Routine Use Training Workbook

Starrsed ST (Inversa)

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Sysmex House, Garamonde Drive, Wymbush, Milton Keynes, MK8 8DF, United Kingdom · Phone +44 333 320 3460 · Fax +44 1908 267 901
academy.training@sysmex.co.uk · **www.sysmex.co.uk**

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Disclaimer

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Revision History

Revised section	Alteration	Name	Date
All	New document to replace the following documents: - Starrsed ST Onsite Training Workbook	K Elgerton	November 2020
All	Hazard symbols added	K Elgerton	May 2021
Contact Us	Removal of 'Online'	K Elgerton	July 2021
Maintenance	Cleaning fill nozzle added to daily maintenance	N Thompson	November 2024
All	Updated branding	N Thompson	November 2024

Reference Documents

Document title	Version	Date
Starrsed ST Instructions for Use	D0054067-EN Version B01	October 2023

Explanation of Symbols

Symbol	Explanation
	**Risk of infection -** Always be aware of the dangers of infection, use caution and take appropriate measures
	**Risk of Injury -** Always be aware of the dangers of injury due to sharp objects, use caution and take appropriate measures.
	**Caution –** Potentially hazardous situation, use caution and take appropriate measures to avoid injury or harm.

Starrsed ST Overview

The Starrsed ST is a pay per test Erythrocyte Sedimentation Rate (ESR) analyser that uses the Westergren method, utilising automated sample ID, aspiration, dilution (EDTA mode only), pipette filling, measurement and system rinsing.

Facts and Figures	
Aspiration Volumes	1.2ml EDTA mode 1.4ml Citrate mode
Minimum Sample Volume	2.0ml
Sample Types	EDTA Citrate
Modes	30 minutes 60 minutes
Method	Semi-automated Westergren method
Dilution (EDTA only)	4 (whole blood):1 (Sodium Citrate)
Other	24 Westergren Pipettes Temperature correction 18°C

Analyser components

1. **Card reader**: Chip card must be in place for the analyser to function. The card contains the number of tests available and counts down as ESRs are performed. Cards should be placed in the card reader with the printed side facing forwards. Different cards are available depending on the amount of credits and access required.

Card Type	Description
A	100, 000 tests
B	500, 000 tests
C	1, 000, 000 tests
D	5,000,000 tests
E	10,000,000 tests
Q	Operate instrument without credit limits
S	Service card, allows higher access to menus
T	Technicians' card, used by service technicians

2. **Pipette Carousel**: The pipette carousel holds 24 Westergren pipettes held vertically. These pipettes are automatically filled to the correct level via the filling station. The fill level is checked using a fill sensor. After 30mins or 60mins (depending on mode) the pipette will travel around the carousel to the measure station where the ESR measurement is made and the pipette is rinsed.

3. **Mains power switch**: Turns analyser 'ON' and 'OFF'.

4. **Sample aspiration**: Samples are placed here for aspiration. Prior to aspiration the sample ID is obtained via the barcode reader.

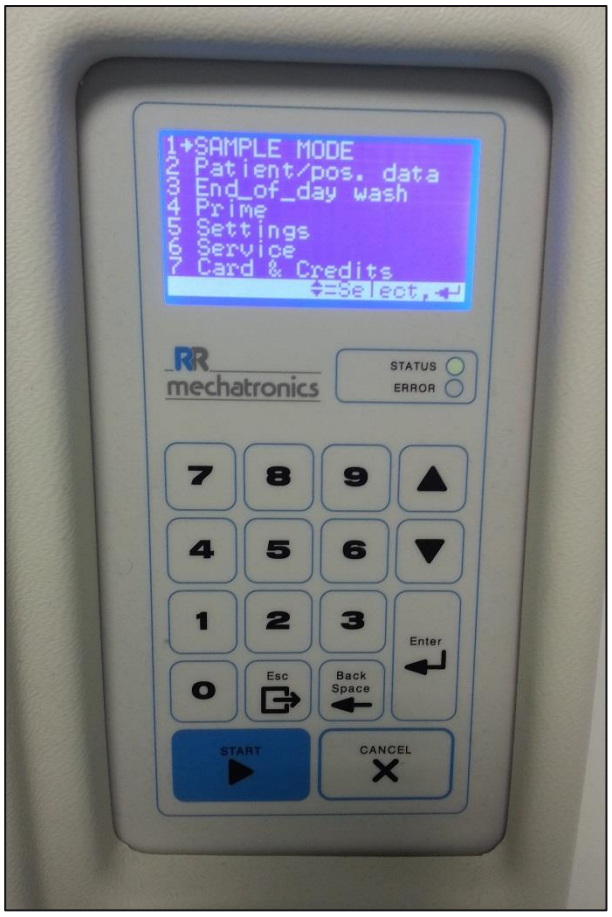
5. **Thermal Printer**: Used to print results, error logs, pipette data etc.

6. **Diluter Syringe Unit**: Responsible for automatic dilution of EDTA samples and priming of the lines with sodium citrate. EDTA samples are diluted in a 4:1 dilution with sodium citrate

7. **LCD screen**: User interface. Used to perform various functions such as running patient samples, viewing patient results, performing maintenance etc. Also contains data base of samples run and all settings.

Menu options can be selected by scrolling using [▲] or [▼] and pressing [Enter], or by pressing the appropriate row number using the keypad.

To exit a menu press [ESC].



Principles of Analysis

When a clean pipette reaches the fill position, the sample tube is aspirated and the necessary blood volume is drawn from the sample where there is an on-board dilution of the whole blood with sodium citrate (4:1). Blood is then drawn into the pipette via the fill nozzle due to the vacuum created by the fill block until the fill sensor is triggered. Activation of the fill sensor triggers the fill block to be drawn up, stopping further aspiration of the sample into the pipette. After aspiration the needle unit, sample tubes and fill nozzle are automatically washed with saline.

Following filling of the Westergren pipette, the pipette is checked for column height, usage of diluent and possible air bubbles. Any deviations will result in an alarm. Once the pipette has been filled, the pipette will move around to the measurement position. The time taken depends on the measurement time set, 30mins or 60mins.

Measurement Principles

Once at the measurement position a measure sensor moves along the pipette taking infra-red absorption readings every 0.25mm. The absorption readings are relative to the darkest, 100% (highest) and lightest 0% (lowest) readings, with the highest absorption readings being detected over the settled red cells and the lowest readings being found over the plasma.

The sedimentation value, in mm, is determined as the distance between the 50% absorption (meniscus) and the 87.5% absorption which represents cell/plasma separation. Results will be reported as clear if the distance between 87.5% and 75% (Hazy detection level) is less than 3mm. Distance greater than 3mm will result in one of 3 ‘Hazy’ error messages, depending on distance between 87.5% and 75.0% absorption.

By definition the absorbance levels are:

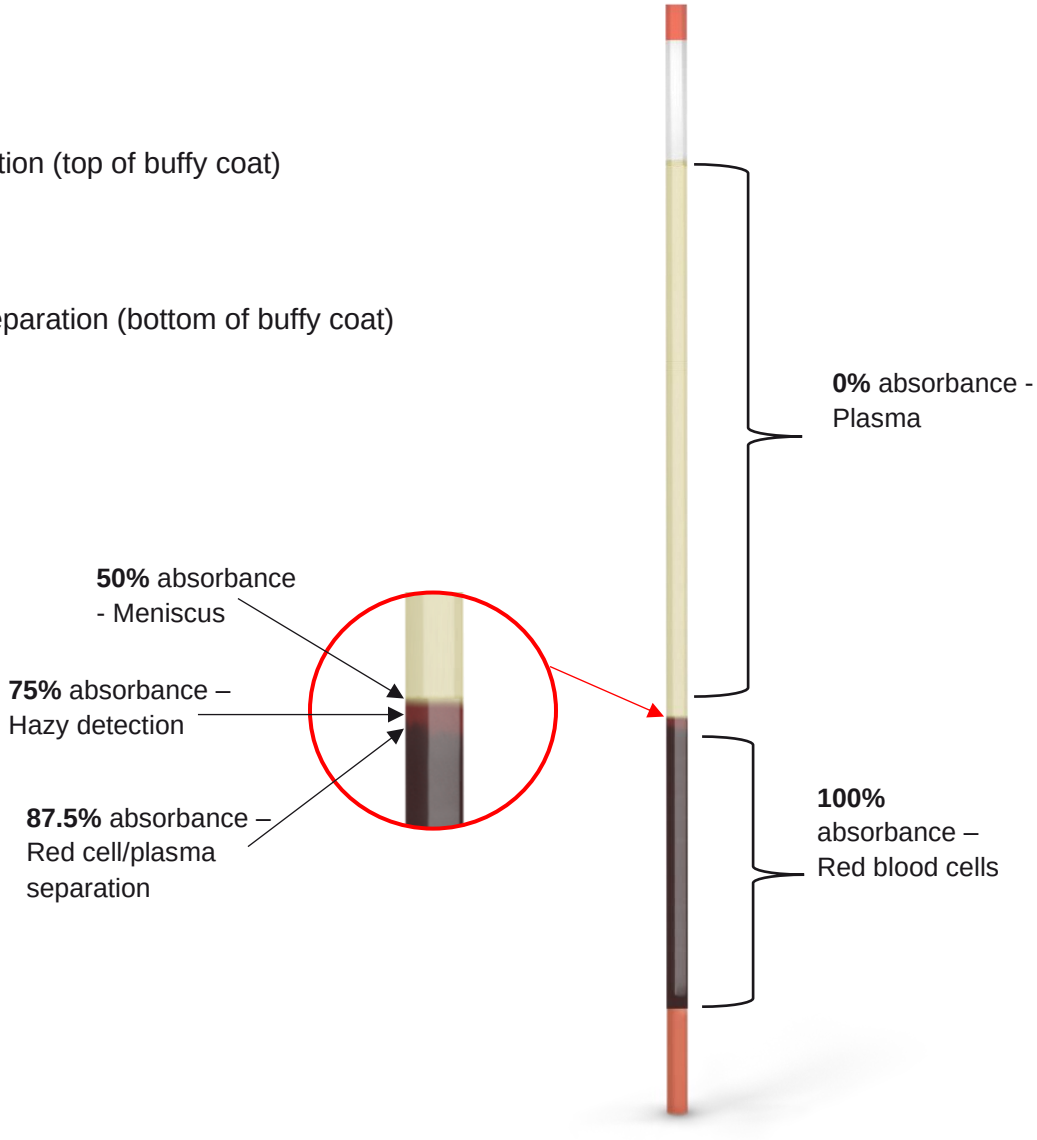
0% Plasma

50% Meniscus detection (top of buffy coat)

75.0% Hazy detection

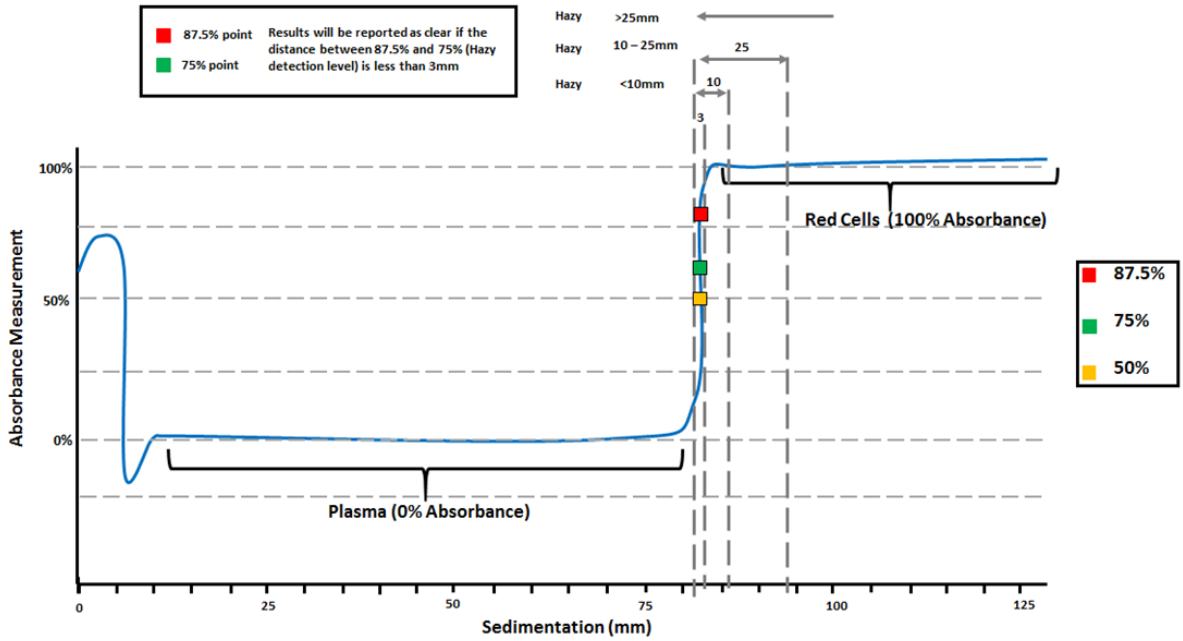
87.5% Cells/plasma separation (bottom of buffy coat)

100% Red blood cells



The absorption values are then plotted against column height to produce the absorption graph below.

Figure 1: Typical absorption graph.



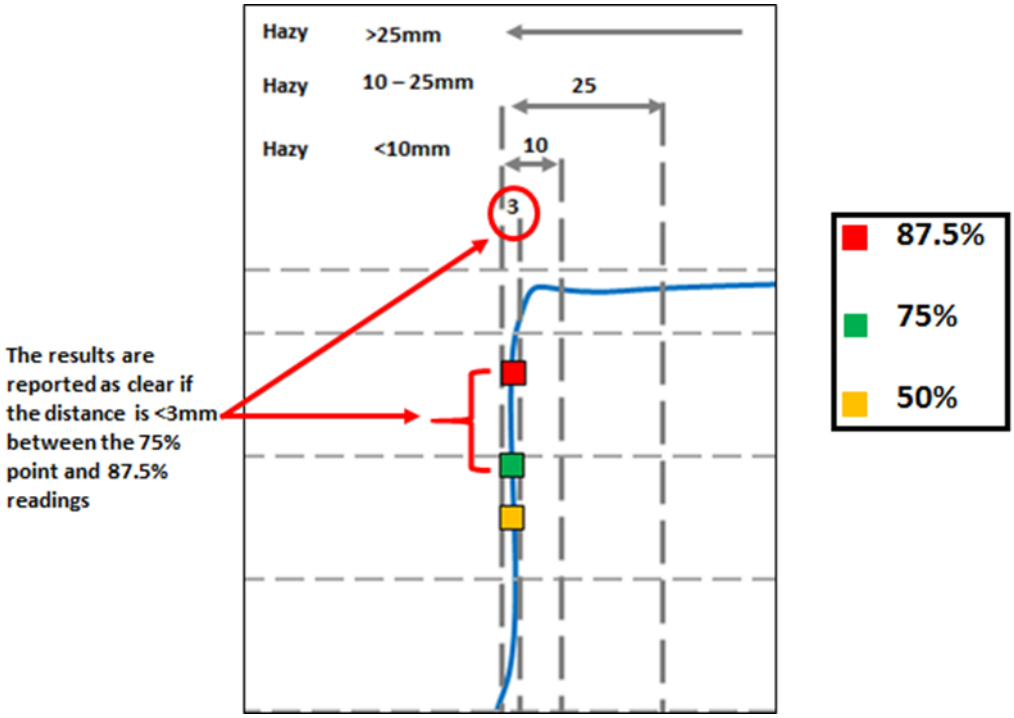
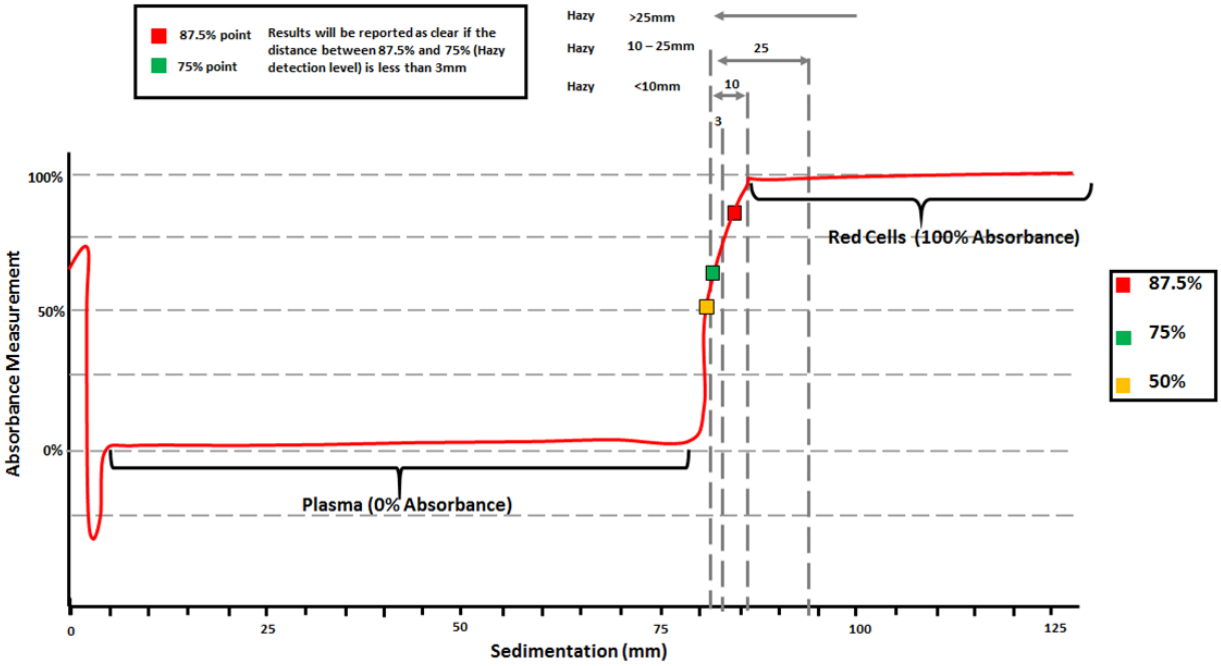
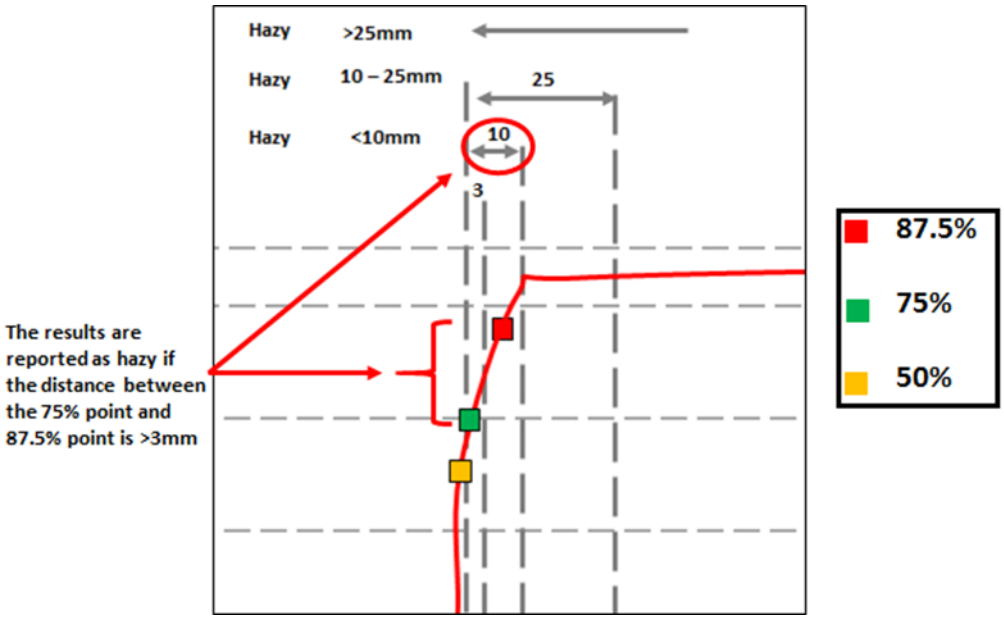


Figure 2: Absorbance graph showing a Hazy reading of 3mm to 10mm.





Length of Hazy area	Reported class	Error Code
<3mm	CLEAR	0 Sample clear
3mm to 10mm	HAZY	1 Sample is Hazy <10
>10mm to < 25mm	HAZY	2 Sample is Hazy <25
>25mm	HAZY	3 Sample is Hazy >25mm

Once the sedimentation distance has been determined the result is corrected for time (if in 30min mode) and temperature.

Starrsed ST Reagents

Diluent

The diluent is Sodium citrate and is used during the automatic 4:1 dilution of undiluted EDTA samples and rinsing of the Starrsed ST between samples. Approximately 5ml of diluent is used per sample. A 1-litre onboard container can be re-filled using the 5-litre bulk container when the container becomes empty.

NOTE: The diluent over time can become turbid due to bacterial contamination and at this point should be discarded. If the diluent does become turbid, the container should be rinsed with 5% Sodium Hypochlorite solution, then thoroughly rinsed with distilled water before refilling with diluent.

X-Clean

X-Clean is the ready to use cleaning agent used during the ‘End of day wash’. During this, it removes proteins that will build up within the Westergren Pipettes. X-Clean is stored onboard the analyser in a 1-litre container and can be re-filled using the 5-litre bulk container when the container becomes empty.

Quick Guides

Maintenance

It is recommended to turn the Starrsed ST off at the end of the day. Before the instrument is turned off, it is good practice to carry out the daily maintenance. Failure to perform planned preventative maintenance will increase the risk of analyser failure and inaccurate analysis of samples.

IMPORTANT: Failure to follow recommended maintenance protocols can lead to unnecessary downtime.

Daily Maintenance 

Daily maintenance consists of:

- Cleaning lower tube holder and outside of aspiration needle
- Cleaning drip plates
- Cleaning fill nozzle
- End-of-Day wash
- Check for leakages

RECOMMENDED: A 5% disinfectant solution should be used for cleaning of all external parts that are exposed to blood. To prepare disinfectant add 10 ml bleach (sodium hypochlorite) to 190 ml de-ionised water.

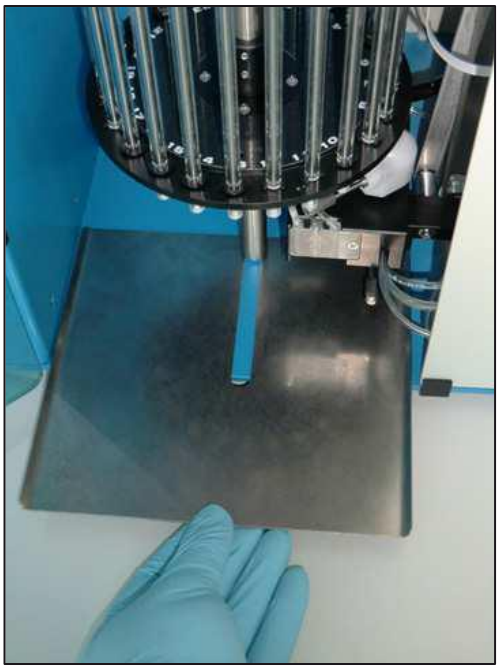
Daily Maintenance Procedure

Before performing any maintenance, please ensure no samples are on the analyser. Powering down of the analyser is not necessary.

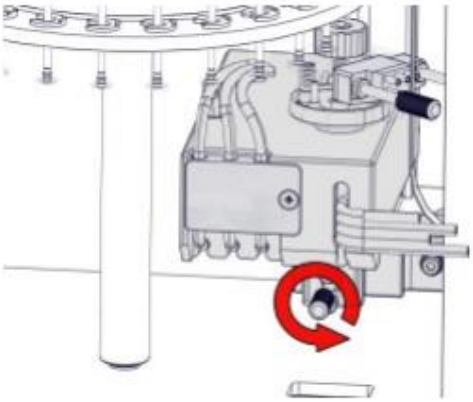
1. Using a disinfectant, wipe the lower tube holder of the needle unit.

2. Clean the outside of the aspiration needle.

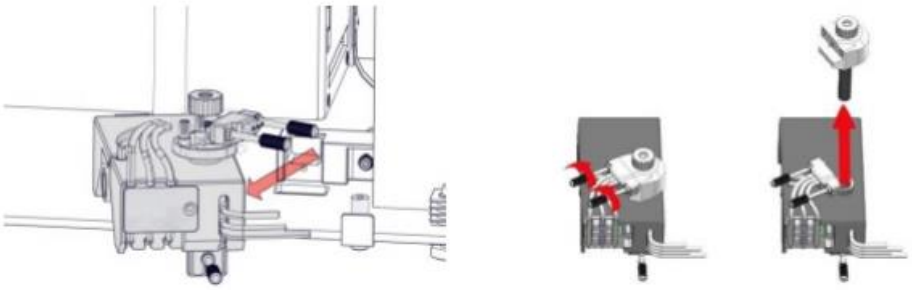
3. Wipe the stainless-steel drip plates below the pipette carousel and needle unit. **Note:** the below left picture shows a dual needle system, your instrument may be a single needle system but the same process applies.



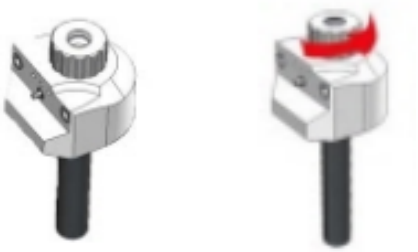
4. To clean the fill nozzle, loosen the thumb screw on the main fill unit.



5. This releases the fill unit from the analyser, giving access to the two thumb screws shown below. Loosen these thumb screws to gain access to the fill nozzle unit.



6. The round fill nozzle can be unscrewed from its unit and cleaned with a detergent based solution or alcohol wipe, removing any dried blood.



7. Re-attach the fill nozzle after cleaning, following the steps 4-6 in reverse to insert the main fill unit back into the analyser.

8. From the Main menu screen select option 3 - [END_OF_DAY WASH].

9. Check the system for leakages.

Weekly Maintenance

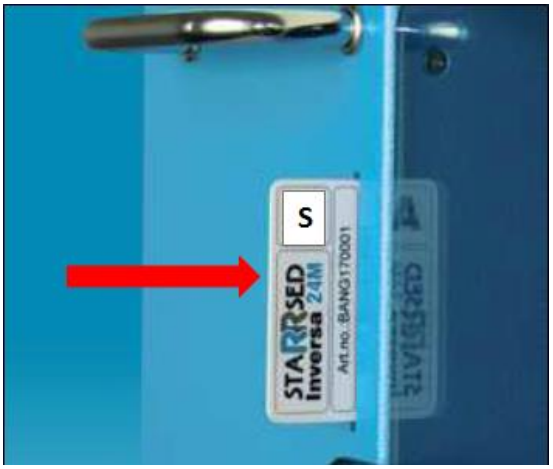
This maintenance should be performed on a weekly basis and is performed in addition to the daily maintenance. The purpose of the weekly maintenance is to check for worn components.

Weekly maintenance consists of:

- Performing the daily maintenance
- Inspecting the sample needle condition
- Checking the sensors

Before performing the weekly maintenance, ensure no samples are being processed and all appropriate PPE is used. Chip card type S (Service) is required for to perform weekly maintenance (activate card PIN: 3964).

1. Perform Daily Maintenance.
2. Activate service chip card (S)
    - Insert card type S into the analyser and select option 7 [Card & Credits]
    - Select option 2 [Read Service Card]



3. Inspect sample needle condition:
    - From the Main Menu select option 6 [Service]
    - Select option 7 [Next]
    - Select option 1 [Motor Control]
    - Finally select option 5 [Needle M31]
    - Press the [ARROW DOWN] twice to expose the needle.

4. Check sensors:
    - From the Main Menu select option 6 [Service]
    - Select option 7 [Next]
    - Select option 3 [Sensor status]
        - Blood sensor value range: 110 – 160
        - Measure head value range: 40 – 60

Monthly maintenance (Level 4 Maintenance)

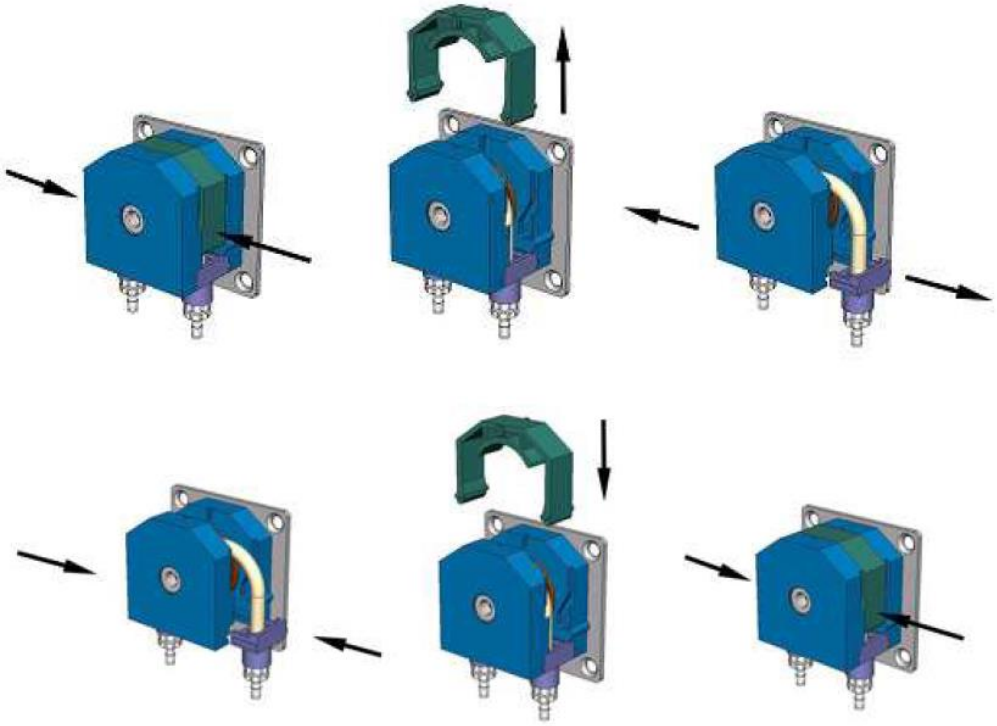
The monthly maintenance is carried out in conjunction with the daily and weekly maintenance.

Monthly maintenance consists of:

- Performing daily and weekly maintenance
- Check waste pump tube condition
- Replace pipette sealing and nozzle O-rings

Before performing the monthly maintenance ensure no samples are being processed and all appropriate PPE is used. Chip card type S (Service) is required for to perform monthly maintenance (activate card PIN: 3964).

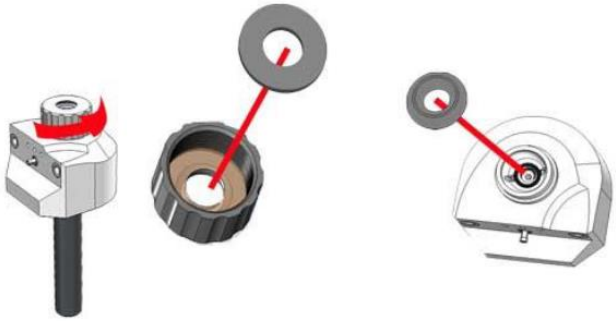
1. Perform Daily Maintenance.
2. Perform Weekly Maintenance.
3. Check the waste pump tube condition, replace the tube if it appears worn or leaking.



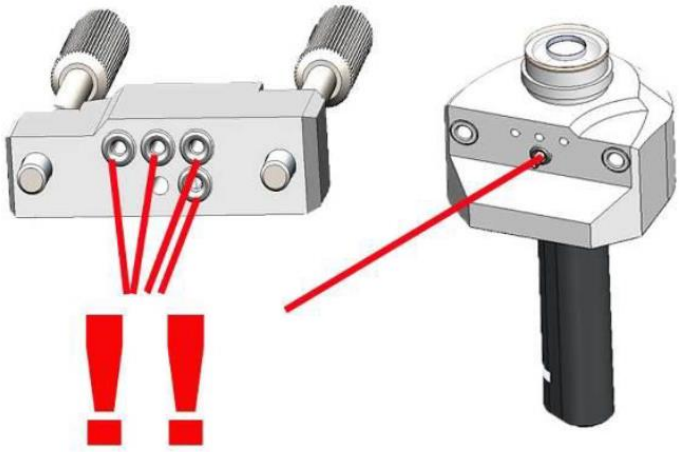
4. Replace the Pipette sealing and the nozzle O-rings.

The seals are housed inside the pipette filling station. For a full step-by-step procedure see work instruction Level 4 Maintenance of the Instructions for Use (version 1.14).

- Replace O-ring and pipette sealing ring



- Check all 5 O-rings as pictured and replace if necessary.



Three Monthly Maintenance (Level 3 Maintenance)

The 3 monthly maintenance is to be carried out in conjunction with the daily, weekly and monthly maintenance.

Three monthly maintenance consists of:

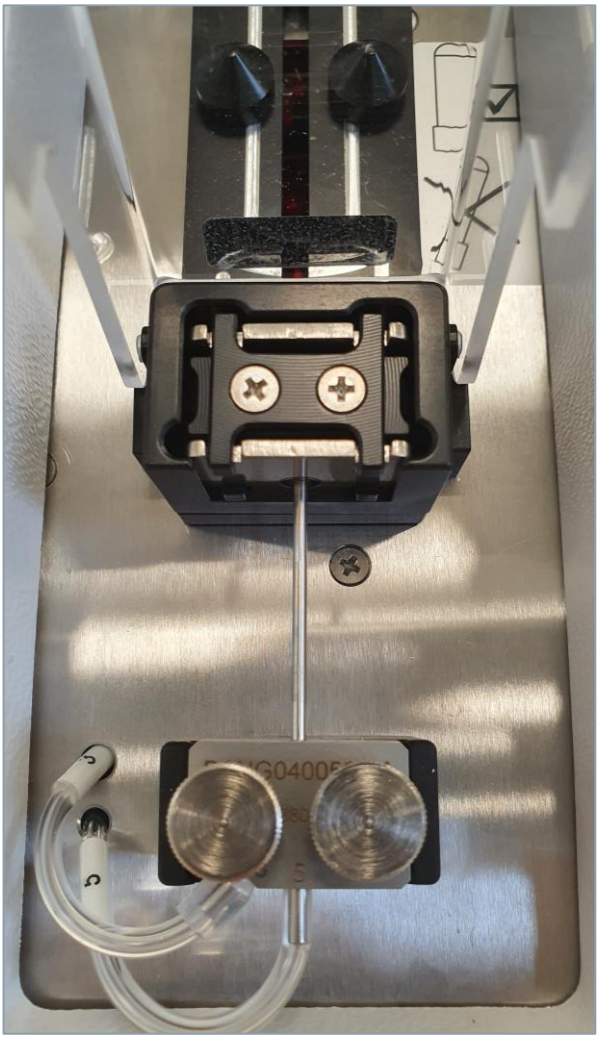
- Perform daily, weekly and monthly maintenance.
- Replace needle sealing block (not applicable for single needle version)
- Replace disk filter
- Replace waste pump tubing

Before performing the 3 monthly maintenance, ensure no samples are being processed and all appropriate PPE is used. Chip card type S (Service) is required for to perform 3 monthly maintenance (activate card PIN: 3964).

1. Perform Daily Maintenance.
2. Perform Weekly Maintenance.
3. Perform Monthly Maintenance.
4. Replace needle sealing block.

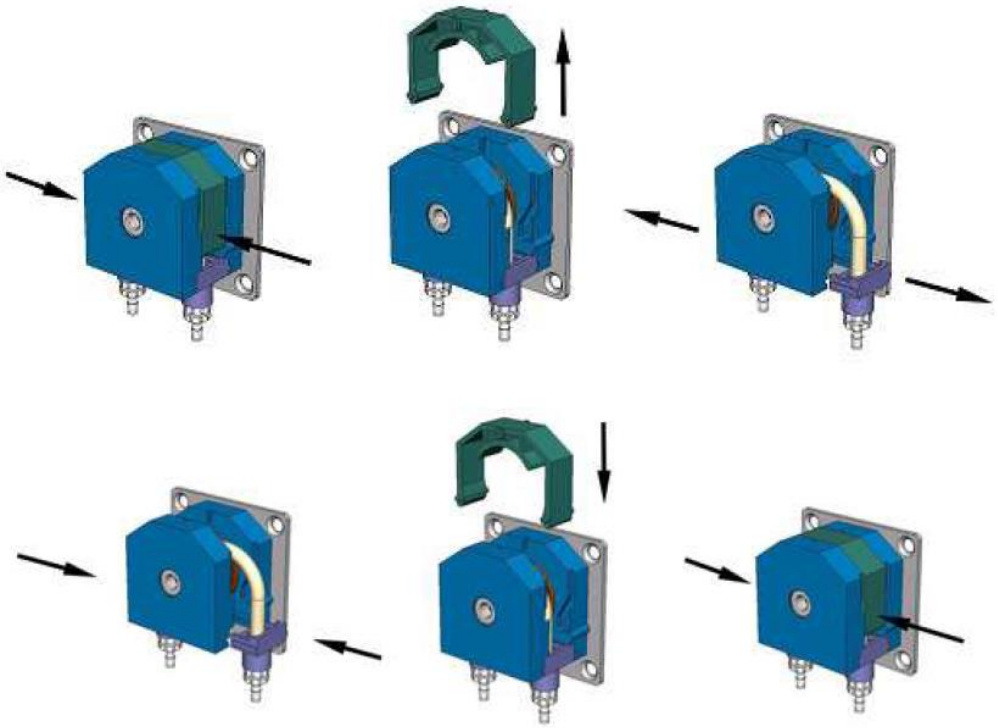
For a full step-by-step procedure of this process please see work instruction Level 4 Maintenance of the Instructions for Use (version 1.14).

Please note: Replacing the needle sealing block is not required for single needle systems.



5. Replace Disk filter. The disk filter QWLV040001 is the filter found on the waste bottle.

6. Replace the waste pump tubing by squeezing either side of the housing unit to release and gain access to the tubing.



As Required Maintenance

Reagent Replacement

Reagent levels on the Starrsed ST are automatically checked by sensors. When liquid levels fall, the level sensor triggers the alarm. Reagent replacement should be performed as soon as possible following alarm.

To remove the reagent container from the analyser, pull the appropriate reagent slider up and remove the reagent bottle. Bottles can be refilled from the appropriate bulk container. We recommend letting bottles become completely empty with the 'old' reagent prior topping up with 'new' reagent to prevent bacterial contamination. To replace the reagent container, reverse the process.

Empty Waste Container

1. Unscrew the waste container cap and lift the waste container slider.

2. Remove the waste container from the analyser and discard waste according to your local procedure. Clean the waste container with bleach and rinse thoroughly.

System Prime

The Starrsed ST will display a warning screen if the analyser has been idle for more than 12hours since the last prime sequence.

System prime can be performed at any point by selecting option 4 [Prime] from [Main menu] and pressing [Enter].

The ‘prime cycle’ takes approximately 2 minutes.

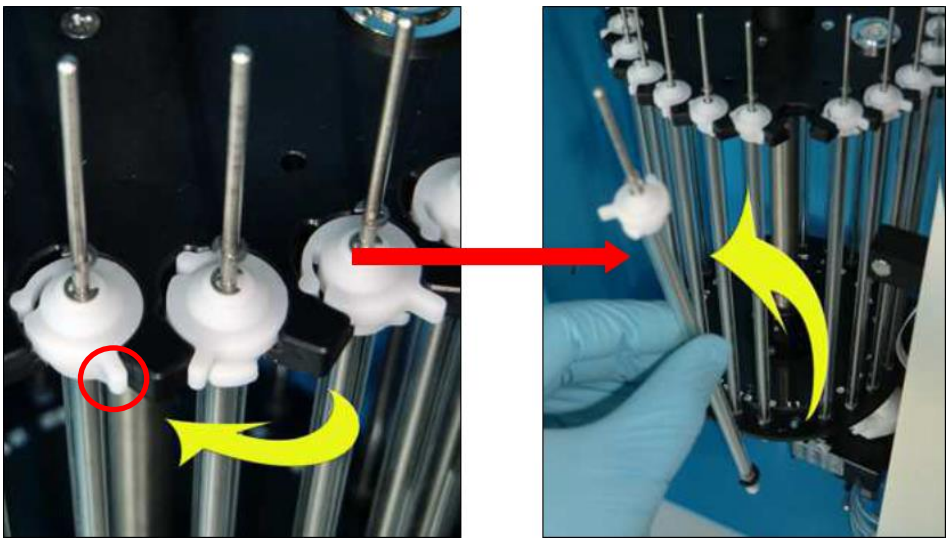
Leaking Pipettes

NOTE: Chip card type S (Service) is required (Activate card PIN: 3964)

Pipettes may leak if the tip of the plunger becomes worn, resulting in a column height error detected due to differences in the column height between aspiration and measurement. If detection limits are triggered, the pipette will automatically be disabled by the analyser.

Before replacing pipette, ensure no samples are running through the analyser.

1. From the [Main menu] select option 6 [Service] followed by option 7 [Next].
2. Select option 6 [Replace Pipette].
3. Enter the number of the pipette to be replaced, this will cause the carousel to rotate so that the desired pipette is presented at the carousel door.
4. Open the pipette cap by rotating the lever to the left, gently pull the pipette forward and up to remove from the carousel. Discard the pipette and replace with a new pipette. Once replaced, the pipette must be enabled manually if previously disabled. See ‘Enable/Disable Pipettes’ on page 26 for more information.

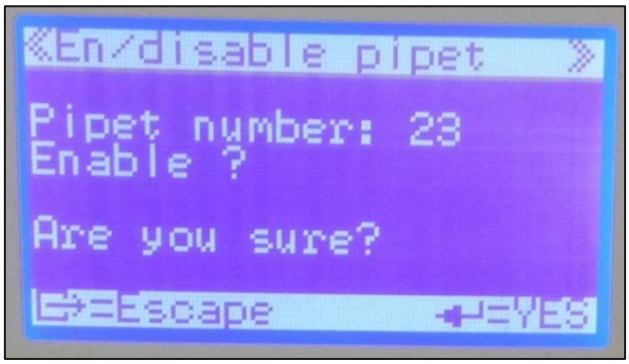


Enable/Disable Pipettes

1. Select option 5 [Settings] from the [Main menu].
2. Select option 1 [En/Disable Pipet]. This will allow the status of each pipette to be viewed.

Enabled pipettes are marked with a dot '●' and disabled pipettes are marked with a cross '**X**'.

3. To select the pipette to be disabled, use the [UP ARROW] and [DOWN ARROW].
4. Press [Enter] to toggle between states. Press [Enter] to confirm.



Replace Printer Paper

Printer paper approaching the end of the roll is indicated by red lines appearing across the length of the printout.

To replace printer paper, open the printer cover by pulling the handle and insert new printer paper roll as shown.

Quality Control (QC)

Starrsed Controls are in-vitro diagnostic quality control material used to monitor the accuracy and precision of Erythrocyte Sedimentation Rate (ESR) instruments and procedures. The Starrsed ST recognises the test tube by its barcode, reads the ESR range, checks the expiration date of the control, and analyses the sample.

QC material for the analyser are Starrsed Control Level N (Normal) and Level A (Abnormal). They are stored at room temperature and must be mixed thoroughly for at least 15mins prior to aspiration. Using your hands or a roller/rotator mixer is recommended, do not vortex.

Quality Control Procedure

Starrsed Control is provided in ready-to-use sample tubes and is used in the same manner as patient samples.

Starrsed controls can be linked using both Starrsed Control Sample ID and Lab ID Barcode.

- Starrsed Control Sample ID – the results are recorded on the software and an error message is displayed when test results are out of range
- Lab ID Barcode – The user can use their own Lab sample number and link them to the Starrsed QC samples.

1. From the main menu select option 1 [Sample Mode].

2. Invert the Starrsed Control tube until packed cells have been completely re-suspended. Avoid foaming. DO NOT VORTEX.

3. If using Link ID, Link the Lab ID with Starrsed Control Sample ID and attach the lab ID label on the tube on top of the original Starrsed Control label. If using the Starrsed barcode, place QC sample with barcode facing reader.

4. Push the [►] key to begin sampling. The Starrsed Control sample is processed in the same manner as a patient sample.

QC Results

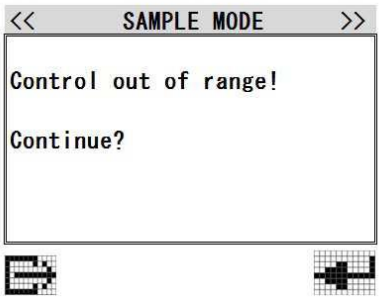
The measured QC results are compared with the assay mean value and the acceptable range. If the QC sample is out of range the message [CONTROL OUT OF RANGE!] appears. This warning is also given when patient sampling is started. Press ESC for aborting patient sampling, press ENTER to continue sampling.

If results are out of range, it is advised to perform a daily maintenance and/or End-of-day Wash and then perform another QC sample step before releasing patient results

QC Error Messages

When the result is within range, no message is shown. When the result is out of range, an error message is shown.

The message [CONTROL OUT OF RANGE!] will be shown until a correct QC result is performed or this message is ignored (with continue). When this warning is kept "active“ no patient samples can be performed.



Error Codes

E141: The uncorrected and the corrected result are out of range.
E142: The uncorrected result is out of range, but the corrected result is within range.
E143: The uncorrected result is within range, but the corrected result is out of range.

For further information also see ***Quality control trouble shooting*** in the Instructions For Use (version 1.14).

Running Patient Samples

Before running a patient sample, ensure that the blood cells are evenly dispersed throughout the sample. The sample tube must be mixed immediately before placing it in the sampling unit, it is recommended that the sample must be fully inverted at least 8 times. Do not shake the sample.

After mixing, insert the sample tube into the needle assembly with the cap downwards and the barcode label pointing towards the instrument.

Sample Tubes with Barcodes

1. From the main menu, select option 1 [Sample Mode].

2. Push the [►] key to begin sampling.

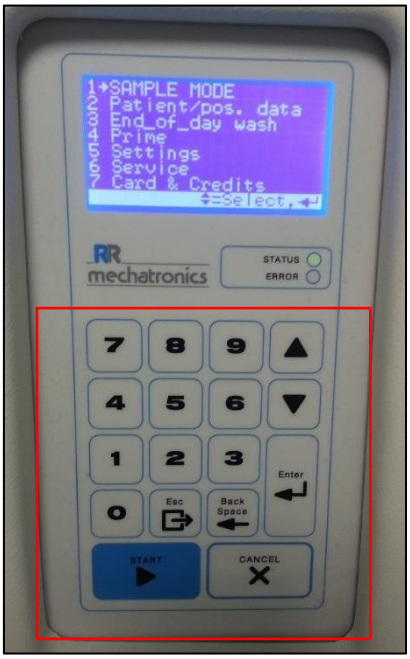
3. Check that the scanned ID number appears on the display.

4. If the ID number does not appear on the display, the barcode could not be read. Rotate the sample tube slightly and push the [►] key again or enter the ID manually. For more information on how to manually insert IDs, see below.

Sample Tubes without Barcodes

If the sample tube has no barcode or the barcode cannot be read, you can enter the sample ID manually.

1. From the main menu select option 1 [Sample Mode].
2. Enter the ID number using the user interface key pad.



3. Push the [►] key to begin sampling.

NOTE: Aspiration will not occur immediately if no pipette is available but will start automatically within 90secs if a pipette becomes available. If it takes longer than 90secs, the operator must remix the sample to prevent an insufficiently mixed sample from being aspirated. Once the sample is remixed, the sample must be replaced and the [►] button pressed.

NOTE: If the analyser is bidirectional with a HOST, if no ESR is requested the message 'No ESR' will appear.

Dealing with Errors

Whenever an error occurs on the system an alarm will sound. The following error messages are associated with the Starrsed ST:

Error message	Error or Warning	Definition
No cells/plasma found	Error	No contents could be detected in the pipette
ESR probably > 140mm	Error	Extremely high ESR value
Too many boarders found	Error	More than three borders found, possibly air bubbles
Column height <nnn>	Warning	Column height must be between 180 and 210mm. <nnn> = the actual column height.
Measure error	Warning	The down count is not equal to the up count from the measure head
Bubbles on top	Warning	Air bubble on top of the ESR
Limit error	Error	One of the following limits are out of the setting range - ESR time - Column height - Dilution - Bubbles on top - Hazy aspect - Temperature

General Error Procedure

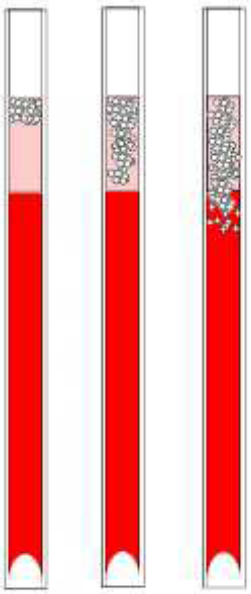
Whenever an error occurs, follow the instructions given in the Error list. If no instructions are given, follow this general procedure:

1. Clear the error by pressing the [ESC] key.
2. If the error is not cleared or the error occurs again, switch the instrument off and restart.
3. If error persists, switch instrument off and call for service.

Troubleshooting Faults

After a normal aspiration, the Westergren pipette must be free of air bubbles. The following examples are different patterns of air bubbles which can appear in the pipettes if there is a fault.

Foam in Column



A layer of air bubbles that is concentrated on top of the blood column does not affect the sedimentation process itself. The sedimentation develops normally below the bubbles. However, too many bubbles bring about a shortening of the effective blood column, which is a deviation from the Westergren method.

A layer of bubbles from 5 - 25mm results in "Bubbles on top" error message. Results should be reviewed before release.
A layer of bubbles larger than 25 mm results in "Too many borders found" error message. No ESR result will be given.

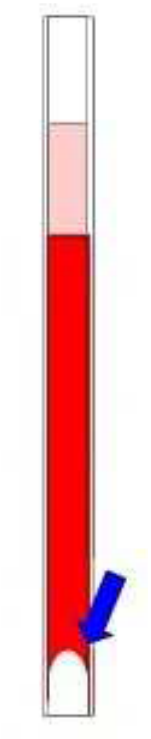
SOLUTION

- Check that tube connections are not leaking.
- Check the fill nozzle condition.
- Check for air in diluter system.
- Inspect for cracks in the base that holds the nozzle washer or O-ring.

One Air Bubble in Pipette

Air bubbles are seen in pipette after filling. This occurs during sample aspiration and can be caused if the sample is not mixed or inverted sufficiently. According to the ICSH, a sample should be gently inverted at least eight times. Do not shake the sample.

Large Air Bubble at the Bottom



1. Check diluter (syringe)
2. Check Diluent bottle.
3. Insufficient or no sample volume.

For further information also see ***Troubleshooting*** in the Instructions For Use (version 1.14).

Contact Us

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