

ESR Automatic Clinical Analyzers (Professional in vitro diagnostic instrument)

Highlights

- ESR from blood / EDTA samples combining smart and innovative "ccd cam" technology and the Westergren method.
- Direct from EDTA samples used for complete blood count (CBC), without the need for ESR tubes.
- Without reagents and respectful with the environment.
- With smart cards for loading tests.
- Multiple calibration. Advanced quality control program including LJ graphics.
- Clots in samples do not affect the result. Detects sampling errors, without loss of tests due to invalidation
- Free maintenance, low cost and profitable
- LCD screen. Voice and written messages. LIS / HIS connection. Integrated thermal printer.

Compact, cost-effective equipment, automatic and intelligent combining ccd cam technology and Westergren method

Direct from EDTA samples without reagents, no maintenance cost, no need for ESR tubes

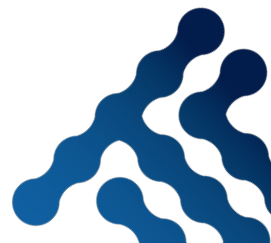
Continuous loading until the first result (20 min) and thereafter every 3 seconds
Up to 120 tests / hour

Multi-factor calibration
Advanced Quality Control and LJ graphics
Detects sampling errors. No data loss

SABIO140



SABIO JR



Product description

SABIO140 is a benchtop instrument designed and planned to measure the **erythrocyte sedimentation rate (ESR)** of up to a maximum number of **40 blood samples in less than 24 minutes**, contained in the **same test tubes from the EDTA test tubes used in the laboratory for hematology (CBC)**. In this way, **neither a double blood draw nor a transfer of biological material is required**.

The test is **performed automatically** and the **results** are **comparable** to those obtained with the **Westergren method**. Results are determined with a **high-resolution CCD camera** and can be **stored** for checking at any time or for user monitoring and evaluation.

SABIO JR has been developed taking into account the needs of small and medium-sized laboratories with the **same specifications as SABIO140**. The only difference with SABIO140 is the load capacity of the sample, having **16 positions** instead of the 40 of SABIO140.

SABIO140 / SABIO JR provides **excellent results equivalent** to the **Westergren** method (1 hour) in **just 20 minutes**.

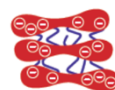
SABIO is completely **cost effective, comfortable** for the patient and is **environmentally friendly** as it uses the **same EDTA tubes** from hematology tests. It has the **capacity** for a **continuous charge** for 19 minutes when you start to use the instrument, it does **not require maintenance** and is **respectful** with the **environment**. It has an **LCD touch screen** and **data transmission** to **LIS**, some of the advanced features of the analyzer that provide more convenience to the laboratory and productivity.

Background of the method

Since the scientist Alf Westergren developed the method that bears his name for the determination of Erythrocyte Sedimentation Rate (red blood cell sedimentation rate - ESR) in 1921, ESR is currently the second most commonly performed test in hematology and plays an important role in the early detection of diseases and for the monitoring of the effectiveness of therapy related to inflammation and other pathologies (for example: neoplasms).

ESR measures how quickly red blood cells settle into plasma over a specific period of time. Sedimentation takes place in three different stages:

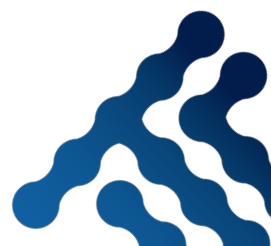
Phase 1 - Aggregation or Rouleaux formation - from 0 to 19 min:



Phase 2 - Cell setting or precipitation - 5 to 15 min:



Phase 3 - Packing or stacking of cells at the bottom of the column - 15 to 60 min:



Therefore, **for a good correlation with the Westergren standard method, the ESR measurement must cover all these steps, therefore it must be longer than 20 minutes.**

Clinical concept and normal values of ESR

Clinical concept of ESR

The SABIO analyzers **provide information on the erythrocyte sedimentation rate (ESR)**, a measure of the acute response phase to an inflammatory condition and which reflects the rate at which erythrocytes sediment. The ESR value measured at a given time is influenced by the concentration of some proteins, the plasma concentration of which changes in the presence of inflammation and other pathologies (for example, neoplasms). It is also affected by some properties of erythrocytes and the degree of anemia (hematocrit).

Extremely high values are typical in multiple myeloma, leukemia, lymphoma, breast and lung carcinomas, rheumatoid arthritis, SLE, pulmonary infarction. It is high in infections of any type, in carcinomas especially in the presence of liver metastases, acute and chronic inflammations.

ESR normal values (Westergren – citrate)

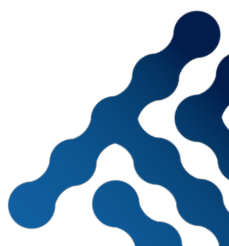
During the first hour, ESR values are normally between 1 and 10 for men and between 1 and 15 for women; in pathological conditions, the results can increase to values of up to 100 and more.

Normal range for SABIO140 instrument

- MEN up to 10 mm / h
- WOMEN up to 15 mm / h

Normal ESR (Westergren EDTA) Values

In general, since the ESR value varies with age and gender, the reference values must respect this characteristic and must be established in relation to gender and age. The reference values must be established by the laboratory and in accordance with the "Guidelines for the determination of reference values". In addition, there are other clinical variables (for example: hemoglobin level, some medications, menstrual cycle, pregnancy, smoking) that can influence ESR values and, therefore, also be reflected in physiological reference values. To evaluate EDTA values, consult the table in the reference document: **ICSH Recommendations for the measurement of erythrocyte sedimentation rate. J. Clin. Pathol. 1993; 46: 198–203.**



General operation of the instrument

Blood obtained in the RSC (blood cell count) test tube examination or complete blood count is carefully loaded into the sample tray after mixing. The instrument takes the first reading and the samples remain at rest for a predetermined period of time to allow sedimentation to occur. After that time, the instrument performs the second reading.

Through the CCD camera readings, the instrument automatically determines the level of erythrocyte sedimentation; the information is then extrapolated and then **automatically printed or displayed on the screen**.

Installation environment requirements

Maintain air exchange to ensure good air circulation. The wind should not blow directly into the analyzer.

Keep the analyzer away from electric motors, flashing fluorescent equipment and electrical contact equipment that are frequently switched on / off.

Site

- Stable floor and workbench with load capacity ≥ 100 kg.
- Free from dust, mechanical vibrations, sources of heat and wind, pollution, source of intense noise or electrical interference.
- Avoid direct sunlight and maintain good ventilation.
- It is recommended to evaluate the electromagnetic environment of the laboratory before operating the analyzer.
- Keep the analyzer away from sources of strong electromagnetic interference, otherwise its correct operation may be affected.

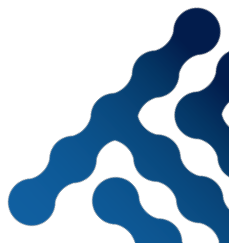
Space

In addition to the space required for the analyzer itself, consider:

- At least 10 cm on each side, which is the preferred access to carry out service procedures.
- At least 20 cm from the back for wiring and ventilation.
- Place the analyzer near the power outlet and avoid being blocked by any object so that you can easily disconnect the power plug as needed.

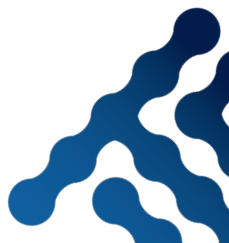
Optimum operating temperature humidity

Temperature 15 ° C ~ 30 ° C Humidity 30% ~ 85%



Technical Specifications

Technical specifications		SABIO140	SABIO Jr
Specification & Performance	Principle	Westergren method by CCD camera	
	Sample tube loader	40 positions, direct loading of blood / EDTA samples	16 posiciones, carga directa de muestras de sangre / EDTA
	Tray rotation speed	1 rotation every 1.5 seconds during normal operation	
	Performance	Up to 120 samples / hour	Hasta 48 muestras / hora
	Time to first result	First result in 20 minutes	
	Time to result	3 seconds	
	Minimum sample volume	2 ml	
	Sample test volume	2.5ml-3ml	
System & Interfaces	Central unit	With low dissipation 32 BIT technology; PERSONAL COMPUTER; tube rotation motors; stepper motor tray	
	Optical unit	High resolution CCD camera	
	Sample sensor	Determine loaded tube / measure temperature	
	RF ID reader	RF ID reader for test smart card	
	Internal thermal printer	Alphanumeric with 58 mm wide thermal paper, 36 characters per line, speed 20 mm / sec.	
	LIS / HIS communication	Yes	
	Screen	1024X600 pixel liquid crystal display, with backlight.	
	Code bar scanner	External (optional)	
Energy & Dimensions	Operating environment	Temperature: 15 ° C-35 ° C, Humidity: ≤80%	
	Power requirements	AC 110-230V ≤300VA 50 / 60Hz	
	Energy consumption	65W maximum	
	Dimension	510mm (l) x 500mm (w) x 350mm (h)	450 mm (l) x 320 mm (a) x 250 mm (h)
	Weight	20KG	10KG
IEC Classification		Class I Equipment	



Supplied materials

SABIO140 is supplied with the following materials:

- An operation manual
- Two 1A fuse units (5x20) each.
- A power cord of international IEC standard [IEC 320 C-13 female plug; Schuko CEE 7-VII male plug; Rating: 10A / 250Vac].
- Packing list and installation report Warranty certificate

Consumables to use the instrument:

- **Smart card** / test device for SABIO140 or SABIO JR: **1000** tests / **5000** tests / **10000** tests
- **VSG controls** - Precision and quality control of the test
- Thermal printer paper (1 pack)

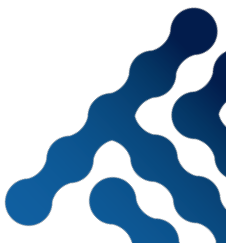
Preparation of sample

No specific preparation of test tubes is necessary, as SABIO140 uses sample tubes from another analytical system (hematology analyzers, EDTA tubes). However, it is necessary to **follow the regulations used by the International Council for Standardization in Haematology (ICSH)**, the most important of which are detailed below:

- Blood must be obtained by extraction for a maximum duration of 30 seconds and without excessive venous stagnation.
- Blood can be collected in both vacuum test tubes with EDTA and non-vacuum test tubes with EDTA. Remember that the SABIO140 uses the test tubes directly from the blood cell counters.
- Mix blood immediately after collection with at least 2 full inversions of the test tube.
- Mix the blood at least 2 full inversions of the test tube before loading it into the sample tray.

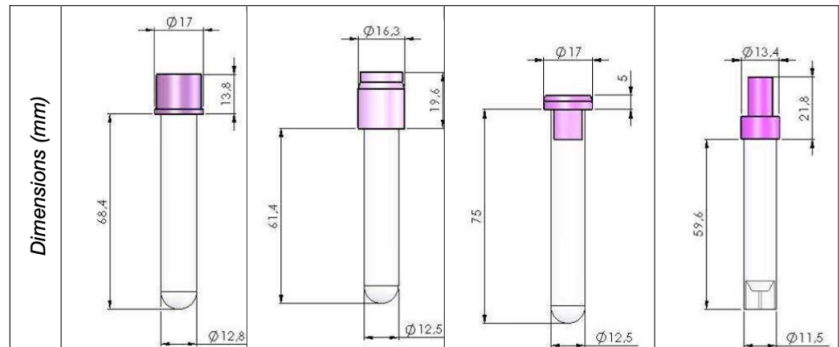
Types of test tubes

ETDA compatible test tubes are described below:



Considerations:

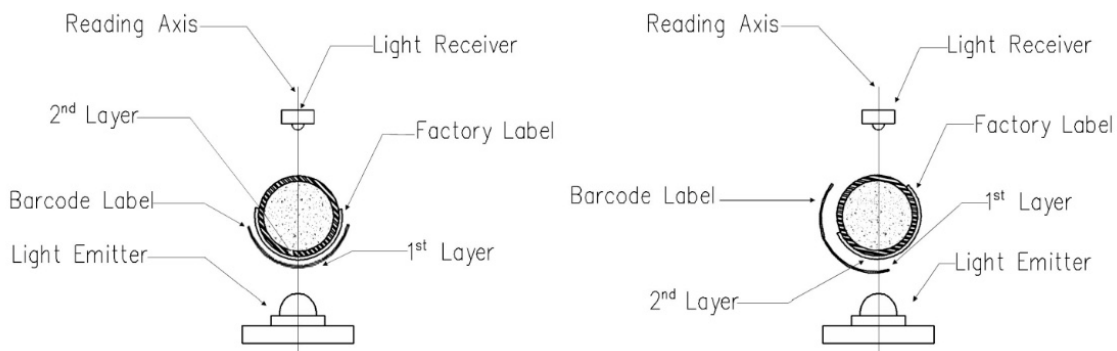
The test must be carried out within four hours after the blood is drawn.
If the test is performed on a blood sample stored at 4 ° for a maximum period of 24 hours, make sure the sample has reached room temperature before inserting it into the instrument.



Sample labeling

SABIO is prepared to work with a **maximum of 2 labels** that do **not overlap** and that are applied to the test tube sample to be analyzed, **reading** it through a **maximum of 3 layers of paper**, along the reading axis. Therefore, **if a test tube has two labels**, it is necessary to **introduce** the sample in such a way that the **reading axis has no more than three layers of paper** (see figure).

It is also **preferable** to introduce the samples in such a way that the **sample layers** are **opposite** the **emitter**.



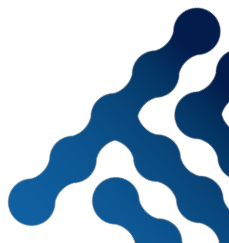
Dedicated Smart card

Single use for reloading erythrocyte sedimentation rate **tests** performed on SABIO series automated ESR analyzers. The insertion (RF ID approximation) of the Smart Card allows the instrument to be recharged for the number of tests indicated in the reference:

1000 tests device (REF: SA-TD1000) - 1 smart card containing 1,000 tests

5000 tests device (REF: SA-TD5000) - 1 smart card containing 5,000 tests

10000 tests device (REF: SA-TD10000) - 1 smart card containing 10,000 tests



To load Test Contour:

- Click "Check Device Charge" on the main menu,
- You will see the message to load the test on the screen and then,
- Have the instrument read and load the test device by moving the card to the reading area

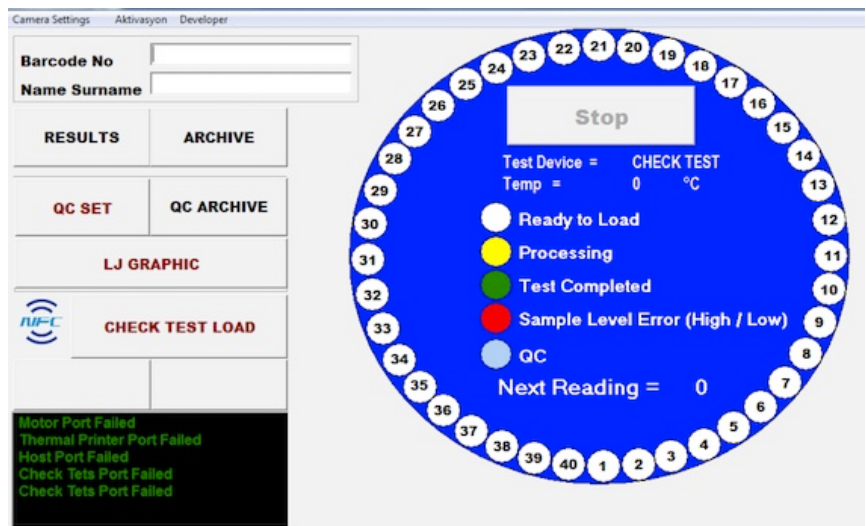


Test Contour should be detected automatically. Check the test device part on the main menu screen if the test contours have been loaded correctly.

Summary of the operation procedure

When the instrument has been turned on, the instrument performs a self-test and verifies the available test contours.

After the instrument completes its self-test, the main menu appears on the screen. The main menu is also the operating menu in which we run the tests. Includes: Results, File, QC Set, QC File, LJ Chart, Check Test Load, and Start / Stop Buttons.

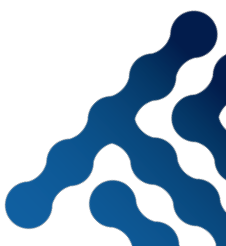


Loading the test device (tests)

If there is a test contour loaded on the instrument, you can run the samples. However, if there is no test contour loaded on the instrument (if the test contour appears 0 on the screen), you must load the test contour with the test device.

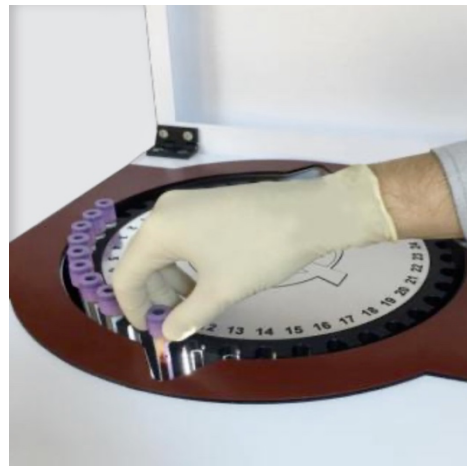
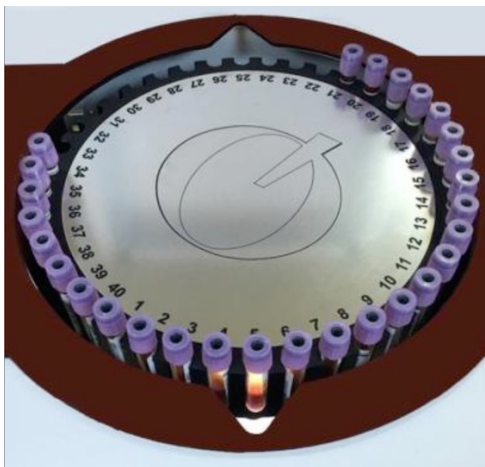
To load Test Contour:

- Click "Check Device Charge" on the main menu,
- You will see the message to load the test on the screen and then,
- Have the instrument read and load the test device by moving the card to the reading area



Testing execution

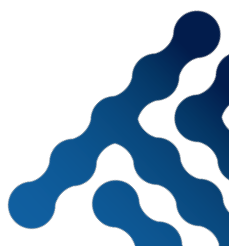
- Mix the sample 5-10 times,
- If there is a barcode reader, read the barcode of the sample,
- If there is no barcode reader, you can enter the sample ID and / or name manually from the main menu (main screen),
- Load the sample tube as explained in the Labeling of samples section (tube labels should be on the back).
The open part where you can see the sample inside the tube must face the open part of the sample tray.



- Start loading the sample at the first empty position (first empty position number. If you start to run the test again, the first empty position will be number 1. If you already load 5 samples, the first empty position will be number 6)
- The instrument will directly determine the sample loaded by the chamber and will take the first sample reading as soon as the sample is loaded.
- The instrument will give a valid or invalid sample message on the main screen depending on the sample level and loading position. If you receive an invalid sample message, first check the loading position and if it is correct, check the sample volume.
- Until the second reading, up to 23 minutes, you can continue to load new samples in the next empty position.


Archive

Archive is the part where the previous results are automatically stored. By entering the Archive menu, you can find all the results of your study.



You can reach previous results through:

- Bar code Sample number or
- Date of the test



SN	Barcode	Name - Surname	Result mm/h	R1	R2	Date	Time
1				136	0	28.01.2009	28.01.2009
1			1	137	138	28.01.2009	28.01.2009
1			1	138	137	28.01.2009	28.01.2009
1			1	138	137	28.01.2009	28.01.2009
1			1	138	138	28.01.2009	28.01.2009
1			1	140	140	28.01.2009	28.01.2009
1			1	140	0	29.01.2009	29.01.2009
1			1	140	140	29.01.2009	29.01.2009
1			1	141	140	28.01.2009	28.01.2009
1			1	142	0	28.01.2009	28.01.2009
1			1	142	140	29.01.2009	29.01.2009
1			1	143	143	30.01.2009	30.01.2009
1			1	144	143	29.01.2009	29.01.2009
1				219	0	07.06.2019	07.06.2019
1				221	0	07.06.2019	07.06.2019
1				226	0	07.06.2019	07.06.2019

ESR Controls

The control is used periodically to check the accuracy and precision of the erythrocyte sedimentation rate (ESR) determined by the SABIO140 automated ESR analyzer running directly from EDTA tubes.

First, you must enter the reference range of the controls. To enter the reference range of controls:

- Open the QC menu from the main menu,
- Select "QC Set",
 - If there is a barcode reader, read the barcode for the barcode number to enter directly,
 - If there is no barcode reader or barcode on the control, provide a barcode number for each control, such as 1001 for normal, 1002 for abnormal.
- Enter values (reference range) of the controls

The above data must be ready on the instrument in order to run the controls.

To run controls:

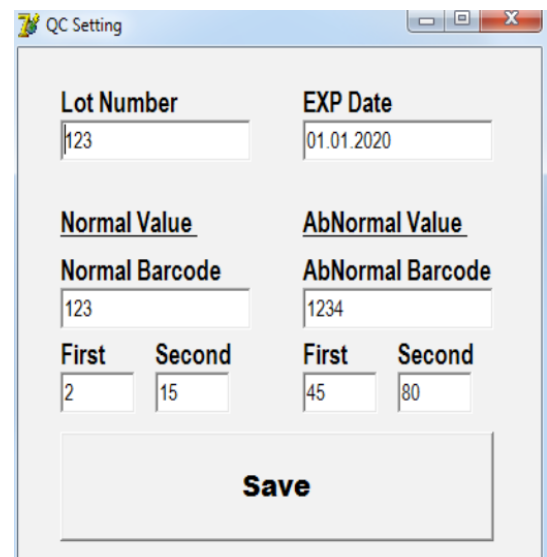
- Read the barcode from level 1 control and load it into position 1,
- Read the barcode of the level 2 control and load it into position 2,

If there is no barcode, write the number you have given for the controls. The instrument will directly determine the control loaded by the chamber and will take the first control reading as soon as it loads the sample.

Attention: Controls should ALWAYS be loaded as:

Level 1 to Position 1

Level 2 to Position 2



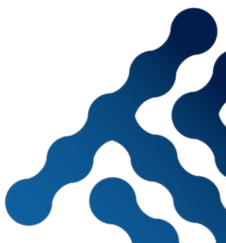
QC Setting

Lot Number: 123 EXP Date: 01.01.2020

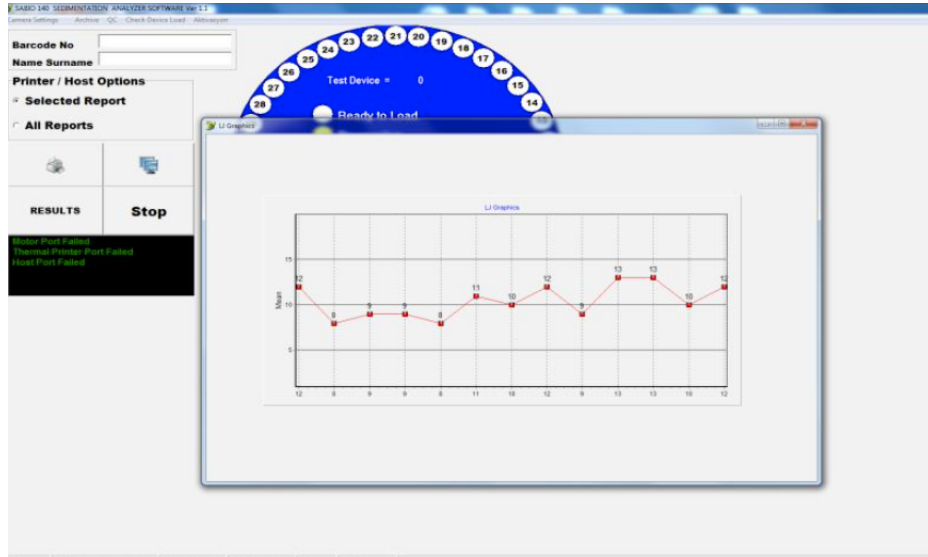
Normal Value: Normal Barcode: 123 AbNormal Value: AbNormal Barcode: 1234

First: 2 Second: 15 First: 45 Second: 80

Save



To view LJ charts for quality control studies; go to the QC menu and then press LJ Graphics.



Classification

According to CE classification, the automatic hematology analyzer belongs to the in vitro diagnostic medical devices.

BIOTA GROUP
BIOTA

DECLARATION OF CONFORMITY

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We hereby declare that the below mentioned products meet provisions of the Council Directive 98/79/EC In vitro Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Description Of The Product : ESR Analyzer
Product Brand : SABIO
Product Type/Model : SABIO140 Automated ESR (running directly EDTA samples) and SABIO140 Test Device
Classification : Others, according to Annex III of IVD 98/79/EC

General Applicable Directives
In vitro Diagnostic Directive council directive 98/79/EC of October 1998 concerning in vitro diagnostic instruments (IVD 98/79/EC)

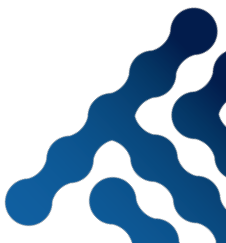
Standards
All applicable harmonized standards published in the official journal of the European Communities:
EN13612:2002; EN ISO 13485; EN 61010-1:20010; EN61010-2-101:2002; EN61326-1:2013; EN61326-2-6:2013; EN62304:2006; EN62366:2006; EN13640:2002

Date Of Issue : 25.02.2019
Signature : 

Name : Volkan Aghasi
Position : CEO

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BIOTA GRUP EC Declaration Of Conformity 1 of 1 pages



SABIO 140

Automated ESR Analyzer

BiOTA GROUP

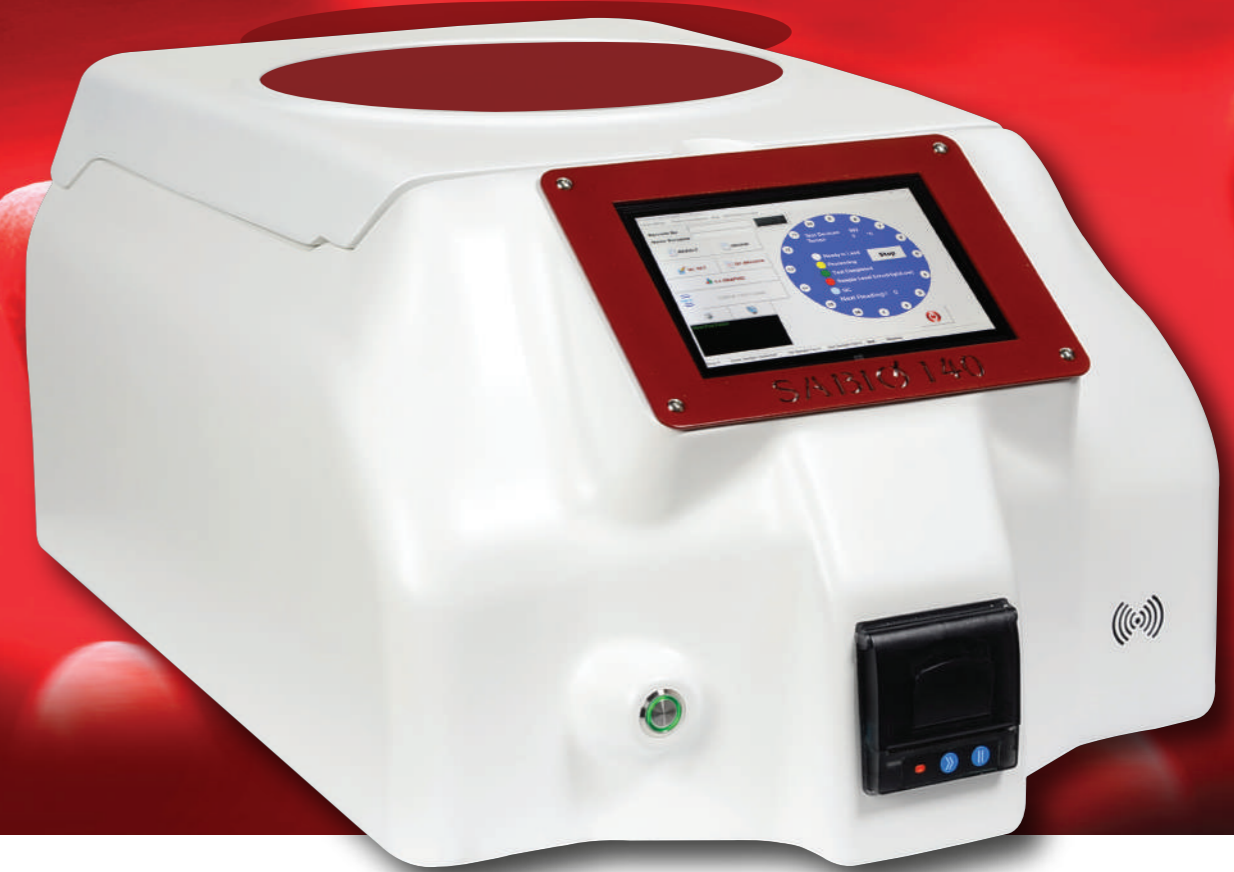
Technical Specifications

Principles	: Westergren method by CCD Camera
Sample Loading Positions	: 40, Direct loading of Blood/EDTA Samples
Throughput	: Up to 120 samples/hour
Time to First Result	: First result in 20 minutes
Time to Result	: 3 seconds
Minimum Sample Volume	: 2 ml
Sample Test Volume	: 2 ml-4 ml
Barcode Reader	: External (optional)
Internal Printer	: Yes
LIS Communication	: Yes
Display	: Liquid Touch Screen , 800x600 pixel
Operating Environment	: Temperature: 15°C-35°C, Humidity: ≤80%
Power Requirement	: A.C. 110-230V ≤300 VA 50/60Hz
Dimension	: 550mm(L) x 440mm(W) x 315mm(H)
Weight	: 13 KG

SABIO 140

Automated ESR Analyzer

For the direct determination from blood/EDTA Samples



BiOTA GROUP

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CE ISO 13485:2012

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P/N-ENG-SABIO140-26102023

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SABIO 140

Automated ESR Analyzer

SABIO140 Automated ESR Analyzer is a bench top system which has complete integration in the hematology laboratories by the direct determination of ESR from blood/EDTA samples with its smart and innovative technology combining “ccd cam” and internationally accepted Westergren method.

SABIO140 is completely cost effective, provides patient comfort and environment friendly since it is using same EDTA tubes coming from CBC tests.

40 sample loading positions, suitability to continuous loading for 19 minutes when you start running the instrument, being maintenance free, being environment-friendly, LCD touch screen and data transmission to LIS are just some of the advanced features of the analyzer which provides laboratory comfort and productivity.

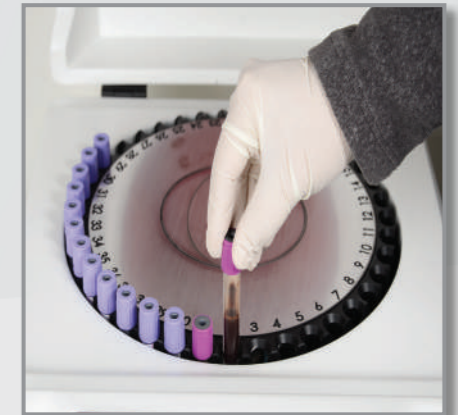
- **Use of the same CBC tubes. No dedicated citrate tube needed**
- **Westergren method by CCD camera**
- **Use of smart cards**
- **No reagents required, environmentally friendly**
- **40 sample loading positions, up to 120 tests/ hour**
- **Continuous loading of samples until the first result**
- **First result available after 20 minutes and each following result within 5 sec.**
- **Advanced QC Management by LJ Graphics**
- **7 inch LCD touch screen**
- **User friendly software**
- **Built-in thermal Printer (optional external printer)**
- **LIS connection**
- **Optional Barcode reader**

RELIABILITY | PRODUCTIVITY | SATISFACTION



USE OF CBC TUBES

No dedicated ESR citrate tube needed.
No reagents required.



EFFICIENT & USER FRIENDLY

Easy to use. 40 sample positions
and continuous loading



FEEL THE EXCELLENCE...

INTENDED USE

Control to be used to check accuracy and precision of Erythrocyte Sedimentation Rate (ESR) determined by SABIO140/JR Automated ESR Analyzer running directly from EDTA Tubes.

REAGENTS

SABIO ESR Controls contain human red blood cells, preservatives and stabilizer in EDTA tubes.

PREPARATION

Ready to use.

STORAGE & STABILITY

Store at 2-10 °C. Do not use SABIO ESR Controls after their expire date.

Do not freeze the controls. Protect from the light.

MATERIALS PROVIDED

1x 3ml. Normal ESR Control
1x 3ml. Abnormal ESR Control
Ready to use in EDTA tubes

MATERIALS REQUIRED BUT NOT PROVIDED

SABIO Series Automated ESR Analyzer





PRECAUTIONS & WARNINGS

All precautions adopted in laboratory practice should be followed when handling material of human origin.

Material of biological origin once used must be treated as infectious residuals and eliminated according to law.

A loss of colour of the product may be a sign of degradation. **Do not use the product if a loss of quality is suspected.**

VALUE SHEET OF CONTROLS

COMPLETE KIT		Normal Control		Abnormal Control	
		 016  31.10.2025		 016  31.10.2025	
Method/Instrument Model	Units	Mean Value	Range	Mean Value	Range
EDTA Sample SABIO140/SABIO JR/SABIO M	Mm/h	5	1-9	31	21-41