

ESRI 109000 StaRRsed Compact Fully Automated Sedimentation Rate Analyzer

Introduction

The StaRRsed Compact 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 Compact is the sequel to the StaRRsed series. As the name implies, it is smaller than the StaRRsed III in that it only takes up 80 cm on the laboratory's bench and has the vacuum pump and waste container included in the main and only body (please refer to images on this page). The system caters to hospital and private institution's laboratories.



The entire StaRRsed family does not require any periodical investment in disposable tubes thus saving the owner/operator money since the cost per test is significantly lower. 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 prefilled 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

always 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 automated 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 later.⁵ Other requirements of ESR workflow optimization include 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.

Workflow and the StaRRsed Compact

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 Compact 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.

Description of the StaRRsed-Compact

A tube with the blood sample is placed in the front receptacle of the StaRRsed-Compact. The system will aspirate 1.3 ml of blood from the tube. The sample tube can either be open or sealed. Aspiration takes place via double needle.

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 84 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 2ml amount of saline solution.

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

The temperature is corrected to the standard value of 18°C as recommended by the ICSH (reference 3). This feature may be switched off.

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

Results of the test are expressed as ESR per mm. This data together with the patient ID number is both printed and sent to the laboratory information system. The operator has the option to provide comments before printing takes place. The sedimentation time used (60 or 30 minutes), the temperature and the dilution ration are included.

Hazy blood samples are detected as well. As the StaRRsed Compact measures the optical density every 0.25 mm length of the pipette, it reports the maximum change in

optical density as the ESR. In addition the degree of haziness is reported as Hazy < 10 mm, Hazy 10 – 25 mm or Hazy > 25 mm.

For waste disposal, 0.1ml of disinfectant is added per sample which takes all blood and wash solution either straight down the drain or to a 2.5 liter waste container. Disposal takes place manually at the end of each daily shift.

The entire system is protected by microbiological filters.

The various containers for detergent, water, saline, disinfectant and waste are all housed in the same body of the StaRRsed Compact. Level sensors in each container monitor the amount of fluid and give warnings at pre-set levels.

The user interface consists of a large back-lit screen and a 20-key wipe-clean key pad. The screen measures 80 x 100 mm.

StaRRsed Performance

The table outlines the rate of output:

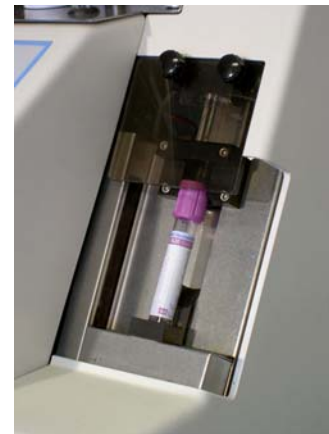
Mode	Maximum Output per hour (number of samples)	Required Operator Time for 80 samples (minutes)
30-minute	135	20
60-minute	75	
Maximum output (in 30-minute mode)	120	

In 30-minute mode, the Compact has a maximum hourly capacity of 135 samples.

In 60-minute mode, the system puts out a maximum of 75 samples.

The maximum output is calculated based on constant sample loading.

The required operator time of 80 minutes is necessary to do a total batch of 320 samples.

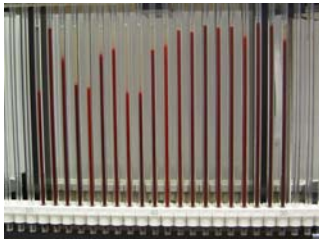


Compliance with regulatory institutions

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

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StaRRsed Compact conforms in every regard to the Reference Method⁷. 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

RS-232 interface. 84-character data string. Single direction of information flow. Baud-rate can be set by the operator. Serial output.

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 Fahrenheit).

The table on which the system 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

Width x depth x height is 750 x 360 x 800 mm. Weight is 45 kg.

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

Maximum noise level is <45 dB.

CE marking established.

FDA Regulation Number: 864.5800⁸.

Clinical Validation

1. Fåhræus R. The suspension-stability of the blood. *Acta Med Scand* 1921;55:1-228.

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. Recommendations for measurement of erythrocyte sedimentation rate. *J Clin Pathol* 1993; 46:198-203.

4. 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.

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. The Starrsed Compact automated ESR Analyser *Medical Devices Agency Evaluation Report MDA 00050*. August 2000

8. FDA. Center for Devices and Radiological Health. *Federal Registers* December 7, 1994 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfocd/classification.cfm?ID=1538>