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CE

Sed Rate Timer 10/II (SRT10/II) including Software (G2M100BO, Vers. 1.0)

ESR Analyzer

(optional thermal printer available)

USER'S MANUAL

MAN-003 – Revision 6
Revision date: November 30, 2012

This user manual follows the directions as prescribed by the CEN/TC 140 recommendations for in -vitro diagnostic instruments (EN ISO 18113-3:2009):

INSTRUMENT NAME:

Sed Rate Timer 10/II (SRT 10/II)
including Software (G2M100BO, Vers. 1.0)
Short cut name: SRT 10/II

Automatic Sed-Rate analyzer,
10 measuring channels

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PLEASE READ THIS ENTIRE PRODUCT MANUAL BEFORE USING THE INSTRUMENT FOR THE FIRST TIME.

CONTENTS

1. INTRODUCTION

1.1 Intended use

The SRT 10/II analyzer is an automatic instrument controlled by a microprocessor and exclusively employed for analysis of the in vitro diagnostics determination (IVD) of erythrocyte sedimentation rate (ESR). It constantly and simultaneously scans 10 test tubes, which are custom-made for ESR analysis. The SRT 10/II follows the sedimentation of each sample independently, memorizing levels for the whole period of analysis.
Every attempt to use the SRT 10/II ESR analyzer with a purpose different from the intended use, must be considered improper.

2. POTENTIAL DANGERS AND SAFETY PRECAUTIONS

2.1 User Precautions

Before beginning the use of the analyzer, the operator must know the rules for handling potentially infectious materials and for handling Electro-mechanical systems.

2.1.1 User Identification

This ESR analyzer is intended for professional use only. The operator must be trained for working in laboratory using hazardous materials and professional equipment. The use of this ESR analyzer by a not trained operator is considered an improper use.

2.2 Electrical equipment

As all electrical equipment, the power supply is a potential source of danger. Please avoid handling electrical parts before disconnecting them from the power supply. Never carry out maintenance on the instrument when it is under electrical tension. Until the instrument is packaged, as supplied, the operator is protected against electric shock. Pay attention to the following electrical parts: the power supply and the printer. The SRT 10/II analyzer, is powered by low voltage, and it doesn't present the same dangers of the equipment's powered by an electrical line. Even though it has a voltage elevator circuit inside, and it could provoke strong electrical shocks, it is not dangerous for the service assistance personnel. We suggest to disconnect the power supply every time a technical operator make instrument maintenance.

2.3 Mechanical equipment

For the mechanical part of the analyzer, we suggest to not open the machine before having disconnected it from the power supply. If the power is on, it is not dangerous for the operator, but instrument would damage if brought into contact with the parts in movement.

2.4 Biohazardous material

As with all in vitro diagnostic equipment, patient samples and quality control (QC) products that are assayed on this system, should be treated as potentially bio-hazardous. All materials should be handled according to your facility's biohazard procedure. Always wear the personal protective equipment recommended by your facility when using the analyzer.

2.4.1 Human samples

Always wear gloves and eye protective glasses when handling human samples. Treat all samples as potentially bio-hazardous and infectious. If any sample is spilt on the instrument, utilize the correct personal protective equipment (PPE-gloves, lab coat, etc.), wipe it up immediately and clean the contaminated surface with a disinfectant (e.g.sodium hypochlorite 0.5%) solution.

2.4.2 Waste solution and solid waste

Avoid direct contact with waste solution and/or solid waste. Both should be handled as potentially bio-hazardous. Dispose of waste solution and/or solid waste according to local governmental regulations.

2.5 Notes on safety measure

Please pay attention to the sample collection. The vacuum test tubes used for this instrument, have been studied to draw the right level of blood. To fill the test tube with a higher volume of blood, could cause a serious infection risk for tube leakage. Furthermore the leakage could damage the inner optical part of the instrument and annul the guarantee.

2.6 Disposal And Recycling

Herewith we declare that this instrument is subject to the European Directive 2002/96/EC (RAEE Directive) and 2003/108/EC. Therefore the instrument must be disposed separately, not as urban waste and delivered to the specific collection centre in accordance with the Directive 2002/96/EC and 2003/108/EC.

The user may request that the supplier collect the instrument for correct disposal, if a new instrument is ordered.

2.7 Bio-Hazardous Parts Disposal

All parts which have a direct contact with samples must be disposed as POTENTIALLY INFECTIOUS. Follow local regulations.

2.8 Additional Precautions

The following symbols are placed on the instrument to assure correct usage:

Attention: read use instruction

For in vitro diagnostic use only

ELECTROSTATIC DISCHARGE SENSITIVE DEVICE (ESDS):
The device could be damaged by electrostatic potentials

BIOHAZARD RISK
Adopt protective measures to avoid any contamination (gloves, glasses etc…)

DO NOT DISPOSE
The instrument cannot be disposed as urban waste

DC DIRECT CURRENT

3. INSTALLATION

3.1 Positioning of the analyzer

The SRT 10/II must not be placed near centrifuges, oscillating agitators or other vibrating instruments that might cause movement of the bench. Please keep in mind that ESR is very sensitive to vibrations that could cause a false increase of results. The bench must be flat and level. Direct light on the instrument and sudden changes of temperature should be avoided. Keep a free area of at least 15 cm around the instrument to allow instrument cooling by the internal back panel fan. Connect the instrument power supply only of the type described in this User's Manual. Use the mains plug to disconnect the apparatus from the mains supply. The mains plug must be accessible at all times.

3.2 Configuration

Before switching on the analyzer, please set-up the dip-switch placed in the rear panel following the table below:

SWITCHES CONFIGURATION
----

1 - enable 30' result
2 - enable 1h and 2h result (ON = 1h and 2h; OFF = 1h)
3 - enable temperature compensation
4 - enable the printer
5 - enable sedimentation curve graph
6 - not used
7 - enable the internal fan
8 - enable power supply on thermal printer connector (836582-DPT100 printer)
WARNING!: Do not switch on power when using a different type of printer, as serious damage could be caused.

To enable each function, be sure that the corresponding switch is placed in ON position.

For example to configure instrument for results corresponding to 1 hour Westergren, with temperature compensation, connected to the thermal printer (Item number 836582), switches are placed: (Default Setting)

N° Switch	Position
1	OFF
2	OFF
3	**ON**
4	**ON**
5	OFF
6	OFF
7	**ON**
8	**ON**

3.2 Power on

The cable that connects the instrument to the electrical circuit is the most important system of disconnection from the electrical source. For this reason, the cable must be easily reached and accessible by the user.

Connect power supply outlet to the instrument. Insert the power supply plug in a socket with an earth connection. If the instrument has an optional printer it should be connected to the SRT 10/II with the appropriate cable and plugged in. Connect and switch on first the printer, then the SRT 10/II using the switch situated at the rear of the instrument.

Each time SRT 10/II is switched on, it carries out an electronic initialization, a cancellation of the memory and an instrument check test.

On the display appears this message:

```
greiner Bio-One
SRT10/II V.1.0
```

then configuration data appears:

```
30/60' working time
results: 30', 1h, 2h mm
```

If the printer has been connected, this message will be also printed, followed by the header of the results given at the end of each analysis.

If the printer is connected, on the display appears this message:

```
print curve ON...
printer OK...
```

If the printer is off or not connected the following message appears:

```
check the printer!
```

if the temperature compensation is active, the following message appears on the display:

```
18°C temp. of reference
27.5°C internal temp.
```

Instrument starts the auto test for mechanical and electronic control

Several seconds after, the display will indicate:

Now the instrument is ready for the analysis. On the display appears this message:

4. SYSTEM DESCRIPTION

4.1 Analyzer unit

The SRT 10/II ESR analyzer is an automatic instrument controlled by a microprocessor and exclusively employed for analysis of the erythrocyte sedimentation rate. It's total absence of commands, its precision and its ability to obtain the result already corrected to a temperature of 18℃ (according to Manley) in only 30 minutes ma ke it the most innovative and versatile system for this kind of analysis. It constantly and simultaneously scans 10 test tubes, which are custom-made for ESR with this system.

SRT 10/II follows the sedimentation of each sample independently to each other, memorizing levels for the whole period of analysis. The instrument can be used for random and continuous loading of samples to a capacity of 10 test tubes each time. When a sample has been analyzed, it can be replaced by another, so it is possible to analyze up to 20 tests / h.

SRT 10/II has been developed to simplify ESR analysis, avoiding sample manipulation and operator 's infection risk. To carry out the analysis, the operator puts the sample test tube into the instrument. The result appears on the display in only 30 minutes. This feature allows the instrument to be used directly on the ward, in the blood sample collection department and in small laboratories. In carrying out the analysis SRT 10/II controls the room temperature and converts the result to the reference temperature of 18℃. (In accordance with Manley table).

The results conversion is necessary to avoid substantial variations of values due to different room temperatures.

4.2 Pre-Indication of the results

Only 9 minutes after putting the sample in, before the end of analysis, the SRT 10/II can show on the display messages indicating a prediction of the result.

Result pre-indication:(after 9 minutes)

mm/h	Visualization
< 9.0	- -
9,0 - 29	+-
> 29	++

These symbols appear on the display in the same position of the sample channel.

4.3 Display

A 40-character two-line LCD display with backlight, allows a continuous monitoring of the analysis and a visualization of the results. On the display can be also shown a sample or a system error message. Please note that the display can indicate more than one results for each sample, according to dip-switch configuration set up by operator. To know which kind of analysis results are referred to, please look in the bottom-left position on the display where the message 30', 1h or 2h will flash. On the display the operator can also see the symbols shown below: These symbols suggest for each sample the analysis time remaining.

time remaining symbols

4.4 Reading Plate

One row of 10 test tube channels, numbered from 1 to 10.

4.5 Power Supply

The low voltage supply, built in accordance with international safety standards, offers a valid solution to improving assistance service.

4.6 Printer

The printer is hooked up to the instrument with RS232 C outlet. Whenever an analysis is completed, it prints out the ESR results following the loading sequence. The printer is external so it can be easily replaced when necessary. It can also be replaced by other printers with serial entry.

4.7 Test Tubes

The test tubes for this instrument are VACUETTE® (vacuum tube) specially made for the SRT 10/II instrument. These tubes contain 3.2% sodium citrate and a vacuum which allows a 1.5 ml or 1.6 ml blood drawing.

4.8 Performance criteria and limitations

1) PERFORMANCE CRITERIA

A. Mechanical / Optical precision of detection : +/- 0.2 mm

B. Variability Coefficient of analysis : C.V. < 5 % (sample depending)

C. Automatic temperature conversion to 18℃. (Manley table) : Accepted range: 15° - 32°C.

D. Acceptable range for blood drawing : -10 + 4 mm from normal

E. Max 10 Measuring points : Intervals of 3 minutes

F. Measuring range : 1 - 140 mm/h

2) LIMITATIONS

A. Strongly lipemic or hemolytic samples may alter reading capability.

B. Sed rate values > 140 mm/h will be indicated with this mark only.

C. Temperatures outside the given range will be accepted as 15 °min and 32°max

5. OPERATING PROCEDURE

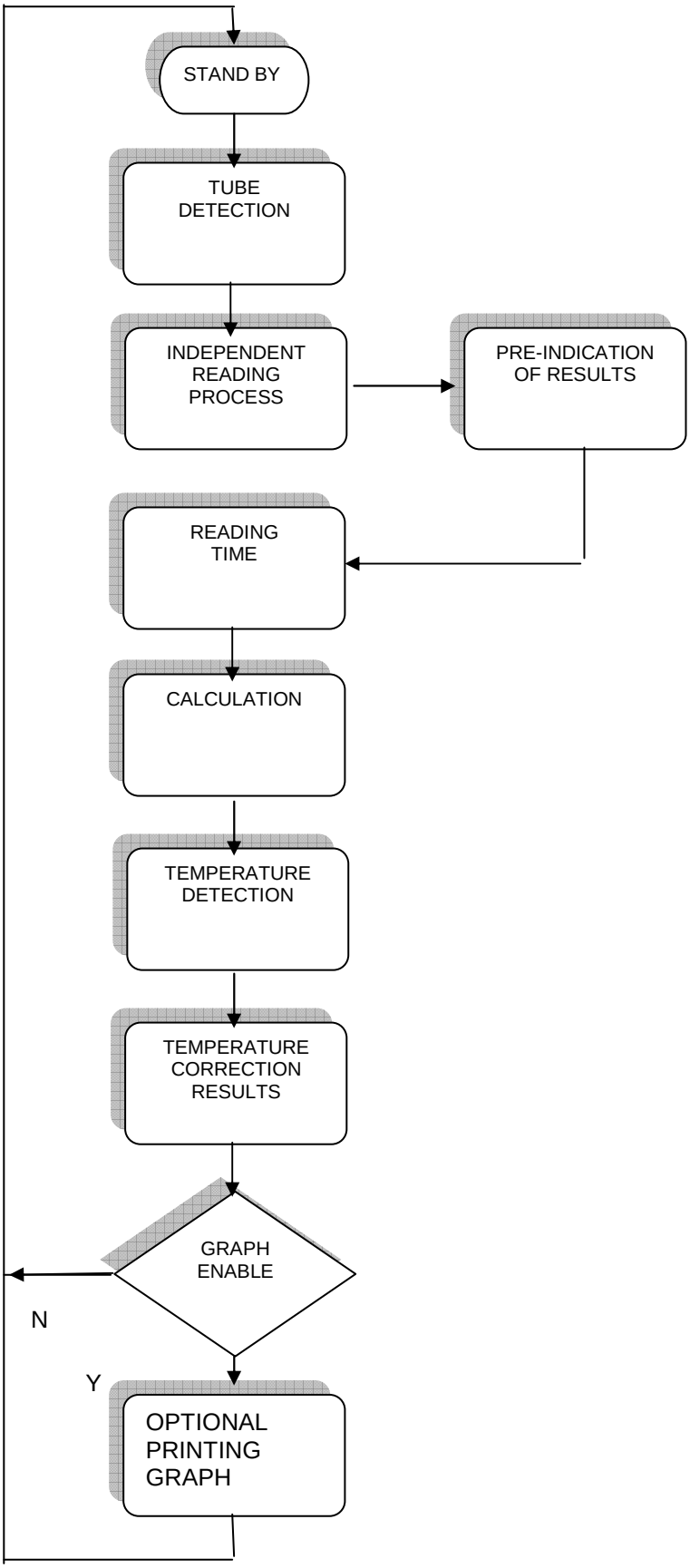
5.1 Reading principle

Ten infrared barriers cover vertically the ten test tubes with a cycle of about 60”. The whole test tubes, every 0.2 mm gap are analyzed. As soon as the reading plate, including 10 pairs of I.R. TX / RX, begins to rise, the software recognizes any positions occupied by samples containing the right level of blood.

At the first rising (when the instrument has ensured that the meniscus is clearly distinct) the level of the sample collection just inserted is checked and the analysis begins.

The computer records the "zero" time for each sample and all the following readings, until 30 minutes have elapsed. During this phase the instrument also recognizes if the sample is being proper kept in its channel.

5.2 Functional Sequence of Analysis



5.3 Sample collecting

Samples must be collected following the vacuum technique with VACUETTE® ESR Vacuum Test Tubes, 1.6 ml draw (Item Nr. 729093) or 1.5 ml draw (Item Nr.729073).

During sample collecting to be sure to have the right volume of blood, it is necessary to wait until the test vacuum tube finished the blood drawing.

5.4 Labeling

Identify the sample writing on the original test tube label or applying a barcode label. Follow the scheme in Fig. (6) to carry out this action correctly. In the figure, the test tube (A) has the correct blood level and the original label on which write patient code or other data if the barcode is absent. The part (H) shows the zone that must be absolutely free and transparent to allow the infrared rays to recognize the right blood volume. Test tube (B) shows label correct position. Test tubes (C) and (D) illustrate how, erroneous label positioning, obstruct the reading of the analysis.

If the instrument is installed in the surgery, samples can be immediately analyzed by SRT 10/II, simply placing test tubes in free position. Otherwise samples should be analyzed within three hours, paying attention to external agents shown below, that might alter ESR values in the pre-analysis phase.

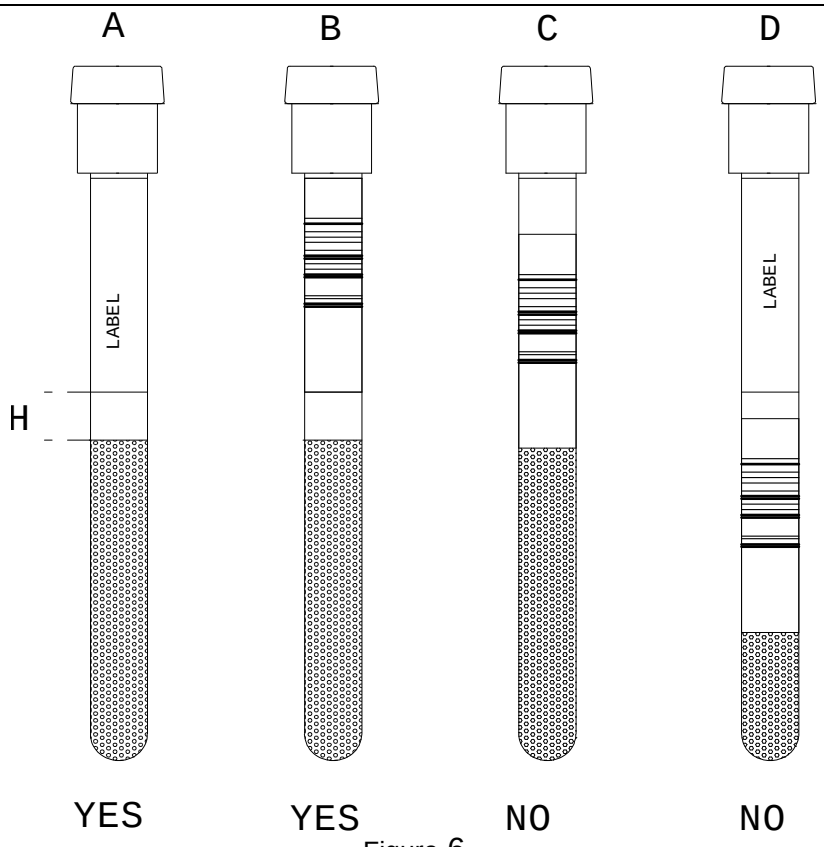


Figure 6

a) Dilution ratio
b) Bubbles
c) Strongly hemolytic samples
d) Sudden agitation
e) Temperature
f) Time after sample-taking
g) Direct sunlight
h) Foam
i) Lipemic samples

5.5 Sample mixing

When it is not possible to analyze the sample immediately after sample collecting, it must be gently mixed by inverting for at least five minutes. The use of a rotating agitator (VACUETTE® MultiMixer, Item Nr. 836577) is recommended. The suggested rpm-value for the mixer is 15-20 RPM.

5.6 Sample positioning

After mixing, the sample must be promptly transferred to the analyzer. We suggest to place the mixer near the SRT 10/II. It is also recommended following a numerical sequence while channels loading. After inserting the tenth sample, wait for the results of first loaded samples, remove the analyzed samples from their channels and put new test tubes in these channels to continue the analysis. On the display the operator can also check the proper location of the right channel in which to put the new test tube.
The sample positioning on the analytic plate are numbered from 1 to 10. Numbering is meant progressively in groups of 10 samples, so when the analysis of the sample in channel number one is completed, the new sample put in channel one, automatically becomes the sample number 11, and so on with the other samples.
For sample identification (if printer is disconnected) the operator can use a form in which write the patient name or code number before the tube is put into the analyzer.

5.7 Sample removal

During the reading, SRT 10/II shows on the display the operative state of the instrument and the updated situation of current and already concluded analysis. Before the final result is shown on the display, the operator is advised by two short acoustic signals.
When the analysis is finished, the result will be automatically shown on the display and transmitted by the serial line to the printer (when connected and switched on). Data will remain memorized on the display until the operator, having noted the values, removes the corresponding test tube from the plate. After removing the test tube the data on the display disappear in about one minute and in the corresponding channel, the operator can put a new sample.

5.8 Brief working instructions

1. Set up instrument:
   Connect power supply and printer,

2. Switch on printer and analyzer unit: On the display appears some information (i.e. software release) and this symbol: **“ . ”** appears for each free channel. It indicates free positions on which the operator can put samples.

3. Sample identification:

   a) Prepare E.S.R. data report form
   b) Write name or patient N°on the tube and on the form, following the channel position.

4. After gently mixing for about 5 min., put the tubes into reading channel, following the form data.

5. After 30/60 minutes the operator can read or print the results:

   a) If printer is connected , there will be an automatic printout
   b) If printer is disconnected the operator must read and record on the form values indicated on the display.

6. After having the results remove tubes :
   This symbol **“ . ”** will appear, indicating that this channel position is free for a new test tube.

Follow points 3 - 6.

6. TEMPERATURE COMPENSATION

6.1 Results correction to 18℃

The results achieved are correlated to the method of reference, considering the room - temperature. SRT 10/II, measures constantly the inner temperature; further reconverts the values in according to the Manley table **(1)** shown below, at the temperature of 18 degrees. Therefore this instrument guarantees a better reproducibility instead of instruments which perform results without temperature compensation.

(1) Manley table

correct values	---------- analysis temperatures ----------				
18 degrees C.	15 degrees C.	18 degrees C.	20 degrees C.	25 degrees C.	30 degrees C.
5	4	5	5	6	8
10	9	10	10	12	16
20	18	20	21	25	31
30	27	30	31	37	45
40	36	40	42	49	58
50	46	50	52	60	71
60	55	60	62	71	82
70	63	70	72	82	93
80	72	80	82	93	104
90	81	90	93	103	114
100	90	100	103	114	125

SRT 10/II converts the results to 18 degrees according to the table if room temperature is in the range 15 - 32 degrees C. For lower or higher room temperatures the instrument convert temperature in this way: 15 degrees C for lower and 32 degrees C for higher temperature.

6.2 Result

Each laboratory should validate and evaluate its ESR reference values.

7. PRACTICAL USE

7.1 How to Use the Instrument

SRT 10/II is very simple to use and the procedure can be learnt quickly. Being already pre-set, no configuration is necessary after switching on, so the operator does not input data. For this reason there is no user interface keyboard.

The standard conditions, which can be modified, are the following:

a) analysis time: 30 minutes with report related in mm to 1 h / Westergren (refer to page 6 for different configurations).

b) automatic adjustment of temperature with report related to the reference temperature of 18°C in accordance with Manley table .

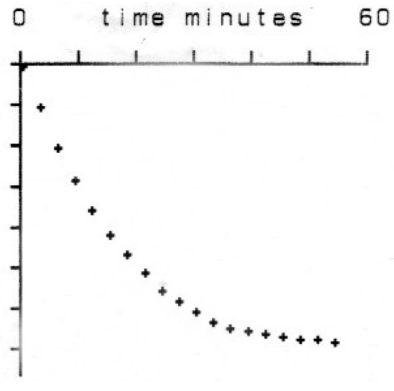
After collected the sample, observing instructions given in chapter 6 “Operating procedure”, the operator can put the sample into the first free position of the SRT 10/II. Before putting the sample in, the operator must record on the appropriate form, the patient name or the patient code, the sequence number of the analysis and mostly the position number (1-10) in which the sample is putted in. After few seconds, the display, in the same position of the loaded channel, shows this symbol: " ▓ " meaning the analysis start.
If after two minutes this symbol remains unchanged, it means that the sample has been accepted by the level control made by SRT 10/II at the beginning of the analysis.
If the sample is not accepted, the message **"LEV"** appears, meaning that the sample has not been properly drawn and the blood level in the test tube is not within the limits permitted by the instrument (+ 4, - 10 mm from the theoretical level).
For samples with blood levels in the range +4 and -10 mm, the results will be automatically adjusted by the SRT 10/II software. Other test tubes may be putted in, following the progressive position order up to 10.

Half an hour later each insertion, the result in mm/h Westergren, will appear on the display in the position corresponding to the respective test tube and remains until the sample is removed. 60 seconds after the sample removing, the result will disappear to the display. Now other samples can be loaded in the vacated positions. If the printer is connected to SRT 10/II, it will print out the results at the end of each analysis as follows:

```
Smpl.Chan.PatID#
 104   14   ..........
-----------------------
 30'   1h    2h
  5    13  >124          mm
```

Smpl = sample sequential number (1 - 999)
Chan = Channel number (1 - 10)
Pat-ID = fixed value at "……."

If the graphic printout has been activated, you can see the diagram (here below) in addition to the results:

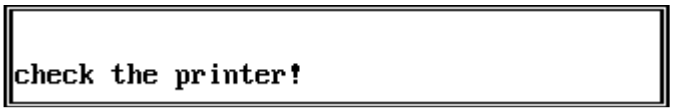


7.2 Limit of the Instrument

SRT 10/II reading limits is max. 140 mm. at 18℃. When a sample has a value > 140 mm, this message is displayed or printed: "**> 140**"

8. ERROR INFORMATION AND WARNINGS

8.1 Warnings information

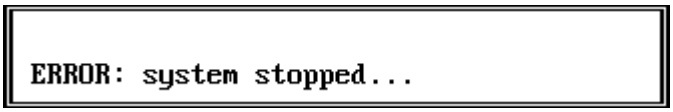


This message appears when printer is enabled in the SRT 10/II, but not switched on.

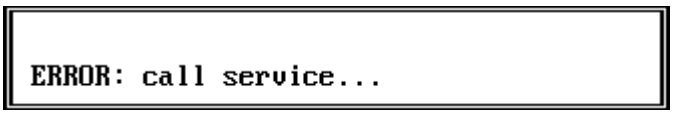
Meaning of symbol on display

"xxx" Result = xxx
" . " Awaiting sample
">xxx" Sample value higher than "xxx"
"lev" Error: initial level error
"rem" Error: removed sample

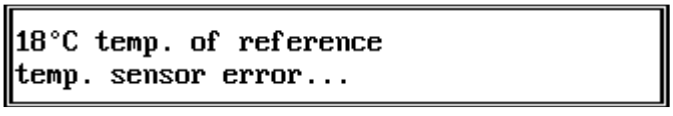
8.2 System Error Warnings



This warning will be given if the instrument finds problems with the mechanical movement of the reading plate during the initial self-test. (Call service)
After this indication the instrument will stop and it need to call the technical service.



This message can appear if there is a mechanical problem during analysis.



This message can appear if the internal thermometer has problems. In this case, analysis results are displayed without temperature compensation.

9. MAINTENANCE

The instrument does not require a maintenance under normal user conditions, but a preventive maintenance can reduce a spontaneous instrument failure. Please pay attention to the cleanliness of the upper part (test tube positioning plate), which must be covered when the instrument is not used. Do not clean the upper plate with liquids or damp cloths. The entry of liquids or solid material into the reading channels can cause considerable damage to the instrument.

9.1 Cleaning and decontamination instructions

Dust can be removed using an ordinary vacuum cleaner. Pay particular attention to the test tube: it must be well closed and the cap should not be never removed. The label must be correctly positioned and well stuck to the test tube surface. Label fragments could fall into the test channel and obstruct a correct reading function during analysis.

1. Wipe potentially contaminated areas of the SRT 10/II with a cloth or paper towel wet with 1% bleach solution (Solution A). Solution A (about 1%): 200 ml hypochloride and 800 ml of reagent grade water.
2. Let solution set for at least 15 minutes.
3. Wipe Solution A from areas.
4. Wipe areas again with cloth or paper towel with reagent grade water to remove the Solution A.
5. Dry areas thoroughly.

9.2 Periodic test

In order to assure the correct performance of instrument and obtaining precise results, it needs to perform a periodic test, once a month, which controls the accurate calibration of the device. The test has to be done using the Greiner Control Unit (Control Tool).

This tool can be used by service people to check the mechanical calibration and functionality of the instrument.

It can be used to check:
- Mechanical calibration of the reading system.
- Mechanical level reading reproducibility.
- Tubes reference levels reading at ambient temperature.
- Results conversion at the reference temperature of 18℃.
- Internal temperature sensor readings.

HOW TO ENTER INTO "SELF TEST" FUNCTION

- Insert the "Control *Tool*" tubes, with 60, 50 and 30 mm reference level, respectively in positions 1, 2, and 3 of the instrument reading plate. All other reading positions must be empty.
- Turn on the instrument and wait. The instrument detects this special condition and starts the self-test.

After a while (the reading plate must complete a reading cycle down/up) on the display the following information will appear (this is just a screen example).

```
SELF TEST     ( a.t.     1     24     93 )        M.STEPS
Temp. 25.0 C. ( 18C      1     19     81 )          300
```

On the left, at the bottom of the display you can find the value of the internal instrument temperature. On the right of the display there the mechanical calibration reference (**must be 300 +/- 10**)

The 1st results row values must be: **1, 24(+/-5), 93 (+/-5)**

The 2nd row values depends on the internal instrument temperature. The table below must be used to get the reference values for the 2nd row. Look at the column where your internal instrument temperature is included within a specified range.

Temperature correction table for 2nd row values (℃).

Reference Values	Temp. <= 16.3°	Temp. 16.4–18.7	Temp. 18.8–21.2	Temp. 21.3–23.7	Temp. 23.8–26.2	Temp. 26.3–28.7	Temp. 28.8–31.2	Temp. > 31.3
24	27	24	23	21	19	17	15	15
93	103	96	91	86	81	75	70	70

10. TROUBLESHOOTING GUIDE

Before calling a service technician, please check the handling of sample collection, mixing procedures and operating instructions.

ALARM OR TROUBLE	CAUSE	REMEDY
lev	a) sample level high or low b) the label was not placed in its proper position. Refer to page 15.	a)repeat sample collection b)replace label and repeat analysis
rem	sample has been removed	repeat analysis
Temp. sensor error	"Temperature error" sensor malfunction	data-analysis is not converted to 18 C. Call service assistance
System stopped	motor or mechanical defect	Call service assistance
Data result is not printed	a) Printer power b) Printer cable c) Printer configuration	a) Check power supply b) Check cable c) See manual for check printer configuration d) Check printer test by power on when key f/f is pressed. e) Replace printer
Data result is not credible	a) sample clot b) sample has foam c) sample measured after 4 hours from sample collection d) have the instructions for sample mixing been used ? e) Did you consider the automatic temp. conversion of the SRT-10/II	a) repeat sample collection b) re-mix gently
One or more " ▓ " appear on the display without tubes being introduced.	a) possible obstruction of infrared barrier by external materials(label parts, etc,) b) disconnection or defect of internal cable.	a) Call service assistance b) Call service assistance
No info on display	a)power switched on? b)power supply working? c)internal problem	a)Switch power on b)Check power supply, replace if necessary. c)Call service assistance
Info on display scrambled		call service assistance
Check the printer (on the display)	a) Printer is connected but in OFF position	a) Switch-on the printer and re-switch the SRT-10/II b) Set SW4 in "ON" position
Call service	a) mechanical problems during analysis.	a) call the service.

NOTE:
For validations of test results please refer to:

CLSI document H02-A5 Vol. 31 No 11
"Procedure for the Erythrocyte Sedimentation Rate Test"
Fifth edition; Approved Standard
(National Committee for Clinical Laboratory Standards)

11. TECHNICAL SPECIFICATIONS

Area of application :	Blood sedimentation rate analysis
Instrument size:	Width 290 mm Depth 190 mm Height 170 mm
Weight:	about 2 kg
Voltage: Hz	external power: 100 - 240 V AC +/-10%, 1.8 A, 50-60 output: 12 V DC 1.5 A
Operating Conditions:	temperature 15°- 32°C ro om temperature humidity: 45% - 85% altitude: up to 2.000 m overvoltage: category II pollution: degree 2 for indoor use only sound level 32 dBA
Reading chambers	10
Analysis time:	30'
Analytical capacity:	max 20 tests/h
Loading capacity:	max 10 samples at a time
Loading pattern:	random
Results:	(1 h mm Westergren (by interpolation) (or ½ h and 1h Westergren) (or 1 h and 2 h Westergren) (or with graphics on the printer)
Temperature correction:	automatic compensation referred to 18□ C. (Manley)
Measuring method:	infrared barrier
Reading resolution:	+/- 0,2 mm
Results resolution:	+/- 1 mm
Reading points	up to 20
Blood draw level acceptance from normal level	+ 4 mm / - 10 mm
Interface:	RS 232 C for printer
Applicable standards	ISO 9001:2008, ISO 13485:2003, EN ISO 14971, EN ISO 18113-3, EN 13612, EMC Directive 2004/108/EC and LV Directive 2006/95/EC and following amendments.

General Directives:	2002/95/EC 2003/108/EC
EMC Standards:	EN 61326-6:2006
Safety Standards:	IEC/EN 61010-1:2001 IEC/EN 61010-2-101:2002 IEC/EN 61010-2-051:2003
Machine Directives:	98/79/EC 2006/42/EC
Transport and storage:	Do not refrigerate during transport Storage temperature : 4 – 30℃ Storage relative humidity: 20%-85%

12. PACKAGING INFORMATION

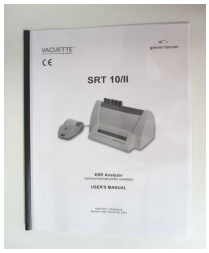
BOX SIZE: 30 x 60 x 36 cm
WEIGHT: 3.5 kg

open box

instrument protection

ACCESSORIES

dust cover



user manual

power supply

power cable

self-test tool

APPENDIX

A. THEORETICAL INFORMATION

A.1 Westergren Method

This is the standard method in accordance with the National Committee for Clinical Laboratory Standards. It consists in a support that keeps the Westergren tubes, containing non-clottable blood perfectly vertical and hermetically sealed. Westergren tubes have a diameter of not less than 2.55 mm and are graduated up to 200 mm.

As soon as the sample is taken, it is mixed with a 3.2 % sodium citrate solution, in the ratio of respectively four to one (1.6 ml + 0.4 ml of sodium citrate). The blood thus prepared and well mixed is drawn into a Westergren tube up to the zero mark. The tube is putted in the appropriate support and the erythrocyte level is read after 60 and 120 min.

A.2 Variations of ESR

A. Net increase of ESR (100 mm or more per hour)

1. Multiple myeloma and Waldenstrom macroglobulinemia
2. Malignant lymphoma
3. Leukemia
4. Serious anemia
5. Carcinomas
6. Sarcomas
7. Serious bacterial infections
8. Collagenosis
9. Biliary or portal cirrhosis
10. Ulcerous colitis
11. Serious nephrosis
12. Internal hemorrhage
13. Acute hepatitis
14. Ectopic pregnancy unbroken after the third month
15. Broken ectopic pregnancy
16. Menstruation
17. Normal pregnancy after the third month
18. Oral contraceptives taken
19. Tuberculosis
20. Postcommissurotomy syndrome
21. Dextran administered intravenously

B. Moderate increase of ESR

1. Acute and chronic contagious diseases
2. Acute localized infections
3. Reactivation of a chronic infection
4. Rheumatic illness
5. Rheumatoid arthritis
6. Myocardial infarction
7. Malignant tumor with necrosis
8. Hyperthyroidism
9. Hypothyroidism
10. Lead or arsenic poisoning
11. Nephrosis

C. Normality of ESR (most cases)

1. First stage acute appendicitis (in the first 24 hours)
2. Precocious integral ectopic pregnancy
3. Malarial paroxysm
4. Cirrhosis of the liver
5. Arthrosis
6. Mononucleosis
7. Acute allergies
8. Viruses without complications
9. Peptic ulcer
10. Typhoid fever
11. Undulant fever
12. Rheumatic carditis with cardiac decompensation
13. Whooping cough

1) THYGESEN, J.E.(1942). The mechanism of blood sedimentation. *Acta Medica Scandinavica,* Suppl. 134.

2) WINTROBE,M.M. and Landsberg, J.W. (1935). A standardized technique for the blood sedimentation test. *American Journal of Medical Sciences,* **189**, 102

3) HARDWICKE, J. and SQUIRE, J.R. (1965). The basis of the erythrocyte sedimentation rate. *Clinical Science,* **11,** 333

4) International Committee for Standardization in Hematology (1977). Recommendation for measurement of erythrocyte sedimentation rate of human blood. *American Journal of Clinical Pathology*, **68**,505

5) LASCARI, A.D. (1972). The erythrocyte sedimentation rate. *Pediatric Clinics of North America,* **19**,1113

6) MANLEY, R.W. (1957). The effect of room temperature on erythrocyte sedimentation rate and its corrections. *Journal of Clinical Pathology*, **10,** 354

7) CLSI Document H02-A5, vol. 31 N°11 " Procedure f or the Erythrocyte Sedimentation Rate Test".

B. PRINTER CONNECTOR

Please turn off the instrument before connect any cable to the instrument.

PIN	DIRECTION	NAME	DESCRIPTION
1	---	---	(Do not connect!)
2	INPUT	RXD	Serial data input
3	OUTPUT	TXD	Serial data output
4	OUTPUT	DTR	Data Terminal Ready
5	---	GND	Ground
6	---	---	(Do not connect!)
7	OUTPUT	+12	Power supply for external printer
8	INPUT	CTS	Clear to send
9	---	---	(Do not connect!)