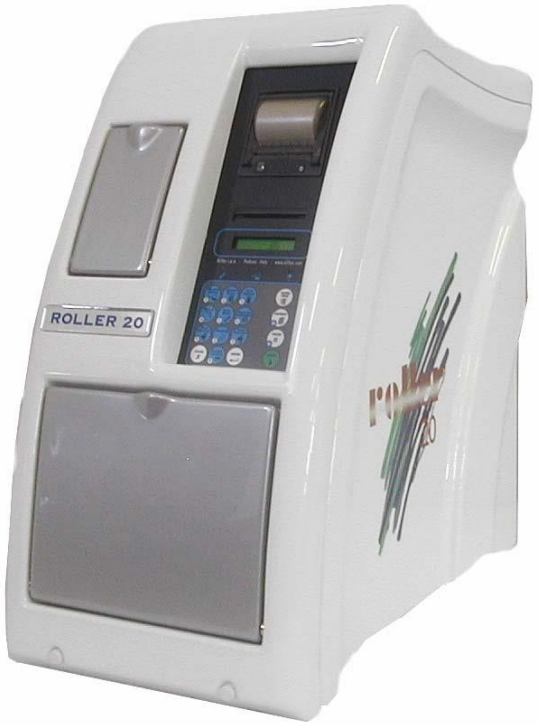
Rev. 2.0 – Effective from: 2022 May 25

ROLLER 20-LC

USER MANUAL

Valid for Software Version **8.00X**

Quantitative Capillary Photometry for the measurement of the Erythrocyte Sedimentation Rate (ESR)



CE IVD

In Vitro Diagnostic Medical Device for professional use

USER MANUAL
ROLLER20LC

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NOTES: Paragraphs written on italic blue characters, point-out an update or modification in the manual as regards the previous version.

1. ALIFAX ESR INSTRUMENTS PRESENTATION

Dear Customer,

thanks for choosing the Alifax technology for the measurement of the Erythrocyte Sedimentation Rate (ESR).
Alifax instruments, dedicated to the ESR measurement analysis, are the result of years of technological developing, aimed at create reliable, robust and highly performing instruments.
Alifax instrumentation it' s present in the world from over twenty years, and is recognized in the hematology sector for the technical and technological prerogatives it offers, thanks to which it allows to perform ESR measurements for laboratory blood samples in a very short time and with a very high rate of accuracy.

ESR Introduction
The Erythrocyte Sedimentation Rate (ESR) measured according to the classical sedimentation method (Westegren-1921) detects the sedimentation rate of blood in non-coagulated plasma. The blood sample is left for 60 minutes in a special pipette called Westergren's wand, the result is expressed in mm/h.
Many pathologic processes can lead to an increase in ESR value: infections of various kinds, anaemia, inflammation or even temporary alteration of biological processes. In the presence of inflammatory processes, the increased blood concentration of inflammation proteins (e.g. fibrinogen and agglomerins) alters and weakens the surface charges of red blood cells, favoring their aggregation, their stacking and the Rouleaux formation, which start to precipitate.
The classical method according to Westergren, is affected by many variables (e.g. lack of perpendicularity of the glass wand to the support surface, during the vibration analysis to which the wands can be subjected, variable temperature, low levels of hematocrit of the sample), described by the international guidelines CLSI H02A-5 Vol.31. N.11 Procedures for ESR Test: Approved Standard - 5th Edition , which is why the technological innovation proposed by Alifax, has been developed with the intention of overcoming these variables and offering, in a very short measurement time, a precise, reliable and repeatable result, free from influences from extrinsic and intrinsic variables of the method.
The red blood cell aggregation phase is the first step necessary for a sedimentary blood sample or not, when the analysis is performed according to Westergren technique. This phase is followed by others, of stacking of red blood cells (Rouleaux formation) and subsequent precipitation and stacking, in a typically sigmoidal pattern, at the end of which, at the 60th minute, the distance travelled by the column of blood in the stick is read, and referred in mm/hour

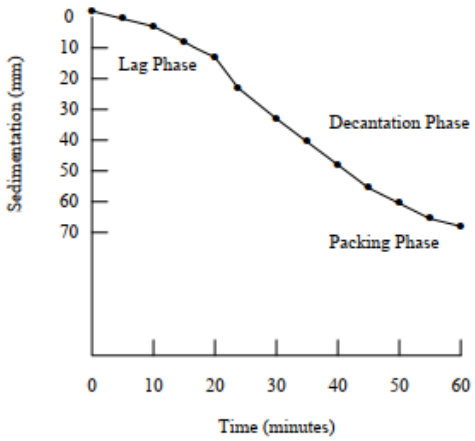


Figure 1. Sigmoid Sedimentation Curve. Evolution of the erythrocyte rouleaux formation in the different phases of ESR in a case with a high level of acute phase proteins.

Picture extracted from the guide lines of CLSI H02A-5 Vol.31 N.11 Procedures for ESR Test: Approved Standard – 5th Edition – Chapter 5 – Principle

The technology applied by Alifax's ESR instrumentation is Quantitative Capillary Photometry, which allows in just 20 seconds of analysis, to obtain the ESR result of the sample, expressed in mm/hour, as per guidelines and reference method.

Quantitative Capillary Photometry studies the dynamic behavior of red blood cells (RBCs). The blood sample flows in a transparent capillary inside the instrument and the reactivity of the red blood cells is analyzed when this flow is suddenly interrupted: this abrupt interruption, together with the rheological characteristics of the sample itself, and the presence or absence of the proteins of the acute phase in it, starts or not the process of aggregation by stacking red blood cells.
The diagnostic algorithm of the **Alifax ESR** instrumentation transforms the measurement performed in just 20 seconds of analysis, into a photometric quantity, expressed in mm/hour, without waiting for the entire stacking, sedimentation and sample stacking process.
The red blood cell aggregation (formation of RBC aggregates), the first step of the sigmoid curve described, is strongly correlated with the end-point results of the classical Westergren method, but is not affected by the interference affecting both the classical method and the modified Westergren-based methods

Advantages of Alifax ESR instrumentation

Preparation of the suitability of the sample
-The system is structurally designed to automatically re-suspend the samples, by complete rotation of the tubes (360°) immediately before the analytical phase of each sample.
- In the **Alifax ESR** instrumentation, a great deal of attention has been paid while designing the part concerning the detection of the physical state of the samples and their correct quantity, as well as the reporting of any anomalies which allows the operator to directly verify the samples, in order to prevent an incorrect response. In fact, if there's no detection of the sample or it's insufficient or coagulated, the analysis is not performed and the problem is indicated by a special message printed and stored next to the sample identifier.
- A similar report is given for samples having a ratio between red blood cells/plasma defining an hematocrit value < 20%. For such samples, the ESR measurement performed by the **Alifax ESR** instruments is correctly performed, and the instrument prints an asterisk next to the measured value to alert the operator to the patient's potential state of anemia. A more thorough investigation of the blood parameters of the identified patient could confirm the instruments results.
- Constant thermostating of the sample analysis cell at 37 °C to ensure that the temperature influence on ESR measurement is reduced.

Management of blood sample quantities below standard levels
The sample rate necessary for the analysis (175ul only) is taken by perforating a test tube closed by a special cap piercing system. This system is therefore suitable also in the case of reduced samples, such as those coming from pediatric patients, samples coming from oncology and in all cases of difficult sampling.

Adaptability to laboratory workflows
The operator loads the samples into the instrument using the same racks coming from the cell counter, for a total capacity of 4 racks in continuous access, without any manipulation of the single tube by the operator. The racks and tubes will be returned by the instrument in the same order in which they were loaded. This allows to have a total traceability of the loading order, of the report-sample association, and a high degree of work order, with reduction of the risk of error due to sample manipulation, incorrect positioning in the rack in or out of the instrument. In addition, operators save time and can carry out other activities in the meantime.

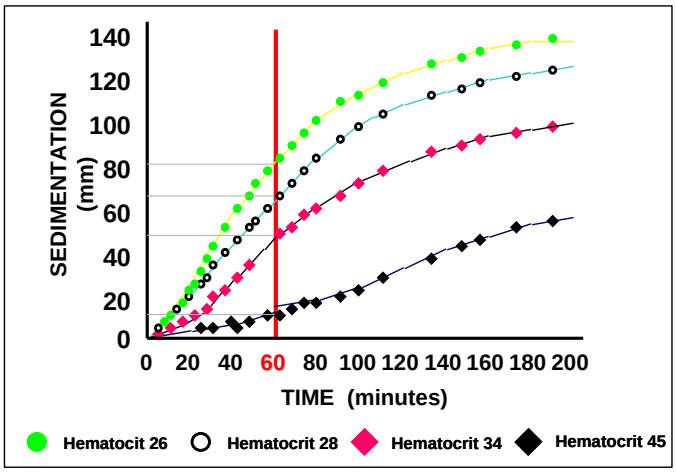
Technological modulability
The TEST1 instrument is compact, adaptable to the working needs of the laboratory, can be integrated with other units of the same or different types, in order to allow the management of different workloads, from minor to greater capacity. The instrument can be perfectly integrated in a dynamic haematology routine, since it uses the same racks of the most common blood cell counters on the market and can be inserted before or after the blood count examination. In addition, in the same work session it can house test tubes of different types, simplifying workflows.

Exceeding the low hematocrit variable
Low hematocrit values interfere significantly on the result of ESR processed with the classic and modified Westergren method, as reported in the literature and especially in the current guidelines CLSI H02A-5 Vol.31 No.11 Procedures for ESR Test: Approved Standard - 5th Edition. Chapter 5 - Principle.

Thanks to the technology used, (capillary quantitative photometry), **Alifax ESR** instrumentation suffers negligible interference. The very short analysis time per sample (20 seconds), and the non-sedimentation

based principle of operation, do not allow the low hematocrit to influence ESR measurement by quantitative capillary photometry. This is also described in the recent publication:
Automated measurement of the erythrocyte sedimentation rate: method validation and comparison Ivana Lapić, Elisa Piva, Federica Spolaore, Francesca Tosato, Michela Pelloso and Mario Plebani Clin Chem Lab Med 2019 : "discussion – […] TEST1 with its capillary photometric kinetic method is less susceptible to variations in erythrocyte morphology or hematocrit levels. "*

A further example is given by the following evidence:
The graph below shows an ESR analysis for the same sample whose hematocrit value has been modified by diluting the sample with autologous plasma.
Four cases have therefore been reproduced: hematocrit (Ht) of 45 , 34, 28 and 26
It can be noted that the sedimentation ESR, at the time of 60 minutes, is very different for the 4 samples (about 10mm/h, about 50mm/h about 60mm/h and about 85mm/h), depending on the hematocrit value, which influences the sedimentation dynamics of the sample.
The TEST1 system does not work on the sedimentation principle and therefore is not influenced by the hematocrit value.



As indicated in Appendix C of this manual, the **Alifax ESR** instrumentation indicates with an asterisk the sample for which an altered plasma/part corpuscles ratio is detected. A more thorough investigation of the hematologic parameters of the identified patient could confirm what has been pre-alerted by the TEST1.

Quality control
A statistical internal quality control of the population, to which the calibrators and latex controls must be added, allow constant verification of the alignment of the instrument, to ensure reliability of the result and optimal inclusion of the instrument in the accreditation processes of the laboratory.

Latex control:
The kits (Latex Controls 6 tests or 30 tests) are based on the use of three samples with known turbidity values, on which the instrument performs photometric measurements related to ESR values.
The 6 test kit consists of 3 test tubes containing 3 ml of synthetic latex solution:
1 x Level 2 Latex Test Tubes ("LATEX Test tube L 2")
1 x Level 3 Latex Test tube L 3 ("LATEX Test tube L 3")
1 x LATEX Test tube level 4 ("LATEX Test tube L 4")

The 30 test kit consists of 15 test tubes containing 3 ml of synthetic latex solution:
5 x Level 2 Latex Test Tubes ("LATEX Test tube L 2")
5 x Level 3 Latex Test tube L 3 ("LATEX Test tube L 3")
5 x LATEX Test tube level 4 ("LATEX Test tube L 4")

The three control levels, Low (level 2), Medium (level 3), and High (level 4), have narrow acceptability ranges that combined with the dedicated software ensure Accuracy and Sensitivity. Below is the reference of a scientific publication on this subject:

A new turbidimetric standard to improve the quality assurance of the erythrocyte sedimentation rate measurement
Elisa Piva, Rachele Pajola, Valeria Temporin, Mario Plebani -- Dipartimento di Medicina di Laboratorio, Università degli Studi di Padova, Azienda Ospedaliera di Padova, Padova, Italy -- Clinical Biochemistry 40 (2007) 491–495

New scientific work in 2019:

Among the latest scientific work carried out by external bodies, the article Automated measurement of the erythrocyte sedimentation rate: method validation and comparison must be mentioned.
Ivana Lapić*, Elisa Piva, Federica Spolaore, Francesca Tosato, Michela Pelloso and Mario Plebani
Clin Chem Lab Med 2019
In this work precision, interference due to sample hemolysis, influence due to the presence of fibrinogen in the sample, carryover, sample stability and hematocrit were analyzed.
Among the results, the correlation obtained between the classic Westergren reference method and Test 1 instrument, on 245 samples analyzed, which was equal to $\rho = 0.99$ with $p < 0.001$, according to Passing-Bablok linear regression analysis:
$Y = -0.28 + 1.04x$, intercept A -0.28 , [95% C.I.: -1.17 to -0.10].
The article is available at http://dx.doi.org/10.1515/cclm-2019-0204

2. TYPOGRAPHICAL CONVENTIONS

The warnings, notes and symbols described hereafter are used in the current manual, on the instrument and on its packaging.

DISPLAY of WARNINGS and NOTES

The signal word "Danger" and a relating symbol point to imminent dangers.
The non-observance of a danger warning can result in death or at least serious irreversible injury. A damage of the system or an adverse effect on the system function cannot be excluded.

The signal word "Warning" and a relating symbol points to potential dangers.
The non-observance of a warning can result in death or at least serious irreversible injury. A damage of the system or an adverse effect on the system function cannot be excluded.

The signal word "Caution" and a relating symbol point to potential dangers/ problems.
The non-observance of safety instructions can result in minor injuries. A damage of the system or an adverse effect on the system function cannot be excluded.

The signal word "Caution" points to potential problems.
The non-observance of a safety instruction can result in damage of the system or an adverse effect on the system function.

The signal word "Note" points to potential problems.
The non-observance of notes can result in an adverse effect on the system function (result deterioration).

USED WARNINGS SYMBOLS

Caution, risk of danger to person or damage to equipment!
Consult instructions for use!

Biohazard!

Caution, moving parts inside!

Electrical hazard!

Mechanical hazard!

Laser hazard!

Cut injury / sharp hazard!

Ground!

Automatic start-up!

Consult instructions for use

OTHER SYMBOLS

Manufactured by

Lot number

Expiration date

Temperature limitations

CE mark

Mains in AC voltage

ID number

Weight

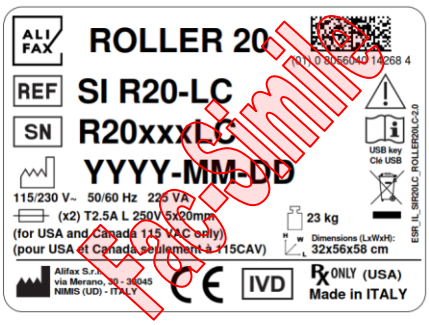
Serial number

Fuse

Disposal of Electrical and Electronic Equipment
In the European Union, electrical and electronic equipment must not be disposed of with other household-type waste. It must be collected separately. Please observe the relevant legal regulations effective in your country.

Size, [L] Lenght, [W] Width, [H] Heigh

NOTE The following label refers to ROLLER20LC and contains between others the reference serial number of the instruments



Rx Only (USA) Explantation:
Caution: U.S. Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device

3. WARNINGS FOR A CORRECT USE OF THE INSTRUMENT

The following safety instructions must be observed at all times, both before and during operation and during maintenance.

Handling of Instructions for use Manual
User Manual is provided for Your safety and gives important instructions for the handling of the system described.

- Read all instructions!
- Keep the instructions for use manual nearby the system.
- he instructions for use manual must be accessible to the user at any time.

Roller20-LC system is designed and manufactured in accordance with the safety requirements for electronic and medical systems. If the law issues regulations concerning the installation and/or operation of the instrument, then it is the operator's responsibility to adhere to them.
The manufacturer have done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The systems are tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

"NOTICE TO THE USER [REGULATION (EU) 2017/746] Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established"
“serious incident” means any incident that directly or indirectly led, might have led or might lead to any of the following:
(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
(c) a serious public health threat;

GENERAL SAFETY

Non-Observance of Warnings
The non-observance of warnings can result in serious personal injury and material damages.

- Follow all warnings included in this manual.
- If the instrument has been stored in cold places, wait at least 30 minutes before switching ON the instrument for the first time in order to avoid eventual damages due to dew presence on internal parts of the instrument.

Use of the System according to Intended Use only
Improper use of the instrument, not in compliance with the manufacturer specifications, could lead protection impairment and damages to both operator and/or instrument as well as can result in wrong results, damage of the system and personal injury.

- The handling and maintenance of the system must only be performed by trained and authorized personnel.
- Before the operation of the system, the Instruction for use manual must have been read and understood.
- The instrument must only be used in accordance with its intended use.
- The instrument is designed for indoor uses only.
- For professional in vitro medical diagnostic use only. The English language knowledge is required in those countries where neither Italian nor French nor Spanish nor German is spoken.
- Use only the consumables and accessories described herein.
- Use consumables that are within their expiration date.
- Keep away any kind of objects, liquids, or substances not required for the instrument’s use from the instrument.
- The manufacturer assumes no liability for any damages, including those to third parties, caused by improper use or handling of the system, installation not in compliance with the manufacturer's specifications, use of the instrument not in security, use of not suitable materials regarding those specified in the user's manual, use of the instrument for various scopes different from those for which it has been designed and built, use of the instrument by not expert staff person or

however non-authorized to the use of the instrument and/or in case the sanitization procedure will not be carried out if required.

- **This instrument is not intended for use by persons with reduced physical, mental and sensorial capabilities or lack of experience and knowledge, unless they have been given supervision or preliminary instructions for the use of the analyzer by a person responsible for their safety.**

NOTE IN CASE UNAUTHORIZED SOFTWARE IS INSTALLED ON THE INSTRUMENT, THIS MIGHT GENERATE MALFUNCTIONING OF THE INSTRUMENT AND/OR EVENTUALLY UNRELIABLE ANALYTICAL RESULTS; FURTHERMORE INSTALLING UNAUTHORIZED SOFTWARE INVALIDATE THE WARRANTY OF THE INSTRUMENT.

OPERATIVE SAFETY

WARNING

Mobile Phones

Do not use a mobile phone next to a running system. .

WARNING

Instrument use in routine

- Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C) / 98,6°F (±0,9°F)
- Before starting a new session, the instrument visualizes a control check-list, is mandatory to verify all check that all the parameters in the check-list are as expected, otherwise contact the Technical Service
- Roller20-LC is an In Vitro Diagnostic Medical Device for professional use only. The English language knowledge is required in those countries where neither Italian nor French nor Spanish nor German is spoken.
- Use only consumables and accessories described in the user manual.
- Consumables good must be used respecting the expiration date.
- Check the waste tank level before starting the measures. Dispose or replace it, if filled to security level; for the disposal of waste tank content, follow the standard safety procedures in use in the laboratory and the local regulations.
- Carry-out appropriate "WASHING PROCEDURES" to a good instrument maintenance
- Important: to avoid capillary obstruction from rubber particles it is suggested to use maximum two times the same washing tubes. Keep away any kind of objects, liquids, or substances not required for the instrument's use.
- Check if the tube contains at least 800 uL of blood and verify that the blood is not neither haemolysed nor coagulated. Use exclusively blood samples withdrawn in EDTA anticoagulant (K_2 or K_3).
- Use preferably tubes with a capacity of 3 ml verifying that the sample volume should in any case not exceed the 50-60% of the total volume of the test-tube in order to optimise the blood homogenization.
- The mixing is done rotating completely upside-down the sample tube.
- Samples mixing is done at the beginning of the analysis with the purpose of disaggregating erythrocytes. A possible ineffective disaggregation could affect the results given by the instrument which measures system is based on the detection of the kinetics of aggregation of the red cells
- In the event paediatrics samples are used, the minimum volume suggested is 500 uL,
- It is possible to use "BD Microtainer MAP®" tubes directly (also in conjunction with other 13x75 tubes) without the use of adapter (but could be necessary to verify the needle offset adjusting its excursion in case of volumes lower than 500 uL
- Start the analysis within 4-6 hours from vein-puncture, otherwise keep the samples in refrigerator at +4÷8 °C (+39,2 / +46,4 °F), for a maximum of 24 hours. If the samples have been conserved in refrigerator at +4 ÷ 8 °C (+39,2 / +46,4 °F), it is necessary to leave them at room temperature at least for 30 minutes before their analysis, even if it is in any case suggested to let the samples remain at room temperature preferably for about 60 minutes, then, execute the analysis within 4 hours.

- Remove from the refrigerator the box containing the Latex Control that must be stored in the refrigerator at + 4÷8 °C (+39,2 / +46,4 °F).
  To use the Latex Controls, please refer to the IFU included inside the Latex Control Box
- Do not pour liquids or leave to fall anything inside the fridge and thermostat units. In such case, switch OFF **IMMEDIATELY** the instrument and call the Technical Service. Do not try to remove any object, even if visible, when the unit is switched ON.
- In case of a sample tube is broken inside the instrument, it is mandatory to call the Technical Service
- An acoustic signal will be activated when the loading door remains opened. Close the door to allow the system to progress with the analysis.

MECHANICAL SAFETY

Danger of Electrocution or Mechanical Injury by Missing or Opened Protective Covers

To avoid serious injury with lethal consequences due to electrocution or injury by the system (e.g. contusion, cuts etc.), protective covers must not be opened or removed by no reason by **user**; only authorized Technical Service Engineers or manufacturer Engineers can remove protective covers.

- Do not remove the panels neither camper the reading sensor.
- The internal carriage moves over a sliding guide which is an “auto lubricating” guide, so it is not necessary to lubricate or add any kind of oil or grease along the rails of the carriage guides.
- Maintenance operations may only be carried out by technical personnel authorized by the manufacturer.
- Switch off the system, separate it from the mains supply and protect it against restarting.
- For your safety, if any part should be damaged, ask for the immediate replacing with original spare parts, specially for the parts connected to mains (power cord, fuse-holder and mains switch …)
- Use only original spare parts supplied by the manufacturer.
- Use only peripherals authorized by the Manufacturer

Maintenance must be carried out only by qualified Technical Engineers authorized by the manufacturer

- Use only original spare parts supplied by the manufacturer.
- Use only peripherals authorized by the Manufacturer
- Make sure that nobody works on the system and that all covers are attached and closed before you reconnect the system to the mains supply.
- Perform maintenance works with highest caution.
- Only perform maintenance works described in this manual.
- The unit shall be inspected and maintained each 30 000 analyses.

ELECTRICAL SAFETY

Electrocution/Fire Hazard!

Non-observance of rules and regulations can cause serious personal injury with lethal consequences and material damage.
National rules and legal regulations for the safe electrical operation of the system must be observed.

During Installation please be sure

- Avoid improper connection of the system and the peripheral devices to mains supply can cause serious personal injury with lethal consequences and material damage (e.g. fire).
- Use only connection and extension cables with a protective conductor and sufficient capacity (performance, power) to connect the system and the peripheral devices to the mains supply.
- Supply cord shall have cross section area at least 0,75 mm^2 or at least AWG 18

- Never interrupt the grounding contacts.
- Grounding of the system and its peripheral devices to the same protective earth potential must be ensured and it is connected to a mains socket with a Protective Earth terminal before its use
- The use of a multi plug is not allowed!
- Damaged connecting cables can cause serious personal injury with lethal consequences. Damaged connecting cables must be replaced immediately!
- No objects may be placed on the connecting cables.
- Connecting cables must be laid so that they cannot be squeezed or damaged.
- Connecting cables must be laid so that they do not lay in accessible or drivable areas.
- Switch OFF the instrument and unplug power cable before connecting any external peripheral as external bar code readers, printer cables and/or RS232 serial cables and for maintenance.

Danger due to Improper Place of Installation
Improper place of installation of the system can cause accidents with serious injuries with lethal consequences, fire or serious system damages because the system cannot be switched off or be separated from the mains supply.

- Ensure the place of installation of the system is so that the power supply and mains switch are easily accessible and disconnectable from the power grid.
- Unit shall be connected to external installation with overcurrent device of 20 Ampere max.
- The instrument has to be installed in a dry environment and sheltered from sun light to avoid sun rays hit the door sensor when the door is open generating unplanned consequences.
- The manufacturer does not assume any responsibility for eventual damages to persons or things due to improper, installation not in compliance with the manufacturer's specifications.

Electrocution/Fire Hazard!
During the normal routine working please:

- Keep away any kind of objects, liquids, or substances not required for the instrument's use.
- Do not pour liquids or leave to fall anything inside the fridge and thermostat units. In such case, switch OFF **IMMEDIATELY** the instrument and call the Technical Service. Do not try to remove any object, even if visible, when the unit is switched ON.

Electrocution/Fire Hazard!
During Maintenance/ Technical Service activities be sure to:

- Immediately separate the defective system from the mains supply, if a safe usage is no longer possible.
- Secure the defective system against reconnection.
- Label the defective system clearly as being defective.

Battery Handling
The product may contain an internal lithium manganese dioxide, vanadium pentoxide, or alkaline battery or battery pack. There is risk of fire and burns if the battery pack is not handled properly. To reduce the risk of personal injury:

- Do not attempt to recharge the battery.
- Do not expose to temperatures higher than 60°C (140°F).
- Do not disassemble, crush, puncture, short external contacts, or dispose of in fire or water.
- Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.
- Replace only with the spare designated for this product.
- Lithium battery VL 2020 type inside CPU board.

NOTE

Transient Emissions and Interference Resistance

The instrument meets the requirements described in standard IEC 61326 and IEC61326-2-6 emissions and immunity requirements.

- This instrument can cause radio interference in domestic environment. In this case it may be required to take action to eliminate such interference.
- Before setup and operation of the instrument, the electromagnetic environment should be evaluated.
- Do not use the instrument in the vicinity of sources with excessive electromagnetic radiation (e.g. unshielded, deliberately operated high frequency sources) since they could interfere with the proper operation of the instrument
- Avoid if possible the connection to mains through plug adapters and choose an electrical outlet far from any strong impulsive voltages, usually generated from centrifuges, refrigerators, elevators and freight elevators.
- Avoid the use of the instrument near electromagnetic sources like for example CB's, radio transmitting units and similar
- 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

BIOLOGICAL SAFETY

DANGER

Risk of infection!

The instrument, can be exposed to potentially infective materials; system therefore must be treated as being potentially infectious**, is thus indispensable to adopt all the precautions and warnings necessary apt to avoid the contact (mandatory the use of gloves and glasses during vial and needle manipulation) in accordance with national laws.**

Improper handling of infectious parts can cause skin irritations, illnesses and possibly to death.

- Use appropriate gloves!
- Use an appropriate lab coat!
- Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument.
- Clean, disinfect and decontaminate the system immediately if potentially infectious material has been spilled.
- Do not use broken or chipped tubes or bottles.
- Observe the instructions in the package inserts for a correct use of the reagents.

DANGER

Waste and Disposable procedures

- Observe local and national provisions, legislation and laboratory regulations.
- Observe the legal regulations for the handling of infectious material.
- **Dispose used vials, following the standard safety procedures in use in the laboratory.**

DANGER

Maintenance

During Maintenance/ Technical Service activities be sure to:

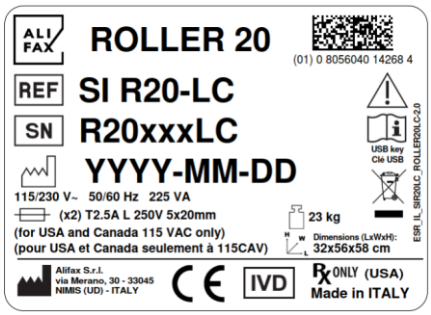
- **use gloves to protect agains any possible accidental contact with infectious materials presents inside instrument .**
- if during maintenance the instrument has been stored /moved to a cold places, wait at least 30 minutes before switching ON again the instrument for the first time in order to avoid eventual damages due to dew presence on internal parts of the instrument.
- It is mandatory to do the sanitization (use gloves and protective glasses) and locking drawers procedure before maintenance or before send back to the manufacturer

4. LABELS

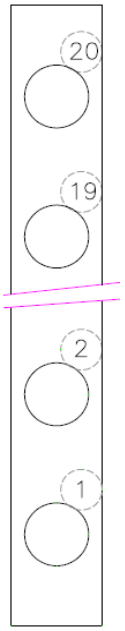
WARNING

THE FOLLOWING LABELS ARE STUCK AS WARNINGS ON THE INSTRUMENT AND MUST NOT BE REMOVED..

Instrument plate label



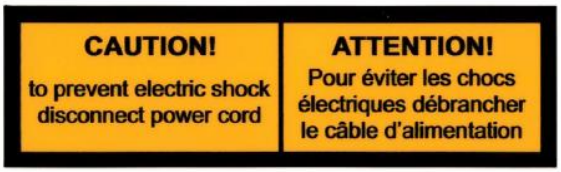
Disc numbering label



Instrument identification label

Biohazard label with compulsory use of gloves
Accidental puncture hazard label when changing the needle

Electrical shock hazard label - disconnect the power cord

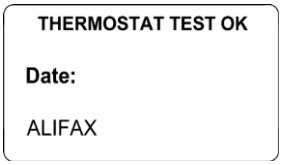


Earthing point label

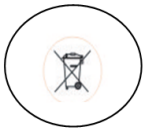
Serial port 1 label

Serial port 2 label

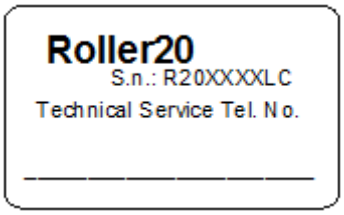
Thermostat test label



Label to indicate to collect separately from other waste.



Label for technical assistance number



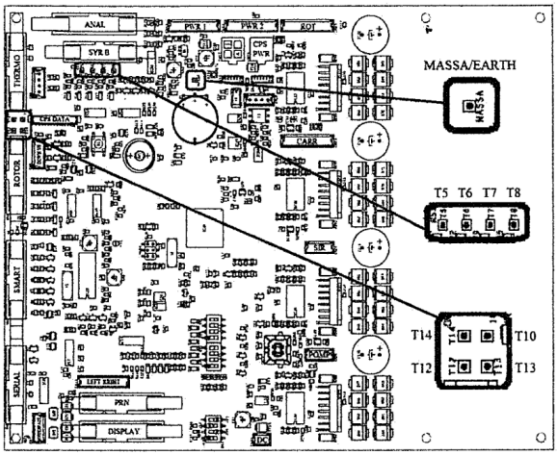
Biohazard label with indications about tank replacement

Fuse indication label

Warning + Biohazard label

Power selector switch identification label

CPU connection diagram label



EAC label

PROCEDURE OF INSTRUMENT WASTE AT THE END OF ITS OPERATIONAL LIFE

	As stated in the European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) related on waste of electrical and electronic equipment (WEEE), appropriate measures should be adopted to minimize the disposal of the instrument as unsorted municipal waste and to achieve a high level of separate collection of WEEE, according to the applicable local laws and rules. The crossed-out wheeled bin symbol on side, placed also close to the plate of the apparatus, points out the necessity of the separate collection of the electrical and electronic equipment (WEEE). The separate collection of this instrument at the end of its life is organized and managed by your distributor. The user who is going to get rid of it will therefore contact his distributor and follow the system that he has adopted in order to dispose the separate collection of the equipment that has reached the end of its working life. The unauthorized disposal will be pursued according to the local laws and the rules in the nation of use. Fines will be effective, proportionate and dissuasive.

5. UNPACKING, INSTALLATION and FIRST START-UP

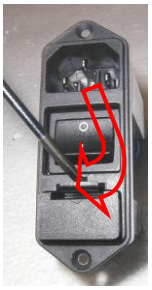
NOTE The unpacking installation and instrument Start-up is done directly by Alifax (or local Distributor) Field Service Engineer

6. VOLTAGE SELECTOR AND FUSES REPLACEMENT

Before turning the instrument on for the first time, it is necessary verifying the voltage selector position (from factory is set to 230 Vac).

Locate the voltage selector set on the rear side of the instrument and by a flat screw driver, select the right power according to the mains power you country supplies.

On the Main Switch block are located 2 fuses, which are easily accessible to be replaced.



To replace the fuses use the following procedure:

- Locate the fuses box
- Using a flat screwdriver push down the small tongue that keeps the box inside the switch block and pull it out using a small pliers (if necessary).
- Remove completely the fuse box
- Replace BOTH fuses (*)
- Then insert again the fuse box inside the Main Switch block.
- Finally press firmly to assure the box's tongue fits on the hook




FUSE-FUSIBLE
T2,5A L 250V 5x20mm

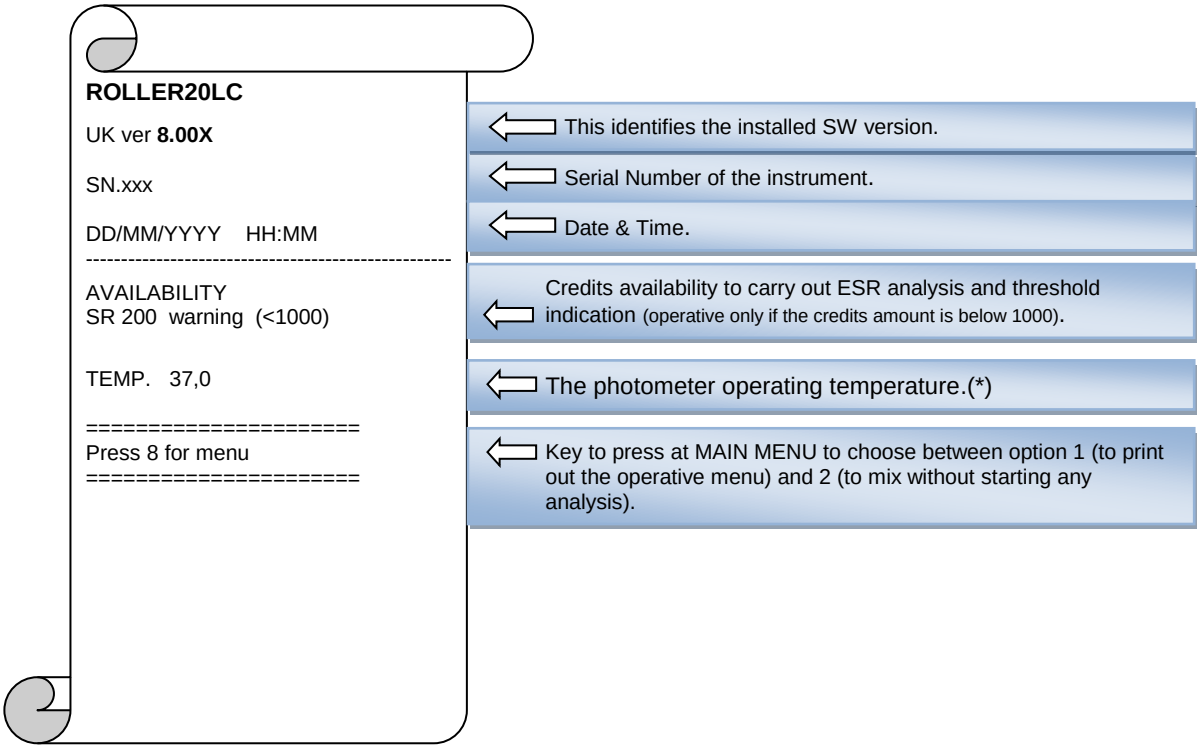
(*)
The fuse which is placed in appliance inlet is a T2,5 A L 250Vac dimensions 5x20 mm; a T2,5 A L fuse; it is suitable for both 115 and 230Vac.

7. TURNING THE INSTRUMENT ON

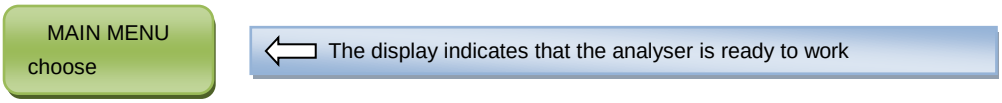
Verify whether the front door is closed, then turn the instrument on pressing the rear-side switch.
At the first daily switch ON wait 3 minutes before starting an analysis cycle to allow the thermal stabilization.

Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C) / 98,6°F (±0,9°F)

Once activated, the instrument is going to print out information like :



(*) If the temperature of the reading unit is out of range, the instrument does not allow the analysis to be carried out, indicating on the display the message "LOW TEMPERATURE" or "HIGH TEMPERATURE".



Display 1

PAPER ROLL REPLACING

The described procedure has to be done at instrument ON.

1. Press the green central key, open the paper cup lid and remove the remaining paper. If the printer
2. Reel off 15 centimetres of paper roughly from a new roll. Remove the pasted part.
3. Hold approximately 5cm of paper outside the device as you place the new roll into the reservoir.
4. Close the lid by applying equal amount of pressure on each side ensuring the lid is in the locked position. Now tear the spare paper away.
5. If it is necessary to recover paper from the printer, press **PAPER FEED** over the keyboard or the key over the printer.

SMART CARD TO LOAD CREDITS

Termination of roll is normally evidenced by a red colour line painted on the last part of the roll paper. Remember that from the initial appearance of colour line, the roll guarantees 60 lines printing and therefore it is suggested to replace the roll immediately after finishing the analysis cycle.
Paper part number is **SI195800**

The instrument works with credits which can be loaded by means of Smart Card ALIFAX supplies. The amount of credits the customer can load is 1000, 4000, 10000, 20000. By this software version, the Smart Card and loading processes are managed by the instrument which includes options printed-out on paper during the loading process activation.

UNIVERSAL CARD

The **U**niversal **C**ard can load the stylized credits by a unique process in all the ESR devices line ALIFAX develops. Credits cannot be split up between instruments.
The procedure to work with this kind of card is explained on the next pages.

Starting from April 2019 a smart card with a new graphical layout is available on the market; below example refers to the 10000 test.

8. AVAILABILITY TEST INCREASING

DESCRIPTION

Pushing **0** at **MAIN MENU**, the printer is going to print-out the Smart Card menu as represented below while the display displays the message reported at "**Display 2**" :

Photo 3

MENU SMART CARD
choose

Display 2

MENU SMART CARD

1- INCREASE AVAIL.
2- SMART STATUS
3- PRINT LOG SMART
4- AVAILABILITY
CLEAR - EXIT

To increase credits by a Smart Card, press key **1**, insert the Smart Card into the reader slot and wait. If the instrument's personalization is the same than the Card personalization, the analyser accepts the new credits. They will be added to the present ones. The printer is going to print out message as reported on the right. again and Remove the Card and press **ENTER**

AVAILABILITY

ESR xxxxxxx
Card matched
Actual personalization

Loaded xxxxx tests

MENU SMART CARD

1- INCREASE AVAIL.
2- SMART STATUS
3- PRINT LOG SMART
4- AVAILABILITY
CLEAR - EXIT

To verify the Smart Card status, press key **2**. The instrument will display the request to insert the Card into the reader slot. Insert the card and wait. The Smart Card status will be displayed while the printer is printing messages like those reports on the right. Remove the Card and press **ENTER**.

Used card
Sn yyyy
Download date xx/xx/xx

MENU SMART CARD

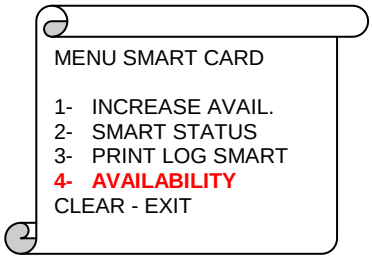
1- INCREASE AVAIL.
2- SMART STATUS
3- PRINT LOG SMART
4- AVAILABILITY
CLEAR - EXIT

To print-out the Smart Card log list, press key **3**. The printer is going to print out the history of the loading processes as the example on the right reports. Below a short description.

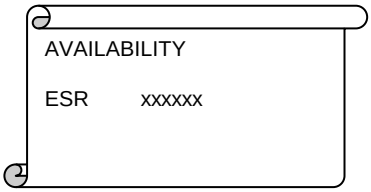
	Meaning:
Date	Date of the loading process
OP	Hexadecimal value for service
Test	Number of tests executed after a general reset
Aut	Present availability of credits.
Serial	Serial number of the Smart Card used to load credits.

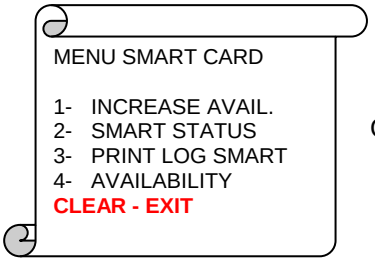
LOG SMART CARD

Date	Op	Test	Aut	Serial
100215	30E	000031	00169	7682662
180815	30E	000031	01169	7757655



Option **4** is to check the availability of credits in the analyser.





Option **CLEAR** is to exit from this menu.

NOTES:

When **Rack insertion** (key1) is pressed and the present availability is between 1 and 1000, the procedure to increase the availability will be recalled automatically. If the availability is 0 or negative, the instrument will not allow the execution of new analysis until new credits are loaded by a new Smart Card.

POSSIBLE ERRORS ALONG THE CREDITS LODING

During the loading process, possible malfunctions can be caused by:

1. the smart card not inserted properly or inserted upside-down
2. the card contact plaque not set to the internal side of the instrument.
3. The reader contacts don't allow the card to be read.

Error messages could appear on display like:

Display 3

it means the card has a number of tests that is outside the normal ranges: 1000 – 4000 – 10000 – 20000

Display 4

it means the inserted card has a personalization that doesn't match the instrument personalization and so the instrument rejects that card.

9. ANALYSIS CYCLE

PRIMING DESCRIPTION

At the analysis cycle run and only whether the capillary is cleaned because washed previously, at the middle of the mixing phase, the instrument is going to withdraw a blood aliquot from the first and then from the second test-tube inserted in the rotor or from the same test tube twice, if there is only one inserted. Before discarding in the waste tank, the two aliquots of blood are moved forward and backward into the capillary for three \ four times in order to remove any residual particle of water from the Teflon capillary. This procedure is called "**priming**". If the priming execution has not passed the test, the instrument carries out an automatic washing by aspirating distilled water from the test tubes, inserted previously in the positions 19th and 20th of the rotor. The instrument then will repeat "priming" automatically. Afterwards and only if priming is passed, the mixing process runs gain in order to complete the specimens homogenization.
Afterwards the system is going to aspirate the suitable amount of blood to carry-out the analysis and the printer, if it has been enabled, then, will print-out the ESR outcome. The successive ones, will be printed-out at 20 seconds intervals.

10. ANALYSIS CYCLE WITH IDs READ BY EXTERNAL BCR

DESCRIPTION

If an external Scanner (**E**xternal **B**ar **C**ode **R**eader) has been connected to the ROLLER20LC at SERIAL PORT1 connector, the patient identification code (ID) printed out on the label applied on each test tube can be read at the beginning of the analysis cycle and before inserting the matched test tube in the rotor. If the instrument is connected to host computer (LIS) through SERIAL PORT2 serial connection, after the ID code reading, and in case the ESR is requited for that specimen, the rotor rotates to one position for the test tube inserting. If the rotor does not rotate, it means that the ESR is not required for that specimen and you switch to the next ID reading. The instrument accepts from 1 to 18 blood specimen test tubes and two test tubes to insert in the 19th and 20th position of the rotor for the automatic washing. The rotor rotates after having closed the door and pressed the **START** key if not filled but contains blood specimen test tubes between 1 to 17. It will rotate automatically, in case of the maximum capacity loading, (18 specimens). If the two test tubes intended to do the automatic washing had been inserted at the previous analysis cycle and not used, the instrument will run the cycle without asking new test tubes for the automatic washing. On the contrary, if the two test tubes have been used at the previous analysis cycle, the instrument will ask for new ones before running.
The automatic washing is done at the end of the pre-set time set by the technician at the installation time.
Its counter starts counting from the end of the analysis and going back to Main Menu.
At the end of the analysis cycle, announced by three acoustic beeps, and having 0 or negative credits availability, the analyser won't run new analysis until new credits are loaded. Any negative credit is recovered from a new loading process by Smart Card.

ANALISYS START-UP

Press key **1**(**Rack Insertion)** at **MAIN MENU** to run the analysis cycle.

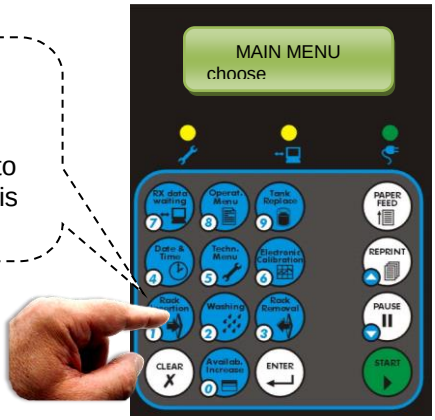


Photo 1

INCREASE AVAIL
Insert CARD

Display 5

NOTES:

In case the message as reported in **Display 5** is displayed, it means that the residual of credits (Availability) is below than the set threshold and new credits should be loaded. References for the credits loading at chapter “AVAILABILITY TEST INCREASING”.

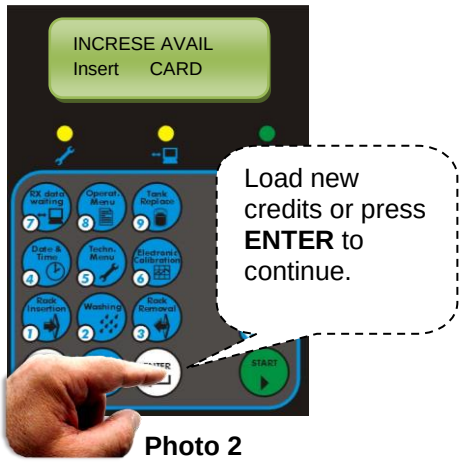


Photo 2

Photo 3

Open the front door, read the identity code ID by the Scanner and if the rotor moves to one position, remove any test tube that might be present in that position and insert the test tube containing the blood specimens to analyse. If the rotor does not move, it means that there had not been required the analysis for that specimen. In such case read the ID code of another specimen to analyse. At the end of the specimens insertion for the same analytical cycle, close the door and press **START**. At the **START** key pressure, the rotor rotates to reach the 19th position and remains waiting to receiving a test tube with 3ml of distilled water inside. After the test tube insertion, the rotor rotates to reach the 20th position and remains waiting to receiving the second test tube with 3ml of distilled water inside. After the test tube insertion for the automatic wash, close the door and press ENTER to run the mixing process followed by the analysis process.

NOTES:

1. If 18 specimens to analyze have been inserted in the rotor, after having closed the door, the rotor rotates to reach the 19th position automatically and therefore without pressing any key.
2. The two test tubes in the 19th and 20th positions of the rotor for the automatic washing are required:
   - at first analysis cycle of the new working day assuming the analyzer has been turned off for the night.
   - at the first analysis cycle after having turned off and the on the analyzer.
   - at the first analysis cycle after an automatic washing executed.

   The instrument does not require these two test tubes if:
   - the capillary has been washed through a manual washing procedure.
   - a new analysis cycle is run before the end of the scheduled time calculated from the end of the previous analysis cycle as water has not been aspired from the test tubes still inserted in the rotor.

END OF THE ANALYSIS

At the end of the analysis cycle announced by three acoustic beeps, the **REPRINT** key offers the possibility to access to a sub menu (reported at **Display 6**) for the choice of all ESR outcomes reprinting of the last analysis cycles and\or to send them to LIS again whereas the analyser has been connected to the local informatics system.

1-REPRINT
2 Com. RS232

Display 6

Photo 4

Photo 5

Pressing **ENTER,** the analyser goes straight on to the exit process from the analysis cycle. This includes the test tubes recovering (every single test tube will be brought to the loading window after the previous one removing), the front door closing and going back to the MAIN MENU..

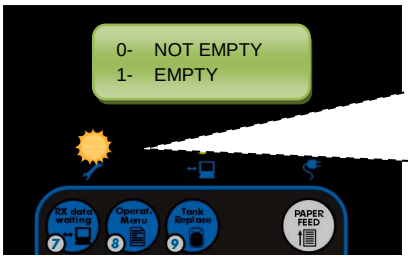
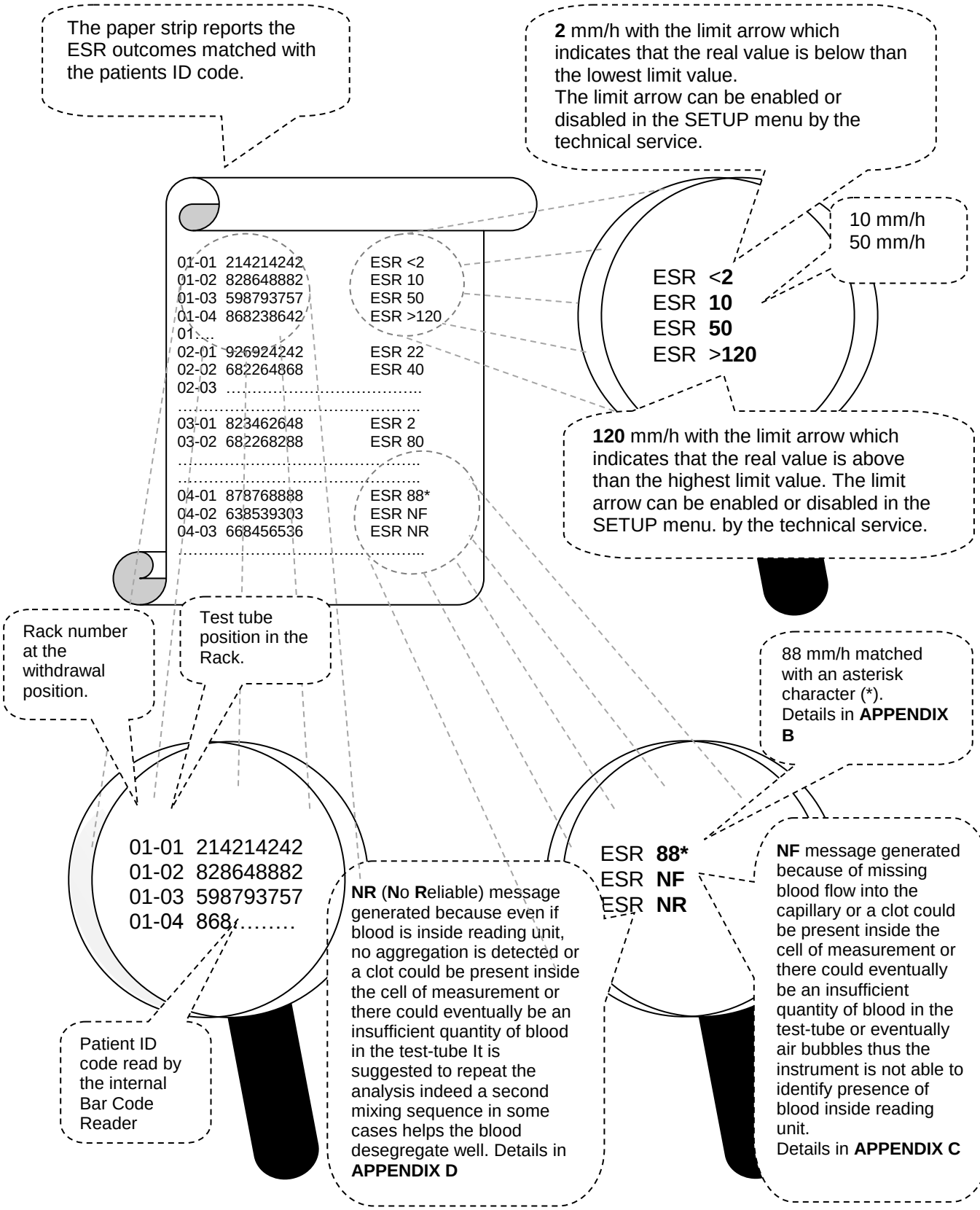


Photo 6

If at the MAIN MENU return, the display displays this message, while the left LED is blinking, it means that the tank is full of liquid. It must be replaced or emptied and the key 1 pressed to reset the counter to **0**. Detailed information is present at chapter “TANK EMPTYING / REPLACING”

MESSAGES AND RESULTS PRINT OUT AT THE END OF THE ANALYSIS CYCLE



In case of three consecutive **N.F.**s the analysis cycle stops working and a washing procedure required. On Roller20LC after 3 consecutive NF's the instrument washes automatically without the necessity the operator load 2 washing tubes.

11. PATIENT ID INTRODUCED BY KEYBOARD

DESCRIPTION

If the ROLLER20LC is not equipped by an external Scanner (**E**xternal **B**ar **C**ode **R**eader), the patient identity code (ID), printed out on the label, can be typed at the beginning of the analysis cycle and before inserting the matched test tube in the rotor. In case of mistakes during the programming time, it is possible to correct the code pressing **CLEAR** for many times up to reaching the wrong character, alphanumeric or numeric. After correcting ENTER key confirms the typed code. The instrument accepts from 1 to 18 blood specimen test tubes and two test tubes to insert in the 19th and 20th position of the rotor for the automatic washing. The rotor rotates after having closed the door and pressed the **START** key if not filled but contains blood specimen test tubes between 1 to 17. It will rotate automatically, in case of the maximum capacity loading, (18 specimens).
If the two test tubes intended to do the automatic washing had been inserted at the previous analysis cycle and not used, the instrument will run the cycle without asking new test tubes for the automatic washing. On the contrary, if the two test tubes have been used at the previous analysis cycle, the instrument will ask for new ones before running.
The automatic washing is done at the end of the pre-set time set by the technician at the installation time.
Its counter starts counting from the end of the analysis and going back to Main Menu.
At the end of the analysis cycle, announced by three acoustic beeps, and having 0 or negative credits availability, the analyser won't run new analysis until new credits are loaded. Any negative credit is recovered from a new loading process by Smart Card.

ANALISYS START-UP

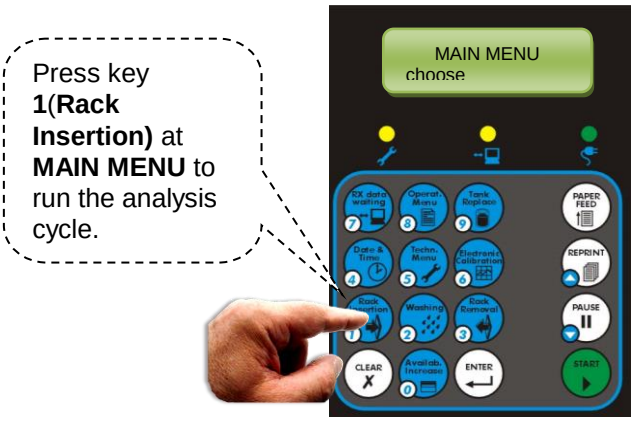


Photo 7

INCREASE AVAIL
Insert CARD

Display 7

NOTES:
In case the message as reported in **Display 7** is displayed, it means that the residual of credits (Availability) is below than the set threshold and new credits should be loaded. References for the credits loading at chapter "AVAILABILITY TEST INCREASING".

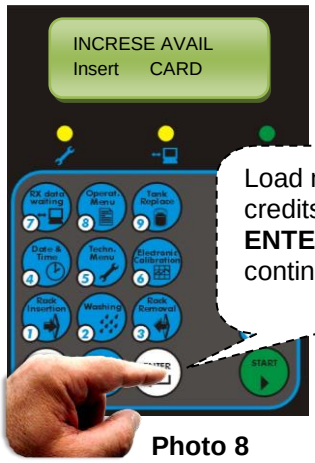


Photo 8

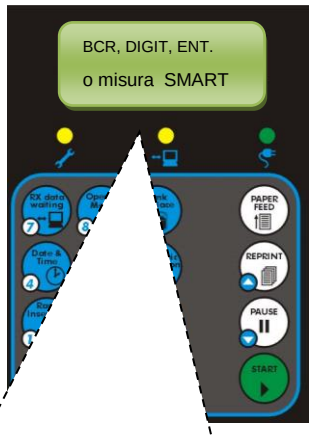


Photo 9

At this displayed message, open the front door, type the ID identity code of the first specimen to analyse and press **ENTER**. The rotor will move to one position. Remove any test tube that might be present in that position and insert the test tube containing the blood specimens to analyse. Repeat the same process to insert others specimens in the same analytical cycle. At the end, close the door and press **START**. At the **START** key pressure, the rotor rotates to reach the 19th position and remains waiting to receiving a test tube with 3ml of distilled water inside. After the test tube insertion and having pressed **ENTER**, the rotor rotates to reach the 20th position and remains waiting to receiving the second test tube with 3ml of distilled water inside. After the test tube insertion and having pressed **ENTER**, close the door. The mixing process will start followed by the analysis process.

NOTES:

1. If 18 specimens to analyze have been inserted in the rotor, after having closed the door, the rotor rotates to reach the 19th position automatically and therefore without pressing any key.
2. The two test tubes in the 19th and 20th positions of the rotor for the automatic washing are required:
   - at first analysis cycle of the new working day assuming the analyzer has been turned off for the night.
   - at the first analysis cycle after having turned off and the on the analyzer.
   - at the first analysis cycle after an automatic washing executed.

   The instrument does not require these two test tubes if:
   - the capillary has been washed through a manual washing procedure.
   - a new analysis cycle is run before the end of the scheduled time calculated from the end of the previous analysis cycle as water has not been aspired from the test tubes still inserted in the rotor.
3. The end analysis cycle is the same described on chapter “MESSAGES AND RESULTS PRINT OUT AT THE END OF THE ANALYSIS CYCLE”

12. ANALITICAL CYCLE WITH AUTOGENERATED ID CODES

DESCRIPTION

If a specimen test tube does not have label code or ID code, the instrument can auto-generate it at the beginning of the analysis cycle and before inserting the matched test tube in the rotor.

ANALISYS START-UP

Press key **1(Rack Insertion)** at **MAIN MENU** to run the analysis cycle.

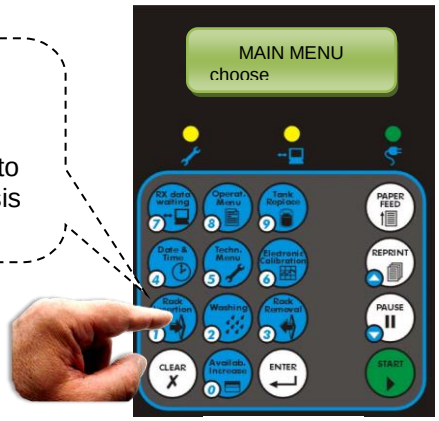


Photo 10

INCREASE AVAIL
Insert CARD

Display 8

NOTES:
If the message, as reported in **Display 8,** is displayed, it means that the residual of credits (Availability) is below than the set threshold and new credits should be loaded. References for the credits loading at chapter "AVAILABILITY TEST INCREASING".

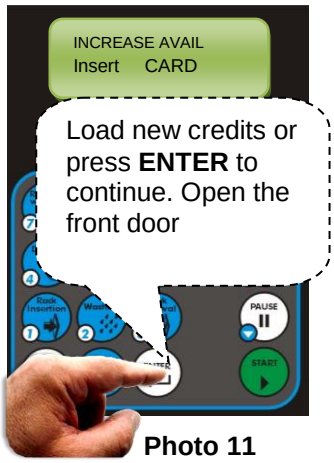


Photo 11

Photo 12

The ID code of the specimen is represented by the instrument number (workstation) followed by the instrument serial number followed by the rotor position where you insert the test tube.

0101130101
INSERT 1

Display 9

Insert the test tube in the rotor then press either **ENTER** to insert another specimens in the same analytical cycle or **START**. Close the door. The rotor rotates to reach the 19th position and remains waiting to receiving a test tube with 3ml of distilled water inside. After the test tube insertion and having pressed **ENTER**, the rotor rotates for the next position and remains waiting to receiving the second test tube with 3ml of distilled water inside. After the test tube insertion and having pressed **ENTER**, close the door. The mixing process will start followed by the analysis process. The end of the analysis process is described at chapter "MESSAGES AND RESULTS PRINT OUT AT THE END OF THE ANALYSIS CYCLE".

WASHING REQUESTING AT TIMEOUT.

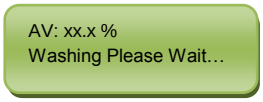
In order to avoid leaving the capillary dirty of blood for long time of inactivity and so to preserve the capillary from the opacity increasing, at the end of the analysis cycle and MAIN MENU return a counter is activated to reach the pre-set time set by the technical service. Once the pre-set time is reached and assuming that no one has pressed a key on keypad to do new operations, the instrument runs an automatic washing aspirating water from the inserted 19th and 20th test tubes. The automatic washing execution causes the **priming** process at the successive analysis cycle run. The use of automatic washing modality is described at **APPENDIX F**.

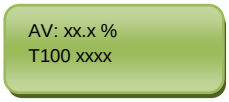
NOTES:

- The scheduled waiting time can be modified by the technical service by, request, which can vary from 5 minutes to 180. The choice has to be done according to the specimens frequency that come in the laboratory. If the specimens frequency is high, than you can chose a high waiting time (example 180 minutes from the end of the lase analysis cycle) in order to avoid doing washings too much frequently.
  If the specimens frequency is low, than you can chose a low waiting time (example 30 minutes from the end of the lase analysis cycle) to avoid leaving the instrument dirty of blood for long time of inactivity.
- Every time along the waiting time a new analysis cycle is run, the counter is re-set to **0**.
- If the operator at the end of the analysis cycle carries-out a washing as described on “WASHING PROCEDURE WITH 2 TEST TUBES” chapter, the waiting time counter will be set to **0** as the instrument is able to recognize whether the capillary is cleaned or contains blood traces inside.

13. WASHING PROCEDURE

This procedure is designed to clean the complete capillary tubing and so to set it free from blood or Latex residuals. Since along the working life Latex flow inside the Teflon tube, particles of them tend to hang on the internal walls of the capillary. This fact, accordingly, increases the capillary opacity reducing the reading scale of the ESR values.
Starting from Firmware version 8.00A onwards, visualization of washing cycles have been slightly modified, now on display is visible a value in % on first row while on second row there are still displayed the T100 references:





AV% value is the ratio between the water value read and the theoretical value of the water (3589).
At the end of the washing cycle if everything is ok, instrument will print out a report on paper as well as will ask to remove washing tubes. If things goes wrong, instrument will issue a Z-0 error.

It is in any case recommended to not use more than 2 times the same washing tubes in order to avoid possible needle and/or capillary obstructions due to rubber particle released by the washing tubes stoppers if used more than two times.

In order to maintain the capillary cleaned and to increase its own working life, the operator should carry-out washings in different ways as described in the next pages.

WASHING USING 2 TEST TUBES

It should be used during the instrument working day to avoid leaving the capillary dirty of blood for long time in absence of analysis and you want to leave the test tubes for the automatic warning integer. To activate the procedure, prepare 2 test tubes filled with 3ml of distilled water and insert them in the position 1 and 2 of the rotor after pressing key **2 (Washing)** on MAIN MENU.

It is in any case recommended to not use more than 2 times the same washing tubes in order to avoid possible needle and/or capillary obstructions due to rubber particle released by the washing tubes stoppers if used more than two times.

Wait until MAIN MENU is displayed again which points-out the end of the process.

WASHING USING 3 TEST TUBES

The execution of this option is suggested at the **end of the working day** to maintain the capillary cleaned during the night and for an easy way to remove residuals of blood particles, will be discarded into the waste tank, from the needle and capillary tubing at the beginning of the new working day .
To activate the procedure, 3 test tubes with 3ml of distilled water each have to be prepared and put into the first three positions of the rotor after having pressed key **2** (**Washing)** on **MAIN MENU**.
Wait until "**Test 1 off**" message is displayed then the operator can chose to continue with the ordinary activities pressing "**ENTER**" or to switch the instrument off for the night. On both cases and during the washing process, the needle aspirates the content of the first and second test-tubes completely and remains filled with distilled water as well as part of the capillary inside the third test-tube. Pressing either "**ENTER**" or immediately after switching the instrument on, the needle is going to exit from the third test-tube and the instrument then goes to empty the needle and capillary.

WASHING PROCEDURE FOR MAINTENANCE

For a good maintenance of the instrument and in case the needle and/or capillary are obstructed, carry-out this procedure using distilled water and Sodium Hypochlorite (5% of dilution).
The maintenance procedure should be carried out on a daily basis, in any case it is required previous to the latex control procedure.
The procedure is:

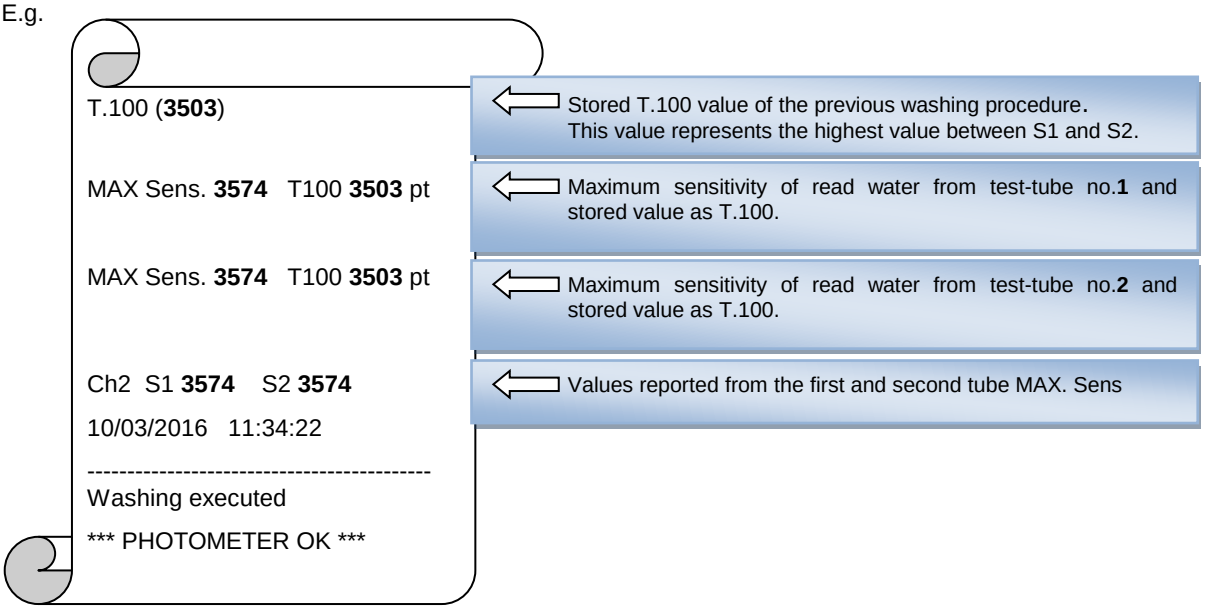
1. Prepare two test-tubes filled 3/4 with distilled water and put them in the 1st and 2nd position of a rack. Press key **2 (Washing)**, select Manual Washing option to start the procedure, insert the rack into the instrument and wait for the end of the procedure.
2. Prepare one test-tubes filled 3/4 with Sodium Hypochlorite (5% of dilution) and put it in the 1st position of a rack. Prepare one test tube filled 3/4 with distillate water and put it in the 2nd position of the rack.. Press key **2 (Washing)**, select Manual Washing option to start the procedure, insert the rack into the instrument and wait for the end of the procedure.
3. In order to rinsing the capillary, prepare two test-tubes filled 3/4 with distilled water and put them in the 1st and 2nd position of a rack. Press key 2 (**Washing**), to start the procedure, insert the rack into the instrument and wait for the end of the procedure

WASHING PROCEDURE WHEN USING LATEX CONTROLS

The washing procedure required for the Q.C. (which is recommended) to be carried-on on a daily basis by means of Latex is the same of the previous procedure described (**washing procedure for maintenance**). It has to be used every time before starting with the control process in order to carry-out quality control of the instrument (QC).

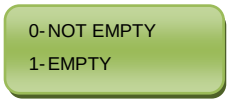
WASHING REPORT

At the end of each washing procedure, the software is going to report its value matched with the suffix **T100**.
E.g.



NOTES:

- T. 100 value is reported on the flag list which can be obtained pressing REPRINT key within two seconds after hearing two beeps sounds immediately after turning the instrument on.
- **Z** error can be differentiated to **Z-0, Z-1** and **Z-2.**
  Z-0 is generate in case of no detected or no continuous water flow.
  Z-1 Only for TEST1 THL.
  Z-2 Only for TEST1 DI Models
- At the end of the washing procedure, in case the left LED blinks and the display shows a message like the example on the left, it means that the tank level has been exceeded. Follow the indication described on chapter “TANK EMPTYING / REPLACING”.

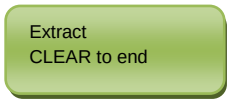


At every incorrect washing procedure, the printed-out result will be **2048** and the software will generate **Z** error and a new washing procedure requested.
If T. 100 tends to reach 2960, it means that the tubing is going to be opaque.
In this case try to carry-out the WASHING PROCEDURE FOR MAINTENANCE in order to reduce the opacity of the capillary. The value then should rise to 3505.
If it remains closed to 2960, the technical service should be called in order to replace the complete tubing.

14. TEST TUBES EXTRACTION

At the end of the analysis cycle the instrument activates the test tubes extraction process. This procedure, however, can be executed on MAIN MENU also.

Pressing key **3 (Rack Removal)** at MAIN MENU
The LCD display is going to shows this message:



Display 10

Open the front door, extract the test tube from the rotor which, after the extraction, rotates to the next position where another test tube is inserted. It stops then and remain waiting for the test tube extraction.
At the end, close the front door and wait for the MAIN MENU.

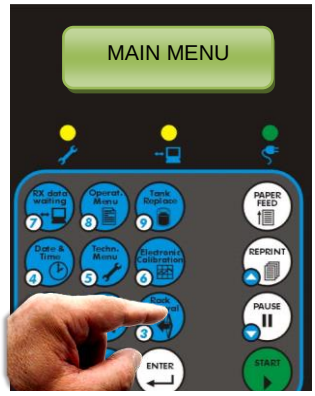


Photo 13

15. CHANGE DATE & TIME

To change **Date & Time**, press key **4** on MAIN MENU. The LCD display will show this message:

where DD=Day, MM=month, YYYY=Year

Display 11

If the date is correct press **ENTER** key to confirm. Unlikely, if the date needs to be changed, press **CLEAR** and type the correct date. For the year, only the last two digits can be changed.

At this point the displayed message is:

where DD=Day, MM=month, YYYY=Year

Display 12

If time is correct, then, press **ENTER**. Unlikely, if the time needs to be changed, press **CLEAR** and type the correct one.

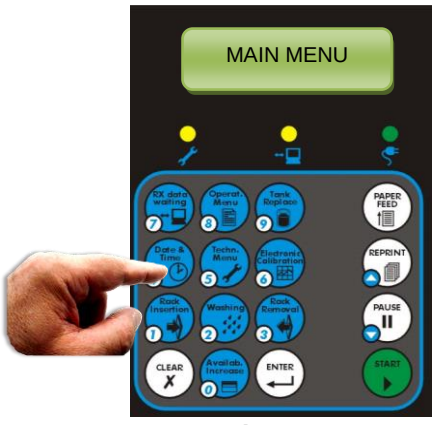


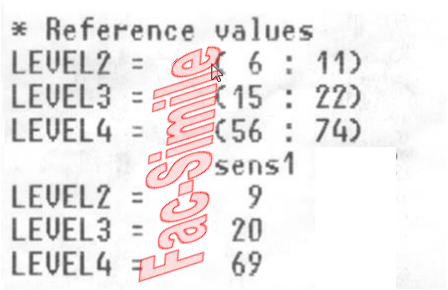
Photo 14

16. RESERVED FOR TECHNICAL SERVICE

17. CHECK USING LATEX KIT

With the purpose of guarantee an always optimum performance of the instrument, the daily use of the latex control kit is recommended.
Latex Controls kit is a valid check tool to monitor the reliability of the analyser during its working life. The kit is supplied in a box. It can contain three test tubes filled with Latex that allow executing a total of 6 controls (sale code **SI 305.100-A**) or it can contain five test tubes filled with Latex that allow executing a total of 30 controls (sale code **SI 305.300-A**). Before starting the Control process, the analyser can require a washing procedure. In this case, the operator should carry-out a washing procedure as "WASHING USING 2 TEST TUBES", chapter.

At the end of the control process, the instrument printout an hardcopy of the results as the facsimile strips present here on the right side.



Speaking in general terms, "level 2", "level 3" and "level 4" corresponds to the ESR intervals that indicatively represents the low, medium and high ESR areas (in any case take as official reference the laboratory intervals for the classification of the ESR results)

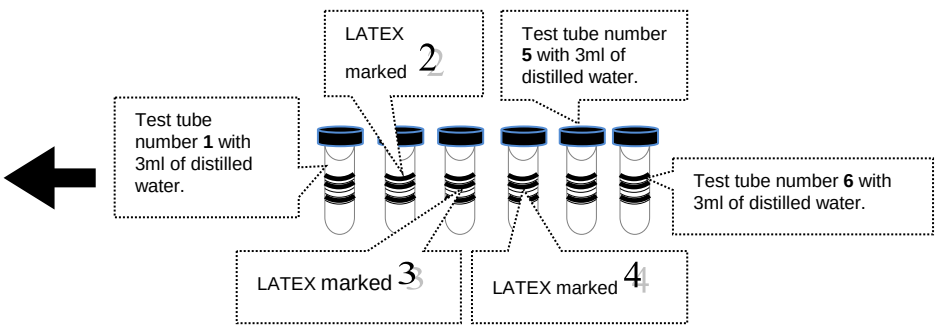
The effective reference ranges to be used to confirm that the instrument is "in control", are in any case those indicated in the Latex Controls Box's outer label.

If the obtained results are into to the expected ranges, independently they are close each other or separate (but in any case inside the acceptable range) means that the analyzer is calibrated correctly.

On the contrary, if one or more of the results is / are out of the expected ranges, it is recommended to call the Technical Service to carry out a functional verification of the analyzer.

Before running a Control, carry-out a washing procedure:
Important: to avoid possible capillary or needle obstructions, please be sure to use maximum two times the same washing tubes.

a. Execute a first washing procedure by **2** test tubes with 3ml of distilled water in each of them as "WASHING USING 2 TEST TUBES" chapter.
b. Execute a second washing procedure by **1** test tube with 3ml of Sodium Hypochlorite in the 1st position of the rotor and **1** test tube with 3ml of distillate water in the 2nd .
c. Prepare the sequence of test tubes set as the below example shows:



Then:..

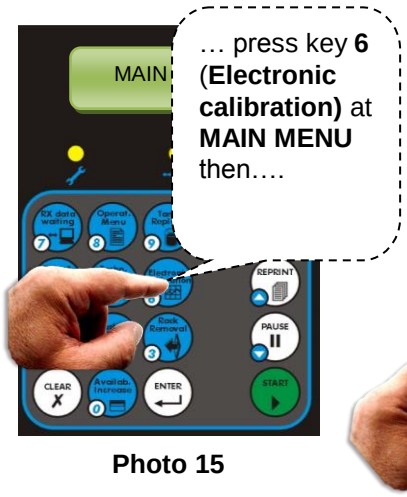


Photo 15

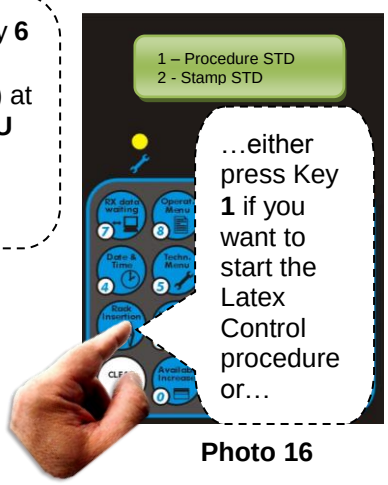


Photo 16

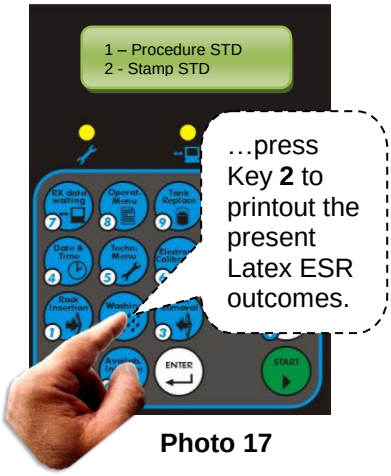
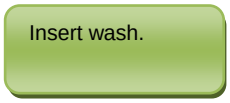
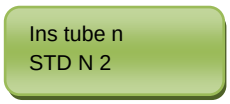


Photo 17

At the Control procedure activation, the display shows the request to insert the first test tube with distilled water inside. Open the door, insert the test tube in the rotor and press **ENTER.** The rotor will move to the next position and wait for the second test tube (first Latex test tube marked **2**) insertion after the ID code reading by the Scanner. After the test tube insertion and having pressed **ENTER**, the rotor moves to the next position and so on, up to complete the insertion of all test tubes set. At the end and after having closed the door, the analyser is going to start mixing but only whether the *Lot* and *kit* numbers of the three Latex codes are the same in all three Latex test tubes and do not give expiry date. At the end of mixing, the controls process runs and if the correlation between the referent values and the read ones overcome the 97% (0.97) the Control process will be completed. Otherwise, if the correlation is below than 97%, the **"Correlazione NoK, Procedure aborted**" message will be printed out on paper and the procedure aborted.

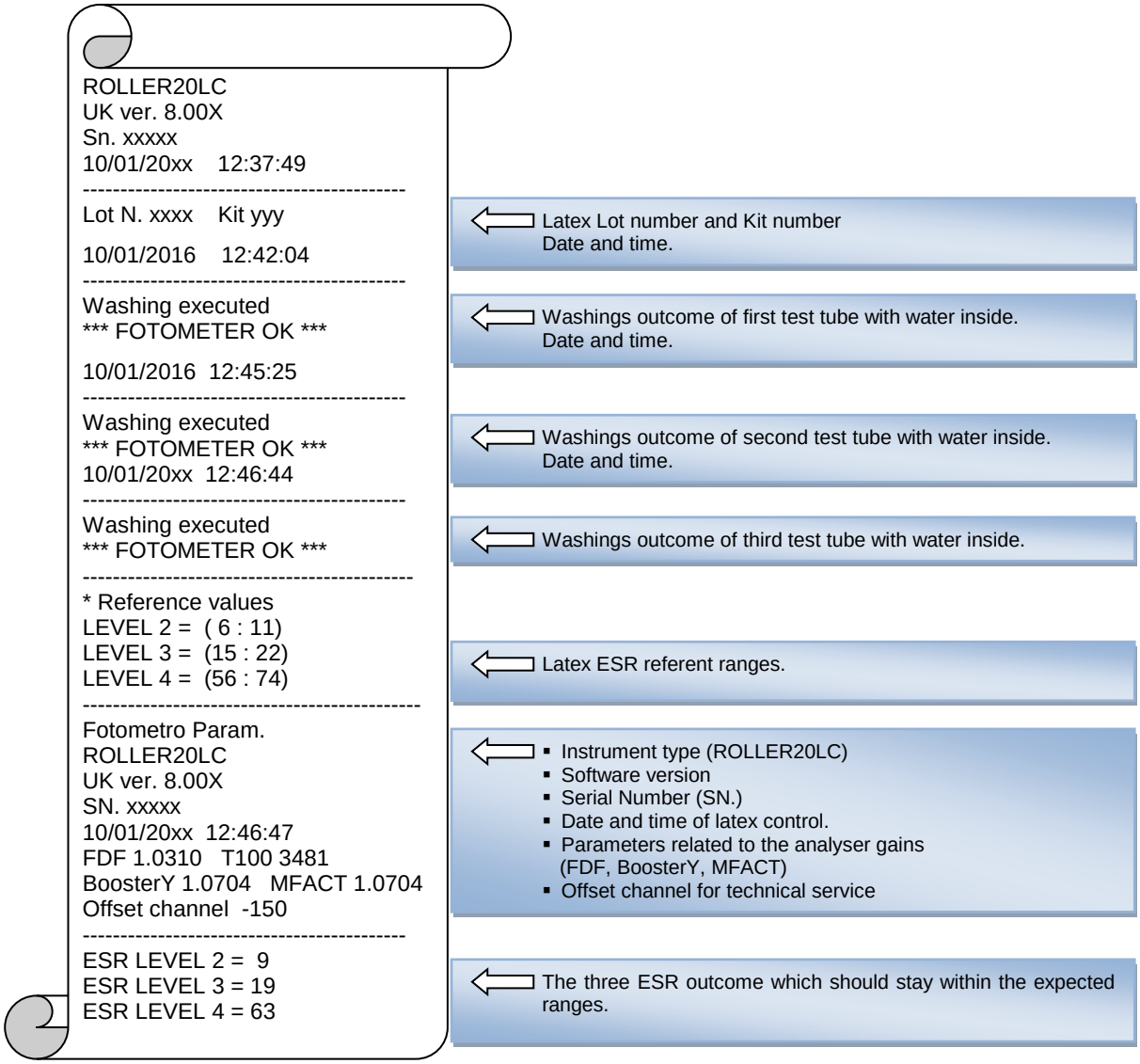


Display 14



Display 13

When the analysis is completed, the printer is printing the latex analysis report as on the example below and the removing rack requesting message displayed.



NOTES: If after the rack introduction you get a message like **STD xxxx NX,** means that the scanner did not read the bar code on the test tubes. In this case, type manually the code as described on **APPENDIX D**

NOTES:

- If at the MAIN MENU, the display shows the message represented by Display 16 while the left LED blinks, it means that the tank level has been overtaken. Please follow the indication described on chapter “TANK EMPTYING / REPLACING”

0 - NOT EMPTY
1 - EMPTY

Display 15

WITHDRAWAL STEPS WITH PRIMING AT THE LATEX CONTROL PROCESS.

At the beginning and after the water aspiration from the first test tube:

a. The pump aspirates 116 micro-liters of Latex from the second test tube marked **2** on the label.
b. The analyzer moves the aspirated Latex forwards and downwards inside the capillary for 3\4 times.
c. The Latex aliquot is discarded.
d. The pump aspirates the Latex sample from the same test tube and carries on the measuring phase.
e. The pump aspirates the Latex sample from the successive test tube and carries on the measuring phase
f. The pump aspirates the Latex sample from the successive test tube and carries on the measuring phase
g. The pump aspirates water from the successive test tube for rinsing the capillary
h. The pump aspirates water from the successive test tube for rinsing the capillary
i. The instrument generates the 3 Latex ESR outcomes which have to be inside the referent ranges.

8. NO FUNCTION IN THE ROLLER20LC

19. KEYBOARD OPERATING FUNCTIONS

DESCRIPTION

At "**MAIN MENU"**, each key of keypad reports not only the numerical value but also the function that can be activated by pressing that key.

Photo 18

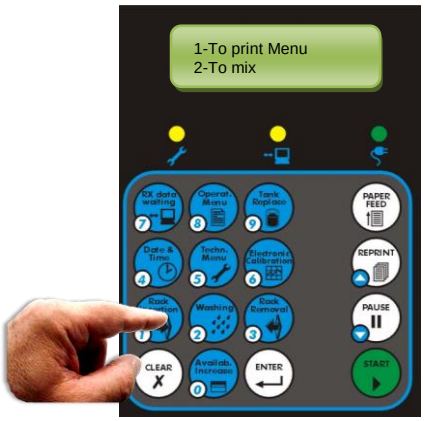


Photo 19

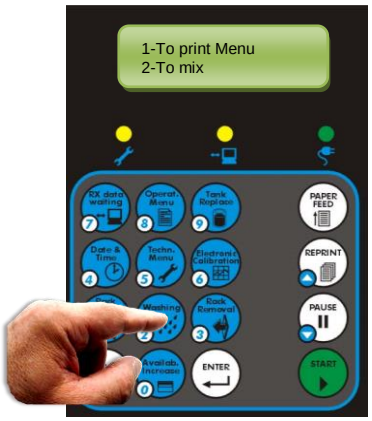


Photo 20

Pressing **key 8** and then **2** (Photo 24) you activate the mixing function without the analysis execution.
This is useful if there is not an external mixer available for the comparative proofs between the instrument and manual method or for premixing the specimens in case they were kept in the fridge for the night.
The specimens are mixed by the same number of rotations and speed set for the analysis cycle to then maintained mixed by a rotation at every 30 seconds intervals till **ENTER** is pressed.

Pressing **key 8** and then **1** (Photo 23) you activate the options list printing.

MAIN MENU

0-AVAILABILITY
1-MEASURE
2-WASHING
3-RACK EXTRACTION
4-DATE & TIME
5-TECHNICAL MENU
6-CALIBRATION EC
9-TO CHANGE TANK
REP-STATISTICAL DATA

List:

0 - (to increase the availability of credits
1 - (to run an analysis cycle)
2 - (to start a washing procedure)
3 - (to remove test tubes from the instrument)
4 - (to modify date and time)
5 - (to access Technical Menu)
6 - (to start a Control process by Latex kit)
9 - (to reset the tank counter after the tank replacement)
REP-(to run the internal Quality Control)

20. TANK EMPTYING / REPLACING

At the end of every analysis cycle, and after having removed the test tubes from the instrument, if the quantity of discarded liquid (blood, water, Latex) brings a value into the last 200 respect the scheduled threshold (1500 as default stored in the setup), the instrument will print out the message “TANK ALMOST FULL”. Such message warns the operator about the necessity of emptying the tank and re-set the counter to **0**.

Procedure:

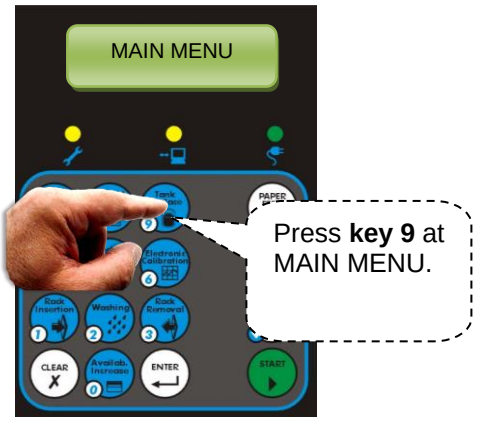


Photo 21

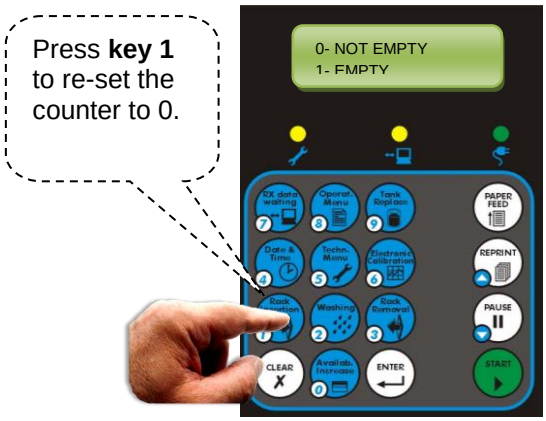


Photo 22

If you ignore the message “TANK ALMOST FULL” and you continue analysing specimens, at the threshold maximum level overtaken, the display will show a message as reported at Photo 26, the left LED above the keyboard will blink and the printer prints out “WASTE LEVEL DETECTED EMPTY THE TANK”. The instrument won’t allow running a new analysis cycle till the tank is empty, as the tank is filled of liquid, and the counter re-sets to **0**.

To simplify and keep at the same time safe the waste bottle movements from instrument to waste collection basin inside laboratories for the disposal of wastes according with laboratory safety rules or requirements, and increase the security level during the liquid disposal (a mix of blood, water, chlorine and latex), Alifax ESR instruments waste bottle is supplied with a plastic cap (Photo 1). The connection between cap and capillary is guaranteed by a click ’n seal connector. Every time the bottle has to be emptied, the bottle has to be removed from the lodgment inside the instrument; it is important to check the black cap is well tight, then it is required to unscrew the click’s seal connector unscrewed (Photo 2). To empty the waste bottle, remove the black cap, empty the bottle in the collection basin or the area dedicated to collect wastes in the laboratory being careful to avoid waste material leaching on the outer surfaces of the bottle and dirtying, therefore, the internal parts of the analyzer (bottle lodgment).
Once bottle is empty, place again the black cap and be sure it is tightened, then place again the capillary and tight the click ‘n seal connector till a “click” is heard (Photo 3).
Finally place again the bottle in the lodgment inside the instrument (Photo 4)

Photo 1
Waste bottle cap view

Photo 2
Unscrew the click’s seal connector in order to separate the tank from the instrument.

Photo 3

Photo 4

To disposal the waste tank content, follow the standard safety procedures the laboratory works with.

Note:

1) If it is not necessary emptying or replacing the tank, press **0** to close the procedure without resetting the counter.
2) Pressing key **9** at MAIN MENU it is possible recalling the displayed options as described above.

21. PAPER FEED

DESCRIPTION

Pressing **PAPER FEED** on keypad or the mode button on printer (), paper is going to be fed through the printer.

Photo 23

22. STATISTICAL TOOLS

In order to do internal Quality Control, the software includes a series of tools which report and plot the instrument performances.
Such control tools are the following:

1. INSTRUMENT QUALITY CONTROL USING LATEX CONTROL KIT (Kit code SI 305.100 for 6 tests or code SI 305.300 for 30 test)

- The first graph represents the Control Latex results executed daily and accordingly with the results it wants to drain a linear exposition of them or drifts.
- The second graph drains the difference of the gain value, any Latex Control process generates, respect the referent position obtained from the Calibration process. The maximum CV allowed is 10%.

2. HEMATIC STATISTICAL DATA PRINTOUT
   Generates black and white circles which point-out cumulative and daily averages of ESR results of analysed blood samples which belong to patients who refer to the lab.
   From the beginning of the instrument working life, the Quality Control system stores couples of both cumulative and daily averages which day by day go to increase the plot which the maximum length represents 30 days of analysis. The complete plot, then, will be updated automatically moving the plot up and so leaving space below to add new points that represent the last day of analysis.

3. ESR VALUES DISTRIBUTION PRINTOUT
   There are four different plots divided in different ranges:
   two of them points out ESR results from 2 to 120 mm/h (cover the complete range) and the other two points out ESR results from 2 to 30 mm/h which in Italy they are considered not pathologic results.
   This tool is useful to each lab to split-up pathologic results from the not pathologic ones and get a referent cut-off from pathologic and not pathologic results.

4. WATER DATA PRINTOUT
   By a black point for each day, this wants to report the daily average of the photometrical check done during each washing procedure. *The allowed CV can vary from 0 to 1,6%.*

LATEX QUALITY CONTROL TRENDS

At the end of every process with Latex Control kit, each obtained result is stored in the instrument and it can be represented by a circle or asterisk in the Quality Control system. The Quality Control activation allows printing all represented circles or asterisks that form a plot.

After pressing **REPRINT** at **MAIN MENU** and waiting for a couple of seconds, the message as reported at Display 17 and 18 will be displayed in sequence:

Photo 24

STATISTICAL DATA ESR STD RATE (1)

Display 16

STATISTICAL DATA M (2) Sp (3) W (4)

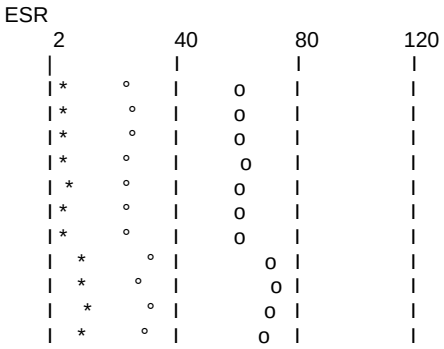
Display 17

After REPRINT, by pressing key **1** the display will show the message as represented at Display 19

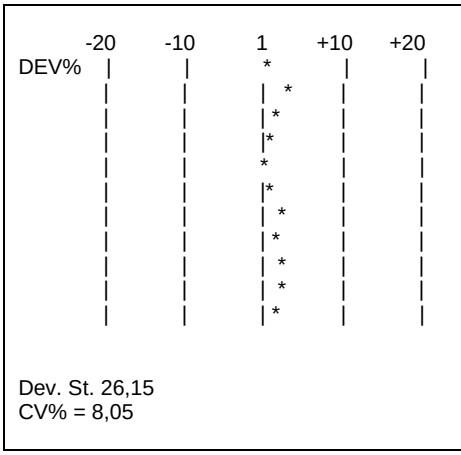
1 – TREND ESR 2 – TREND FACT

Display 18

Press key **1** (TREND ESR) to print out the following graph
Press key **2** (TREND FACT) to print out the successive graph:



Graph explanation
This graph shows the trend of the three Latex Controls values as the checks are performed along the time. The first series of the symbols (* ° o) lined up on the top, represents the ESR values of the Latex Controls process first execution. The one on the line at the bottom, instead, represents the results of the Latex Controls process last execution. Thought this graph, it is possible to see any variation in trend and any drifts from sides. Therefore, if a new Latex lot characterised by different values from the previous lot number generates shifted points on the graph, like the first four series of symbols in the aside example, it is suggested to monitor the trend of the new Latex Control lot for a few days.



Graph explanation:
During the calibration process by Latex, the software identifies and stores the necessary gain, called **ModelFact,** to obtain the expected ESR Latex results. That gain is represented by the vertical axis marked number **1** (see the graph). Beneath the graph, the Standard Deviation (Dev. St.) and the Percentage Coefficient of Variation (CV%) of the results are reported to know whether the analyser works efficiently. In fact, if the CV% remains under +/- 10% it means that the analyser works efficiently but if the CV% exceeds this limit, a revision of the analyser calibration by the technical service is recommended.

The coefficient of variation (CV) is defined as the ratio of the standard deviation σ to the mean μ, this is CV = σ / μ

From Fw 8.00A the mean itself is calculated based on a fixed value of 30 days, this is why at the beginning the CV calculated has an high value which itself is meaningless. In order to have a relevance, the CV value of the latex trend must have at least 30 days of data accumulated; in any case what it is important hand, is not the CV as number but the trend itself and the SD.

ESR STATISTICAL TRENDS

The Quality Control section of the program foresees the print out of the statistical data relating to the average of the daily session (white dots) and those related to the average of all data accumulated since the beginning of the instrument working life until the print out time (blacks dots). This option assumes the value of an **analytical control based on the "population of the samples"**, and it has **the effectiveness of a monitoring of the instrument.**

It can be assumed that, for a large number of accumulated samples (about 6000) by an instrument in a certain laboratory, the distribution of ESR values in the graph, then the average of these values, can oscillate slightly. The greater the number of patients tested daily, the more this is true.
It is also conceivable that the type of sample that is received by the laboratory is always representative of the population that refers to the laboratory, and that this population presents, on average (for large numbers), always the same values distribution.

If the analytical characteristics of the instrument are reliable, it is expected that the black points of the cumulative averages do not fluctuate a lot and remain into three standard deviations of the average of the cumulative averages, which acts as a stable reference. The graph of the cumulative average helps to see if there are systematic drifts over time which points out possible functioning problems in the instrument.

The distribution of the cumulative mean values, is undoubtedly more stable than the average values of patients on different days may come from different or particular departments, etc. This distribution, in fact, is not affected by the contribution of any abnormal samples that can be sporadically present in different percentages in the various days. One must also remember that patients with ESR in the normal range are also, usually, the majority of the samples that arrive at the laboratory.

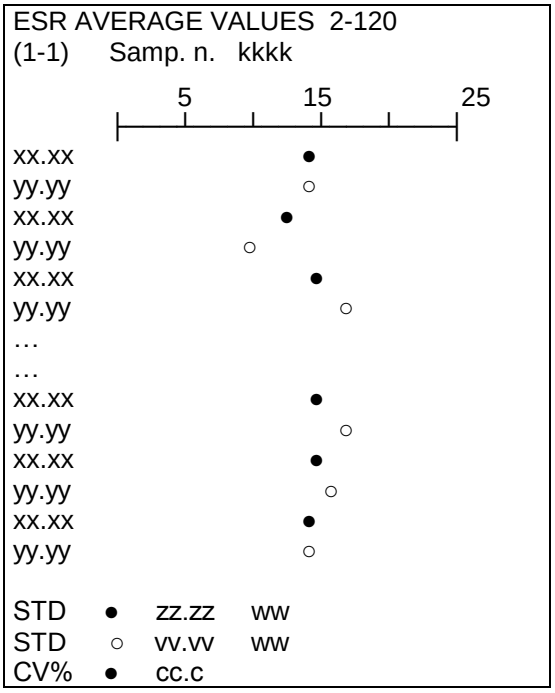
STATISTICAL DATA - Graph meaning

Press **REPRINT** key on MAIN MENU to access in the Quality Control system.
After displaying a first option, this message comes in streaming:

Display 19

Press key 2 to activate the graph printout which represents the behaviour of the ESR mean values.

ESR MEAN value print out in the FULL RANGE (2-120 mm/hr)



Where:

kkkk = represents the whole number of analysed samples.

xx.xx = represents the cumulative mean ESR value on ESR range from 2 to 120 mm/h.

yy.yy = represents the ESR daily mean value on ESR range from 2 to 120 mm/h.

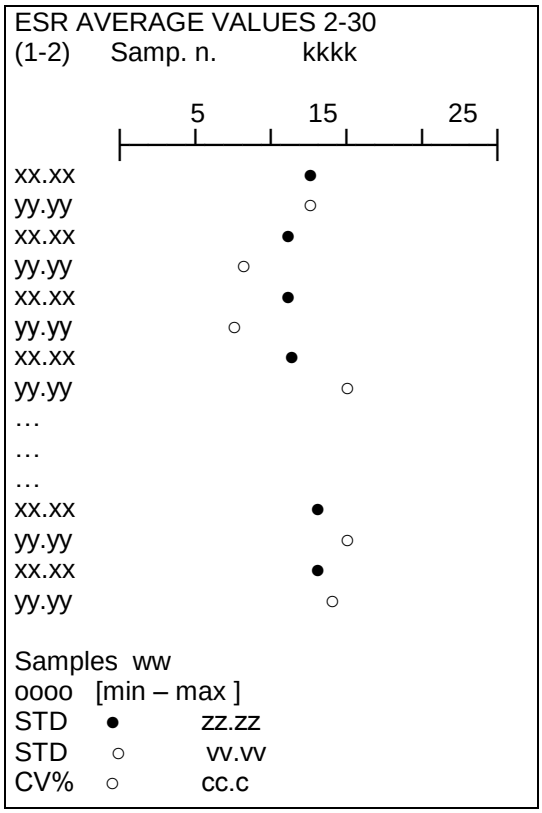
zz.zz = standard deviation of cumulative mean ESR value

vv.vv = standard deviation of daily mean ESR value

cc.c = CV% of the cumulative mean ESR value

ww = represent the days of analysis spent to reach kkkk

Printout of ESR MEAN value in the NORMAL RANGE (2-30 mm/hr)



Where:

kkkk = represents the number of analysed samples

xx.xx = represents the **cumulative mean ESR** value for **samples within the range 2-30 mm/hr**

yy.yy = represents the ESR **daily mean value** for samples falling **within the range 2-30 mm/hr**

zz.zz = standard deviation of cumulative mean ESR value

vv.vv = standard deviation of daily mean ESR value

cc.c = CV% of the cumulative mean ESR value

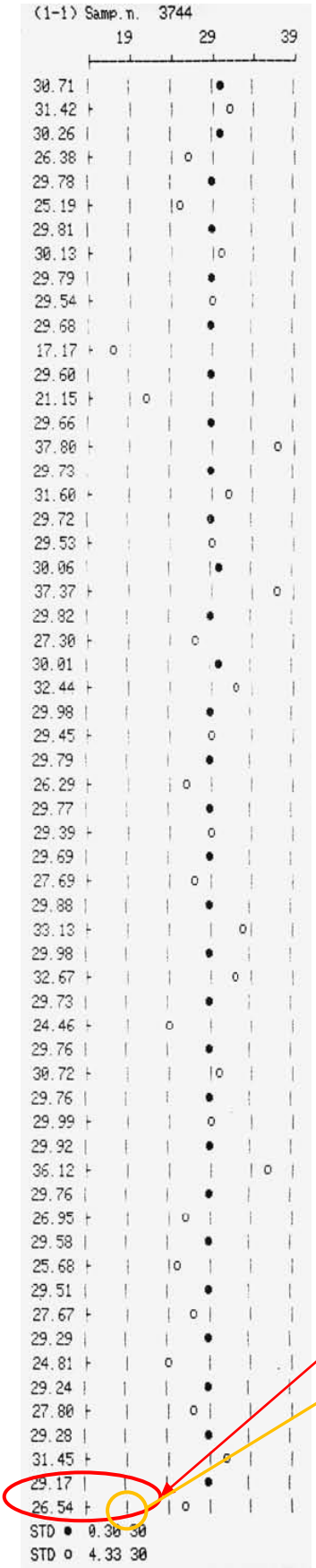
ww = represents the days of analysis spent to reach kkkk

oooo = reports the last value xx.xx which has to fall down into the calculated range (**[min**. and **max]**)

-[min = min limit allowed to the daily STD (= cumulative mean - 3 x cumulative STD)

-[max = max limit allowed to the daily STD (= cumulative mean + 3 x cumulative STD)

Guide to the interpretation of the graph of values between 2-120 and the clinical / statistical meaning.



- (1-1) Samp. n. 3744 points out the total number of samples processed in 30 days.
  The first couple of values (30,71 – 31,42) matched to the relative symbol, points out the cumulative and daily averages value of the first day of analysis. The successive couples, convey the values average of the successive day of analysis except the black symbol which wants to be the average value between the analysis of that day and the previous cumulative averages.

Example:

19 29 39
|-----|-----|-----|-----|-----|

30.71 ● is the cumulative average of the first day of analysis.
31.42 o is the daily average of the first day of analysis.
30.26 ● is the updated cumulative average (1st day + 2nd day)
26.38 o is the daily average of the successive day
29.78 ● is the updated cumulative average (1st day + 2nd day + 3rd day)
25.19 o is the daily average of the successive day
……. …… ……

This graph **represents the last 30 days of analysis**. By this, it is possible to identify an anomalous tendency of daily averages respect the cumulative once. This is not a big problem because the analysed specimens that could have been come from different sites day by day, could have been affected by pathologies which vary the daily average and the matched symbol position in the graph. . An anomalous tendency of the cumulative averages, instead, should alert the user for a possible systemic error.
The data are shown from the oldest (on the top) to the most recent (on bottom of graph).

Pay attention on the data interpretation. It is necessary **to consider the number of specimens that come daily** and even **their origin**. The cumulative average line becomes stable after 100 samples stored and the daily average moves around the cumulative trend line. In this way a problem on instrument could be pointed out immediately by a rapid deflection of the daily trend line and cumulative averages.

The instrument is able to collect at maximum 5900 samples to calculate the average, therefore large variations of daily statistics will not change the cumulative average in determinant manner.
As soon as 5900 samples are reached, the first 1000 will be discarded coming back to 4900 samples. This is to avoid the cumulative average becomes too stable for a variation.

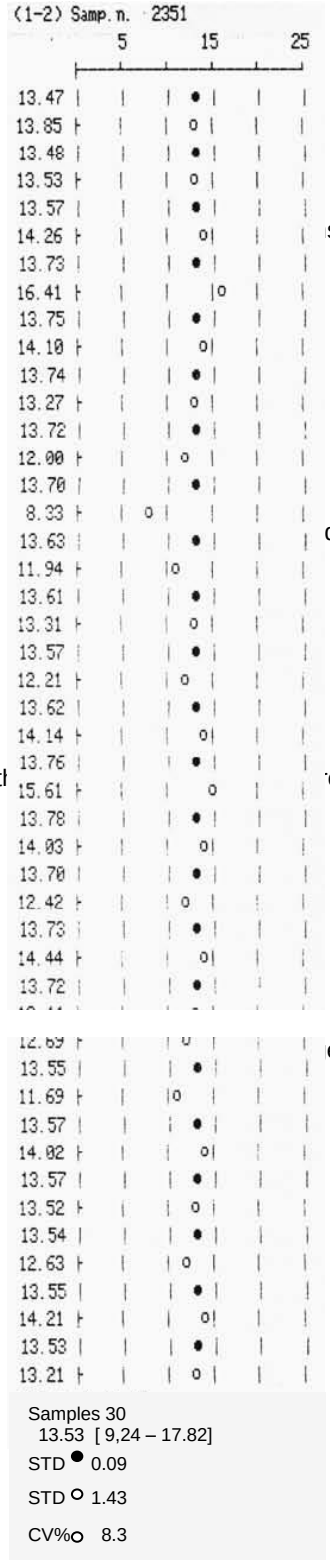
At the end of the graph, the printer prints out the Standard Deviations of both cumulative and daily average:

STD ● 0.30 30 Standard Deviation for cumulative data (last 30 days)
STD o 4.33 30 Standard Deviation for daily data (last 30 days)

From a statistical point of view, the daily data can be considered stable if they stay into three Standard Deviations of the cumulative average.
In this example of graph, taking into account the last cumulative average data (29.17) and the three standard deviations of the cumulative average (0,30 x 3 = 0,9), we can say that the average of the last day fall down inside the range whether doesn't exceed the three standard deviations of the cumulative data.
In this example, the lower limit is: 29.17 - 12.99 = 16.18 and the upper limit 29.17 + 12.99 = 42.16. In this case, the daily value 26.54 enters inside between the two lower and upper limits, so the instrument is working properly.

Remember that if this doesn't happen, the cause should be searched on the processed samples during the day and from the kind of patients analysed (a lot of pathological or a lot of healthy patients).

Guide to the interpretation of the graph of values between 2-30 and the clinical / statistical meaning.



This graph has both the daily and cumulative data more stable because the analysed specimens were not affected with pathological diseases.

In this case, the considered specimens are less (2351 vs. 3744) than those represented in the previous graph, and this is logical because the no pathologic values in Italy are surrounded from 2mm/h to 30mm/h.

As on previous case, we can analyse the meaning of this graph and the results in s of stability.

- (1-2) Samp. n. 2351 this is the total number of samples processed in 30 days. The first couple of values (13,47 – 13,85) matched to the points, points out the values average of the first day of analysis. The successive couples, convey the values average of the successive days of analysis.
  Example:

```
          5          15          25
          |-----|-----|-----|-----|-----|
13.47                 ●                  the black circle is the cumulative average of the day.
13.85                 o                  the white circle is the daily average of first day.
13.48                 ●                  updated cumulative average (day 1 + day 2)
13.53                 o                  daily average of second day
13.57                 ●                  updated cumulative average (day 1 + day 2 + day 3)
14.26                 o                  daily average of the third day
……. ……              ……
```

As the previous graph, this **represents the last 30 days of analysis** and in the graph, tl egular tendency in the daily averages compared with the cumulative ones and establish the functioning stability of the analyser.
From a statistical point of view, data can be considered stable if stays inside three Standard Deviations of the cumulative average.

At the end of the graph, there are the Standard Deviations of both cumulative and daily averages:

STD ● 0.09 Standard Deviation for cumulative data
STD o 1.43 Standard Deviation for daily average

In this case the last cumulative average (13.53) has to remain inside the calculated e:

([9,24 – 17,82]).

ESR DISTRIBUTION PRINTOUTS

From a population who refers to the same laboratory, the ESR results distribution should allocate on constant manner along the time. This is particularly true for the results distribution which stands in the ordinary range. The user, therefore, could separate the range that contains pathologic results from the one that contains no pathologic results. Eventually he can define the two ranges. Nevertheless by the distribution, it is possible to explain any daily averages deviation easy. At the beginning, averages deviation could alert the user but assuming they were not present the day before, this fact can depend from an increase of patient affected by pathologies, maybe came from particular wards. In this case verifying the distribution of the daily data it is possible to observe an increasing of the medium-high values and a constant distribution in the ordinary range. This last observation, grants that the analyser is working correctly and that the daily average swing depends only by a different composition of patients.
The values distribution, moreover, allows checking the **"population constancy"**.
This check is complementary to this described previously for the mean values.

ESR VALUES CUMULATIVE AND DAILY DISTRIBUTION PRINTOUT

Press **REPRINT** key on MAIN MENU to activate the statistical data printout procedure.
After displaying a first option this message comes in streaming:

STATISTICAL DATA
M (2) Sp (**3**) W (4)

Display 20

Press key 3 to activate the following sub menu.

STATISTICAL DATA
S (**1**) D (2)

Display 21

Press key 1 to activate the **cumulative ESR distribution** printout represented by (2 -1) (2 -2) tables.

Press key 2 to activate the **daily ESR distributions** printout represented by (3 -1) (3 -2) tables.

Cumulative distribution printing in the range 2-120 mm/hr (step 5 mm/hr)

(2 -1)	Samp. n.		ww	
Av.	xx.xx	Std	yy.yy	
==========				
1	-	5	zz.zz	nn
6	-	10	zz.zz	nn
11	-	15	zz.zz	nn
…				
…				
…				
106	-	110	zz.zz	nn
111	-	115	zz.zz	nn
116	-	120	zz.zz	nn

Where:

ww = represents the number of samples considered in the ESR range 2 - 120 mm/hr
xx.xx = represents the mean ESR value of the samples
yy.yy = represents the standard deviation

zz.zz = represents the distribution percentage in the considered range step, respect to the total range 2-120 mm/hr
nn = represents the number of samples in the considered range, respect to the total number of samples in the range 2 - 120 mm/hr

Cumulative distribution printing in the range 2 to 30mm/h (step of 2 mm/hr).

```
(2 -2)    Samp. n.        ww

Av.       xx.xx    Std    yy.yy
============================
1  -      2               zz.zz          nn
3  -      4               zz.zz          nn
5  -      6               zz.zz          nn
…
…
…
25 -      26              zz.zz          nn
27 -      28              zz.zz          nn
29 -      30              zz.zz          nn

Norm.              jj.jj %
```

Where:

ww = represents the number of samples considered in the ESR range 2-30 mm/hr
xx.xx = represents the mean ESR value of the samples
yy.yy = represents the standard deviation

zz.zz = represents the distribution percentage in the considered range step, respect to the total range 2-30 mm/hr
nn = represents the number of samples in the considered range, respect to the total number of samples in the range 2-30 mm/hr
jj.jj = represents the percentage of values in the range 2-30 mm/hr, respect to the total number of samples

Daily distribution printing in the range 2-120 mm/hr (step 5 mm/hr)

```
(3 -1)    Samp. n.        ww

Av.       xx.xx    Std    yy.yy
============================
1  -      5               zz.zz          nn
6  -      10              zz.zz          nn
11-       15              zz.zz          nn
…
…
…
106 -     110             zz.zz          nn
111 -     115             zz.zz          nn
116-      120             zz.zz          nn
```

Where:

ww = represents the number of samples considered in the ESR range 2-120 mm/hr
xx.xx = represents the mean ESR value of the samples
yy.yy = represents the standard deviation
zz.zz = represents the distribution percentage in the considered range step, respect to the total range 2-120 mm/hr
nn = represents the number of samples in the considered range, respect to the total number of samples in the range 2-120 mm/hr

Daily distribution printing in the range 22-30 mm/hr (step 2 mm/hr)

```
(3 -2)    Samp. n.        ww

Av.       xx.xx    Std    yy.yy
============================
1  -      2               zz.zz          nn
3  -      4               zz.zz          nn
5  -      6               zz.zz          nn
…
…
…
25 -      26              zz.zz          nn
27 -      28              zz.zz          nn
29 -      30              zz.zz          nn

Norm.              jj.jj
```

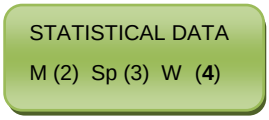
Where:

ww = represents the number of samples considered in the ESR range 2-30 mm/hr
xx.xx = represents the mean ESR value of the samples
yy.yy = represents the standard deviation
zz.zz = represents the distribution percentage in the considered range step, respect to the total range 2-30 mm/hr
nn = represents the number of samples in the considered range, respect to the total number of samples in the range 2-120 mm/hr
jj.jj = represents the percentage of values in the range 2-30 mm/hr, respect to the total number of samples

WASHING TRENDS

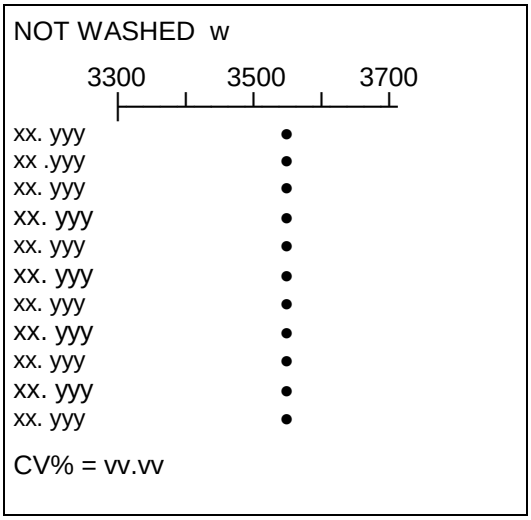
The print out of washing control allows to evaluate the efficiency of the TEST1 photometer (CPS). The graph visualizes the course of the washing signal, that is directly correlated to the photometrical signal. Normally, the instruments are regulated for an absolute value of 3600 during the washing with distilled water. This value trends to decrease during the time, because biological residuals release deposit inside the capillary.
A weekly washing like described in the washing character, will bring again the photometrical signal to an absolute value of around 3500. If this signal decreases under the value of 3300 or increases above the value of 3700, the instrument will generate Z-0 error. In this case try to repeat the washing weekly process and if the value does not come again inside the range 3300-3700, call to the technical service for maintenance.

Press **REPRINT** key on MAIN MENU to activate the statistical data printout procedure.
After displaying a first option this message comes in streaming:



Display 22

Press key **4** to activate the graph printout which point out the trend of the washing mean values



Where:

w = Represents the missing washing number

xx.= Represents the washing progressive number

yyy = Represents the water daily value read

vv.vv = Variation percentage coefficient.

23. PAUSE

PAUSE key does not activate functions at MAIN MENU.

24. NEEDLE CLEANING PROCEDURE

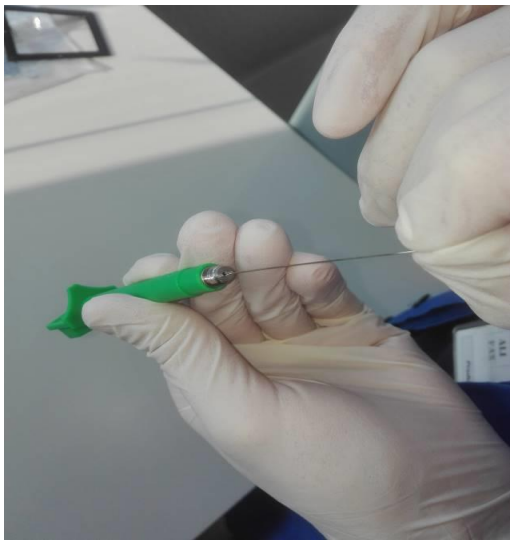
PROCEDURE:

Wearing protective gloves, carefully remove the empty green Alifax key from the instrument's support.

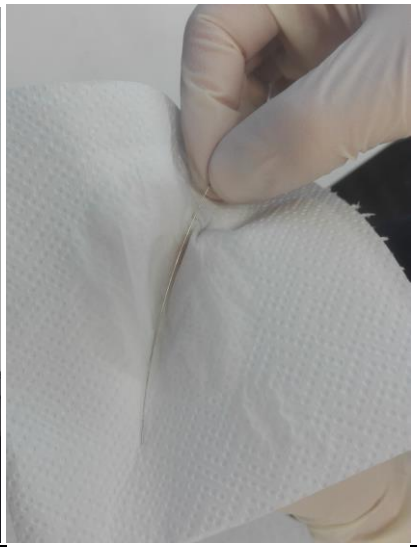
Carefully remove the piston of the syringe, carefully insert the tool over the needle, until you find the right connection point with the needle, and start to unscrew the needle..
Extract the key, keeping the needle inside it.

Now, without removing the needle from the tool, remove the metal probe.

As for the picture below, insert in and out several times the probe in order to clean the needle.



NOTE: Once finished, just repeat all the operation backwards, remembering to sanitize the tool and the probe, using a disinfection product and paper towel as for the following pictures.


25. NEEDLE REPLACEMENT PROCEDURE

WARNINGS:

- **To start the needle replacing process, it is recommended wearing gloves and protective glasses, to avoid any contact with potentially infected biological material.**
- **Avoid absolutely to touch the top of the syringe piston, because also a light pressure could allow the needle to escape and its tip could become extremely dangerous because it could pierce the glove and the skin. Operate with extreme caution.**

REPLACING PROCEDURE
With the instrument OFF, follow the indication described below**:**

Photo 25
Open the plastic flap

Photo 26
Pull firmly the piston assembly towards you so that the retaining magnets release the assembly.

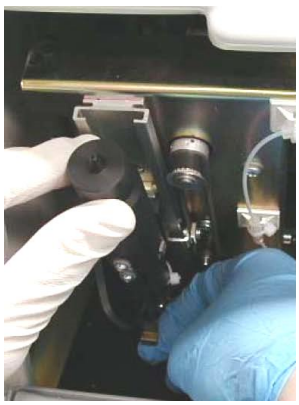


Photo 27
Push down the piston and with one finger of your other hand pull out the retaining clip. Remove the piston completely. Be careful the needle tip that will come out from the piston top!

Photo 28
Replace the needle using the red or green tool tightening the new-one without excessive force to avoid damaging the plastic thread part.

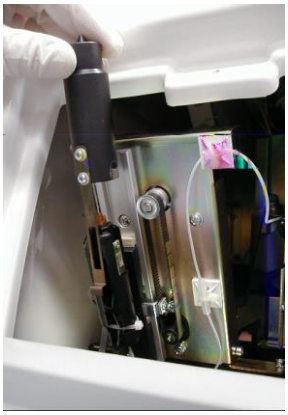


Photo 29
Insert the piston looking at its metallic clip that has to fall down in front of you

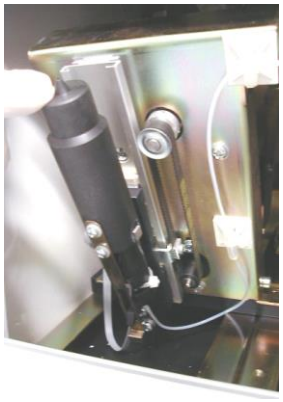


Photo 30
Push the piston down until the metallic clip will be over the aluminum hook then release the piston.

Photo 31
Push the piston assembly until the magnets retain the piston assembly

NOTE:

We suggest to do a washing procedure after replacing the needle, using two test tubes with 3ml of distilled water inside and verifying if water flows is fluent from the tube into the capillary during the withdraw phase.

PISTON CHOICE

ROLLER20LC is equipped, normally, by the Cell Blood Counter piston which is developed to work with BC \ Greiner test tubes. It is however possible to require the instrument with the appropriate piston to work with either Sarstedt or Terumo test tubes.

Photo 32
Syringe CBC.
Code SI195.021

Photo 33
Syringe Sarstedt
Code SI195.022

Photo 34
Syringe Terumo
Code SI102M23

26. USE OF PAEDRIATIC TEST-TUBE

The insertion of pediatric test-tube in the rack, requires the use of adapter. Such adapter is not universal but designed in three different measures for

SARSTEDT (Photo 39)
TAPVAL (Photo 40)
VACUTAINER (Photo 41)

The sale codes of the adapters are:

SI195595 (adapter for SARSTEDT test-tube)
SI195590 (adapter for TAPVAL test-tube)
SI195593 (adapter for VACUTAINER test-tube)

Photo 35

Photo 36

Photo 37

Other kind of paediatric test-tube cannot be used because of lack of adapter.

BD Microtainer MAP from 250 to 500 uL pediatric cuvette into 13x75mm tube with pierceable cap
In reference this specific pediatric tube, it can be used without any adapter in all TEST1 configurations

27. TURN THE INSTRUMENT OFF

Before turning the instrument OFF it is essential carry-out a WASHING procedure with three test-tubes with 3ml of distilled water each. Then the instrument can be switched OFF.
Switched ON the instrument again, the instrument is going to print out "**WASHING PERFORMED",** whether the washing was done previously. On the contrary the message will be **WASHING NOT PERFORMED** .

28. MAINTENANCE PROCEDURE

A counter in the analyzer, counts the executed analysis from the last maintenance time.
When, along the working days, it reaches the preset maintenance warning again, which value is 30000 normally, the LED set on the left side, above the keypad, blinks.
The operator, therefore, warned by the analyzer about the necessity to carry out a new maintenance service, has to call the technician trained to carry out this stage.

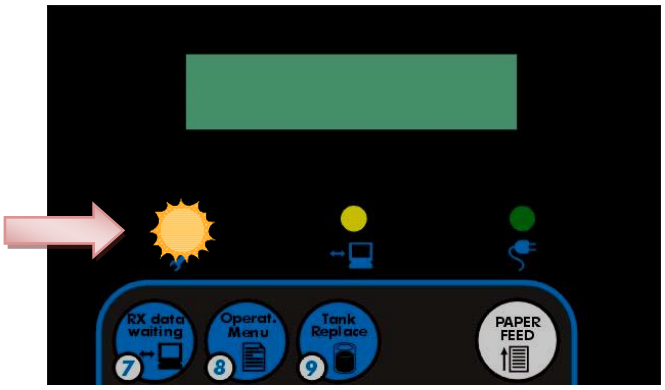


Photo 38

29. SANITIZATION PROCEDURE

The following procedure must be executed before:

1) Collection/shipment of the instrument from laboratory after a demo or for replacement/reparations.
2) Technical service repair or check inside the instrument.

Protection tools and suggested materials to be used:

1) Glasses.
2) Latex gloves.
3) Absorbing paper towels.
4) Plastic bag for waste disposal.

For the description of sanitization procedures of a working instrument: refer to the chapter **Sanitization Form**

The Sanitization Form MUST be filled up and accompany the instrument.

In case the sanitization cannot be executed due to a failure of the washing system, contact your Local Technical Service.

NOTES:

We suggest to make a copy of the SANITIZATION MODULE sheet and to fill it according to the sanitization procedure.

NOTES:

The errors of the below list have been inherited from software versions 6.51x designed to work with the previous kind of CPU board. Because of the new kind of CPU board, this list could be updated along the revisions.

30. ERRORS LIST

1) THE INSTRUMENT DOES NOT TURN ON.

Verifications:

- ❖ Is the power cable connected to the mains group of the instrument?
- ❖ Is the power cable connected to the electricity plug?
- ❖ Is the switch at ON?

Solutions:

S1 Turn the instrument off and unplug the power cable.

S2 By a tiny cross screw-driver, lift the external fuses box retaining tongue, remove the fuses box and check the efficiency of the fuses. If they are burned, go to **S3**; otherwise if they are not, go to **S5.**

S3 Replace the fuses (250VAC 2.5AT (T=time-lag)).

S4 Reinsert the fuses box into the lodgement, plug the power cable in and turn the instrument on. If the instrument does not work yet, go to **S5**. Otherwise if it works, skip **S1.4b** and **S1.4c**.

S5 By a V-meter set to AC, check if J4 (on power supply board) is powered by 220VAC. If it is and the red LEDs are dark, then go to **5.a,** otherwise if it is not, go to **5.b.**

5.a -Turn the instrument off, replace the power supply board and turn the instrument on again.
5.b -Turn the instrument off, replace the power selector and turn the instrument on again.

S6 Verify the power cable efficiency connecting it to another instrument or checking the power by a V-meter.

1.1) The fuses burn again:

Solutions:

S1 Replace the fuses (250VAC 2.5AT (T=time-lag)).

S2 To identify which part is on short-circuit, unplug the power connectors from each board and one by one plug them in again turning the instrument on after each connection.

2) THE INSTRUMENT TURNS ON BUT NO MESSAGES APPEARS ON DISPLAY.

Verifications:

- ❖ Try to turn the instrument OFF, wait for 10 seconds and turn it again.
- ❖ If the display is light without characters, go to **S1** of **Solutions**; if it has characters, go to **S2.**

Solutions:

S1 Replace the CPU board.

S2 Identify the correctness of the information.

3) THE INSTRUMENT TURNS ON BUT "ERROR F-0" MESSAGE APPEARS ON DISPLAY.

Symptoms and Verifications:

- ❖ One key could be pressed during the lighting of the analyser.
- ❖ The keyboard could be damaged; turn the instrument off, unplug J1 (Keyboard) and on again.
- ❖ If "ERROR F-0" message is still present, then go to **S1** of **Solutions**; if it is not, go to **S2**

Solutions:

S1 Replace the CPU board.

S2 Replace the keyboard.

4) DURING THE INITIALIZATION PHASE, THE PISTON ASSEMBLY OF THE INSTRUMENT GENERATES NOISE.

Symptoms and Verifications:

- Have a look at the power supply board if the LED, marked F1, which points-out the presence of 8VDC, is dark. If it is go to **S1** of **Solutions**; if it is not, go to **S2** of **Solutions.**

Solutions:

S1 Turn the instrument off, replace the fuse of 250V 1AT marked F1 and try again.
S2 Replace the carriage cabled sensor and check the right position of it by DIAGNOSTIC option:
2.a Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5.
2.b Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door.
2.c Close the door.
2.e Press key 6; the carriage assembly is going to move toward to all positions of the linear encoder printing a couple of values for each vertical black and silver colour of the linear encoder.
2.f Move the sensor towards or away from the linear encoder and press 6 again.
2.g Repeat the alignment process until the silver bar gives a value close to 40. *e.g. Black 40*.

5) STABLE LOW TEMPERATURE MESSAGE ON DISPLAY.

Symptoms1:

- In the diagnostic field the temperature remains stable to room temperature.

Checks and solutions

S1 The 33VDC are missed:
1.a Turn the instrument off.
1.b If the fuse works, go to **1.c**, otherwise if the fuse is burned, replace it and check again.
1.c Turn the instrument on and plug the probes, of a V-meter set to Vdc,.
1.d Check if the V-meter measure a value around 33Vdc. If they are not, check F3 on the *Power supply board* or change the complete board. If they are not again go to 1**b**. If they are present, then change the booster power board set on the right metallic wall.
1.e Check the mains transformer AC powers or change it.

Symptoms2:

- The power is present.

Checks and solutions

S1Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5.
S2 Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door.
S3 Press PAUSE key and check the status on display; the information of the first line points-out:
3.a The temperature (it should be around 20÷25); e.g. **T 25**..
3.b The differences in temperature to reach the scheduled 37°C; e.g. **– 12.**
3.c If the thermostat works or not; e.g. **1**.

S4 Change the CPS unit.
S5 Change the CPU board.

6) A-0

Symptoms1:

- Message that occurs after 3 consecutive NFs with debug OFF.

Checks and solutions

S1 Check the needle and capillary functioning.
S2 Carry out a complete washing procedure even with Hype-Chlorite.

7) A-1.

Symptoms1:

- Message that occurs after 3 consecutive errors of syringe movement (the motor lose more than 250 steps at rising up).

Checks and solutions

S1 Check the mechanical parts of the syringe assembly.
S2 Check the toothed belt.

8) A-2.

Symptoms1:

- Message that occurs after 3 consecutive “Q-0” errors (capillary obstructed) on the same specimen.

Checks and solutions

S1 Check and unlock the capillary circuit.
S2 Carry out a complete washing procedure even with Hype-Chlorite.

9) B-0

Symptoms1:

- During the analysis cycle the carriage assembly creates noise.

Checks and solutions

S1 Run a new analysis cycle and verify if the carriage assembly hits the beginning of the carriage support. If yes have a look at the power supply board. If the LED, marked F1, which points-out the presence of 8V-DC, is dark, replace the fuse of **250V 1AT.** Otherwise if it lights, take a V-meter set to DC, plug the black colour probe to ground and the red one to the left external pin of the sensor connector set on the carriage board to feel if +8V-DC are present. If they are, go to **1**; if they are not, go to **3**:

S2 Turn the instrument off and move the carriage assembly manually towards the front side of the instrument.

S3 Replace the cabled sensor and check the right position of it by DIAGNOSTIC option.

3.a Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5.
3.b Press key 2 to access DIAGNOSTC and insert a rack in after having opened the door; close the door.
3.c Press key 6; the carriage assembly is going to move towards to all positions of the linear encoder printing a couple of values for each vertical black and silver colour of the linear encoder;
3.d Approach the sensor to the linear encoder or move it away from the linear encoder and press 6 again.
3.e Repeat the alignment until the printed out message of the white lines reports a value closed to 40**.**

S4 Turn the instrument off, check and (if it necessary) replace the flat cable which links the carriage board to the CPU board.
S5 Check the carriage assembly connector and its wires.
S6 Repeat the test from **S2** to **S3**.

10) B-1 ERROR

Symptoms1:

- Home carriage error.

Checks and solutions

S1 Check or replace the carriage home sensor**.**

11) C-0 ERROR

Symptoms1:

- The syringe group does not go up and down correctly.

Checks and solutions

S1 Turn the instrument off and move the carriage assembly manually towards the front side of the instrument.
S2 Check the piston sensors glued on the carriage board and the presence of the square magnet glued on the piston support.
S3 Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5. Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door. Pressing key 3; the syringe assembly should move to the nearest positions of the tube cap. The piston tooted belt could be ruined and so it needs to be replaced. The syringe motor could not work correctly cause an incorrect driving of it; the CPU board needs to be replaced. Repeat the test for many times to see if now it is working well.

12) C-1 ERROR

Symptoms1:

- Excessive friction between mechanic parts during the syringe movement.

Checks and solutions

S1 Turn the instrument off and move the carriage assembly manually towards the front side of the instrument.
S2 Remove the syringe motor and separate the belt from the pulley.
S3 Take a tiny flat head screwdriver and separate the washer and seger to 1mm from the pulley. Rotate the pulley manually to feel if it is able to rotate free of friction.
S4 Have a look if the belt, set on the support, if it is aligned vertically to the better way. If it is necessary, rotate a little bit the retaining square washer.
S5 Surround the pulley motor and pulley guide with the belt again, reinsert the pinions guides into the appropriate holes and set again all metallic parts as set originally.
S6 Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5.
Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door.
S7 Pressing key 3; the syringe assembly should move to the nearest positions of the tube cap. If it cannot and during the piston movement a noise is heard, the piston tooted belt could be ruined and so it needs to be replaced. If the syringe motor does not work correctly cause an incorrect driving of it; the CPU board has to be replaced.

13) C-2 ERROR

Symptoms1:

- Analysis cycle blockage for Syringe sensor error.

Checks and solutions

S1 Change the Syringe sensors board.
S2 Replace the CPU board.

14) C-3 ERROR

Symptoms1:

- The Syringe is not at home position

Checks and solutions

S1 Change the Syringe sensors board.
S2 Check the square magnet set at the syringe external side
S3 Replace the CPU board.

15) C-9 ERROR

Symptoms1:

- *Instrument still ask to remove tubes from rotor*

Checks and solutions

S1 *The error C-9 means the R20LC cannot finalize the initial check procedure because it still detect the presence of tubes in the rotor.*
Obviously if the tubes have been physically removed, and the instrument still issuing C-9 means the tube sensor it is not working.
Could be the emitter or the receiver.

16) D-0 ERROR

Symptoms1:

- EEPROM error.

Checks and solutions

S1 *Press ENTER ones or twice. If "Err. MicroTEST1/TEST1, not initialized" is displayed, then press START. The instrument will display "Are you sure?, 0=NO | 1=YES". Press "1" and then "99" as password. If the problem appears again, replace the CPU board.*

17) D-1 ERROR

Symptoms1:
- Database version error respect the firmware installed version.

Checks and solutions
S1 Turn the instrument off, wait for a few seconds and turn it again.
If the problem appears again, re-install the firmware.

18) D-2 ERROR

Symptoms1:
- Writing error on eeprom.

Checks and solutions
S1 Turn the instrument off, wait for a few seconds and turn it again.
If the problem appears again, re-install the firmware or replace the CPU board.

19) D-3 ERROR

Symptoms1:
- Correctness verification of the writing phase on eeprom.

Checks and solutions
S1 Turn the instrument off, wait for a few seconds and turn it again.
If the problem appears again, re-install the firmware or replace the CPU board.

20) D-8 ERROR

Symptoms1:
- Saving error on eeprom of the Smart Card log.

Checks and solutions
S1 Turn the instrument off, wait for a few seconds and turn it again.
If the problem appears again, re-install the firmware or replace the CPU board.

21) D-9 ERROR

Symptoms1:
- Initialization phase error.

Checks and solutions
S1 Turn the instrument off, wait for a few seconds and turn it again.
If the problem appears again, re-install the firmware or replace the CPU board.

22) E-0 ERROR

Symptoms1:
- The rotor doesn't rotate correctly for sensor or motor malfunctions. Sometimes this error is also due to the front door that is not closed well or the sensor does not see well the metallic reflecting plate.

Checks and solutions
S1- Check the rotor sensor alignment respect to the magnet glued on the rotor pulley.
S2- Check if the distance between the reflecting metallic tongue set on the front door and the door sensor is 5 - 6mm.
S3 - Clean the reflecting metallic tongue set on the front door.

23) E-1 ERROR

Symptoms1:

❖ The rotor doesn't rotate correctly for sensor or motor malfunctions. Sometimes this error is also due to the front door that is not closed well or the sensor does not see well the metallic reflecting plate.

Checks and solutions

S1 Check the rotor sensor alignment respect to the magnet glued on the rotor pulley.
S2 Check if the distance between the reflecting metallic tongue set on the front door and the door sensor is 5 - 6mm.
S3- Clean the reflecting metallic tongue set on the front door.

24) E-2 ERROR

Symptoms1:

❖ The rotor doesn't rotate correctly for sensor or motor malfunctions. It occurs after three died away attempts, of the CPU board, to correct incorrect positions of the rotor respect the withdrawal position. It could occur even whether the loading door has been opened frequently during mixing (voluntary or by mistake or due to door sensor vibrations).

Checks and solutions

S1 -Check the label code functioning applied on the test tube.
S2-Check the correct position of the scanner and the laser beams respect the centre of the label code.
S3 -Check the correct position of the rotor at the withdrawal time.

25) E-3 ERROR

Symptoms1:

❖ Error because all four racks have been disabled.

Checks and solutions

S1 Enable at least one rack.

26) F-1 ERROR (ERR_CPSM_COMM)

Symptoms1:

❖ *Error at the start-up phases because the CPS-MC not connected to the CPU board but selected by dipswitch JS2 and JS4* of DS1.

Checks and solutions

S1 Check if *JS2 and JS4* of DS1 are set to OFF
S2 Replace the CPS-MC board.
S3 Replace the CPU unit.

27) F-2 ERROR (ERR_CPSM_PUMP)

Symptoms1:

❖ The instrument does not communicate with the peristaltic pump at start-up.

Checks and solutions

S1 Check the connection of the peristaltic pump.
S2 Re-install the complete firmware.
S2 Replace the CPS board.
S3 Replace the CPU unit.

28) F-3 ERROR (ERR_CPSM_LATEX)

Symptoms1:

❖ Reading error at the Latex Calibration \Control phase.

Checks and solutions

S1 Turn the instrument OFF and then ON and repeat the process again.
S2 Change the Calibration \Control kit and try again

29) F4 ERROR

Symptoms1:

❖ FIRST-UP error .

Checks and solutions
S1 Repeat the FIRST-UP for two – three times.
S2 Check that the water flow is fluent along the aspiration and repeat the FIRST-UP for two – three times.

30) F5 ERROR

Symptoms1:
❖ The CPS does not measure the blood sample at the analysis cycle.

Checks and solutions
S1 Turn the instrument OFF and then ON and repeat the analysis again.
S2 Check that the blood flow is fluent along the aspiration phase.

31) G-0 ERROR

Symptoms1:
❖ The cycle's number of the day has reached its maximum value (250) and it has been reset.

Checks and solutions
S1 - Verify that the Patient IDs, not read from the IBCR, are correct according by cn snsn rk pn. cn means cycle number, snsn serial no., rk rack, pn position.
S2 - Press ENTER to continue.

32) H-0 ERROR

Symptoms1:
❖ "*Washing not executed xx*" printed-out message where xx is the number of missing washings.

Checks and solutions
S1- Press ENTER and carry-out a washing procedure.

33) K-0 ERROR (the piston position is not recognized)

Symptoms1:
❖ The instrument stops its working displaying K-0 error.

Checks and solutions
S1- At MAIN MENU press CLEAR; the piston assembly should move towards the front side.
S2 - Check if the piston's sensor wires are broken or the sensor is out of its position.
S3 - Have a look if the square magnet glued on the external side of the piston is present.
S4 - If it is not go to **S3,** otherwise if it is present, go to **S4.**
S5 -Seek the square magnet (probably it is fallen down on the instrument bottom) and glued it again on the piston external side right position.
S6 -Check or replace the internal sensor.

34) M-0 N-0 ERROR

Symptoms1:
❖ The syringe lifter motor does not rotate, the piston is still on the low position.

Checks and solutions
S1- Turn the instrument off.
S2- Check the sensors of the carriage board and the magnet glued on the piston assembly support.
S3- Check the syringe motor cables and connector.
S4- Check the flat cable connectors, which link the carriage board to the CPU board.
S5 Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5.
S6 Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door.
S7 Plug the probes of a Vmeter between ground and the wires (one by one) of the syringe motor connector to detect if it measures a value between 13 - 18V-DC. If the voltages are right go ahead to **S8.**
S8 Press key 2 to move the piston up and the syringe inside the tube.
Have a look to the complete movement of the piston unit during its movement to see if it works right.
If there is any problem:

S9 – Turn the instrument off, replace the CPU board and go back to **S5**.

35) O-0 ERROR

Symptoms1:

- ❖ The pump doesn't rotate during the withdrawing time.

Checks and solutions

S1- Turn the instrument off.
S2- Try to rotate the pump head manually to feel if it is locked.
If it is, go to **S2**; otherwise if it is not, go to **S3**.

S3 Remove the pump head and have a look if the plastic spacer is inserted on the pump motor pinion.
S4 Replace the pump motor.

S5 Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5.
S6 Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door.
S7 Press key 9 to move the pump CW and REPRINT to move it CCW to see if the pump works correctly.
If there is any problem:

S8 Have a look if one of two square magnet glued on the pump head is missed.
If it is, seek it on the instrument button and glued it again on the pump head but at the right side.
S9 Check the flat cable, which links the carriage board to the CPU board, connectors.
S10 Try to replace the CPU board.

36) Q-0 ERROR

Symptoms1:

- ❖ The analysed sample has not been wasted to the waste bottle.

Checks and solutions

S1 Press ENTER to continue. If the same error code appears again, try to do a washing procedure.

37) R-1 ERROR

Symptoms1:

- ❖ The availability of credit has not been increased on TEST1 memory.

Checks and solutions

S1 Keep it checked during the successive loadings. If any malfunctions are repeated again, then replace the reader or the CPU board.

38) S-0 ERROR

Symptoms1:

- ❖ Generic error during data transferring from CPU to new TRANSFER CARD.

Checks and solutions

S1 Try again.
S2 Change the TRANSFER CARD.
S3 Change the CPU board.

39) S-1 ERROR

Symptoms1:

- ❖ Reading error of the old TRANSFER CARD after the ESR transferring process.

Checks and solutions

S1 Change the TRANSFER SMART CARD.
S2 Change the CPU board.

40) T-0 ERROR
Symptoms1: ❖ REAL TIME CLOCK error.
Checks and solutions **S1** Turn the analyzer OFF and then ON. **S2** Update the software **S2** Change the CPU board.

41) T-1 ERROR
Symptoms1: ❖ It occurs when you attempt to transfer credits from an old TRANSFER CARD to the CPU despite the set threshold of credits, for the old TRANSFER CARD, have been exceeded.
Checks and solutions **S1** Load credits by using a TRANSFER CARD new design.

42) X-0 ERROR
Symptoms1: ❖ Checksum calculation error of the communication protocol
Checks and solutions **S1** Turn the analyzer OFF and then ON. **S2** Update the software **S2** Change the CPU board.

43) X-1 ERROR
Symptoms1: ❖ Expiry date verification error of the Latex Calibration kit.
Checks and solutions **S1** Check and correct data and time **S2** Erase the Latex log. **S3** Update the software

44) Y-8 ERROR.
Symptoms1: ❖ Writing error in the flash memory.
Checks and solutions **S1** Turn the analyzer OFF and then ON. **S2** Update the software **S3** Change the CPU board.

45) Y-9 ERROR
Symptoms1: ❖ Erasing error in the flash memory.
Checks and solutions **S1** Turn the analyzer OFF and then ON. **S2** Update the software **S3** Change the CPU board.

46) Z-0 ERROR.
Symptoms1: ❖ During a washing procedure the water value should be outside the scheduled ranges (3500 - 3900).

Checks and solutions

S35.1 - Do a washing procedure with Hypo Chlorite.

S35.2 - Check the tubing and click's seal connectors which could have misalignments.

S35.3 - Check the needle which could have obstructions caused by rubber particles unglued from the test tube cap and assessed into the needle during aspiration. Train your customer about the test tubes for water: they must not be used more than twice.

47) Z-1 ERROR.

Symptoms1:

- ❖ At the washing procedure time, the syringe goes up to aspirate water but the test tube is not detected.

Checks and solutions

S1 Check if the test tube is dropped down.

S2 Check if the syringe is vertically aligned respect the test tube.

48) Z-2 ERROR.

Symptoms1:

- ❖ In the instruments equipped by direct insertion kit, at the washing procedure time, the syringe goes up to aspirate water but the internal Scanner reads the label (NO) which points out the absence of the test tube.

Checks and solutions

S1 Rotate or set the test tube on a way the label (NO) applied on the rack container is covered.

ESR AND LATEX ERRORS LIST

Message	Cause	Solution
NF is printed instead of ESR value	The blood flow was not regular, or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube	If this message begins to appear frequently, it is suggested to execute a washing cycle before proceeding with further analysis.
NR (Not Reliable) is printed instead of ESR value	The reading unit detects the transition between air (empty capillary) and blood, but not the aggregation starting. Sometimes this is also due to a poor mixed blood or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube	Try to mix again the blood and repeat the measure
CM = SM (Sample Missing) is printed instead of ESR value	This error appears when test tube has slipped out from the rotor. Instrument is expecting to find a tube (because it has recognized it when loaded) but at the analysis time, the tube is not physically present in the rotor.	Check tubes loaded are in conformity with technical data sheet of the instrument
On display appears the following message **Increase Avail.** **Insert CARD**	The test availability is under the set threshold. The instrument alerts the customer that is necessary to increase the test availability.	Press Enter to by-pass. To avoid the message, it's necessary to increase availability inserting a new TEST1 CARD.
The following message is printed at power up **Waste level detected** **EMPTY the tank**	The waste tank counter has reached the value of tank alarm threshold. The instrument enters automatically in waste tank replacing procedure (9)	Replace or empty the waste tank, then press key "**1- empty**" to advice the instrument that the tank is now empty. The waste tank counter is so put to zero.
The following message is printed at power up **Maintenance Request**	The maintenance counter has reached the value of maintenance alarm (30000 by default). Maintenance is required.	Carry out the ordinary maintenance and then reset the counter to 0.
The following message is printed **Exceed expiry date** **Procedure aborted**	The three control tubes are expired, the calibration control could be unreliable, thus the procedure is aborted.	Check the expiry date of the kit, if it is expired replace it with a new one and repeat the control procedure.

The following message is printed **Exceed control availability** **Procedure aborted**	The three control tubes were used more than 6 times. The calibration control could be unreliable thus the procedure aborted.	The number of controls for one Latex kit is limited to six to avoid excessive piercing of the rubber cap which allow air to enter in causing Latex damaging. Repeat the control with a new kit.
The following message is printed **Different kit number** **Check tube labels** **Procedure aborted**	The three control tubes don't report the same lot and sub-lot code (the last 6 figures on bar-code) thus the analyser cannot verify the calibration data coherence. Into the kit for 30 test there are 5 columns of three test-tubes that must remain matched.	Check that on labels of the three test-tubes is reported the same code of lot and sub-lot (the last 6 figures of bar-code). If the codes are different, probably one or more tubes comes from different kit or are from the same kit but from a different column (for the 30 test kit)..
The following message is printed **Correlation Not OK**	The values read by the reading cell are not correlated. The three values cannot be plotted over a line and thus the correlation limit falls outside the minimum reference R^2 >= 0,97.	Check that the three tubes have been inserted in the right sequence and have the same level of latex; check the needle is not obstructed, if this happens, follow the washing procedures for maintenance.
The following message is printed **Unavailable memory in E2PROM** **Procedure aborted**	The memory of expirations of the kits is momentary not available or exhausted. The date memorized from the analyzer is not the current one.	Check the date of the analyser, correcting it if is not the current one. Try to repeat the control after few days (two or three) to verify if the memory frees an the message disappears. If after two or three days the message is still printed, call the technical service.

31. SOFTWARE VERSIONS

Version 8.00A

- First revision released officially.

Version 8.00B

- Not released to the market

Version 8.00C

Bugs Fixed:

- Fixed Bug involving random issuing of error D-0, D-1 and D-9 which lead to the complete blockage of the CPU
- Fixed Bug involving the non reading of some alphanumeric characters using External Bar Code reader (reported mainly on Roller20LC)
- Fixed bug involving the generation of the Error X-1 when latex were processed
- Fixed bug involving the impossibility to maintain DAT-15 configuration once instrument is restarted, now if DAT 15 is selected and instrument switched of and the on, the configuration remains as DAT-15

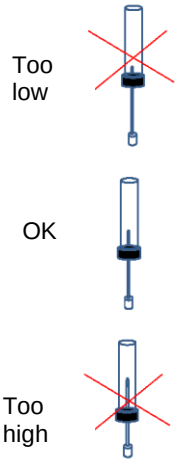
APPENDIX

APPENDIX A (asterisk meaning)

If the photometer of the instrument detects a low hematocrit level, indicatively lower than 30%, along the measuring phase of the specimen, the instrument software prints out an * (asterisk) symbol near by the ESR outcome, this symbol warns the operator of potential anaemia

APPENDIX B (NF meaning)

It appears when the system is not able to aspirate blood.
It could be possible:



- The excursion of the needle is not enough and accordingly the needle cannot aspirate blood. If this is true, you should call the technical service in order to increase the excursion of the needle inside the test tube:
- The excursion of the needle is too high and accordingly the needle cannot aspirate blood because its tip is over the blood level. If this is true, you should call the technical service in order to reduce the excursion of the needle inside the test tube:
- Air access into the capillary during aspiration.
  If this is true, the terminal part of the capillary which touches the needle base could be ruined.
  The capillary, therefore, has to be replaced and the analogical board adjusted. To do that, call the technical service.
- The needle is obstructed partially for a limited flow. The photometer, therefore, reads blood mixed with air. Check or replace the needle.
- The pump rubber tube is not able to aspirate blood correctly. The technical service should be called in order to replace the tube.

APPENDIX C (NR meaning)

NR is a printed out message which warns the operator that the result is no reliable.
The reading unit detects the transition between air (empty capillary) and blood, but not the aggregation starting. Sometimes this is could be caused by a poor mixed blood. or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube. Consequently ESR result is flagged as NR because not reliable.
A possible solution is in the pre-mixing of the specimen (referent point on “KEYBOARD OPERATING FUNCTIONS” chapter (Pre-mixing paragraph) and the successive analysis cycle.

APPENDIX D (latex codes typed manually)

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If the Scanner is not able to read one or more codes of the three, the label could be ruined or applied incorrectly, each missed code could be typed manually **(*)** but the test tubes insertion sequence has to be respected. Before mixing the display should show a messages like:

STD N 2

Display 23

In that case type the complete code of the test-tube marked number **2**.
The space between the two parts of code will be assigned automatically.

STD N 3

Display 24

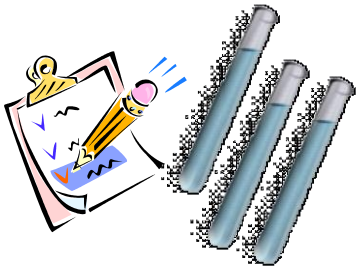
In that case type the complete code of the test-tube marked number **3**.
The space between the two parts of code will be assigned automatically.

STD N 4

Display 25

In that case type the complete code of the test-tube marked number **4**.
The space between the two parts of code will be assigned automatically.

(*) Press **CLEAR** twice to go back MAIN MENU, recover the test tubes and take a note of the three codes on paper.
After that, press key **6** again and restart the Control process.



NOTES:

If the ID code read by the Scanner is not equal than the displayed one, it is possible to erase the code pressing **CLEAR** and repeat the reading.

If the Scanner is not able to read one or more of the three codes during the second or the remaining four Latex Control processes, the display will report the code stored at the first Control process. In that case press **ENTER** basically and the stored code will be confirmed automatically.

APPENDIX E (note for analysis cycles and washings)

1. The analytical cycle cannot be interrupted to insert others samples to analyse.
2. Upon introduced the fourth rack and closed the door, the analysis cycle starts automatically.
3. Eighteen specimens can be inserted in the rotor + two with distilled water inside for the automatic wash.
4. If the availability of credits is below than the scheduled and stored, in the setup, threshold, beyond the real availability the printer is going to print out even a warning near by the reported availability.
   E.g. **ESR 200 warning (<1500).**

Important: to avoid possible capillary or needle obstructions, please be sure to use maximum two times the same washing tubes.

APPENDIX F (note for automatic washings)

The analyser requires two test tubes for the automatic wash to insert into position 19 and 20 of the rotor:…

- …at first analysis cycle of a new working day assuming that the analyser has been turned OFF for the night.
- ...at the first analysis cycle after lighting. When it is OFF in-fact, the analyser loses all information concerning the inserted test tubes.
- …at the first analysis cycle after an automatic washing execution.
- …if an automatic washing between one analysis cycle and another has being executed as the scheduled time is finished in the meantime. At the successive analysis cycle the test tubes will be required again.

The analyser does not require the two test tubes for the automatic wash:…

- …the capillary has been washed by a manual washing.
- …a new analysis cycle has been run before the end of the pre-set time as water did not aspired from the tubes.

REFERENCES

Manufacturer:

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CE IVD

SANITIZATION FORM

This module must be filled by the Laboratory / Technical Service Engineer and attached to the instrument before the shipment. The cleaning of the instruments can be difficult regards the elimination of the etiological agents of the TSE (Encephalopathy Spongiform Transmissible). It is reported that after exposure to high titre preparations of TSE agents, detectable infectivity can remain bound to the surface of the laboratory instruments. The removal of all adsorbed protein by the use of sodium hydroxide or chlorine releasing disinfectants (e.g. 20 000 ppm. Chlorine for 1hour) have been considered acceptable approaches where equipment that cannot be replaced as been exposed to potentially contaminated material.

Description of sanitization procedures to be done by the Laboratory:

Switch ON the instrument:

	OK	NOK
➢ Execute the following washing procedure		
1. Perform a first wash using two tubes filled with distilled water.	☐	☐
2. Perform a second wash using one tube filled with water and one tube filled with sodium Hypochlorite.	☐	☐
3. Empty and clean very well the Waste tank avoiding to leave blood residual inside	☐	☐

For the disposal of the waste tank content follow the standard safety procedures in use in the laboratory.

If due to a failure, the instrument cannot be switched ON, mark as NOK .

Description of sanitization procedures to be done by the Technical Service Engineer:

Wear protection tools (glove and glasses) and remove the cover of the instrument.

If Laboratory Operator marked the washing procedure as **NOK**, verify if it is possible to make in some way the washing procedures.

	OK	NOK
➢ Execute the following washing procedure		
1. Perform a first wash using two tubes filled with distilled water	☐	☐
2. Perform a second wash using one tube filled with water and one tube filled with sodium hypochlorite	☐	☐
3. Empty and clean very well the Waste tank avoiding to leave blood residual inside	☐	☐

For the disposal of the waste tank content follow the standard safety procedures in use in the laboratory.

If due to a failure the instrument cannot be switched ON, mark as NOK.

To continue with the sanitization procedure, switch the instrument OFF and unplug it from the power supply cable.

➢ If some part inside the instrument are contaminated with blood:		
1. Spray the parts with a disinfectant (cationic surfactants).	☐	☐
2. Collect liquid from the sprayed parts with absorbing paper towels.	☐	☐
3. Wash with water and dry with paper	☐	☐

For the disposal of the contaminated stuff and Waste Tank content, follow the standard safety procedures in use in the laboratory.

➢ If there are no parts contaminated with blood:		
Wash with water and dry with absorbing paper	☐	☐

In the event contaminated material is penetrated inside the instrument (thermostated plate) IT IS MANDATORY TO INDICATE ON the INSTRUMENT and on the SANITIZATION SHEET that contaminated material has percolated inside the instrument and it has not been possible eliminate using the external sanitization procedure.

MANDATORY:
If the sanitization was carried on, please cut the lover right side of the page (or make a photocopy) and include the tag in the shipping documents.

SANITIZED

ATTACHMENT 1 – PRODUCT TECHNICAL DATA SHEET (PTDS)

ESR_PTDS_SI102_PTDS

PRODUCT TECHNICAL DATA SHEET
ROLLER 20-LC

Rev.2.0 – Effective from 2022 May 25

OPERATIONAL SPECIFICATIONS

Equipment name: **ROLLER 20 (SI R20-LC):** model with thermoplastic white cover and Latex Control management.

Intended Use: ROLLER 20 is an automated in vitro diagnostic analyzer for the quantitative determination of erythrocyte sedimentation rate (ESR) in human blood samples with EDTA from adult and pediatric patients with suspected inflammation.
ROLLER 20 provides results to inform clinical management of serious and non-serious conditions requiring further diagnostic investigation and assessment of clinical status.
The physician performs the assessment based on the information provided by the device using his or her professional knowledge, skills and abilities as required by local law.

Principle of measure: Quantitative Capillary Photometry for the Erythrocyte-Sedimentation Rate (ESR)

- At the first daily switch ON wait 3 minutes before starting an analysis cycle to allow the thermal stabilization.
- Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C) / 98,6°F (±0,9°F)

Results: **ESR:** results are printed in mm/h on the range from 2 to 120 mm/h**.**

Sample requirements:

- The sample must be whole blood collected in EDTA anti-coagulant.
- The blood sample must be neither coagulated nor hemolyzed.
- It would be better to test the sample within 4-6 hours from venipuncture or within 24 hours if kept at +4/+8 °C (+39,2 / +46,4 °F), provided it is rewarmed to room temperature before testing.
- The minimum blood volume (dead volume) is 800 microliters.
- The working volume is 175 microliters (average) with the exception of the first two samples for which further 116+/-10% microliters are needed for priming (232+/-10% in case there is only one sample).
- Samples separation into the capillary using air bubble of about 530 mm (255 microlitres).
- In case of use of sample coming from patients affected by an oncological pathology, we remark that ESR result of those samples could be eventually NOT reliable as explained in chapter “method limitations” paragraph 2.

Tube requirements:

- Test-tubes 13x75 mm (0,512 x 2,953 in) like BD Vacutainer® or Greiner Bio-one Vacuette® or with 13 mm diameter and from 75 to 83 mm (2,953 to 3,268 in) high, cap included (like for example the Sarstedt Monovette® tubes that measure 11,5x66 mm. (0,453 x 2,598 in) without cap).
- It is possible to use “BD Microtainer MAP®” tubes directly (also in conjunction with other 13x75 tubes (0,512 x 2,953 in) without the use of adapter (but could be necessary to verify the needle offset adjusting its excursion in case of volumes lower than 500 uL
- It is possible to use “Sarstedt S-Monovette EDTA®”, “Tapval® pediatric tube”, “BD Vacutainer® pediatric tube” for these models of test tubes it is required the use of specific test tube adapters as well as it could be necessary to verify the needle offset adjusting its excursion in case of volumes lower than 500 uL
- In general, with the aim to obtain a good homogenization of the sample It is in any case suggested the sample volume should not exceed the 50-60% of the total volume of the tube.

 Sarstedt S-Monovette EDTA 1.2 ml pediatric tube and SI195595 Tube Adapter	 Tapval pediatric tube and SI195590 Tube Adapter	 BD Vacutainer pediatric tube and SI195593 Tube Adapter

 BD Microtainer MAP from 250 to 500 uL pediatric cuvette into 13x75mm tube with pierceable cap It does not require any tube adapter	Can be used together with other 13x75mm test-tubes if the blood volume is at least 250uL and the following shrewdness: turn upside down each tube and give a flip to the cap for bring down the blood towards the cap just before loading the tube into the rack

Pediatrics Tubes compatibility; for any other kind of tube, please contact your Alifax Distributor

Operative performances:

- Instrument offers three mixing speeds (60 rpm, 32 rpm, 24 rpm) and the analysis time per each sample is 20 seconds. Sample mixing is done by a full rotation of the sample tubes.
- Using a speed of 60 rpm and 140 mixing cycles is possible to process up to a maximum of **126** samples hour without considering the time required to load/unload samples from instrument. At this specific speed (60 rpm and 140 cycles) first result is available after 2,3 minutes of mixing and 20 seconds of analysis; the other results (from 2nd to 18th) are obtained each 20 seconds.
- Using a speed of 32 rpm and 140 mixing cycles is possible to process up to a maximum of **100** samples hour without considering the time required to load/unload samples from instrument. At this specific speed (32 rpm and 140 cycles) first result is available after 4,4 minutes of mixing and 20 seconds of analysis; the other results (from 2nd to 18th) are obtained each 20 seconds.
- Samples mixing is done at the beginning of the analysis with the purpose of disaggregating erythrocytes. A possible ineffective disaggregation could affect the results given by the instrument which measures system is based on the detection of the kinetics of aggregation of the red cells.
- To obtain an appropriate homogenization of the sample, set the instrument at medium speed (32 rpm) and 140 cycles.
- The above throughput could be reduced in case of connection to the Host Computer with reply output time more than 1 second.
- Audible alarm in case of error or malfunction: The instrument emits a series of 62,5dBA sounds until the error is solved.

Capacity: 20 position wheel, 18 positions for samples plus 2 positions for washing test tubes.

Analytical performances (obtained with 3 ml Test-tubes):

Trials made using TEST1 as comparison instrument **[1]:**

Correlation: R^2 = 0.97, Slope: 0.942

Repeatability:

Evaluated by performing 5 replicates using the same samples ob blood **[2]**

ESR values range (mm/h)	N° Samples	Coefficient of Variation (%)
~ 0 – 20	10	8.96
~ 21 - 40	11	4.06
~ 41 - 60	8	2.78
~ 61 - 80	5	2.70
~ 81 - 120	3	2.38
	37	4.99

To do this evaluation, has been used 37 samples, obtaining a mean CV% = 5% ranging from ~ 0 - 120 mm/h

Stability of samples stored for 24 h at room temperature:

In order to view the effects of different methods of storage on the ESR value, 272 K_3EDTA-anticoagulated whole blood samples, some of which have been stored at 4 °C and some others at room temperature, have been analyzed after 4 hrs and after 24 hrs on TEST1 device.

Good correlation was found between the results taken at 4 hrs and those taken at 24 hrs on the samples stored at 4 °C (r=0.980). Those stored at room temperature did not correlate quite as well as those stored at 4 °C, but still had very good correlation (r=0.917) **(3)**.

Method limitations:

1. The phenomenon of erythrocyte sedimentation is related to the fresh blood sample, and is transient (9). It is therefore not a corpuscular or molecular component of the blood sample.
The procedures for the determination of ESR are subject to multiple variables, with different degrees of influence.
The ESR instrumentation of Alifax, as demonstrated by numerous scientific studies, thanks to its technological innovation, has been able to overcome many of these variables, completely cancelling some of them (e.g. verticality of the measuring device adopted by the classical Westergren technique, temperature, vibrations). and making others almost negligible (e.g. low sample hematocrit value).
For this reason, when conducting analyses comparing methods and technologies different from those used by Alifax ESR instrumentation, it is recommended to consider the influence these variables have on the above methods.

2. "Erythrocyte sedimentation remains an only partly understood phenomenon….is a nonspecific reaction (from a clinical point of view) …" **(9)** that is affected by several technical aspects (5). "The ESR is often normal in patients with cancer..." (5).

International guidelines for diagnosis and management of multiple myeloma do not mention the Erythrocyte Sedimentation Rate (6). However, there are national guidelines that include ESR together with other clinical tests. It is then necessary to point out that even though TEST1 analytical performances have been confirmed in patients affected by multiple myeloma (7;8), there have been some cases of patients affected by multiple myeloma in which TEST1 Laboratory ESR Analyser has reported clinically negative ESR values in comparison to other methods.

Furthermore, in presence of these disease and/or other oncological pathologies it is possible to observe deviations from other methods since other phenomena in addition to the rouleaux formation can contribute to the sedimentation like for example amorphous aggregates formation (crystallization of paraproteins or mineral materials like calcium) resulting from bone tissue alteration.

It is then highly recommended to perform other tests together with TEST1 ESR in the diagnosis of cancer since a normal ESR value is not enough to exclude that the patient is not affected by this pathology.

3. Samples mixing is programmed at the beginning of the analysis with the purpose of disaggregating erythrocytes. An inefficient disaggregation could affect the results given by the instrument that in fact measures erythrocytes aggregation kinetics.

4. The above instrument performances have been obtained using test tubes with a capacity of 3 ml and 13x75 mm size with K_3EDTA anticoagulant. This kind of tubes has a sufficient air volume that favours the blood homogenization and consequently the results reproducibility.

ENVIRONMENTAL AND PYSICAL SPECIFICATIONS

Permissible environment conditions for operation:

Temp. from +10 to +30°C. (+50 / +86 °F),
Humidity from 15% to 85% - no dew

Permissible environment conditions for transportation and storage:

Temp: from -20 to +65°C. (-4 to +149 °F),
Humidity: from 5% to 95% - no dew, no frost

Size and weight:

Width:	32 cm (12,60 in)
Depth:	56 cm (22,05 in)
Height:	58 cm (22,83 in)
Weight:	23,2 Kg **(**51,15 lb)

PRODUCT TECHNICAL DATA SHEET
ROLLER 20-LC

Rev.2.0 – Effective from 2022 May 25

Packaging: Cardboard box

Width: 41 cm (16,14 in)
Depth: 64 cm (25,20 in)
Height: 65 cm (25,59 in)
Gross Weight: 35 Kg **(**77,16 lb)
Volume: 0,1706 m^3 (6,025 ft^3)
Pallet: No

ELECTRICAL SPECIFICATIONS

Voltage: 230 Vac ± 10% or
115 Vac ± 10% selectable with voltage selector

Power cons: 100 VA, about 56W
Switch on cons: 225 VA, about 135 W

Frequency: 50 or 60 Hz ± 2 Hz

Classification: Class I (EN61010-1 – IEC 1010-1 – CEI 66-5); OVC II

OTHER OPERATIVE SPECIFICATIONS:

Heat dissipation in the environment: about 190 BTU/hour

Noise: 54,0 dB(A)

Maximum rated altitude: 3000 mt asl

Communication: 2 serial RS232 DB 25 ports located on the rear side of the instrument:
Port 1 is dedicated to connect an external scanner
Port 2 is dedicated to connect the instrument to an Host Computer

Functioning: The instrument is designed to remain switched ON 24 hours a day, it is however suggested to switch it off at the end of the working day, applying previously a washing procedure using 3 washing tube to ensure a long capillary's and sensors' life.

Restrictions: Instrument engineer for Indoor and dry environmental uses appliance,

Rated pollution degree: Grade 2

Working life of the instrument: 10 years (if maintenance is done correctly)

CONSUMABLES

Printer Paper: Thermal roller 57 mm (2,244 in) x 25 meters (82 ft) (code **SI19580001** 4 rolls)

Smart Card: Conform to ISO 7816-1 specifications - 85.6 x 54 x 0.8 mm (3,337 x 2,126 x 0,0321 in) - coded using Alifax proprietary algorithm.
Available for 1,000 (code **SI 195.901**) - 4,000 (code **SI 195.904**) - 10,000 (code **SI 195.910**) - 20,000 (code **SI 195.920**) tests/ Universal Card for the TEST1 family instruments TEST1 (TEST1, MicroTEST1, Roller20LC, Roller20PN, Roller20MC, Roller10PN).

Waste Tank: 250 ml plastic waste tank with screw cap (code **SI10280101)**

INTERNAL QUALITY CONTROL

Latex Controls: With the purpose of guarantee an always optimum performance of the instrument, the daily use of the latex control kit is recommended.

Latex Controls for TEST 1 family analysers allow the control of the calibration stability of TEST1 (TEST1, MicroTEST1, Roller20LC, Roller20PN, Roller20MC, Roller10PN and JO-PLUS. They are available in two kinds of test tubes:

- 13x75mm (0,512 x 2,953 in Greiner:
  Latex Controls (6 tests) - code SI 305.100-A;
  Latex Controls (30 tests) - code SI 305.300-A.

- 11,5x66mm (0,453 x 2,598 in) Sarstedt:
  Latex Controls (6 tests) - code SI 305.102-A;
  Latex Controls (30 tests) - code SI 305.302-A.

VARIOUS / OTHER FEATURES

Patient identification: External CCD bar-code reader (**SI195820**).

Common features:
- New design with thermoplastic cover, front door for an easier access to waste tank and to the needle.
- Simplified-needle replacing procedure with magnetic unlocking and screw needle
- Automatic rotation of the wheel during the test-tube insertion / removal.
- Automatic priming at the end of the mixing cycle.
- Simplified Smart Card downloading using a single operation.
- Automatic washing if no blood flux is detected after three successive test-tubes.
- Automatic washing at the end the analysis cycle (programmable from 0 to 99 minutes).
- Photometer check at the end of each washing to ensure continuous control of instrument.
- Management of Latex Controls Kit for TEST1 family analyzers SI 305.100-A/SI 305.102-A (6 tests) – SI 305.300-A/SI 305.302-A (30 tests) for the control of the calibration stability of the instrument.

REGULATORY INFORMATIONS:

Classification	IVD	
UDI-DI (GTIN14)	08056040142684	
CND Code	W02029001	APPARECCHIATURE PER VELOCITA` DI ERITRO-SEDIMENTAZIONE
FDA-CFR Code	Product code: GKB	Regulation Number: 864.5800 Automated sedimentation rate device
GIVD Code	23.09.10.01	Other_HHIHC Hardware + accessories + consumables + software
GMDN Code	56691	A mains electricity (AC-powered) laboratory instrument intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen. The device operates with minimal technician involvement and complete automation of all procedural steps.

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(8) Mercurio S. et al.: "Confronto tra due metodi per la determinazione della VES in pazienti con mieloma", 37° Congresso Nazionale SIBioC, 11-14 ottobre 2005 Roma

(9) H02-A5 vol 31 No.11 PROCEDURES FOR THE ERYTHROCYTE SEDIMENTATION RATE TEST; APPROVED STANDARD – FIFTH EDITION

(10) Automated measurement of the erythrocyte sedimentation rate: method validation and comparison Ivana Lapić*, Elisa Piva, Federica Spolaore, Francesca Tosato, Michela Pelloso and Mario Plebani Clin Chem Lab Med 2019

(11) ICSH recommendations for modified and alternate methods measuring the erythrocyte sedimentation rate Kratz . Plebani M. Peng Y.K. Lee R. McCafferty S.J. Machin on behalf of the International Council for Standardization in Haematology (ICSH) – International Journal of Lab Hematology

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