

LENA NE

USER'S MANUAL



***Random Access Auto analyzer for
Determination of the Erythrocyte Sedimentation Rate
(ESR)***

GUIDE

0- INTRODUCTION

1- INSTALLATION

- 1.1 SAFETY REQUIREMENT
- 1.2 INSTRUMENTS REQUIREMENTS
- 1.3 TRANSPORT
- 1.4 INSTALLATION

2- DESCRIPTION

- 2.1 INSTRUMENT DESCRIPTION
- 2.2 CONTROL PANEL
- 2.3 WORKING PLANE
- 2.4 REAR CONNECTIONS PANEL

3- OPERATION

- 3.1 SWITCHING ON THE UNIT
- 3.2 GENERAL
- 3.3 MAIN SCREEN AND FUNCTIONS
- 3.4 QUICK GUIDE

4- ERROR MESSAGES

- 4.1 ERRORS
- 4.2 ANALYTICAL ERRORS

5- ON-LINE COMMUNICATIONS PROTOCOL

- 5.1 GENERAL
- 5.2 ON-LINE FEATURES
- 5.3 ON-LINE DATA PACKAGE CONTAINS
- 5.4 BARCODE

6- SERVICE AND MAINTENANCE

- 6.1 GENERAL
- 6.2 PAPER CHANGE

CE CERTIFICAT

INTRODUCTION

LENA NE is a random access auto analyzer to determine the Erythrocyte Sedimentation Rate (ESR), capable of processing up to 20 samples simultaneously by means of an IR LED optical system.

LENA NE requires a minimal handling of the sample, as the test is performed directly on the test-tube, admitting both open and vacuum tubes.

LENA NE allows the test to be made in two different operatives modes. The results are expressed in Westergren millimeters.

MODE QUICK, to obtain 1 hour results (default setting). The elapsed time is 24 minuts.

MODE STANDARD, to obtain 1 and 2 hour results. The elapsed time is 48 minuts for both results.

30 MINUTS RESULTS OPTION, the elapsed time is 12 minuts. This option can be activated in both Quick and Standard modes.

The temperature conversion is programmable.

LENA NE is capable to process 50 samples per hour with uninterrupted sample loading as analysis positions are left free. **LENA NE** features structured software to facilitate its learning and use, with a clear and concise display, and touch panel with icon functions. The Instrument requires a minimum user's intervention, and handling is simple and user-friendly.

1. INSTALLATION

This Section describes installation, applicable safety regulations and the transport packing dimensions of the **LENA NE**. Physical location, environmental conditions and electric power requirements are indicated for the correct installation of the Instrument.

1.1 SAFETY REQUIREMENTS

NOTE: Under no circumstances should the user deliberately modify the safety features of the Instrument. Any modification of the Instrument will cancel the warranty or the technical service agreement, if any.

In case the cable or the power supply begins to get damaged or broken, they should immediately be replaced.

This Instrument is an electro mechanic device of which the user may not handle the internal parts. For any technical issue, contact the Technical Service of your Distributor, whose staff is trained and qualified to carry out any repairs.

WARNING: The Instrument must be disconnected from the power supply before starting any technical corrective work. Operators should not attempt to repair faults or breakdowns.

In case of accidental spillage of the analyzed samples, the spill must immediately be cleaned with an appropriate disinfecting solution, to avoid the possible contamination of the laboratory personnel and Equipment.

Note: When cleaning de LCD DISPLAY use soft damp clothe with a mild solvent, such as Isopropyl or Ethyl alcohol. The use of water, ketone or aromatic is not permitted.

Note: The Instrument can be cleaned with a water and soap solution or with 70% alcohol. Do not use a larger alcohol concentration, as it could damage the cover of the Equipment.

1.2 INSTRUMENT REQUIREMENTS

The **LENA NE** must be placed on a **perfectly flat and level surface not exposed to any vibrations**. It is important for the rear of the Instrument to have sufficient clearance to allow the air to circulate properly. Recommended clearance for a good air circulation is approximately 15 cm.

Weight : 4 Kgs.

Width : 31 cm.

Height : 18 cm.

Depth : 31 cm.

Main voltage 100V to 240V

Frequency 47-63 Hz

Frequency line variation ± 2 Hz

Output DC: 5v, 4.0A, voltage accuracy $\pm 2\%$

INSTRUMENT VOLTAGE INPUT: Only use the AC ADAPTER supplied by the manufacturer.

The **LENA NE** has been designed to operate under certain environmental conditions:

Room temperature 15°-32°C

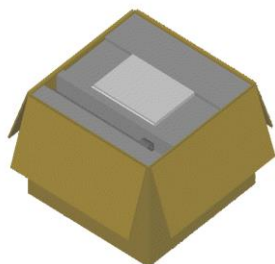
Max. relative humidity 80% at 32°C

1.3 TRANSPORT

The packing of the **LENA NE** (Weight : 6 Kgs. Dimensions : 41x32x41 cm.) contains: Instrument, Power Supply cable, User's Manual with CE Certificate.

Previous to the installation of the Equipment, a visual packing inspection is recommended, in order to detect any abnormality that could affect the Instrument. If any problem is observed, notify the supplier before accepting the unit.

If it is necessary to prepare the Instrument for a new transport, it must be operated (without any test on the move) for at least two minutes. This period elapsed, the reading plate will automatically be switched to a safety position, allowing you to turn off the Equipment and subsequently transport it with no problem.



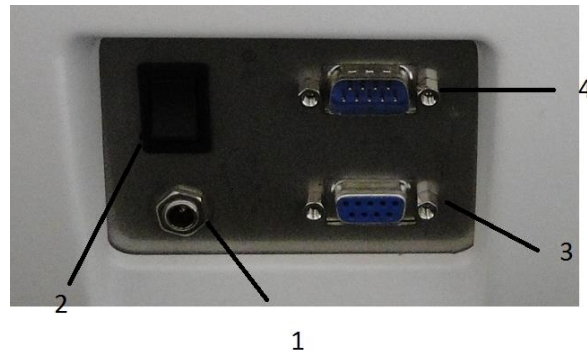
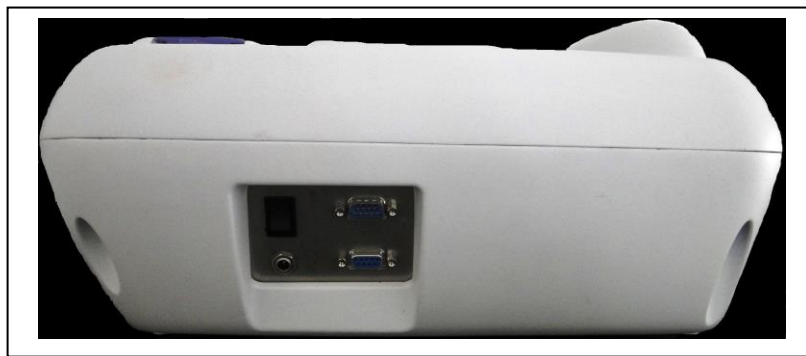
1.4 INSTALLATION

Place the Instrument in its final location.

Make sure the mains cable is properly connected to the power receptacle of the Instrument (1).

Start the Instrument using the power switch (2) located on the right rear part of the instrument.

The Instrument will check the mechanism for an approximate period of 1 minute and immediately after the main screen will be displayed.



2. DESCRIPTION

DISPLAY (1) PRINTER (2) WORKING PLANE (3)



2.1 INSTRUMENT DESCRIPTION

The **LENA NE** has been designed to operate, without needing an adapter, with either open or vacuum tubes containing a sodium citrate solution as anticoagulant.

The capacity of the working plane is 20 positions. The duration of the test cycle depends of the analysis mode chosen (see Introduction chapter). In both cases results are expressed in Westergren millimeters. System throughput is 50 samples per hour.

The instrument uses a random access sampling system, such that the analytical cycle begins once each tube is inserted, is not necessary to fill all 20 positions to begin an analytical cycle. When the analysis time for a sample is completed, the instrument provides a printout containing the results.

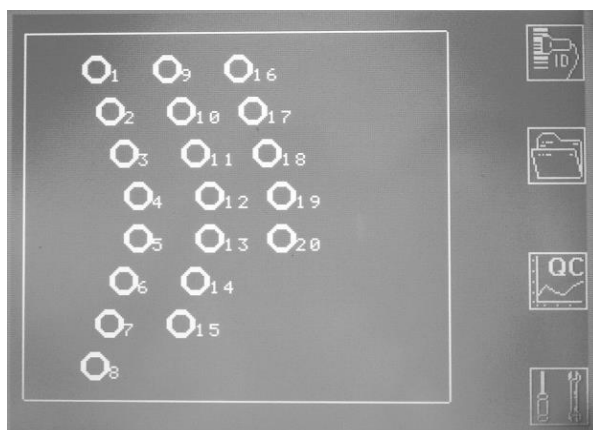
The system allows the user to enter sample I.D. codes either via keyboard or barcode reader (or both) and by a host connexion.

The results are sent to the printer, and can also be viewed on the display or sent to a host computer via online uplink.

2.2 CONTROL PANEL

2.2.1 DISPLAY

The **LENA NE** is equipped with a backlight **graphic LCD with touch panel**. The status of every position and the different functions (icon) are displayed.



2.2.2 PRINTER

The **LENA NE** is equipped with a thermic printer to obtain a print copy of the results.

2.3 WORKING PLANE

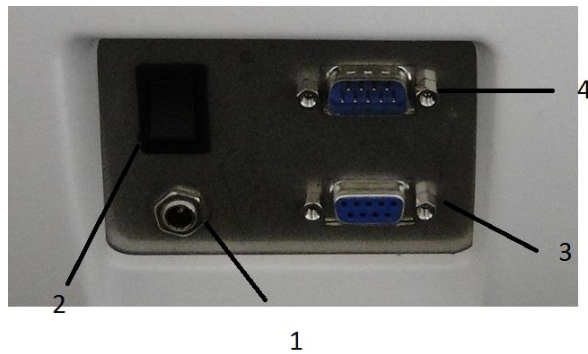
Located in the upper part of the Instrument, it features 20 positions for samples, divided into 3 numbered rows of 8, 7 and 5 positions for each one respectively.



2.4 REAR CONNECTOR PANEL

Located at the rear of the Instrument, it contains the following elements:

1. Power connector (1).
2. Switch (2).
3. SUB-D9 connector (female) for ON-LINE connection (3).
4. SUB-D9 connector (male) for BARCODE (4)



3. OPERATION

This section describes the system starting and working procedures.

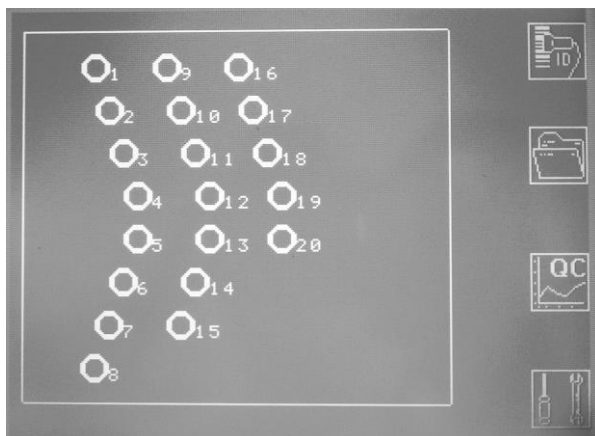
3.1 SWITCHING-ON THE UNIT

Switch on the unit using the switch located on the rear right side of the Equipment. This image will be displayed while the instrument makes the start-up test checking electronic and mechanical components.



The instrument has backup memory up to **400 samples**, it means that the data remain in memory as far as we start-up the instrument in a new day. When we switch-on the instrument in a new day the memory will be deleting.

The checking being completed (max. 1 minute), the instrument feed paper and then main screen appear in the display.



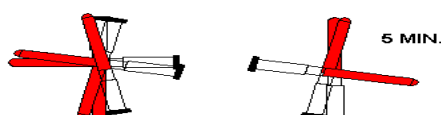
The Instrument is now ready to begin an analysis cycle. We can access to the different menus with the touch panel press over the specific icon with a finger or some other not sharp object.

3.2 GENERAL

Tubes must be **correctly levelled** with the blood sample, according to the **level** marking on the tube. The tolerance of the equipment with regard to the level is **+5mm. And –5mm.** Otherwise, the Instrument will mark the result with a “.” between the 1h and the 2H results **in the case of excessive blood**, or will printout an “**L.E.**” level error message **in the case of insufficient blood.**



The sample should be shaken by slowly inverting the tube during approximately 5 minutes before inserting it in the instrument.



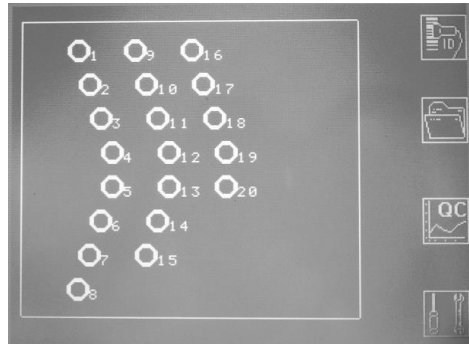
The analysis begins when the tube is inserted in the instrument.

The instrument has two sample memory. One it's the work memory where you can enter the ID of the sample that will be read in that position, and the other memory, where the sample be stored by list number in order of the end of analysis. That means that the first sample that finish the analysis will be the stored in first position.

Do not remove the tube from its position until the analysis is completed. If you do, the analysis will be aborted. In this case, the results printout would contain the message “S.E.”.The result are printed out, at the end of the analysis elapsed time. The end of the analysis is showed, by the visualization of a “F” in the appropriate position of the screen.

3.3 MAIN SCREEN AND FUNCTIONS

In the main screen can see:

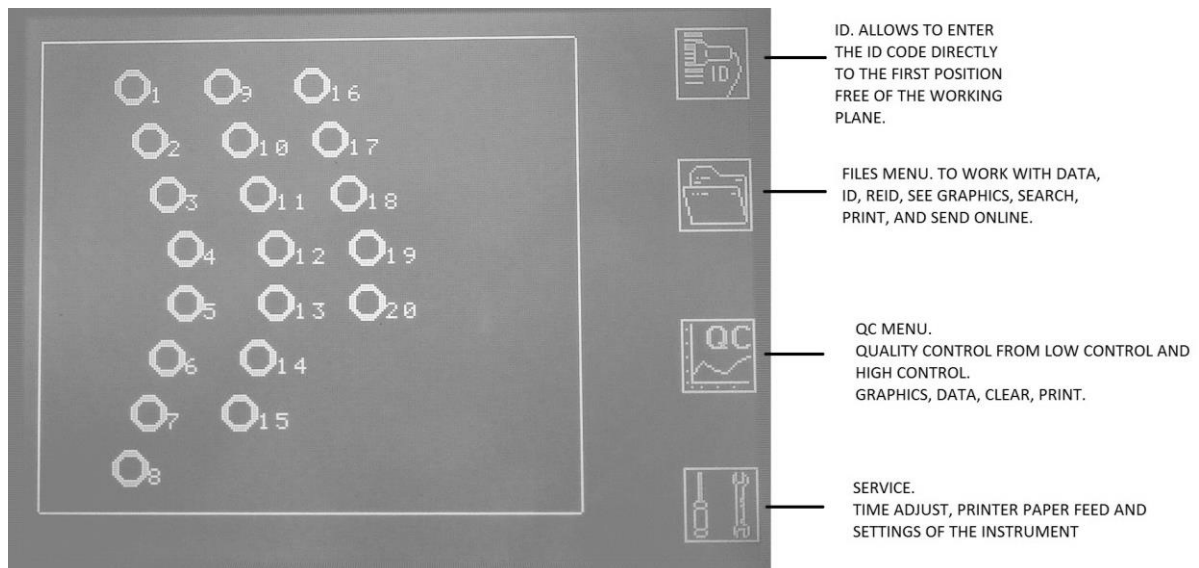


Every icon allows us to enter in a specific function.

The main screen it's divided in 2 zones:

The 4 icons in the right side allow us to directly enter the ID-CODE or to enter in the files menu, the quality control menu, or in the service menu.

The central draw means the working panel with the 20 positions numerated. We can see the status of every position, and if we press over one specific position we can see the graphic (partial readings) of that sample.



3.3.1 PARTIAL READINGS



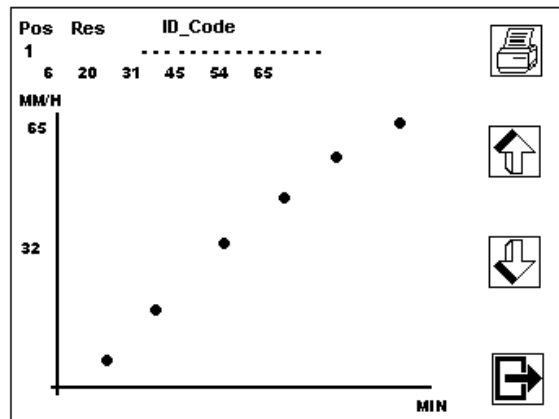
If you press exactly over one position, can see the partial readings screen. In that screen can see the partial readings of that sample and can go to the next sample



, the previous



or printout



3.3.2 ID MENU



This list can contain up to 20 entries.

To introduce the ID-CODE, press









The screen shows the working memory with the first position with the ID-CODE free marked with one arrow.

Pos	Res	ID_Code
→ 1	
2	
3	
4	
5	
6	
7	
8	
9	
10	



KR
















ID

To introduce the ID-CODE, press  or press  or  to go to another position and then press  to introduce the ID-CODE.

Then introduce the ID-CODE with the specific keyboard (icons) and then press OK , to be me stored and go to the next sample. To clear a wrong ID-CODE press DEL , and the cursor returns to the beginning of ID-CODE.

It is also possible to introduce an ID_CODE with a BARCODE reader connected at the instrument (we need only read the label) the instrument memorized and goes to the next sample automatically. In that moment it's possible too send from a host the ID_CODE of one or a group of samples(see Online section). It goes to the next sample automatically.


It's possible to identify the sample with QC1  or QC2 
In that way these samples will be added in the respective QCFILES to have quality control statistics and graphics.

Pos	Res	ID_Code
1	
		
		
		
		
		




When the ID-CODE was introduced put the sample in the specific position and does it again with the next sample, until you don't have more samples to read. Then press exit to return at main screen.





3.3.3 FILES MENU






To manage data stored of finished samples press in that icon  and enter in files menu. In the screen appears all the finished samples ordered by his list number. The list number it's assigned in order of the end of analysis. The first sample finished has the first list number.


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List	Ps	R1h	R2h	ID_Code	
→ 1	1	5	15	
2	2	12	30	
3	3	54	135	
4	0	0	0	
5	0	0	0	
6	0	0	0	
7	0	0	0	
8	0	0	0	
9	0	0	0	
10	0	0	0	








In each screen it has 10 samples. To see the other samples we can press  or .

You can see the partial readings of a sample pressing in the icon . Then you can see and printout, the partial readings and if you won, go to the next sample or the previous.

If you would like to search a specific sample press the icon  and introduce the ID_CODE, then the instrument show us the sample if there's in memory.


To print the results press PRINT  and introduce from which list number to which number do you want to print.

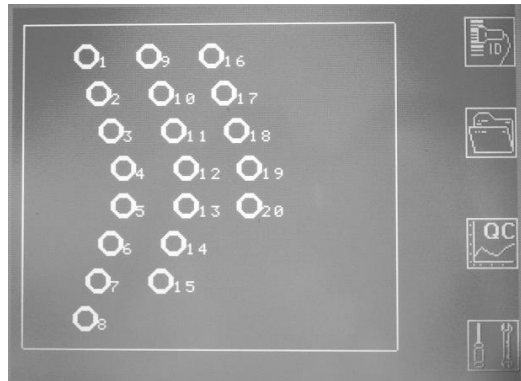
To send ONLINE the results press SEND  and introduce from which list number to which list number do you want to send.

To come back to the main screen press EXIT .

3.3.4 QUALITY CONTROL MENU



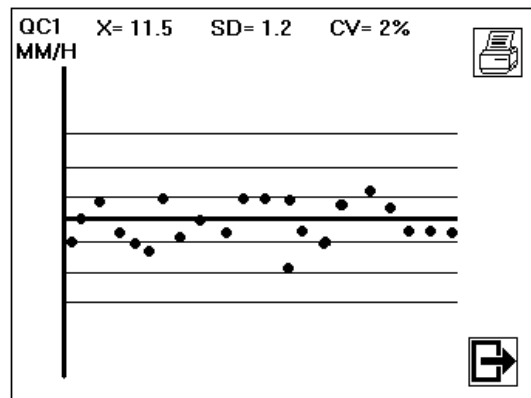
In the main screen press QC icon  to enter in QC statistics.




To see the graphic of the QC samples press .

Like in the case of sadistic we have two different curves one for QC1 and another for QC2. To see the QC2 curve go to QC1 statistics and enter in curve. It's necessary to have more that 10 QC samples to see the graphic.

The instrument need some time to make the calculations and draw the curve please be patient. That time depends of the differences between the results. Please if you see in the list of QC samples a wrong result please delete before enter in graphic.



We can see the lines of standard deviation, the statistics (media standard deviation and coefficient of variation), and the QC samples (in left the last sample, in the right the older sample)

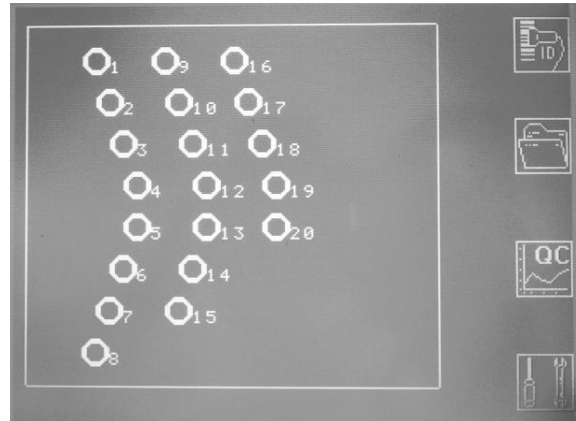
To print the curve press PRINT .

To come back to the precedent screen press EXIT.

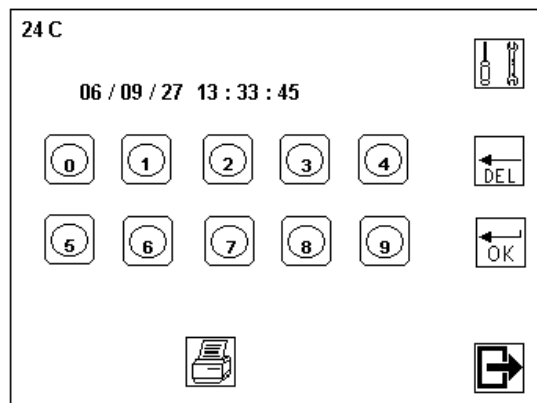
3.3.5 CONFIGURATION SYSTEM







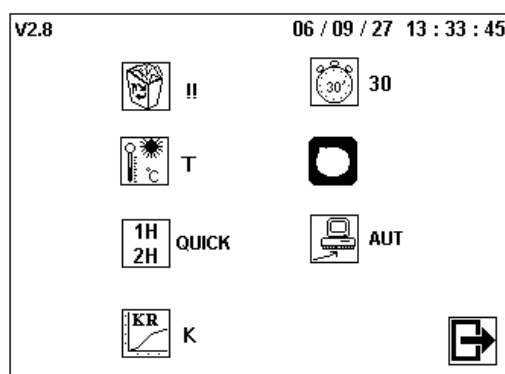
In the main screen press SERVICE





To enter in service menu





We can intro the date and time with the specific icons and then press OK , will be memorized and come back to main screen. To clear a wrong date or timer press DEL , and the cursor returns to the beginning, in the right the older sample). We can feed the paper of the thermal printer pressing in . If we press in  we can go to configuration screen.





If press  the memory will be cleared (**WARNING: that operation reset any analysis in process, and clear the data of all samples stored, finished or not**). The QC data don't be cleared in that operation. The instrument save in memory 400 samples, but every morning when it start-up the entire memory it's automatically cleared, to start to work at the list number 1.


To work with automatic temperature conversion(default), set by pressing  as far as "T" appears at right side. Press as far as nothing appears at right side to work without temperature conversion.

Press in  to choose between the operative modes QUICK or STANDARD (see Introduction chapter).

To work with automatic kinetic control, set by pressing  as far as "K" appears at right side. Press as far as nothing appears at right side to work without automatic kinetic control(default). Kinetic control controls the linearity of the ESR and flag at side of the results with a "?" if between two readings it find a very high fall of hematite's.

Press  to obtain the result of 30 minuts at 12 minuts and printed at real time.

The icon  for special configurations on line.

Press in  to select the sending mode of results across the ON LINE channel of communication.


Two available modes:

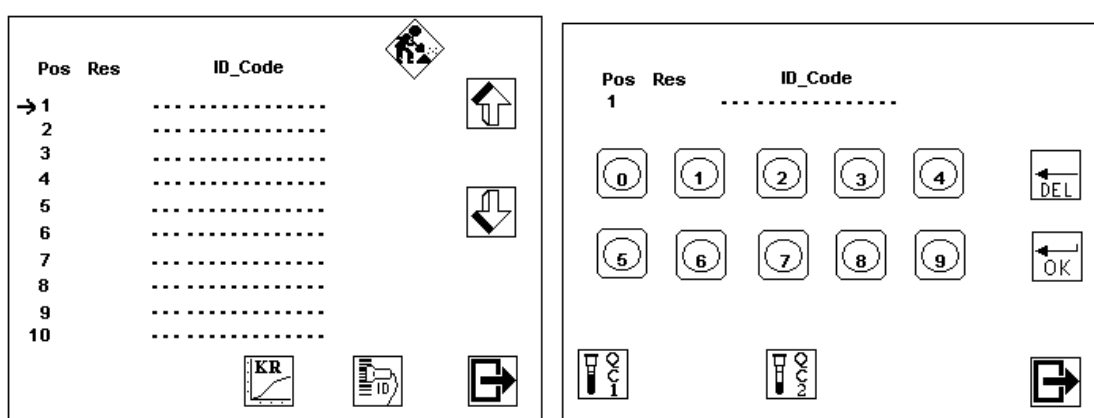
Select MAN mode to send the results at the end of all the analyses. To sending of the results, operate from Files Menu screen (see **3.3.3 FILES MENU**)

Select AUTO mode to send automaticaly at the end of every sample result.



3.4 QUICK GUIDE



Switch on the instrument and wait as far as the main menu appears in the screen.


Then press  and the instrument show the first position without ID-CODE. It's not needed to work in order, but it's important to introduce the correct ID_CODE in the corresponding position. The sample must be inserted in an empty position, that means in the main screen must be showed like an empty circle ○ (first mix the tube). When this sample is recognized in that position by the instrument with a filled circle ● in their position the sample starts his cycle.




We can intro the ID-CODE reading with a BARCODE (we need only read the label) the instrument memorized and goes to the next sample automatically.


We can intro the ID-CODE with the specific icons and then press OK , will be memorized, put the sample in the specific position and go to the next sample. To clear a wrong ID-CODE press DEL , and the cursor returns to the beginning of ID-

CODE. It's possible to identify the sample with QC1  or QC2 , in that way these samples will be added in the respective files of QCFILES to have quality control statistics and graphics.


When we are finished to input the samples and his ID-CODE(or we are input 20 samples), press EXIT  to come back at main screen.

The analysis starts automatically, at the moment that the instrument detects that the tube it's inserted in his position.

After 1 minute the instrument controls if the filing level it's correct. If the level is wrong it printout a message and mark its position with . The print out of the

results starts to the ending of each analysis, and mark the positions in main screen with  in that position.

Data can be transmitted to the computer system of the laboratory. So it is necessary to know the communication protocol (Section 5 of this Manual).

Note: It's very important to wait until the instrument shown an empty circle  In the corresponding position, because in that way the instrument recognize the position empty and it's able to accept another sample.

Note: Don't forget to mix properly the samples.

4. ERROR MESSAGES

This Section describes the error messages which may be generated.

4.1 ERRORS

1.-“L.E” Level Error

It indicates that the blood level is insufficient. Fill to the correct level and repeat the test. If this error message is displayed for a position with no sample tube, call the Technical Service.

In the case of excessive blood, the Instrument will mark the result with a “.” between the 1h and the 2H results.

The tolerance of the equipment with regard to the level is **+0,5mm. And –20mm.**

2.-“S.E” Sample Error

Indicates that a sample has been removed before completing the analysis.

Repeat the analysis.

If this error message is displayed for a position with no sample tube, call the Technical Service.

3.- Mechanic error.

The instrument controls every time the movement of the reader. If it find that the quantity of steps between a movement and the next one it's significant, print out a warning message like :

Please Check Mechanic...

High= 1185 Low= 896

That indicates that the mechanic doesn't have a stable work and must be checked.

If this error message persists call the Technical Service.

4.2 ANALYTICAL ERRORS

Low results:

- a) Possible blood clot in the sample.
Repeat the test with a new sample.
- b) When more than 2 hours have elapsed from the taking out of the sample until the test.
- c) Excessive sample amount, which alters the proportion between blood and anticoagulant, affecting the test result.

High results:

- a) Sample not shaken correctly.
- b) If the Instrument has been installed on a surface that is not perfectly level.
A 3% inclination can increase the ESR by 30%.

Insufficient sample amount, which alters the proportion between blood and anticoagulant, affecting the test result.


5. ON-LINE COMMUNICATIONS PROTOCOL.

This Section describes the different connection possibilities of the Instrument: to the printer, computer or bar code reader.

5.1 GENERAL

The instrument has a bidirectional connexion. That means it can receive the sample ID-code and transmit the result.

To receive the ID work list, we have to make the same operations as in the manual input, and then send the data of one sample or a group of samples from the host in the appropriate format. The instrument goes to the next position automatically.

To send ONLINE the samples, in Files Menu press SEND  and introduce from which list number to which list number do you want to send.

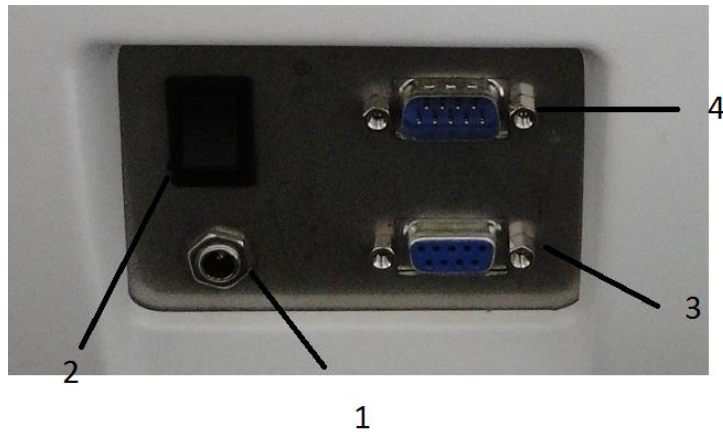
Once being pressed the transmission will automatically is made, provided that the linkage has already been established, and all the interface functions of the instrument will be blocked as far as the end of the transmission.

To input identification codes by means of the bar-code reader, we have to make the same operations as in the manual input, but reading the code with the reader.

5.2 FEATURES

One-way connection with a remote computer system.

DATA OUTPUT VIA RS232 9CTS FEMALE CONNECTOR (3)



NOTE: For a correct functioning of the linkage and the Equipment it is very important that only these 2 pins are connected to the shortest coupling wire.

INSTRUMENT PINS

TX : PIN 3 (transmission)

GND : PIN 5 (ground)

PROPERTIES

BAUD RATE : 9600

DATA BITS : 8

PARITY : NONE

STOP BIT : 1

WITHOUT FLUX CONTROL

5.3 ONLINE DATA PACKAGE CONTENTS

5.3.1 TRANSMISION

The following is transmitted at the beginning of the transmission:

CR "START" LF CR

Then one record for each sample will be transmitted. That record is composed of 31 BYTES followed by LF and CR. It is a text record and its format is as follows:

"LLL_PPP_R1H_R2H_CCCCCCCCCCCCCC" LF CR

Where:

- . " " it's a blank space = (20h).
- . "LLL" it's the list number of the sample (1 to 400).
- . "PPP" equals the position on the working panel (1 to 20).
- . "R1H" is the sample result of the first hour(1 to 200).
- . "R2H" is the sample result of the second hour(1 to 200).
- . "CCCCCCCCCCCCCCCC" is the ID code of the sample, with a maximum of 15 digits. If no ID was entered, 15 " " (blank spaces) are transmitted.
- . LF = (0Ah) and CR = (0Dh) are transmitted at the end of every record.

If the instrument it's adjusted to calculate de 30" results at every sample record will be added the 30" results record

That record is composed of 16 BYTES followed by LF and CR. It is a text record and its format is as follows:

"_____30" _"MIN: " _R30 "

Where:

- . " " it's a blank space = (20h). 5 spaces in the beginning.
- . "30_MIN:" it's a text.
- . "R30" is the sample result of the 30minute (1 to 200). If no result is available, 3 blank spaces are transmitted.

The end of the sample data transmission is indicated by
0Bh, 0Ah, 0Dh

5.3.2 RECEPTION

To receive the ID work list, we have to send the ID-CODE with the ID Menu in the corresponding sample position.

One record for each sample position must be transmitted.

The record must be composed of 15 BYTES followed by CR and must be a text record as follows:

"CCCCCCCCCCCCCCCC" CR

Where:

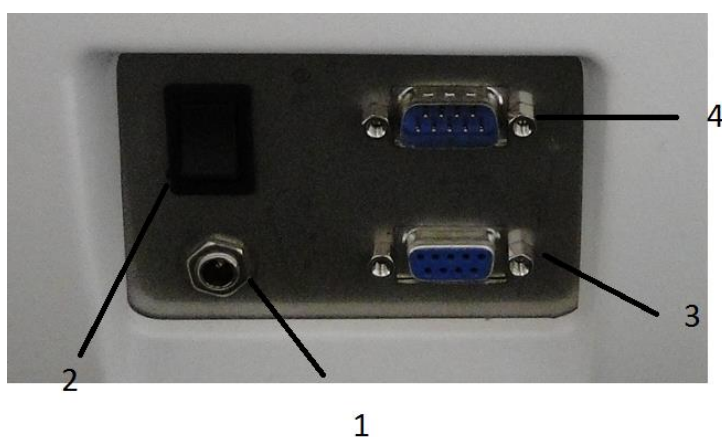
- . "CCCCCCCCCCCCCCCC" is the ID code of the sample, with a maximum of 15 digits. If no ID was entered, 15 " " (blank spaces) are transmitted.
- . CR = (0Dh) are transmitted at the end of every record.

5.4 BARCODE

NOTE : Barcode readers delivered by LINEAR CHEMICALS, S.L. have already been adjusted in the plant to operate with the Equipment, so the only necessary operation is to connect them to the Equipment (in connector 5) and start the Instrument.

To enter I.D. codes by means of the bar-code reader, make the same operations as for its manual entering, but read the bar code with the reader.

The DB9 male connector (5) of the Instrument has a standard connection, to operate with any BAR-CODE reader with series RS232.



Don't must be necessary to change the pins connection, since it is a standard one. These configuration is:

PINS OF BARCODE READER

TX : PIN 2 (transmission)

GND : PIN 5 (ground)

VCC : PIN 9 (supply 5 Volts)

It could be necessary to change the features of the reader communication interface. To do so, the reader is delivered with a programming manual, on the basis of reading bar-code labels. Connect the reader to the Instrument, start it and read the corresponding labels to set-up the reader as follows:

- Type of communication: RS 232
- Baud Rate: 9600
- Data Bits: 8 bits
- Parity: Even
- Handshaking: No

- Stop Bit: 1
 - End of Record or End of Text: CR
- Do not enable the transmission of any other control signal.

It's usually had to read a BEGINNING label and, having read the configuration codes, a FINAL label or to save configuration.

Once the Equipment is configured, stop the Instrument and restart it to test the reader.

6. SERVICE AND MAINTENANCE

6.1 GENERAL

The Instrument has been designed to need the minimum maintenance during several years, although there are some factors that can influence the duration of this period.

. The Instrument has to operate in a clean ambiance and with little dust, as it could be adhered to the reader and movable parts of the machine. So it is advisable to cover the Instrument when no used.

. Clean the Instrument with a humid cloth, when needed.

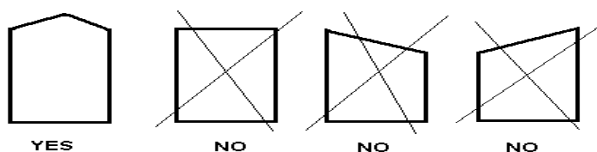
. Avoid spilling liquids or reagents over the Equipment, and above all the breakdown of tubes.

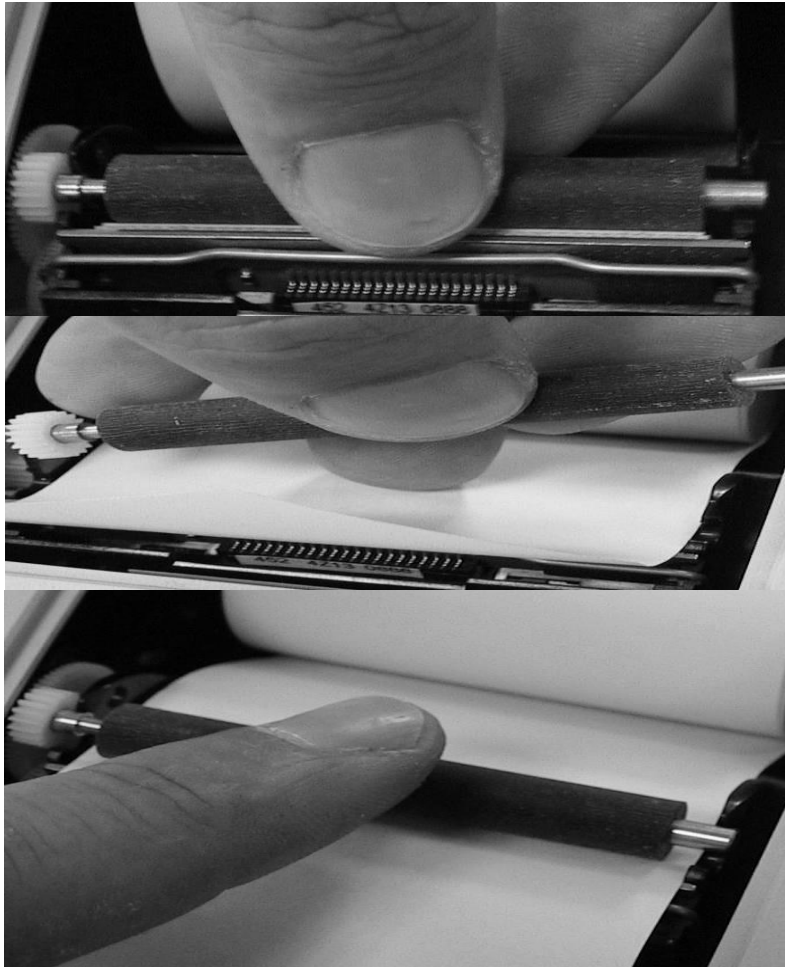
.The stability of the mains in the laboratory affects the life of the electrical components of the Equipment. So it is desirable to keep it away to the maximum from other equipments generating electromagnetic disturbances, such as centrifuges, autoclaves, and equipments not marked CE and, generally, equipments using electronic power devices such as motors, pumps, electro valves and compressors.

6.2 PAPER CHANGE

To replace the printer paper, proceed as follows:

- Open the printer covers and extract the old paper.
- Cut the paper.
- Insert the paper in the printer(3).
- Insert the paper in the cover aperture and close the cover.





CE DECLARATION OF CONFORMITY

We herewith declare, in exclusive responsibility, that the instrument:

LENA NE

for the determination of Erythrocyte Sedimentation Rate (ESR) in blood specimens.

Was developed, designed and manufactured to conform with the:

- Ⓢ Council Directive 73/23/EEC, Low Voltage Directive (LVD)
- Ⓢ Council Directive 89/336/EEC, Electromagnetic Compatibility (EMC)
- Ⓢ European council Directive 98/79/EC (IVD)

including their amendments up to the date mentioned below.

The following harmonized standards were applied:

- Ⓢ EN 61010-1:2001
Safety requirements for electrical equipment for measurement, control and laboratory use.
- Ⓢ EN 61010-2-101:2002
Safety requirements for electrical equipment for measuring, control and laboratory use.
- Ⓢ EN 61000-6-3:2001 Emissions.
- Ⓢ EN 61000-6-1: 2001 Immunity (Residential Commercial & Light Industry)

In addition, the following in-house standards were applied:

- Ⓢ EN ISO 9001:2008 Quality System
- Ⓢ EN ISO 13485:2003 Quality System

Signed by,



Manuel Rodríguez
General & Technical Director

LINEAR CHEMICALS, S.L.