Sed Rate Screener 100/II (SRS100/II) including Software (G2S140BO, Vers. 1.4)

ESR Analyzer

USER MANUAL

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 Screener 100/II (SRS 100/II)**
                             including Software (G2S140BO, Vers. 1.4)
                             Short cut name: SRS 100/II

                             Automatic Sed-Rate analyzer,
                             100 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 SRS 100/II ESR analyser is an automatic instrument controlled by a microprocessor and exclusively employed for the in vitro diagnostic determination (IVD) of erythrocyte sedimentation rate (ESR). It constantly and simultaneously scans 100 test tubes, which are custom-made for ESR analysis. The SRS 100/II follows the sedimentation of each sample independently, memorizing levels for the whole period of analysis.

Every attempt to use the SRS 100/II ESR analyser 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 SRS 100/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 Bio-hazardous 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 or 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:

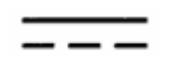|	
⚠	Attention: read use instruction
IVD	For in vitro diagnostic use only
	ELECTROSTATIC DISCHARGE SENSITIVE DEVICE (ESDS): The device could be damaged by electrostatic potentials
☣	BIOHAZARD RISK Adopt protective measures to avoid any contamination (gloves, glasses etc…)
	DO NOT DISPOSE The instrument cannot be disposed as urban waste
⎓	DC DIRECT CURRENT

3. INSTALLATION

3.1 Positioning of the analyzer

The SRS 100/II must not be placed near centrifuges, oscillating agitators or other vibrating instruments that might cause movement of the bench. Keep in mind that the 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.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with proper operation.

This equipment has been designed and tested to CISPR 11 Class A.
In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Therefore the electromagnetic environment should be evaluated prior to operation of the device.

3.2 Power on

Connect the power supply and all other devices according to the description of the instrument connections. Insert the power supply plug in a socket with an earth connection. Connect and switch-on the SRS 100/II using the switch situated at the rear of the instrument. Each time the SRS 100/II is switched on, it carries out an initialization of electronic parts and auto test mechanical checking. The following information is printed out:

> **SRS 100/II   V. X.XX**   (software version)
> **(date)   (time)**
> **temperature ref. to 18 C** (if temp. correction is programmed)
> **temperature** (internal instrument temperature)

This indication appears every time the instrument is switched on a new day. This message indicates that by pressing "ENT" key, all data from the previous day will be deleted and memory will be cleared and positioned into position one. By pressing "ESC" key, all the results remain stored in the memory (max 500 results).

```
THE DAY IS CHANGED...

deleting results...
(ENT to accept!)
press ESC to abort!




SRS100/II 1.4 CHECKUP...
```

Instrument will start the initialization.

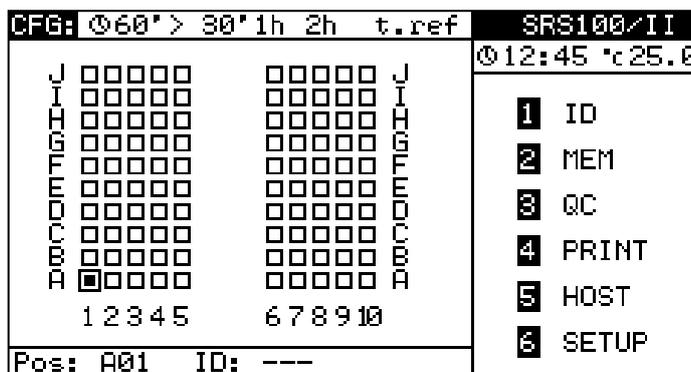```
SRS100/II 1.4 wait, please...
```

At the end of initialization, appears this message:

```
SRS100/II 1.4 self-test OK..
```

Main menu:

On the screen, the main menu appears:

In the first line "CFG" is an indication of which configuration is present at that moment. The clock symbol indicates the selected measurement time, this can be 15, 30 or 60 minutes. The arrow points to the results reference, this can be a combination of 30 minutes, 1 hour or 2 hour Westergren.
If the text "**t.ref**" is displayed as in the figure, temperature correction to 18°C is active. If "**t.ref**" is striked-through

```
CFG: ⏱60'▷ 30'1h 2h   t.ref    SRS100/II
                                ⏱12:45 °c25.0
J □□□□□      □□□□□ J
I □□□□□      □□□□□ I          1  ID
H □□□□□      □□□□□ H
G □□□□□      □□□□□ G          2  MEM
F □□□□□      □□□□□ F
E □□□□□      □□□□□ E          3  QC
D □□□□□      □□□□□ D
C □□□□□      □□□□□ C          4  PRINT
B □□□□□      □□□□□ B
A ■□□□□      □□□□□ A          5  HOST
  1 2 3 4 5    6 7 8 9 10
                             6  SETUP
Pos: A01   ID: ---
```

temperature correction is disabled. The configuration can be changed using the function 6 "SETUP".
In the lower part of the screen, it is possible to see the ID of the sample in analysis.
Simply move the cursor on the screen over the position of the sample, using the arrow keys.
Functions are numbered from 1 to 6. To fully understand each function please refer to the "Software" chapter.

3.3 Instrument set up
Once that the instrument is installed, the operator, entering in function 6 when instrument is in stand-by mode, can decide the work method. Following appears on the display:

Using the arrow key, move the cursor to select the desired configuration.
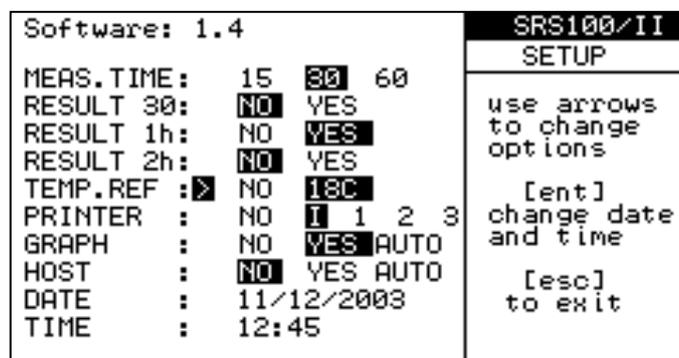
This instrument has an internal printer, therefore the default setting is already on "I" (internal). If the operator chooses an external printer, select 1 or 2 or 3 that are the types of printer.

```
Software: 1.4              SRS100/II
                             SETUP
MEAS.TIME:    15  30  60
RESULT 30:    NO  YES      use arrows
RESULT 1h:    NO  YES      to change
RESULT 2h:    NO  YES      options
TEMP.REF :▷   NO  18C
PRINTER  :    NO  I 1 2 3   [ent]
GRAPH    :    NO  YES AUTO  change date
HOST     :    NO  YES AUTO  and time
DATE     :    11/12/2003
TIME     :    12:45         [esc]
                            to exit
```

To show graphics of sedimentation, select "YES". If you select "AUTO", the graphic will be printed automatically at the end of analysis.
3.4 Instrument Stand-by
On stand-by mode, the instrument is ready to accept and analyze samples. Before starting the operator should read carefully chapter 5 (SOFTWARE).

4. SYSTEM DESCRIPTION

4.1 Sample collecting

Samples must be collected following the vacuum collection technique using VACUETTE[®] ESR 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.

The test tube contains 3.2% sodium citrate as anticoagulant and, immediately after collecting blood, it must be gently mixed by inverting it at least five times. If SRS 100/II is installed in the surgery, the sample can be immediately analyzed by placing it in the first free channel. Anyway the sample must be analyzed within three hours after blood collecting, paying attention to external agents shown below, that might alter ESR in the pre-analysis phase.

External agents

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

4.2 Labeling

Identify the sample writing the patient identification code on the original test tube label or applying a barcode label. Follow the scheme in Fig. (1) to carry out this action correctly. In the figure the test tube (A) has the correct blood level and original label on which to write the patient code or other data if the bar code is absent. The part (H) shows the zone that must be absolutely free to allow the infrared rays to recognize the right blood volume. The test tube (B) shows bar coded label in correct position. Test tubes (C) and (D) illustrate how an erroneous labels positioning can obstruct the reading of the tube.
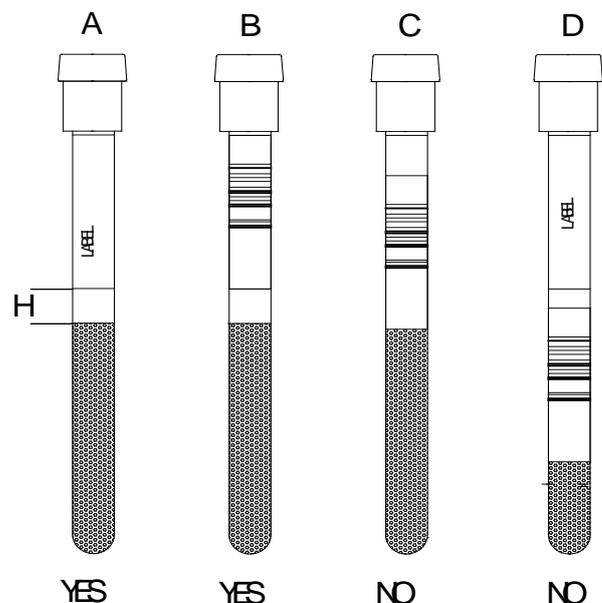
4.3 Test Tubes handling

Handling requirements

The vacuum test tube needs to be inserted properly into its holder to obtain the automatic draw of 1.5 ml or 1.6 ml of blood, required by the analysis. Tubes are removed from the holder only after the drawing has been completely terminated, i.e. the required amount of blood for the analysis has been properly evacuated.

In case of an incorrect blood collection, the SRS 100/II will refuse to analyze the sample, indicating **"lev"**(Level Error), because the Sedimentation Rate result would be incorrect, due to an erroneous ratio between blood and the anticoagulant present in the tube.

All vacuum test tubes need to be mixed gently immediately after the blood collection, to ensure the proper mixing of the sodium citrate with the freshly drawn blood.

Therefore, tubes are gently turned inverted five times, ensuring that the air-bubble floats from one end of the tube to the other end.

It is essential that before ESR determination is started, the sample tube is carefully re-mixed ten times, according to the procedure as described above.

Storage requirements

Store the test tubes at room temperature, always below 30°C. Never place the bench top tube container (50 tubes) near a heating device or close to a window where direct sunlight could create unwanted heating effects.

4.4 Sample mixing
If it is not possible to analyze the sample immediately after sample collection, it must be mixed delicately by inverting for at least five minutes before putting the sample into the instrument. Use a rotating laboratory agitator or a dedicate agitator (optional part: VACUETTE® MultiMixer Item Nr. 836577).

The recommended rpm-value for mixing is 15-20 RPM. If manually mixed, the samples must be inverted at least 10 times, ensuring that the air bubble floats from one end of the tube to the other end.

4.5 Sample insertion

After mixing, the sample must be promptly transferred to the analyzer.
For this reason we suggest to place the mixer near the SRS 100/II.
For practical use we suggest to insert the ID# code immediately after removing the test tube from the agitator, to avoid a consequent beginning of sedimentation (Function ID 1).

If the samples are in large number it is advisable to insert the PAT. ID# before (function ID 2) and then place the samples in the instrument, following the position indicated in the printed sample list. The sample positions on the analytic plate are marked with letters from A to J, indicating the horizontal rows, and numbered from 1 to 5 and from 6 to 10, to indicate the position of each vertical row.

4.6 Symbols identification

 empty position

 sample inserted without identification

 position with path. ID awaiting the sample

 sample with identification.

 end analysis

4.7 Performance criteria and limitations
1) PERFORMANCE CRITERIA

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

B. Coefficient of determination (reading time 15 min.) : $R^2 = 0.969$

C. Coefficient of determination (reading time 30 min.) : $R^2 = 0.975$

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

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

F. Measuring range : 1 - 140 mm/h

G. Memory capacity : Up to 500 results

H. Patient identification limitation : Up to 12 digits

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

4.8 Functional Diagram
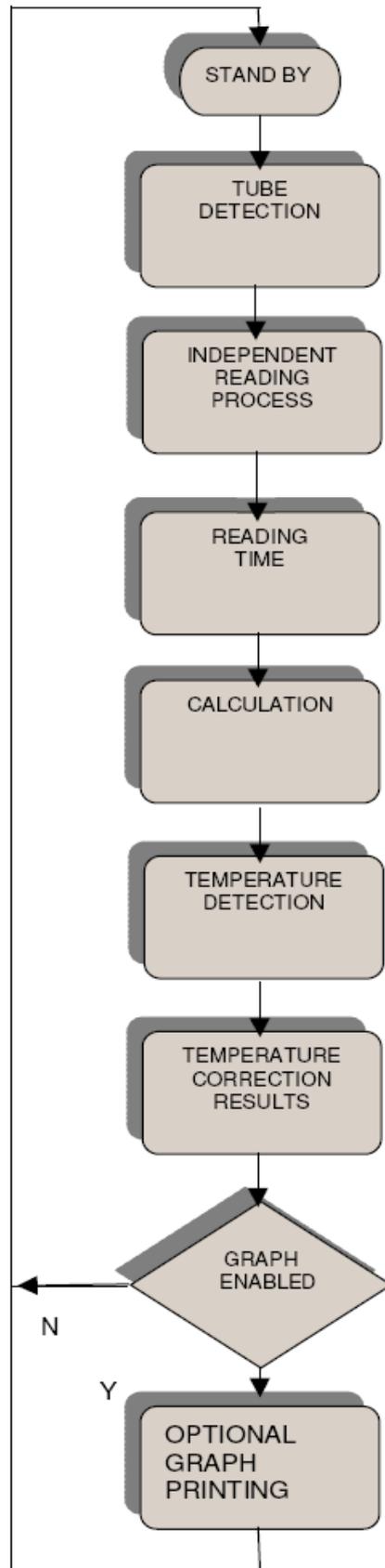
5. SOFTWARE

5.1 ID: (Function: 1)

To identify the samples use function ID, which has 2 options:

```
CFG:⊕60'> 30'1h 2h  t.ref │ SRS100/II
                          │⊕12:45 °C25.0
J □□□□□   □□□□□ J
I □□□□□   □□□□□ I          │ 1 ID1
H □□□□□   □□□□□ H
G □□□□□   □□□□□ G          │ 2 ID2
F □□□□□   □□□□□ F
E □□□□□   □□□□□ E
D □□□□□   □□□□□ D
C □□□□□   □□□□□ C
B □□□□□   □□□□□ B
A ■□□□□   □□□□□ A
   12345   678910
Pos: A01   ID: ---
```

ID1: Identification or inserting of the sample

The instrument requests insertion of sample identification code, either using the keyboard or by using a barcode reader.

```
C:B05 N.  1 ID8002321.....│ SRS100/II
C:C01 N.  2 ID8002322.....│ SAMPLE ID
                          │
                          │ insert id
                          │
                          │ ▬▬▬▬▬
                          │
                          │
                          │  [esc]
                          │  to exit
```

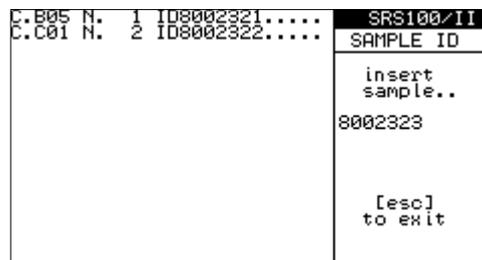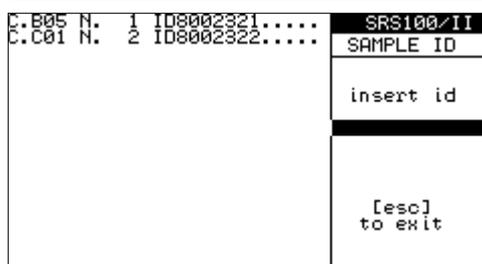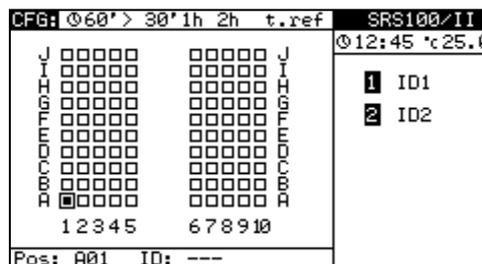The instrument then waits for the insertion of the sample in whatever position. The position will be immediately identified and the relative information appears on the left part of the screen. When you do not have any more sample to insert, you can return to the previous menu with the [ESC] key. The [ESC] key can be used also to terminate the waiting time of the sample insertion, if necessary.

```
C:B05 N.  1 ID8002321.....│ SRS100/II
C:C01 N.  2 ID8002322.....│ SAMPLE ID
                          │
                          │ insert
                          │ sample..
                          │ 8002323
                          │
                          │
                          │  [esc]
                          │  to exit
```

ID2: Identification of the sample without insertion (with work list)

Similar to the previous function, but the difference is that the instrument does not wait for the sample insertion but gives automatically the co-ordinates value of the inserted codes. Please pay close attention when inserting samples in order to avoid identification mistakes.

5.2 MEM: (Function: 2)
Results memory Management.

The "MEM" menu enables the operator to control the results saved in the memory. It is possible to erase memory with the "CLEAR" function or to modify data with "EDIT" function.

```
CFG:⊕60'> 30'1h 2h  t.ref │ SRS100/II
                          │⊕12:45 °C25.0
J □□□□□   □□□□□ J
I □□□□□   □□□□□ I          │ 1 CLEAR
H □□□□□   □□□□□ H
G □□□□□   □□□□□ G          │ 2 EDIT
F □□□□□   □□□□□ F
E □□□□□   □□□□□ E
D □□□□□   □□□□□ D
C □□□□□   □□□□□ C
B □□□□□   □□□□□ B
A ■□□□□   □□□□□ A
   12345   678910
Pos: A01   ID: ---
```

CLEAR: Erasing of results memory

This function allows for results to be erased completely, and for the sequential numeration to be re-set. Confirmation is requested, if the commend to delete data is given. The [ENT] key must be pressed. When data is erased, this has not effect on the controls memory (QC).

```
                          │ SRS100/II
                          │⊕12:45 °C25.0
                          │
 deleting results...      │ 1 CLEAR
 (ENT to accept!)         │
 press ESC to abort!      │ 2 EDIT
                          │
                          │
                          │
                          │
                          │
Pos: A01   ID: ---
```
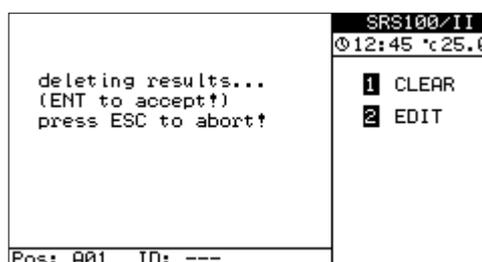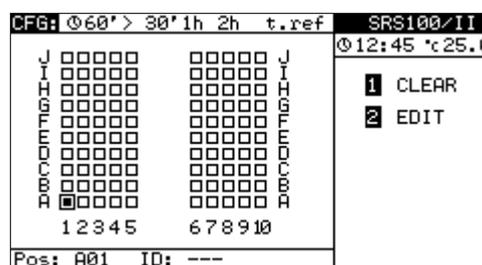
The results memory can save 500 results. When the capacity is exceeded, it is indicated on the screen with "full memory". Pushing the [CANC] key does not cancel the memory, it just deactivates the signal. If necessary, the user has to cancel the results memory. In any case, any further result, can only be saved if the previously data are erased.
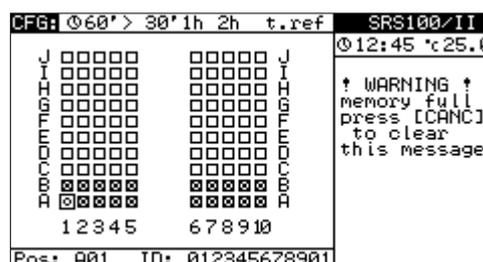
EDIT: Modification of data in the results memory

With this function, data from the memory can be visualized, and modifications can be made. With the arrow keys it is possible to shift the cursor in the memory. The arrow key left and arrow key right allow the shift of one page at a time, in order to quicken the mo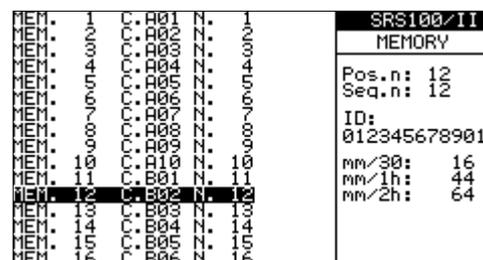vement operations. By pushing the [ENT] key it is possible to modify the values relating to the results or to cancel possible mistakes, which the instrument has detected. Note that result options (30', 1h, 2h) are only visible if the result format was enabled for that specific sample.

5.3 QC: (Function: 3)
General information

The instrument has a complete quality control management system, so that the user can be assured of correct reader functioning and calculations. Theoretical values of sedimentation controls can be inserted, to activate control reading via their identification, to view and modify theoretical control values, to view and print out the control graph and to delete data if the operator has made a mistake. It is not possible to alter control values measured by the instrument. If necessary, the controls memory may be cancelled. There are two memories for control management, one for normal controls, one for pathological controls. The capacity of both memories is 30 values, corresponding to 30 days a month, if the control is viewed daily.
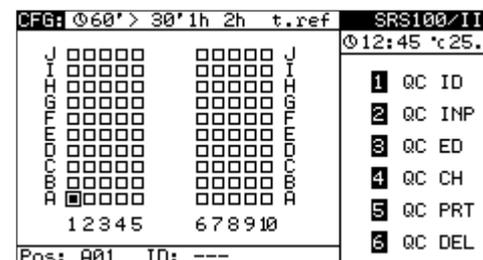
IMPORTANT. For the correct use of the control material, please read carefully the instructions contained in the hematological control kit.

QC / ID:
Identification and insertion of control samples.

As for the normal function ID, this function allows the insertion of bar codes for the identification of the controls operator wants to analyze. The instrument will accept only previously inserted codes with the function "ID / INP".
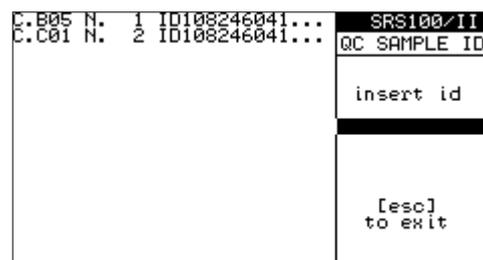
Insertion of the code is then required and control insertion is expected. The instrument identifies the position automatically and shows in the left part of the display, control co-ordinates and code. The [ESC] key allows to interrupt the inserting procedure. The so-identified controls will be analyzed as the normal samples and the final result will be available both in the results memory and in the controls memory.

```
C.B05 N.  1 ID108246041:::    SRS100/II
C.C01 N.  2 ID108246041:::    QC SAMPLE ID

                                 insert
                                 sample..

                              108246041


                                 [esc]
                                 to exit
```

QC / INP:
Inserting theoretical data for controls.
This function enables insertion of theoretical data referring to controls used for testing the correct functioning of the instrument. The identification code is required and it contains all the necessary information. This code is included in the control insert and can be easily put in using a barcode reader connected to the instrument. Alternatively, the code can be inserted by the keyboard.

```
                              SRS100/II
                              QC INPUT

QC CODE: ███████            insert id




QC.1: 103108027               [esc]
QC.2: 108246041               to exit
```

If the inserted code is not correct, the instrument displays an error message.

```
                              SRS100/II
                              QC INPUT

QC CODE: ███████            insert id


CODE NOT VALID...

                              [esc]
QC.1: 103108027               to exit
QC.2: 103245054
```

If the inserted code is recognized by the instrument, no further operation is required. If the code is not known, the instrument warns that it is a new code and awaits confirmation by the user in order to go on with cancellation of the memory relative to the type of control previously inserted.

```
                              SRS100/II
                              QC INPUT

QC CODE: 103108027          insert id

NEW QC CONTROL !
DELETE OLD QC DATA !
[CANC] TO CONFIRM..
                              [esc]
QC.1: 108108024               to exit
QC.2: 108246041
```

The cancellation of memory is necessary to avoid juxtapositions of data of different controls. The confirmation requires the pushing of 2 different key: [CANC] and then [ENT].

```
                              SRS100/II
                              QC INPUT

QC CODE: 103108027          insert id

NEW QC CONTROL !
DELETE OLD QC DATA !
[CANC] TO CONFIRM..
[ENT] TO CONFIRM...
                              [esc]
QC.1: 108108024               to exit
QC.2: 108246041
```

QC / EDIT:
Visualization and modification of control values.
This function allows to visualize and modify the theoretical values of the controls. By using the arrow key left and right, you can select the controls 1 or 2, and with the [ENT] key you can modify the value "Mean" and "SD". You can use the [ESC] key to return to the previous menu. The lower part of the screen displays the values calculated by the instrument itself and relative to the results present in the controls memory.

```
- THEORIC QC REF. EDIT -      SRS100/II
QC.1        |QC.2             QC EDIT
ID: 108108024|ID: 108246041
Lot : 108   |Lot : 108
Mean:  8    |Mean: 46         [ent]
SD :  2     |SD :  4          to edit

Calculated...|Calculated...   use arrows
SMPL.N: 20  |SMPL.N: 20       to move
MEAN :  8   |MEAN : 46
SD   :  4   |SD   :  9        [esc]
CV%  : 54.5 |CV%  : 20.0      to exit
```

QC / CH: (chart)
Visualization of the control chart (Juden-Plot).

This function displays the control chart relative to the QC values memorized in the memory which are visible in the left part of the screen.

The cursor is highlighted by an inverted color bar and can be shifted by using arrow keys. The right part of the screen displays the control graph and the value, which is highlighted by a small square. The values, which fall outside the area of the control chart, are highlighted with small squares, all completely black. The rest of the graph includes a series of information calculated automatically by the instrument itself. The information is: Number of the control, number of results in memory, average, standard deviation and variation coefficient. The points on the graph represent the intersection between the values of normal control (horizontal axis) and the pathological one (vertical axis). The values are acceptable when the points fall in the area of the central square (limit +/- 2s). When the values fall outside this area, the system is out of control and has to be controlled.
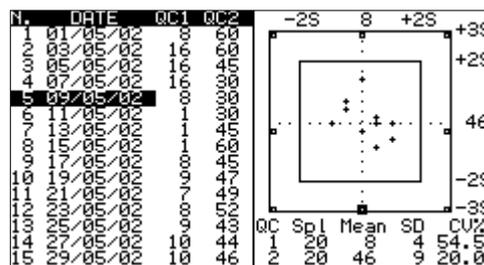
QC / DEL:
Cancellation of control memory

This function allows the total cancellation of QC data gathered in the memory. Please note: the theoretical values of the controls will not be in any way altered. Only QC/INP and QC/EDIT functions can modify such values. A confirmation of the cancellation of data using the [ENT] key is required.
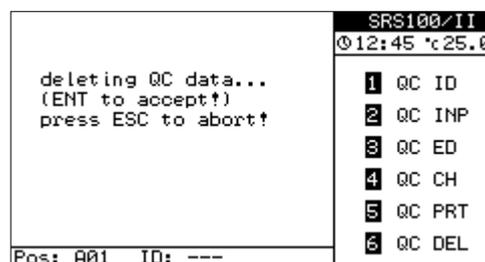
5.4 PRINT: (Function: 4)
Printing results or work list

W.LIST:

With this function the instrument prints a detailed list of the samples currently under analysis. The data relative to the co-ordinates and the identification codes will be printed.
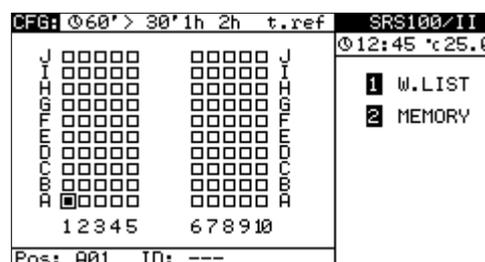
MEMORY:
With this function the instrument prints all the results contained in the memory. The data comprise a sequential number, identification code and the values relative to the memorized results.

5.5 HOST: (Function: 5)
### Transmission data to a host system

This function starts the transmission of the data relative to the values contained in the results memory. A confirmation to transmit through the [ENT] key is required. The transmission can be interrupted at any time with the [ESC] key. The protocol used for transmitting data is documented in the Appendix. Transmission can be requested directly by the host system through a button as described in the Appendix, however, transmission can only be started if the user is not carrying out operations on the main menu. For this reason, the instrument always returns to the main menu when the keyboard is not used for a certain period of time.
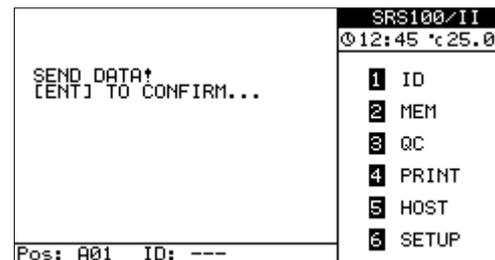
5.6 SETUP: (Function: 6)
Configuration of the instrument

This menu includes many possible configurations, which can be modified by the user. Normally configuration takes place during installation of the instrument and does not require modification.
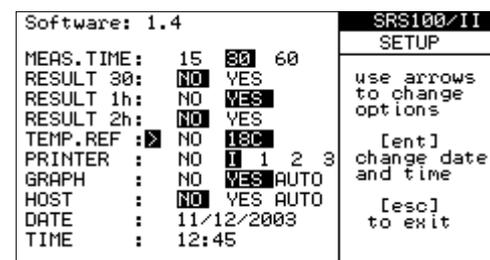
The configuration menu can be activated only if the instrument finds itself in the stand-by mode, when there are no samples under analysis. Note: the variation of some parameters of configuration requires a further re-setting of the instrument. The instrument identifies these cases and re-starts automatically.

The configuration of the instrument can be varied simply by using the key cursors. The cursor, by emphasizing the symbol ">" (white on black background), identifies the configuration that can be modified with key cursors left and right, or in case of date and time with [ENT] key followed by the desired value.
The parameters of possible configuration are:

- **MEAS.TIME: 15', 30' or 60':** The operator chooses the time the instrument takes to acquire results. This can be either 15 minutes, 30 minutes or 60 minutes.

- **RESULT 30', 1h and 2h**: The operator can choose in which format(s) the results are presented, where the options are 30 minutes, 1 hour or 2 hour Westergren. Not all result formats are compatible with all measurement time options. In 15' mode only the 1h result is possible, in 30' mode the 30' and 1h result are possible, in 60' mode all result formats are possible. The software automatically selects only compatible result formats. The operator should change the measurement time (see above) if the desired result format cannot be selected.

- **TEMP.REF.:** if this function is selected ("YES") the results will be referred to the standard temperature of 18°C to avoid the result falsification due to external temperature.

- **PRINTER**: This function permits the operator to choose different printing (see Appendix). In the default setting is selected the internal printer ("I"), which is incorporated in the instrument. Any other selection implies an external printer connected to the instrument.
- **GRAPH**: The option "NO" deactivates sedimentation curve visualization. In this way the instrument will not analyze the intermediate level every 3 minutes and so the life of the mechanical and electronic parts subject to movement are prolonged. The option "YES" permits management of the curve, which can be viewed and printed by pushing the button [ENT] from the main menu. The option "AUTO" activates the automatic printing of the sedimentation graph together with the printing of the results of the samples.

- **HOST**: If the option "NO" is chosen, when the operator switch on the instrument, it doesn't control the HOST system connection but the function "HOST" still remains available. If the option "YES" is chosen, the instrument makes the initial control of HOST system connection. The system HOST must be connected and ready to receive the data. The option "AUTO" means that as soon as analysis is finished, data will be transmitted immediately to the host. In any case will be transmitted only the results and data concerning the sample identification.

- **DATE / TIME:** Time is printed, memorized and transmitted to the host. With this function the operator can set the internal clock.

5.7 Printer paper feed:
When the instrument shows the main menu, the printer paper can be advanced by pressing the "CANC" key on the keyboard. **Warning**, do not pull out the paper by hands. If the printer paper needs to be replaced please follow instructions explained at the end of this manual on "**Paper Replacement Instructions**" appendix.

6. RESULTS

SRS 100/II can give different kinds of results:
a) results correlated to 30 minutes Westergren
b) results correlated to 1 hour Westergren (most commonly used)
c) results correlated to 2 hour Westergren

The operator can select the kind of result by using the SETUP function. Each laboratory should validate and evaluate its own ESR reference values.

6.1 Results correction to 18°C
The results achieved are correlated to the method of reference considering the room temperature. SRS 100/II measures constantly the inner temperature, further reconverts the values, in according to the Manley table **(6)** shown below, at the temperature of 18 °C.
Therefore this instrument guarantees a better reproducibility instead of instruments which perform results without temperature compensation.

(6)   **Manley Table**

corrected values	——————	analysis temperature	——————		
18 °C.	15° C.	18° C.	20° C.	25° C.	30° 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

SRS 100/II converts the results to 18 degrees according to the table if room temperature is in the range 15 - 32 °C. For lower or higher room temperatures the instrument converts temperature in this way: 15 °C for lower temperatures and 32 °C for higher temperatures.

7. WARNINGS INFORMATION

7.1 " lev " (level error)
When **"lev"** is printed, the instrument has found an erroneous sample volume. It means that the blood level is outside the range + 4 or -10 mm from the theoretical value of 60 mm (corresponding to a sample volume of 1.6 ml). The message is given together with the sample co-ordinates to allow an easy identification of the wrong sample. Sample collection needs to be repeated.

7.2 " rem " (sample removed error)
When "rem" is printed, the instrument has found abnormal behavior of the sample, for instance extremely fast sedimentation or tube removing during the analytical phase. The message is given together with the sample co-ordinates to allow an easy identification and replacement of the sample.

7.3 System Error Warnings
If some troubles are found during the instrument operation, samples analysis is not compromised, but a symbol will be displayed in the center of the monitor as in the following picture. In this case the instrument must be checked by the service assistance, in order to identify and eliminate any trouble.
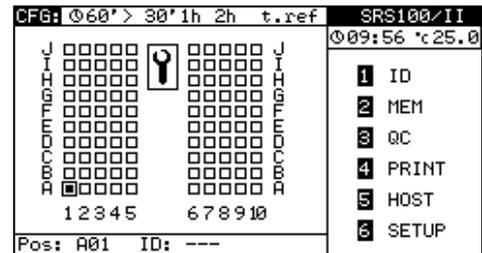
If the problem is more serious (for instance the instrument finds problems with the mechanical movement of the reading plate), the following message will appear on the display: **"ERROR: System Stopped…".** After this indication the instrument will stop to operate and the technical service must be called.

8. 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.

8.1 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 infrared functioning during analysis.

1. Wipe potentially contaminated areas of the SRS 100/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.

8.2 Paper replacement instructions

    1) Press the green lever down as in picture below to lift the printing head

2) Cut the paper as in the picture.

3) Lift the paper well centered

4) Align the paper and press the green lever back as in the picture.

NOTE: If the paper is stuck into the printer please do the same as in point n.1 by pressing the green lever in order to remove the paper without making damage to the printer.

8.3 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 checks the accurate calibration of device. The test has to be done using the Greiner Control Unit (Control Tools).

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°C.
- Internal temperature sensor readings.

HOW TO ENTER INTO "SELF TEST" FUNCTION
- Enter SETUP menu function and then press "002". The reading plate starts to move up and down.
- 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.

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).

```
 TEST

 Temperature  :   21.5          ← internal instrument temperature
 Calibration  :   300           ← mechanical calibration reference (must
be 300 +/- 10)
       Delta  :    0            ← mec. delta between reading cycles (must be
within +/-2)
```

```
 a.t.    1        24      93     ← 1st row values
 18c     1        21      86     ← 2nd row values
```

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 (°C).

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

9. TROUBLESHOOTING GUIDE

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

ALARM	CAUSE	REMEDY
lev	a) Sample level high or low b) The label was not placed in its proper position. Refer to page 23.	a) Repeat sample collection b) Replace label and repeat analysis
rem	Sample has been removed	Re-insert sample
Thermometer error	"Temperature error" sensor malfunction	Data are not converted to 18 C. Call service assistance
System stopped	Motor or mechanical defect	Call service assistance
Data are not printed	Verify in setup menu (6) if printer (I) is enabled.	a) Check power supply b) Check cable c) Replace printer
Data are 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 SRS 100/II?	a) Repeat sample collection b) Re-mix gently
CCD Scanner does not read barcode		a) Check cable b) Re-configure scanner (See manual) c) Call service assistance
HOST communication failure	a) Cable b) Is SRS 100/II in main menu? c) There is no data in memory	a) Check cable if it is correct b) Call service assistance
Info on display is readable, but background is dark.	Neon lamp display broken	Call service assistance
Memory error	Memory broken	Call service assistance
Keyboard is malfunctioning		Call service assistance
Clock error	Lithium battery flat or clock IC broken	Call service assistance

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)

10. TECHNICAL SPECIFICATION SRS 100/II

Area of application:	Blood sedimentation rate analysis
Instrument size:	Width 360 mm
	Depth 520 mm
	Height 190 mm
Weight:	about 7 kg
Voltage:	external power: 100-240 V AC +/-10%, 0.6 A, 47-63
Hz	output: + 5 V DC 0.3 A, + 12 V DC 1.2 A
Operating Conditions:	temperature 15° - 32° C (Room temperature)
	humidity: 45% - 85%
	altitude: up to 2.000 m
	overvoltage: category II
	pollution: degree 2
	for indoor use only
	sound level 24 dBA
Analysis time:	15', 30' or 60' operator selectable
Analytical capacity:	max 400 tests/h
Reading chamber:	100
Loading capacity:	max 100 samples at a time
Loading pattern:	random
Results:	in Westergren mm (by interpolation) correlated to ½h or 1h or 2h.
Temperature correction:	automatic compensation referred to 18°C (Manley)
Measuring method:	infrared barrier
Reading resolution:	+/- 0,2 mm
Results resolution:	+/- 1 mm
Blood drawing level acceptance from normal	+4 mm / -10 mm
Display:	Graphic LCD with back-lighting
Keyboard:	15 keys
Interface:	RS 232 bi-directional
Printer interface:	RS232 serial output
CCD scanner interface:	TTL serial input
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°C
                              Storage relative humidity: 20%-85%

11. PACKAGING INFORMATION

BOX SIZE: 43 x 60 x 30 cm
WEIGHT: 11 kg

open box

instrument protection

ACCESSORIES

dust cover

user manual

power supply

power cable

thermal printer paper

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 for the Erythrocyte Sedimentation Rate Test".

B. PRINTER TYPES PROTOCOL DESCRIPTION

The printer setup can be changed to 5 different modes:

NO - Printer output is disabled;

I - Internal printer APS CP205MRS;

      1 - for CUSTOM ENGENEERING DP24 and DPT282 printers (custom protocol);

      2 - ESC/POS Graphic protocol type 1;

      3 - ESC/POS Graphic protocol type 2;

The ESC/POS type 1 protocol use the following control codes:

      ESC "1" 0   to set min line space (1/8")

      ESC * 0 nn dt to print graphic line

      ESC "1" 32   to set normal line space (1/6")

The ESC/POS type 2 protocol use the following control codes:

      ESC "0" 0   to set min line space (1/8")

      ESC * 0 nn dt to print graphic line

      ESC "2" 0   to set normal line space (1/6")

C. HOST CONNECTION PROTOCOL

Referred instruments: SRS 100/II-SRS 20/II
Contents: - Description of the host connector pin out and output data format.

```
--------------------------------------------------------------------------------
      "HOST" CONNECTOR SIGNALS DESCRIPTION.
--------------------------------------------------------------------------------


    Instrument 9 pin male connector:

    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   ---        ---       (Do not connect!)
     8   INPUT      CTS       Clear to send
     9   ---        ---       (Do not connect!)


    NOTE for system using only 3 wires:
    To force a 3 wires connection (TXD, RXD e GND) it is possible to
    connect, on the device, pin 4 to pin 8.


    EXAMPLE OF A CONNECTION TO A PC IBM COMPATIBLE COMPUTER
    ------------------------------------------------------


    Note:  Connectors are 9 pin female.


                   2 ------------ 3
                   3 ------------ 2
                   4 ------------ 8
                   8 ------------ 4
                   5 ------------ 5

--------------------------------------------------------------------------------
      "HOST" CONNECTOR SIGNALS DESCRIPTION.
--------------------------------------------------------------------------------
```

1) Data format is: 9600 bps, 8 data bit, 1 stop bit, no parity, hardware protocol RTS-
   CTS or no protocol.

2) In order to make this document clear the character tilde ("~") is used in place of a
   space (" ") when there is more of one space and spaces are important for data
   collection.

3) Control characters sent by the instrument is:

   - STX code (2 decimal) in this document, replaced by the string "[STX]";
   - ETX code (3 decimal) in this document, replaced by the string "[ETX]";

```
--------------------------------------------------------------------------------
      "HOST/DATA TRANSMISSION" REQUEST FROM HOST COMPUTER
--------------------------------------------------------------------------------
```

The host computer could require data transmission by sending the character "?". Data
transmission starts only if the operator is not using the instrument. If the instrument
still executing any menu command, no chars will be transmitted.

```
--------------------------------------------------------------------------------
        MESSAGES SENT IN THE BEGINNING
--------------------------------------------------------------------------------
```

Instrument model: **"#MODEL: xxxxxxxx V.x.x"**

Note: The model name and version of the software can be different.

Device configuration: **"#MODE: xx' T.CORRECTION ON"**

where xx' is either 15', 30' or 60'. This indicates the analysis duration in minutes.
The string "~T.CORRECTION ON" will be added only if the temperature correction is enabled.

Date and Time: **"#DATE: GG/MM/AAAA~~HH:MM"**

Operating temperature: **"#TEMPERATURE: gg.rC"**

where: gg.r is the operating temperature value with one decimal. Transmitted only if the temperature correction is enabled.


```
--------------------------------------------------------------------------------
        MESSAGE SENT FOR ANY RESULT STORED IN MEMORY
--------------------------------------------------------------------------------
```

"sss ppp cccccccccccc mm30 mm1h mm2h"

where: sss = is the sequential sample number (001 - 999).

    ppp = sample position

        example: on 100 channel instrument from "A01" to "J10"
              on 20 channel instrument from "~~1" to "~20".

    cccccccccccc = patient ID - code ("............" if not present), left aligned.

    mm30 = Sedimentation in 30 minutes, [mm/30']. Values can be shown as:

        "~~~0" sample under analysis.
        "~LEV" if error level.
        "~REM" if sample error.
        "~mmm" mmm = result in millimeters (right aligned).
        ">140" result more than 140 millimeters.

    mm1h = Sedimentation in 1 hour, [mm/1h], whose values can be shown as:

        "~~~0" sample under analysis.
        "~~~~" if there was an error.
        "~mmm" mmm = result in millimeters (right aligned).
        ">140" result more than 140 millimeters.

    mm2h = Sedimentation in 2 hour, [mm/2h], whose values can be shown as:

        "~~~0"   sample under analysis.
        "~~~~"   if there was an error.
        "~mmm"   mmm = result in millimeters (right aligned).
        ">140"   result more than 140 millimeters.

    Note: the mm30, mm1h and mm2h results are only sent if these results formats are enabled (via setup menu).

```
--------------------------------------------------------------------------------
      DESCRIPTION OF THE DATA FRAME
--------------------------------------------------------------------------------
```

Any string of characters is transmitted with the following frame:

      `<STX>string<ETX>ECC`

ECC represent the checksum used to detect if a string transmitted is defective. The checksum is encoded as two characters sent after the <ETX> character. The checksum is computed by adding the binary values of the characters in a string (modulo 256) and keeping the least significant 8 bits of the result. The 8 bits can be considered as two groups of 4 bits which are converted to ASCII and represented in hexadecimal format. The two ASCII characters are transmitted as the checksum with the most significant character first.

Using the following frame as an example, the checksum for this frame is calculated.

Example:

      `<STX>ABCDEFGHI<ETX>70`

Character	ASCII value	
A	065	1st character for calculation
B	066	2nd
C	067	etc
D	068	etc
E	069	etc
F	070	etc
G	071	etc
H	072	etc
I	073	etc
<ETX>	003	etc

Total sum value =   624
Module 256 (624) is: 112

Then 112 (decimal) is 70 (hex) ECC is: **70.**

If ECC length is 1 character, the resultant ECC is adding a zero character (ASCII 48) on the left.

    Example: First ECC: **A**   The resultant ECC is **0A**

D. INSTRUMENT CONNECTORS

Please turn off the instrument before connect any cable or device to the instrument connectors.

PINOUT OF THE PRINTER CONNECTOR

```
PIN DIRECTION  NAME     DESCRIPTION
----------------------------------------------
 1   ---       ---      (Do not connect!)
 2   ---       ---      (Do not connect!)
 3   OUTPUT    TXD      Serial data output
 4   OUTPUT    DTR      Data Terminal Ready
 5   ---       GND      Ground
 6   ---       ---      (Do not connect!)
 7   ---       ---      (Do not connect!)
 8   INPUT     CTS      Clear to send
 9   ---       ---      (Do not connect!)
```

PINOUT OF THE HOST CONNECTOR

WARNING: For the host connection please use the cable wiring explained in the "Host Protocol" section of this manual.

```
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   ---       ---      (Do not connect!)
 8   INPUT     CTS      Clear to send
 9   ---       ---      (Do not connect!)
```

PINOUT OF THE BARCODE CONNECTOR

WARNING: Connect only original scanners. Commercial scanner, with RS232 connection may damage the instrument.

```
PIN DIRECTION  NAME     DESCRIPTION
----------------------------------------------
 1   ---       ---      (Do not connect!)
 2   ---       ---      (Do not connect!)
 3   INPUT     RXD      TTL Serial data input
 4   ---       ---      (Do not connect!)
 5   ---       ---      (Do not connect!)
 6   ---       GND      Ground
 7   ---       ---      (Do not connect!)
 8   ---       --       (Do not connect!)
 9   OUTPUT    +5V      Scanner power supply
```