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VERA109900
StaRRsed Auto Compact
Fully Automated Rack Loader Sedimentation Rate Analyzer

Introduction
The StaRRsed Auto 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 StaRRsed Auto Compact builds on the success of the StaRRsed Compact and is a direct consequence of customers demanding much more advanced automation of blood sample entry into the sedimentation rate analyzer.
The Upgrade to StaRRsed Auto Compact package allows current Compact users to add the Rack system. This provides the full functionality of the Rack.
The Rack is shown on the right of the Compact in Figure 1 below.

Figure 1 – The Newly Introduced StaRRsed Rack on the right of the Compact

The entire StaRRsed family does not require any periodical investment in disposable tubes. This saves money for the owner / operator and results in a significantly lower cost per test. The systems are friendlier to the environment at the same time.
Table 1 below outlines where this new system is positioned relative to the entire line-up of Mechatronics Automated ESR systems:

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

Table 1 – Product Positioning

The newly introduced Auto Compact provides the full walk away operation of the larger systems, the StaRRsed-III and InteRRliner systems.

General Aspects in Sedimentation Rate Determination: Westergren method
In the 1920s two Scandinavian scientists developed what has since become the standard method. Fåhraeus[1] and Westergren[2] used diluted blood (4 vols blood plus 1 vol citrate) in open-ended glass tubes mounted vertically in a rack or stand.
The International Committee for Standardization in Haematology (ICSH)[3] 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 specifications. 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 goes on to describe a Standard Method based on dilution of blood with isotonic sodium citrate solution which is essentially the Westergren method with all the physical parameters, including tube length and diameter, clearly laid down. In a later report[4] they go on to describe Selected Methods based on tubes which do not conform to the Westergren dimensions. The ICSH recommends that an independent study be undertaken to compare all Standard and Selected methods and results to the above-described Reference method.
All StaRRsed ESR Analyzers conform to the Standard Method as described by Westergren and subsequently by the ICSH[3]
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, temperature correction, an optional half hour method, built-in algorithms to deal with possible sample anomalies and automated data transfer to the laboratory computer in addition to the Printer provided.

Workflow and the Auto Compact
Compared to the Compact, which requires manual loading of samples, the Auto Compact has fully automatic sample loading. It has been designed to accept racks of EDTA blood samples. A universal rack holder is fitted to each rack and all known makes of Blood Cell Counter Rack can be accommodated. Up to five racks at a time may be placed on the entry platform. From here operation is *totally walk-away*.
The infra-red barcode reader positively identifies the patient sample number and checks whether an ESR has been requested.
The sample reading is done after exactly one hour (or thirty minutes in the half hour mode) The ESR is measured to the nearest 0.25mm though only reported to the nearest millimeter. This ensures great accuracy and reproducibility.
The sample results and the corresponding patient number are passed directly to the Lab Computer (and/or printer) thus eliminating transcription errors and ensuring swift presentation of results to Clinicians.
The processed racks may be collected by the operator at the exit platform of the loader.

No pre-sorting of ESR or NON-ESR samples
The Auto Compact has a bi-directional communication interface which allows it to interrogate the Lab Computer and determine which EDTA blood samples require an ESR. Only those needing an ESR get samples, it skips the rest. This saves the time and effort of first separating the ESR from the non-ESR samples.

Description of the Auto Compact
The Auto Compact accommodates racks from most common types of blood cell counters. The individual rack with the blood samples is snapped into the Mechatronics universal rack adapter and simply placed on the loader's entry platform. The operator simply presses 'Start' and walks away (see Figure 2 below).
The Rack-assembly then picks up the rack and mixes the blood by rotating the rack eight times, as recommended by the ICSH[3]. Bar Code labels are read and, if an ESR has been requested, 1.4ml of blood is aspirated. Thereafter the Rack is rotated once each time another sample is picked up to ensure each blood sample is thoroughly mixed. Aspiration takes place via Mechatronics' proprietary double needle mechanism.

Figure 2 – Close up of the Rack loader

The citrate dilution takes place in a 4+1 ratio and is achieved with ± 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 each 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. ESRs may be read after one hour or 30 minutes in the 30-minute mode, in which case a predicted one-hour result is presented[6].
This data together with the patient ID number is both printed and sent to the laboratory computer along with the sedimentation time used (60 or 30 minutes), the temperature and the dilution ratio together with any remarks manually added by the operator.

Hazy Blood Samples
Hazy blood samples are often difficult to measure by eye. The Auto Compact measures the optical density through the pipette every 0.25 mm. The

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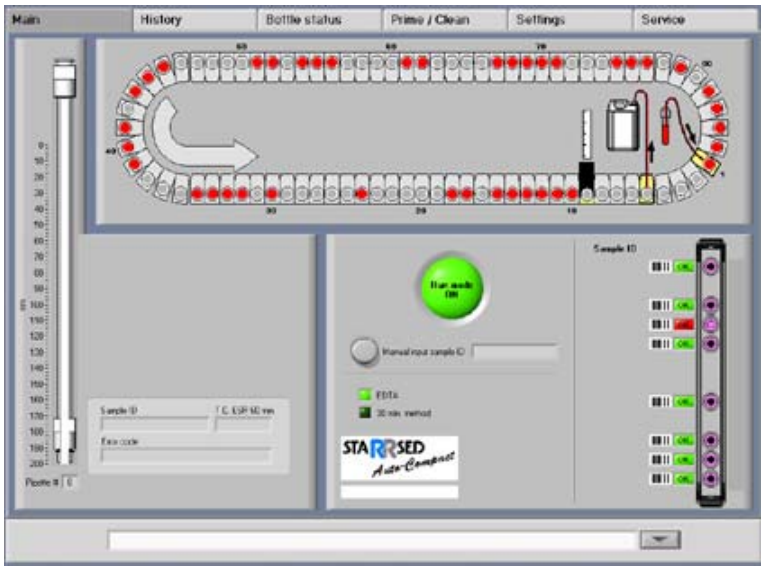
point where the maximum change in optical density occurs is taken to be the ESR. In addition, the degree of haziness is reported as Hazy < 10 mm, Hazy 10 – 25 mm or Hazy > 25 mm.
After measurement, blood and wash solution are mixed with 0.1ml of disinfectant and either washed straight down the drain or to a 2.5 liter waste container in which case 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 Auto Compact. Each container is monitored by a high or low level detector and gives warnings when nearly full (in case of waste container) or nearly empty (with each reagents container).

PC Operation and User Interface
The entire operation of the Auto Compact is driven by a personal computer and is Windows-based. The user interface is intuitive and can be activated via the keyboard or the optional touch screen. All the data from each sample, including the raw measuring data and the pictogram of the pipette, (as shown on the screen display, figure 3 below) is stored and may be retrieved later if needed.

I. Shows pictorially the pipette layout and which pipettes are full. The section in the middle of the layout gives the sample number and status for each pipette including "time to go" before the result is due;
II. A pictorial representation of the pipette at the measuring position and a graph of the optical density over the length of the entire pipette. This data is retained in the memory for subsequent retrieval if required. This can be useful if close examination of hazy samples is required at a later date.

The PC clearly makes for easy and quick learning of the operating protocol. The intuitive interaction greatly assists in reducing operator learning time.

Figure 3 – Interactive Graphical User Interface



StaRRsed Auto Compact Performance
Table 2 outlines the rates of output:

Mode	*Maximum Output per hour (number of samples)*	*Required Operator Time for 80 samples*
30-minute	135	< 1 minute
60-minute	75	
If 50% of samples require an ESR	115	

Table 2 – Performance of the StaRRsed Rack

In 30-minute mode, the Auto 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 for 80 samples is less than one minute.
The throughput will be slightly lower if there are a number of EDTA samples going through which do not require an ESR measurement

Compliance with regulatory institutions
The Auto Compact conforms in every regard to the Standard Method and has been shown to correlate with the Reference Method[7].

Connectivity
RS-232 interface. 84-character data string. Bi-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 Celsius (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 1,100 x 660 x 800 mm. Weight is 70 kg. Power requirements are 115-230V, 50-60Hz and 300VA. Maximum noise level is < 45dB.
CE marking established.
FDA Regulation Number: 864.5800[8].

Clinical Validation
1. Fåhraeus R. The suspension-stability of the blood. *Acta Med Scand* 1921;55:1-228.
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3. 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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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.
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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/cfpcd/classification.cfm?ID=1538
9. ESR Quality Control, a report on the first year's use in the UK of SedCheks *Pathology in Practice. 2002; March.*

Logistics Upgrade from Compact to Auto Compact
The Mechatronics field engineer performs the upgrade in your laboratory during one day.

Ordering Information
Depending on the racks that your laboratory uses, ***one*** of the following catalog numbers is to be ordered in conjunction with ordering VERA109901:
VERA109100 – Sysmex racks
VERA109300 – Coulter racks
VERA109500 – Abbott racks
VERA109600 – Advia racks or
VERA109800 – ABX racks.