

BZA 01-953 StaRRsed-III Sampler Fully Automated Sedimentation Rate Analyzer

Introduction

The StaRRsed-III is a system that measures the sedimentation rate in human blood samples. This rate may be relevant as input to a patient's therapy.

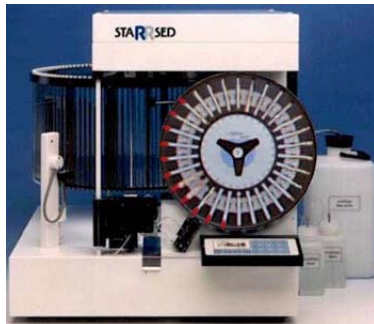
The sedimentation rate is measured in a batch fashion and hence is typically used in high-volume settings such as hospitals and commercial clinical laboratories.

The StaRRsed-III is the sequel to the StaRRsed-I and -II series, which were developed in the late 80s and early 90s. The current "-III" is the middle system of a range of three in the Mechatronics' offering:

System	Daily Blood Sample Load
StaRRsed Compact	< 150
StaRRsed-III	150 – 300
InteRRliner	> 300

As the table above shows, each system has its own optimal number of samples it routinely handles, both from a physical and a financial perspective.

These systems cater to hospital and private institution's laboratories alike.



The entire StaRRsed family does not require any periodical investment in disposable tubes thus saving the owner/operator money as the cost per test is significantly reduced. The systems are friendlier to the environment at the same time.

General Aspects in Sedimentation Rate Determination: Westergren method

In the 1920s two Scandinavian scientists developed what has since become the reference method. Fåhræus¹ and Westergren² used diluted blood (4 vols blood plus 1 vol citrate) in open-ended glass tubing mounted vertically in a rack or stand.

The ICSH³ set out to define standards in 1988 to enhance inter-method comparability and proposed an Erythrocyte Sedimentation Rate (ESR) performed on undiluted blood samples of a haematocrit value of 0.35 or less under standardized conditions in a Westergren open-ended glass pipette that meets ICSH specifications⁴. These undiluted blood samples are anticoagulated with EDTA (dilution less than 1%) but not diluted with

citrate anticoagulant. This method is the ICSH reference method.

The same paper referenced under 3 outlines subsequently the ICSH standardized method. The committee authoring the paper recommends that an independent study be undertaken to compare methods and results used to the above-described ICSH methods.

The ESR is the distance in millimeters of diluted plasma above the red cell interface in the glass pipette.

ESR Workflow Requirements

Generally ESRs require a dedicated blood collection tube pre-filled with Citrate solution. All StaRRsed Analyzers have citrate dilution built in and are therefore able to work with EDTA blood.

In practice the same blood sample that has already been taken for the Full Blood Count can be used since there is usually more than enough left over after the FBC. This has several advantages, firstly a blood collection tube has been eliminated, resulting in substantial savings over time, secondly, citrate dilution has been auto-mated resulting in greater accuracy compared to adding blood to a citrated tube, and thirdly EDTA blood is considerably more stable than citrated blood as far as ESR is concerned. ESRs on citrated blood should be done within 4 hours whereas EDTA blood will give the same result up to 24 hours later⁵.

Other workflow requirements are positive patient identification by the reading system, fully automated reading of the samples, built-in algorithms to deal with possible sample anomalies and automated data transfer to the laboratory's information system.

Furthermore, the demand for daily ESRs requires a high degree of 'walk-away' capability. That means that once the sample tubes are loaded, the laboratory operator can see to other tasks while the results are presented automatically.

Workflow and the StaRRsed-III

The loading tray (disc-shaped device at right front of system; please see image to the left) allows for sequential entry of 30 blood samples. In less than ten minutes these samples are loaded in the tray.

The infra-red barcode reader positively identifies the patient information eliminating the risk of identity exchange. The sample reading is done after exactly one hour (or thirty minutes). In addition, the interpretation is standardized thus further reducing variation in sample reading. Any possibly hazy conditions in the sample are interpreted via a standard algorithm. The StaRRsed-III furthermore reports any error codes to the operator thus communicating its findings swiftly.

The sample results and the corresponding patient information are passed digitally, eliminating any error of interpretation and any human intervention at the same time. This is long after the operator has physically introduced the samples to the StaRRsed-III. ESR is usually performed within four hours of venepuncture. The literature however supports storing samples up to 24 hours⁵. This reduces dependency upon systems' limitations for the hospital staff: ESRs can thus be performed with much less time restriction.

Description of the StaRRsed-III

Up to 30 blood sample tubes at a time are placed in the auto-loader of the StaRRsed-III. The system is engaged by the operator to perform the ESR test on the sample tubes upon which no operator monitoring is required.

The system will aspirate 1.6 ml of blood from a tube. The aspiration takes place via double needle, piercing the septum of the tube.

The citrate dilution takes place in a 4+1 ratio and is achieved with $\pm 2\%$ accuracy. Less than 0.5 ml citrate solution is used per sample.

A total of 120 Westergren pipettes are housed in the carousel. Each is of precision bore glass. After a cycle, the pipette cleaning takes place automatically with 8 ml of low foam detergent followed by a drying cycle. The fill line is back-flushed using a 2 ml amount of saline solution.

Positive patient identification is achieved with a bar code reader which occurs at the time of aspiration.

Blood samples may be read in a 30-minute mode. A predicted one-hour result is presented⁶.

The temperature is corrected to the standard value of 18.3°C as recommended by the ICSH (please see reference 3). This feature may be switched off.

Containers for detergent, water, saline, disinfectant and waste are all housed in a separate unit that is typically stored under the laboratory bench. Level sensors in each container monitor the amount of fluid and give warnings at pre-set levels.

The user interface consists of a 2-row 40 character LCD screen and a 16-key wipe-clean key pad.

StaRRsed-III Performance

The table outlines the rate of output:

Mode	Maximum Throughput per hour (number of samples)	Required Operator Time for 80 samples (minutes)
30-minute	180	< 5
60-minute	105	

In 30-minute mode, the StaRRsed-III has a maximum hourly capacity of 180 samples. In 60-minute mode, the system puts out a maximum of 105 samples.

Compliance with regulatory institutions

The recommendations to date are those laid down by the ICSH. ESRs should be performed either by the Reference Method or a Selected Method which can be shown to correlate with the Reference Method. The StaRRsed Compact conforms in every regard to the Reference Method.

Since the ICSH reported in 1993 a number of ESR Quality Controls have come onto the market. These have proved to be very useful in checking day-to-day performance within the Laboratory and Lab to Lab performance across the world.

Connectivity

Uni-directional data RS-232 interface. 80-character serial result data string. Baud-rate can be set by the operator. Serial output.

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System Requirements

The system is to be placed in a draft-free environment, not exposed to direct radiation from the sun. The ambient temperature is 18 – 28 degrees C (64 – 82 degrees F). The table on which the main unit is placed is to be free of vibrations.

Maintenance

All parts are easily accessible. Weekly cleaning is mostly automated and takes one hour.

Monthly maintenance takes 30 minutes. Daily automated pipette rinsing highly recommended; the system does this by itself via two-button operation.

Dimensions

Main unit: Width x depth x height is 620 x 580 x 650 mm. Weight is 56 kg.

Vacuum unit: Width x depth x height is 340 x 650 x 400 mm. Weight is 55 kg.

Power requirements are 115-230 V, 50-60 Hz and 300 VA.

Standby power consumption for the main unit 30 VA and in full operation 80 VA.

Standby power consumption for the vacuum unit 10 VA and in full operation 1000VA.

Maximum noise level is <45dB.

CE marking established.

FDA Regulation Number: 864.5800⁷.

Clinical Validation

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2. Westergren A. Studies of the suspension stability of the blood in pulmonary tuberculosis. *Acta Med Scand* 1921;54:247-82.
3. Stuart J. International Committee for Standardization in Haematology (Expert Panel on Blood Rheology). Guidelines on selection of laboratory tests for monitoring the acute phase response. *J Clin Pathol* 1988;41: 1203-12.
4. Stuart J. International Committee for Standardization in Haematology. Recommendations for measurement of erythrocyte sedimentation rate. *J Clin Pathol* 1993; 46:198-203.
5. Melville ID. The Use of a Sequestrene-citrate Mixture in the Estimation of the Blood Sedimentation Rate. *J Clin Pathol* 1959;12:258-261.
6. Rogers, R. The Development of 30-minute ESRs on the StaRRsed ESR Analyser. *Medical Laboratory World*. April 1994.
7. FDA. Center for Devices and Radiological Health. *Federal Registers* December 7, 1994 <http://www.accessdata.fda.gov/scripts/cdrh/c/docs/cfpd/classification.cfm?ID=1538>