000

Important!

Do not use “0” for a sample number, as the analysis will neither be saved nor can it be transferred to the host computer.

Rack number and tube position must be specified solely in numerals.

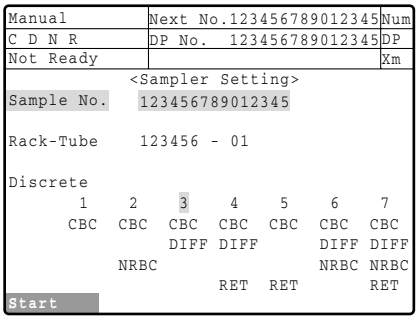
The rack number is automatically incremented by one as soon as a new rack reaches the analyse line.

The first rack position is always “1”. If an analysis is started at the first position, it does not need to be entered.

Selecting an analysis profile

Note:

When working with bar codes and a bidirectional connection is available, the selection of an analysis profile is not required.



1. Check the analysis profile settings.
2. Press ▼ if you wish to make changes. Select the desired setting with the ◀▶ arrow keys.

C	CBC
C N	CBC + NRBC
C D	CBC + DIFF
C D R	CBC + DIFF + RET
C R	CBC + RET
C D N	CBC + DIFF + NRBC
C D N R	CBC + DIFF + NRBC + RET

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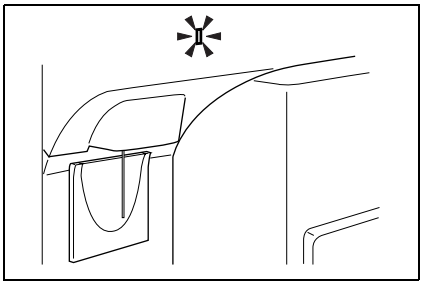
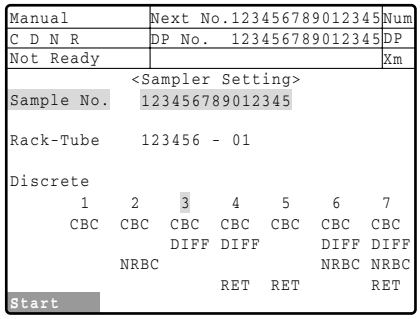
6.14 Analysing in Sampler mode

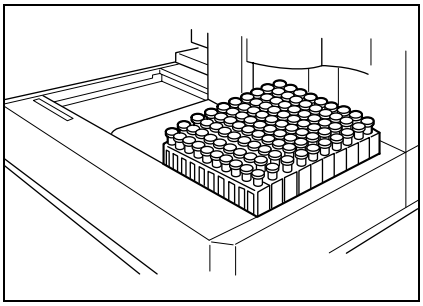


1. Ensure the Main Unit is ready to operate and displays **Ready**.
2. Press the **SAMPLER** button on the Main Unit.



The dialogue for setting the sample ID will open.

3. Enter the first sample number.
4. Check the rack number and the tube's position in the rack, correct if necessary. If all input is correct, press ▼ to move to the next line.



5. Place the racks in the right-hand part of the Sampler.

Important!

Prior to analysing, samples must not have been in a static position for more than 4 hours, as then the plasma will settle. In order to obtain reliable results, such samples must be mixed thoroughly before they are placed in the Sampler.

6. Select the analysis profile, if necessary.
7. To start the analysing process in Sampler mode, use the selection key to select **Start**
   or:
   press the **SAMPLER** key again.

Warning!

Do not touch the piercer cover during operation. Risk of personal injury!

Caution!

Do not manually push (or move) the sample rack forward while instrument is in operation.

Note:

Opening the piercer cover will cause the analysis operation to stop.

More racks can be added at any time.
When all analyses have been completed **Ready** will be displayed.

Analysing urgent samples

If urgent samples need to be analysed before current samples have been processed by the sampler, the course of the Sampler analysis can be interrupted.

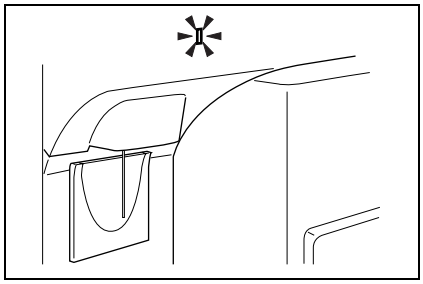
– Press the **SAMPLER** button.

  The display will show “Stat”.

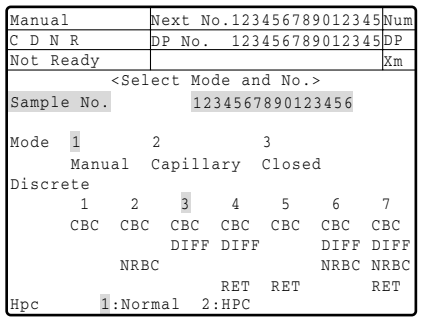
  When the display shows “S-Ready”, any number of analyses in manual or Capillary mode can be performed.

– To resume analysing in Sampler mode press the **SAMPLER** button again.

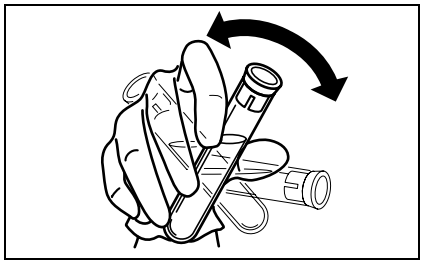
6.15 Analysing samples in Manual mode



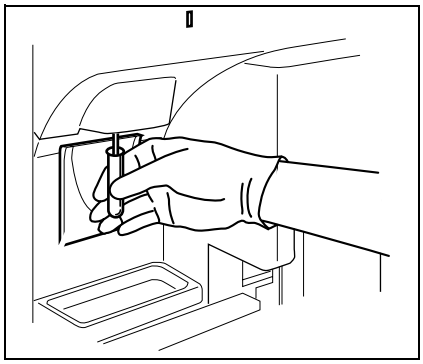
1. Ensure the Main Unit is ready to operate and displays **Ready**.
2. Press the **MANUAL** button on the Main Unit's panel keyboard.



3. The dialogue for setting the sample ID will open.
4. Enter the sample ID on the keyboard or scan it with a manual barcode reader (accessory).
5. Press ▼. Using the ◀▶ keys select the analysis mode “Manual”.
6. Choose the analysis profile, if necessary.



7. Mix sample thoroughly.



8. Hold the opened sample tube under the aspiration pipette, so that the aspiration pipette immerses into the sample.

   Important!

   The aspiration pipette should not contact the tube's bottom, which would prevent proper aspiration of the sample.

9. Press the start switch.

   The sample is aspirated.

10. When two short beeps are sounded, the sample tube should be lowered first and then taken away sideways.

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Important!

If the sample is removed beforehand, the analysis can not be correctly performed.
Take care not to bend the aspiration pipette.

The aspiration pipette will be automatically cleaned on the inside and outside. There is no need to wipe the aspiration pipette.

The analyse operation starts. After completion of the analysis the tube system is rinsed.

When the status display indicates “Ready”, the next sample can be prepared. Repeat the process detailed above.

6.16 Analysing samples in Capillary mode

Important!

Analysing in Capillary mode requires a 1:5 dilution.

Analyse the sample within 30 minutes after the dilution was prepared.

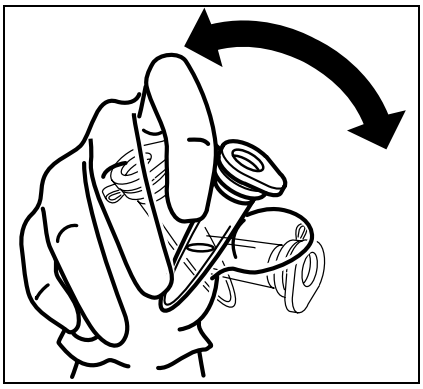
A minimum of 40 µL capillary blood is required.

Required materials

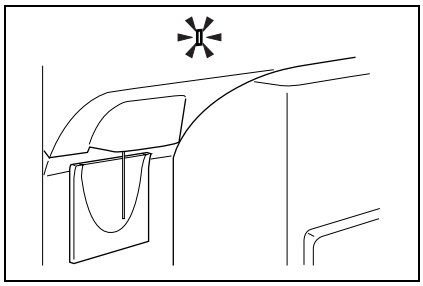
- Diluent (CELLPACK)
- Micro-tube (MT-40 or similar)
- Pipettes (e.g. 40 µL/160 µL or 50 µL/200 µL)

Diluting the sample

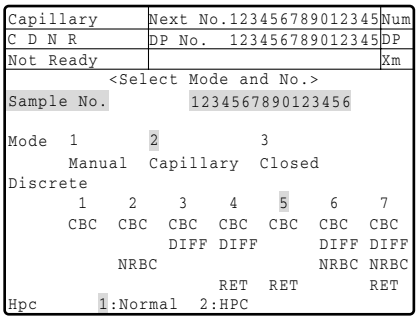
1. With a transfer pipette measure 160 µL or 200 µL CELLPACK and dispense into a micro-tube.
2. Collect 40 µL or 50 µL blood with a capillary tube and dispense into the micro-tube.
3. Put a cap on the tube and mix the diluted sample thoroughly.



Analysing the sample

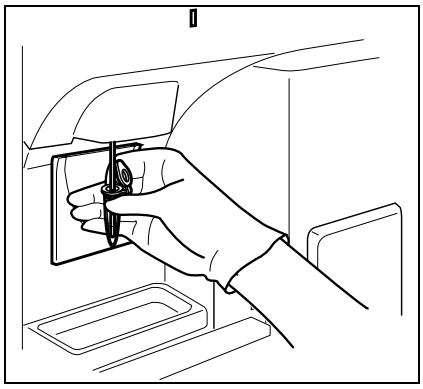


1. Ensure the Main Unit is ready to operate and displays **Ready**.
2. Press the **MANUAL** button on the Main Unit's panel keyboard.



The dialogue for setting the sample ID will open.

3. Press ▼. Using the ◀▶ keys select the analysis mode “Capillary”.
4. Select the analysis profile, if necessary.



5. Hold the opened sample tube under the aspiration pipette, so that the aspiration pipette immerses into the sample.

Important!

The aspiration pipette should not contact the tube's bottom, which would prevent proper aspiration of the sample.

6. Press the start switch.

   The sample is aspirated.
7. When two short beeps are sounded, the sample tube should be lowered first and then taken away sideways.

Important!

If the sample is removed beforehand, the analysis can not be correctly performed.
Take care not to bend the aspiration pipette.

The aspiration pipette will be automatically cleaned on the inside and outside. There is no need to wipe the aspiration pipette.

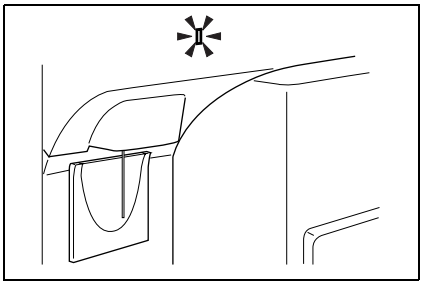
The analyse operation starts. After completion of the analysis the tube system is rinsed.

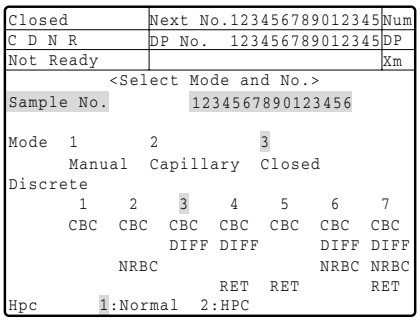
When the status display indicates “Ready”, the next sample can be prepared. Repeat the process detailed above.

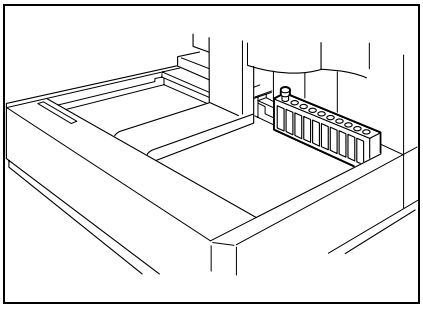
Important!

If possible diluted samples should be analysed twice. Compare the measured values to obtain a reliable result.

6.17 Analysing samples in Closed mode







1. Ensure the Main Unit is ready to operate and displays **Ready**.
2. Press the **MANUAL** key on the Main Unit's panel keyboard.

   The dialogue for setting the sample ID will open.
3. Enter the sample ID on the keyboard or scan it with a manual barcode reader (accessory).
4. Press ▼. Using the ◀▶ keys select the analysis mode “Closed”.
5. Ensure the sample tube is capped.
6. Mix sample thoroughly.
7. Set the tube at the left-most position in the rack (position 1).
8. From the right-hand side, place the rack in the analysis line.
9. Press the start switch to start the analyse operation.

   The rack will be moved to the analysis line and the sample is analysed.

Warning!

Do not remove the piercer cover during operation. Risk of personal injury!

Important!

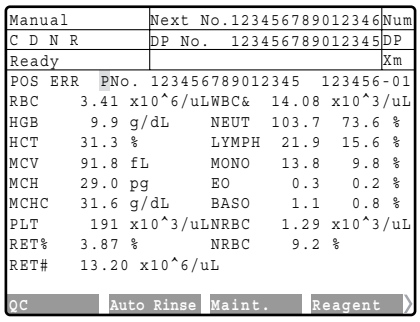
Opening the piercer cover will cause the analysis operation to stop.

In this mode the sample is not mixed.

When the analysis has been completed **Ready** will be displayed.

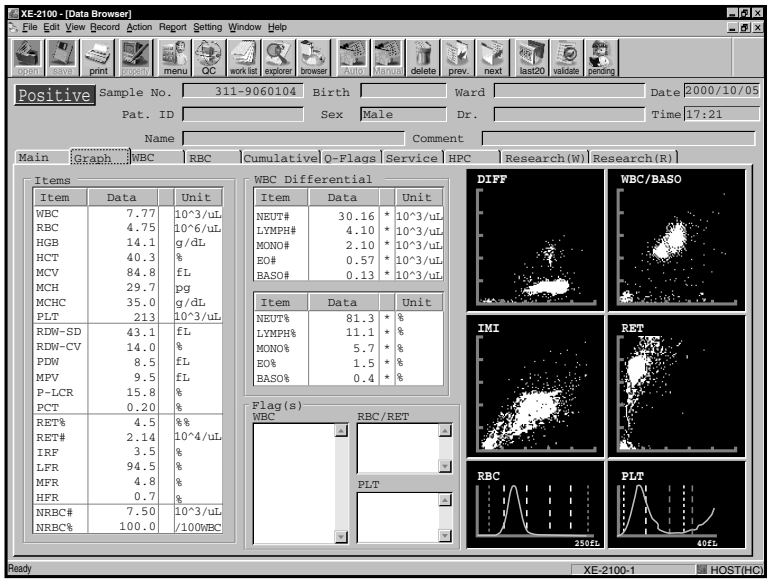
10. Remove the rack from the analysis line.
11. If necessary, prepare the next sample and repeat the process.

6.18 Display of analysis results



The results of the last performed analysis are displayed on the LCD screen. The complete display consists of 5 screen pages – use the ◀▶ cursor keys to scroll through the pages.

The “Data Browser” display on the IPU screen displays further details of the analysis results.



For more information about the displays, interpretation and the means of printer output, refer to chapter “7. Display and output of analysis results”.

6.19 Output of analysis results

If automatic output is enabled, the predefined analysis results will be transmitted to the host computer, data printer or graphics printer (see chapter “13. Settings”).

If automatic output is disabled the data to be output and the device can be chosen (see chapter “10. Output”).

6.20 Interruption of operation

Automatic compressor shutdown

If no analysis is performed within a defined time period, the compressor shuts off automatically, to

- save power;
- extend the service life of subsystems;
- reduce noise generation in the laboratory.

Important!

A requirement is an enabled timer. Detailed information on how to enable the timer and how to set the time period is available in chapter “13. Settings”.

– Press any key to return the instrument to the ready state after an interruption.

An automatic rinsing with a subsequent background check will be performed and the system status returns to “Ready”.

Reduced LCD-screen brightness

To protect the LCD-screen, the brightness of the Main Unit's LCD-screen is reduced if no key is pressed for a defined period of time.

– To re-activate the LCD-screen, tap anywhere on the screen.

Reduced PC monitor brightness

If no key is pressed for a defined period of time, the brightness of the PC's monitor is reduced or a screen saver will appear.

– To re-activate the monitor, press any key or move the mouse.

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6.21 End of operation

Shutdown

Prior the turning the instrument OFF the Shutdown process should be carried out. The measuring chambers and the hydraulic system are cleaned.

Execute a Shutdown:

- when all analyses have been performed,
- at least every 500 samples or every 24 hours, respectively, if the XE-2100 is used in continuous operation.

Important!

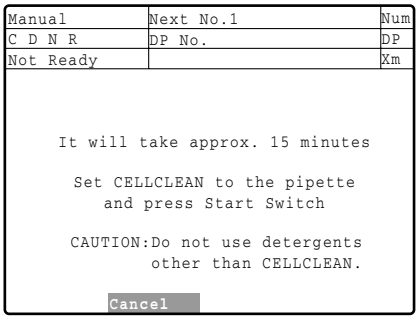
If you turn the instrument OFF without having performed a Shutdown, deposits may build up in the system which could cause measurement errors.

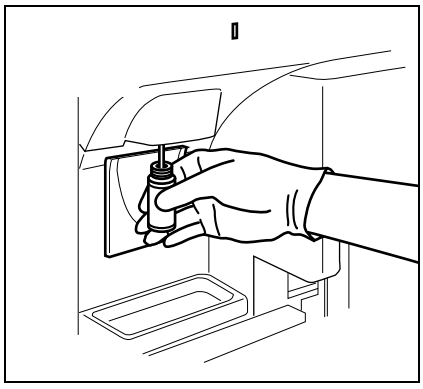
Note:

The Shutdown sequence takes approx. 15 minutes.

1. Be sure the status display indicates “Ready”.
2. Press **SHUTDOWN**.
   The screen shown at left will come up.

- If you wish to abort the Shutdown sequence and continue analysing, choose **Cancel**.





3. Hold CELLCLEAN under the aspiration pipette and press the start switch.

Caution!

CELLCLEAN is a strong alkaline cleaning material. It should not come in contact with skin or clothing. If it happens nevertheless, rinse skin or clothing with plenty of water to avoid injury or damage, respectively.

4. When two short beeps are sounded, the container with the CELLCLEAN should be lowered first and then taken away sideways.

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Important!

Take care not to bend the aspiration pipette.

The Shutdown sequence is automatically executed.

When the Shutdown sequence is completed, the message “Please Power Off” is displayed.

– To restart the instrument choose **Restart** on the “Shutdown completion” display. An automatic rinse and a background check will be performed. Afterwards the XE-2100 is ready for operation.
– To turn the Main Unit OFF, set the main switch to the **0 OFF** position.
– If the power to the compressor is not supplied from the Main Unit, turn the compressor OFF also.

Important!

To avoid damage to the instrument, wait at least 1 minute before switching the Main Unit or the compressor ON again.

Note:

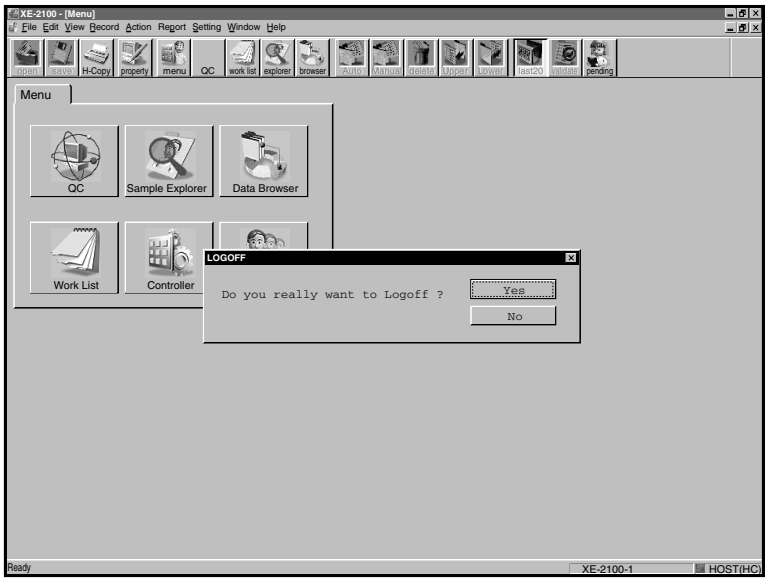
Afterwards the IPU can still be used, e.g. for data output or editing.

– To turn the entire system OFF the IPU must be shut down (see “IPU shutdown”).

User logoff, new user logon

– On the **File** menu choose **Logoff**.

The Logoff dialogue box will appear.



- To log off choose **Yes**.
- To abort the logoff choose **No**.

– To log on as a new user, enter user name and password.

Program termination, Windows shutdown

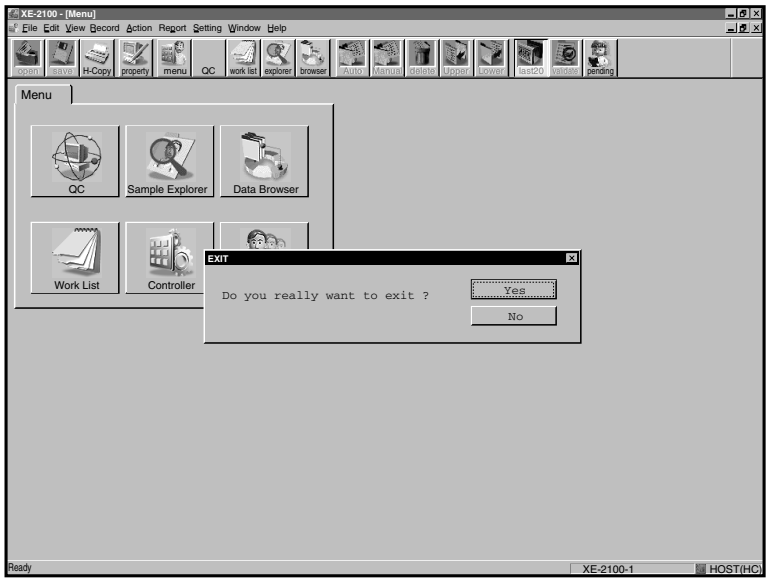
To exit the program:

– On the **File** menu choose **Exit**.

or:

– Click on the Close button at the top right of the window's title bar.

The Exit dialogue box will come up.

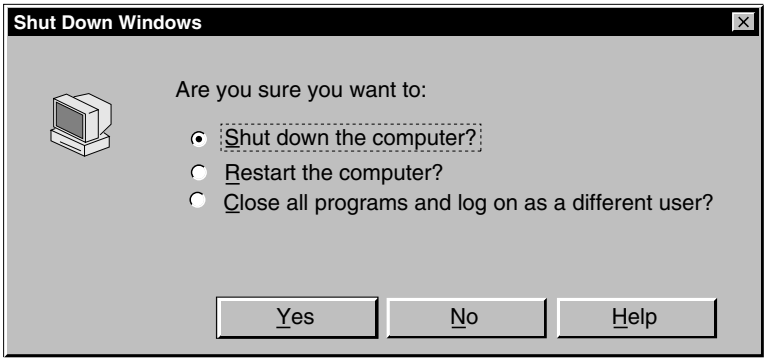


- To exit the program choose **Yes**.

- If you do not wish to exit the application software click on **No**. The Logon dialogue box will reappear.

1. Click on the “Start” button in the taskbar.
2. Click on **Shut down**.

   The Shut Down Windows dialogue box will appear.

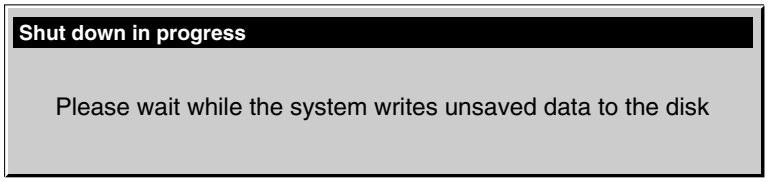


- To turn the IPU OFF click on **Yes**.
- To restart the IPU, click on **Restart the computer?** and then on **Yes**.

  After the restart the Logon dialogue box will appear.
- Clicking on **No** brings you back to the Logoff dialogue.
- To call up the online help click on **HELP**.

IPU shutdown

While the computer is shut down the message shown below is displayed.



Important!

Do not turn the IPU OFF as long as this message is shown on the monitor. This will prevent data loss and avoid possible system damage.

When the message shown below is displayed, the IPU can be turned OFF at the power supply.

Note:

Clicking on **Restart** will start the system again.

Afterwards all peripheral devices can be turned OFF.

6.22 Special functions

Work List

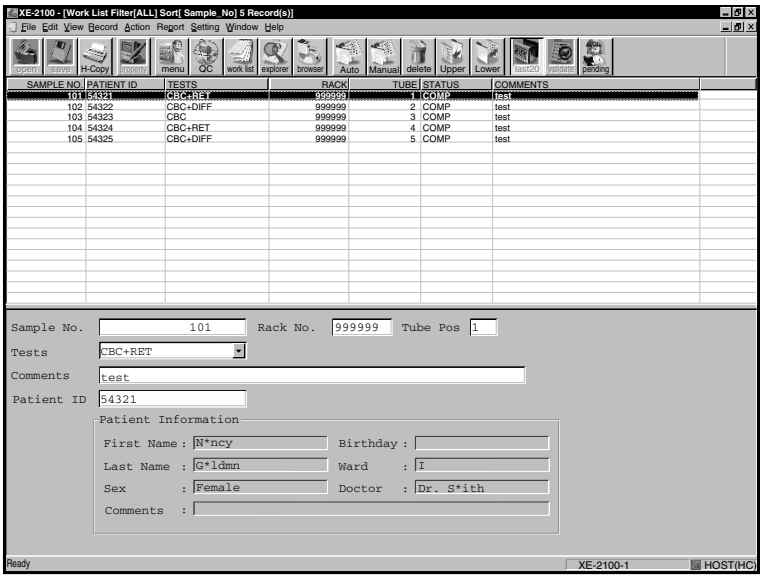
Important!

The Work List is only required when working without bar codes.

Before starting the analyse operation, the required data (patient information, analysis profile, etc.) are entered in the Work List. Afterwards the samples are processed.

To create a Work List proceed as follows:

1. Open the **Work list** window.



In the upper window pane the outstanding samples to be processed are displayed:

In the lower window pane an existing job can be edited or a new job added.

2. To create a new data record open the **Record** menu
   - and choose **Auto Add** (the sample ID will be incremented automatically)

   or:

   - choose **Manual Add** (the sample ID must be entered).

3. The cursor is in the “Sample No.” entry box. Enter the sample number. Use the Tab-key to move the cursor to the next entry box.

Sample No.	15 characters maximum
Rack	6 characters maximum
Tube	for Sampler mode only: a numerical between 1 and 10
Tests	Click on the arrow at the right of the entry box and choose the desired analysis parameters from the pull-down list.
Comments	additional information, for example the sample state (40 characters maximum)
Patient ID	16 maximum without blanks

4. Click on **Save** to store the information.

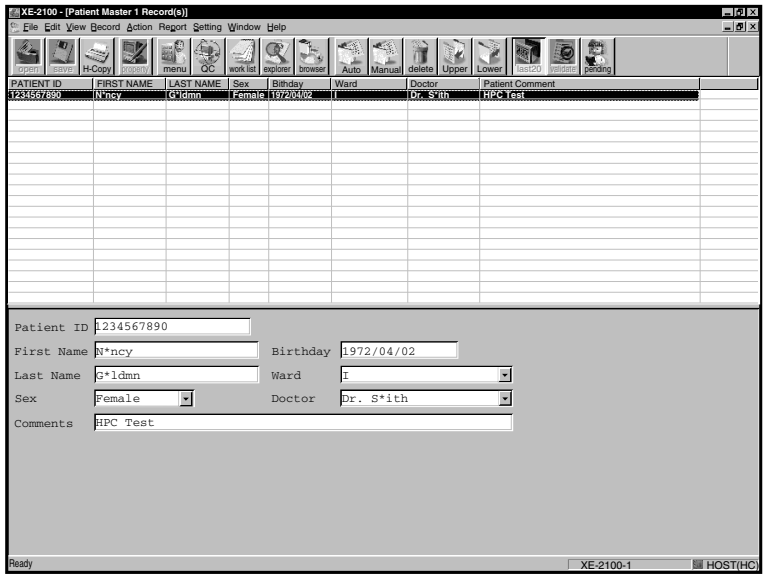
Note:

The following lists complement the Work List information.

Patient Master

– Open the **View** menu and choose **Menu** or click on the **menu** button.

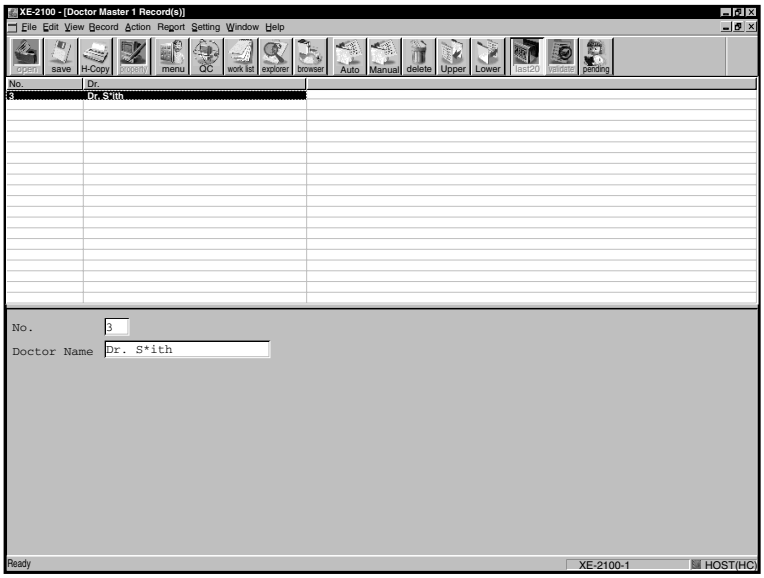
In the **Patient Master** window patient information saved on the hard disk drive (5000 data records maximum) can be viewed, saved, deleted or edited.



Doctor Master

– Open the **View** menu and choose **Menu** or click on the **menu** button.

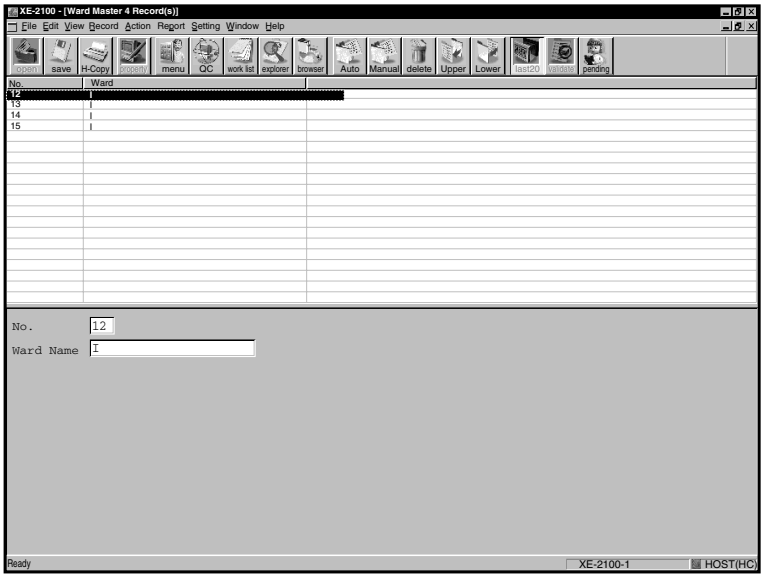
In the **Doctor Master** window doctor information saved on the hard disk drive (99 data records maximum) can be viewed, saved, deleted or edited.



Ward Master

– Open the **View** menu and choose **Menu** or click on the **menu** button.

In the **Ward Master** window ward information saved on the hard disk drive (99 data records maximum) can be viewed, saved, deleted or edited.



7. Display and output of analysis results

After each analyse operation the results of the analysis are displayed on the Main Unit's screen and at the IPU.

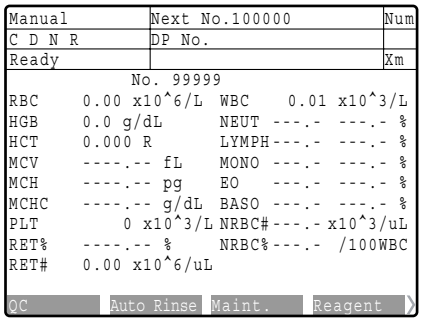
7.1 Latest sample

The XE-2100 saves the analysis results and histograms of up to 3 samples in the Main Unit. In a list date and time, sample number and errors are displayed.

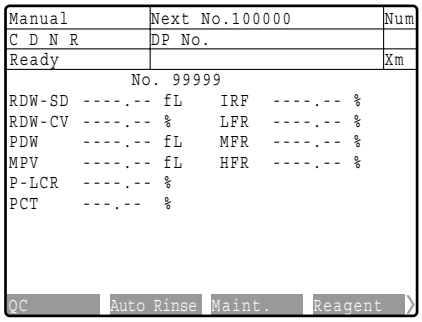
The analysis results can be highlighted in the list and the details viewed. Data no longer required can be deleted.

The entire display consists of five screen pages.

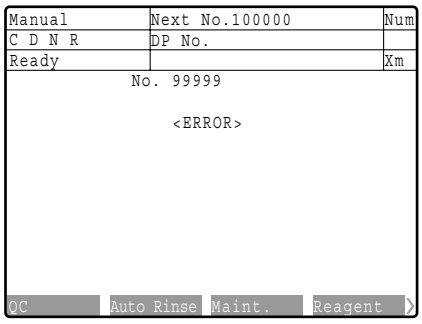
– Press ◀▶ to scroll through the screen pages. The following are displayed in succession:



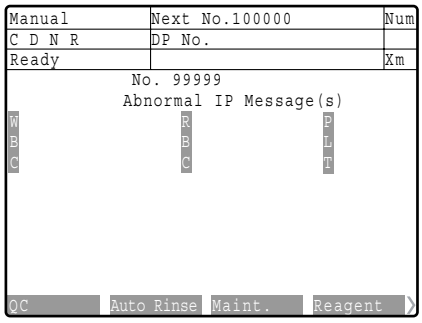
List of all analysis data



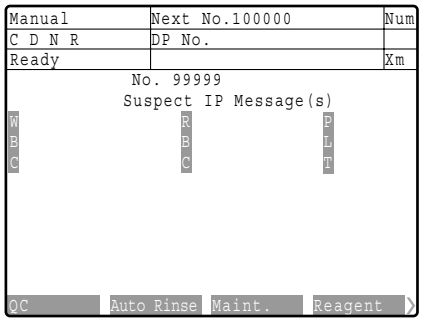
Additional parameters



Display of error messages



Abnormal message(s)



Suspect message(s)

Analysis data

Analysis data without preceding sign are within the preset limiting values. Preceding signs indicate an analysis result is out of the prescribed limiting values:

@	Value out of the linearity limits
+	Result exceeds the upper patient limit.
-	Results falls short of the lower patient limit.
*	Result is low in reliability.
&	Corrected value (e.g.if NRBC is present the WBC value will be corrected).

Note:

See chapter “13. Settings” how to change the patient limits.

If an analysis error has occurred and a value is not available, one of the following is displayed:

+++.+	Value exceeds display range
***.*	Value could not be calculated due to instrument failure.
---.-	Value could not be calculated due to data error.

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7.2 Display at the IPU

The data of up to 10,000 samples are saved in the IPU and can be displayed in various views after the analyse operation.

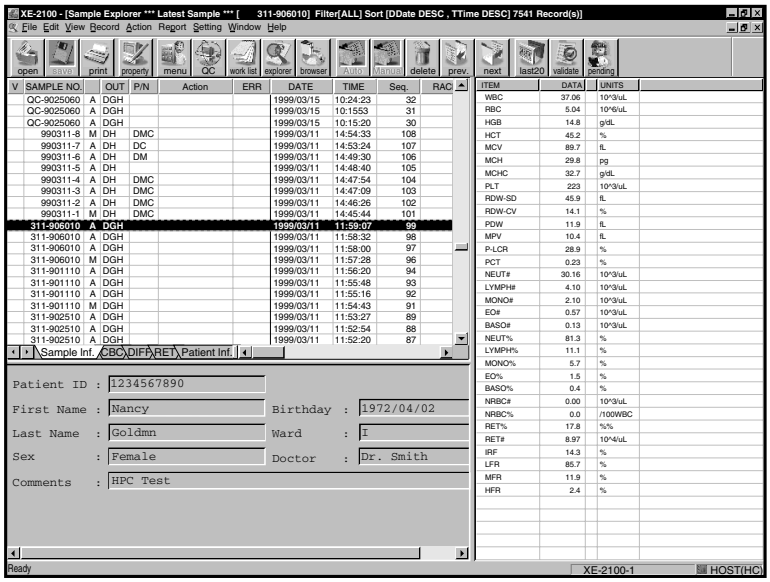
Note:

The analysis data can also be displayed and edited,

- while the Main Unit is still analysing samples,
- while a Shutdown is performed, or
- if the Main Unit is turned off.

List

The **Explorer** button will open a list displaying the analysis data of 20 samples.



The screen is divided into 3 window panes:

- display of sample data (contained on 5 tabs)
- list of parameters
- patient data

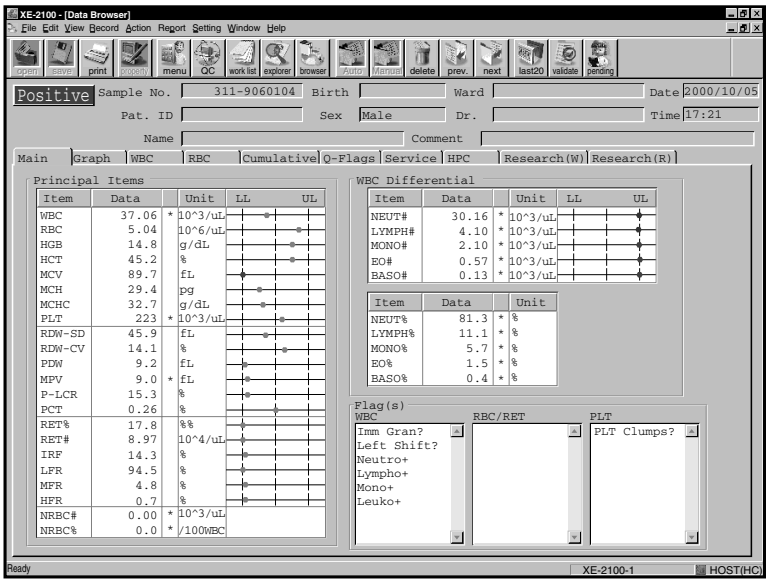
See chapter “8. Sample Storage (Explorer)” for more information.

Important!

To mark a sample, left-click on the corresponding line or click on the **prev./next** buttons. The line of the marked sample will be highlighted by a blue background.

Detailed information

The **Browser** button will open a window in which the analysis results of the highlighted sample are shown in a graphical representation.



Choose the appropriate tab for a representation as scattergram, histogram, etc.

See chapter “9. Data Browser” for more information.

8. Sample Storage (Explorer)

The **Explorer** shows a list of all saved samples. The XE-2100 can save the analysis results of up to 10,000 samples. The data are stored, even after the instrument is switched OFF.

Important!

If there are already 10,000 data records in the memory and a new analysis is performed, the oldest data record is deleted (first in, first out).

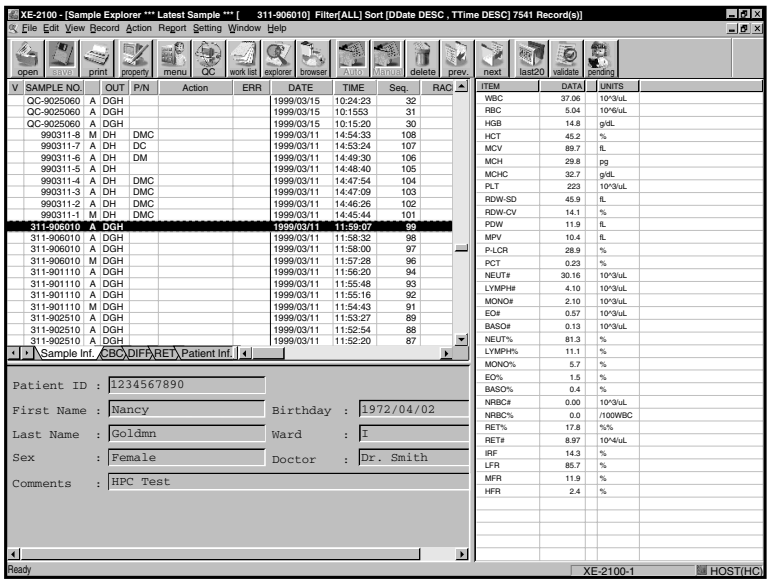
Data of selected samples can be copied to a floppy disk (refer to chapter “8.6 Backing up data”).

8.1 Opening the Explorer

To open the **Explorer**,

- click on the explorer icon, or
- open the **View** menu and select the **Explorer** submenu.

The list of data records will be displayed.



Note:

Backgrounds and samples without results are not displayed in this list.

There are various ways to scroll through the list:

- Use the mouse to move the scroll bar on the window's side, or click on the ▲ or ▼ arrows.
  Click on a line to highlight this sample.
- Press the ↑ or ↓ cursor keys on the keyboard.
- Click on the **prev.** or **next** button to go to the previous or next line.

When a sample is highlighted, the respective line is displayed in a different colour. The respective analysis results and numerical values are displayed on the right hand window pane. The respective patient data are displayed on the lower window pane.

8.2 LAST20

- To display only the 20 most recent samples, click on the **LAST20** button.
- To display all samples again, click on the **LAST20** button again.

8.3 Sorting the list

The list of data records can be sorted by sample ID, date and time of the analysis.

Sorting rules

Important!

The rules described below apply to the “ascending order”. With an “descending order” the sorting is made exactly opposite.

- The list begins with the data record having the least number of characters in this field.
- If there is an identical number of characters, the characters are compared starting from the left.
- The sequence of characters is:
  -, 0, 1, 2 ... 9, A, B, ... Z, a, b, ... z

1. Open the **Record** menu and select **Sort**.

   Important!

   This function is **not** available when only the last 20 samples are displayed. Change the display mode, if necessary (see chapter “8.2 LAST20”).

   A dialogue box showing the currently set sort keys will come up:

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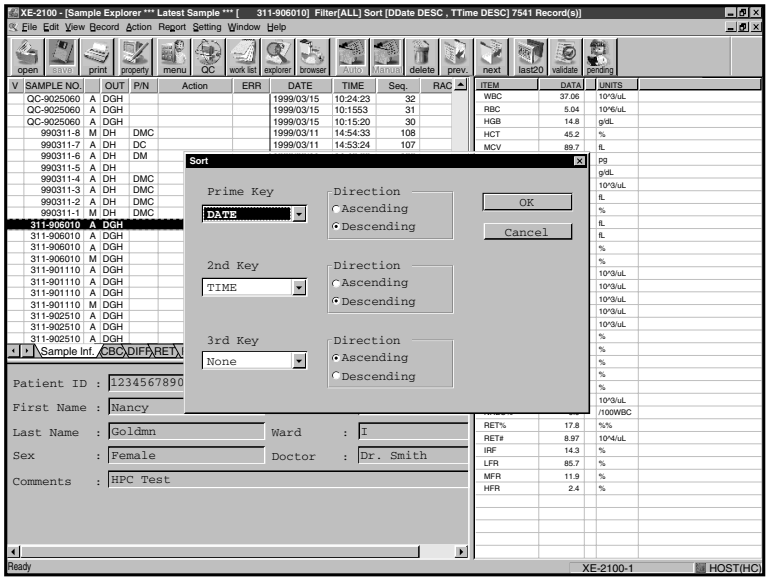


1. Set at least one sort key and select the desired sort order.
2. Click on **OK** to have the list sorted.

   or:

   Click on **Cancel**, if you do not want to have the list sorted.

The Explorer window will open. The data records are sorted according to your settings.

The settings for the sort criteria are displayed in the window's title bar:

Note:

The **Sort** function can be combined with the **Filter** function (see chapter “8.4 Limiting the list”).

8.4 Limiting the list

Since a list can be very extensive, it may make sense to limit the display.

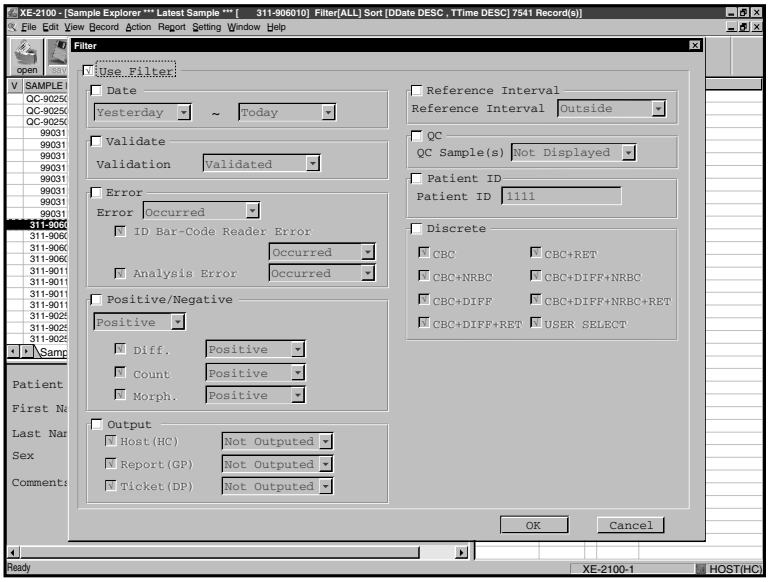
To display only specific data records of the entire list, proceed as follows:

1. Open the **Record** menu and select **Filter**

Important!

This function is **not** available when only the last 20 samples are displayed. Change the display mode, if necessary (see chapter “8.2 LAST20”).

A dialogue box showing the currently set filter criteria will come up:



2. Check if there is a check mark in the **Use Filter** check box.

   If not, click in the check box.

3. Activate the desired filters.
4. Enter the relevant values or select from the available options.
5. Deactivate the filters not to be applied.
6. Click on **OK** to apply the filters.

   or:

   To leave the list unchanged, click on **Cancel**.

The Explorer window will open displaying the data records matching the set filter criteria. The set filter criteria are displayed in the window's title bar:

Note:

The **Filter** function can be combined with the **Sort** function (see chapter “8.3 Sorting the list”).

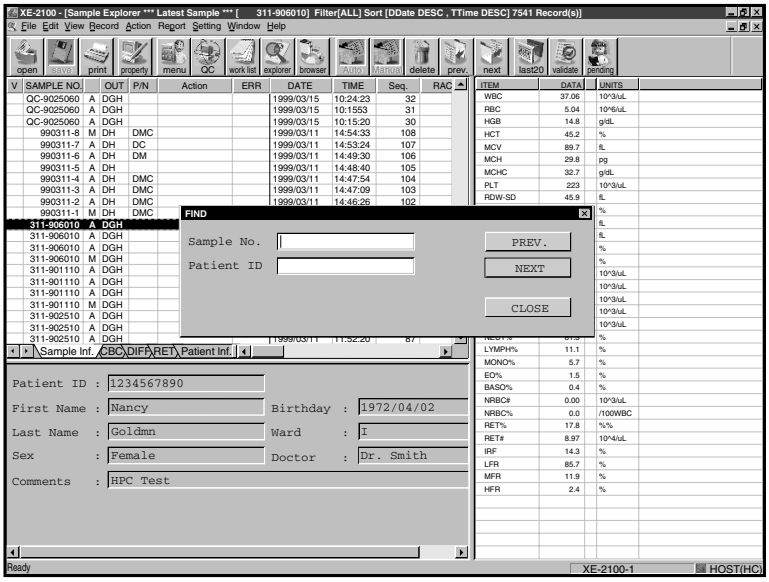
8.5 Searching the list

You can search the list for a particular data record by means of the sample ID and/or patient ID.

To do so, proceed as follows:

1. Open the **Edit** menu and select **Find**.

   The Find entry box for the search keys will come up.



2. Specify at least one search key.

Note:

In order to save typing in the complete sample ID or patient ID, respectively, wildcards can be used:

? represents any character

***** represents a string

Note:

The asterisk (*) may be used as wildcard only at the end of the search key

3. Click on **PREV.**, to search the list backward.

   or:

   Click on **NEXT**, to search the list forward.

   If a data record is found, it is highlighted in the list.

Important!

If no data record matches the search keys, the message “Not found!” will be displayed.

Change the search keys or search direction, if necessary. Check if the desired sample is not found because of a filter set.

– To continue the search with the same keys, click again on **PREV.** or **NEXT**.
– To end the search, click on the **CLOSE** button.

8.6 Backing up data

To save specific sample data onto a floppy disk, proceed as follows:

1. Open the **Explorer**.
2. Highlight the samples which contain the data you wish to save.

   To highlight a sample place the cursor on the relevant line.

   To highlight multiple samples, hold the **Ctrl** key down and left-click on the relevant lines.
3. Place a floppy disk in drive A.
4. Open the **Record** menu and select **Backup**.

   The Backup dialogue box will come up. A file name (made up of the date and time of the analysis) is suggested.
5. If you do no want to use this file name, specify a name for the backup file to be created or select a file.
6. To save all highlighted sample data, click on **Save**.

   or:

   Click on **Cancel** to cancel the backup.

Important!

The hard disk drive (drive C) is reserved for the system software. Use a floppy disk (drive A) for the backup.

8.7 Restoring data

To restore sample data saved on floppy disk to the system, proceed as under:

1. Open the **Explorer**.
2. Place the floppy disk in drive A.
3. Open the **Record** menu and select **Restore**.

   The Restore dialogue box will come up.
4. Select the file containing the desired sample data.
5. Click on **Open** to restore the data.

   or:

   To cancel the restore, click on **Cancel**.

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8.8 Deleting an analysis result

To delete analysis results proceed as follows:

1. Open the **Explorer**.
2. Highlight the analysis results you wish to delete.
3. Open the **Record** menu and select **Delete**.
4. To delete the analysis result, click on **OK**.

   or:

   Click on **Cancel** to cancel the deletion of the analysis result.

8.9 Sample properties

In the Sample Property entry box the following information can be changed:

- Sample ID number
- input of sample ID (increment, manual input, etc.)
- Sample rating (positive/negative)
- Patient ID number

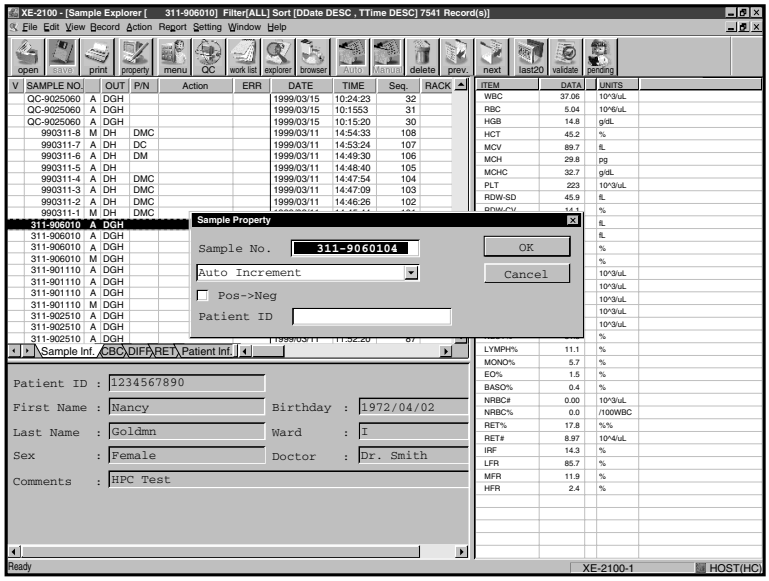
Note:

The sample properties can only be changed as long as a sample has not yet been validated.

To do so, proceed as follows:

1. In the list, highlight the data record you wish to edit.
2. If a validation needs to be undone, click on the **Validate** button.
3. Open the **Edit** menu and select **Property**, or click on the  (**property**) icon on the icon bar.

   The Sample Property entry box will come up:



4. Change the values or select an option.
5. Click on **OK** to save the changed data.

   or:

   To cancel any changes and keep the existing data, click on **Cancel**.

   The list of data records will be displayed again.
6. To validate the sample anew, click on the **Validate** button.

8.10 Tabs

In the **Explorer** different tabs are available. The display style and order style of these are configurable. For detailed information refer to chapter “13.5 Changing the display of the Work List, Sample Explorer and Data Browser”.

9. Data Browser

The **Data Browser** shows the following analysis result details of a sample:

- all numeric results,
- histograms,
- scattergrams,
- flag information.

The information is contained in several tabs.

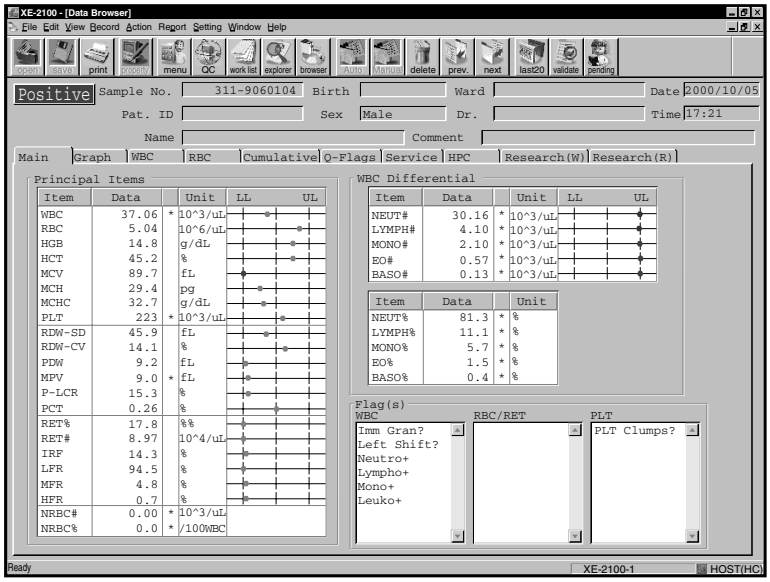
On the upper window section the general sample information is displayed – this is shown on each tab.

9.1 Opening the Data Browser

To open the **Data Browser**,

- click on the  icon,
- open the **View** menu and select **Data Browser**, or
- double-click in **Explorer** view on a line.

A view of the selected sample will be displayed.



Note:

When the **Browser** is called up, the last selected window or tab, respectively, will be displayed. After a restart and a sample analysis the Explorer is displayed.

Scrolling

There are two ways to display the previous or next sample:

- either click on the **Upper/Lower** buttons

  or

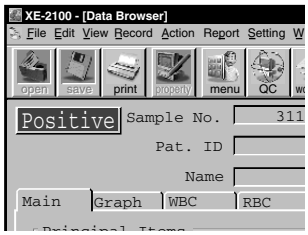
- press the ↑ or ↓ cursor keys on the keyboard.

9.2 General Information

Flags, interpretative messages

The system checks the numeric analysis data, the histograms, scattergrams, etc. to evaluate a sample.

To facilitate a quick discrimination of positive and negative samples, a colour marking is displayed at the upper left.



Green button = negative:
No analysis errors occurred and there are no interpretative messages.

Red button = positive:
Based on the preset criteria for numeric analysis values and cell morphology the sample has been rated abnormal.

In addition flags and interpretative messages (IP) are displayed, which provide more details on the test results.

Diff.	Abnormality in the leucocyte differential count parameters
Morph.	Abnormal cell morphology
Count	Abnormal cell count

– Double-click on the **Positive** button.

  A list showing the type of the messages will open. The IPs are explained in chapter “20. Appendix”.

Action messages

If the **Action** button is displayed, action messages exist.

– Double-click on the **Action** button.

  A list showing the action messages will open. The action messages are explained in chapter “20. Appendix”.

– Carry out the recommended actions.

List of error messages

If the **Error** button is displayed an error exists.

– Double-click on the **Error** button.

  The error list will open. The error messages are explained in chapter “20. Appendix”.

Sample information

Caution!

POSITIVE or ERROR judgments indicate the possibility of sample abnormality. Such results should be reviewed carefully and may require further examination in accordance with the protocol of your laboratory.

In the upper area of the window, information pertaining to the sample is shown:

Sample No.	Sample ID number
Pat. ID	Patient ID number
Name	Patient name
Birth	Patient date of birth
Sex	Sex of patient
Ward	Ward the patient is in
Dr.	Name of the patient's doctor
Comment	Comment on the sample
Date	Date analysis was performed
Time	Time analysis was performed

Note:

The order style of the boxes can be rearranged to suit individual preferences.

9.3 Tabs

“Main” tab

On this tab all numeric results, differential count and IP messages are displayed. The tab is subdivided into several sections.

Section name	Contents
Principal items	numeric data of up to 22 parameters
WBC Differential	absolute and percentage values of the 5 leucocytes sub-populations
Flag(s)	IP messages The flags are divided into three categories. • WBC • RBC/RET • PLT They are displayed on the Main, Graph, WBC, and RBC tabs.

Furthermore, it is distinguished between

- numerically quantifiable abnormalities of the sample (IP message “Abnormal”),
- suspected pathological abnormalities of the sample (IP message “Suspect”).

Caution!

These two types of IP messages are intended solely for use in the clinical laboratory and indicate possible abnormal results to the laboratory staff. As a result special measures can be taken or further analyses performed. **The IP messages are not for patient diagnosis!**

Abbreviations are explained in chapter “20. Appendix”.

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“Graph” tab

On this tab all numeric results, IP messages, scattergrams and histograms are displayed. The tab is subdivided into several sections.

Section name	Display
Items	numeric data of up to 22 parameters
WBC Differential	absolute and percentage values of the 5 leucocytes sub-populations
Flag(s)	IP messages (see above)
(Scattergrams)	two-dimensional scattergrams of DIFF, WBC/BASO, IMI, RET
(Histograms)	histograms of RBC and PLT

“WBC” tab

On this tab all numeric results, differential counts and IP messages as well as scattergrams of leucocytes are displayed. The tab is subdivided into several sections.

Section name	Display
WBC	numeric values of WBC
WBC Differential	absolute and percentage values of the 5 leucocytes sub-populations The **pie-chart** shows the Diff distribution as colour representation.
NRBC	absolute and percentage values of the NRBC parameter
Flag(s)	IP messages for WBC
(Scattergrams)	two-dimensional scattergrams of DIFF, WBC/BASO, IMI, NRBC

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“RBC” tab

On this tab all numeric results, differential counts and IP messages as well as scattergrams of erythrocytes are displayed. The tab is subdivided into several sections.

Section name	Display
Items	numeric values of RBC
Flag(s)	IP messages for RBC/RET and PLT
(Scattergrams)	two-dimensional scattergrams of RET and PLT-O
(Distribution)	histograms of RBC and PLT

“Cumulative” tab

On this tab all saved data of samples collected to date from this patient (i.e. the same patient ID!) are displayed and changes indicated by seven measured values.

Proceed as follows:

1. Select the reference data in the **Sample Explorer** list.

   

   Note:

   If you do not select any other data, the latest data will be used as reference.

   If you select an older data record from the saved data as reference, only the data **collected before** the selected data record will be considered.

2. Select a category (CBC, DIFF, RET).
3. Select the type of representation (numerical, chart, or scattergram/histogram).

   The selected results will be displayed.

   

   Note:

   Up to seven results – including the reference data – can be displayed simultaneously.

In the **Delta Check** section it is indicated whether the data are abnormal or not. The rating is based on the relation between the reference data record and the development of the analysis data.

Check Sample: A wrong sample was possibly analysed, a mistake may have occurred.

Check Film: For this sample a smear should be created.

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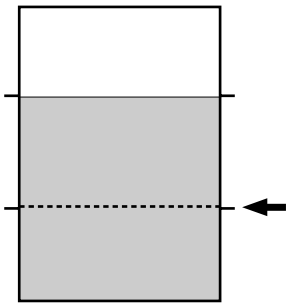
“Q-Flags” tab

In the bar chart, NEGATIVE judgments of the sample are diplayed in green, and POSITIVE judgments are diplayed in red. In the Sample Judgment Information area below the histogram, judgment values are displayed. These values range from 0 - 300, in increments of 10. When judgment is not or cannot be performed, the reason is indicated as “Discete” or “Error” underneath the bar chart.



This is the border line between POSITIVE and NEGATIVE. Values above this level are POSITIVE. Values below it are NEGATIVE.

Following is the reason for each message:

Discrete	no rating, because parameter was not requested
Error	no rating due to an analysis error

Note:

Please note the Q-Flag feature of the XT analyzers are designed with adjustable settings capable of being customized to meet the individual requirements of your laboratory.

This procedure must be performed by an authorized Sysmex representative working closely with your laboratory personnel. When Q-Flag settings are adjustes, the performance characteristics for sensitivity and specificity of sample flagging may also change.

Therefore, it is the responsibility of your authorized laboratory staff to appropriately validate and approve potential changes in performance characteristics resulting from adjustments in Q-Flag settings.

Appropriate documentation related to validation and approval should be retained as an integral part of your ongoing Quality Assurance program.

“Service” tab

On this tab the service data of the highlighted sample are displayed. Seven categories are available to select from.

“HPC” tab

On this tab the human progenitor cell monitoring information is displayed.

“Research (W)” tab

On this tab the research parameters of the “white cells” are displayed.

“Research (R)” tab

On this tab the research parameters of the “red cells” are displayed.

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10. Output

Analysis results and the values of quality controls or calibrations, respectively, can be output on a connected device or transmitted to a host computer.

Important!

Only validated samples can be output. By using the **Validate** button, the sample can be validated manually.

There are various options to start the output:

– On the **Report** menu choose a system in the list.

HC	output to host computer
DP	output to data printer
GP	output to graphics printer
LP	output to line printer

The output is made to the selected system.

Note:

If a line is greyed out, this system is not enabled.

– To make a “hardcopy”

- choose **Print** on the **File** menu,
- simultaneously press the **Ctrl** and **P** key, or
- click on the  button.

A hardcopy of the screen will be printed on the default printer.

Note:

The default printer is set in the Windows NT/2000 operating system.

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11. Quality Control

Quality controls ensure instrument and reagent reliability. With quality controls the stability of the measured values is monitored over an extended period of time and problems are detected early on or prevented.

A quality control should be performed:

- before any start of operation – prior to analysing samples,
- at least every 8 hours during operation,
- after replenishment of components,
- after maintenance,
- if there is any doubt about the accuracy of the analysis values.

11.1 Control material

As control material e-CHECK Level 1, e-CHECK Level 2, e-CHECK Level 3 is used. This is equivalent to the Low, Normal and High level.

Important!

Do not use any other control material than e-CHECK Level 1, e-CHECK Level 2 and e-CHECK Level 3. This control material is specially matched to the analyser's measuring technology.

11.2 Control methods

The XE-2100 offers different control methods. Choose the control method meeting your laboratory's internal regulations.

$\overline{X}$ control

Control blood will be analysed. For the $\overline{X}$ control two analyses are performed in succession (repeat determination). An average is derived from both results and saved as QC data.

Levey-Jennings control

Control blood will be analysed. For the Levey-Jennings control only one analysis is performed (single determination) and the result saved as QC data.

Xbar-M control

The Xbar-M control should be run in the background, parallel to one of the control methods mentioned above.

During daily analyse operations the average values of a defined number of samples are calculated and saved. The

Xbar-M control is a flexible weighted average. It is used for as a means to check the functionality of the analyser.

See chapter “11.3 Preparations” on how to set the settings of the Xbar-M control.

11.3 Preparations

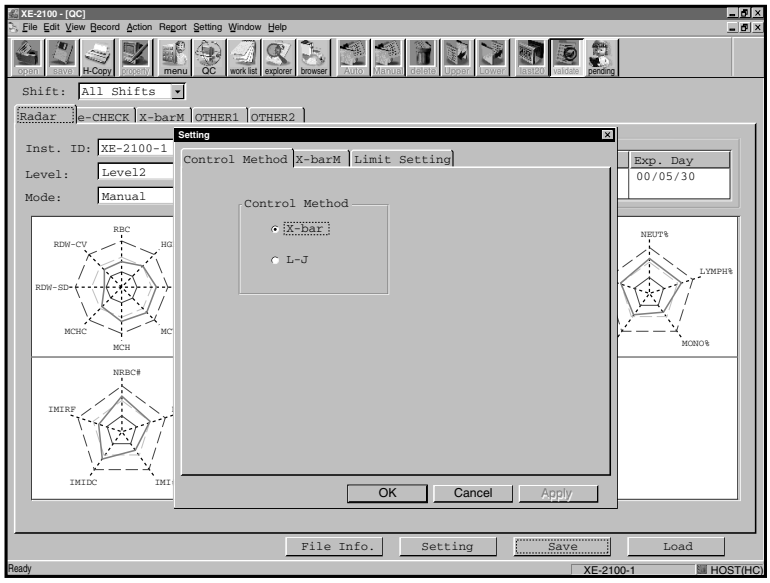
Important!

Main unit and IPU must be ready to operate.

Control method selection

If you wish to perform the $\overline{X}$-control or Levey-Jennings control, proceed as follows:

1. At the IPU open the **QC** menu.
2. Click on the **Setting** button.
3. On the **Control Method** tab choose the desired control method:
   X-bar for $\overline{X}$-control
   L-J for Levey-Jennings control



4. Confirm with **OK**.

Enabling/disabling the X-bar-M control

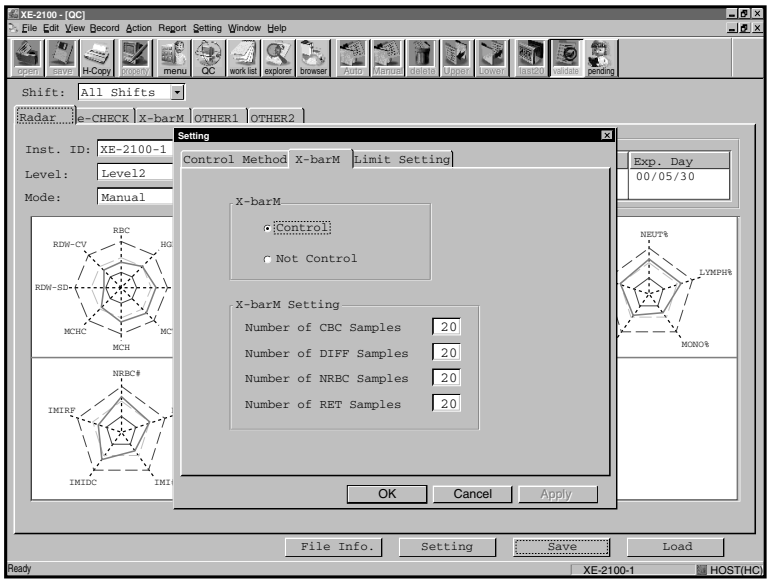
1. At the Main Unit choose the **QC** function.

   The QC menu will open.

2. On the QC menu choose the **Xm STT/STP** function.
   - If **Xm** is displayed on the upper right of the screen the XbarM control is enabled.
   - If **Xm** is not displayed the XbarM control is disabled.

To change the settings proceed as follows:

1. At the IPU open the **QC** menu.
2. Click on the **Setting** button.
3. Click on the **X-barM** tab.



- If the X-barM control is not to be performed check the **Not Control** option.
- If the X-barM control is to be performed check the **Control** option. Enter the number of samples of which an average for the QC data is to be calculated (batch size).

Important!

The following batch sizes are recommended:

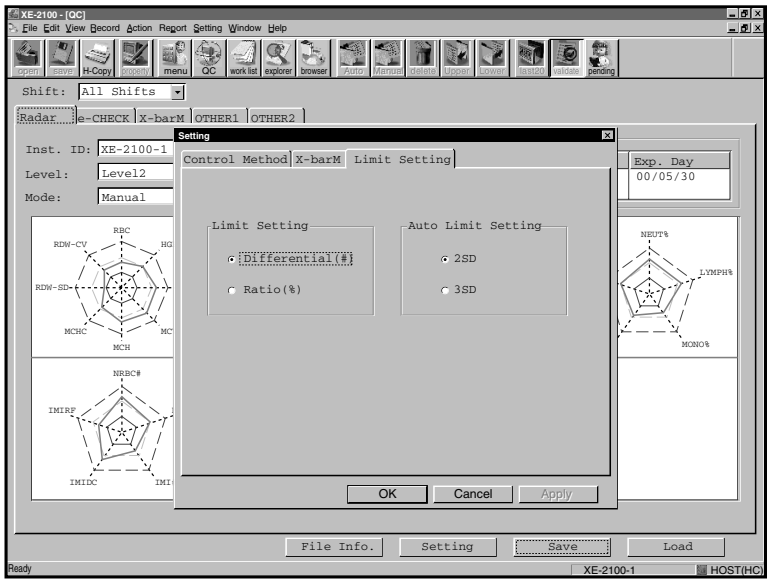
Laboratories with up to 150 samples per day:	approx. 30
Laboratories with up to 300 samples per day:	approx. 40
Laboratories with more than 300 samples per day:	approx. 50

The batch size should not be set higher since sensitive will be lowered.

Limit setting

1. Click on the **Setting** button.
2. Select the **Limit Setting** tab.
3. In the **Limit Setting** section select the type of output of the QC limits:

Differential (#)	The limit is calculated as a numerical value with respect to the average value (TARGET).
Ratio (%)	The limit is calculated as a percentage with respect to the average value (TARGET).



4. In the **Auto Limit Setting** section choose the limit deviations:

2SD	Limit standard deviation 2SD range
3SD	Limit standard deviation 3SD range

Preparing control blood

Warning!

Control blood can contain potentially pathogenic germs. To prevent any danger of infection always wear rubber gloves when handling control blood. After completion of work, wash hands with disinfectant.

1. Remove a vial of control material from the refrigerator and equilibrate to room temperature (18–30 °C) for 15 minutes before use.

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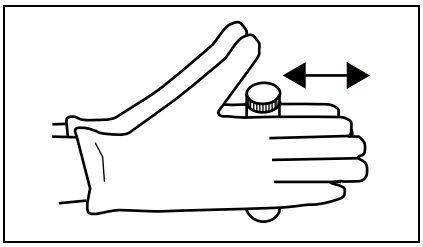

2. Place the vial between the palms and roll it back and forth 10 times (see illustration).
3. Turn the vial upside down and roll 10 more times.
4. Repeat steps 2. and 3. eight times or a total of 2 minutes.

Important!

Examine the bottom of the vial and assure that mixing is complete by confirming that there is no pellet of cells adhering to the bottom of the vial **before** performing the analysis.

Wipe the rim of vial and cap **after** performing the analysis with a lint-free cloth before recapping. Recap vial tightly. Store at 2-8 °C in an upright position.

11.4 Performing a quality control

QC analysis in Sampler mode

If working in Sampler mode, a quality control sample can be set together with other samples in a rack.

Important!

In Sampler mode only the Levey-Jennings control can be performed.

Prescribed control material must be used, **or** a bar code label for the QC file must be on the sample tube.

Bar code labels must either be of the CODABAR or NW-7 format. The first and last character have to be a “C”. Between the two must stand the file number. Therefore only the file numbers 1 though 9 can be used.

Example: for file number “1” the label must be marked “C1111111C”.

1. Prepare the control blood (see chapter “11.3 Preparations”).
2. Perform the analysis as detailed in chapter “6.14 Analysing in Sampler mode”.

   The QC analysis results are output like regular analysis results, or they can be assessed in more detail on the QC menu (see section “Assessing a quality control”).

QC analysis in Manual mode

1. At the Main Unit select **QC**.

   The QC menu will open.

2. On the QC menu select the **Exec. QC** function.

   The **Select Files** dialogue box will open; it contains a list of QC files.

3. Select the file number of the file you wish to save the analysis results in. If necessary, press ▼ to move down the list.

4. Select **Select**.

5. Analyse the sample as detailed in chapter “6.15 Analysing samples in Manual mode”.

   The QC analysis results are output like regular analysis results, or they can be assessed in more detail on the **QC** menu (see section “Assessing a quality control”).

6. To exit the program select **Return**.

QC analysis in Closed mode

1. At the Main Unit choose **QC**.

   The QC menu will open.

2. Choose **Exec. QC**.

   The **Select Files** dialogue box will open; it contains a list of QC files.

3. Select the file number of the file you wish to save the analysis results in. If necessary, press ▼ to move down the list.

4. Choose **Select** on the Functions menu.

5. Analyse the sample as detailed in chapter “6.17 Analysing samples in Closed mode”.

   - The **Execute X** functions analyses the control blood two times in succession. The average value of these measurements is saved as QC value.
   - Using the **Execute L-J** function the control blood is analyse once. The result of this measurement is saved as QC value.

   The QC analysis results are output like regular analysis results, or they can be assessed in more detail on the **QC** menu (see section “Assessing a quality control”).

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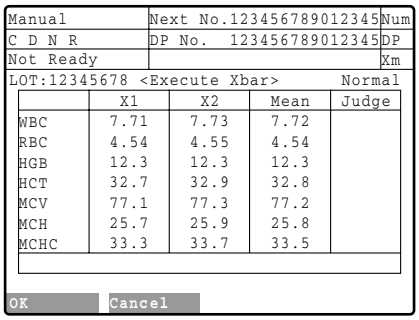
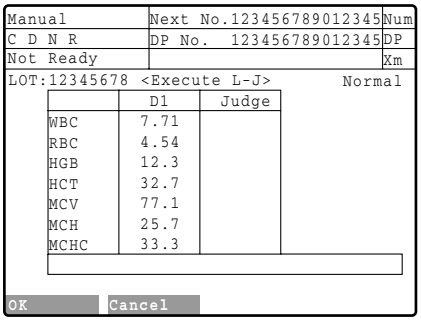
11.5 Displaying QC data

When the QC analysis is completed, the data are saved and displayed on the Main Unit's screen.



Display of the Xbar control



Display of the L-J control

The following messages or markers may be shown:

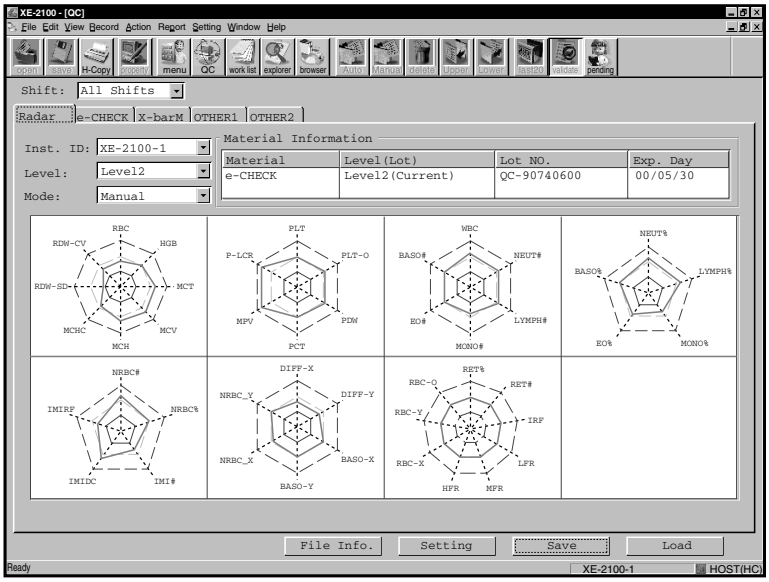
+ in the Judge column	Parameter is above the limit.
- in the Judge column	Parameter is below the limit.
Check QC Chart	The analysis results exceed the control limits. Check the graph and reanalyse, if necessary.
Re-analyze the sample (+ and - shown on grey background)	The analysis results exceed the control limits threefold. The values will not be saved. Reanalyse.

Assessing a quality control

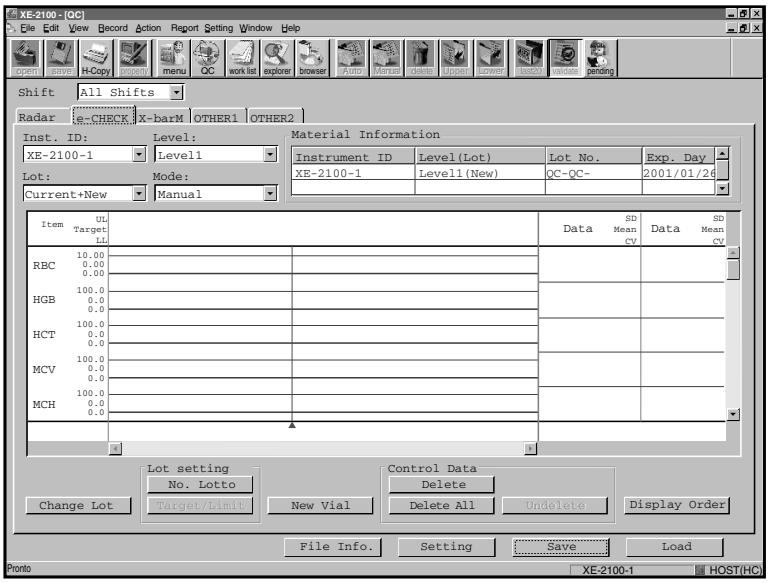
Detailed information about the QC results can be displayed at the IPU.

1. Open the **QC** menu at the IPU.

The QC screen will be displayed.



2. Select the **e-CHECK** tab.



3. Select the level of the control material to be read.
4. Select the mode (closed or manual).

Note:

To display the lower part of the screen with more parameters, use the scroll bar at the right of the window pane.

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Internal quality control

If a QC analysis with e-Check on average does not produce the values stated on the assay sheet, either the haematology analyser used, the reagent used or the control blood are faulty. Measures to locate the error:

1. Make sure that
   - no additional error messages are displayed
   - the cleaning cycles are kept
2. Check the reagents used:
   - expiration dates must not be exceeded
   - has the prescribed storage temperature been kept?
   - reagents should not be contaminated
3. Check the e-Check used:
   - expiration dates must not be exceeded
   - has the prescribed storage temperature been kept?
4. Analyse a fresh vial of e-Check.

Note:

In case of any discrepancy contact the Sysmex service.

Printing QC data

1. At the IPU open the **QC** menu.
   The QC screen will come up.
2. Select the **e-CHECK** tab.
3. Set the desired level and mode (closed or manual).
4. To print the QC data open the **Report** menu and choose a system in the list.

   GP output to graphics printer

   LP output to line printer

   The output is made to the selected device.

Note:

QC files can only be printed on the graphics printer or line printer. If a line is greyed out, this device is not enabled.

Deleting QC data

In cases where the result is considered faulty or when an incorrect control blood was used, the data of one or multiple quality control measurements can be deleted.

To do so, proceed as under:

– To delete the QC data record under the cursor, click on the **Delete** button.

or:

– To delete all QC data of the currently displayed file, click on the **Delete All** button.

Important:

Deleted data will no longer be displayed on the screen. However, they will remain saved until the display changes or the QC display is closed; they can be restored by clicking on the **Undelete** button.

– To undo the deletion of QC data, click on the **Undelete** button.

Saving

Lot information and QC data can be saved to floppy disk.

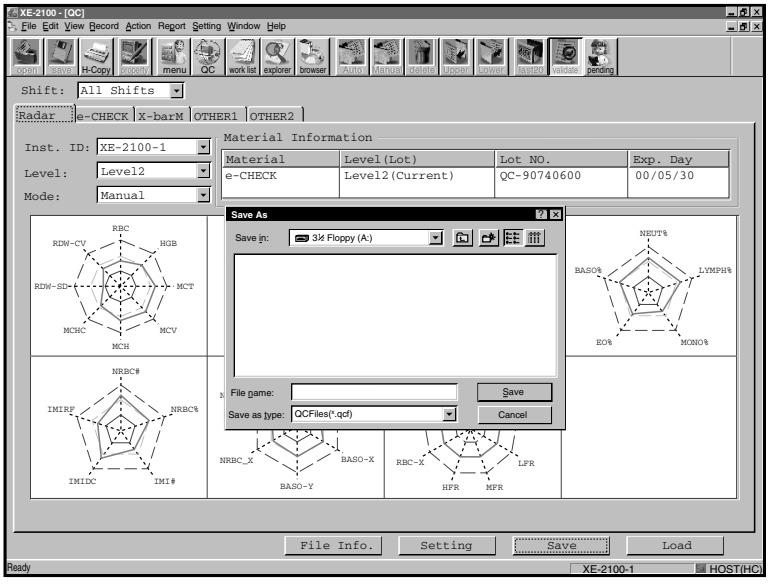
1. Place the floppy disk in drive A.

Important!

The hard disk drive (drive C) is reserved for the system software. Use a floppy disk (drive A) for the backup.

2. Click on the **Save** button.

The Save As dialogue box will open.



3. Enter the file name of the file you wish to save.
4. To save all lot information and QC data saved under the file name to the floppy disk, click on **Save**.

   or:

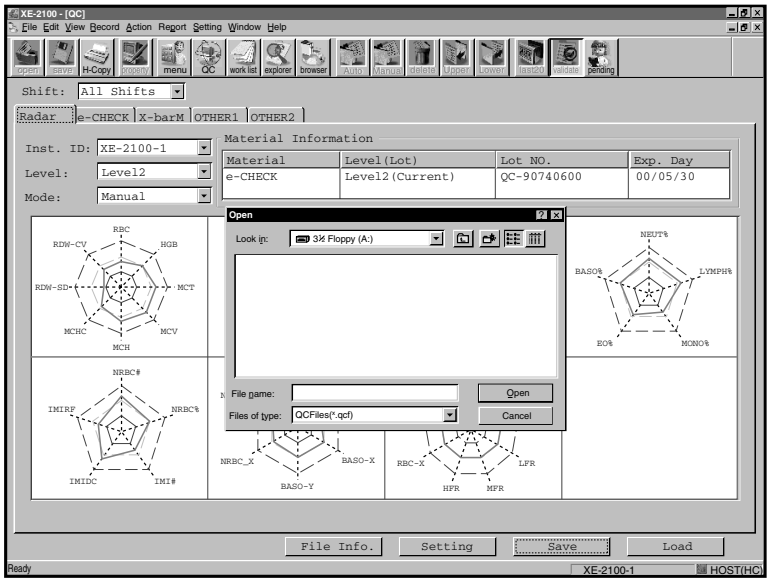
   Click on **Cancel** to abort saving.

Read-in

If necessary, lot information and QC data can be read-in from floppy disk.

1. Place the floppy disk in drive A.
2. Click on the **Load** button.

The Open dialogue box will appear.



3. Select the name of the file you want to read in.
4. To display the lot information and QC data saved on the floppy click on **Open**.

   or:

   Click on **Cancel** to abort the process.

Note:

The data will be read back from the floppy disk to the QC program. To display the current data again, press **Esc** to exit the screen. Change the display by, for instance, opening another tab.

11.6 Read-in of a new quality control

Reading values from floppy disk

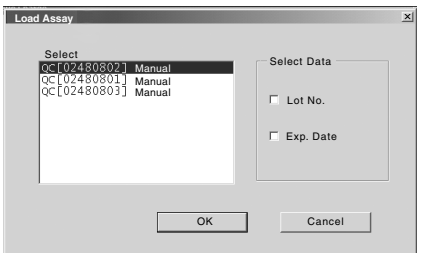
1. Put the floppy disk supplied with the control material in drive A.
2. At the IPU open the **QC** menu.

   The QC window will open.
3. Choose the **e-CHECK** tab.

   Important!

   The quality control should be measured at all three levels and both manual and closed mode (according to local requirements). This means the process detailed below should be performed up to six times.
4. Choose the level of the control material to be read.
5. Choose the mode (Closed or Manual).
6. In the **Lot.** box choose the option **New**.
7. Click on the **Lot No.** button of the **Lot Setting** section.
8. Choose **Read FD**.

   A list will come up.



9. Select the relevant QC file in the list.
10. When selecting the data, check if both Lot No. and Expiry Date are checked.
11. Click on **OK** to exit the list.
12. Confirm again with **OK**.
13. Click on the **Target/Limit** button of the **Lot Setting** section.
14. Mark all parameters with the mouse; they will be highlighted by a blue background.
15. Choose **Read Assay**.
16. In **Select Data** check the **Target** and **Limit** option or **Limit** only.
17. Confirm your selection with **OK**.
18. Confirm again with **OK**.

Change

For each lot of control blood information is saved. To convert the new lot into a current lot proceed as follows:

1. At the IPU open the **QC** menu.

   The online help will be displayed.
2. Choose the **e-CHECK** tab.

3. Choose the level of the control material to be read.
4. Choose the mode (Closed or Manual).
5. Click on the **Change Lot** button.

   The message “Current Lot Data will be Replaced By New Lot Data.” is displayed.
6. Click on **Yes**.
7. Insert the floppy disk the data are to be saved to, or choose the relevant folder on the hard disk.
8. Specify a file name.
9. Click on **Save**.

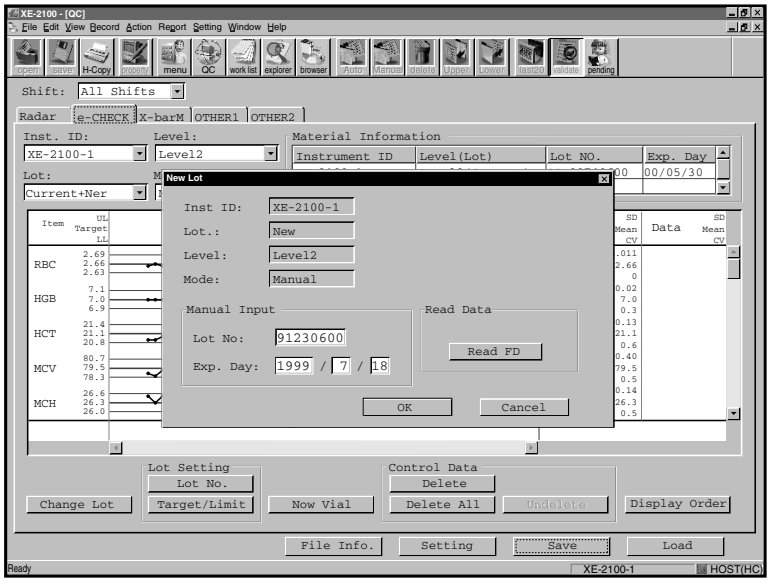
Important!

The quality control should be measured at all three levels and both manual and closed mode (according to local requirements). This means the process detailed below should be performed up to six times.

Manual input

1. Click on the **Lot No.** button.

The New Lot dialogue box will come up.



2. Input the lot information:
   - lot number
   - control blood expiry date
3. Click on **OK** to close the dialogue box. A dialogue box for the confirmation of target and limit values will open.

   Click on **Cancel** to ignore the values entered and close the dialogue box.
4. Click on **Yes** or **No**.

Yes: a dialogue box for setting the target and limit values will come up.

No: variable limits will be set. For these limits the current values will be copied from the corresponding file.

11.7 Additional information on the QC menu

Tabs

Various graphs – depending on function and type of the control blood – can be displayed using the tabs.

The **Radar** tab displays the newest QC data as “Radar graphs”.

On the **e-CHECK**, **X-barM**, **OTHER1** and **OTHER2** tabs the relevant QC data are shown as bar-graphs.

– Select the desired settings, if necessary:
  - instrument ID (if two main units are connected);
  - QC material level;
  - lot of the QC material to be represented;
  - mode (Closed or Manual).

Above the graphs the information pertaining to the control material is displayed.

With the buttons below the bar-graphs the following can be set:

- **Change** changes between the lots
- **Lot Settings**
  Lot No. for entering the control material's lot number;
  Target/Limit for input of the target and limit values of the control material.
- **New Vial** places a blue vertical line at the position a new vial was opened.
- **QC data**
  Delete
  Delete All
  Undelete
- **Display Order** opens a list, in which the display sequence of the parameters can be changed.

Shifts

If the XE-2100 operates in shifts, a shift can be assigned to each user. This way the quality control can be performed correctly for each shift (see also chapter “Settings”).

– Select the desired shift or **All Shifts**, respectively, if not operated in shifts.

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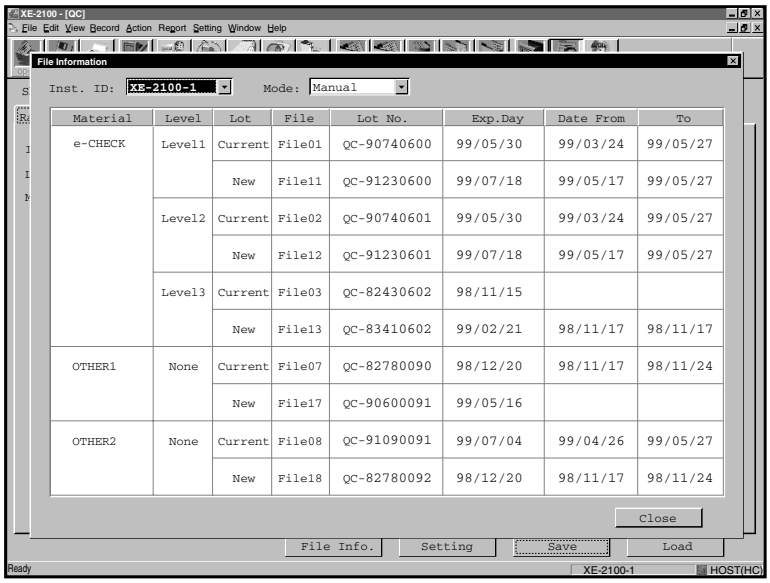
File information

– Click on the **File Info.** button to display a list of QC file information.

The contents of this list depends on the type of analysis.



Material	Level	Lot	File	Lot No.	Exp.Day	Date From	To
e-CHECK	Level1	Current	File01	QC-90740600	99/05/30	99/03/24	99/05/27
		New	File11	QC-91230600	99/07/18	99/05/17	99/05/27
	Level2	Current	File02	QC-90740601	99/05/30	99/03/24	99/05/27
		New	File12	QC-91230601	99/07/18	99/05/17	99/05/27
	Level3	Current	File03	QC-82430602	98/11/15		
		New	File13	QC-83410602	99/02/21	98/11/17	98/11/17
OTHER1	None	Current	File07	QC-82780090	98/12/20	98/11/17	98/11/24
		New	File17	QC-90600091	99/05/16		
OTHER2	None	Current	File08	QC-91090091	99/07/04	99/04/26	99/05/27
		New	File18	QC-82780092	98/12/20	98/11/17	98/11/24

– If necessary, select individual analyser for data display by using the **Inst. ID** list box.

Note:

This is only required if several XE instruments are connected.

– Select the **mode** (Closed or Manual).

– To close the list click on **Close**.

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12. Calibration

Calibration is performed to compensate for any reproducible inaccuracies of the system. The HGB and/or HCT values are corrected by a calibration value.

In **automatic calibration** the reference values of 5 samples are entered. The instrument determines the calibration value automatically.

In **manual calibration** the calibration value must be calculated according to a designated formula and entered.

The XE-2100 needs to be calibrated:

- before initial operation (carried out by the Sysmex service representative!);
- when quality controls show deviations in the same direction which are determined repeatedly;
- when a major component, such as the sample rotor valve, has been replaced.

Caution!

Calibration needs not to be performed at specific intervals. Follow the internal laboratory regulations for performing a calibration, if existing.

Abnormal QC data due to instrument problems, reagent degradation, or deterioration of control blood can not be eliminated by calibration.

12.1 Samples used for calibration

For calibration, use five or more samples of fresh normal blood meeting the following conditions:

- blood of a healthy person who is not taking any medicine;
- blood added with an appropriate quantity of anticoagulant;
- per-sample whole blood volume to exceed 2 mL;
- HGB value to exceed 10.0 g/dL;
- HCT value to be within 35.5 % and 55.5 %.

Important!

Control blood is **not** suitable for calibration.

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12.2 Establishing the reference values

As reference values for calibration HGB and HCT values are determined on another, calibrated instrument.

Recommended measuring methods:

HGB: Determination of haemoglobin concentration (DIN 58931)

HCT: Determination of the concentration of blood corpuscles in blood (DIN 58933)

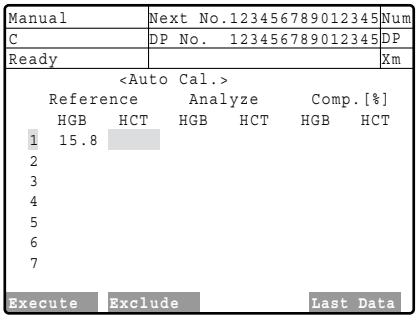
Important!

Each sample should be analysed at least three times.

- Mark or number the samples and make notes of the values determined.

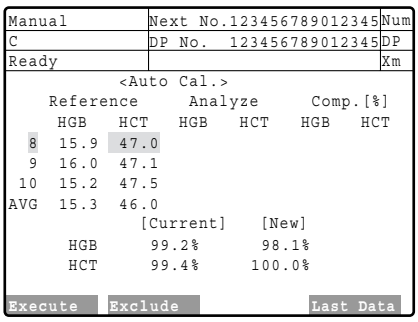
12.3 Automatic calibration

Invoking the automatic calibration function



1. To display the additional menu items on the Main menu's second screen page press **MORE**.
2. Choose **Cal.**.
   The calibration log will be displayed.
3. Choose **HGB/HCT**.
   The Auto Calibration screen will open.
   If you want to abort the calibration click on **Return**, then confirm with **OK**.

Entering reference values



– Enter the reference values determined in the **Reference** column.

- Use the **C** key to delete a character.
- Pressing **ENTER** or ▲▼ confirms the input; the cursor moves to the next field.

Note:

If multiple values are entered, the average is calculated and displayed in the **AVG** line of the second screen page.

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Preforming analyses

When all target values have been entered, the instrument is ready for analysing.

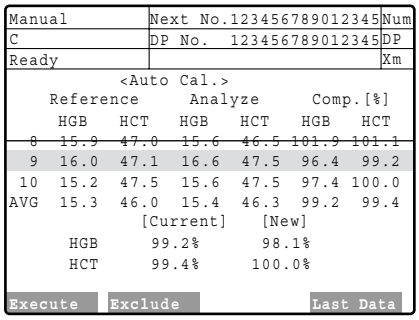
Important!

The automatic calibration must take place in Manual or Closed mode. By default the **CBC** profile is used.

– Analyse the samples in succession.

Important!

It is important to analyse the sample belonging to the reference value. The values of the sample to be analysed are indicated by the underline cursor.



When an analysis was performed, its values are listed in the **Analyze** column. In the **Compensation** column the calculated calibration values are shown. If more then one sample is analysed, a mean value is derived from the different values.

Exclusion

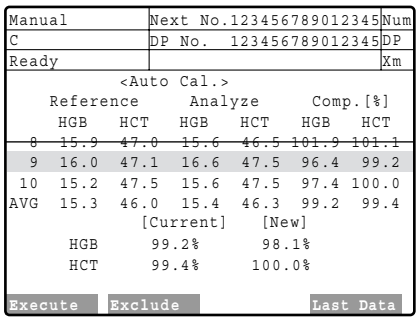
If the calibration value is very distant to 100 %, such results should be excluded from the calibration value calculation.

Reasons may be:

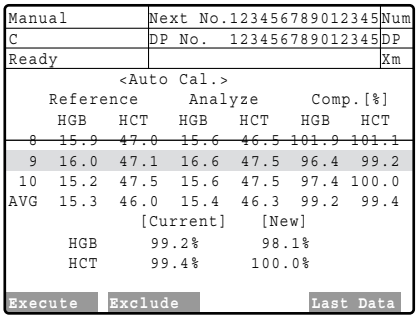
- insufficient mixing
- analysis errors

Note:

If required, such excluded results can be restored.



1. Using the cursor ▲▼ keys, move the cursor to the line with the results you wish to exclude.
2. Choose **Exclude**.



The line is striked through. The averages of reference values, analysis results and calibration values are recalculated, without the values of the striked-through line. The cursor will move to the next line.

– Exclude further results, if necessary.

Important!

Be sure at least 5 result lines remain.

Note:

To admit the excluded result(s) again, highlight the respective striked-though line and press **Exclude** again.

Updating calibration values

– After all analyses have been performed choose **Execute**.

Based on the current calibration value and the value determined by the analyses a new calibration value is calculated.

Important!

A calibration error is displayed, if

- the value determined by the analyses exceeds 105 % or is less than 95 %;
- the new calibration value exceeds 120 % or is less than 80 %.

– Choose **OK** to return to the previous display and continue with the automatic calibration.

– Repeat the analysis of the calibration sample with the XE-2100. Make sure the analysis results are within the permitted range and do not deviate too much from the reference values.

– Perform the calibration again if the HGB and HCT values are much higher are lower than the reference values.

Important!

If, after repeated calibration, the analysis values are not within the permitted range or abnormal results have occurred, check

- sample coagulation
- blood cell morphology
- patient drug intake
- patient age

If the samples show no abnormal data, contact Sysmex service.

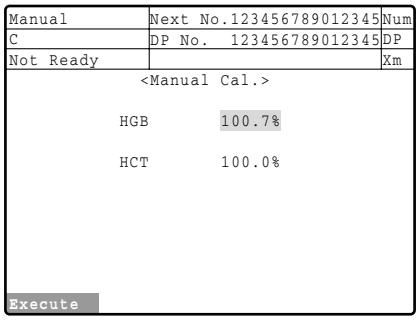
Note:

If the new calibration value exceeds 120 % or is less than 80 %, a manual calibration can be carried out.

12.4 Manual calibration

Reading the current calibration value

1. To display the additional menu items on the Main menu's second screen page press **MORE** key.
2. Select the **Calibrate** function.
3. Select the **Manual** function.
   The calibration log will be displayed. The current calibration values are displayed on the Manual Calibration screen.



Calculating the calibration value

1. Establish the reference values as described above.
2. Calculate the average.
3. Analyse the samples in WB mode (see chapter “6. Operation”).
4. Calculate the average.
5. Calculate the calibration value using the following formula:

$$\text{New calibration value} = \text{Previous calibration value} \times \frac{\text{Average of values gained by reference method}}{\text{Average of values gained by this instrument}}$$

Example:

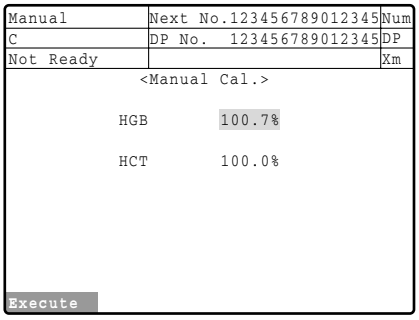
Average of HGB values gained by the reference method HGB = 15.6 g/dL
Average of HGB values gained by this instrument = 15.5 g/dL
Previous calibration value = 100 %

Calculation of the new calibration value:

100 x (15.6/15.5) = 100.65 % (100.7 % rounded off)

The calibration value of HGB has increased by 0.7 % and needs to be set at 100.7 %.

Updating calibration values



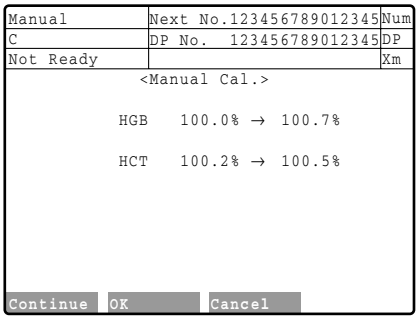
1. To display the additional menu items on the Main menu's second screen page press **MORE** key.
2. Select the **Calibrate** function.

   The **Calibration** submenu will come up.
3. Select **Manual**.

   The Manual Cal. screen will open.

   If you want to quit calibrating, click on **Return** and then confirm with **OK**.
4. Using the ▲▼ cursor keys, select the value to be changed.
5. Enter the new calibration value.
   - Use the **C** key to delete a character.
   - Pressing **OK** or ▲▼ confirms the input; the cursor moves to the next field.
   - No entry, or entries containing blanks will not be accepted by the system.
6. Press **Execute** after all values have been input.

   On the display the previous and updated HGB and HCT calibration values are displayed.



Important!

A calibration error is displayed, if

- the value determined by the analyses exceeds 105 % or is less than 95 %;
- the new calibration value exceeds 120 % or is less than 80 %.

7. If you want to make the entered values permanent and return to the Analysis screen, select **OK**.

   or:

   If you want to input more values or correct any input, select **Continue**.

   or:

   If you want to quit calibrating and return to the Analysis screen, select **Cancel**. The previous calibration value remains valid.

Important!

Should a calibration of more than ± 20% be necessary, contact the Sysmex service.

– Repeat the analysis of the calibration sample with the XE-2100. Make sure the analysis results are within the permitted range and do not deviate too much from the reference values.
– Perform the calibration again if the HGB and HCT values are much higher or lower than the reference values.

Important!

If, after repeated calibration, the analysis values are not within the permitted range or abnormal results have occurred, check

- sample coagulation
- blood cell morphology
- patient drug taking
- patient age

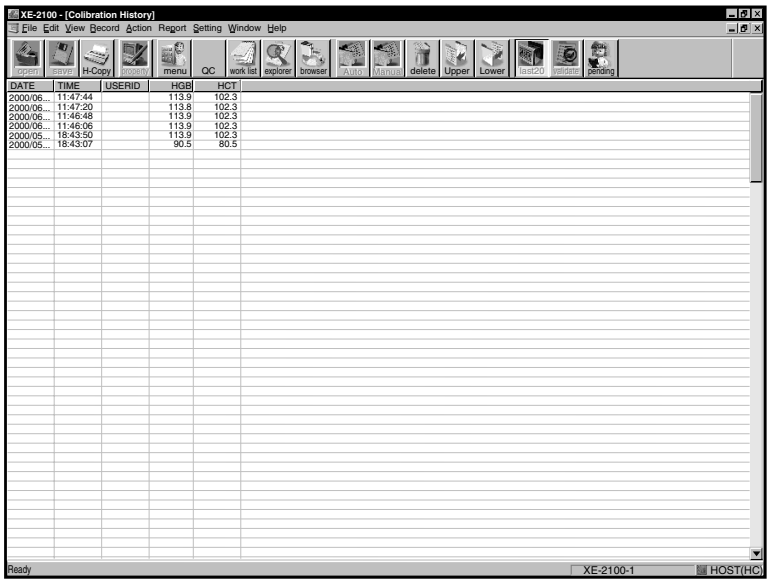
12.5 Calibration log

In the calibration log the latest calibration processes are recorded. The processes are sorted by occurrence in chronological order. Up to 10 calibrations can be saved. When further calibrations are performed, the oldest entry will be deleted automatically.

To open the calibration log proceed as follows:

1. At the IPU open the **Controller** view.
2. Click on the **Calibration History** button.

The calibration log will be displayed.



12.6 Printing calibration processes

It is possible to print out an overview of the last five calibration processes on any of the printers connected.

1. Open the calibration log as detailed above.
2. Start the printing as detailed in chapter “10. Output”.

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13. Settings

By individual settings the users can adapt the Main Unit and the IPU to their needs or existing laboratory conditions, respectively.

Note:

Upon initial operation some settings need to be updated, e.g. the current date and time.

– Make sure both Main Unit and IPU are ready for operation.

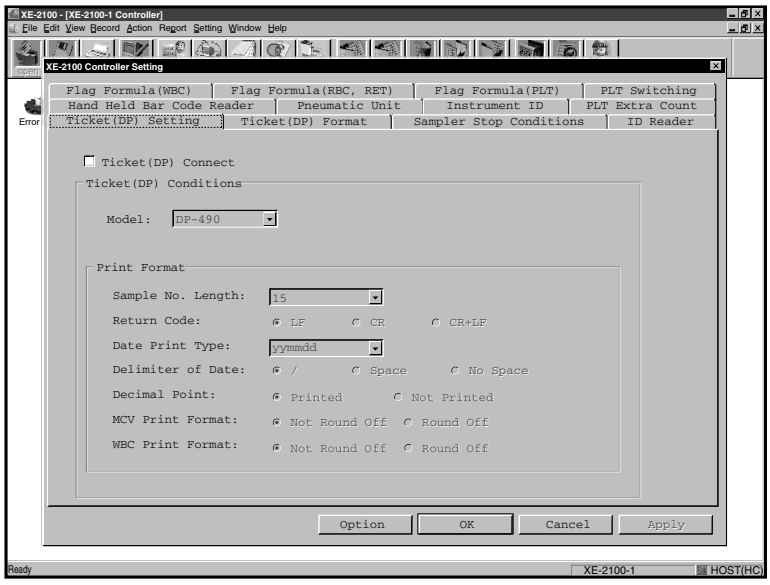
13.1 Main Unit settings

Important!

To make any changes to the Main Unit's settings, the Main Unit must be operational.

1. Click on the **Controller** button.
2. Click on the icon **Setting**.

   The window shown below will open.



3. Select the tab of the setting to be changed:

ID Reader	to enable/disable the integrated barcode reader; to make settings
Hand Held Bar Code Reader	to enable/disable a manual barcode reader; to make settings

Pneumatic Unit	Input of time in minutes, after which the compressor is to shut off when not used
Instrument ID	Instrument serial number
PLT Extra Count	Limiting value of additional PLT sampling
Flag Formula (WBC)	Definition of WBC abnormal messages
Flag Formula (RBC/RET)	Definition of RBC/RET abnormal messages
Flag Formula (PLT)	Definition of PLT abnormal messages
PLT-Switching	Input of defined values for the PLT switching algorithm
Ticket (DP) Setting	Data printer settings
Ticket (DP) Format	Card format
Sampler Stop Conditions	Stop conditions for Sampler

4. Enter values or select any of the offered options.
   - Select **OK** to save the changed settings. The window will be closed.
   - Select **Cancel** to ignore any changes made. The window will be closed.
   - If you want to apply the new settings but wish the window to remain open, select **Apply**.

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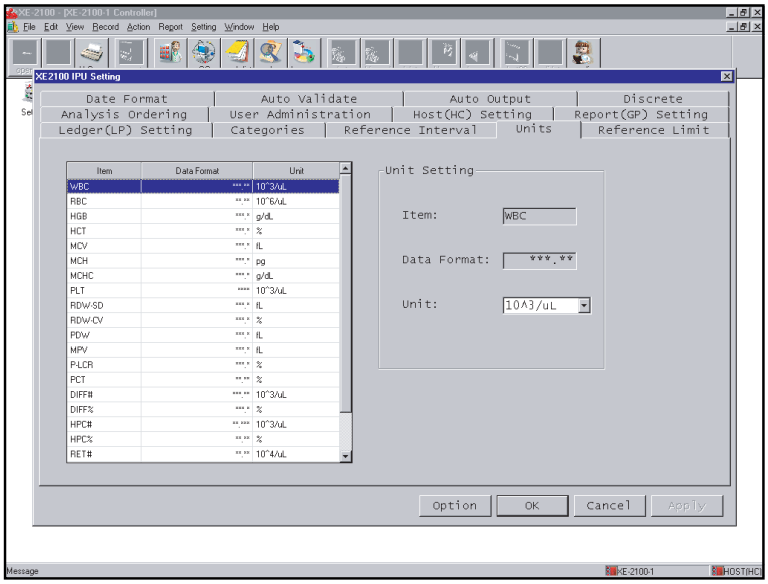
13.2 IPU settings

1. On the menu bar open the **Settings** menu and select the submenu that contains the setting you wish to change.



2. Enter values or select any of the offered options.
   - Select **OK** to save the changed settings. The window will be closed.
   - Select **Cancel** to ignore any changes made. The window will be closed.
   - If you want to apply the new settings but wish the window to remain open, select **Apply**.
3. If further settings are to be changed, click on the corresponding tab.

Date Format

YYYY/MM/DD	1999/12/31
MM/DD/YYYY	12/31/1999
DD/MM/YYYY	31/12/1999

Auto Validate

Caution!

Depending on the user-definable “Auto Validate” setting, POSITIVE or ERROR data may be validated automatically. Having this fact in mind, “Auto Validate” must be set in accordance with the protocol of your laboratory.

The XE-2100 can be set so that samples, fulfilling specific criteria, are validated automatically.

None	No auto validation
All Sample	All samples are automatically validated.
Negative	Only negative samples will be automatically validated.
Negative + Unmarked	Only negative and not highlighted samples will be automatically validated.
Negative + Delta-Check negative	Only negative samples and samples with a negative Delta Check (value not consistent with the previous value) will be automatically validated.
Negative + Unmarked + Delta-Check negative	Only negative samples, samples not highlighted and samples with a negative Delta Check (value not consistent with the previous value) will be automatically validated.

Auto Output

The XE-2100 can be configured so that results are output automatically.

– Check the check box of the device the data are to output on or deactivate the other devices, respectively:

DP	Printing on data printer
GP	Printing on graphics printer
HC	Output to host computer

Important!

If an output device is not turned on it can not be set as output device.

– Afterwards select the conditions for the automatic output to the respective device. Click on the button to change between “Output” and “No Output”.

Negative	Analysis data with no abnormality detected and no error having occurred during the analyse operation.
Diff. Posi.	Analysis data with abnormal differential count
Morph. Posi.	Analysis data with abnormal morphology
Count Posi.	Analysis data with abnormal cell count

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Error	Samples where an error has occurred during the analyse operation (except barcode read error)
QC Data	Analysis data having been checked by the QC system

Note:

If Error is set to “No Output” and the sample is classified as to be output in one of the other criteria, the sample data which has an analysis error will be output.

Discrete

In “User Select” mode of the Work List's “Order” function an individual requirement profile can be processed.

1. Click on the **Discrete** tab.

   A window showing the current requirement profile will open.

2. Click on the analysis parameters to activate or deactive the check boxes.

Analysis Ordering

Here you can set a method for analysis ordering.

1. Click on the **Analysis Ordering** tab.

   A window showing the current analysis ordering will open.

Sample ID	Analysis commissions are processed by sample number.
Rack no./ tube position	Analysis commissions are processed by rack number and tube position.
Real time (Manual mode) [sample ID]	Real-time query of the analysis information is made by subject. In Manual mode this is the sample number.
Real time (Auto mode) [Key]	Real-time query of the analysis information is made by subject, which is predefined in the [Key] box.

Note:

The options “Sample ID” and “Rack no./tube position” are mutually exclusive.

User Administration

On this tab the access rights of the individual users are predefined.

Note:

Users will only have access to system areas for which they have been assigned access rights. Contact your administrator if in doubt.

The preset profiles **Admin** (for the system administrator) and **Sysmex** (for the service) can neither be changed nor deleted.

1. Click on the **User Administration** tab.

   A user list showing logon name, user name and user information will come up.

- To add a new user click on the **Add User** button.
- To edit or check the settings of an existing user, click on the respective line of the list and then on the **Properties** button.

  A list showing the current settings will come up.
- To delete a user click on the **Delete User** button.

  Confirm with **Yes** to delete the user.

2. Edit the information and rights or add a new user, respectively.

General

Logon Name	(this box must be filled in!)
Operator Name	Name of the user
Operator Information	Information pertaining to the user

User Permission

Change password	

Analysis Permission

Instrument Analysis	Analysing of samples permitted
Order Entry/Update	Working with Work List permitted
Accept Results	
Modify/Delete results	
Output Results	

System Permission

Basic QC Operation	Access to QC tests and administrative information
Modify QC/Cal	Access to all QC text and test operations
Research Items Operation	Access to research functions
Modify Settings	
Modify Operator Settings	

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Select Shift

If the XE-2100 is used in shifts, each user can be assigned to a shift in order to perform the quality control correctly for each shift.

Shift 1
Shift 2
Shift 3

Host (HC) Setting

On this tab the settings for the host computer interface are made.

1. Put a check mark in the **Host (HC) Connect** check box, to connect to the host computer.

Note:

If there is no active HC connection, no settings for the interface can be selected or implemented.

2. Select the connection type.

Serial	select also COM1 or COM 2
TCP/IP	

Interface settings for serial connection:

Port settings

- Baud rate

600
1200
2400
4800
9600
14400

- Code (data bits)

7-bit
8-bit

- Stop Bit

1-bit
2-bit

- Parity Bit

None
Odd
Even

Options (transmission format)

- Class

Class A
Class B

- Interval (in seconds)

0
1
2
3
5
7
10
15

Interface Setting:

HOST IP address

Port

Report (GP) Setting

– Put a check mark in the check box to connect to the graphics printer.

Ledger (LP) Setting

– Put a check mark in the check box to connect to the line printer.

Categories

Here age ranges and sex of the reference groups can be set. Based on the patient information, the corresponding reference group is assigned to each sample and the analysis results compared with the defined limits. If no matching reference group does exist, the universal limit set is used.

 **Note:**

The limits are set on the “Reference Interval” tab (see below).

1. Click on the **Categories** tab.

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A window will come up, showing the current settings of the reference groups.

2. Put check marks in the check boxes of the desired groups.
3. Specify the minimum and maximum age as years, months and weeks.

 **Note:**

Do **not** enter any date of birth.

4. Select if the limits shall apply to male or female patients, or for both sexes.

Reference Interval

On this tab the upper and lower analysis parameter limits are assigned to the reference groups.

1. Click on the **Reference Interval** tab.

   A window showing the current settings will open.
2. In the Category box select the reference group for which you want to make or change settings.

 **Note:**

“Universal” is used for samples not fitting any of the reference groups.

The list of analysis parameters with their defined limits will be displayed.

3. Click on the analysis parameter you want to set.

   In the “Reference Interval Setting” section to the right of the listing, the selected parameter is displayed together with the upper and lower limit.
4. Enter values for the upper and lower limit.
5. To enter the limits of the other analysis parameters proceed accordingly.

 **Important!**

If no limits are required, set the lower limit to “0” and the upper limit to “99.99”, “999.99” or “9999.99”, respectively.

Units

1. Click on the **Units** tab.

   The list of analysis parameters with their defined units will be displayed.
2. Click on the analysis parameter you want to set.

In the “Unit Setting” section to the right of the listing, the selected parameter with its data format and unit is shown.

3. In the “Unit” box select the desired unit.

   The indication of the data format changes correspondingly.

Note:

The available units are dependent on the selected parameter.

4. To enter the units of the other analysis parameters proceed accordingly.

Reference Limit

On this tab the upper and lower analysis parameter limits can be set. Data that exceed these limits will be marked by a red "+" or "-" and “Data Error”.

1. Click on the **Reference Limit** tab.

   The list of analysis parameters with their defined limits will be displayed.

2. Click on the analysis parameter you want to set.

   In the “Reference Limit Setting” section to the right of the listing, the selected parameter is displayed together with the upper and lower limit.

3. Enter values for the upper and lower limit.

4. To enter the limits of the other analysis parameters proceed accordingly.

Important!

If no limits are required, set the lower limit to “0” and the upper limit to “99.99”, “999.99” or “9999.99”, respectively.

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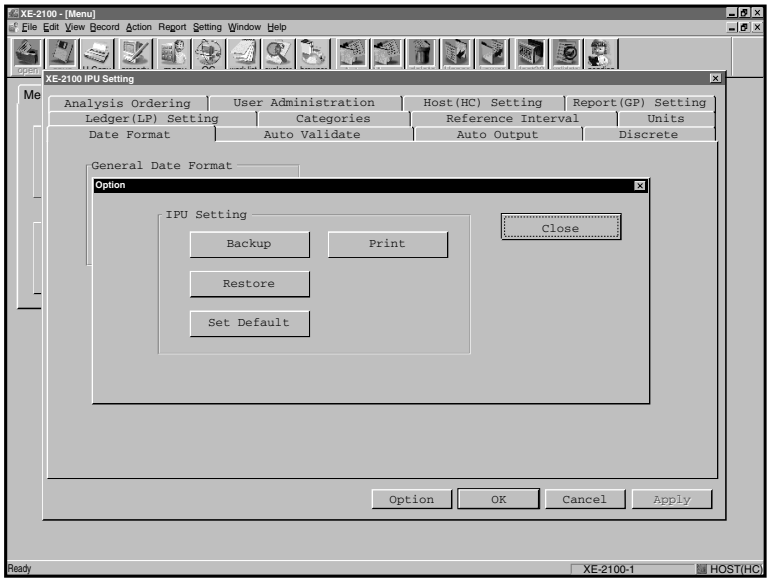
Options

1. Click on the **Option** button of any tab.
   The Option window will open:



2. Click on the desired button.

Backup	saves all current settings of the Main Unit to floppy disk
Restore	restores settings from floppy disk, overwrites the current settings
Set Default	resets the current settings to the factory defaults
Print	prints the current settings of the Main Unit on the graphics printer

13.3 Factory Settings

Controller Settings

Ticket (DP) Setting

check box “Ticket (DP) connect”	off
Model	DP-490
Sample No. Length	15
Return Code	LF
Date Print Type	YY/MM/DD
Delimiter of Date	/
Decimal Point	Printed
MCV Print Format	Not Round off
WBC Print Format	Not Round off

Sampler Stop Conditions

Sampler Stop Conditions	
check box “X-barM Limit Error”	ON
check box “L-J Limit Error”	ON
check box “ID Read Error”	ON
check box “Rack-ID-Read Error”	ON
check box “Low Count Error”	ON
check box “Manometer Error”	ON
check box “Control Expired Error”	ON
Sensors Sampler Stop Conditions	
check box “Blood Sensor”	ON
check box “Inadequate Sample”	ON
check box “Aspiration Sensor” (Sampler Stop Conditions)	ON
QC Sample	
check box “Unregistered QC Sample”	ON

ID Reader

ID Reader Conditions	
check box “Tube ID”	ON
check box “Rack ID”	ON
Check Digits Conditions	
check box “ITF: Modulus -10”	ON
check box “CODABAR/NW-7: Modulus -16”	ON
check box “CODE39: Modulus-43”	ON
check box “JAN/EAN/UPC: Modulus-10”	ON
check box “CODABAR/NW-7”:	ON
check box “CODE39”:	OFF

Hand Held Bar Code Reader

check box “Hand Held Bar Code Reader”	off

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Pneumatic Unit

pneumatic off timer	10 minuets

Instrument ID

Nick Name	XE-2100
Instrument ID	XE-2100^{00000}

PLT Extra Count

PLT Extra Count Limit	70 x 10^3/µL

Flag Formula (WBC), WBC Abnormal Flags

Neutropenia	NEUT# < 1,0 x 10^3/µL or NEUT% < 0.0 %
Neutrophilia	NEUT# >11,0 x 10^3/µL or NEUT% > 1,0 %
Lymphopenia	LYMPH# < 0,80 x 10^3/µL or LYMPH% < 0,0 %
Lymphocytosis	LYMPH# > 4,00 x 10^3/µL or LYMPH% > 100,0 %
Monocytosis	MONO# > 1,00 x 10^3/µL or MONO% > 100,0 %
Eosinophilia	EO# > 0,70 x 10^3/µL or EO% > 100,0 %
Basophilia	BASO# > 0,20 x 10^3/µL or BASO% > 100,0 %
Leukocytopenia	WBC# < 2,50 x 10^3/µL
Leucocytosis	WBC# > 18,00 x 10^3/µL
NRBC Present	NRBC# > 2,0/100 WBC

Flag Formula (RBC/RET)

Reticulocytosis	RET% > 5,00 % or RET# > 1,00 x 10^3/µL
Anisocytosis	RDW-SD >65,0 fL or REDW-CV > 20,0 %
Microcytes	MCV < 70.0 fl
Macrocytes	MCV > 100.0 fl
Hypochromia	MCHC < 29.0 g/dl
Anemia	HGB < 10,0 g/dL
Erythrocytosis	RBC > 6,50 x 10^3/µL

Flag Formula (PLT), PLT Abnormal Flags

Thrombocytopenia	PLT# < 60 x 10^3/µl
Thrombocytosis	PLT# < 600 x 10^3/µl

PLT Switching

PLT	< 50 x 10^3/µL

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IPU settings

Date Format	YYYY/MM/DD
Auto Validate	none
Auto Output	no-check
Discrete	check on all parameters
Analysis Ordering	Key: Sample ID or Rack no./ tube position Real time (Manual Mode) [Sample ID] Real time (Auto Mode) [Key]
Host (HC) Setting	HOST (HC) Connect Serial_COM2 is selected Baud Rate: 2400 Code: 7-Bit Stop-Bit: 2-Bit Parity-Bit: Even Class: Class B Interval: 2
Report (GP) Setting	Check on Report (GP) Connect
Ledger (LP) Setting	Check on Ledger (LP) Connect

Categories

	Age Lower			Age Upper			
	Year	Month	Week	Year	Month	Week	Sex
Group 1	0	0	0	0	0	1	Both
Group 2	0	0	1	0	1	0	Both
Group 3	0	1	0	1	0	0	Both
Group 4	1	0	0	12	0	0	Both
Group 5	12	0	0	60	0	0	Male
Group 6	12	0	0	60	0	0	Female
Group 7	60	0	0	999	0	0	Both

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Reference Interval
Group 1 - Group 7 or Universal

Parameter	Reference Interval		
	LL(-)	UL(+)	Unit
WBC	3.00	15.00	x 10^3/µL
RBC	2.50	5.50	x 10^3/µL
HGB	8.0	17.0	g/dL
HCT	26.0	50.0	%
MCV	86.0	110.0	fL
MCH	26.0	38.0	pg
MCHC	31.0	27.0	g/dL
PLT	50	400	x 10^3/µL
RDW-SD	37.0	54.0	fL
RDW-CV	11.0	16.0	%
PDW	9.0	17.0	fL
MPV	9.0	13.0	fL
P-LCR	13.0	43.0	%
PCT	0.17	0.35	%
NEUT#	1.50	7.00	x 10^3/µL
LYMPH#	1.00	3.70	x 10^3/µL
MONO#	0.0	0.70	x 10^3/µL
EO#	0.0	0.40	x 10^3/µL
BASO#	0.0	0.10	x 10^3/µL
NEUT%	37.0	72.0	%
LYMPH%	20.0	50.0	%
MONO%	0.0	14.0	%
EO%	0.0	6.0	%
BASO%	0.0	1.0	%
RET#	0.0000	0.9999	x 10^6/µL
RET%	0.00	99.99	%
IRF	0.0	100.0	%
LFR	0.0	100.0	%
MFR	0.0	100.0	%
HFR	0.0	100.0	%

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Units

Parameter	Data format	Unit
WBC	***.*	x 10^3/µL
RBC	**.**	x 10^3/µL
HGB	***.*	g/dL
HCT	***.*	%
MCV	***.*	fL
MCH	***.*	pg
MCHC	***.*	g/dL
PLT	****	x 10^3/µL
RDW-SD	***.*	fL
RDW-CV	***.*	%
PDW	***.*	fL
MPV	***.*	fL
P-LCR	***.*	%
PCT	***.*	%
DIFF#	**.**	x 10^3/µL
DIFF%	***.*	%
HPC#	**.***	x 10^3/µL
HPC%	**.**	%
RET#	**.**	x 10^4/µL
RET%	***.*	%
IRF	***.*	%
NRBC%	****.*	/100 WBC

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13.4 Adapting the graphical user interface

When the instrument is delivered, buttons and tabs for the most important functions have been activated by the Sysmex service.

You can add, delete or rearrange any buttons and tabs you like later on.

Adding tabs

1. Open the Main menu by clicking on the **Menu** button or by choosing **View** → **Menu**.
2. Right-click and choose **Add** → **Tab** on the context menu.
3. An empty tab named “Menu” will be added.

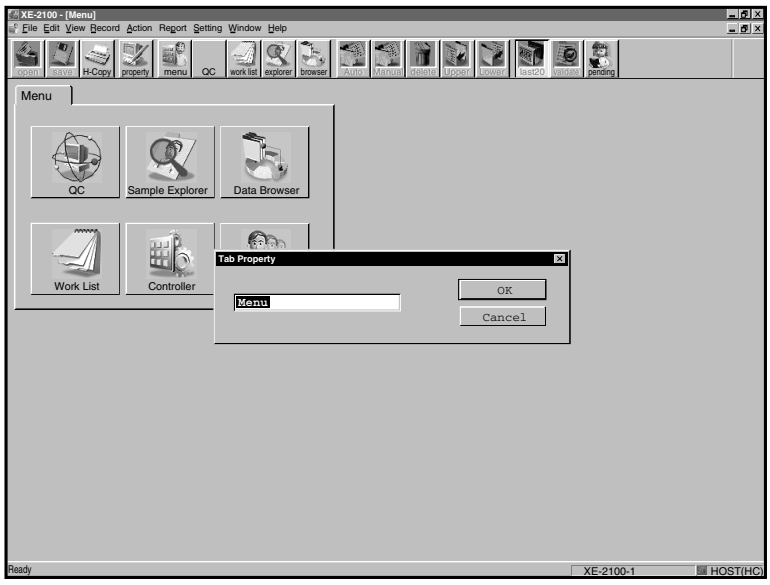
Note!

If you want to rename the tab, proceed as detailed in chapter “Renaming a tab”.

Renaming a tab

1. Click on the tab you want to rename.
2. Right-click and choose **Property** on the context menu.

   The **Tab Property** window will open.



3. Enter the desired name in the textbox.
4. To accept the new name and to return to the tabs, click on **OK**.

   or:

   Click on **Cancel** to keep the existing name.

Moving a tab

1. Click on the tab you want to move.
2. Right-click and choose **Move** on the context menu.

   A grey border is added to the tab.
3. Press and hold the left mouse button and move the tab to the desired position.

Deleting a tab

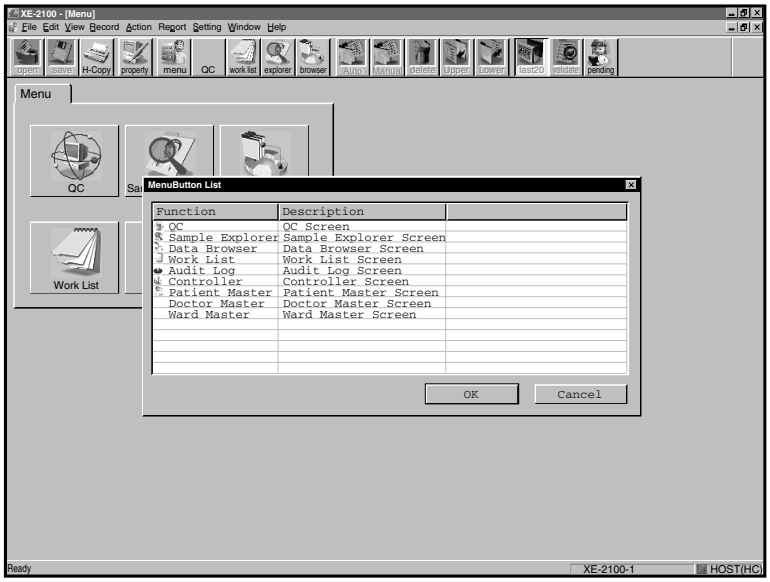
1. Click on the tab you want to delete.
2. Right-click and choose **Delete** on the context menu.

   The tab will be deleted.

Adding tabs

1. Open the Main menu by clicking on the **Menu** button or by selecting **View** → **Menu**.
2. Click on the tab you want to add a button to.
3. Right-click and choose **Add** → **Button** on the context menu.

   A list of available buttons will come up.



4. Choose the button to be added in the list.
5. To add the button click on **OK.**

   or:

   If you do not want to add the button click on **Cancel**.

The new buttons will appear. Should it cover existing buttons partly or completely, proceed as detailed in chapter “Moving a button”.

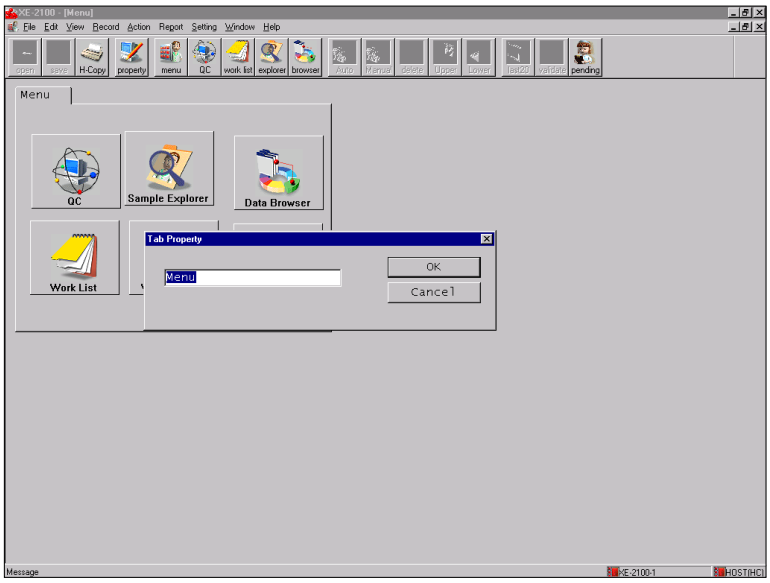
Note:

More than six buttons should not be placed on a tab. Add another tab, if necessary.

Renaming a button

1. Right-click on the button you wish to rename.
2. Choose **Property** on the context menu.

   The **Tab Property** window will open.



3. Enter the desired name in the textbox.
4. If more than one Main Unit is connected select the instrument ID.
5. To make the changes permanent and return to the Main menu click on **OK**.

   or:

   To ignore the changes made click on **Cancel**.

Moving a button

1. Right-click on the button you wish to move.
2. Choose **Move** on the context menu.

   A grey border is added to the button.
3. Press and hold the left mouse button and move the button to the desired position.

Deleting a button

1. Right-click on the button you wish to delete.
2. Choose **Delete** on the context menu.
   The button will be deleted.

13.5 Changing the display of the Work List, Sample Explorer and Data Browser

You can adapt the windows to your preferences:

- change the column width
- change the size of the display area
- define the order style of the display
- select the parameters to be displayed

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14. Cleaning and Maintenance

To ensure proper functioning of the XE-2100, it is necessary to periodically clean and service the instrument. Perform maintenance according to the schedule below and record the results in the Maintenance Checklist (see “20. Appendix”).

Warning!

To avoid the risk of infections, electric shock or burns, wear rubber gloves for all cleaning or maintenance work. After completion of work, wash hands with disinfectant.

14.1 Maintenance schedule

Daily

- Cleaning transducer (TD) chambers and diluted sample lines (see chapter 14.3)
- Trap chamber checking (see chapter 14.4)

As-needed maintenance

- Cleaning the Sample Rotor Valve (SRV) (see chapter 14.5)
- Trap chamber draining (see chapter 14.4)
- Cleaning the rinse cup (see chapter 14.6)
- Cleaning the SRV tray (see chapter 14.7)
- Cleaning the cap-piercer tray (see chapter 14.8)
- Clog removal (see chapter 14.9)
- Cleaning the IMI detector aperture (see chapter 14.10)
- Cleaning the RBC detector aperture (see chapter 14.11)
- Removing air bubbles from the flowcell of the optical analyser unit (see chapter 14.12)
- Cleaning the flowcell of the optical analyser unit (see chapter 14.13)
- Waste tank replacement (see chapter 14.14)
- Replacing reagents (see chapter 14.15)
- Replacing the piercer (see chapter 14.16)
- Replacing the hand clipper or rubber pads (see chapter 14.17)
- Replacing fuses (see chapter 14.18)
- Adjustment of pressure and vacuum (see chapter 14.19)

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14.2 Reading counter counts

In the Counter display the counter counts are displayed, showing how many analyse operations have been performed since initial operation of the instrument or after replacement or cleaning of a component, respectively.

1. On the Main Unit open the **Test** menu.
2. Choose **Status**.

   The status display will appear.
3. Choose **Counter**.

   The counter count display will appear.

TOTAL	Analyse operations of the system since initial operation
CBC	Analyse operations in CBC mode
DIFF	Analyse operations in DIFF mode
NRBC	Analyse operations in NRBC mode
RET	Analyse operations in RET mode
FFS	Analyse operations in DIFF mode after STROMATOLYSER-4DS replacement
SHUT	Analyse operations since last Shutdown
PIAS	Number of piercer cycles after piercer replacement
SRV	Analyse operations since last SRV cleaning
FCM-MT	Analyse operations of the FCM sheath motor
RBC-MT	Analyse operations of the RBC sheath motor
WB-MT	Analyse operations of the WB aspiration motor
LASER	Oscillation cycles of the laser

14.3 Cleaning transducer (TD) chambers and diluted sample lines

Deposits in the instrument can cause measurement errors. This is why the transducer chambers and diluted sample lines must be cleaned. This process is identical to the Shutdown sequence at the end of operation.

Execute a Shutdown:

- when all analyses have been performed,
- at least every 500 samples or every 24 hours, respectively, if the XE-2100 is used in continuous operation.

Important!

If you turn the instrument OFF without having performed a Shutdown, deposits may build up in the system which could cause measurement errors.

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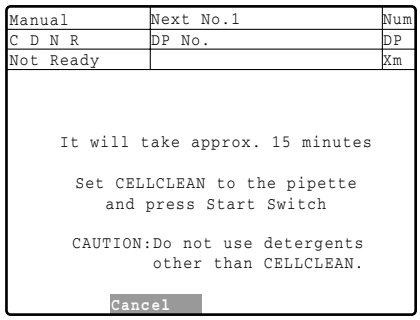
Note:

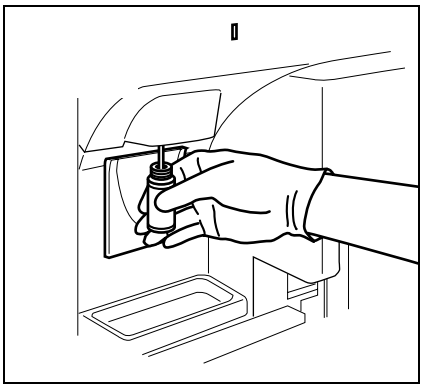
The Shutdown sequence takes approx. 15 minutes.

1. Be sure the status display indicates “Ready”.
2. Press **SHUTDOWN**.

   The screen shown at left will come up.



- If you wish to abort the Shutdown sequence and continue analysing, choose **Cancel**.



3. Hold CELLCLEAN under the aspiration pipette and press the start switch.

Caution!

CELLCLEAN is a strong alkaline cleaning material. It should not come in contact with skin or clothing. If it happens nevertheless, rinse skin or clothing with plenty of water to avoid injury or damage, respectively.

4. When two short beeps are sounded, the container with the CELLCLEAN should be lowered first and then taken away sideways.

Important!

Take care not to bend the aspiration pipette.

The Shutdown sequence is automatically executed.

When the Shutdown sequence is completed, the message “Please Power Off” is displayed.

– To restart the instrument choose **Restart** on the “Shutdown completion” display. An automatic rinse and a background check will be performed. Afterwards the XE-2100 is ready for operation.

– To turn the Main Unit OFF, set the main switch to the **0 OFF** position.

– If the power to the compressor is not supplied from the Main Unit, turn the compressor OFF also.

Important!

To avoid damage to the instrument, wait at least 1 minute before switching the Main Unit or the compressor ON again.

Note:

Afterwards the IPU can still be used, e.g. for data output or editing.

– To turn the entire system OFF the IPU must be shut down (see “IPU shutdown”).

14.4 Trap chamber checking and draining

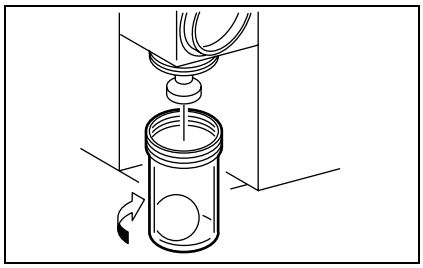
After completion of analyse operations for the day, the trap chamber of the pneumatic unit must be checked.

– Check if any fluid has accumulated in the trap chamber.

Note:

Tap against the trap chamber. If the ball moves easily there is no water in the trap chamber and no further action is required.

To remove any accumulated fluid, proceed as follows:



1. Turn the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
2. Remove the trap chamber by turning it clockwise.
3. Discard the fluid.
4. Rinse the trap chamber with hot water, then dry it thoroughly.
5. Reinstall the trap chamber.

Important!

The Main Unit could break down if fluid accumulates every day. Contact the Sysmex service representative.

14.5 Cleaning the Sample Rotor Valve (SRV)

Important!

The Sample Rotor Valve is an important component of the Main Unit. Scratches on the valve surfaces can cause leakage and incorrect analysis results. Exercise due care when dismantling and cleaning the valve disks.

Take care not to loosen or bend any of the tubes.

Tip:

To make cleaning easier use a soft toothbrush and warmed-up detergent (CELLCLEAN).

Every 30,000 samples, a message requesting a check of the Sample Rotor Valve is displayed when switching the instrument on.

Caution!

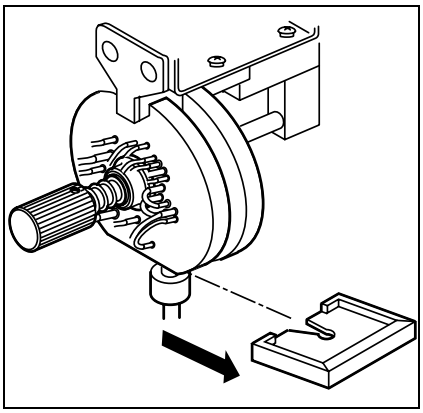
The Sample Rotor Valve is only cleaned when required (e.g. at increased backgrounds) or when instructed to do so by the Sysmex service representative.

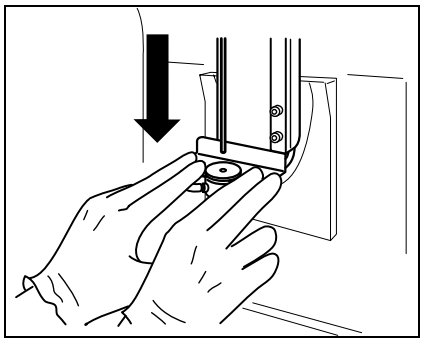
1. Turn the Main Unit and the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
2. Open the front cover.

Tip:

Place some cloths under the rinse cup, as fluid will come out.

3. Carefully remove the SRV tray.

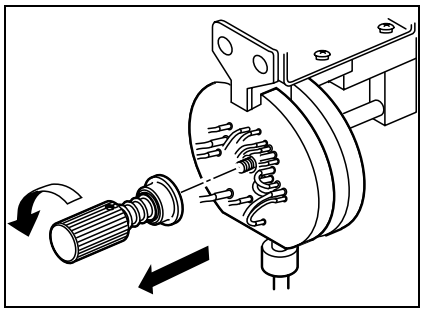




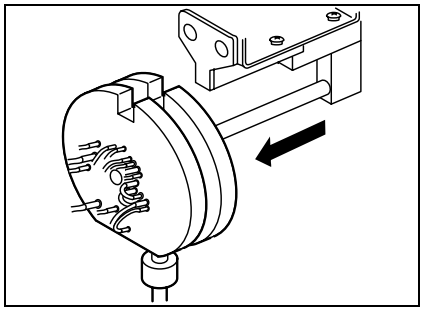
4. Gently pull down the rinse cup **using both hands**.

Important!

Make sure the rinse cup is removed completely, otherwise the aspiration pipette could be damaged when removing the SRV.



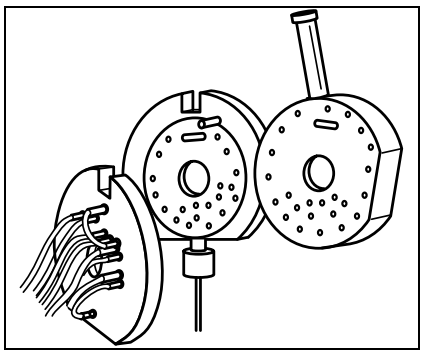
5. Remove the fixing screw.



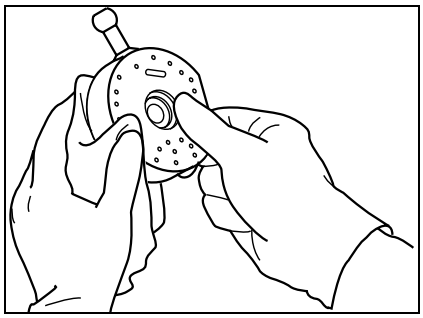
6. Remove the entire Sample Rotor Valve.

Tip:

If the Sample Rotor Valve cannot be easily pulled off, spray some warm water on it.



7. Disassemble the three disks by moving and turning them against each other.

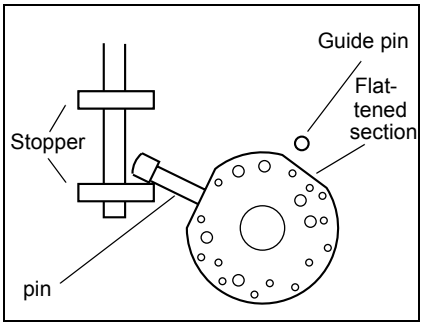


8. Clean the centre disk with distilled water or a CELLCLEAN solution (1 part CELLCLEAN, 10 parts of water).

Important!

Use only CELLCLEAN for cleaning. After cleaning with CELLCLEAN the valve must always be rinsed with distilled water.

9. Clean the contact surfaces of the two outer disks with a wet cloth or rinse with water. Use distilled water or a CELL-CLEAN solution (1 part CELLCLEAN, 10 parts of water).



10. Make sure the valve contact surfaces are free from dirt or dust.
11. Put the discs, one after the other, on the guide pin. Note the following:
    - The contact surfaces must be wet.
    - The notches on both outer valve disks must face upward.
    - The pin of the centre valve disk must be positioned at an angle and between the two stoppers, otherwise malfunction will occur.
    - The pin of the rear valve disk must fit on the flattened section of the centre valve disk.
12. Install the fixing screw. Ensure it is in correct position.
13. Push the screw in and tighten it.
14. Replace the rinse cup and push it up against the stop.
15. Re-mount the SRV tray, ensuring a correct position.
16. Close the front cover.
17. Start the instrument and make sure no background error occurs.
18. Perform a quality control.

Resetting the counter

After cleaning the SRV the counter must be reset. To do so, proceed as follows:

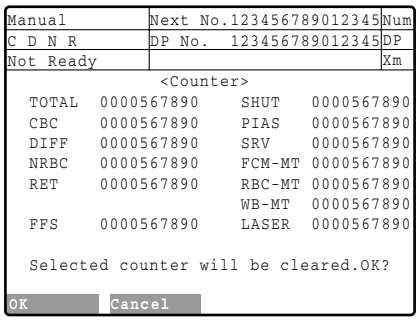
1. On the Main Unit open the **Test** menu.
2. Select **Status**.

   The status display will appear.
3. Select **Counter**.

   The counter count display will appear.
4. Using the cursor keys ▲▼ select the **SRV** counter.
5. Select **OK** to clear the counter.

   Select **Cancel** to not clear the counter and to return to the status display.

The “Number of cycles since cleaning” is reset to 0.



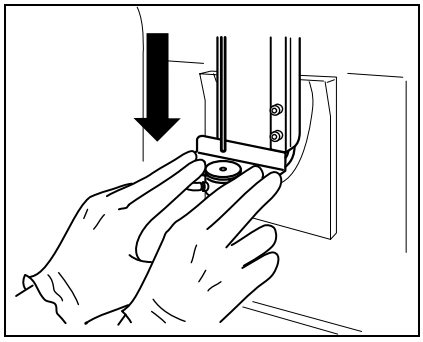
14.6 Cleaning the rinse cup

The rinse cup requires cleaning when it is dirty or clogged.

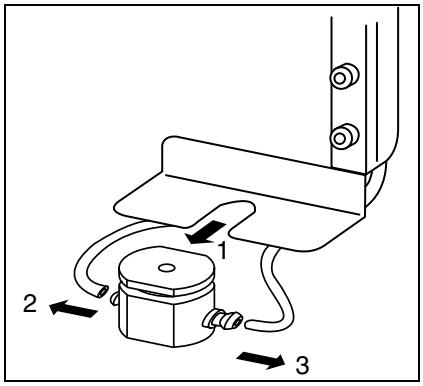
1. Turn the Main Unit and the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
2. Open the Main Unit's front cover.

Caution!

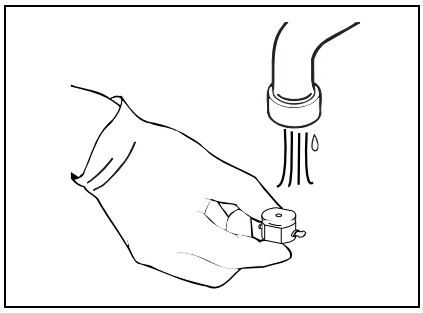
Secure the front cover with the stop bar.



3. Gently pull down the rinse cup **using both hands**.



4. Pull the rinse cup forward and pull off the tubes.



5. Clean rinse cup thoroughly under running water.
6. Wipe rinse cup dry and install the tubes in reverse order.
7. Replace the rinse unit and push it up against the stop.
8. Close the front cover.
9. Perform an automatic rinse.

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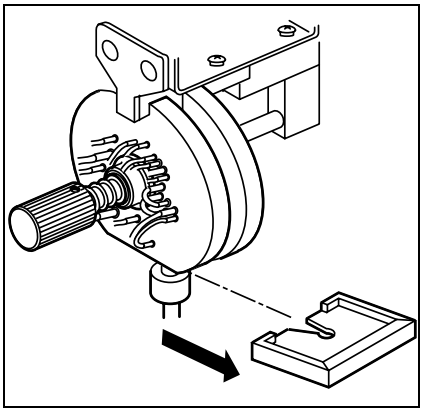
14.7 Cleaning the SRV tray

Salt and dirt accumulate in the SRV tray.

1. Turn the Main Unit and the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
2. Open the Main Unit's front cover.

Caution!

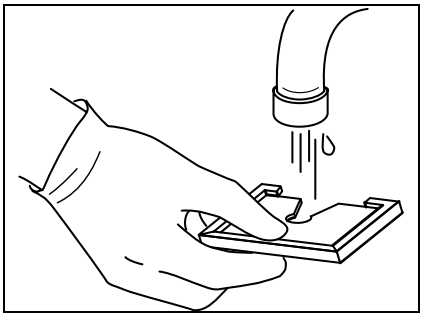
Secure the front cover with the stop bar.



3. Carefully remove the SRV tray.

Important!

Take care not to loosen the fixing screw for the aspiration pipette. If analyses are performed with a loose aspiration pipette, air bubbles can affect the measurement.



4. Wash the SRV tray using tap water. Remove all contaminants.
5. Wipe dry with a clean cloth.
6. Re-mount the SRV tray, ensuring a correct position.
7. Close the front cover.

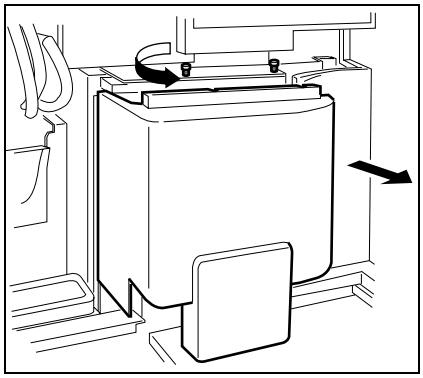
14.8 Cleaning the cap-piercer tray

Salt and dirt accumulate in the cap-piercer tray.

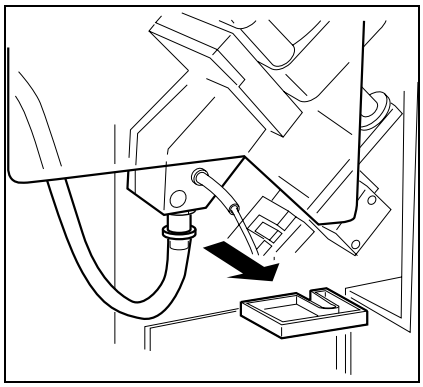
1. Turn the Main Unit and the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
2. Open the Main Unit's front cover.

Caution!

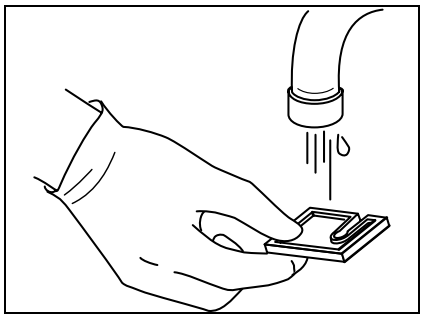
Secure the front cover with the stop bar.



3. Loosen the locking screws at the cover of the cap-piercer and remove the screws.



4. Carefully pull the cap-piercer tray out towards the front.



5. Rinse the cap-piercer tray under running water. Remove all contaminants.
6. Wipe dry with a clean cloth.
7. Replace the cap-piercer tray. Ensure it is in the correct position.
8. Replace the cap-piercer cover and secure with the locking screws.
9. Close the front cover.

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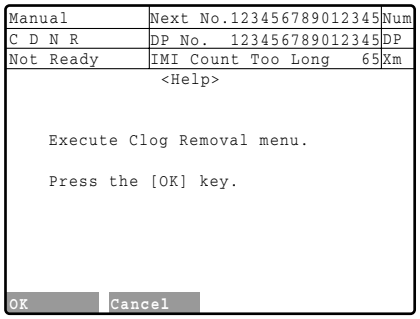
14.9 Clog removal

Cleaning sequence after error message



1. When an error message indicating a clog is displayed, press the **HELP** key on the Main Unit's panel keyboard.

   The online help will be displayed.

2. To start the cleaning sequence for clog removal, choose **OK**. The cleaning sequence takes approx. 1 minute.

   or:

   to cancel choose **Cancel**.

Cleaning sequence at any given time

1. On the Main menu choose **Mainte.**.

   The Maintenance menu will come up.

2. Choose **3. Clog Removal**.
3. To start the cleaning sequence for clog removal, choose **Execute**.

14.10 Cleaning the IMI detector aperture

If the aperture clogging is not removed by the cleaning sequenced detailed in chapter 14.9, the IMI detector aperture requires mechanical cleaning.

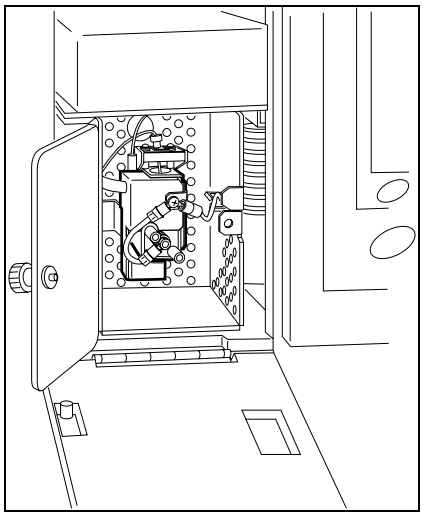
1. On the Main menu choose **Mainte.**.

   The Maintenance menu will open.

2. Choose **1. Drain IMI**.
3. Choose **Execute** to rinse the sample from the IMI chamber.
4. Turn the Main Unit and the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
5. Open the Main Unit's front cover.

   Caution!

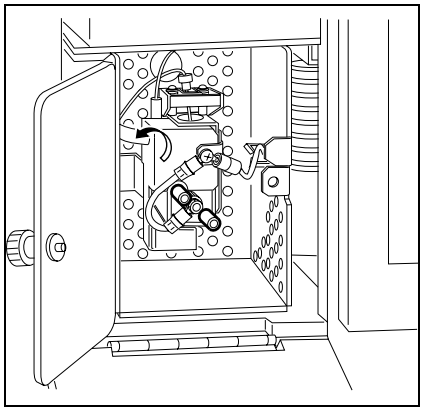
   Secure the front cover with the stop bar.



6. Open the cover of the IMI detector and check to see that the sample was rinsed away.

Warning!

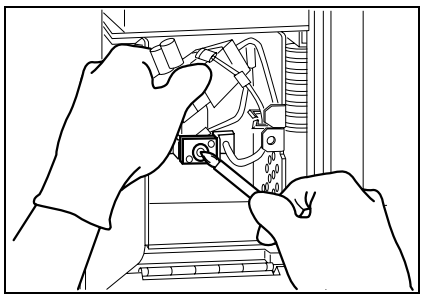
Never open the cover with the power ON.



7. Loosen the locking screws of the measuring chamber and carefully remove the chamber.

Important!

Do not pull too hard on the tube connected to it.



8. Using the brush supplied with the instrument, apply CELL-CLEAN to the aperture.
9. Clean brush with water before putting away after use.
10. Replace the measuring chamber.

Important!

Make sure the O-ring is positioned at the intended location.

11. Tighten the locking screws.

Important!

Tighten the locking screws alternately and equally. IF the chamber is in an inclined position no correct analysis results will be achieved.

12. Close the cover of the IMI-detector.
13. Close the front cover.
14. Switch instrument ON again.

    A background check will be performed automatically.

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14.11 Cleaning the RBC detector aperture

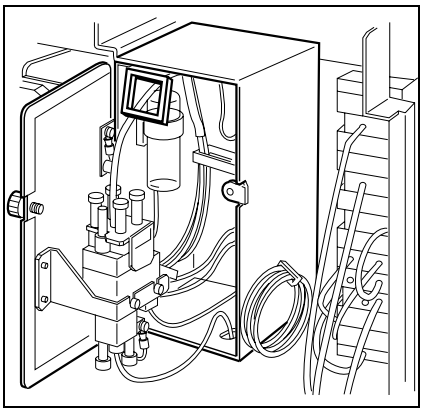
If the aperture clogging is not removed by the cleaning sequenced detailed in chapter 13.10, the RBC detector aperture requires mechanical cleaning.

Cleaning the aperture from below

1. Turn the Main Unit and the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
2. Open the Main Unit's front and right-hand cover.

Caution!

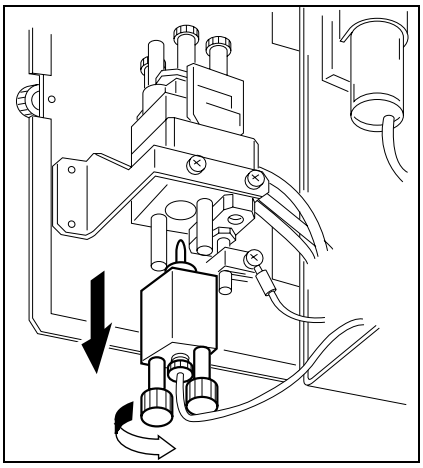
Secure the front cover with the stop bar.



3. Open the RBC detector cover. Swing the holder out so the cover will stay open.

Warning!

Never open the cover with the power ON.

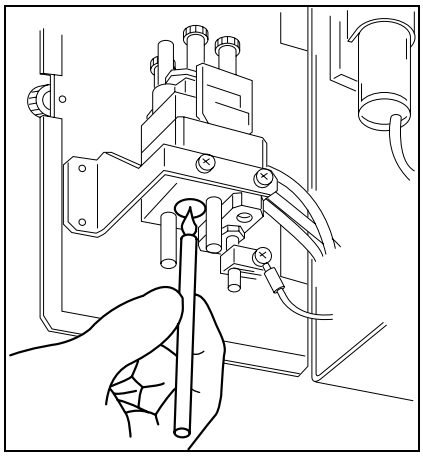


4. Loosen the locking screws on the underside of the measuring chamber and **carefully** remove the ceramic pin by pulling it downwards.

Important!

The ceramic pin breaks easily. Handle it carefully and do not drop it.

Do not pull too hard on the hose connected to it.



5. Using the brush supplied with the unit, apply CELLCLEAN to the aperture.
6. Clean brush with water before putting away after use.
7. Put the ceramic pin back into the measuring chamber.
8. Tighten the locking screws.

Important!

Tighten the locking screw alternately and equally. If analyses are performed with loose locking screws, air bubbles can affect the measurement.

9. Close the detector cover.

Important!

Make sure the lines are not kinked. If kinked no correct analysis results will be achieved.

10. Close the Main Unit's front and right-hand cover.
11. Switch instrument ON again.

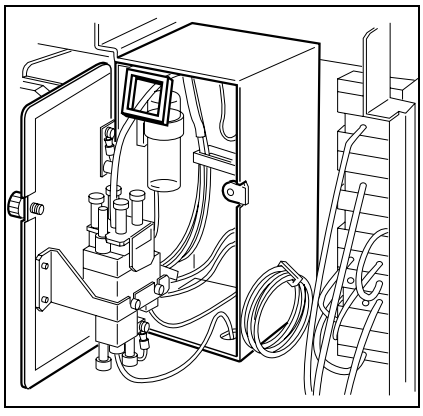
    A background check will be performed automatically.

Cleaning the aperture from the top

1. Turn the Main Unit and the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
2. Close the Main Unit's front and right-hand cover.

Caution!

Secure the front cover with the stop bar.



3. Close the detector cover. Swing the holder out so the cover will stay open.

Warning!

Never open the transducer cover with the power ON.

4. Loosen the four locking screws.

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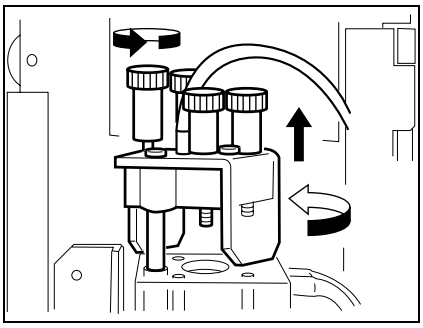
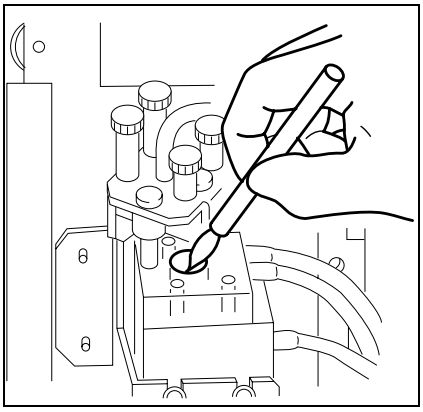


5. Pull the cover of the measuring chamber up.



6. Using the brush supplied with the unit, apply CELLCLEAN to the aperture.
7. Clean brush with water before putting away after use.
8. Replace the top cover and tighten the locking screws.

Important!

Tighten the locking screw alternately and equally. If analyses are performed with loose locking screws, air bubbles can affect the measurement.

9. Close the detector cover.

Important!

Make sure the lines are not kinked. If kinked no correct analysis results will be achieved.

10. Close the Main Unit's front and right-hand cover.
11. Switch instrument ON again.

    A background check will be performed automatically.

14.12 Removing air bubbles from the flowcell of the optical analyser unit

If the scattergrams' state of aggregation becomes poorer, air bubbles have possibly accumulated in the flowcell. To remove the air bubbles proceed as follows:

1. On the Main menu choose **Mainte.**.

   The Maintenance menu will come up.
2. Choose **2. Air Bubble Removal**
3. Choose **Execute** to start the cleaning sequence.

14.13 Cleaning the flowcell of the optical analyser unit

If the message “Rinse Flowcell” is displayed, the flowcell of the optical analyser unit is possibly contaminated. To rinse the flowcell proceed as follows:

1. On the Main menu choose **Mainte.**.

   The Maintenance menu will come up.
2. Choose **4. Rinse Flowcell**.
3. Hold a vial with CELLCLEAN under the aspiration pipette and choose **Execute** to start the rinsing.

14.14 Waste tank replacement

Note:

To avoid annoyance caused by bad smell, the waste tank should be replaced when it is 3/4 filled, or latest after one week.

If your system is fitted with a waste sensor for automatic waste level monitoring, the message “Drain Waste” will be displayed.

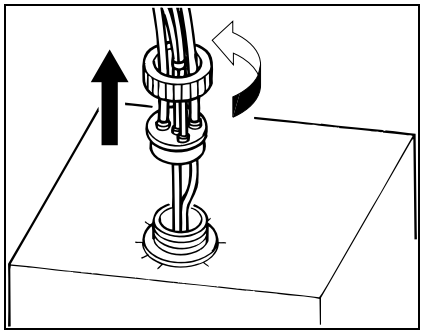
To replace the waste tank proceed as follows:

1. Turn the Main Unit and the compressor OFF and wait until the compressor's pressure gauge indicates “0”.
2. Make ready an empty waste tank and remove the cap.

Important!

If you are using an empty reagent container as waste tank, it must be clearly marked as such.

Instrument with waste level sensor



– Unscrew the lid from the filled waste tank and pull it up, together with the tubing.
– Put the tubing immediately into the new waste tank and screw the lid on.

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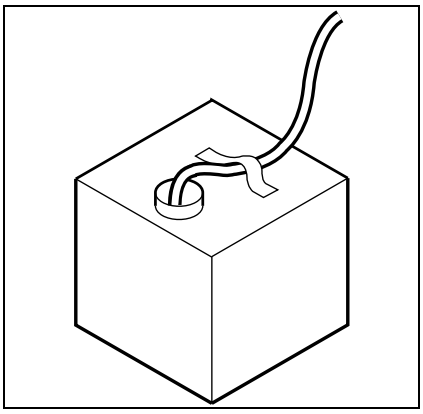
Instrument without waste level sensor



– Pull the tube off the filled waste tank and insert it into the empty waste tank. Secure with tape, if necessary.

14.15 Replacing reagents

If reagent runs low during an analyse operation, the system is stopped automatically and an error message is shown on the Main Unit's display.

Replacing reagent containers

This procedure applies to the following reagents:

- CELLPACK (EPK)
- CELLSHEATH (ESE)
- STROMATOLYSER-FB (FBA)
- STROMATOLYSER-4DL (FFD)
- SULFOLYSER (SLS)
- STROMATOLYSER-IM (SIM)

1. Check to see that the expiration date of the fresh reagent is not passed.

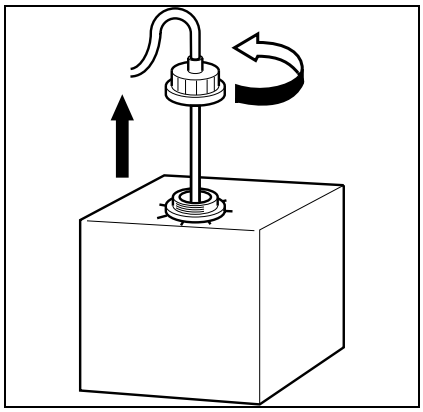
   Caution!

   To prevent contamination of the system, replace fresh reagent only. Never use collected residues.

   Use only reagents having been stored for at least 24 hours at room temperature (15 – 30 °C).

   Follow the manufacturers directions if a reagent was frozen.

2. Open the new container.



3. Unscrew the lid of the empty container and pull the float switch or spout kit out.
4. Set float switch or spout kit into the new container and tighten the lid.
5. Change the white plate for the float switch from the empty to the full container.

   Caution!

   The container spout set must not be contaminated. Otherwise impurities will get into the system, affecting the analysis results. **Do not touch the container spout set.** Remove possible contamination with a clean cloth, before inserting the float switch or spout set.

   The float switch must not be inserted in an inclined position.

   Spilled reagent must be wiped up immediately to avoid discolouring of the floor.

6. Press the **HELP** button on the Main Unit's panel keyboard.

   The status display will appear. The reagent requiring replacement is highlighted in the overview.
7. Choose **OK.**

   The reagent will be aspirated and replaced in the Main Unit.
8. Enter the data into the Reagent Overview (see “20. Appendix”).

Replacing STROMATOLYSER-4DS (FFS)

STROMATOLYSER-4DS must be replaced after 2000 analyse operations. On the Main Unit's display the error message “Replace Container FFS” will be displayed.

To replace STROMATOLYSER-4DS proceed as follows:

1. Check to see that the expiration date of the fresh reagent is not passed.
2. Open the Main Unit's front cover.

   Caution!

   Secure the front cover with the stop bar.

3. Remove the empty container from the device holder.
4. Remove the lid from the empty container and pull the tube out.
5. Remove the lid from the new container and put the tube in straight.
6. Close the lid.

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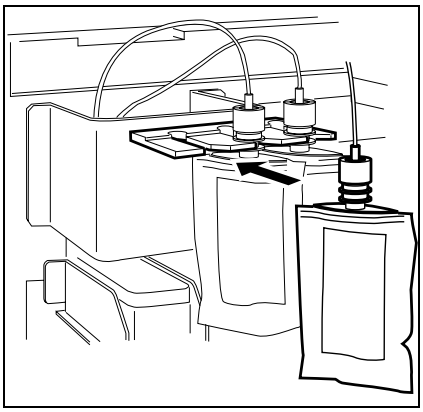
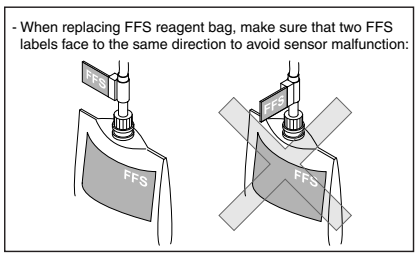


7. Place the new container in the device holder.



Important!

To prevent malfunctioning of the sensor, the label must face the bag.

8. Close the Main Unit's front cover.
9. Press the **HELP** button on the Main Unit's panel keyboard.

   The Help display will appear. The reagent requiring replacement is highlighted in the overview.
10. Choose **OK.**

    The reagent will be aspirated and replaced in the Main Unit.
11. Enter the data into the Reagent Overview (see “20. Appendix”).

Replacing STROMATOLYSER-NR (SNR) and RET SEARCH (II) (RED)

Caution!

To ensure correct analysis results please note:

- STROMATOLYSER-NR lyse and STROMATOLYSER-NR dye must always be replaced **at the same time**.
- RET SEARCH (II) diluent and RET SEARCH (II) dye must always be replaced **at the same time**.

Important!

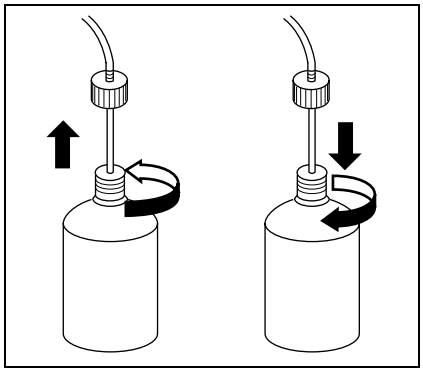
RET SEARCH (II) is a dye. Should RET SEARCH (II) get in contact with skin, it will stain the skin blue; this staining is very difficult to remove. It is therefore strongly recommended to wear rubber gloves when replacing the reagent.

Should RET SEARCH (II) get on skin nevertheless, wash the affected spot immediately with a disinfectant and afterwards thoroughly with soap.

To avoid discolouring of surfaces, wipe up spilled dye immediately with a cloth (wetted with alcohol, if possible).

The residue bag must be disposed of as “hazardous refuse”.

Replacing lyse reagent or diluent



1. Check to see that the expiration date of the fresh reagent is not passed.
2. Remove the lid from the new container.
3. Remove the lid from the empty container and pull the spout kit out.
4. Put the spout kit immediately into the new container and close the lid.

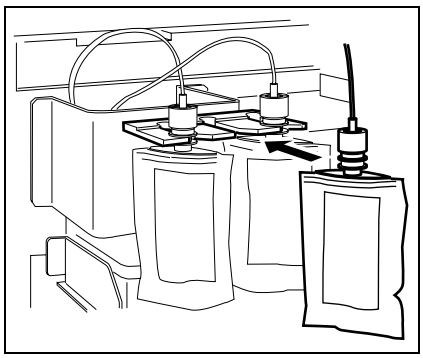
Replacing the dye

1. Open the Main Unit's front cover.

   Caution!

   Secure the front cover with the stop bar.

2. Remove the container from the device holder.
3. Remove the lid from the empty container and pull the tube out.
4. Remove the lid from the new container and put the tube in straight.
5. Close the lid.
6. Place the new container in the device holder.



   Important!

   To avoid air bubbles getting into the system, it is absolutely necessary that the dye containers are placed **fully** and **upright** into the device holder. Air bubbles in the system can corrupt the analysis results.

7. Close the Main Unit's front cover.
8. Press the **Reagent** button on the Main Unit's panel keyboard.

   The Reagent overview will appear.

9. Select the corresponding reagent and confirm with **Select**.
10. Choose **Execute**.

    The reagent will be aspirated and replaced in the Main Unit.

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11. Enter the data into the Reagent Overview (see “20. Appendix”).

14.16 Replacing the piercer

If the XE-2100 is used in Sampler mode or Closed mode the cap piercer's tip will become blunt in the course of time; it could break off or cause other problems.

To ensure proper functioning, the piercer should be replaced periodically. At the latest after having performed 30,000 analyse operations with the Sampler, the message “Replace Piercer” will show in the display.

Tip:

The functions depends on the draw-off system used. Therefore the piercer is replaced as required or when instructed by the Sysmex engineer.

Important!

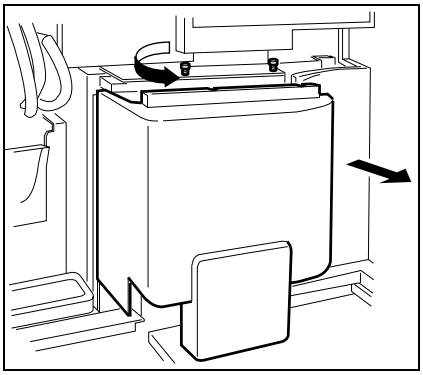
A spare piercer is supplied with the instrument. To avoid extended down times it is recommended to order a new spare piercer after a replacement without delay.

Removal

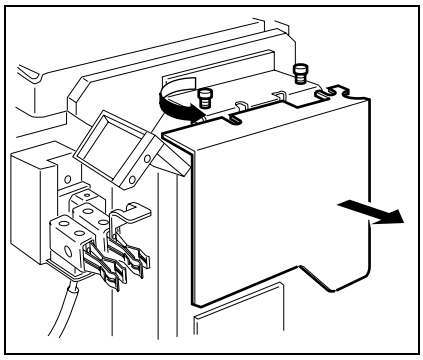
1. Turn the Main Unit OFF at the mains switch.
2. Open the Main Unit's front cover.

Caution!

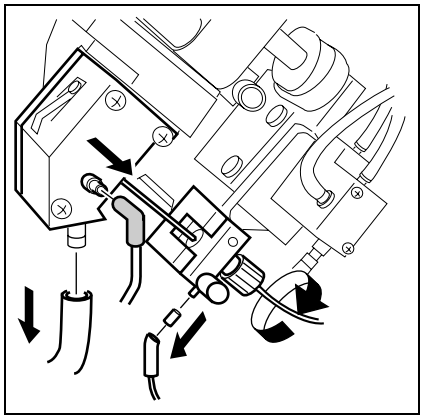
Secure the front cover with the stop bar.



3. Loosen the locking screws and remove the cover of the cap piercer.



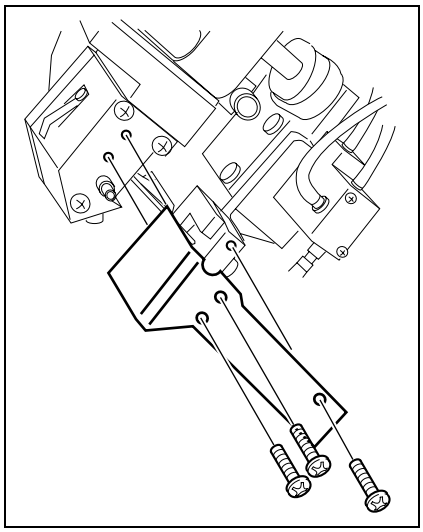
4. Loosen the locking screws and remove the cover of the piercer.



5. Remove the four tubes from the piercer unit.

Note:

One of the tubes contains another tube inside. Pull off both inner and outer tube together. The inner tube will later be fitted to the new piercer unit.



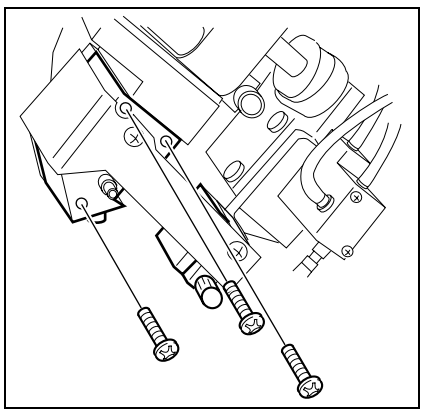
6. Attach the piercer safety plate with the screws to the piercer unit.

Warning!

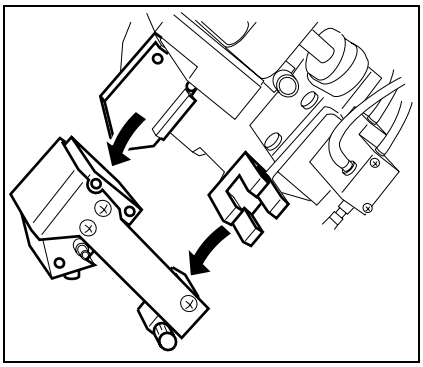
The piercer safety plate must be installed to avoid injury! Otherwise the piercer can move out and cause personal injury.

Note:

The piercer safety plate is included with the spare parts supplied.

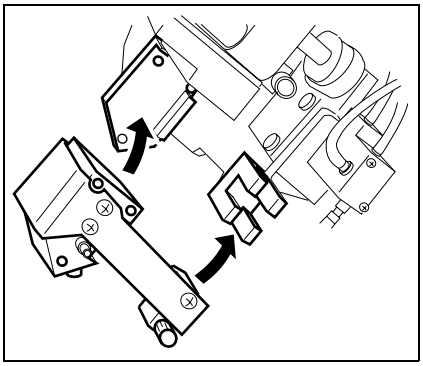


7. Loosen the locking screw of the rinse cup.
8. Remove the three fixing screws of the rinser and the screw holding the piercer plate.

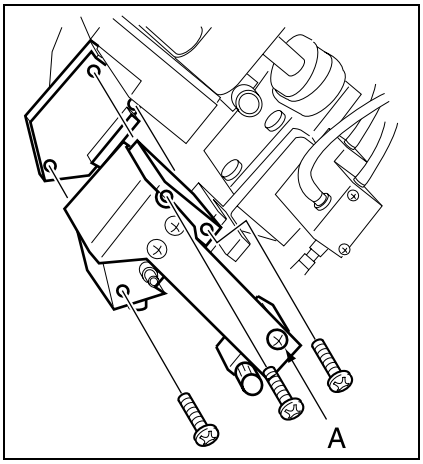


9. Remove the complete piercer unit and dispose of properly.

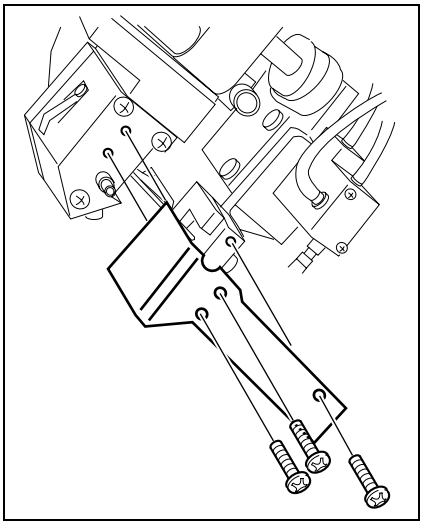
Installation



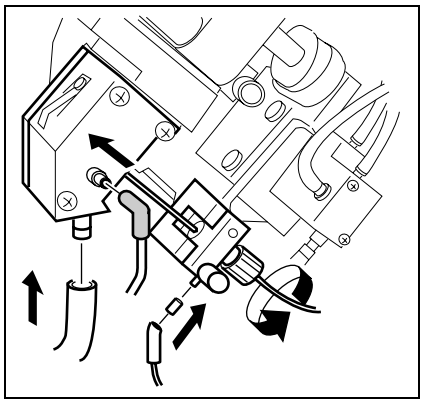
1. Set a new piercer unit on the slider.
2. Turn the three fixing screws of the rinser and the screw holding the piercer plate in by hand.



3. Loosen screw **A** of the piercer safety plate slightly.
4. If necessary, slide the rinser up and press it against the slider.
5. Tighten the four screws.



6. Remove the three screws of the piercer safety plate.



7. Connect the tubes and rubber connection in reverse order to the rinse cup and the piercer unit (see also chapter “Removal”).
8. Replace the covers of piercer unit and piercer.

Important!

To ensure correct analysis results the tubes must not be kinked or squeezed.

9. Close the front cover.

Resetting the counter

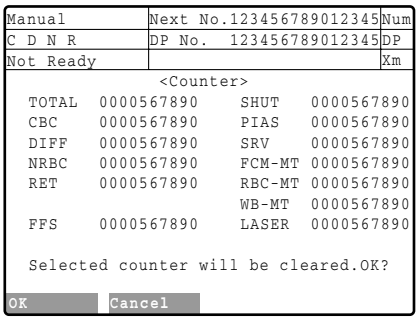
After a cap piercer replacement the counter must be reset. To do so, proceed as under:

1. On the Main Unit open the **Test** menu.
2. Choose **Status**.

   The status display will appear.
3. Choose **Counter**.

   The counter count display will appear.
4. Using the cursor keys ▲▼ choose the **PIAS** counter.
5. Choose **OK** to clear the counter.

   Choose **Cancel** to not clear the counter and to return to the status display.



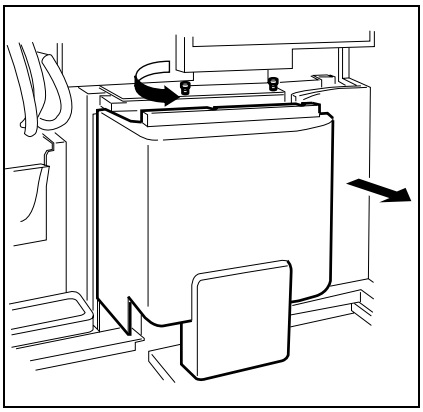
14.17 Replacing the hand clipper or rubber pads

If a hand clipper is bend or the rubber pads in the clamp worn-out, the sample tubes can no longer be properly held. Sampler mode and Closed mode are then faulty.

1. Turn the Main Unit OFF at the mains switch.
2. Open the Main Unit's front cover.

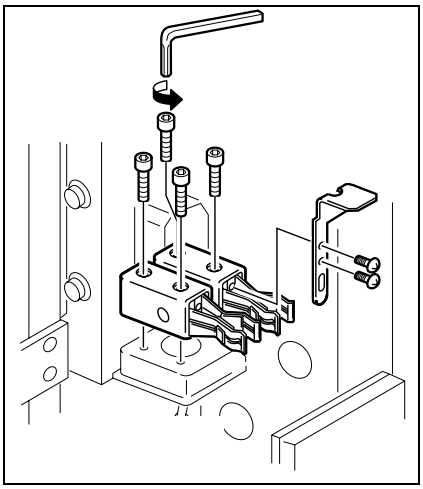
Caution!

Secure the front cover with the stop bar.

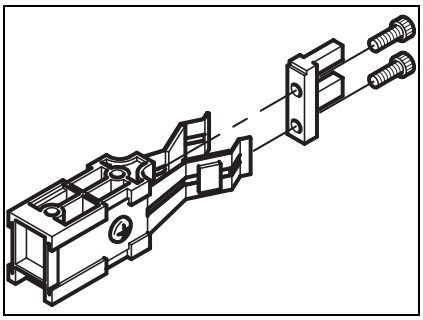


3. Loosen the locking screws at the cover of the cap-piercer and remove the screws.

Hand clipper replacement



1. Loosen both locking screws of the hand clipper you wish to replace.
2. Remove the hand clipper.



3. Hand clipper for Mixing Only:

– Remove the fixing plate from the old hand clipper for mixing.

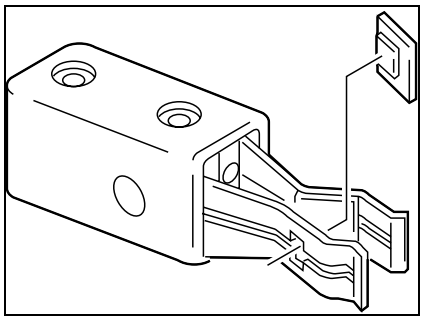
– Remove the F-bracket from the new hand clipper and attach the fixing plate (just removed) on the new hand clipper.

4. Install the new hand clipper to the original position using screws removed in step 1.

Please note: Hand clippers for mixing uses fixing plate.

– Install the cover of the cap-piercer and close the front cover.

Rubber pad replacement



1. Remove the rubber pad from the clamp.
2. Fit a new lining.

– When done, replace the piercer cover.

Important!

To ensure correct analysis results the tubes must not be kinked or squeezed.

– Close the front cover.

14.18 Replacing fuses

Both Main Unit and compressor are protected by built-in fuses against overvoltage.

Warning!

Replace only with fuses of the type specified (see “14.20 List of recommended reagents and supply parts”).

– Turn OFF the Main unit, the compressor and the IPU.
– Unplug the power supply cable of the device you will be replacing the fuse.

Important!

First check to see if there is power at the outlet.

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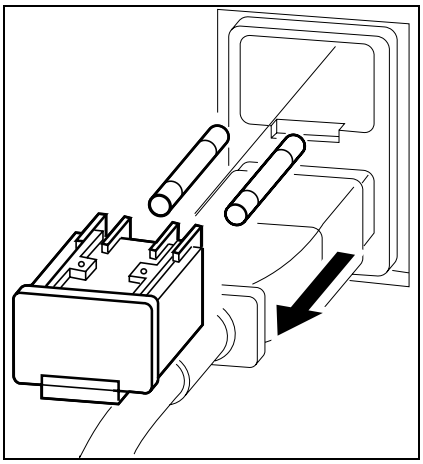
At the Main Unit



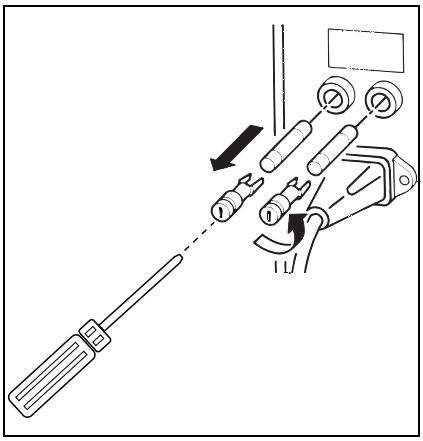
1. Use a screwdriver to press on the lock, then pull the fuse carrier out.
2. Replace the blown fuse.

Tip:

If it is not clear which fuse is blown, replace both fuses.

3. Put the fuse carrier back in place. It will lock in place with an audible click.

At the compressor



1. Use a flat-bit screwdriver to unscrew the fuse holder counter-clockwise.
2. Replace the blown fuse.

Tip:

If it is not clear which fuse is blown, replace both fuses.

3. Replace the fuse holder.

14.19 Adjustment of pressure and vacuum

For the accuracy of analyses it is very important to have the pressure and vacuum correctly adjusted.

The set points are:

Pressure	0.25 MPa ± 0.01 MPa
Pressure	0.16 MPa ± 0.001 MPa
Pressure	0.07 MPa ± 0.001 MPa
Pressure	0.03 MPa ± 0.001 MPa
Compressor vacuum	-0.07 MPa
Vacuum	-0.04 MPa

Important!

For initial operation adjustment is made by the Sysmex service engineer.

Tip:

Mark the nominal value at the compressor.

During operation the values are monitored.

If any of the values exceeds tolerances, an error message is displayed.

Important!

Start with checking all tubes and connections for cracks or leaks. If such damage can be ruled out, continue with the adjustment of pressure and vacuum, respectively.

Pressure test

– Squeeze the pressure tube.

If the pressure remains unchanged with a blocked pressure tube, the fault is at the compressor or at any of the compressor's internal pressure tubes.

Vacuum test

– Squeeze the vacuum tube.

If the vacuum increases the fault is at the Main Unit.

If the vacuum remains unchanged, the fault is at the compressor or at any of the compressor's internal vacuum tubes.

1. Ensure the instrument is ready for operation.
2. On the Main Unit open the Test menu.
3. Select the **Test** function.

   The **Test** submenu will come up.
4. Select **Status**.

   The status screen will appear.
5. Select **Sensor 1**.

   The display for Sensor 1 will open. The following information is displayed:

Pressure	Nominal values and actual pressures or vacuum, respectively
Temperature	Temperatures in the measuring chambers and the reagent heater
PMT (SSC)	Photo multiplier voltage
PMT (SFL)	Photo multiplier voltage
LASER PWR	Laser current draw
HGB	Background

6. Check to see which value deviates from the set point.

Manual	Next No.123456789012345	Num
C D N R	DP No. 123456789012345	DP
Not Ready		Xm

<Pressure>		<Temparature>	
0.25MPa	0.2464	REACT CMB	12.3°C
0.16MPa	0.1570	REAG40	45.3°C
0.07MPa	0.0687	REAG33	35.3°C
0.03MPa	0.0295	IMI DTCT	32.8°C
-0.07MPa	-0.0733	OPT DTCT	40.3°C
-0.04MPa	-0.0399	RBC DTCT	25.2°C
		ENVIRONMENT	23.1°C
PMT(SSC)	- 234 V		
PMT(SFL)	- 256 V	HGB	1234
LASER PWR	65.3mA		
	Cancel		

Important!

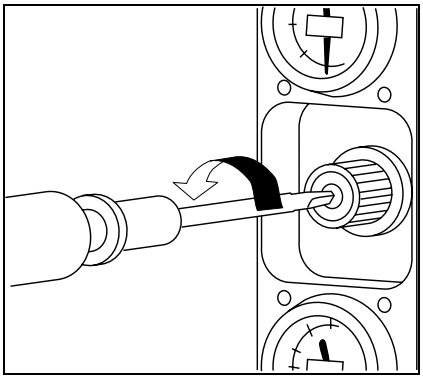
If multiple pressures deviate from the nominal value, always adjust the highest pressure first.

Pressure adjustment (0.25 MPa)

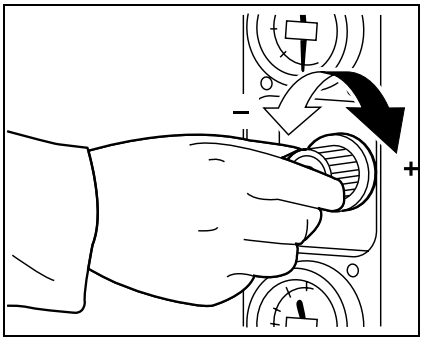
Tip:

The following tools are required:

- flat-bit screwdriver



1. Loosen the locking screw counter-clockwise by a quarter turn.



2. Watching the display on the screen, adjust the pressure with the knob:
   - Turning in the direction of **+** (clockwise) increases the pressure
   - Turning in the direction of **-** (counter-clockwise) reduces the pressure

Important!

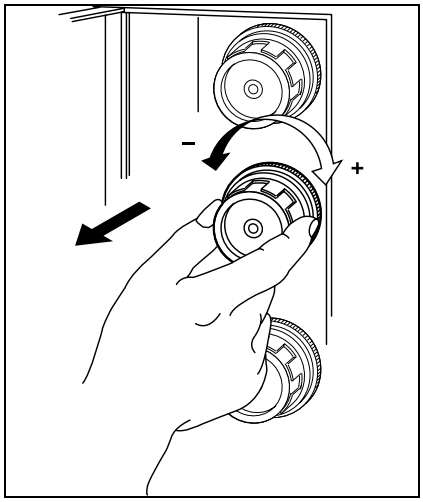
Pressure adjustment should always be made from a lower value. When the set point has been exceeded, reduce the pressure to below the set point, then increase and fine-tune it.

3. Once finished with the adjustment tighten the locking screw again. Take care that the adjusting knob does not turn!

Pressure adjustment (for 0.16 MPa, 0.07 MPa, 0.03 MPa)

Important!

The adjustment knobs are at the left-hand side of the Main Unit. To open the cover press on it.



1. Pull the pressure regulator knob out to unlock.

   Note:

   Some knobs may be stiff and do not unlock easily.

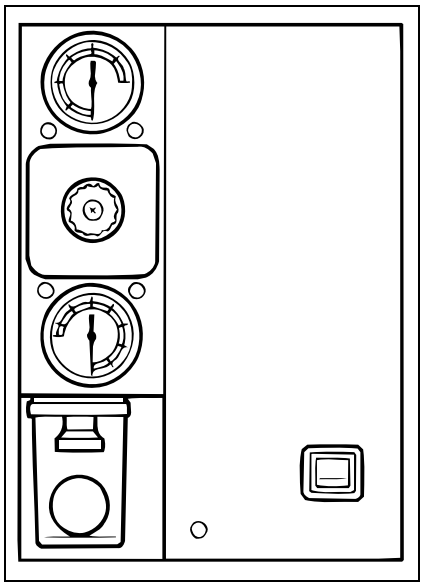
2. Watching the display on the screen, adjust the pressure with the knob:
   - Turning in the direction of **+** (clockwise) increases the pressure
   - Turning in the direction of **-** (counter-clockwise) reduces the pressure

   Important!

   Pressure adjustment should always be made from a lower value. When the set point has been exceeded, reduce the pressure to below the set point, then increase and fine-tune it.

3. Once finished with the adjustment push the pressure regulator knob back in. Take care that the adjusting knob does not turn!

Checking the vacuum in the compressor



If the vacuum in the compressor is less than 0.04 MPa, proceed as follows to check the compressor:

– Squeeze the tube between compressor and Main Unit.

Important!

If the vacuum increases to 0.04 MPa or above with a blocked tube, a leak exists in the Main Unit. Contact the Sysmex service representative.

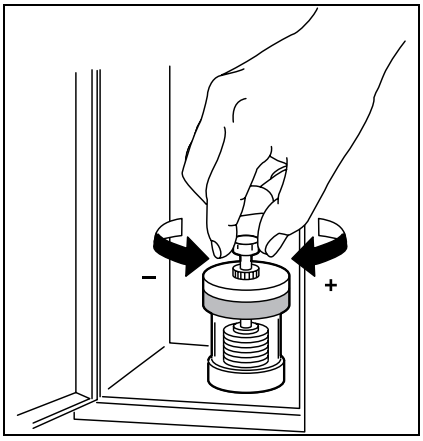
– Check the tubing between Main Unit and compressor and inside the compressor. Should a tube have come off, put it back on.

Important!

The vacuum in the compressor can not be adjusted. If the compressor is in use over an extended time, its performance and with it the generated vacuum will lessen. In such

case the vacuum pump must be repaired or replaced. Contact the Sysmex service representative.

Vacuum adjustment



1. Loosen the locking nut.
2. Watching the display on the screen, adjust the vacuum with the adjusting screw:
   - Turning in the direction of **+** (clockwise) increases the pressure
   - Turning in the direction of **-** (counter-clockwise) reduces the pressure

   Important!

   Vacuum adjustment should always be made from a lower value. When the set point has been exceeded, reduce the vacuum to below the set point, then increase and fine-tune it.
3. When done with the adjustment tighten the locking nut again. Take care that the adjusting screw does not turn!

14.20 List of recommended reagents and supply parts

Note:

We recommend to always keep sufficient supply of the following reagents and supply parts available. Only then it can be assured that a failure of the instrument is quickly eliminated.

Reagents

Product code	Product name
884-0871-1	CELLPACK (PK-30L) (20 L)
834-00111-0	CELLPACK (PK-30L) (10 L)
834-0032-4	CELLSHEATH (SE-90L) (20 L)
834-0032-10	CELLSHEATH (SE-90L) (10 L)
944-0461-3	STROMATOLYSER-FB (FBA-200A) (5 L)
984-1771-2	STROMATOLYSER-4DL (FFD-200A) (5 L)
984-1721-6	STROMATOLYSER-4DS (FFS-800A) (3 x 42 mL)
984-1671-7	STROMATOLYSER-NR (SNR-900A) (Lyse: 1 L; dye: 12 mL)
904-1151-1	SULFOLYSER (SLS-220A) (5 L)
934-0671-6	STROMATOLYSER-IM (SIM-220A) (10 L)
984-1621-1	RET SEARCH (II) (RED-700A) (Lyse: 1 L; dye: 12 mL)
834-0162-1	CELLCLEAN (CL-50) (50 mL)

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Supply Parts

Product code	Product name
971-0583-5	Piercer Set No. 1 (XE/Standard)
366-1229-0	Tube Holder No. 56
366-1231-8	Tube Holder No. 58
833-3312-0	Sample Rack (6/Pack) (C-2)
923-8101-4	Hand Clipper S#4 Assy (C1/Pier)
368-0079-9	Rubber Plate No. 39
266-5293-0	Fuse 250V 3.15A No. 19195 (Europe)
443-2224-6	HEPA-Filter (with PRE)
462-3520-5	Transducer Brush
983-8861-9	Float Switch No. 25 Assy (C1/5L)

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15. Troubleshooting

On a complex instrument such as the XE-2100, different errors can occur:

- General faults, instrument failure.
- Other errors are indicated by a beep and an error message displayed on the LCD screen. Press the **HELP** key to call up the online help, which will list in plaintext on the LCD screen all steps to be taken to rectify the error. If multiple errors occur simultaneously, they are displayed ranked by importance.
- If an error affects only a specific analysis result, it will be marked by a flag (see chapter “9. Data Browser”).

Warning!

Unplug before opening the instrument. Otherwise there is a risk of personal injury by electric shock and damage to the instrument.

Important!

If you are unable to rectify the error, contact the Sysmex service representative for assistance. Write down the following information beforehand to enable the Sysmex Service to provide assistance quickly:

- exact instrument designation (see name plate)
- the instrument's serial no. (on the Main Unit, front cover opened!)
- customer no.
- error messages

Important!

In case of a power failure during operation set the main switch to the **0 OFF** position.

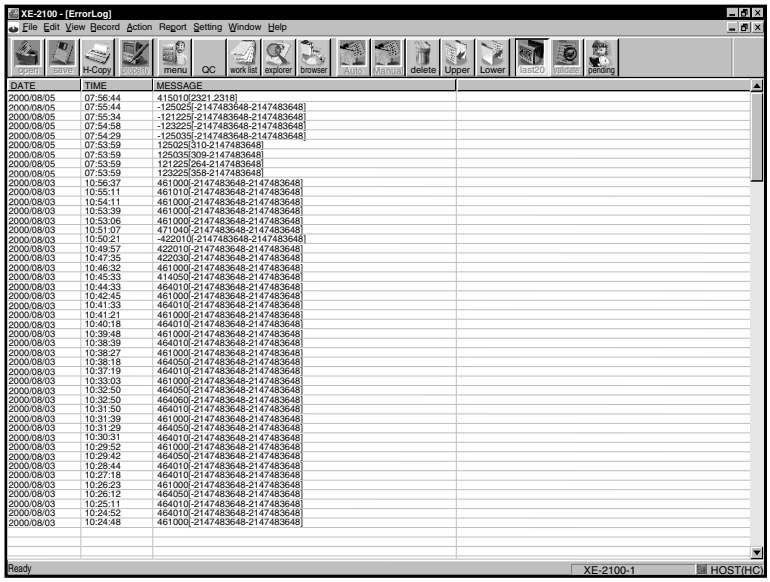
Error log

In the error log all errors that have occurred are listed with error code and error parameters. The errors are sorted by occurance in chronological order. Up to 100 errors can be saved. If more errors occur, the oldest entry is automatically deleted (first in, first out).

To open the error log proceed as follows:

1. Choose **Controller** view.
2. Click on the **Error log** button.

The error log will be displayed.



15.1 General faults, instrument failure

Trouble	Action
The XE-2100 is switched ON but will not start.	Check if plugged in properly. Use another appliance to check if the outlet is live. Check fuses and circuit breakers, replace if necessary (see “14.18 Replacing fuses”).
After switching ON the LCD screen remains blank, a beep sounds.	A memory error has occurred. Switch the instrument OFF and wait 2 minutes before switching ON again. If the error occurs again, contact the Sysmex service representative.
No display on LCD screen.	Check the contrast setting of the screen (see “5.5 Basic instrument settings”).
No reaction when keys are pressed.	If the message “PU Sleeping” is displayed, the pneumatic unit was shut off automatically. Press **SELECT** to bring up the analysis screen, then press the start switch.
Fluid leaks from the instrument.	Switch the instrument OFF and wipe off leaking fluid. If fluid leakage persists after switching ON again, switch the instrument OFF and contact the Sysmex service representative.

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15.2 Error messages

General

If an error occurs, a beep sounds and an error message is displayed on the LCD screen.

– Press **HELP** to turn the beep off.

On the LCD screen steps for rectifying the error are displayed in plaintext.

– Follow the instructions.

In some cases the error message can be suppressed. In such case an analysis can not be performed, you can, however, view the saved data and evaluate them.

If multiple errors occur simultaneously, they are displayed ranked by importance.

– Press the **HELP** key again.

The Help menu of the error at the top of the list will be displayed.

– Follow the instructions.

Important!

With many error messages it is suggested to perform a check. Detailed instructions on how to perform such checks are given in chapter “15.3 Tests”.

- Sampler test
- Piercer
- Barcode
- Motor
- SRV
- Counter

– Press **HELP** to go to the next screen.

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Categories

The possible errors have different effects on the currently performed analysis and the instrument. They are classified into the following categories:

Analysis error:

The analyse operation is stopped, analysis data are marked as abnormal and saved. The system returns to the “Ready” state.

The message “Analysis Error” and “Check Stored Data” are displayed.

Not Ready

The analyse operation has stopped. Afterwards the system is Not Ready and no further analyses can be performed until the cause for the error has been removed.

The message “Not Ready” and the corresponding error message are displayed.

Analysis Error/Not Ready:

- The analyse operation is stopped, analysis data are marked as abnormal and saved.
- Only one error message is displayed.

Afterwards the system is Not Ready and no further analyses can be performed until the cause for the error has been removed.

The messages “Not Ready” and “Analysis Error” are displayed.

When working in Sampler mode the messages “Analysis Error” and “Check Stored Data” will be displayed.

Warning messages:

The analysis can be performed, but the results should be checked afterwards. A warning message is displayed. When the cause for the warning message has been removed, the message will disappear.

Emergency stop:

The analysis is interrupted immediately, all sequences are stopped. Turn the instrument OFF and wait 10 minutes before switching ON again.

 **Note:**

Results of samples which had an error occurred during analysis, are marked with **** or ----.

List of error messages (sorted alphabetically)

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List of error messages (sorted by function)

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Error messages, causes and elimination

Error message: 0.25 MPa Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Adjustment error of 0.25 MPa pressure • Pressure in compressor not sufficient • Air leakage at tube or nipple **Action to resolve the error:** 1. Adjust pressure to 0.25 MPa (see chapter 14.19). 2. Check the compressor's power supply, switch compressor ON if necessary 3. Check pressure line for loose connections or breakage. Reconnect or replace, if necessary.
Error message: 0.16 MPa Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Adjustment error of 1.6 MPa pressure • Regulator for 0.16 MPa pressure faulty **Action to resolve the error:** – Adjust pressure to 0.16 MPa (see chapter 14.19). If it is not possible to adjust the pressure the regulator is faulty. Contact the Sysmex service representative.
Error message: 0.07 MPa Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Adjustment error of 0,07 MPa pressure • Regulator for 0.07 MPa pressure faulty **Action to resolve the error:** – Adjust pressure to 0.07 MPa (see chapter 14.19). If it is not possible to adjust the pressure the regulator is faulty. Contact the Sysmex service representative.
Error message: 0.03 MPa Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Adjustment error of 0,03 MPa pressure • Regulator for 0.03 MPa pressure faulty **Action to resolve the error:** – Adjust pressure to 0.03 MPa (see chapter 14.19). If it is not possible to adjust the pressure the regulator is faulty. Contact the Sysmex service representative.
Error message: -0.07 MPa Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Vacuum in compressor not sufficient • Air leakage at tube or nipple **Action to resolve the error:** – Check vacuum line for loose connections or breakage. Reconnect or replace, if necessary. The compressor is probably faulty. Contact the Sysmex service representative.

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Error message: -0.04 MPa Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Adjustment error of 0.04 MPa • Liquid runs back to the trap chamber • Air leakage at tube or nipple **Action to resolve the error:** 1. Adjust vacuum to 0.04 MPa (see chapter 14.19). 2. Drain the fluid from the compressor's trap chamber (see chapter 14.4). 3. Check vacuum line for loose connections or breakage. Reconnect or replace, if necessary.
Error message: Pressure Lower Error **Status:** Not Ready **Category:** Emergency stop	**Possible cause:** • Compressor was suddenly turned OFF during operation. • Air tube has become detached. **Action to resolve the error:** 1. Check the compressor's power supply, switch compressor ON if necessary 2. Check air tube for loose connections. Reconnect if necessary.
Error message: Close RBC Detect Cover **Status:** Not Ready	**Possible cause:** • RBC detector cover open. • Sensor of RBC detector cover faulty. **Action to resolve the error:** – Close the RBC detector cover. If the error persists the sensor is probably faulty. Contact the Sysmex service representative.
Error message: IMI Detector Cover Open **Status:** Not Ready	**Possible cause:** • IMI detector cover open. • Sensor of IMI detector cover faulty. **Action to resolve the error:** – Close the IMI detector cover. If the error persists the sensor is probably faulty. Contact the Sysmex service representative.
Error message: RBC Detector Temp High; RBC Detector Temp Low **Category:** Analysis error	**Possible cause:** • Temperature of the sample in the RBC detector is not between 10 and 40°C. **Action to resolve the error:** – Make sure the ambient temperature is between 15 and 30 °C (optimal would be 25 °C).

Error message: IMI Detector Temp High; IMI Detector Temp Low **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Temperature in the IMI detector is outside the default range. **Action to resolve the error:** – Wait until the temperature has stabilized to the default range. If the message is still displayed 30 minutes after the Main Unit was turned ON, this indicates a possible malfunction of the instrument. Contact the Sysmex service representative.  **Note:** While this error is displayed CBC and RET analyses can be performed.
Error message: 40°C RH Temp High; 40°C RH Temp Low **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • The temperature of the 40 °C reagent heater is outside the default range. **Action to resolve the error:** – Wait until the temperature has stabilized to the default range. If the message is still displayed 30 minutes after the Main Unit was turned ON, this indicates a possible malfunction of the instrument. Contact the Sysmex service representative.
Error message: 33°C RH Temp High; 33°C RH Temp Low **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • The temperature of the 33 °C reagent heater is outside the default range. **Action to resolve the error:** – Wait until the temperature has stabilized to the default range. If the message is still displayed 30 minutes after the Main Unit was turned ON, this indicates a possible malfunction of the instrument. Contact the Sysmex service representative.
Error message: FCM RU Temp High; FCM RU Temp Low **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • The temperature in the flow cell's reaction chamber is outside the default range. **Action to resolve the error:** – Wait until the temperature has stabilized to the default range. If the message is still displayed 30 minutes after the Main Unit was turned ON, this indicates a possible malfunction of the instrument. Contact the Sysmex service representative.

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Error message: FCM Detector Temp High; FCM Detector Temp Low **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Temperature in the optical detector is outside the default range. **Action to resolve the error:** – Wait until the temperature has stabilized to the default range. If the message is still displayed 30 minutes after the Main Unit was turned ON, this indicates a possible malfunction of the instrument. Contact the Sysmex service representative.
Error message: IMI TD Therm Sens ERR **Status:** Not Ready	**Possible cause:** • One of the IMI detector's sensors is faulty **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.
Error message: 33 °C RH Therm Sens ERR **Status:** Not Ready	**Possible cause:** • One of the 33 °C reagent heater's thermo sensors may be faulty. **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.
Error message: 40 °C RH Therm Sens ERR **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • One of the 40 °C reagent heater's thermo sensors may be faulty. **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.
Error message: FCM RU Therm Sens ERR **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • One of the reaction chamber's thermo sensors is faulty. **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.

Error message: FCM TD Therm Sens ERR **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • One of the optical detector's sensors is faulty **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.
Error message: Env Therm Sens ERR **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • One of the thermo sensors for the ambient temperature is faulty. **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.
Error message: Replace Container ESE; Replace Container SIM; Replace Container EPK; Replace Container SLS; Replace Container FBA; Replace Container FFD; Replace Container FFS; Replace Container SNR; Replace Container RED **Status:** Not Ready	**Possible cause:** • Low reagent level • Float switch malfunction • Hydraulic system error **Action to resolve the error:** – Replenish the corresponding reagent (see chapter “14. Cleaning and Maintenance”. If the error message is still displayed after reagent replenishment: 1. Check the float switch. 2. Check the hydraulic system. Watch out for loose, torn or detached connections and tubes of the reagent named in the error message. If a fault is found, correct it.  **Note:** While the errors “Replace Container SIM”, “Replace Container FFD” or “Replace Container FFS” are displayed, CBC and RET analyses can be performed. While the “Replace Container SNR” error is displayed, CBC, DIFF and RET analyses can be performed. While the “Replace Container RED” error is displayed, CBC, DIFF and NRBC analyses can be performed.

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Error message: Chamber EPK Error; Chamber ESE Error; Chamber SIM Error; Chamber FCM Sheath ERR **Status:** Not Ready	**Possible cause:** • Tubes between reagent containers and Main Unit are bent, clogged or loose. **Action to resolve the error:** 1. Check the tubes. 2. Afterwards press the **HELP** key on the Main Unit's panel keyboard and in **Main Menu** view select **OK**.  **Note:** While the “Chamber ESE Error” is displayed, CBC analyses can be performed.
Error message: Waste Chamber 1 Error; Waste Chamber 2 Error; Waste Chamber 3 Error **Status:** Not Ready	**Possible cause:** • Drain tube bent or clogged **Action to resolve the error:** 1. Check the drain tubes. 2. If the drain tube connected to the waste chamber outlet is bent or clogged, replace or clean it. 3. In particular, check the area around the waste chamber's outlet for contamination or clogging. 4. Afterwards press the **HELP** key on the Main Unit's panel keyboard and in **Main Menu** view select **OK** to rinse the waste chamber.
Error message: RBC Chamber Drain Error **Status:** Not Ready	**Possible cause:** • RBC drain tube bent or clogged **Action to resolve the error:** 1. Check the RBC drain tubes. 2. If the drain tube connected to the waste chamber outlet is bent or clogged, replace or clean it. 3. In particular, check the area around the waste chamber's outlet for contamination or clogging. 4. Afterwards press the **HELP** key on the Main Unit's panel keyboard and in **Main Menu** view select **OK**.
Error message: Exchange Waste Tank **Status:** Not Ready	**Possible cause:** • Waste tank is full **Action to resolve the error:** – Replace the waste tank (see chapter 14.14)

Error message: WB Asp Motor Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • The WB aspiration motor is subjected to an unusual high load. **Action to resolve the error:** 1. Check the WB aspiration pump. 2. Make sure no connections or tubes are in contact with the upper and lower part of the WB pump. 3. Afterwards press the **HELP** key on the Main Unit's panel keyboard and in **Main Menu** view select **OK** to check the function of the pump.
Error message: RBC Sheath Motor Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • The RBC Sheath Injector is subjected to unusual high loads. **Action to resolve the error:** 1. Check the RBC Sheath Injector. 2. Make sure no connections or tubes are in contact with the upper and lower part of the RBC Sheath Injector. 3. Afterwards press the **HELP** key on the Main Unit's panel keyboard and in **Main Menu** view select **OK** to check the function.
Error message: FCM Sheath Motor Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • The flow cell's sheath injector is subjected to unusual high loads. **Action to resolve the error:** 1. Check the FCM Sheath Injector. 2. Make sure no connections or tubes are in contact with the upper and lower part of the FCM Sheath Injector. 3. Afterwards press the **HELP** key on the Main Unit's panel keyboard and in **Main Menu** view select **OK** to check the function.
Error message: Rinse Motor Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • The rinse motor is subjected to unusual high loads. **Action to resolve the error:** 1. Check the rinse unit 2. Make sure no connections or tubes are in contact with the upper and lower part of the rinse unit. 3. Afterwards press the **HELP** key on the Main Unit's panel keyboard and in **Main Menu** view select **OK** to check the function.

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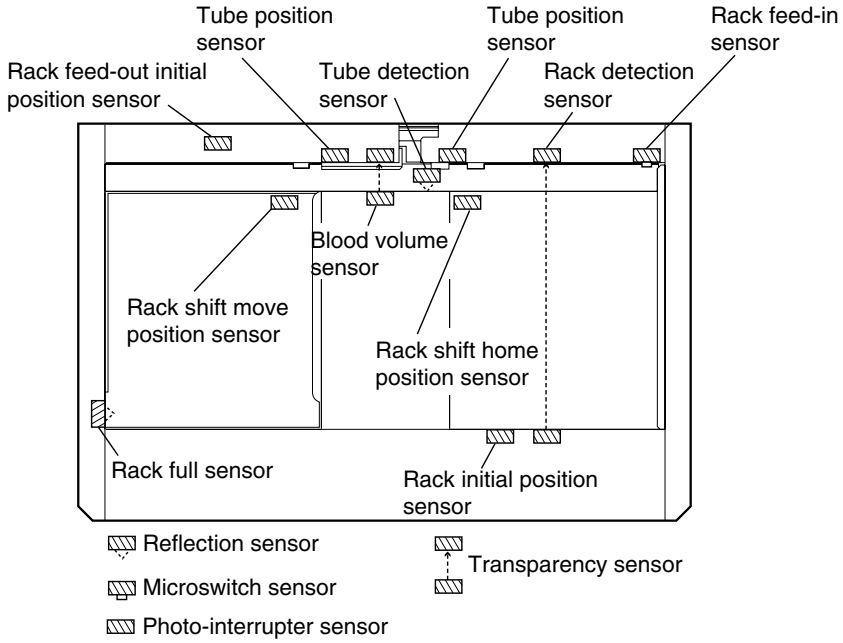
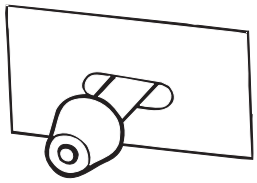
Error message: Mixing Motor Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • The reaction chamber's mixing motor is subjected to unusual high loads. **Action to resolve the error:** 1. Check mixing motor of the reaction chamber 2. Ensure no tubes are in contact with the mixing motor. 3. Afterwards press the **HELP** key on the Main Unit's panel keyboard and in **Main Menu** view select **OK** to check the function.
Error message: Low Blood Volume **Status:** Ready **Category:** Analysis error	**Possible cause:** • Blood volume too low for Sampler analysis (a minimum of 1 mL blood is required). **Action to resolve the error:** – Analyse sample in Manual or Capillary mode.
Error message: Sample Not Asp Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Abnormal sample: sample is partially clotted. Extremely anemic sample • The following parts may be blocked: Piercer Sample rotor valve WB aspiration tubes • WB aspiration tubes are not connected to the Sampler **Action to resolve the error:** – Check sample and analyse again. – Clean piercer, SRV and WB aspiration tubes as follows: 1. Execute a Shutdown (see chapter 14.3). 2. Perform an automatic rinse. 3. If the clogging could not be completely cleared, pour CELLCLEAN in a sample tube. Analyse this in Sampler mode to clean the piercer and the WB aspiration tubes. 4. If the error persists, the Cap Piercer's piercer is likely to be blocked. Replace the piercer (see chapter 14.16). 5. When the instrument is operational again reanalyse the sample. – Reconnect the tubing

Error message: Short Sample **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Not enough blood available; no sufficient amount of sample material could be aspirated. • Piercer or WB aspirating hoses contaminated  **Note:** If the sample tube is contaminated or the bar code label stuck on too low, the Sampler can not measure the blood quantity. Aspiration is performed despite the error message. **Action to resolve the error:** – Analyse sample in Manual or Capillary mode – If this error occures even though there is sufficent blood in the tube, the piercer or the WB aspiration tubes are likely to be contaminated. Clean as follows: 1. Execute a Shutdown (see chapter 14.3). 2. Perform an automatic rinse. 3. If the clogging could not be completely cleared, pour CELLCLEAN in a sample tube. Analyse this in Sampler mode to clean the piercer and the WB aspiration tubes. 4. If the error persists, the Cap Piercer's piercer is likely to be blocked. Replace the piercer (see chapter 14.16). 5. When the instrument is operational again reanalyse the sample.
Error message: SRV Lower Position ERR; SRV Upper Position ERR **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Sample rotor valve malfunction • Sample rotor valve is contaminated **Action to resolve the error:** 1. Perform a SRV check (see chapter 15.3). Ensure no tubing is in contact with the SRV's moving parts. Then press the **HELP** button on the Main Unit's panel keyboard. Select **OK** on the Main menu to check the function. 2. Clean the SRV (see chapter 14.5) and perform the check.

Sensor Overview



Error message: Blood Asp Sensor Error **Status:** Not Ready	**Possible cause:** • The sensor monitoring sample aspiration in Sampler mode is faulty. **Action to resolve the error:** 1. Contact the Sysmex service representative. 2. As a temporary measure the stop conditions for the Sampler mode can be changed, so that the Sampler continues to operate (see chapter “13.1 Main Unit settings”).
Error message: Set Piercer Cover **Status:** Not Ready	**Possible cause:** • The piercer cover was removed **Action to resolve the error:** 1. Replace the piercer cover. 2. When done press the **HELP** button on the Main Unit's panel keyboard. Select **OK** on the Main menu to check the function.
Error message: Rack feed in Func Error; Rack feed In Init. ERR **Status:** Not Ready	**Possible cause:** • Malfunction of the rack feed in sensor, probably contaminated **Action to resolve the error:** – Clean the sensor.

Error message: Rack Shift Function ERR **Status:** Not Ready	**Possible cause:** • Malfunction of the rack shift sensor, probably contaminated • Microswitch of sensor stuck **Action to resolve the error:** 1. Clean the sensor. 2. Apply some oil to the microswitch's mechanism.  **Caution!** Use resin-free oil only.
Error message: Rack Shift Home Pos.ERR **Status:** Not Ready	**Possible cause:** • Malfunction of the rack shift start sensor, probably contaminated **Action to resolve the error:** 1. Clean the sensor.
Error message: Rack Removed **Status:** Not Ready	**Possible cause:** • The rack was removed while a sample tube was in the tube clamp. **Action to resolve the error:** 1. Take the sample tube from the tube clamp and set it back in the rack. 2. Set the rack in the Sampler and repeat the analysis.
Error message: Rack Move Error 1 **Status:** Not Ready	**Possible cause:** • The rack could not be moved. **Action to resolve the error:** – Set the rack anew in the Sampler and repeat the analysis.
Error message: Rack Move Error 2 **Status:** Not Ready	**Possible cause:** • During the Sampler analysis the rack was moved without a sample tube in the tube clamp. **Action to resolve the error:** – Set the rack anew in the Sampler and repeat the analysis.
Error message: Rack Move Error 3 **Status:** Not Ready	**Possible cause:** • The rack was moved during an “Emergency analysis”. **Action to resolve the error:** – Set the rack anew in the Sampler and repeat the analysis.

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Error message: Rack Feed Out Func ERR; Rack Feed Out Init. ERR **Status:** Not Ready	**Possible cause:** • Malfunction of the rack feed out sensor, probably contaminated **Action to resolve the error:** – Clean the sensor.
Error message: Hand Init Position ERR; Hand Move Position ERR **Status:** Not Ready	**Possible cause:** • Malfunction of the cylinder for forward/backward movement **Action to resolve the error:** 1. Take the sample tube from the tube clamp and set it back in the rack. 2. Put the rack back. 3. Perform a tube clamp test (see chapter 15.3). 4. If necessary, remove interfering parts from the movement radius of the tube clamp. 5. After this check press the **HELP** button on the Main Unit's panel keyboard. Select **OK** on the Main menu to check the function.
Error message: Hand Upper Position ERR; Hand Lower Position ERR **Status:** Not Ready	**Possible cause:** • Malfunction of the cylinder for up/down movement **Action to resolve the error:** 1. Take the sample tube from the tube clamp and set it back in the rack. 2. Put the rack back. 3. Perform a tube clamp test (see chapter 15.3). 4. If necessary, remove interfering parts from the movement radius of the tube clamp. 5. After this check press the **HELP** button on the Main Unit's panel keyboard. Select **OK** on the Main menu to check the function.
Error message: Tube Inv. Position ERR **Status:** Not Ready	**Possible cause:** • Malfunction of the sample tube turning cylinder **Action to resolve the error:** 1. Take the sample tube from the tube clamp and set it back in the rack. 2. Put the rack back. 3. Perform a tube clamp test (see chapter 15.3). 4. If necessary, remove interfering parts from the movement radius of the tube clamp. 5. After this check press the **HELP** button on the Main Unit's panel keyboard. Select **OK** on the Main menu to check the function.

Error message: Tube Sensor Error **Status:** Not Ready	**Possible cause:** • Even though a sample tube with blood is present, the sample tube sensor can not detect a sample tube. • Even though no sample tube is present the blood volume sensor signals the presence of blood. **Action to resolve the error:** 1. Clean the sample tube sensor. 2. Clean the blood volume sensor.
Error message: Tube Clamp Error **Status:** Not Ready	**Possible cause:** • Tube clamp can not hold the sample tube • Tube clamp is bent and can not hold the sample tube properly **Action to resolve the error:** 1. Take the sample tube from the tube clamp and set it back in the rack. 2. Put the rack back. 3. Straighten the tube clamp or replace it (see chapter 14.17). 4. Perform a tube clamp test (see chapter 15.3). 5. Check the tube clamp mechanism for malfunction. 6. After this check press the **HELP** button on the Main Unit's panel keyboard. Select **OK** on the Main menu to check the function.
Error message: Rack Full Error **Status:** Not Ready	**Possible cause:** • The sensor of the left rack pool indicates that no more racks can be accepted, thus the Sampler analysis can not be continued. **Action to resolve the error:** – Remove the processed racks from the left pool.
Error message: Sampler Start ERR (BSNS); Sampler Start ERR (SNS4); Sampler Start ERR (SNS5) **Status:** Not Ready	**Possible cause:** • The rack was set to a wrong position in the measuring line. **Action to resolve the error:** – Set the rack into the starting position and start the analysis again.
Error message: Rack Not Exist **Category:** Warning message	**Possible cause:** • In the right rack pool no rack is existing. **Action to resolve the error:** – Set a rack in the right rack pool to perform the analysis.

Error message: IMI Slow To Start; IMI Count Too Long **Category:** Analysis error	**Possible cause:** • IMI detektor aperture blocked **Action to resolve the error:** – Remove the blocking (see chapter 14.9). Probably with the brush (see chapter 14.10).
Error message: IMI Fast To Start; IMI Count Too Short **Category:** Analysis error	**Possible cause:** • Air bubbles in analyser unit **Action to resolve the error:** – Perform an automatic rinse.
Error message: Background Error **Category:** Analysis error	**Possible cause:** • Air bubbles exist • Aperture contaminated • Reagent contaminated **Action to resolve the error:** 1. Perform an automatic rinse. 2. Remove the blocking (see chapter 14.9). Probably with the brush (see chapter 14.10). 3. Replace the reagent (see chapter 14.15).
Error message: RBC Sampling Error; PLT Sampling Error **Category:** Analysis error	**Possible cause:** • Aperture contaminated • Abnormal sample **Action to resolve the error:** 1. Remove the blocking (see chapter 14.9). Probably with the brush (see chapter 14.10). 2. Repeat the analysis.
Error message: WBC/BASO Sampling Error; Diff Sampling Error; NRBC Sampling Error; RET Sampling Error **Category:** Analysis error	**Possible cause:** • Blocking or contamination of the flowcell's optical detector • Abnormal sample **Action to resolve the error:** 1. Clean the flowcell of the optical analyser unit (see chapter 14.13). 2. Repeat the analysis.
Error message: RBC CCSD Noise Error; PLT CCSD Noise Error; IMI CCSD Noise Error; FCM CCSD Noise Error **Category:** Analysis error	**Possible cause:** • Electrical noise emitted by other devices • Sudden electrical interferences **Action to resolve the error:** 1. Remove all devices near the instrument which could emit electrical noise. 2. Repeat the analysis.

Error message: IMI RF Noise Error **Category:** Analysis error	**Possible cause:** • HF noise level is high **Action to resolve the error:** 1. Repeat the analysis. 2. If after this step the same error message is still displayed, contact the Sysmex service representative.
Error message: RBC Bubble Error; RBC Clog Error **Category:** Analysis error	**Possible cause:** • Blocking of RBC detector and air bubbles **Action to resolve the error:** – Remove the blocking (see chapter 14.9). Probably with the brush (see chapter 14.11).
Error message: Low Count Error **Category:** Analysis error	**Possible cause:** • Abnormal sample • Piercer blocked • SRV blocked • Aspiration tube blocked **Action to resolve the error:** 1. Repeat the analysis. 2. Clean the piercer (see chapter 14.9). 3. Clean the SRV (see chapter 14.5). 4. Clean the aspiration tube.
Error message: HGB ERROR **Category:** Analysis error	**Possible cause:** • Air bubbles in HGB analyser unit **Action to resolve the error:** – Perform an automatic rinse.
Error message: HGB Drain Error **Category:** Analysis error	**Possible cause:** • HGB flow cell is drained too slow. **Action to resolve the error:** – Check the drain tubes of the HGB flowcell. Make sure the drain tubing is not bent or blocked. Replace if necessary.
Error message: IMI Detector Error **Category:** Analysis error	**Possible cause:** • Contamination or air bubbles in IMI analyser unit **Action to resolve the error:** – Remove the blocking (see chapter 14.9). Probably with the brush (see chapter 14.10).

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Error message: RET Error **Category:** Analysis error	**Possible cause:** • Abnormal sample • Tubes of RET dye and diluent blocked, bent or having a loose connection **Action to resolve the error:** 1. Repeat the analysis. 2. Check the dye tubes and the amount of reagent.
Error message: WBC/BASO-CH Error; DIFF-CH Error; NRBC-CH Error **Category:** Analysis error	**Possible cause:** • Blocking or contamination of the flowcell's optical detector • Not enough sample material (blood volume too low, air bubbles, etc.) • Abnormal sample (platelet clotting and protein deposits, etc.) **Action to resolve the error:** 1. Clean the flowcell of the optical analyser unit (see chapter 14.13). 2. Repeat the analysis. 3. Check the sample by means of a smear or optically.
Error message: RBC-CH Error; PLT-CH Error **Category:** Analysis error	**Possible cause:** • Because of external noise the number of particles in the RBC/PLT channel exceeds the upper limit of the display range. **Action to resolve the error:** 1. Remove all devices near the instrument which could emit electrical noise. 2. Repeat the analysis.
Error message: RET-CH Error **Category:** Analysis error	**Possible cause:** • Abnormal sample • SRV blocked • Blocking or contamination of the flowcell's optical detector • Air bubbles in the optical analyser unit's flowcell **Action to resolve the error:** 1. Repeat the analysis. 2. Clean the SRV (see chapter 14.5). 3. Clean the flowcell of the optical analyser unit (see chapter 14.13). 4. Remove the air bubbles from the optical analyser unit's flowcell (see chapter 14.12).

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Error message: Data Error **Category:** Analysis error	**Possible cause:** • Analysis result exceeds the Reference Limit set on IPU. • Abnormal sample • Aperture contaminated **Action to resolve the error:** 1. Reset the Reference Limit of IPU (see chapter 13.2). 2. Repeat the analysis. 3. Remove the blocking (see chapter 14.9). Probably with the brush (see chapter 14.10). 4. Perform the quality control analysis, if necessary.
Error message: Laser Tube Aged **Status:** Ready **Category:** Warning message	**Possible cause:** • The service life of the laser is coming to an end. **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.  **Note:** Analyses can be performed. The laser tube, however, should be replaced as soon as possible.
Error message: Laser Power Error **Status:** Not Ready	**Possible cause:** • Laser faulty **Action to resolve the error:** – Repeat the analysis. If the error message is still displayed, contact the Sysmex service representative.
Error message: Close FCM Detect Cover **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Optical detector cover open. • Sensor of optical detector cover faulty. **Action to resolve the error:** – Close the FCM detector cover. If the error message is still displayed, the sensor is likely to be faulty. Contact the Sysmex service representative.

Error message: TC Com. Error; ID Unit Com. Error; Sampler Com. Error **Status:** Not Ready **Category:** Analysis error	**Possible cause:** • Electronics malfunction due to electrical noise or similar. **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.  **Note:** While the “TC Com. Error” or “ID Unit Com. Error” is displayed, analyses can be performed in Manual mode.
Error message: RAM Error; Setup Data Error **Category:** Analysis error **Status:** Not Ready	**Possible cause:** • Electronics malfunction due to electrical noise or similar. **Action to resolve the error:** – Turn the Main Unit OFF at the mains switch and wait at least 5 seconds before turning ON again. If the error message is still displayed, contact the Sysmex service representative.
Error message: DP Error **Status:** Not Ready	**Possible cause:** • No paper in data printer • Data printer offline • Data printer not turned ON **Action to resolve the error:** 1. Check to see that the data printer is turned ON, turn ON if necessary. 2. Check to see that the data printer is online (see the printer manual on how to set it online). 3. Check the paper in the printer, replenish if necessary.
Error message: IPU Com. Error **Status:** Not Ready	**Possible cause:** • IPU was suddenly turned OFF during operation. • The XE application software of the IPU suddenly terminated during operation. • The connection to the Main Unit was interrupted during operation. • Other causes **Action to resolve the error:** 1. Turn the Main Unit OFF; then turn IPU and Main Unit ON again. 2. Turn the Main Unit OFF and reestablish the connection. Turn IPU and Main Unit ON again. 3. If you can not clear the error yourself, contact the Sysmex service representative.

Error message: IPU Error **Status:** Not Ready	**Possible cause:** • The IPU was not running yet when the Main Unit was turned ON. • The XE application software was not running on the IPU when the Main Unit was turned ON. • The connection between Main Unit and IPU was interrupted when the Main Unit was turned ON. • Other causes **Action to resolve the error:** 1. Turn ON the IPU to start the application. Then, on the Main Unit, select “Retry” on the “Retry to connect?” tab. 2. Start the XE application software at the IPU. Then, on the Main Unit, select “Retry” on the “Retry to connect?” tab. 3. Re-establish the connection between Main Unit and IPU, then on the Main Unit select “Retry” on the “Retry to connect?” tab. 4. If you can not clear the error yourself, contact the Sysmex service representative.
Error message: ID Read Error; Rack ID Read Error **Status:** Not Ready	**Possible cause:** • Barcode label contaminated • Barcode poorly printed • Barcode label in incorrect position **Action to resolve the error:** – Check the barcode label (see section “Sticking on a bar code label” in chapter “6.13 Preparations for sample analysing”).
Error message: Xm Limit Error; L-J Limit Error; Xb Limit Error **Status:** Not Ready	**Possible cause:** • Error of the XM, L-J or Xb control **Action to resolve the error:** 1. Check the QC graphics (see chapter 11.5). 2. Check the analysis data for results exceeding the monitor range. 3. If necessary perform a calibration (see chapter 12.).
Error message: Control Expired **Status:** Not Ready **Category:** Warning message	**Possible cause:** • The control blood's expiry date has expired. **Action to resolve the error:** – Use a fresh lot of control blood (see chapter “11.6 Read-in of a new quality control”).

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Error message: Control Entry ERR **Status:** Not Ready **Category:** Warning message	**Possible cause:** • No information about the new control blood lot was saved. **Action to resolve the error:** – Enter the information about the new control blood lot (see “11.6 Read-in of a new quality control”).
Error message: Replace Piercer **Status:** Not Ready **Category:** Warning message	**Possible cause:** • The piercer needs to be replaced. **Action to resolve the error:** – Replace the piercer (see chapter 14.16) and reset the counter.
Error message: Execute Shutdown **Status:** Not Ready **Category:** Warning message	**Possible cause:** • A closing down cleaning needs to be carried out. **Action to resolve the error:** – Execute a Shutdown (see chapter 14.3).
Error message: Clean the SRV **Status:** Not Ready **Category:** Warning message	**Possible cause:** • The Sample Rotor Valve requires cleaning. **Action to resolve the error:** – Clean the SRV (see chapter 14.5) and reset the counter.
Error message: Execute Rinse Flowcell **Category:** Warning message	**Possible cause:** • The flowcell of the FCM detector requires rinsing. **Action to resolve the error:** – Clean the flowcell of the optical analyser unit (see chapter 14.13).

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15.3 Tests

On the XE-2100 various test procedures can be performed. By doing so, the operativeness of the instrument is checked and frequently the cause of the error on the Main Unit can be found.

Important!

The test programs can only be executed if the XE-2100 is ready to operate.

When trying to start a test program while an analysis is in progress, the message ”Please wait” will be displayed. The test program will not be executed. Start the test program again when the XE-2100 is ready.

Likewise no analysis can be started while a test program is running.

Calling up a test program

1. On the Main Unit's Main menu select **Test**.

   The Test menu will open.

2. On the Test menu select the desired function:

Status	of Sensor 1, Sensor 2, Counter counts and Pump counts
Sampler	Check Sampler operativeness
CP	Check Piercer operativeness
Barcode	Check barcode reader operativeness
Motor	Check motor operativeness
SRV	Check SRV operativeness
Replenish	Replenish reagents of the Main Unit

   Either another submenu offering options will open, or the test will be performed directly.

Sampler test

1. Call up the **Sampler** test program.

   A submenu will open. For the Sampler test three options are available:

   - **1. Rack Feed In**, to check Sampler operation at the rack feed in.
   - **2. Rack Movement**, to check Sampler operation when shifting in the measuring line.
   - **3. Rack Feed Out**, to check Sampler operation at the rack out feed.

2. Use the ▲▼ cursor keys to choose the corresponding option.

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1. Rack Feed In

– Place a rack in the rack feed in of the Sampler.
– Choose **Execute** – the test will be started.
– Observe the movement at the rack feed in.

  If all works OK, you can resume routine operation or perform further rack tests, if necessary.

2. Rack Movement

– Set a rack in the analysis line.
– Choose **Execute** – the test will be started.

  The movement for rack shift is performed once.
– Observe the movement at the rack feed in.

  If all works OK, you can resume routine operation or perform further rack tests, if necessary.

3. Rack Feed Out

– Set a rack in the Sampler.
– Choose **Execute** – the test will be started.
– Observe the movement at the rack feed out.

  If all works OK, you can resume routine operation or perform further rack tests, if necessary.

Piercer Test

– Invoke the **CP** test program.

  The motion sequence is carried out once.

If the test is carried out without problem, Sampler analyses can be performed again.

If not, remove interfering parts from the movement radius. If the error occurs again contact the Sysmex service representative.

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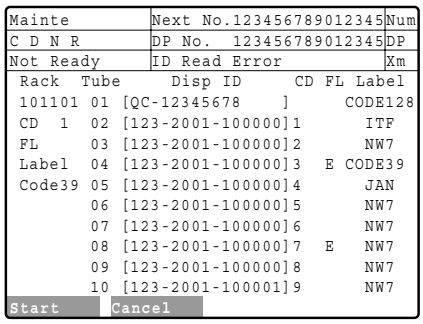
Barcode test



1. Set a rack containing sample tubes with barcode labels in the Sampler's measuring line.
2. Invoke the **Barcode** test program.

   The Barcode Test window will appear.
3. Choose **Start**.

   The barcodes of all rack positions will be scanned and displayed.
   - The sample ID will appear in the **CD** column.
   - In case of an read error an “E” is shown in the **FL** column.
   - In the **Label** column the barcode type is indicated.

Note:

For type CODE128 labels no sample ID will be displayed.

Motor test

1. Invoke the **Motor** test program.

   The Maintenance menu will come up. For the motor test five options are available:
   - **1. WB Asp. Motor**, to check the functioning of the WB aspiration motor and to set it to the starting position.
   - **2. RBC Sheath Injector**, to check the functioning of the RBC sheath injector and to set the motor to the starting position.
   - **3. FCM Sheath Injector**, to check the functioning of the FCM sheath injector and to set the motor to the starting position.
   - **4. Spits Motor**, to check the functioning of the rinsing unit motor and to set it to the starting position.
   - **5. Mixing Motor**, to check the functioning of the mixing motor and the reaction chamber.
2. Use the ▲▼ cursor keys to choose the corresponding option.

1. WB Asp. Motor

– Choose **Execute**.

The WB aspiration motor starts running and the test display will appear.

When the aspiration is completed, the motor returns to the starting position.

If the test is completed without problems, the system returns to the Ready state and analyses can be performed again.

If not contact the Sysmex service representative.

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2. RBC Sheath Injector

– Choose **Execute**.

The RBC sheath motor starts running and the test display will appear.

When the aspiration is completed, the motor returns to the starting position.

If the test is completed without problems, the system returns to the Ready state and analyses can be performed again.

If not contact the Sysmex service representative.

3. FCM Sheath Injector

– Choose **Execute**.

The FCM sheath motor starts running and the test display will appear.

When the aspiration is completed, the motor returns to the starting position.

If the test is completed without problems, the system returns to the Ready state and analyses can be performed again.

If not contact the Sysmex service representative.

4. Spits Motor

– Choose **Execute**.

The rinse motor starts running and the test display will appear.

When the aspiration is completed, the motor returns to the starting position.

If the test is completed without problems, the system returns to the Ready state and analyses can be performed again.

If not contact the Sysmex service representative.

5. Mixing Motor

– Choose **Execute**.

The mixing motor of the reaction chamber starts running and the motor speed is displayed on the test display.

Important!

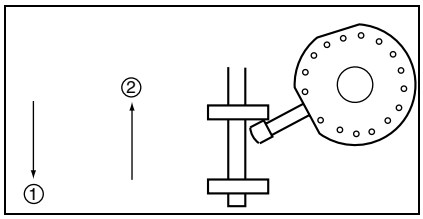
The motor speed must be between 1500 ± 200 rpm.

After approx. 30 seconds the mixing motor stops and the test is completed.

If the test is completed without problems, the system returns to the Ready state and analyses can be performed again.

If not contact the Sysmex service representative.

Sample rotor valve test



1. Open the Main Unit's front cover.
2. Call up the **SRV** test program.

   The Sample Rotor Valve starts working and performs a volume analysis. Afterwards the Sample Rotor Valve returns to its starting position.

If the test is completed without problems, the system returns to the Ready state and analyses can be performed again.

If not contact the Sysmex service representative.

15.4 Reading counter counts

In the Counter display the counter counts are displayed, showing how many analyse operations have been performed since initial operation of the instrument or after replacement or cleaning of a component, respectively.

1. On the Main Unit open the **Test** menu.
2. Choose **Status**.

   The status display will appear.
3. Choose **Counter**.

   The counter count display will appear.

TOTAL	Analyse operations of the system since initial operation
CBC	Analyse operations in CBC mode
DIFF	Analyse operations in DIFF mode
NRBC	Analyse operations in NRBC mode
RET	Analyse operations in RET mode
FFS	Analyse operations in DIFF mode after STROMATOLYSER-4DS replacement
SHUT	Analyse operations since last Shutdown
PIAS	Number of piercer cycles after piercer replacement
SRV	Analyse operations since last SRV cleaning
FCM-MT	Analyse operations of the FCM sheath motor
RBC-MT	Analyse operations of the RBC sheath motor
WB-MT	Analyse operations of the WB aspiration motor
LASER	Oscillation cycles of the laser

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16. Technical Information

16.1 Performance characteristics/specifications

Ambient temperature	15 °C to 30 °C (23 °C would be ideal)	
Relative humidity	30 % to 85 %	
Main Unit dimensions including Sampler	Width:	706 mm
	Height:	711 mm
	Depth:	912 mm
Main Unit weight including Sampler	approx. 93 kg	
Compressor dimensions	Width:	195 mm
	Height:	333 mm
	Depth:	395 mm
Compressor weight	approx. 15.5 kg	
Power supply	Alternating current between 117, 220 or 240 volts ± 10 % (50/60 cycles)	
Current draw	Main Unit and Sampler: 550 VA or less Compressor: 250 VA or less	
Fuse type	250 V, 3.15 A, time-lag	
Display range	WBC	0.0 – 999.9 (x 10^3/µL)
	RBC	0.00 – 99.99 (x 10^6/µL)
	HGB	0 – 30.0 (g/dL)
	HCT	0,0 – 100 %
	PLT	0 – 9999 (x 10^3/µL)
	RET%	0.00 – 99.99 %
	RET#	0.000 – 0.9999 (x 10^6/µL)
Background limits	WBC	0.1 (x 10^3/µL)
	DIFF-WBC	0.2 (x 10^3/µL)
	IMI-TOTAL	0.3 (x 10^3/µL)
	IMI#	0.005 (x 10^3/µL)
	NRBC-WBC	0.2 (x 10^3/µL)
	RBC	0.02 (x 10^6/µL)
	HGB	0.1 (g/dL)
	PLT	5.0 (x 10^3/µL)
	PLT-O	10 (x 10^3/µL)
operational capacity	approx. 150 samples per hour IF a RET analysis of all samples is performed, the operational capacity will be reduced to approx. 113 samples per hour.	

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Accuracy (reproducability) in Manual mode and Sampler mode	WBC	3.0 % or less (4.0 x 10^3/µL or more)
	RBC	1.5 % or less (4.00 x 106/µL or more)
	HGB	1.0 % or less
	HCT	1.5 % or less
	MCV	1.0 % or less
	MCH	1.5 % or less
	MCHC	1.5 % or less
	PLT	4.0 % or less (100 x 10^3/µL or more)
	RDW-SD	2.0 % or less
	RDW-CV	2.0 % or less
	PDW	10.0 % or less
	MPV	3.0 % or less
	P-LCR	15.0 % or less
	PCT	5.0 % or less
	NEUT%	8.0 % or less (30.0 NEUT% or more, WBC 4.0 x 10^3/µL or more)
	LYMPH%	8.0 % or less (15.0 LYMPH% or more, WBC 4.0 x 10^3/µL or more)
	MONO%	20.0 % or less (5.0 MONO% or more, WBC 4.0 x 10^3/µL or more)
	EO%	25.0 % or less or within ± 1.5 EO% (WBC 4.0 x 10^3/µL or more)
	BASO%	40.0 % or less or within ± 1.0 BASO% (WBC 4.0 x 10^3/µL or more)
	NRBC%	25.0 % or less or within ± 1.5 NRBC% (WBC 4.0 x 10^3/µL or more)
	NEUT#	8.0 % or less (1.20 x 10^3/µL or more)
	LYMPH#	8.0 % or less (0.60 x 10^3/µL or more)
	MONO#	20.0 % or less (0.20 x 10^3/µL or more)
	EO#	25.0 % or less or within ± 0.12 x 10^3/µL
	BASO#	40.0 % or less or within ± 0.06 x 10^3/µL
	NRBC#	25.0 % or less or within ± 0.12 x 10^3/µL
	RET#	15 % or less (RBC 3.00 x 10^6/µL or more, RET% 1 - 4 %)
	RET%	15 % or less (RBC 3.00 x 10^6/µL or more, RET% 1 - 4 %)

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	LFR	30 % or less (RBC 3.00 x 10^6/µL or more, RET% 1 - 4 %, 20 LFR% or more)
	MFR	50 % or less (RBC 3.00 x 10^6/µL or more, RET% 1 - 4 %, 20 LFR% or more)
	HFR	100% or less or within ±2HFR% (RBC 3.00 x 10^6/µL or more, RET% 1-4 %)
	IRF	30 % or less (RBC 3.00 x 10^6/µL or more, RET% 1 - 4 %, 20 IFR% or more)
Accuracy (reproducability) in Capillary mode	WBC	9.0 % or less (4.0 x 10^3/µL or more)
	RBC	4.5 % or less (4.0 x 10^6/µL or more)
	HGB	3.0 % or less
	HCT	4.5 % or less
	MCV	4.5 % or less
	MCH	4.5 % or less
	MCHC	4.5 % or less
	PLT	12.0 % or less (100 x 10^3/µL or more)
	RET#	35 % or less (RBC 3.00 x 10^6/µL or more, RET% 1 - 4 %)
	RET%	35 % or less (RBC 3.00 x 10^6/µL or more, RET% 1 - 4 %)
Analysis Parameters	see chapter 1.3	
Mean accuracy of cell counts in Manual mode and Sampler mode	WBC	within +/- 3 %, or within ± 0.20 x 10^3/µL
	RBC	within +/- 2 %, or within ± 0,03 x 10^6/µL.
	PLT	within +/- 5 %, or within ± 10 x 10^3/µL
Mean accuracy of cell counts in Capillary mode	WBC	within ± 10 %
	RBC	within ± 8 %
	PLT	within ± 8 %
Mean accuracy of differential count (stated as correlation of the control method for 100 (20 for NRBC) or more analysed standard blood samples (nucleated RBCs for NRBC))	NEUT%	r = 0.90 or more
	LYMPH%	r = 0.90 or more
	MONO%	r = 0.75 or more
	EO%	r = 0.80 or more
	BASO%	r = 0.50 or more
	NRBC%	r = 0.80 or more
Mean accuracy of differential count (stated as mean deviation from the analysis with a standard instrument)	NEUT%	within ± 3.0 NEUT%
	LYMPH%	within ± 3.0 LYMPH%
	MONO%	within ± 2.0 MONO%
	EO%	within ± 1.0 EO%
	BASO%	within ± 1.0 BASO%

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Mean accuracy of reticulocyte parameters for Manual mode and Sampler mode	RET#	within ± 20 % or ± 0.015 x 10^6/µL
	RET%	within ± 20 % or ± 0.3 RET%
	IRF	within ± 30 % or ± 10 IRF%
	LFR	within ± 30 % or ± 10 LFR%
	MFR	within ± 30 % or ± 10 MFR%
	HFR	within ± 30 % or ± 5 HFR%
Mean accuracy of reticulocyte parameters for Capillary mode	RET#	within ± 30 % or ± 0.025 x 10^6/µL
	RET%	within ± 30 % or ± 0.5 RET%
	IRF	within ± 30 % or ± 10 IRF%
	LFR	within ± 30 % or ± 10 LFR%
	MFR	within ± 30 % or ± 10 MFR%
	HFR	within ± 30 % or ± 5 HFR%
Mean accuracy of correlation with reticulocyte parameters	RET#	r = 0.90 or more
	RET%	r = 0.90 or more
Linearity in whole blood mode	WBC	within ± 2.0 % or ± 0.2 x 10^3/µL (0 - 170.0 x 10^3/µL)
	RBC	within ± 2.0 % or ± 0.03 x 10^6/µL (0 - 8.00 x 10^6/µL)
	HGB	within ± 2.0 % or ± 0.2 g/dl (0.0 - 25.0g/dl)
	HCT	within ± 2.0 % or ± 1.0 HCT% (0.0 - 60.0 HCT%)
	PLT	within ± 5.0 % or ± 10 x 10^3/µL (0 - 1000 x 10^3/µL) (depeding on RBC density the value can also be outside the above range)
	RET%	within ± 20 % or ± x 0.3 RET% (0.0 - 15%) (depending on RBC density the value can also be outside the above range)
	NRBC%	within +/- X% or +/- X NRBC% (0 - 464/100 WBC)
	NRBC#	within +/- X% or +/- X x 10^3/µL (0 - 19.2 x 10^3/µL)
Linearity in Capillary mode	WBC	within ± 4.0 % or ± 0.4 x 10^3/µL (0 - 100.0 x 10^3/µL)
	RBC	within ± 4.0 % or ± 0.06 x 10^6/µL (0 - 8.00 x 10^6/µL)
	HGB	within ± 5.0 % or ± 0.5 g/dl (0.0 - 25.0 g/dl)
	HCT	within ± 4.0 % or ± 2.0 HCT% (0.0 - 60.0 HCT%)
	PLT	within ± 10.0 % or 20 x 10^3/µL (0 - 1000 x 10^3/µL) (depending on RBC density the value can also be outside the above range)

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Carry-over	WBC	1.0 % or less
	RBC	1.0 % or less
	HGB	1.0 % or less
	HCT	1.0 % or less
	PLT	1.0 % or less
Sample stability after blood sample has been taken	variation range for WBC5 Diff analysis values of blood samples of healthy persons, being analysed 36 and 48 hours after the blood sample has been taken	
after 36 hours	NEUT%	within ± 8 NEUT%
	LYMPH%	within ± 7 LYMPH%
	MONO%	within ± 3 MONO%
	EO%	within ± 3 EO%
	BASO%	within ± 1 BASO%
after 48 hours	NEUT%	within ± 8 NEUT%
	LYMPH%	within ± 7 LYMPH%
	MONO%	within ± 4 MONO%
	EO%	within ± 3 EO%
	BASO%	within ± 1 BASO%
	Important! Blood samples should be stored at room temperature between 18 - 26 °C or in a refrigerator at 2 - 8 °C. The values stated above apply for samples having been stored at room temperature or in a refrigerator. If the samples were stored in a refrigerator, they were brought up to room temperature before the analysis. Depending on storage conditions or type of samples the values can also be outside the above ranges.	
Required sample volume	Sampler mode: approx. 200 µL Closed mode: approx. 200 µL Manual mode: approx. 130 µL Capillary mode: approx. 40 µL (required volume for diluting)	
Stored data storage capacity	Analysis data with histogram: 10,000 samples Scattergrams: 10,000 samples Patient information: 5,000 patients Job information: 1,000 samples QC files: 11 files	
Quality Control	Xbar control or L-J control: 300 points x 20 files, 45 parameters XbarM control: 300 points x 1 file, 42 parameters	

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16.2 System limits

WBC: false high leucocyte count

Cause:	Potential Detection:
Lyse-resistant erythrocytes	Difference between WBC count in Diff-channel and WBC/Baso-channel (WBC Abn Scattergram flag and/or RBC Lyse Resistance? flag)
Nucleated erythrocytes	Spot distribution between ghosts and lymphocytes in the Diff Scattergram (NRBC? flag)

RBC: false low erythrocyte count

Cause:	Potential Detection:
Cold agglutinins	Increased MCHC due to decreased HCT, accompanied by an increased MCH with or without an increased MCV (Turbidity/HGB Interf? flag and/or RBC Agglutination? flag)
Fragmented erythrocytes	Histograms of RBC and PLT cannot correctly be separated by discriminators (RBC: lower discriminator, PLT: upper discriminator); the graph does not meet the baseline. (Fragments? flag and/or RBC Abn Distribution flag and/or PLT Abn Distribution flag)
Microcytosis	Low MCV

HGB: false high haemocytometry

Cause:	Potential Detection:
Lipaemia	MCHC > 36.5 g/dL in severe cases (Turbidity/HGB Interf? flag)
Abnormal protein	MCHC > 36.5 g/dL in severe cases (Turbidity/HGB Interf? flag)

HCT: false low hematocrit analysis

Cause:	Potential Detection:
Cold agglutinins	Increased MCHC due to decreased HCT, accompanied by an increased MCH with or without an increased MCV (Turbidity/HGB Interf? flag and/or RBC Agglutination? flag)

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Fragmented erythrocytes	Histograme of RBC and PLT cannot correctly be separated by discriminators (RBC: lower discriminators, PLT: upper discriminators); the graph does not meet the baseline. (Fragments? flag and/or RBC Abn Distribution flag and/or PLT Abn Distribution flag)

HCT: false high haematocrit analysis

Cause:	**Potential Detection:**
Leucocytosis	Very high leukocyte count

PLT: false low platelet count

Cause:	**Potential Detection:**
Platelets aggregate	Abnormal PLT histogram (PLT Clumps(S)? flag) Spot distribution in the lower area of Diff Scattergram (PLT Clumps? flag)
Giant platelets	Abnormal PLT histogram (PLT Clumps(S)? flag and/or PLT Abn Distribution flag)

PLT: false high platelet count

Cause:	**Potential Detection:**
Microcytes	Low MCV
Fragmented erythrocytes	Histograms of RBC and PLT cannot correctly be separated by discriminators (RBC: lower discriminators, PLT: upper discriminators); the graph does not meet the baseline. (Fragments? flag and/or RBC Abn Distribution flag and/or PLT Abn Distribution flag)

RET: False low reticulocyte count

Cause:	**Potential Detection:**
Platelets aggregate	abnormal PLT histogram (PLT Clumps(S)? flag) Spot distribution in the lower area of diff Scattergram (PLT Clumps? flag)
Giant platelets	Abnormal PLT histogram (PLT Clumps(S)? flag and/or PLT Abn Distribution flag)

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RET: False high reticulocyte count

Cause:	Potential Detection:
Microcytes	Low MCV
Fragmented erythrocytes	Histograme of RBC and PLT cannot correctly be separated by discriminators (RBC: lower discriminators, PLT: upper discriminators); the graph does not meet the baseline. (Fragments? flag and/or RBC Abn Distribution flag and/or PLT Abn Distribution flag)

Note:

The abnormal sample conditions listed here are known to affect test results. The majority of the listed sample conditions are not measured quantitatively because these conditions vary due to patient population, patient diagnosis, age, medications, etc. Customers can perform studies in order to show how their specific patient populations are affected by various conditions.

16.3 Interface protocol

Data output can be made in different formats via the serial interface. For further information please contact the Sysmex service representative.

16.4 Program version

To check the current program version, proceed as follows:

1. Select the Help icon of the main menu.
2. Select **About XE-2100**.

   The version number is displayed.
3. Double click the version number for further information.

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17. Warranty

All Sysmex instruments are warranted against defective material or workmanship for a period of one year, commencing on the installation date at the customer's premises.

This warranty does not cover any defect, malfunction or damage due to:

- Accident, neglect or wilful mistreatment of the product;
- Neglect of Instructions for use;
- Failure to use the appropriate reagents and consumables specified for the product.

Important!

If the customer relocates the instrument or operates it at a different location, the warranty expires. Contact the Sysmex service representative before relocating.

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18. Glossary

CBC8-Parameter; “Complete Blood Count”

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT.

Isovolumetric resistance method

Cell counting and dimensioning is made by determination of the isovolumetric resistance, also known as impedance measuring.

The system aspirates the sample, dilutes it in a special ratio and measures the sample when it passes through the analyser unit. When passing the orifices, at which an electrostatic field of a constant current rating prevails a change of the electric potential occurs. This causes an increase of tension between the electrodes, which is proportionate to the cell volume.

Photometric measuring

Optical measuring method to determine the haemoglobin concentration. A luminous beam of 555 nm diameter, emitted by a LED illuminates the haemoglobin flow cell. The haemoglobin concentration is measured as an absorption value.

Hydrodynamic focussing with by-pass flow

This method improves the accuracy and reproducability of blood cell counts.

At the sample nozzle's exit the cells are encompassed by a sheath flow of diluent (Front Sheath Fluid), aligned and transported to the centre of the transducer's orifice, which is the most sensitive area of the analysing system. This reduces interference errors and and the possibility of abnormal cell pulse detection, which is caused by cells passing through the transducer off-centre. As soon as the cells have passed the orifice, they are seized by another, inverse flow (Back Sheath Fluid) and immediately led to the drain. This prevents renewed circulation and the effect involved on the platelet count.

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Flow cytometry with semiconductor laser

Cytometry is used to analyse physiological and chemical properties of cells and other biological particles:

- Information about cell size and structure
- Information about the cell's interior (such as the size of the nucleus)

Flow cytometry is used to examine cells and particles while they are flowing through a very narrow flowcell. A blood sample is aspirated and proportioned, diluted in a default ratio and dyed. Then the sample is transported in the flowcell.

The sample is illuminated by a semiconductor laser beam, which separates the cells by means of three signals. These three signals are the light scattered forward (Forward Scatter or FSc), the light scattered to the side (Side Scatter or SSc) and the side fluorescence activity (Side Fluorescence or SFl). The intensity of the Forward Scatter indicates the cell volume, the Side Scatter provides information about the cell content, such as nucleus and granules. The Side Fluorescence indicates the amount of DNA and RNA present.

SLS haemoglobin method

The SLS haemoglobin determination method uses cyanide-free sodium lauryl sulphate as surfactant. The haemoglobin's reaction with the SLS creates a coulored compound, which has the highest absorbing capacity at 535 nm and the peak at 560 nm. Measuring is done spectralphotometrically.

Discriminator

With discriminators or thresholds the different cell populations are separated (discriminated) from each other to determine the concentration.

Histogram

The graphical representation of quantified data in a line or column chart, where the frequency of each measured value is represented by the size (or height) of a rectangular over the corresponding data class of the abscisse. In haematology, a histogram is the volume frequency distribution of blood cells, from which statements on quantity and quality of the sample can be derived.

Histogramm-Parameter

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

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20. Appendix

- Flags/interpretative messages
- Action messages
- Error messages
- Information on tabs
- Maintenance Record
- Reagent Replenishing Record

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20.1 Flags/interpretative messages

WBC abnormal information

Message	Meaning	Formula/rating
WBC Abn Scg	abnormal WBC scattergram	WBC/BASO scattergram, DIFF scattergram
NRBC Abn Scg	abnormal NRBC scattergram	NRBC-Scattergram
Neutro-	low neutrophils count	NEUT# < 1.00x10^3/µl
Neutro+	high neutrophils count	NEUT# > 11.00x10^3/µl
Lympho-	low lymphocytes count	LYMPH# < 0.80x10^3/µl
Lympho+	high lymphocytes count	LYMPH# > 4.0x10^3/µl
Mono+	high monocytes count	MONO# > 1.00x10^3/µl
Eo+	high eosinophils count	EO# > 0.70x10^3/µl
Baso+	high basophils count	BASO# > 0.20x10^3/µl
Leuko-	low leucocytes count	WBC <2.50x10^3/µl
Leuko+	high leucocytes count	WBC >18.00x10^3/µl
NRBC Present	high nucleated erythrocytes count	NRBC% > 2.0%

WBC suspect information

Message	Meaning	Formula/rating
Blasts?	possible blasts present	Clouds of blasts were found in IMI and DIFF scattergram
Imm Gran?	possible immature granulocytes present	Clouds of immature granulocytes were found in IMI or DIFF scattergram
Left Shift?	possible left shift	Possible GRAN shift to upper right in the DIFF scattergram; possible left shift in IMI scattergram
Abn Ly/L_Bl?	possible abnormal lymphocytes or blasts present	Possible LYMPH shift to upper right in the DIFF scattergram; blast clouds found in IMI scattergram
NRBC?	possible nucleated erythrocytes present	Possible spot distribution between ghosts and lymphocytes in DIFF scattergram
RBC Lyse Res?	possibly problems during RBC-Lyse	Mathematics and comprehensive comparisons of defined algorithms
Atypical Ly?	possibly atypical lymphocytes	Possible presence of cells at the upper right of the DIFF scattergram

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RBC/RET abnormal information

Message	Meaning	Formula/rating
RBC Abn Dst	abnormal RBC distribution	Mathematics and comprehensive comparisons of defined algorithms
Dimorph Pop	RBC dimorphic population (overlapping distribution)	Gap between high and low points; shape of the distribution peak is odd
RET Abn Scg	abnormal RET scattergram	RET scattergram
Aniso	anisocytosis	RDW-SD > 65 fl or RDW-CV > 0.20
Micro	microcytes	MCV < 70 fl
Macro	macrocytes	MCV > 110 fl
Hypochromia	hypochromasia	MCHC < 29.0 g/dl
Anemia	aneamia	HGB < 10.0 g/dl (Note 1)
Erythro+	erythrocytosis	RBC# > 6.5 x 10^6/µl
Reticulo	reticulocytosis	RET% > 5 % or RET# > 0.2000x10^6/µl

RBC/RET abnormal information

Message	Meaning	Formula/rating
RBC Agglut?	possible RBC agglutination	Arithmetic calculation and numerical comparison of a defined algorithm
Turb/HGB?	possible HGB-Interference by chylemia	Arithmetic calculation and numerical comparison of a defined algorithm
Iron Def?	possible iron deficiency anemia	Arithmetic calculation and numerical comparison of a defined algorithm
HGB Defect?	possible HGB anomaly	Arithmetic calculation and numerical comparison of a defined algorithm
Fragments?	Presence of fragmented erythrocytes possible	Arithmetic calculation and numerical comparison of a defined algorithm

PLT abnormal information

Message	Meaning	Formula/rating
PLT Abn Scg	abnormal PLT scattergram	PLT scattergram
PLT Abn Dst	abnormal PLT distribution	Mathematics and comprehensive comparisons of defined algorithms
Thrombo-	thrombocytopenia	PLT# < 60 x 10^3/µl
Thrombo+	thrombocytosis	PLT# > 600 x 10^3/µl

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PLT suspect information

Message	Meaning	Formula/rating
PLT Clumps?	possible PLT aggregation present	Continuous spots in the ghost clouds up to the upper right of the DIFF and IMI scattergram
PLT C(S)?	possible PLT aggregation	Arithmetic calculation and numerical comparison of a defined algorithm

20.2 Positive messages

Message	Explanation	Display in Explorer
Diff	Abnormal differential count	D
Morph	Abnormal morphology	M
Count	Abnormal cell count	C

20.3 Action messages

Message	Explanation
Delta Check Error	Check sample
Count NRBC-CH	Clarification of NRBC suspect message
Count RET-CH	Clarification of the PLT value be fluorescence PLT

20.4 Error messages

Message	Explanation
Func.	Analysis error (except barcode error)
Result	Results may be incorrect
Delta	Abnormal Delta check

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20.5 Information on tabs

Date	Date analysis was performed
Time	Time analysis was performed
Seq	Sequence
Rack	Rack number
Tube	Tube number
Mark	+ or - marking
Abn. histogram	Abnormal RBC or PLT histogram curve
IP (WBC)	Interpretative message WBC
IP (RBC)	Interpretative message RBC
IP (PLT)	Interpretative message PLT
Test	Requested tests
Comment	Comment on the sample
Patient ID	Patient ID number
Patient Name	Name of patient
Birth	Patient's date of birth
Sex	Sex of patient
Ward	Ward the patient is in
Doctor	Name of the patient's doctor
Inst.-Name	Instrument name
Inst.-ID	Instrument number
WBC	Number of all leucocytes
RBC	Number of all erythrocytes
HGB	Haemoglobin concentration
HCT	Haematocrit value: Erythrocytes ratio of total blood volume
MCV	Mean erythrocyte volume in total sample
MCH	Mean haemoglobin volume per RBC
MCHC	Mean haemoglobin concentration of erythrocytes
PLT	Number of all platelets
RDW-SD	Calculated distribution width of erythrocytes, standard deviation
RDW-CV	Calculated distribution width of erythrocytes, coefficient of variation
PDW	Calculated distribution width of platelets

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MPV	Average platelet volume
P-LCR	Ratio of large platelets (volume exceeding 12 fL) to the total number of platelets
PCT	Platelets quota of the total volume
NEUT#	Neutrophils count, absolute
LYMPH#	Lymphocytes count, absolute
MONO#	Monocytes count, absolute
EO#	Eosinophils count, absolute
BASO#	Basophils count, absolute
NEUT%	Neutrophils quota in percent
LYMPH%	Lymphocytes quota in percent
MONO%	Monocytes quota in percent
EO%	Eosinophils quota in percent
BASO%	Basophils quota in percent
NRBC#	Nucleated erythrocytes count, absolute
NRBC%	Quota of nucleated erythrocytes in percent
RET%	Reticulocytes quota in percent
RET#	Reticulocytes count, absolute
IRF	Fraction of immature reticulocytes
LFR	Reticulocytes with high fluorescence quota
MFR	Reticulocytes with high fluorescence quota
HFR	Reticulocytes with high fluorescence quota
Validate	If a sample has already been validated, a “V” is displayed in this column.  **Note:** By validation it is decided whether an analysis result shall be output as a report to an external device. Only validated samples can be printed or transmitted to a host computer.
Sample No.	Sample ID of up to 15 characters (bar code number)
Sample Information	A: manual increment B: bar code available M: manual setting C: connected to host computer W: Work List available

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Off	Indicates that data have been transmitted to a printer or the host computer. No display if the output was triggered by an external source. D: data printer G: graphics printer H: host computer
P/N	Rating of the analysis result as positive or negative. The samples rated negative are not displayed in this column. D: abnormal WBC differential count M: abnormal cell morphology C: abnormal cell count
Action message	Note for checking the NRBC, PLT-O or Delta-Check
Error message	Analysis or function error, respectively

Labelling of numerical values

----	Data are not displayed due to analysis error
++++	Data exceed display capacity
(blank)	Parameter was not tested
+/-	Sample is outside the limits
@	Sample is outside the linearity
*	Sample results are not reliable

Capillary	No rating, because analysis was performed in Capillary mode
Discrete	No rating, because parameter was not requested
Flag error	This information is superseded by other information of higher priority.
Error	No rating due to an analysis error

Maintenance Record XE-2100 _____/_____

Daily

- Clean TD chambers and hydraulic system (Shutdown).
- Trap chamber checking and draining.

✎ Confirm with initials.

	Shutdown	Trap chamber
1		
2		
3		
4		
5		
6		
7		
8		
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27		
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29		
30		

As-needed maintenance

- Clean sample rotor valve (SRV)
- Trap chamber draining
- Clean rinse cup
- Clean SRV tray
- Cleaning the cap-piercer tray
- Clog removal
- Cleaning the RBC detector aperture
- Air Bubble Removal
- Cleaning the flowcell
- Waste tank replacement
- Replacing the piercer
- Clamp replacement
- Replacing fuses
- Adjustment of pressure and vacuum

✎ Enter calendar week and confirm with initials.

CW	Action

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Reagents

CELLPACK			
Lot No.	Expiry date	replaced on:	replaced by: (initial)

CELLSHEATH			
Lot No.	Expiry date	replaced on:	replaced by: (initial)

STROMATOLYSER-FB			
Lot No.	Expiry date	replaced on:	replaced by: (initial)

STROMATOLYSER-4DL			
Lot No.	Expiry date	replaced on:	replaced by: (initial)

STROMATOLYSER-4DS			
Lot No.	Expiry date	replaced on:	replaced by: (initial)

STROMATOLYSER-NR			
Lot No.	Expiry date	replaced on:	replaced by: (initial)

SULFOLYSER			
Lot No.	Expiry date	replaced on:	replaced by: (initial)

STROMATOLYSER-IM			
Lot No.	Expiry date	replaced on:	replaced by: (initial)

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RET SEARCH II			
Lot No.	Expiry date	replaced on:	replaced by: (initial)