

EHST109031, 109032 and 109033 InteRRliner SA-1, -2 and -3 Expert Line Fully Automated Sedimentation Rate Analyzer

Introduction

The InteRRliner is a system that measures the sedimentation rate (ESR) in human blood samples. This rate may be relevant as input to a patient's therapy. The sedimentation rate is processed in a batch fashion and is hence typically used in high-volume settings such as hospitals and commercial clinical laboratories. The InteRRliner is a system that integrates the process of ESR sample measurement into fully automated hematology systems. It consists of a rack-handling unit combined with up to three StaRRsed Compact ESR analyzers. Hence the product numbers SA 1, 2 and 3. It is a standalone unit and is derived from the Sysmex HST system. It uses only Sysmex sample tube racks.



InteRRliner SA-1 EL

The InteRRliner is the sequel to the StaRRsed-III and Compact series, which were developed in the late 80s and early 90s.

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

As the table above shows, each of the three systems has its own optimal number of samples it routinely handles, both from a physical and a financial perspective. None of the systems require any periodical investment in disposable tubes thus saving the owner / operator money resulting in a significantly lower cost per test. 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 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 millimetres of diluted plasma above the red cell interface in the glass pipette.

ESR Workflow Requirements

In a fully automated environment, unattended operation capability is an unequivocal demand. That requires that sample loading and unloading must be fully automated.

Generally ESR's require a dedicated blood collection tube pre-filled with citrate solution. All StaRRsed analyzers, including the InteRRliner 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:

1. A blood collection tube has been eliminated, resulting in substantial cost savings over time
2. Citrate dilution has been automated resulting in greater accuracy compared to adding blood to a citrated tube, and
3. EDTA blood is considerably more stable than citrated blood as far as ESR is concerned. ESR's on citrated blood should be done within 4 hours whereas EDTA blood will give the same result up to 24 hours later⁵ if stored at 4 - 8 degrees Celsius.

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 InteRRliner

Sampling starts immediately, as soon as a sample rack is automatically transferred from the Sysmex SA to the InteRRliner.

The 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 if so chosen by the operator). 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 InteRRliner 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 InteRRliner

InteRRliner works only with closed sample tubes. The sample rack is transported from the entry pool to the sampling unit. The bar codes of all sample tubes are read by a bar code reader. This information is combined with the commands from the laboratory information system (LIS) telling

the InteRRliner which tubes are to undergo an ESR and which ones are not. The tubes requiring an ESR are inverted eight times for mixing and are sampled (in case there was no connection with the LIS and hence no command given to the InteRRliner, then all samples with a barcode will be sampled by default). The first table on the next page outlines the InteRRliner performance and distinguishes between the situations where all samples are undergoing an ESR versus 80% of the samples.

The InteRRliner proceeds then by aspirating 1.4 ml of blood from a sample tube electronically earmarked for ESR measurement. Aspiration takes place via a double needle.

After sampling, the racks are transported to and collected at the exit pool. Racks have to be removed manually from there. InteRRliner does not pass on racks to additional units. As the InteRRliner is typically the last system of the Sysmex chain, not passing on the racks usually does not pose a challenge to the operator(s) and their work flow routine. Upon the aspiration, the citrate dilution of the 1.4 ml of blood takes place in a 4+1 ratio and is achieved with ± 2% accuracy. Less than 0.5 ml citrate solution is used per sample.



InteRRliner SA-3 EL

On the InteRRliner SA-1 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 InteRRliner SA-2 has 168 (two times 84) pipettes and the SA-3 have 252 (three times 84) pipettes.

The fill line is back-flushed using a 2ml amount of saline solution.

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 / hour. This data, together with the patient ID number is both printed and sent to the LIS. 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 ratio are included in the output.

Hazy blood samples are detected as well. As the InteRRliner measures the optical density along every 0.25 mm length of the pipette, it measures the maximum change in optical density as the ESR. The degree of haziness is reported as Hazy < 10 mm, Hazy 10 - 25 mm or Hazy > 25 mm.

For waste disposal, 0.1 ml of disinfectant is added per sample which takes all blood and wash solution either straight down the drain

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or to a 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 housed underneath the StaRRsed Compact on a revolving table.

Level sensors in each container monitor the amount of fluid and give warnings at pre-set levels.

The user interface of the StaRRsed Compact consists of a large back-lit screen (80x100mm) and a 20-key wipe-clean key pad.

The user interface of the rack handling system consists of a 4-row 40 character LCD screen and a 16-key wipe-clean keypad.

StaRRsed Performance

The table outlines the rate of output as defined in number of finished samples per one-hour period:

InteRRliner	30 Minute Mode	10- Minute Mode
100% of samples tested for ESR		
SA-1	130	70
SA-2	255	140
SA-3	370	210
80% of samples tested for ESR		
SA-1	110	70
SA-2	220	130
SA-3	330	195

This table shows that the maximum capacity per one-hour is a total of 370 samples using the 30-minute measurement mode on the InteRRliner SA-3.

These performance numbers are based on actual customer situations and reflect realistic circumstances.

Compliance with regulatory institutions

The recommendations to date are those laid down by the ICSH. ESR's should be performed either by the Reference Method or a Selected Method which can be shown to correlate with the Reference Method. The InteRRliner 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

RS-232 interface (Sysmex SE-9000 and R-3500 protocols), bi-directional information flow, baud rate can be set by operator, parallel printer port.

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).

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

InteRR liner	Width (mm)	depth (mm)	height (mm)	weight (kg)	power consump (VA)
SA-1	1,380	1,010	1,550	270	500
SA-2	2,920			440	850
SA-3	4,020			600	1,260

Power requirements are 115/230 VAC, 50-60 Hz.

Max. Noise level < 45 db.

CE marking established.

FDA Regulation Number: 864.5800⁸

Clinical Validation

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- Stuart J. International Committee for Standardization in Haematology. Recommendations for measurement of erythrocyte sedimentation rate. *J Clin Pathol* 1993; 46:198-203.
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- Melville ID. The Use of a Sequestrene citrate Mixture in the Estimation of the Blood Sedimentation Rate. *J Clin Pathol* 1959;12:258-261.
- Rogers, R. The Development of 30-minute ESRs on the StaRRsed ESR Analyser. *Medical Laboratory World*. April 1994.
- The StaRRsed Compact automated ESR Analyser *Medical Devices Agency Evaluation Report MDA 00050*. August 2000
 FDA Center for Devices and Radiological Health. *Federal Registers* December 7, 1994
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?ID=1538>

Ordering information

- SA109021: InteRRliner SA-1
- SA109022: InteRRliner SA-2
- SA109023: InteRRliner SA-3