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USER MANUAL

Valid for ref code: SI R20-PN
with all Versions of Software 5.00X

Quantitative Capillary Photometry for the Erythrocyte-Sedimentation Rate (ESR)

In Vitro Diagnostic Medical Device for professional use

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Note: The paragraphs written with the italic characters (as on this note), have been added or modified respect to the previous version of the manual; the same is true in case the chapter appears in blue in the index, this means the chapter has been added or there changes done inside this chapter.

We reserve the right to make changes in the course of technical development without previous notice.

1.0 - 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

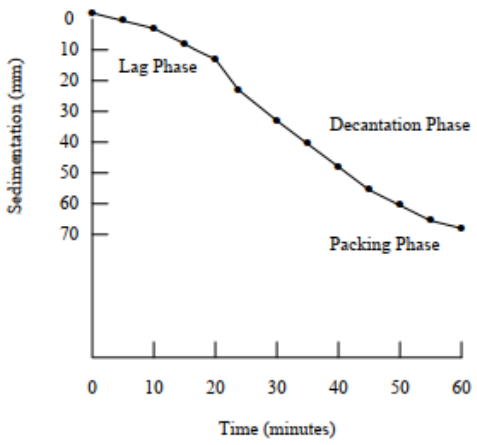


Figure 1. Sigmoid Sedimentation Curve. Evolution of the erythrocyte rouleaux formation in the different phases of ESR in a case with a high level of acute phase proteins.

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 < 30%. 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.

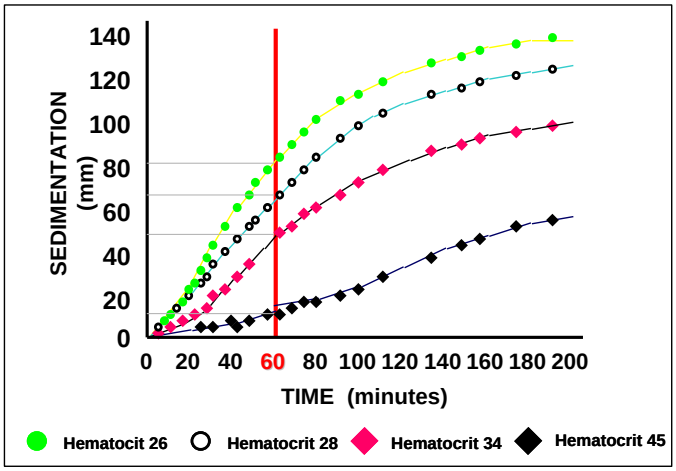
Adaptability to laboratory workflows
The operator loads the samples into the instrument using the same racks coming from the cell counter, for a total capacity of 4 racks in continuous access, without any manipulation of the single tube by the operator. The racks and tubes will be returned by the instrument 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**

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

DANGER

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.

WARNING

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.

CAUTION

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.

CAUTION

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.

NOTE

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

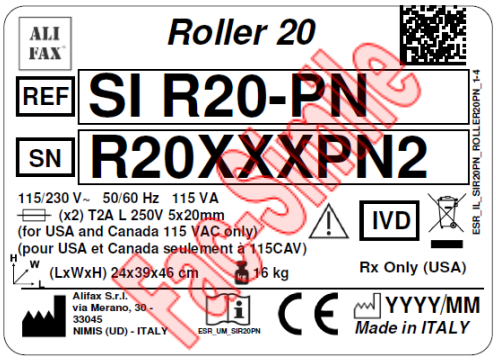
Serial number

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

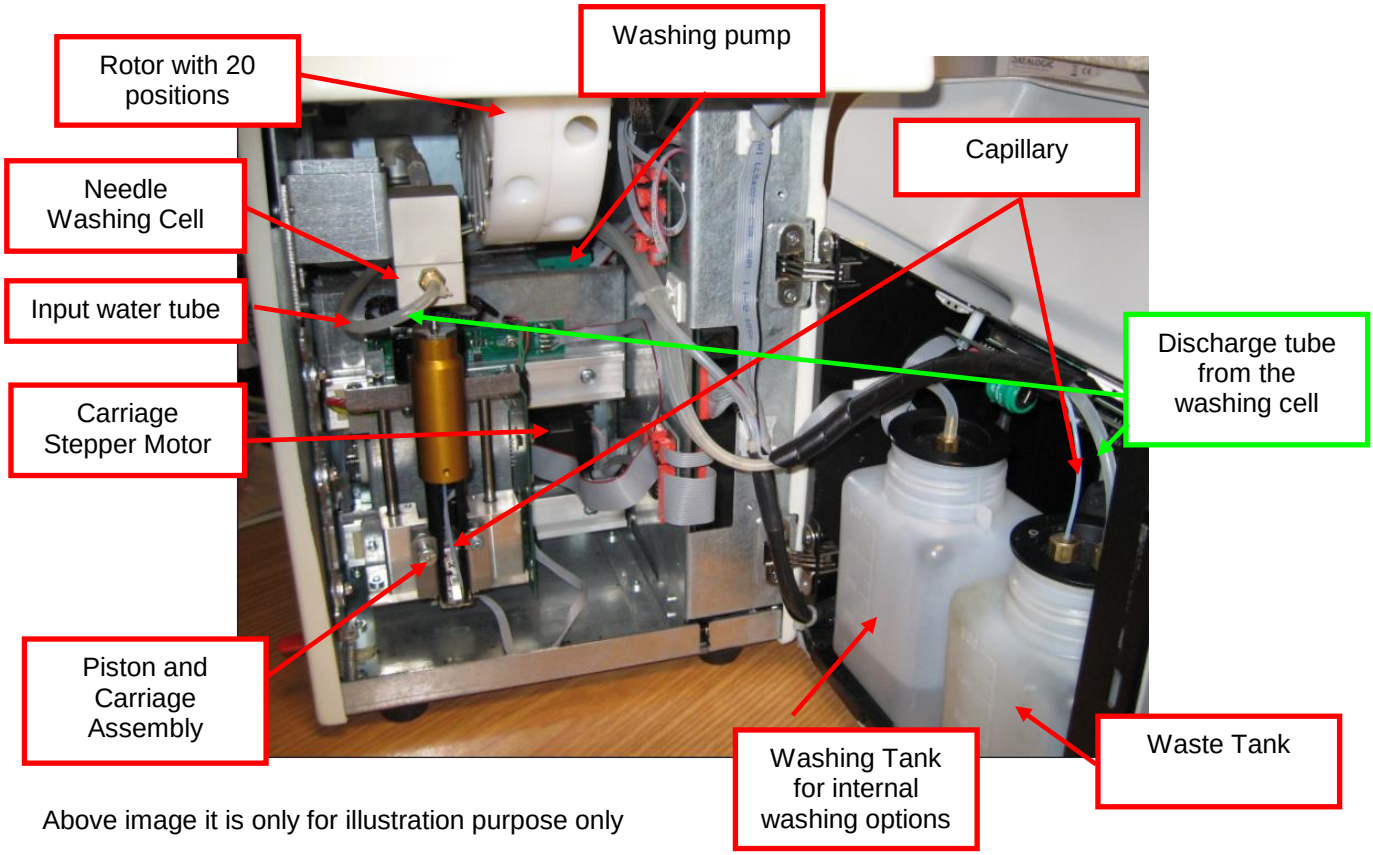
NOTE Following labels refers to Roller 20PN and contains between others the reference serial number of the instruments



Rx Only (USA) Explanation:
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

ROLLER PRESENTATION

ROLLER INTERNAL VIEW

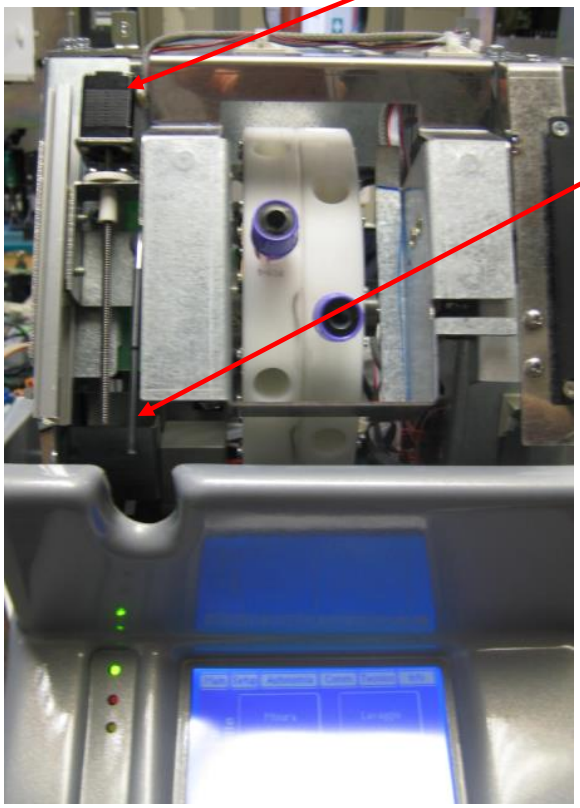


Above image it is only for illustration purpose only

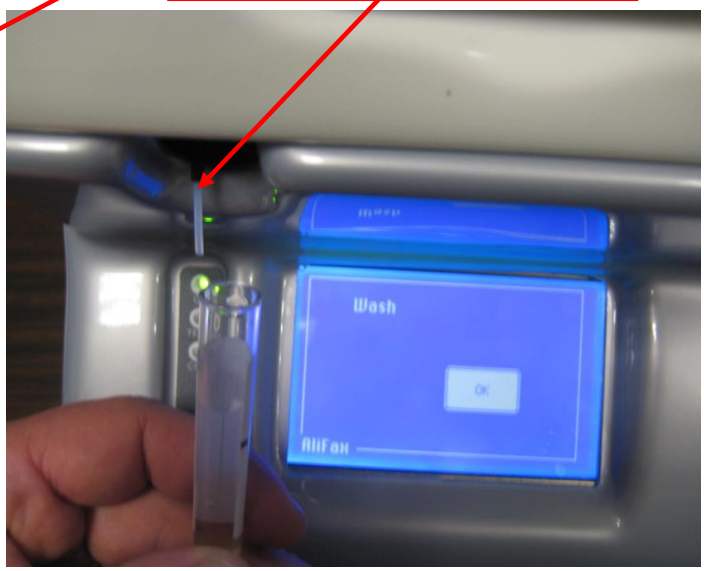
Water and Waste tanks: the Automatic Washing System requires the use of a tank containing distilled water for the cleaning of the hydraulic circuit and a waste tank.

It is suggested to check and refill water tank in average every 2 days and in any case verify also its level every time the waste tank is disposed; waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use.

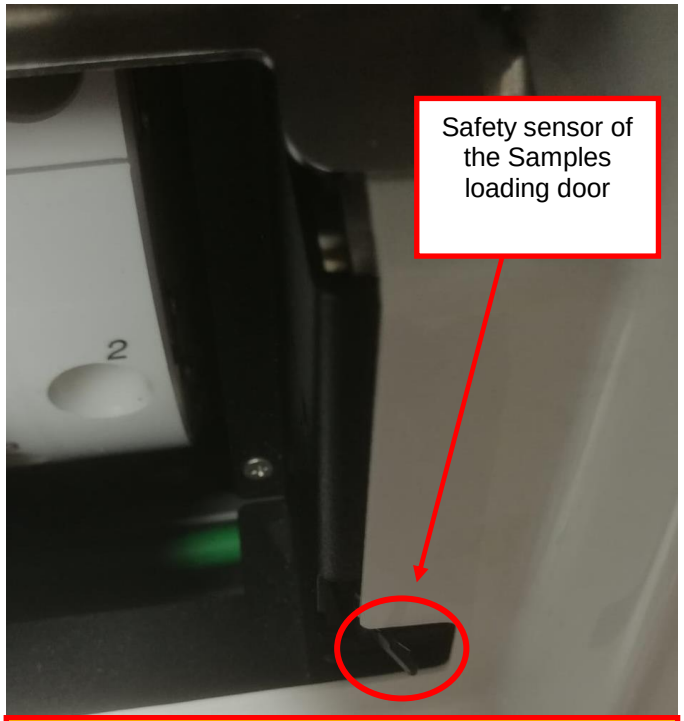
External Tip motor



Retractable Tip for external withdraw (useful for tubes with plastic cap and/or paediatric tubes)



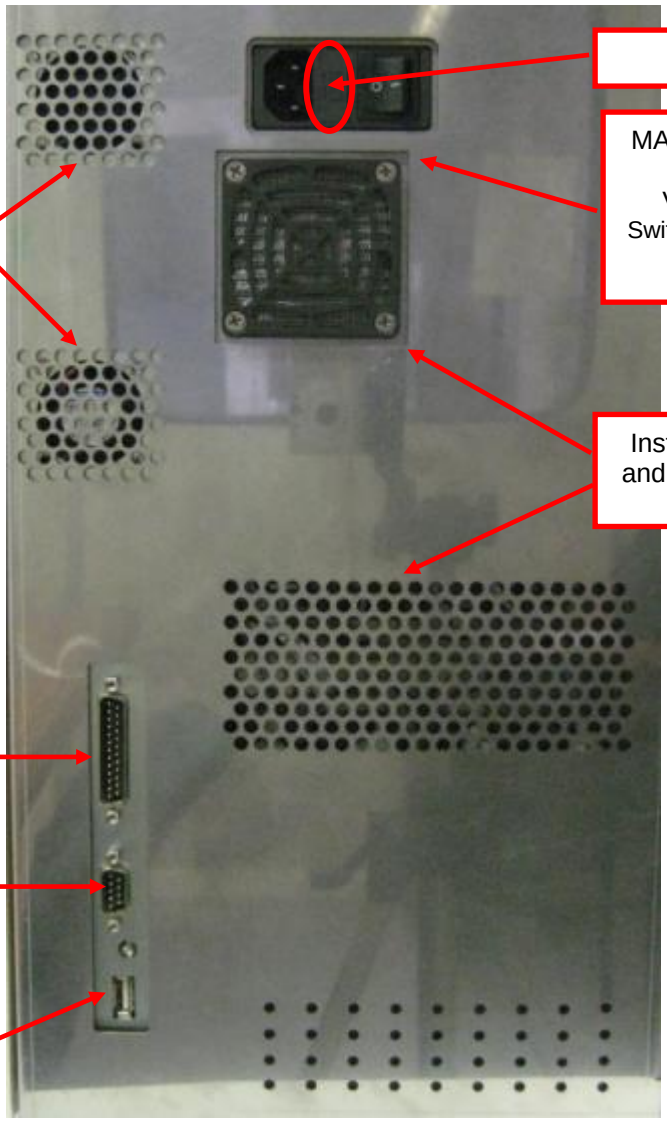
Inside detail of the Samples loading Door.



Safety sensor of the Samples loading door

Warning: pay attention while closing the door, an indelicate operation could break the sensor

ROLLER REAR SIDE VIEW and MAIN FUSES REEPLACEMENT



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
- Remove completely the fuse box and replace BOTH fuses (*)
- Insert again the fuse box inside the Main Switch block pressing it firmly to assure the box's tongue fits on the hook.

FUSE-FUSIBLE
T2A L 250V 5x20mm

(*)
The fuse which is placed in appliance inlet shall be replaced only by a T2A L 250 V dimensions 5x20 mm.
A T2A L 250 V it is suitable for both 115 and 230 Vac.

(**) See page 15 "Transient Emissions and Interference"

INSTRUMENT PLASTIC COVER REMOVING

To remove instrument's plastic cover proceed as follows:

Remove the 4 screws using a Phillips screw driver and then unthread the cover form the instrument pulling a bit both sides and then lifting up the whole plastic cover.

Remove the 2 screws located at the instrument's upper rear side using a Phillips screw driver, there are also two screws located below the loading door, these also must be removed, then unthread the metallic cover pulling toward you and then lifting up.

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.

Roller 20-PN 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.

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 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
- TEST1 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 level of the discharge tank before starting the measurement operation. If the tank has reached the safety level, dispose of it or empty it, following the safety regulations and procedures in the laboratory and 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) on allmodels 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

WARNING

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 authorised 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 peripherals authorized by the Manufacturer

WARNING

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

DANGER

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.

WARNING

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 on a dry surface 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.

DANGER

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.

DANGER

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.

WARNING

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.
- Battery for computer SI205001 is aNi MH #MH60B3AL3; a 3,6 V e a 60 mAh.

NOTE

Transient Emissions and Interference Resistance

The instrument meets the requirements described in standard IEC 61326 and IEC61326-2 on transient emissions and interference resistance.

- 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
- Peripherals to be connected to the ports on the rear side of the instrument (see page 9) must comply with IEC 60950-1 or IEC 62368-1 for IT equipment (to comply with clause 6.6.1 of the standard).

BIOLOGICAL SAFETY

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.

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.**

Maintenance

During Maintenance/ Technical Service activities be sure to:

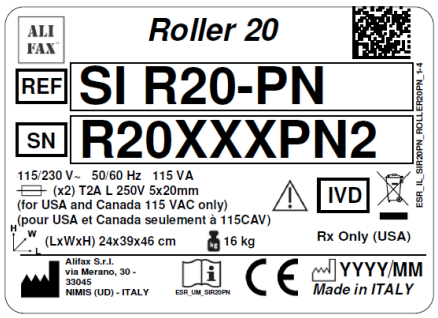
- **use gloves to protect agains any possible accidental contact with infectious materials presents inside instrument .**
- if during maintenance the instrument has been stored /moved to a cold places, wait at least 30 minutes before switching ON again the instrument for the first time in order to avoid 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

2.0 - LABELS

WARNING

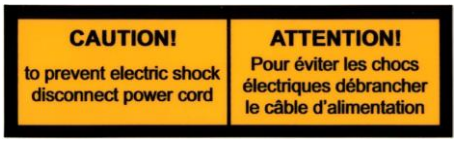
THE FOLLOWING LABELS ARE STUCK AS WARNINGS ON THE INSTRUMENT AND MUST NOT BE REMOVED..

Instrument plate 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

Biohazard label with indications about tank replacement

Washing tank label

Biohazard label with compulsory use of gloves

Accidental puncture hazard label when changing the needle

Moving part identification label

Voltage identification label

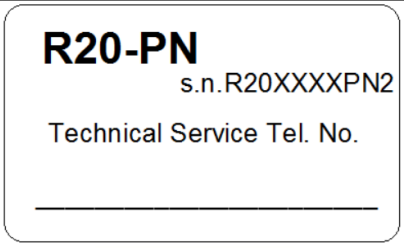
Fuse indication label

Washing tank reference label

Waste tank reference label

Instrument identification label

Label for technical assistance number



Logo Alifax

Push label

ETL conformity label

EAC conformity label

EAC

PROCEDURE OF INSTRUMENT WASTE AT THE END OF ITS OPERATIONAL LIFE

	As stated in the European directive 2012/19/EU 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.

3.0 – UNPACKING

NOTE The unpacking of the instrument is done directly by Alifax (or local Distributor) Field Service Engineer

4.0 – INSTRUMENT START-UP

INSTRUMENT DESCRIPTION and start-up

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

5.0 – WASTE TANK EMPTY / REPLACEMENT

Roller family uses an internal control system to check the level of waste tank:

- at every switch ON of the instrument
- ALWAYS PAY ATTENTION WHILE CLOSING AND OPENING THE TECH. DOOR, TO AVOID ACCIDENTAL DAMAGE TO THE TUBING.
- at every washing procedure start-up
- at the beginning of every cycle of analysis the instrument controls the level of liquid inside the waste tank, using the peristaltic pump to aspire from the tank. If the pump aspires material, the reading unit detects the presence of the material and blocks the operation of the instrument, informing via display that the waste tank needs to be replaced.
- It is important to NOT REMOVE/CUT waste tank discharge tube because the length is designed specifically for measure safely the level of the waste tank and advise the operator to replace the tank.

Waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use.

6.0 – WASHING TANK LEVEL CONTROL

This tank doesn't have any kind of liquid level control, it is suggested at least once per day check the level of washing water inside the tank.

7.0 – INCREASE AVAILABILITY TEST USING THE SMART CARD

All Alifax instruments need a personalized smart card in order to enable the analysis of blood for the ESR determination. The instrument is supplied with 200 test for first demos and first analysis, but a warning message is displayed at the begin of each analysis session alerting the user that test availability increase is required.

When the prefixed threshold alarm is **reached by ESR** parameter, display will show a warning message requiring to increase the availability. All the other test will be also automatically increased.

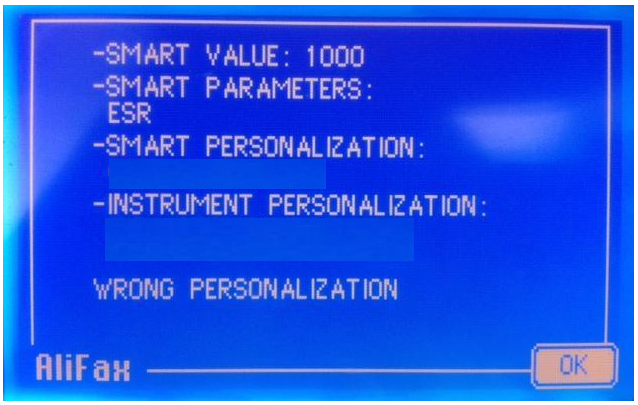
Instrument allows to go in negative availability only one time; supposing the ESR availability is 1, instrument allows to run up to 20 samples and goes in a negative availability of -19; at the next test increase, the availability of test will be discounted by 19 tests.

To increase availability, it is necessary to be in **MAIN SCREEN (**if the card is inserted while the display shows a different menu, it will not considered) then insert the appropriate smart card in the reading slot, facing the card with the integrated circuit toward the left side, like displayed on the picture on chapter 7.1

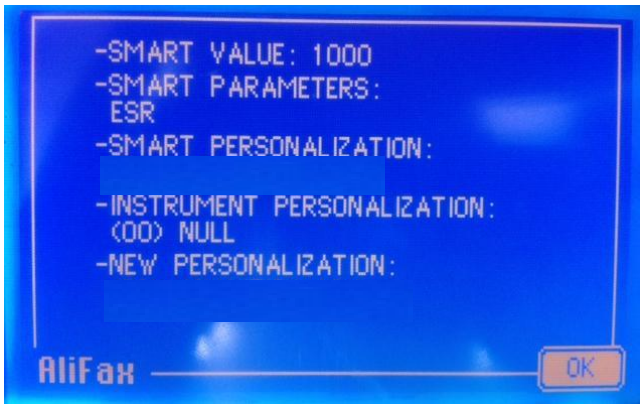
The instrument will printout and display the current availability, only for the credits enabled:

then will check the personalization, the number of credits and which type of credit are enabled:

- If the instrument's personalization is different from the one programmed in the card it will reject the card. Then after pressed "**OK**" the instrument asks to remove the card and comes back to Main Menu. In this case the credits don't increase.



- If the instrument have no personalization, it will acquire the one set in the smart card. Then after pressed "**OK**" the instrument asks to remove the card and comes back to Main Menu. In this case the credits increase as is possible to see in the printout.



- If the personalization is the same as the one stored in the card, the instrument, after pressed "**OK**", asks to remove the card and comes back to Main Menu. In this case the credits increase as is possible to see in the printout.

If, for some reason, the card inserted is defective the instrument will show a message informing about that, then after pressed "**OK**", the instrument asks to remove the card and comes back to **MAIN MENU**.

In case of not properly card loading: possibly malfunction causes are explained in chapter 7.1.

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

7.1 – SMART CARD ERRORS

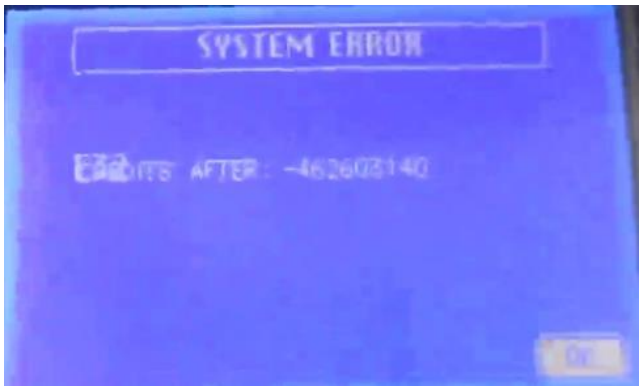
The possibly malfunction causes usually are:

1. The smart card is not properly inserted (upside-down) or the Card contact plaque wouldn't be in the lower position faced to the instrument.
2. The reader contacts don't allow the Card to be read.
3. **Out Std error** means the card has a number of tests that is outside the normal ranges: 1000 – 4000 – 10000 – 20000
4. **Not valid Card** means the card has already been previously loaded, so the instrument is not able to load again, or the card is not personalized for this instrument.

If the instrument displays error OUT STD 24384 means the card has been inserted upside down or with the contacts facing the left side instead the right side

Please refer to **Chapter 9.3** to see the complete and detailed explication and procedures to set the warning level and to see the availability.

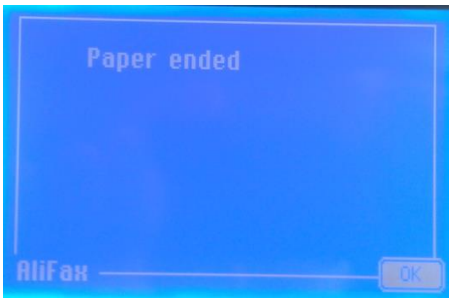
Please notice, with new Software 5.00A, in case during the smart card insertion or during the downloading of the credits from smart card to instrument, one or more of the following error can happen:



Refer to troubleshooting at chapter 11, errors 31, 32 and 33.

7.2 – PAPER ROLL LOADING - REPLACEMENT

In the event the paper ends, instrument shows on screen a message informing paper has ended.



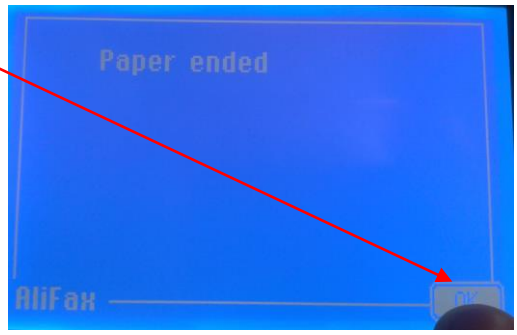
Replace the roll is simple and quick:

Pull the plastic lever of the printer, lift up the plastic cover and remove the plastic core (is present) of the old roll:

Keep the plastic cover up and insert the new roll of paper being sure to pull it a bit in order to allow paper being captured and pressed by printer's rubber roll.

Close the plastic cover and press the "advance paper" button to check if paper is coming out correctly.

after that press OK on the display



Wait while instrument finishes the internal checks; at the end Main menu will be displayed.

8.0 – SWITCH ON

Start the instrument by pressing the switch on upper backside; 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°±0.5°C (98.6°±0.9°F)
The instrument automatically will start the internal check up and then display will show the following image:

then, depending the kind of Roller configured, will be changed, in this case (Roller 20 PN).

This instrument is controlled using the “Touch Screen”, each option, function, process will be activated/deactivated simply touching the screen in the corresponding “button”.

Available buttons are displayed in the upper screen side:

- **Main:** allows accessing to common use functions like measure, wash, mixing, and Quality Control
- **Setup:** allows accessing to some common use functions like date&time, mixing parameters and also to specific functions protected by passwords (accessible only to technical service)
- **Availability:** allows accessing to set the test credit warning alarm and also to printout the availability of credits
- **Comm:** allows accessing to communication functions protected by passwords (accessible only to technical service)
- **Tech:** allows accessing to the whole Technical Menu, protected by passwords (accessible only to technical service)
- **More:** allows accessing to some info, like useful information and technical phone numbers, or to the data of the last session

To be even more user friendly, as you can see, the main screen sets up ready to uses highlighting the **4 main buttons** in order to allow the operator begin analysis without necessity to **“look around”** for the operative buttons.

9.0 – MENU DESCRIPTION

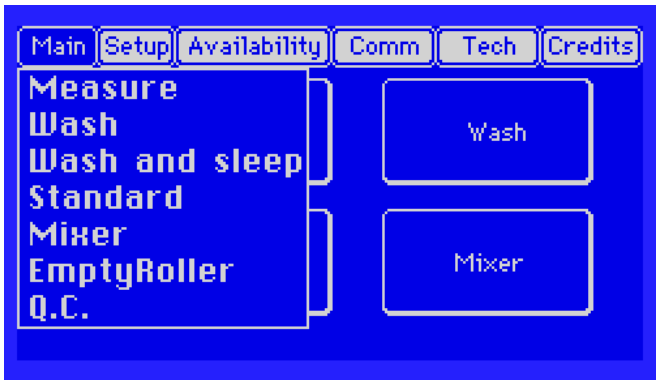
In the next pages will be explained the functionality of each menu.

WARNING!! Remember that not all the functions inside each one of the menus are freely accessible; the instrument has four levels of access:

Level 1 Operator Access:	free without password can access only some functions like date & time
Level 2 Coordinator:	require password can access Level 1 and the Setup functions
Level 3 Technical Service:	require a password, allow access to all functions; this password is **ONLY for Technical Service and Alifax Manufacturing dept**.

9.1 – MAIN MENU

Main Menu:
Pressing "**Main**" in the **MAIN SCREEN,** the instrument shows the following options



9.1.1 – MEASURE MENU

Measure:
Pressing the option **"Measure"**, the instrument, offers these possible options:

- Internal normal withdrawing;
- Internal pediatric withdrawing (only if pediatric flag is enabled);
- External normal withdrawing;
- External pediatric withdrawing (only if pediatric flag is enabled);
- External withdrawing without mixing.

Then, independently from the option previously chosen, the instrument checks the state of the rotor, controls the level of the waste tank, controls the availability of credits and requires to identify and load the samples to be analyzed.

9.1.1.1 – PATIENT IDENTIFICATION BY External Bar Coded Reader

If the sample is identified by a BCR, read using the external scanner the instrument will show the red ID number on the screen and after that will move ahead 1 position the rotor in order to allow the sample insertion.

WARNING!! The tube MUST be inserted **ONLY AFTER** the instrument shows on the display the read ID as in the following example:

If by mistake has been read the wrong patient ID, just pressing "**Back**" is possible to read again the correct one.
To insert the tube open the tilting door, insert the tube in the available tube holder; the instrument **has two sensors** to detect the presence of the tube's cap and also to detect the presence of fingers. If after few seconds the outer sensor still detect the fingers, the instrument will show on the display the following message:

Otherwise this one:

as is possible to observe, after the loading of the first sample, the instrument shows the "**Start**" button; pressing it the instrument start the analysis.
If more samples are required to be analyzed just repeat the procedure or reading ID using the EBCR.

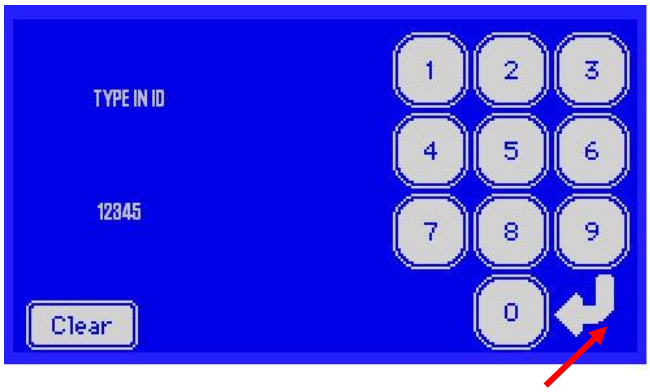
This means that the instrument is ready to read the next sample's ID by EBCR or, by **pressing**:

Start: The instrument will start the analysis cycle
Back: Will ask to remove all the previous inserted tubes, checking one by one they has been removed

9.1.1.2 – MANUAL INSERTION OF THE PATIENT ID

If the instrument doesn't have an external bar code reader (EBCR) but in any case the sample is identified by a barcode label, it is possible to load sample's ID by "keyboard" as explained in this chapter.

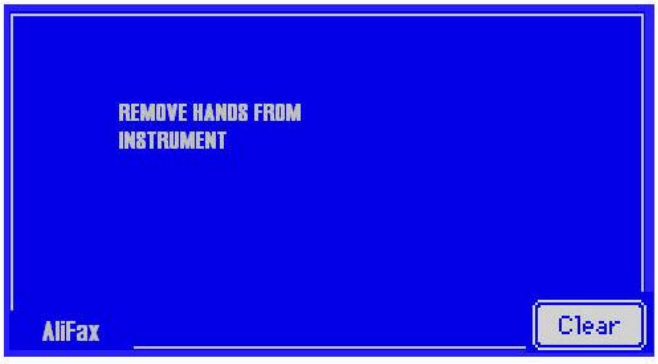
After have pressed "**Measure**" in the Main Menu, the instrument shows the following message:



now pressing **"Manual ID"** the instrument allow to type manually the sample's ID then, pressing "**ENTER**" (in this case the left arrow) the instrument will ask to insert the tube, then pressing "**OK**" the instrument shows this message and moves the rotor to the corresponding position to allow the operator insert the tube.

If by mistake has been written the wrong patient ID, just pressing "**Back**" is possible to write again the correct one.

To insert the tube open the tilting door, insert the tube in the available tube holder; the instrument **has two sensors** to detect the presence of the tube's cap and also to detect the presence of fingers. If after few seconds the outer sensor still detect the fingers, the instrument will show on the display the following message:



Otherwise this one:

as is possible to observe, after the loading of the first sample, the instrument shows the "**Start**" button; pressing it the instrument start the analysis.

If more samples are required to be analyzed just repeat the procedure.

This means that the instrument is ready to read the next sample's ID by EBCR or, by **pressing**:

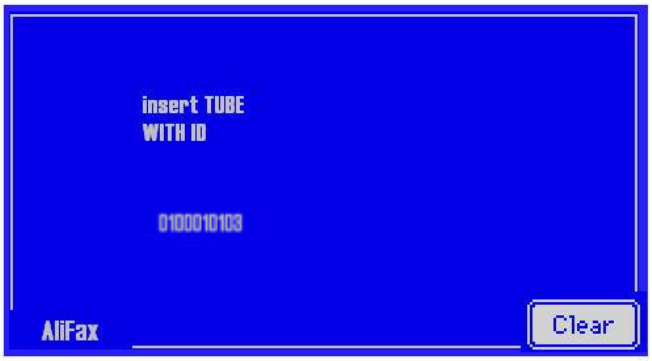
Start: The instrument will start the analysis cycle
Back: Will ask to remove all the previous inserted tubes, checking one by one they has been removed.

9.1.1.3 – AUTOGENERATED ID

If the instrument doesn't have an external bar code reader (EBCR) and/or the sample tube doesn't have a Bar Code Label, it is possible to insert the tube allowing the instrument to autogenerate progressive ID .

After have pressed "**Measure**" in the Main Menu, the instrument shows the following message:

now pressing **"Auto"** the instrument allow to type manually the sample's ID then, pressing, then pressing "**OK**" the instrument shows this message and moves the rotor to the corresponding position to allow the operator insert the tube.



To insert the tube open the tilting door, insert the tube in the available tube holder; the instrument **has two sensors** to detect the presence of the tube's cap and also to detect the presence of fingers. If after few seconds the outer sensor still detect the fingers, the instrument will show on the display the following message:

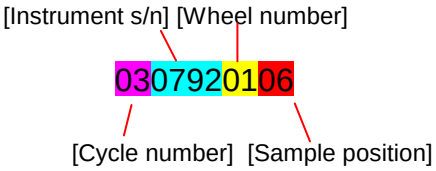
Otherwise this one:

as is possible to observe, after the loading of the first sample, the instrument shows the "**Start**" button; pressing it the instrument start the analysis.
If more samples are required to be analyzed just repeat the procedure.

This means that the instrument is ready to read the next sample's ID by EBCR or, by **pressing**:

Start: The instrument will start the analysis cycle
Back: Will ask to remove all the previous inserted tubes, checking one by one they has been removed

The autogenerated code is composed by a numeric sequence made by the following series of numbers: which represents the cycle number, the serial number of Roller, the wheel number and the position of tube in the rack (1÷10).
Print-out example:

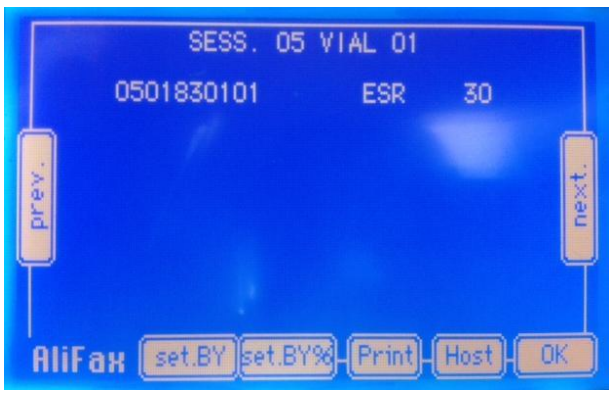


9.1.1.4 – RESTORE LAST SESSION

This function allows to restore the last session, in case of the instrument is switched off for mistake, for an error or for a black out. **Notice that this function doesn't work for external withdrawing without mixing.**
When this occurs, after switched on the instrument again, it after few second asks this question: "Restore last session?"

Then, is possible to choose if restore the session or no, in fact, pressing "**YES**" button, the instrument starts to mixing the champions and after continues with the interrupted session analysing the champions remaining.
Otherwise, pressing "**NO**" or "**Back**" button, the instrument definitively aborts the current session, asks to remove the champions and comes back to main menu.

In any case, when the instrument comes back to main menu, is possible to see the results of the last session, pressing "**Last session**", inside menu **More**.

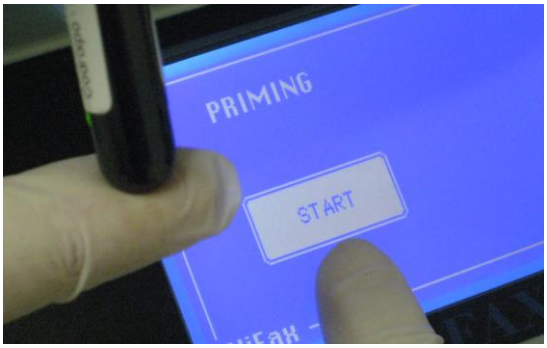


9.1.1.5 – EXTERNAL SAMPLING PROCEDURE, USING INTERNAL MIXING

When using the external withdrawal procedure, it is mandatory to use gloves and all the others protective tools, precautions and warnings necessary apt to avoid the contact in accordance with national laws.

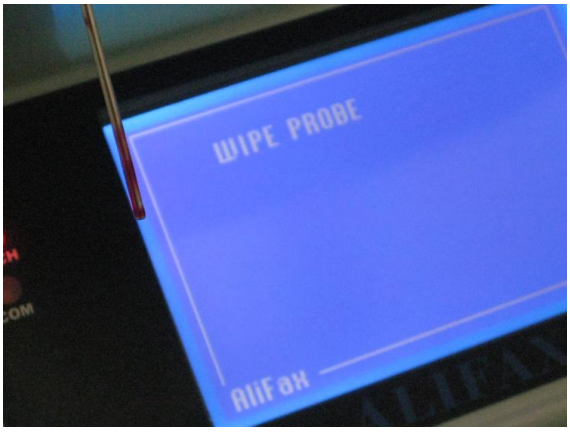
In case the option chosen is external sampling normal or pediatric (with internal mixing), the instrument will ask to load the samples and will mix them; then (after the mixing cycles have been executed) the instrument will require to remove the samples from the rotor.

ONLY If the analysis is done after a washing procedure, the instrument will execute a "Priming procedure".

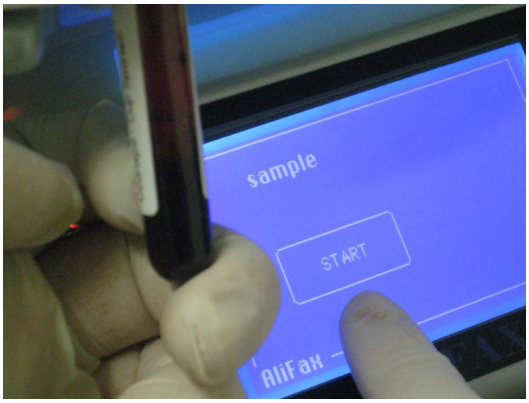


For the priming procedure, instrument will mix the blood loaded for the half of the total mixing cycles (in any case the minimum number of cycles done for mixing is not lower than 10), then the instrument asks to remove tube 1 and withdraw a small quantity of blood for the priming.
Take out tube from position 1, uncap, insert inside the external probe and press START. Instrument will take a small amount of blood form the tube**, then it will issue 3 beeps, this means the tube MUST be removed from the probe.**
Next the blood is moved inside the reading unit to prepare the capillary receive the blood. Meanwhile instrument asks to reload tube in position 1 and continues with the mixing cycles till reaches the programmed mixing cycles.
Note: Only with pediatric session, is possible to do priming with pediatric samples, with normal session, is mandatory to use a normal champion (adult champion) for the priming, in order to don't waste pediatric samples.

To clean the external tip, use simple paper without adding any kind of detergent. Clean gently the tip moving from the top to the bottom, do not pull too hardly in order to avoid to damage the tip. At the end of the priming procedure, the tip come back to home position.



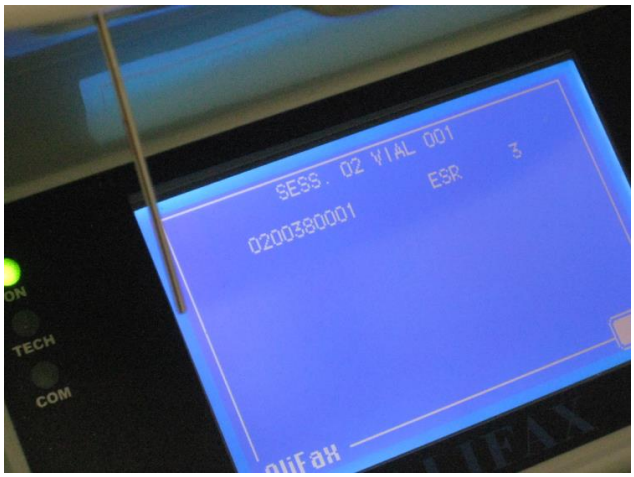
After the instrument has finished the mixing, will ask to remove from rotor the tube, then the probe will be moved out and (after having uncapped) insert the tube over the probe all the way down. Next just press START.

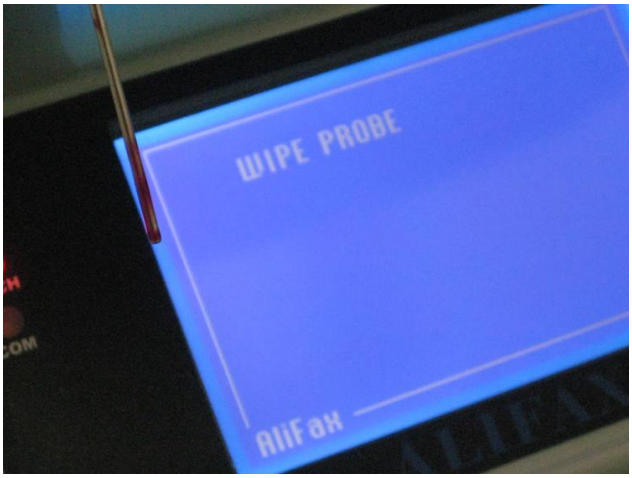


Note; when the aspiration is finished, instrument will beep 3 times, this means the tube must be removed from the external tip and recapped.

The tube can be reloaded on the rotor or left outside the instrument (external rack) for other eventual analysis.

During the analysis, the instrument will ask to clean the external tip. To clean the external tip, use simple paper without adding any kind of detergent. Clean gently the tip moving from the top to the bottom, do not pull too hardly in order to avoid to damage the tip.





Then the instrument will move the rotor to the next position and will ask to pick the next sample to be analyzed. During the session the instrument will display on the screen the results obtained. Based on the printer setup, the printer will printout the results in “real time” (that means after each single analysis) or globally at the end of the analysis cycle.

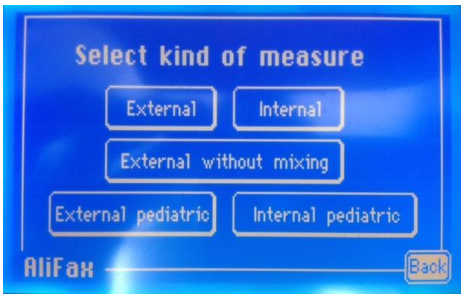
IMPORTANT:

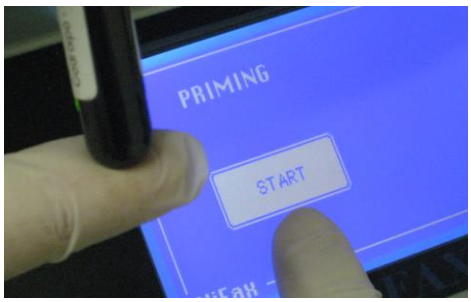
In case of use of the external withdrawing tip, it is mandatory to clean it following the washing procedure in order to avoid blood dries inside the tip causing the formation of blood clogs inside it. The tip must be washed within 10 minutes before last sample analysis.

9.1.1.6 – EXTERNAL SAMPLING WITHOUT INTERNAL MIXING

When using the external withdrawal procedure, it is mandatory to use gloves and all the others protective tools, precautions and warnings necessary apt to avoid the contact in accordance with national laws.

In case the option chosen is external sampling **WITHOUT MIXING**, it is mandatory to mix samples by means of a rotating wheel or a tilting bed set at 32 rpm and 140 mixing cycles to allow a suitable homogenization of the samples prior to the analysis.



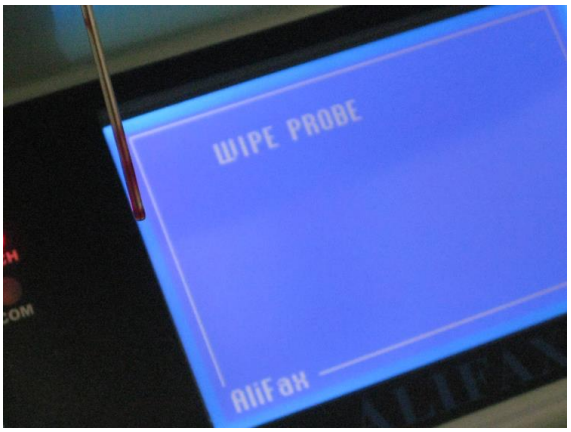


Then, ONLY If the analysis is done after a washing procedure, the instrument will execute a “Priming procedure”.

For the priming procedure, take a tube, uncap, insert inside the external probe and press START. Instrument will take a small amount of blood form the tube**, then it will issue 3 beeps, this means the tube MUST be removed from the probe.**

Next the blood is moved inside the reading unit to prepare the capillary receive the blood. Meanwhile instrument asks to reload tube in position 1 and continues with the mixing cycles till reaches the programmed mixing cycles. **Note: in case of pediatric samples that normally contain few blood, in order not to waste them, the withdrawal for the priming can be done using a previous analyzed sample or blood belonging to an adult).**

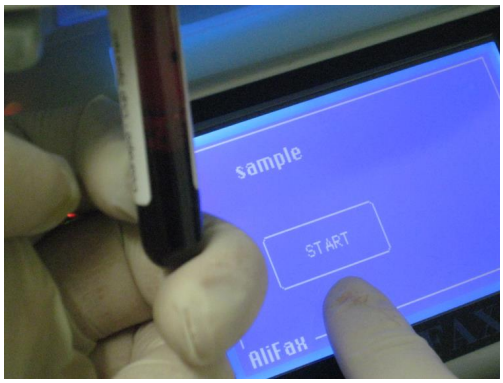
To clean the external tip, use simple paper without adding any kind of detergent. Clean gently the tip moving from the top to the bottom, do not pull too hardly in order to avoid to damage the tip.



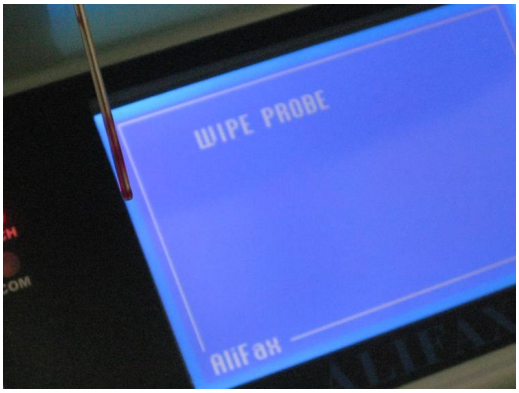
After the priming, instrument asks to identify the sample to be analyzed; as for the previous cases, the option are:

- Autogenerated ID
- Manual ID (typed manually)
- EBCR

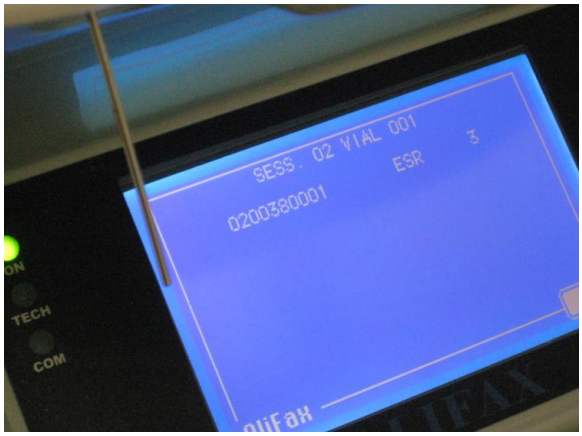
Once pressed OK instrument asks to sample the tube just identified previously; after pressing START the instrument will aspire the blood. In case of mistake, pressing the “BACK” button (not visible in the photo here displayed) instrument returns to previous screen were user can re-insert the ID.



Note; when the aspiration is finished, instrument will beep 3 times, this means the tube must be removed from the external tip and recapped.



During the analysis, the instrument will ask to clean the external tip. To clean the external tip, use simple paper without adding any kind of detergent. Clean gently the tip moving from the top to the bottom, do not pull too hardly in order to avoid to damage the tip.



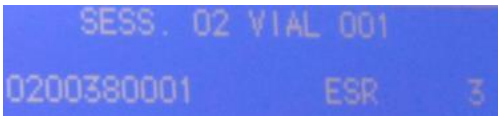
At the end of the analysis, instrument show on the screen the result (and also print it if the flag “print in run” is enable), than after press OK button, reappears the ID insertion screen and so you can choose if analyse another sample, or pressing BACK button, to end the session.

IMPORTANT:

In case of use of the external withdrawing tip, it is mandatory to clean it following the washing procedure in order to avoid blood dries inside the tip causing the formation of blood clogs inside it. The tip must be washed within 10 minutes before last sample analysis.

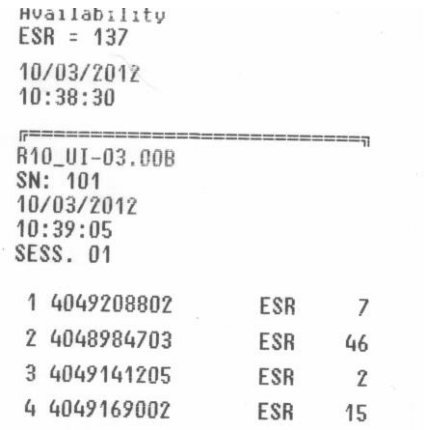
9.1.1.7 – ANALYSIS RESULTS (Display and Printouts)

After the sample analysis (independently of the internal or external withdrawal) the instrument will show on display results and also printout each sample analysis’s result.



During the analysis the instrument will display on the screen the result obtained. Based on the printer setup, the printer will printout the results in “real time” (that means after each single analysis) or globally at the end of the analysis cycle.

The printout result looks like the one showed here:



For each session is reported:
Date and time of analysis
Session number (01 = first session of day)

Then for each sample is printed its position inside the rotor, patient’s ID and the ESR results expressed in (mm/h)

NF message generated because of missing blood flow into the capillary 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 or eventually air bubbles thus the instrument is not able to identify presence of blood inside reading unit.
Details in APPENDIX A on page **81**

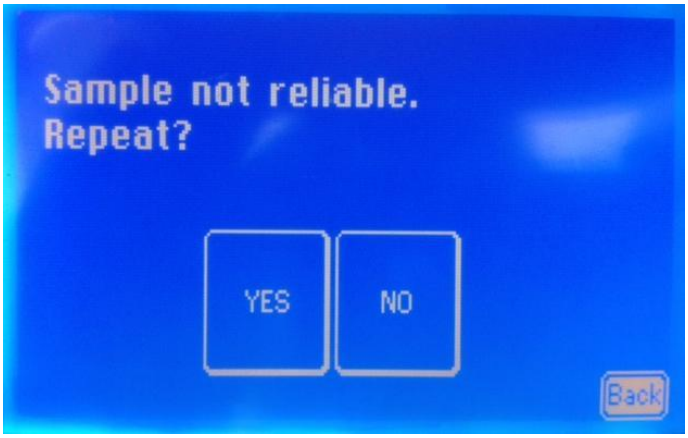
NR (**N**o **R**eliable) message generated because even if blood is inside reading unit, no aggregation is detected or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube It is suggested to repeat the analysis indeed a second mixing sequence in some cases helps the blood desegregate well. Details in APPENDIX B on page **81**

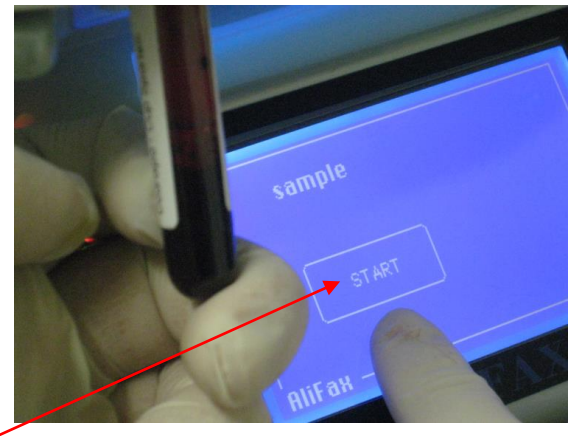
Attention, if the waste tank is full (the control is executed automatically by the instrument before beginning a new session); Waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use of the waste tank before starting a new session; otherwise, the instrument remains in standby until when the waste tank is replaced / emptied.

9.1.1.8 – ANALYSIS RESULTS DURING SECOND TAKE OF SAMPLE AND SAMPLE MISSING

This function allows, in case of the champion value is not detectable [NF (-4) / NR (-2)], to try a second taking.

With external withdrawing (normal, pediatric or without mixing) the instrument asks to following a specific procedure.
When the value of one sample is not detectable, the instrument shows this screen:



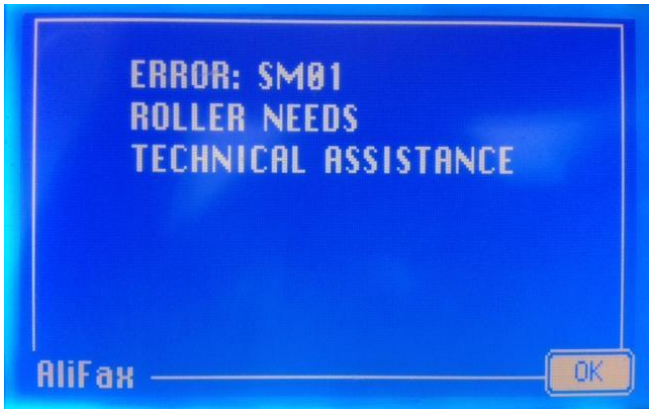


Then, is possible to choose if analyse again the sample or no, in fact, pressing "**YES**" button, the instrument asks to analyse again the sample and after pressing "**START**" button, is executed again the analysis procedure.
Otherwise, pressing "**NO**" or "**Back**" button, the instrument doesn't analyse again the sample and then shows, prints and sends to host (if is present) the value NF (-4) or NR (-2).

With internal withdrawing (normal or pediatric) the instrument does this operation automatically, moving the motors and analyzing the sample again. Also with this kind of withdrawing, if the second attempt fails, the instrument shows, prints and sends to host (if is present) the value NF (-4) or NR (-2).
Moreover only with this kind of withdrawing, if a sample falls out from the rotor, the instrument notices it, in fact, after 2 attempts the instrument shows, prints and sends to host (if is present) the value S.M. (-1).
NOTE: Every failed attempt, is saved inside the Error Log (see chapter **9.2.7.12**) in this way:

1ST NF (INT or EXT) = failed first take (internal or external), not detected continuous blood flow;
2ND NF (INT or EXT) = failed second take (internal or external), not detected continuous blood flow;
1ST NR (INT or EXT) = failed first take (internal or external), sample not detectable;
2ND NR (INT or EXT) = failed second take (internal or external), sample not detectable;
WARN. SM = failed first take (only internal), sample missing;
SM = failed second take (only internal), sample missing;

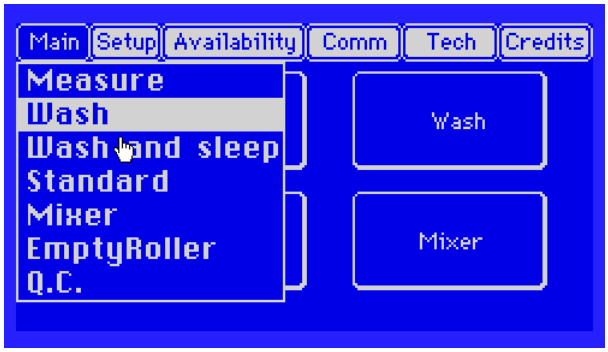
NOTE: After 3 consecutive Samples Missing during the analysis (S.M.) the instrument generate the **SM01** error like in photo:

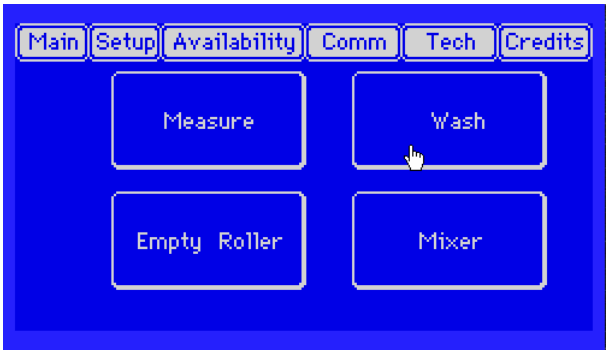


If this happen, please perform Roller technical assistance. However is possible press "**OK**" to continue.

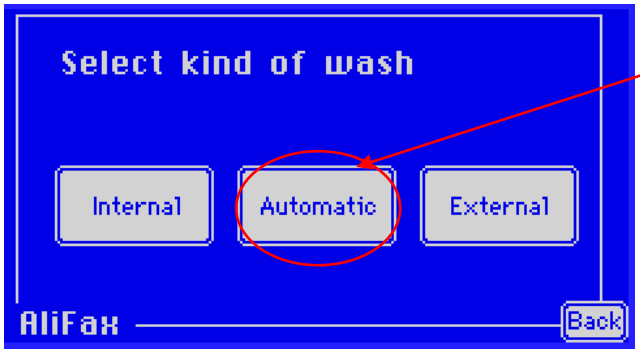
9.1.2 – WASH MENU

Wash:
Pressing "Wash" (from Main Menu or from Main Screen) the instrument will set itself to be ready to perform a wash cycle, will check the rotor status (requiring to remove eventually present tubes).





At this point, instrument requires to select the kind of wash desired:

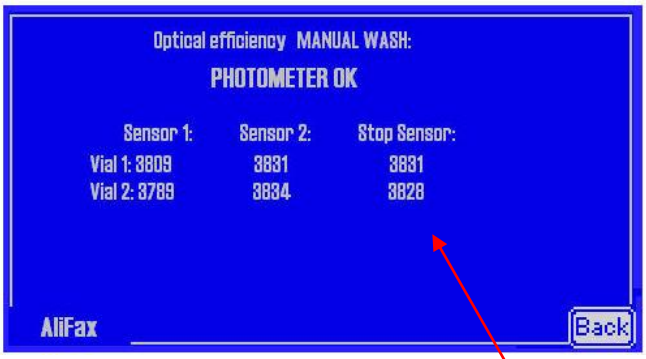


This option is available ONLY in Roller 20PN configuration (chapter 9.1.2.3)

Now the operator need to choose the kind of wash and the instrument will activate the corresponding procedures:

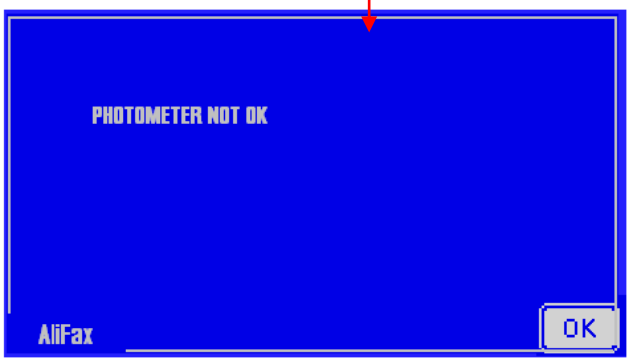
9.1.2.1 – INTERNAL WASH

In this configuration, the instrument requires to load 2 tests-tube filled 3/4 with distilled water and then active the washing procedure.



At the end of the washing cycle, the instrument will printout a report in which it shows the parameters of the photometer and it will also show them on display (this only with "Debug on"), like in the following example.

If for any reason the washing procedure reports **"PHOTOMETER NOT OK"** means that the washing cycle has not been executed correctly.

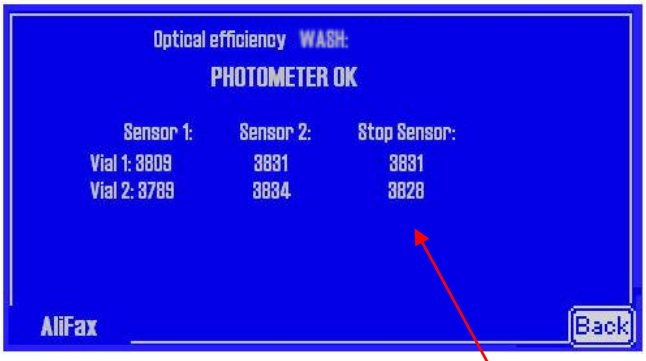


Now pressing "**OK**"; the instrument will display the following message that suggest to repeat the washing procedure.

Attention, if the waste tank is full (the control is executed automatically by the instrument before beginning a new session); Waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use of the waste tank before starting a new session; otherwise, the instrument remains in standby until when the waste tank is replaced / emptied**.**

9.1.2.2 – AUTOMATIC WASH

In this configuration, the instrument executes the washing using the water available in the washing tank located inside the instrument; it is not required to load washing test-tubes.



At the end of the washing cycle, the instrument will printout a report in which it shows the parameters of the photometer and it will also show them on display (*this only with "Debug on"*), like in the following example.

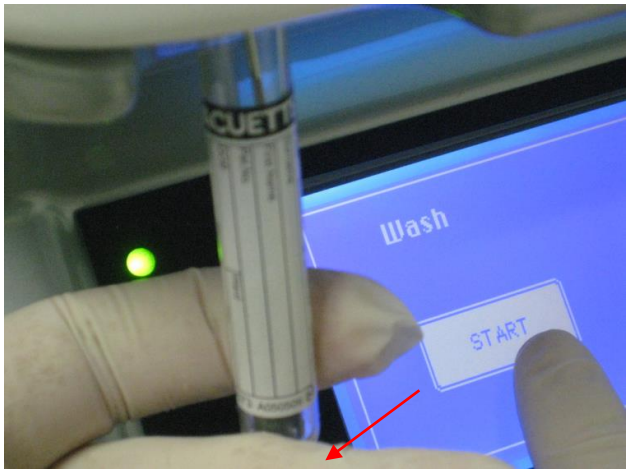
If for any reason the washing procedure reports **"PHOTOMETER NOT OK"** means that the washing cycle has not been executed correctly.

Now pressing "**OK**"; the instrument will display the following message that suggests to repeat the washing procedure.

Attention, if the waste tank is full (the control is executed automatically by the instrument before beginning a new session); Waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use of the waste tank before starting a new session; otherwise, the instrument remains in standby until when the waste tank is replaced / emptied.

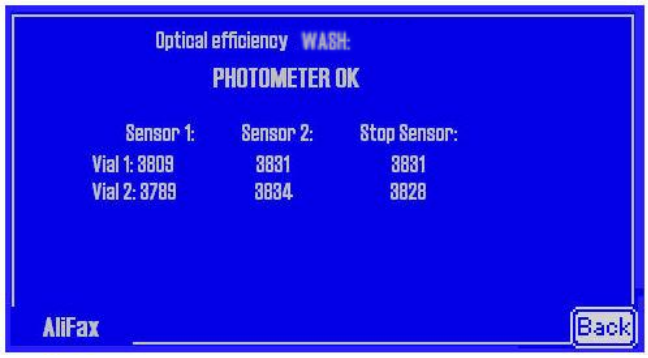
9.1.2.3 – EXTERNAL WASH

Using this option, the instrument executes the wash of the hydraulic circuit connected to the manual withdrawal needle.
In this case the instrument doesn't require to load washing tubes because the washing is executed manually; the instrument moves down the external tip to the withdrawing position, from where it will aspire water from the washing tube.

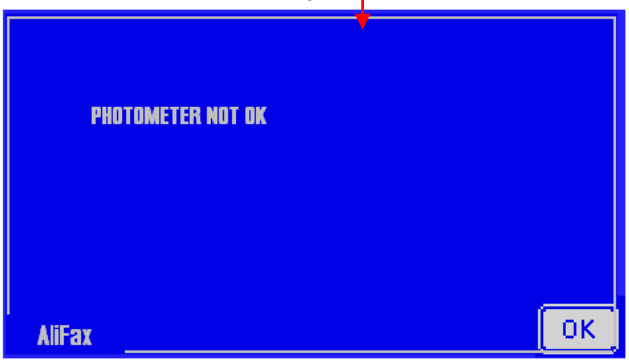


Then after inserting the washing tube over the needle, pressing Start the washing procedures is activated.

At the end of the washing cycle, the instrument will printout a report in which it shows the parameters of the photometer and it will also show them on display (this only with "Debug on"), like in the following example.



If for any reason the washing procedure reports **"PHOTOMETER NOT OK"** means that the washing cycle has not been executed correctly.



Now pressing "**OK**"; the instrument will display the following message that suggest to repeat the washing procedure.

Attention, if the waste tank is full (the control is executed automatically by the instrument before beginning a new session); Waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use of the waste tank before starting a new session; otherwise, the instrument remains in standby until when the waste tank is replaced / emptied.

9.1.2.4 –WASHINGS PROCEDURE DESCRIPTION

This procedure is designed to guarantee the capillary and all the hydraulic circuitries are maintained clean and free of blood residuals.

Considering the instrument uses a Teflon tube in which blood, water and latex flows, it is normal that the internal walls of the capillary tend to become opaque, and also to remain dirty because some blood residual parts remain inside the capillary.
To ensure a long lasting capillary, the instrument allows to use four different washing options (according to the use of the instrument: **with or without use of latex**).
In any case it is important to remember that the use of latex overcomes all the problems related to the use of haematic samples as control standards.

Washing options:

- Washing using 2 test tubes
- Washing using 3 test tubes
- Maintenance washing
- Washing if latex controls are used.

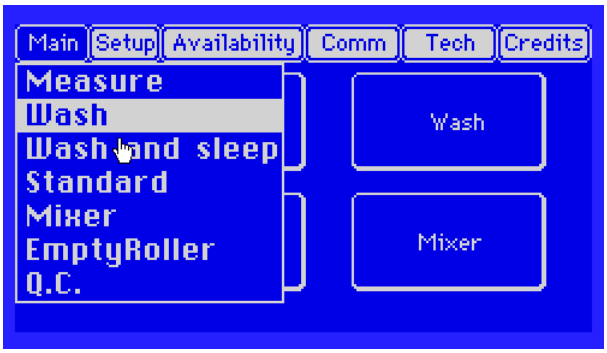
At the end of every washing procedure the software, with the attempt to reach the original value (called **white value**) which is **3800**, updates an internal compensator factor value according to the read water value (e.g. **Wt. 3796**).

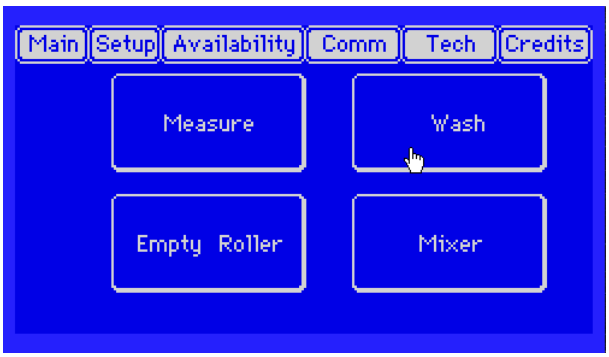
To every incorrect washing procedure, (water value **>4095**, **<2000 water mixed with bubbles, anomalous water flow, etc.)** the instrument will generate a **PHOTOMETER NOT OK error** and a new washing procedure will be requested.

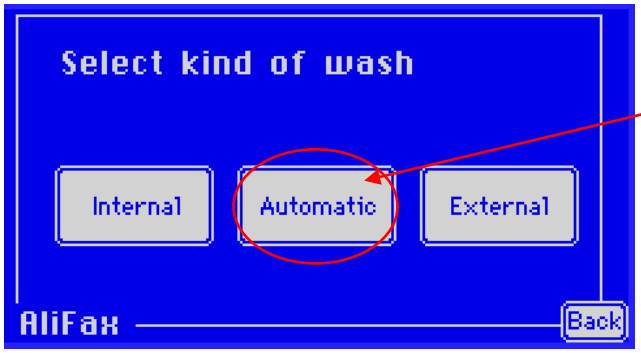
WASHING USING 2 TEST TUBES

This option is used when **the instrument requires or needs to be washed** in a "normal" way. After this has ended the instrument is ready to continue working.
This procedure requires to load 2 test tubes filled 3/4 with distilled water; tubes are loaded in position 1 and 2 of the rotor.
To activate the procedure select **Wash** from the MAIN MENU, and the choose "**Internal**" and load the tubes and wait until the "MAIN MENU (0)" is displayed enabling further choices.

For PN Models, if necessary to wash the external windrowing circuit (manual windrowing), choose the **"External"** option, in this case, will be washed out the external windrowing circuit.







This option is available ONLY in Roller 20PN configuration (chapter 9.1.2.3)

At the end of the washing procedure, the instrument will be ready to continue with the analytical sessions.

WASHING USING 3 TEST-TUBES

This option is used at the **end of the working day** and offers the possibility to maintain the capillary moist overnight. This is useful because all the hydraulic circuitry remains filled with water.
The advantage of this procedure is that all residual blood particles that eventually have remained inside the capillary, are kept moist avoiding them to remain stuck over the internal capillary walls.

This procedure requires 3 test tubes that will be loaded in two consecutive steps.
First step is the same described in the previous chapter "washing using 2 test-tubes".

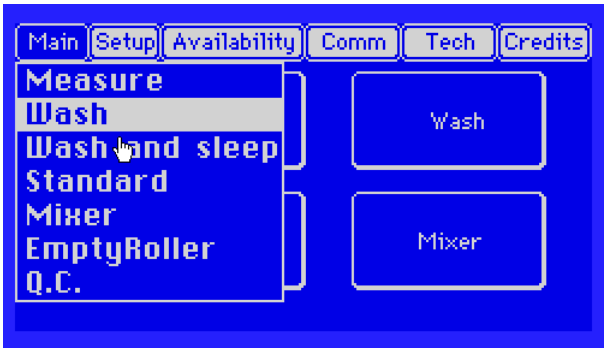
In the second step, independently from the typology of chosen wash **(Internal, Automatic or External),** the instrument prints out the result of washing procedure, then requires to remove the two tests-tube ONLY if the "Internal" washing has been chosen. After have removed the tests-tube from positions 1 and 2, the instrument, independently from its configuration, requires the insertion of an ulterior test-tube always with distilled water in position 1. From this test-tube it will windrow approximately 1/3 of the content, then the instrument will stop the pump leaving the needle inside the test-tube and **it will ask to switch OFF the instrument**.
This system maintains all the hydraulic circuit filled with water and avoids that eventual residual particles of blood dries and stick to the inner wall of the capillary.
At the next **switch ON** the instrument will empty the residual water from the capillary and will ask the removal for the test-tube

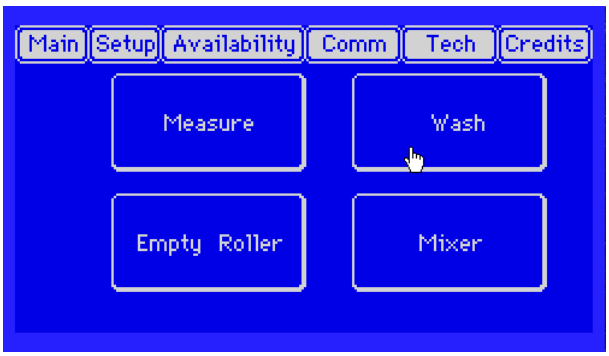
The procedure of washing with 3 tests-tube **IT MUST BE DONE** at the end of the working day in order to guarantee a good and efficient maintenance of the instrument

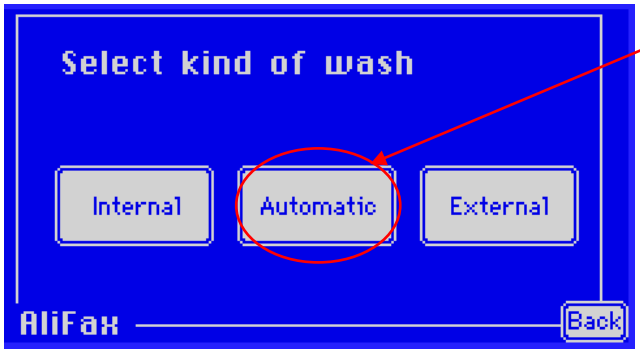
WASHING PROCEDURE FOR MAINTENANCE

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).
This procedure should be done on a daily basis; in any case it is mandatory before the quality control procedure using the Latex Controls.

- Execute one first washing, selecting **"Wash",** then option **"Internal**", load 2 test-tube filled ¾ with distilled water in positions 1 and 2 of the rotor.







This option is available ONLY in Roller 20PN configuration (chapter 9.1.2.3)

- Execute a second washing selecting **"Wash"** then option **"Internal** " and to load in position a 1 test-tube filled up ¾ with sodium hypochlorite (diluted at 5%), while in position 2, a test-tube filled up ¾ with distilled water.

- Execute one third session of washing selecting **"Wash",** then option **"Internal**", load 2 test-tube filled ¾ with distilled water in positions 1 and 2 of the rotor.

- **The procedure can be carried out also of capillary and/or needle in the event obstructed.**

9.1.2.5 WASHING PROCEDURE IN CASE OF USE OF LATEX CONTROLS

The washing procedure in case of LATEX CONTROLS, is the same of the previous procedure described (**washing procedure for maintenance**). It must be used every time before starting with the control process in order to carry-out quality control of the instrument.

If the instrument is controlled using Latex Control Kit, this procedure MUST be done every time latex controls are used.

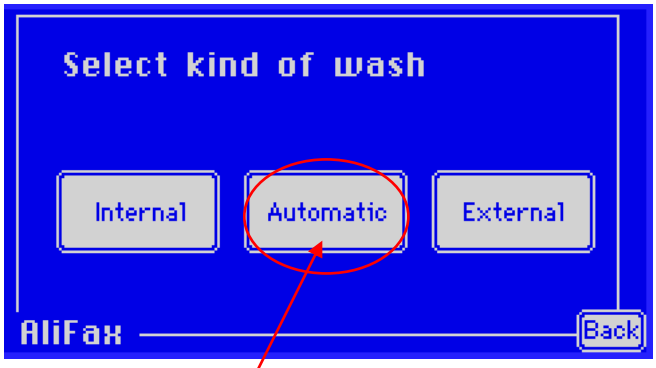
At the beginning of each Latex Controls session:

- Execute one first washing, selecting **"Wash",** then option **"Internal**", load 2 test-tube filled ¾ with distilled water in positions 1 and 2 of the rotor
- Execute a second washing selecting **"Wash"** then option **"Internal** " and to load in position a 1 test-tube filled up ¾ with sodium hypochlorite (diluted at 5%), while in position 2, a test-tube filled up ¾ with distilled water.
- Now is possible to execute the Latex Control session. Choose the option **"Standard"** located inside **"Main"** menu. Load in position a 1 test-tube filled up ¾ with distilled water, then the three latex-tubes and the others two tests-tube filled up for ¾ with distilled water following the instructions indicated on the screen.

9.1.2.6 – END OF WORKING DAY WASHING PROCEDURE (Wash and Sleep)

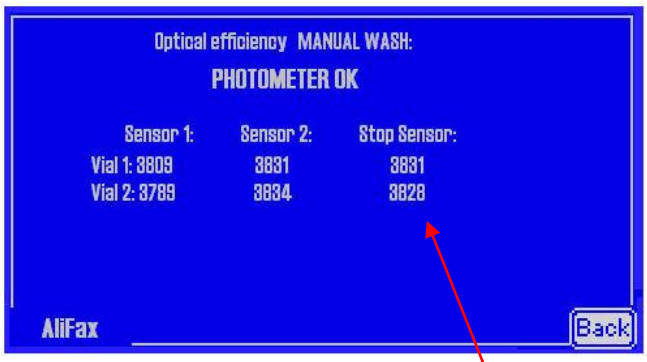
This option is used at the **end of the working day** and offers the possibility to maintain the capillary moist overnight. This is useful because all the hydraulic circuitry remains filled with water.
The advantage of this procedure is that all residual blood particles that eventually have remained inside the capillary, are kept moist avoiding them to remain stuck over the internal capillary walls.

Wash and Sleep:
To activate the procedure select "**Wash and Sleep"** from the MAIN MENU, the instrument asks to select the typology of desired washing:



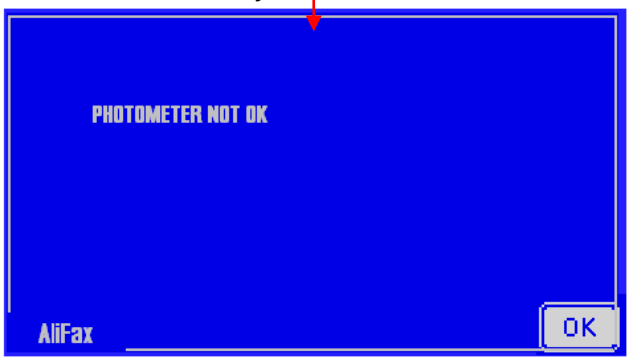
This option is available ONLY in Roller 20PN configuration (chapter 9.1.2.3)

Selecting the “Internal”, the instrument requires the insertion of two tests-tube(in position 1 and 2 of the rotor) filled up 3/4 with distilled water and then active the washing procedure.



At the end of the washing cycle, the instrument will printout a report in which it shows the parameters of the photometer and it will also show them on display (this only with “Debug on”), like in the following example.

If for any reason the washing procedure reports **“PHOTOMETER NOT OK”** means that the washing cycle has not been executed correctly.



Now pressing “**OK**”; the instrument will display the following message that suggest to repeat the washing procedure.

In the second step, independently from the typology of chosen wash **(Internal, Automatic or External),** the instrument after have printed out the result of washing procedure, will requires to remove both tests-tube ONLY if the “**Internal**” washing has been chosen. After have removed the tests-tube from positions 1 and 2, the instrument, independently from its configuration, requires the insertion of an ulterior test-tube always with distilled water **in position 1**. From this test-tube it will windrow approximately 1/3 of the content, then the instrument will stop the pump leaving the needle inside the test-tube and **it will ask to switch OFF the instrument**.

This system maintains all the hydraulic circuit filled with water and avoids that eventual residual particles of blood dries and stick to the inner wall of the capillary.
At the next **switch ON** the instrument will empty the residual water from the capillary and will ask to remove the test-tube.

The procedure of washing with 3 tests-tube **MUST BE EXECUTED** at the end of each working day in order to guarantee a good and efficient maintenance of the instrument.

Attention, if the waste tank is full (the control is executed automatically by the instrument before beginning a new session); Waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use of the waste tank before starting a new session; otherwise, the instrument remains in standby until when the waste tank is replaced / emptied.

9.1.2.7 – WASHING ERRORS

If for any reason the washing procedure reports **"PHOTOMETER NOT OK"** means that the washing cycle has not been executed correctly or has been found anomalies in the system.

The possible causes of malfunctioning can be:

- ☑ It has been inserted an empty WASH tube,
- ☑ One or both tube are missing
- ☑ Washing reference level lower than 2500
- ☑ Washing reference level inside the range (2500 – 4000) but not detected sample's end
- ☑ Washing reference level higher than 4095
- ☑ Detected air bubbles during the washing procedure
- ☑ Washing tank empty

9.1.3 – STANDARD (Latex control)

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 analyzer 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 analyzer can require a washing procedure. In this case, the operator should carry-out a washing procedure as "WASHING USING 2 TEST TUBES", chapter, explains.

The CPS of the R20-PN contains two independent sensors identified as SENS1 and SENS2; at the end of the control process, the instrument simultaneously reports the values obtained by the two sensors, as can be seen here below in the facsimile screenshot.
At the same time the instrument also 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.

PRINCIPLE OF METHOD
The Control kit is based on the use of three samples with known turbidity values, on which the analyzer performs transmittance measurements related to ESR values. The results obtained should fit the expected ranges.
Otherwise the calibration of the instrument shall be verified.
Please refer to **chapter 9.1.6** for quality control and statistical tools.

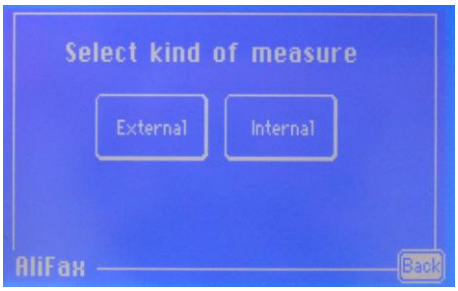
At the beginning of each Latex Controls session:

- Execute one first washing, selecting **"Wash",** then load 2 test-tube filled ¾ with distilled water in positions 1 and 2 of the rotor (or in case of external circuit, wash it using 1 tube)

- Execute a second washing selecting **"Wash"** then option **"Internal** " and to load in position a 1 test-tube filled up ¾ with sodium hypochlorite (diluted at 5%), while in position 2, a test-tube filled up ¾ with distilled water.

- Now is possible to execute the Latex Control session. Choose the option **"Standard"** located inside **"Main"** menu. Load in position a 1 test-tube filled up ¾ with distilled water, then the three latex-tubes and the others two tests-tube filled up for ¾ with distilled water following the instructions indicated on the screen.

Considering the instrument mounts two independent reading units (CPS), after having pressed **"Standard"** (from Main Menu) the instrument will first ask to select which circuit will be interested by the latex procedure.



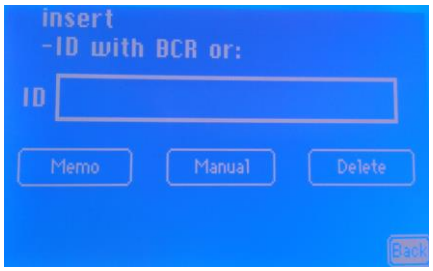
After the selection the procedure is exactly the same for both circuits, the main difference is in the **internal circuit** instrument does everything automatically after water and latex loading on the rotor. If the **external circuit** is chosen, the instrument also asks to load the water and latex tubes (like for internal circuit) but then after mixing it will ask to remove one by one the tubes and perform every step by hand.

After the selection Internal / External instrument asks to insert tubes following a sequence:

- 1 tube filled ¾ with distilled water
- 1 tube "**tube 2**" , "**tube 3**" and "**tube 4**" of Latex control previous identification by EBCR or typing manually the number printed below the bar code

as it is possible to see, latex ID can be inserted by means of:

- External Bar Code Reader (just read the label and insert the tube)



- Typing manually (after having selected "Manual") and pressing the arrow, then press ok and insert the tube

- Recalling an already memorized triplet (after having selected "Memo"), press OK button and insert the tube
- And the 2 more tubes filled ¾ with distillated water

IMPORTANT: AFTER THE SAME TRIPLET'S CODES HAVE BEEN USED 6 TIMES, IN THE EVENT OF A 7th EXTERNAL LOADING PROCEDURE, INSTRUMENT WILL AUTOMATICALLY DISCARD THE TUBE'S CONTENT TO WASTE TANK USING THE INTERNAL NEEDLE

The instrument will check:

- If the Latex expiration date has been passed, in this case it will withdraw the content of the 3 latex tubes without performing the control or calibration
- if the three tubes belongs to the same kit, if not will tell the inserted codes are inconsistent, in that case press "**Exit**" and the instrument will ask to remove the tubes.
- if more than 6 weeks has passed after the first piercing date of the inserted triplet, in this case it will withdraw the content of the 3 latex tubes without performing the control or calibration
- if the loaded triplet has been used more than 6 times, in this case it will withdraw the content of the 3 latex tubes without performing the control or calibration

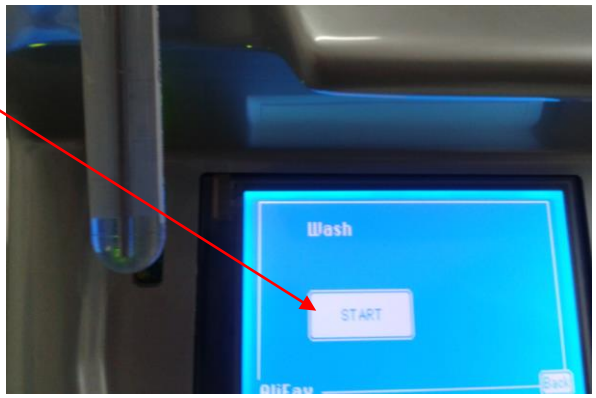
If all checks are ok, it will begin the control procedure.

After the mixing, if the **internal circuit is chosen** instrument does the procedure automatically, if **external circuit is chosen**, instrument will ask to remove one after the other the tubes in sequence.

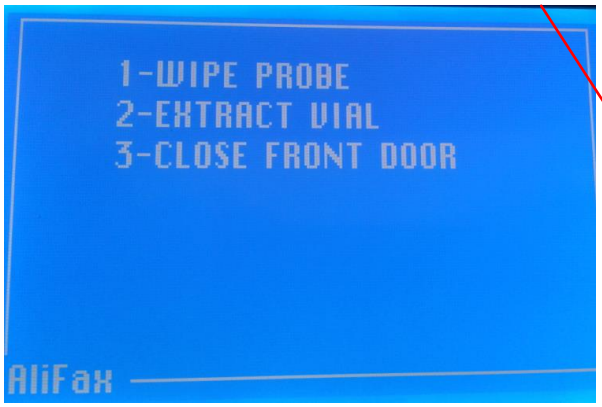
Probe will be moved down and instrument will aspire water and the latex guiding the User step by step.

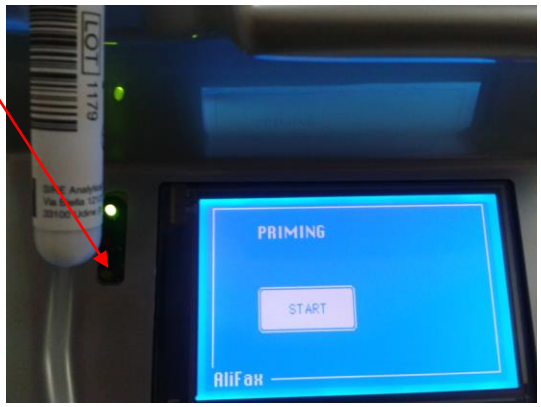
Sequence

1) Take out the first tube (water) and close the door, after that tube is inserted over the probe and user press START

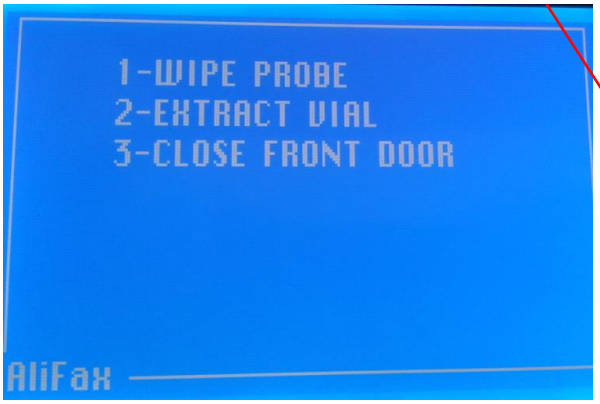


2) Instrument asks to wipe the probe, then to take out the first latex tube, close the door, after that tube is inserted over the probe and user press START, instrument will perform a PRIMING procedure aspiring a small quantity of latex and then will issue 3 beeps, this means the tube MUST BE REMOVED FORM THE PROBE, and the probe wiped out meanwhile the instrument does the priming.





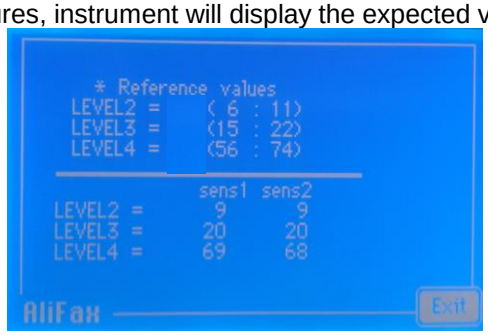
3) After priming instrument asks to wipe the probe, and then to reinsert tube 2 on the probe and pressing START instrument initiate the latex control/calibration aspiring the aliquot of latex, then will issue 3 beeps, this means the tube MUST BE REMOVED FORM THE PROBE and the probe wiped out:



The same procedure will be repeated for tube 3 and 4 of latex.

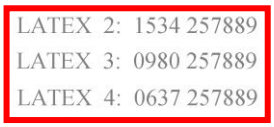
4) After latex, take out tube 5 (water) to run first washing after latex, followed by a second wash after latex (tube 6).

5) Finished the washing procedures, instrument will display the expected values and the obtained values

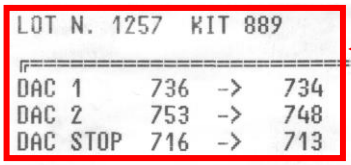


Printout displayed in next page shows a printed report after a Latex Control, as is possible see it is divided in 4 main parts:

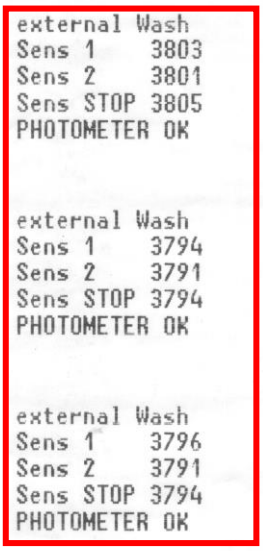
Latex Control Printout:



Part 1:
Barcodes of latex inserted:
Latex 2: first code of latex read
Latex 3: second code of latex read
Latex 4: third code of latex read



Part 2:
Latex lot number and progressive number of the lot.
Values of the DAC before and after washing



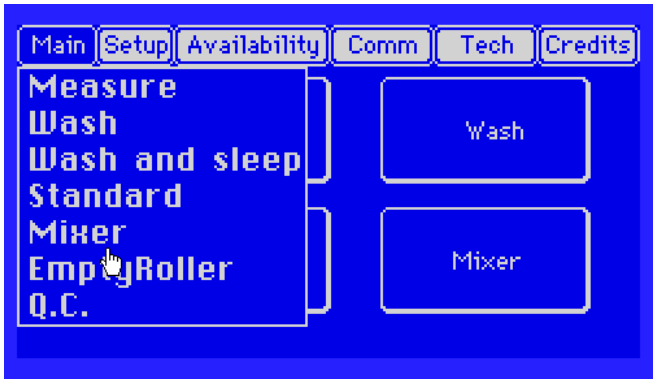
Part 3:
Washing sequence, here instrument print out the water values of the three tubes (1st before latex and then last 2 after latex)
Also report if Photometer is OK or NOT OK

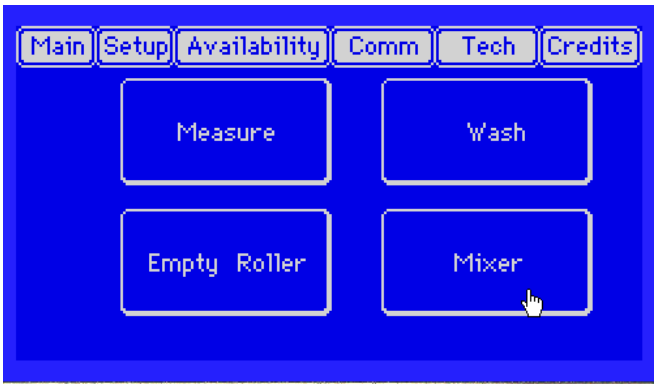
Part 4:
Operative parameters set to the Reading Unit:
Type of reference (EDTA or Citrate)
BoosterY (EDTA or Citrate, in base to the reference chosen)
MFact 1
MFact2
Temperature

Part 5:
In this part the instrument printout the result get after the Control procedure
Expected values
Measured values
.

9.1.4 – MIXER

By pressing **"Mixer"**, (from Main Menu or from Main Screen) the instrument will activate the mixing function that will do the samples mixing without any analysis.

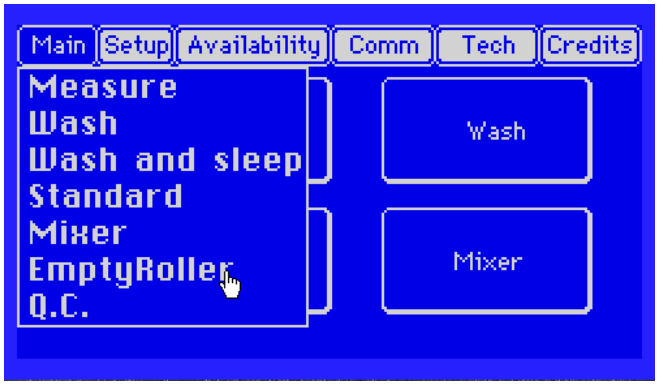


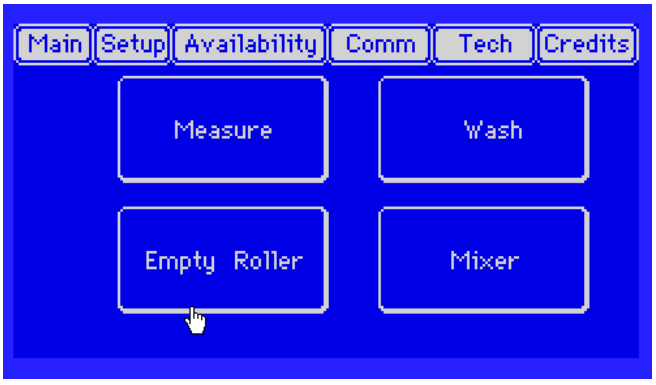


This function becomes useful if a haematology mixer is not available during the comparative proofs between the instrument and the method used in laboratory. The inserted samples are mixed performing the same number of rotations programmed for the analysis, and then are kept mixed through a 3 rotations each 5 seconds up to the pressure **"Back",** the instrument will ask to remove all inserted tubes, checking one by one they has been removed from the rotor, at the last tube remotion, it will display the MAIN SCREEN.
Pressing "**Back**" before starting mixing, is possible to abort the procedure, in this case the instrument will ask to remove all inserted tubes, checking one by one they has been removed from the rotor, at the last tube remotion, it will display the MAIN SCREEN.

9.1.5 – EMPTY ROLLER

By pressing **"Empty Roller",** (from Main Menu or Main Screen) the instrument will allow to remove all inserted tubes, checking one by one they has been removed from the rotor.



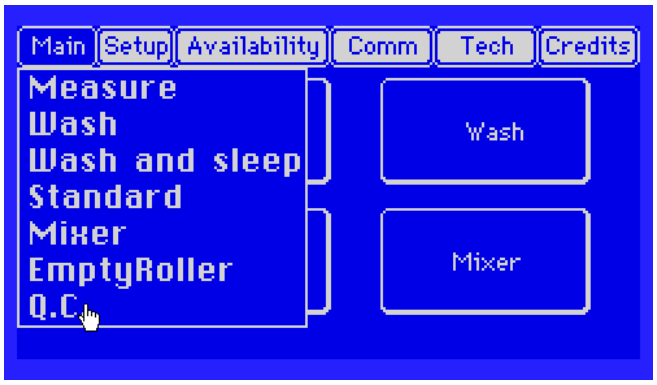


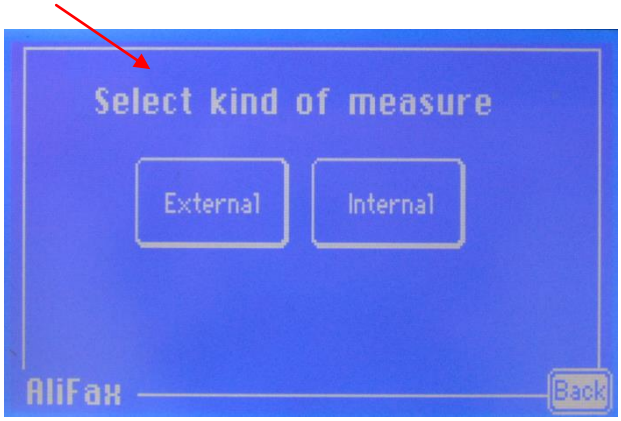
9.1.6 – STATISTICS

ROLLER family analyser provides a series of control tools for an effective product performances monitoring; such control tools are the following:

1. Latex Control statistics
2. Washing statistics.

Pressing **"Q.C.",** (from Main Menu) the instrument, in case of Roller instrument having two independent reading units has also two independent statistical databases so before getting access to the statistics options it is necessary select the circuit of interest:

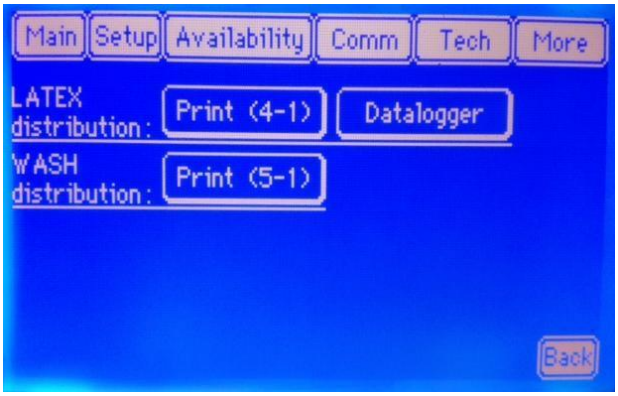




After that, instrument displays the Statistical Main Menu:

The instrument collects data from:

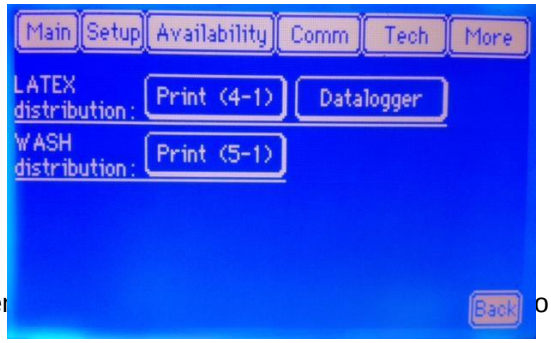
- Latex Control results
- Washing procedures



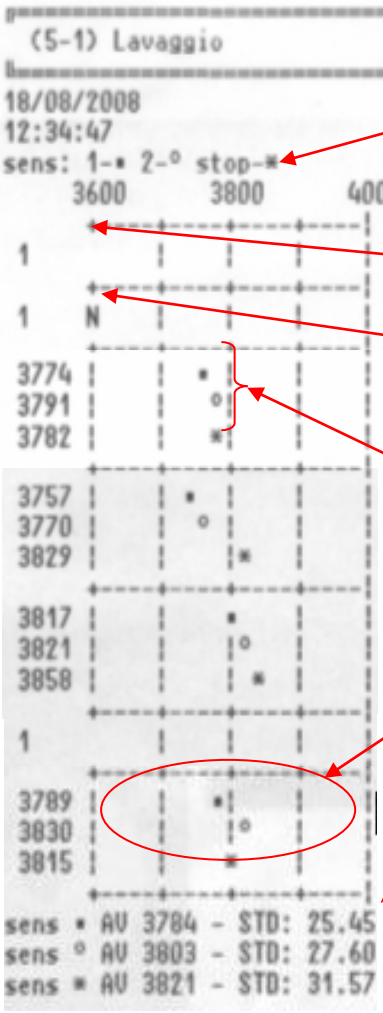
9.1.6.1 – WASHING QUALITY CONTROL PRINTOUT - Graph meaning

This function allows to printout statistical data about the washings (independently they are Internal, External or Automatic) executed on the instrument:
The printout of the washing control allows to estimate the efficiency of the photometer. The diagram visualizes the trend of washing values detected by the three sensors, which are directly correlated to the photometric signal. Normally, the instruments are regulated automatically around to an absolute value of 3800 during the washing with distilled water. This value tends to move down during the time, because of the residues of biological material inside the capillary.

Pressing **"Print (5-1)"** activates the printout that represents the behaviour and the tendency of the photometric values correspondents to the values of the water.



How can see from the graph below, the instrument shows the tren o identify any possible drift or abnormal values.



Explanation and interpretation of the diagram:

References of the sensors: 1, 2 and stop
Lower and Upper limits of water acceptability, ideal reference is 3800.

This indication that identify the instrument has been switched ON, <u>not used</u> and switched OFF

This indication identify that the instrument has been switched ON, <u>used</u> and then switched OFF <u>without have been washed or every time Photometer NOK is issued</u>

This indication means that the instrument has been washed and the three sensors has detected a water value included within the lower and higher limits:

- sensor 1: 3757
- sensor 2: 3770
- stop sensor: 3829

On the graphical print out, the instrument prints always the last washing executed in the day, independently from how many had been effectively is executed. In case more washings had been done during the same day, the data is overwritten. At midnight (change of the day), the instrument memorizes definitively the data of the last wash; that data is the one printed out.

In the lower part of the report is printed out the statistical data about the last 30 days;_ this means, for every sensor: the average and the SD of the period. The most important thing is that the three averages remain as close as possible to 3800 which is the reference value.
Executing the washings as described in below will help to maintain photometrical signals close to an absolute value of 3800.

<u>At the beginning of each Latex Controls session:</u>

- Execute one first washing, selecting **"Wash",** then option **"Internal**", load 2 test-tube filled ¾ with distilled water in positions 1 and 2 of the rotor
- Execute a second washing selecting **"Wash"** then option **"Internal** " and to load in position a 1 test-tube filled up ¾ with sodium hypochlorite (diluted at 5%), while in position 2, a test-tube filled up ¾ with distilled water.
- Now is possible to execute the Latex Control session. Choose the option **"Standard"** located inside **"Main"** menu. Load in position a 1 test-tube filled up ¾ with distilled water, then the three latex-tubes and the others two tests-tube filled up for ¾ with distilled water following the instructions indicated on the screen.

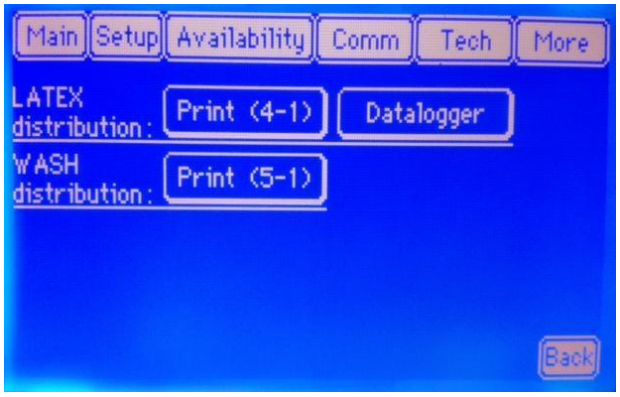
<u>At the end of the working day:</u>

- Prepare 3 tests-tube filled up ¾ with distilled water.
- Select the option **"Wash"** located inside **"Main"** menu, then option **"Internal"** (if the external withdrawing tip has been used, select **"External"**), and follow the instructions shown on the screen.

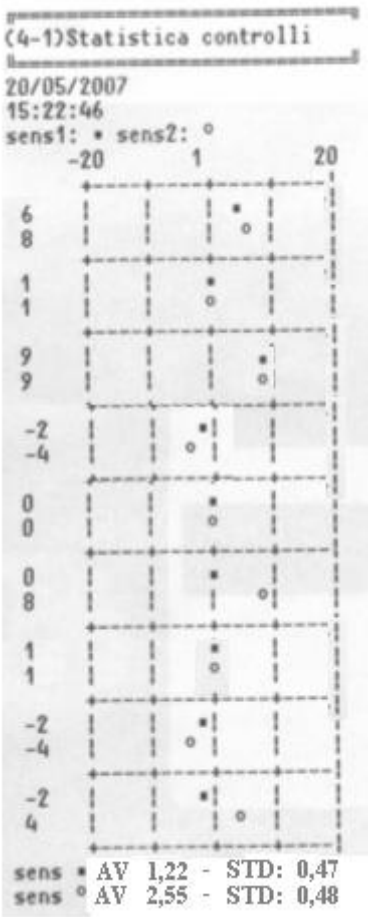
If the photometrical signals fall under a value of 3600 or rises above a value of 4000, the instrument will generate **"PHOTOMETER NOT OK"** error and will suggest to retry the washing procedure. In this case, eventually is possible to try the maintenance washing. If the value does not come again inside the range call the technical service.

9.1.6.2 - LATEX CONTROL STATISTICS

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



Results obtained during the latex control procedure are stored by the instrument; it is therefore possible to print out a report pressing the key **"Print (4-1)".** With this option it is possible to visualize the tendency of the instrument and being able to find eventual drifts that will require an accurate control of the instrument. The graphical printout cover the last 30 days.



The trend of the latex must be interpreted as a tendency pointer.
The starting reference are the values obtained during the calibration and then, for every control executed with the Latex Kit, the trend will show how much the read latex values drifts from the reference values printed on the box and also on the printout report generated during each control procedure.

Analyzing the diagram it is possible to observe that:

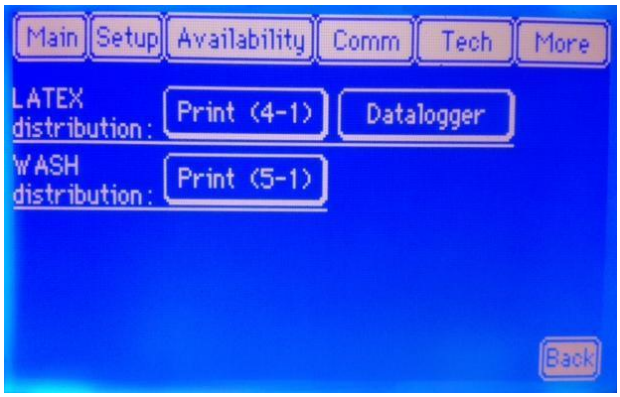
For each sensor there is a reference marker which represents the drift from the reference (1) obtained from the analyzer against the reference values.

This trend, when is completely full, **represents a maximum of 30 days of analysis,** therefore anomalous tendency in the daily values, against the reference is easily identifiable. Consequently the customer is able to understand if there is systematic error or an instrument error. Data are shown from the oldest (lower part) to the most recent (upper part of the diagram).

Explication of the printout report:

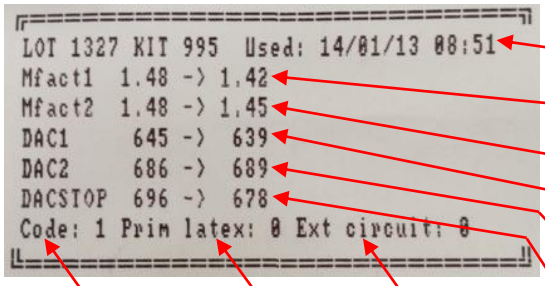
```
          -20       -10         1        +10       +20
DEV %  |----------|----------|----------|----------|
  0    |          |          ●          |          |
  0    |          |          o          |          |
  0    |          |          ●          |          |
  8    |          |          |     o    |          |
  1    |          |          |●         |          |
  1    |          |          |o         |          |
 -2    |          |        ● |          |          |
 -4    |          |      o   |          |          |
 -2    |          |        ● |          |          |
  4    |          |          |  o       |          |

Sens ●  AV   1,22  -  STD:  0,47
Sens o  AV   2,55  -  STD:  0,48
```

In order to better understand the meaning of the results printed out, imagine a series of three controls with values of 9, 19 and 65 mm/h (values of reference). Executing the control of the analyzer, if the values will be identical (9, 19 and 65 that is the ideal case), there won't be a shift (y=1.00*x) and the dots symbol will printed exactly on the column 1, as on the first line on the aside graph. On the contrary, if the results are for example 10, 21 and 70 mm/h, the shift would be +8,00% (y=1.08*x) and the dots will be positioned between column 1 and column +10%, like the fourth white dot in the graph aside.
At the bottom are printed out the Average of DEV% values (AV) and the Standard Deviation (STD).



Results obtained during the latex calibration procedure are stored by the instrument; it is therefore possible to print out a report pressing the key "**Datalogger**". With this option it is possible to visualize precise information about all calibrations done, like the LOT and the KIT of the triplet, the date of withdrawal, old and new Model Fact1 and Model Fact 2, the type of withdrawal and if the flag priming latex is on or off

Printout explanation:



LOT number, **KIT** number, **date** of withdrawal

Mfact1 **old** -> **new** (value of Model Fact1 pre and post calibration)

Mfact2 **old** -> **new** (value of Model Fact1 pre and post calibration)

DAC1 **old** -> **new** (value of DAC1 pre and post calibration)

DAC2 **old** -> **new** (value of DAC2 pre and post calibration)

DACSTOP **old** -> **new** (value of DACSTOP pre and post calibration)

Ext circuit: **0** or **1** (0 = calibration done with internal withdrawal)
(1 = calibration done with external withdrawal)

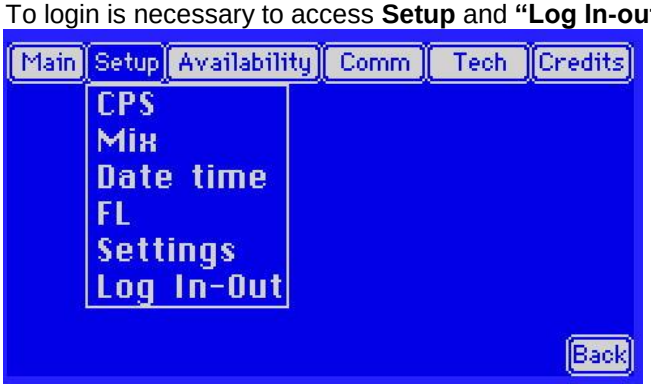
Prim latex: **0** or **1** (0 = calibration done with priming latex disable)
(1 = calibration done with priming latex enable)

Code: **1** or **2** or **3** (1 = ID inserted manually)
(2 = ID inserted with "Memo" button)
(3 = ID inserted with External Barcode Reader)

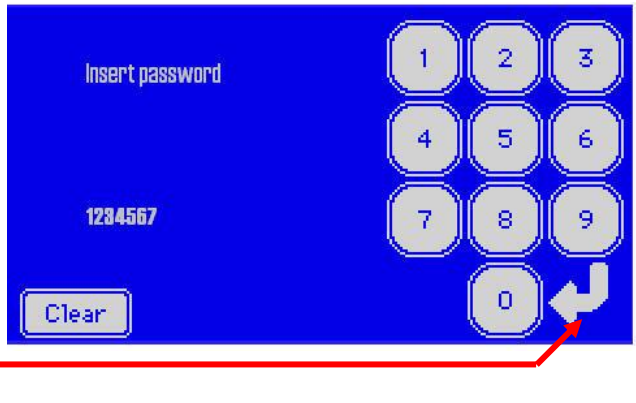
9.1.6.3 – ERASE STATISTICAL DATABASE

To erase statistical database, it is necessary to be logged as Technical User

To login is necessary to access **Setup** and **"Log In-out",** then press "LOGIN"

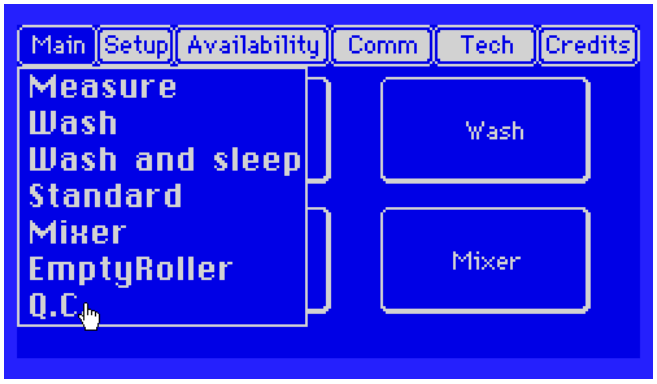


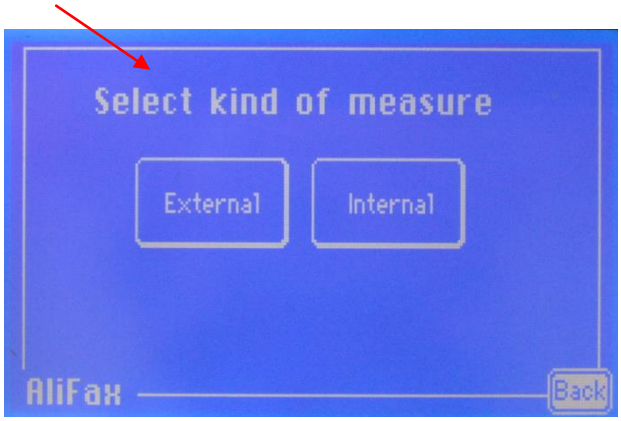
and type the appropriate password:



press the "LEFT ARROW" and then "BACK". On the MAIN SCREEN will be indicated the level of login**: User** or **Technical level"**.

Pressing **"Q.C.",** (from Main Menu) the instrument, in case of Roller instrument having two independent reading units has also two independent statistical databases so before getting access to the statistics options it is necessary select the circuit of interest:





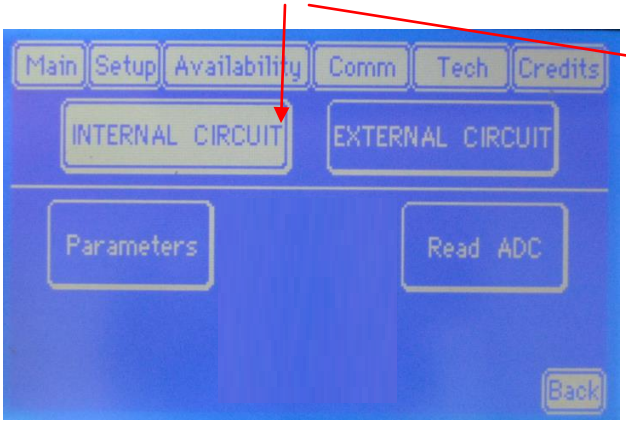
After that, instrument displays the Statistical Main Menu.
Then from Main Menu select **"Q.C.",** the instrument will display the following image:

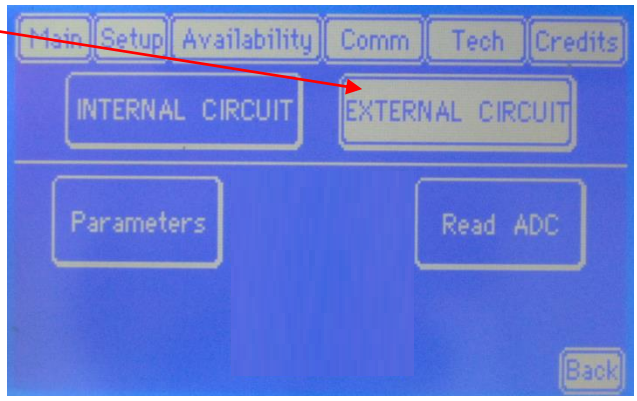
Now just press **"Res."** To erase desired statistical database. Each database is independent so, to erase all database it is necessary to press **"Res."** for each one of them.
For the 2 latex database, "Print (4-1) and "Datalogger", when pressed "**Res.**" also Datalogger database will be erased.
At the end press **"Back"** to return to main menu.

9.2 – SETUP MENU

Setup Menu:
Pressing "**Setup**" from the **MAIN SCREEN**, the instrument shows the following options:

In case of Roller instrument having two independent reading units, before accessing the CPS parameters is necessary to select the circuit of interest:





After having done the selection, the following menus are identical; they reports the configuration for the internal or external circuit.

9.2.1 – CPS MENU

CPS:
This function's accessibility **is linked to a password level**.

Pressing **"CPS"** (in the Setup Menu) without any password level activated, the instrument will display:

9.2.1.1 – CPS' PARAMETERS

Then pressing "**Parameters**" will be displayed CPS's parameter but without the possibility to modify anything as showed in the next image:

9.2.1.1.c – MODIFY WHOLE PARAMETRES' VALUES (Technical password required)

9.2.1.1.d – MODIFY MODEL FACT's VALUES (Technical password required)

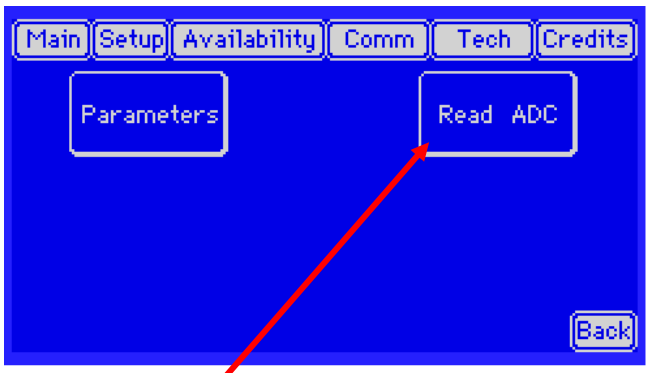
9.2.1.1.e – MODIFY Offset Sensors VALUES (Technical password required)

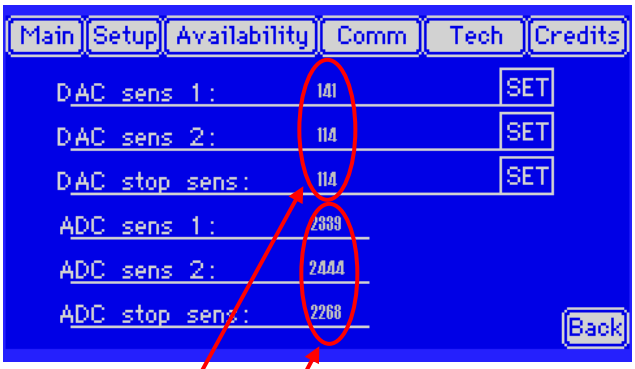
9.2.1.1.f – MODIFY THERMOSTAT reference value (Technical password required)

9.2.1.2 – CPS Correctors Parameters (Technical password required)

9.2.1.3 – CPS Read ADC

This function allow technician to verify CPS's Analog-Digital Converters reference (without the possibility to modify anything if not logged as technical service)





Pressing "**Read ADC**" will be displayed CPS's Analog-Digital Converters reference (without the possibility to modify anything if not logged as technical service).

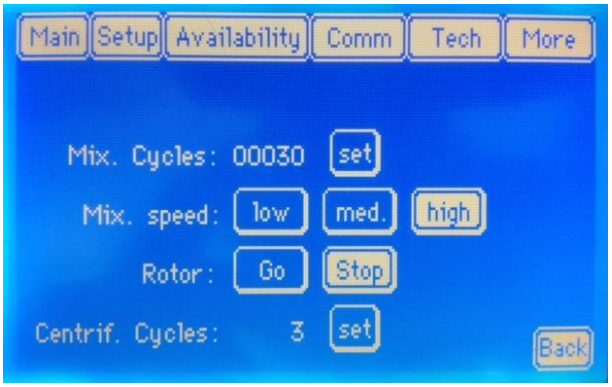
DAC: which is changeable refers to the power emitted by the LED inside the reading unit. This value changes every time a latex procedure is done and the change is adjusted in order to obtain a value of DAC which guarantees a water value as close as possible to the reference value of 3800 (printed out during washing procedure). DAC reference number goes from 0 to 1023; normal working range goes from 300 to 900.

ADC: refers to the effective value that each sensor reads (in other words is the sensibility of the sensor) , in this case this value changes continuously and each value is independent from the others. **ADC reference number goes from 0 to 4095. There is no specific working range even if the normal value should be around 2000 – 2200.**

To modify DAC's values proceed as described for the others examples, for each sensor appears a keyboard in which the technician can set the desired value. Values goes from 0 to 1023.

9.2.2 – MIX MENU

Pressing **"Mix"** (in the Setup Menu), the instrument will display:



this function allow the user to set:

- The desired number of rotations: pressing **"set"** the instrument will display a keyboard where the operator can type the desired number of rotations (from 2 up to 1000), then pressing the **"left arrow"** confirm the new value.
- The desired mixing speed: **"low"**, **"med"** or **"high"**; just press the desired speed "button"
- The desired number of Cycles Centrifugations (for pediatric mode): pressing "**set**" the instrument will display a keyboard where the operator can type the desired number of cycles (from 2 up to 100), then pressing the "**left arrow"** confirm the new value.
- **by default the instrument is set up at medium speed, 140 cycles and 30 centrifugation cycles.**

Finally the operator can check practically the rotor speed, by pressing "**Go**", in this case the rotor being to rotate and will still rotate up when the "**Stop**" is pressed.

Pressing **"Back"** the instrument will go back and will display the Main Screen.

9.2.3 – DATE TIME MENU

This function's accessibility **is linked to a password level**.

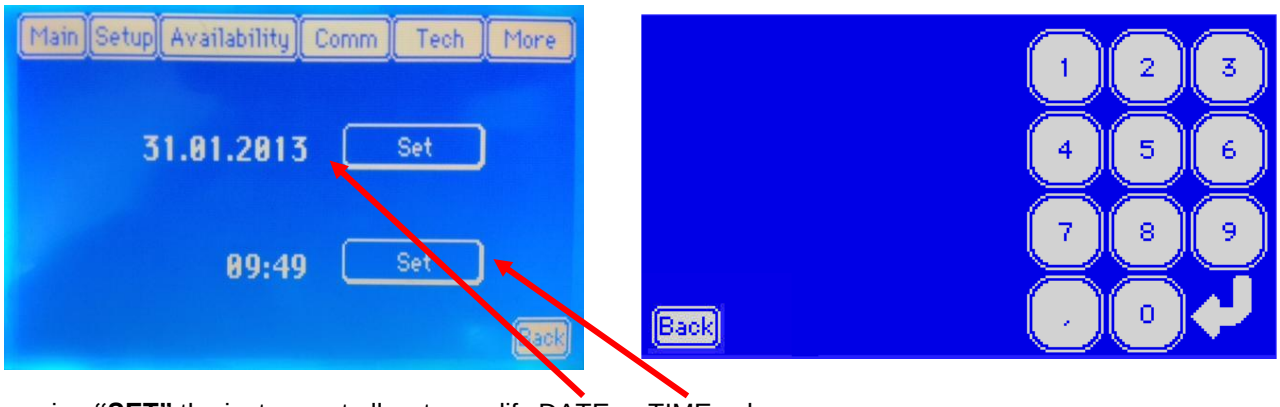
Without a password
Pressing **"Date time"** (in the Setup Menu), the instrument will display:

9.2.3.1 – MODIFY DATE TIME VALUE (User level password required)

As stated before, to have the possibility to modify these parameters it is necessary to be logged as "**user level**" otherwise the instrument will not allow to access the function.

To login is necessary to access **Setup** and **"Log In-out",** then press "LOGIN" and type this password: **1010**, press the "LEFT ARROW" and then "BACK". On the MAIN SCREEN will be indicated **"LOGIN: user level"**.

User level allow to modify date and time values:



Pressing **"SET"** the instrument allow to modify DATE or TIME values;

- If the change is applied to DATE, the instrument will ask to modify in the following order: **Year**, **Month** and **Day** to modify just type the desired value;
- If the change is applied to TIME, the instrument will ask to modify in the following order: **Hour**, and **Minute** to modify just type the desired value.

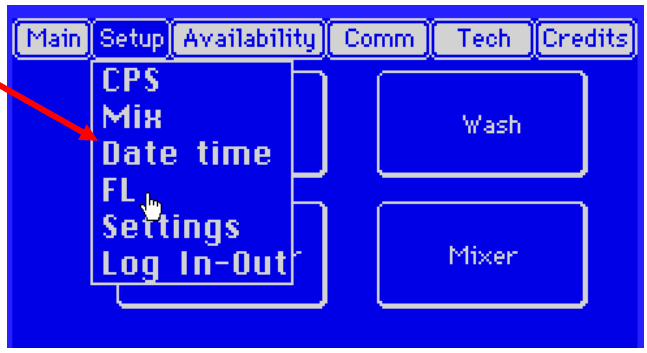
then press the **"left arrow"** to confirm or "**Back**" to exit without change anything, the instrument will display again the previous image with the DATE or TIME new value. Pressing "**Back**" is possible to go back to **MAIN SCREEN**.

9.2.4 – FL (Flag List) MENU

```
15/01/2021
04:40:40
ROLLER 20  Plus Needle
R10-05.00B.00
-------------------------------
R10_UI-05.00B
# Dec 01 2020 12:59:51
# SN: 1
DEBUG: OFF
MAINTENANCE
WARNING: 150
MAINTENANCE COUNTER: 141
washing time: 20
PRINT DURING ANALYSIS: ON
PRINT EXPANDED TEXT: ON
2 CPS On Board: ON
MEC on Board: OFF
Pediatric samples: OFF
Test Mode: OFF
-------------------------------
# ESR =  11200
# Global count ESR: 40
-------------------------------
R10MOT-05.00B
Dec 01 2020 13:00:56
Mixing cycles: 2
Mixing speed: high
Automatic sample ul: 175
Manual sample ul: 100
Steps UP: 3700
Steps up wash: 4500
Tube offset: -10
Syr fast: ON
Centrifugation cycles: 2
-------------------------------
INTERNAL CIRCUIT
R10ANA-03.10D
May 31 2013 17:52:25
REFERENCE: EDTA
BY EDTA:  1.0000
MF1:  1.8255
MF2:  1.8351
OFFSET1: -127.29
OFFSET2: -108.01
31.5 (37)
Wash not ok: 8
T.100 SENS1: 3793
T.100 SENS2: 3826
T.100 STOP: 3842
DAC SENS1: 665
DAC SENS2: 674
DAC STOP: 671
```

Pressing **"FL"** (in the Setup Menu), the instrument will printout the Flag List of both reading Units.

In the Flag List are printed out all the operational parameters of the instrument.

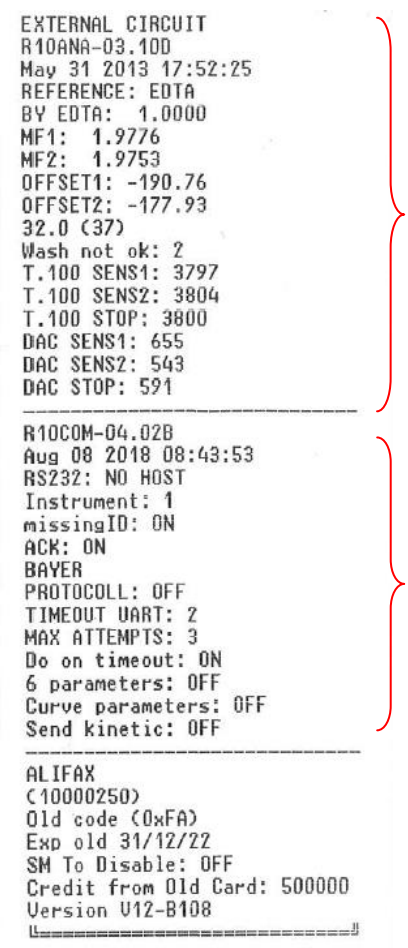


UNIT INTERFACE
- Date and time of the software compilation
- Instrument serial number
- Debug (ON or OFF) **(Only Technical Service)**
- Threshold level for Maintenance intervention requesting. **(Only Technical Service)** reference value: 30000
- Maintenance counter, counts the number of analyses
- Threshold (in minutes) for automatic washing. **(Only Technical Service)** reference value 60
- patient ID and ESR results printing on real time (ON or OFF)
- IDs and ESR results on double height printing (ON or OFF)
- Specify if 1 or 2 CPS are installed on the instrument **(Only Technical Service)**
- Specify if the latex priming is enabled or not **(Only Technical Service)** by default is enabled
- Specify if pediatric samples are enabled or not **(Only Technical Service)**

- Test availability for the ESR and other parameters analysis
- ESR and other parameters counter of executed test
- Smart warning **(Only Technical Service)** reference value 1000
- Smart personalization (distributor name)

MOTOR BOARD
- Motor Board Software version.
- Date and time of the Motor Board software compilation.
- Number of mixing revolutions, from 2 to 1000.
- Mixing speed, 1=60 RPM (default), 2=32 RPM and 3=26 RPM
- Withdrawal volume of blood in automatic sampling, reference value 175
- Withdrawal volume of blood in manual sampling, reference value 100
- Upward steps done by syringe in automatic sampling, reference value 3450
- Upward steps done by syringe in washing procedure, reference value 4500
- Tube offset, (used to align rotor in front of loading sensors), reference value 0
- Syr Fast, define if the syringe moves up-down slow or fast reference value OFF
- Centrifugation cycles, number of cycles for pediatric samples, from 2 to 100

CPS BOARD (INTERNAL)
- Analogical Board Software version.
- Date and time of the CPS Board software compilation.
- Instrument BoosterY reference (EDTA or Sodium Citrate) **(Only Technical Service)**
- Instrument Gain (BY EDTA or CITRATE) in base to the reference chosen **(Only Technical Service)**
- Latex gain factor Sensor 1, values accepted between 0,6000 to 2,0000 **(Only Technical Service)**
- Latex gain factor Sensor 2, values accepted between 0,6000 to 2,0000 **(Only Technical Service)**
- Compensator factor to instrument calibration for Sensor 1 **(Only Technical Service)**
- Compensator factor to instrument calibration for Sensor 2 **(Only Technical Service)**
- Reading Unit temperature, values accepted between 20 to 40 **(Only Technical Service)**
- Instrument switching off counter without washing procedure
- Value of washing water read and memorized for Sensor 1
- Value of washing water read and memorized for Sensor 2
- Value of washing water read and memorized for Stop Sensor
- Analogical Reference for Sensor 1 **(Only Technical Service)**
- Analogical Reference for Sensor 2 **(Only Technical Service)**
- Analogical Reference for Stop Sensor **(Only Technical Service)**



CPS BOARD (EXTERNAL)

Analogical Board Software version.
Date and time of the CPS Board software compilation.
Instrument BoosterY reference (EDTA or Sodium Citrate) **(Only Technical Service)**
Instrument Gain (BY EDTA or CITRATE) in base to the reference chosen **(Only Technical Service)**
Latex gain factor Sensor 1, values accepted between 0,6000 to 2,0000 **(Only Technical Service)**
Latex gain factor Sensor 2, values accepted between 0,6000 to 2,0000 **(Only Technical Service)**
Compensator factor to instrument calibration for Sensor 1 **(Only Technical Service)**
Compensator factor to instrument calibration for Sensor 2 **(Only Technical Service)**
Reading Unit temperature, values accepted between 20 to 40 **(Only Technical Service)**
Instrument switching off counter without washing procedure
Value of washing water read and memorized for Sensor 1
Value of washing water read and memorized for Sensor 2
Value of washing water read and memorized for Stop Sensor
Analogical Reference for Sensor 1 **(Only Technical Service)**
Analogical Reference for Sensor 2 **(Only Technical Service)**
Analogical Reference for Stop Sensor **(Only Technical Service)**

COMMUNICATION BOARD

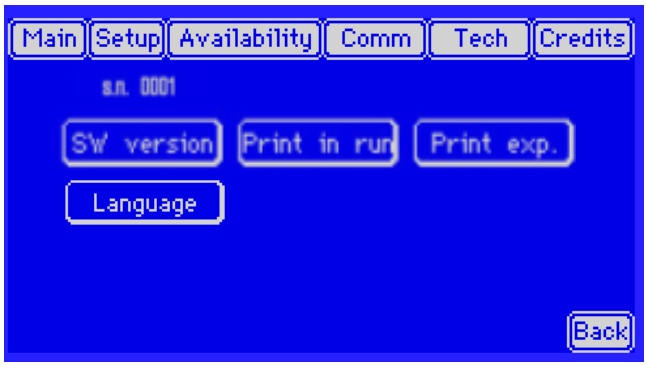
Communication Board Software version.
Date and time of the Communication Board software compilation.
Serial communication protocol
Instrument number, if there is more than one instrument in series.
Analysis enabling for samples with patient ID not recognised.
Enable the extended waiting time to receiving "**T**" messages from Host
Enable (disable) Bayer protocol compatibility.
Timeout for Host waiting in serial interface
Max number of attempts if the host don't receive the ACK
The instrument will/will not do the analysis if TIMEOUT event happens **(Only Technical Service)**

9.2.5 – SETTINGS MENU

This function's accessibility **is linked to a password level**.

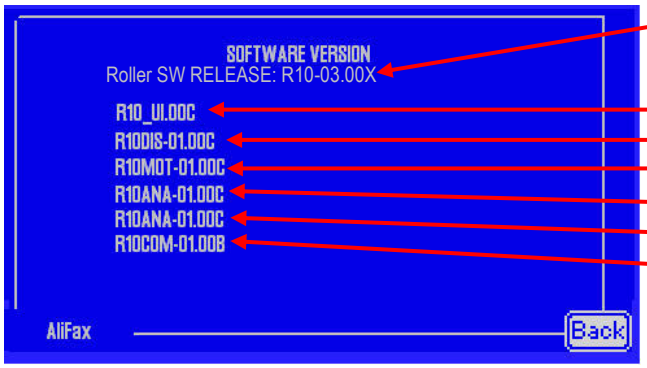
Without a password is possible to access only few functions

Pressing **"Settings"** (in the Setup Menu), the instrument will display:



9.2.5.1 – SOFTWARE VERSION

This instrument uses 5 different processors to work, this means that not all of them necessarily have the same or last version installed; to know which software version is installed in each processor press "**SW version**" the instrument will display software version's installed.



where X means the release of software. The release is expressed by a letter from A up to Z

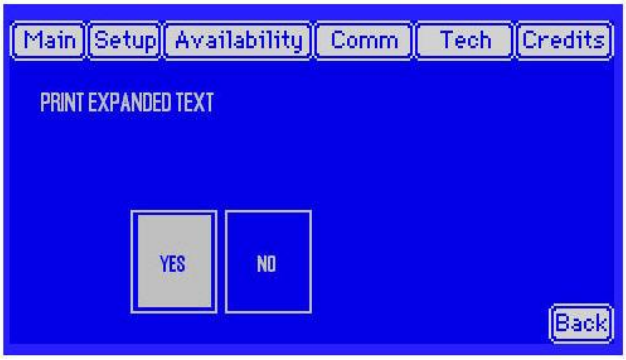
Interface Unit Board Software Version
Display Software Version
Motor Board Software Version
Analogical Board Software Version
Analogical Board Software Version (if is a Roller 20PN)
Communication Board Software Version

Pressing "**Back**" the instrument will display again the **Setting Menu** screen.

9.2.5.2 – PRINT EXPANDED

This function, if activated, allow to printout the IDs and ESR results on double height; to access the function press "**Print exp.**" the instrument will display:

In this example the function is set to "**YES**"



Pressing "**Back**" the instrument will display again the **Setting Menu** screen.

9.2.5.3 – PRINT IN RUN

This function, if activated, allows to printout the IDs and ESR results after the corresponding sample analysis; to access the function press "**Print in run.**" the instrument will display:

In this example the function is set to "**YES**"

Pressing "**Back**" the instrument will display again the **Setting Menu** screen.

9.2.5.4 – LANGUAGE SETUP

This function, if activated, allows to setup the language in which will be displayed messages and warnings; to access the function press "**Language**" the instrument will display:

Available languages are:

- English
- Italian
- Spanish
- French
- Russian

Just press the desired language, in this case English to setup the instrument in **English** language

Pressing "**Back**" the instrument will display again the **Setting Menu** screen.

9.2.6 – SETTINGS MENU with "USER LEVEL" PASSWORD LEVEL ACCESS

As stated before, to have the possibility to modify these parameters it is necessary to be logged as "**user level**" otherwise the instrument will not allow to access the function.

To login as **user level** is necessary to access **Setup** and **"Log In-out",** then press "LOGIN" and type **1010** as password, then press the "LEFT ARROW" and then "BACK". On the MAIN SCREEN will be indicated **"LOGIN: user level"**.
User level allow also to change date and time set up of the instrument:

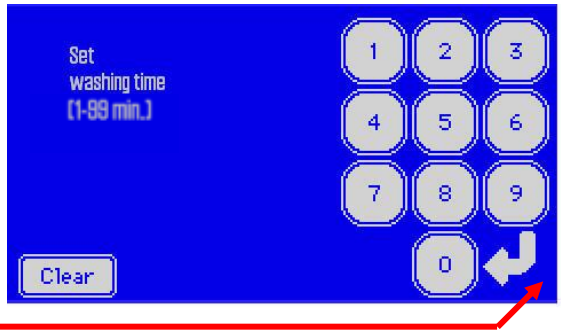
Now, pressing "**Setup**" in the main menu and then **"Settings"** (in the Setup Menu), the instrument will display besides the previously activated options**, also the wash time option**:

9.2.6.1 – WASH TIME

This option allows to modify the delay of time (in minutes) for the alarm activation for a washing procedure requesting. The counter's countdown starts at the end of the analysis cycle.

To access this function, press **"Wash Time"** (in the Setup Menu), the instrument will display:

To modify the waiting time, just type the desired value



then press the **"left arrow"** to confirm or "**Clear**" to exit without change anything, the instrument will display again the previous image. Pressing "**Back**" is possible to go back to **MAIN SCREEN**.

9.2.7 – SETTINGS MENU with "TECHNICAL LEVEL" PASSWORD LEVEL ACCESS

9.2.7.1 – INSTRUMENT SERIAL NUMBER (Technical password required)

9.2.7.2 – DEBUG (Technical password required)

9.2.7.3 – CONFIGURATION OF KIND OF ROLLER (Technical password required)

9.2.7.4 – MAINTENANCE LEVEL RESET (Technical password required)

9.2.7.5 – MAINTENANCE LEVEL THRESHOLD SETUP (Technical password required)

9.2.7.6 – INSTRUMENT GENERAL RESET (Technical password required)

9.2.7.7 – PRINT PARAMETERS (Technical password required)

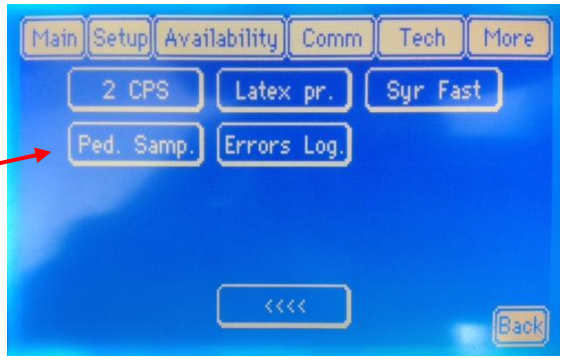
9.2.7.8 – 2 CPS (Technical password required)

9.2.7.9 – LATEX PRIMING (Technical password required)

9.2.7.10 – SYRINGE FAST (Technical password required)

9.2.7.11 – PEDIATRIC SAMPLES

This function, if enabled (by default it is not) configure the instrument to permit it to analyse also the pediatric samples. In this mode, instrument rotor mix the sample with a special function, called centrifugation, that is much powerful and fast than normal mixing. But remember this type of mixing must be used only with pediatric samples, not with normal samples!

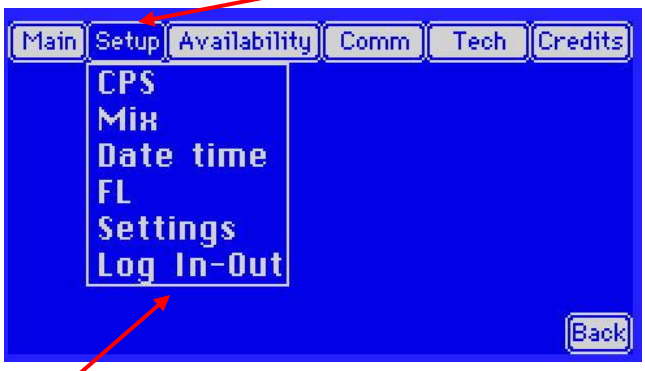


9.2.7.12 – ERROR LOG (Technical password required)

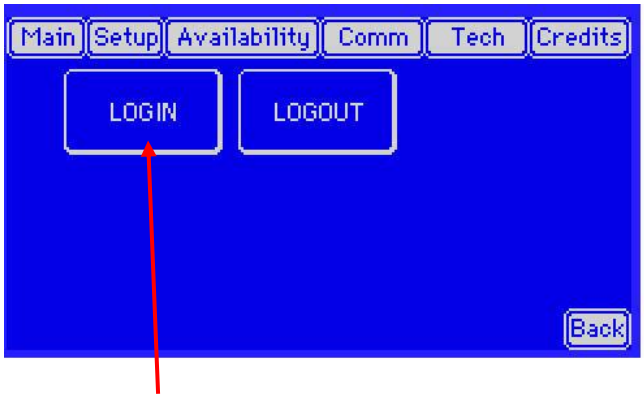
9.2.8 – LOG IN-OUT

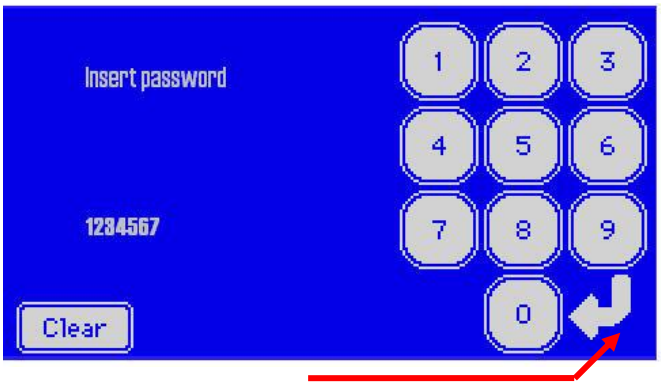
As stated before, the user will be required to type in a password to rise up from the 2nd to the 3rd level of the instrument's setup, otherwise the instrument will not allow to access the whole functions.

To login is necessary to access (from **Main Screen**) to **Setup**



To access this function, press **"Log In - Out"** (in the Setup Menu), the instrument will display:





pressing **"LOGIN"** the instrument will display a keyboard to type the password, type the proper password, then press the **"left arrow"** to confirm or "**Clear**" to exit without change anything, in both cases, the instrument will display again the previous image, then press "**Back**".

To Logout, access this function, press **"Log In - Out"** (in the Setup Menu), press **"LOGOUT"** the instrument will return to **level 1**. Pressing "**Back**" is possible to go back to **MAIN SCREEN**.

Password levels:

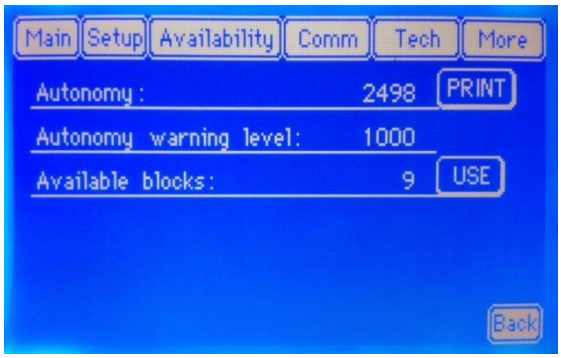
level	access
1	No password required, allow access only to the elementary functions
2	"LOGIN – USER LEVEL": allow access to the elementary setup functions. When the instrument is switched off, the instrument loose this password, so next time the instrument is switched on it will be setup as **level 1 (base level)**.
3	"LOGIN – TECH LEVEL": this level is only for Technical Service Personnel.

9.3 – AVAILABILITY MENU

Pressing "**Availability**" from Main Screen, the instrument shows the following options :

9.3.1 - SHOW AVAILABILITY

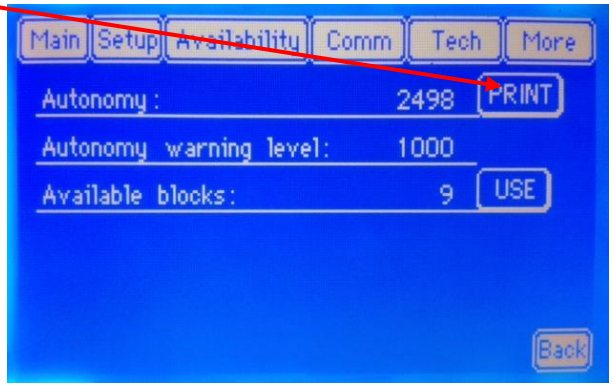
Pressing "**Show**" in Availability menu, the instrument will show this screen:



Press "**Back**" to come back to Main Screen.

9.3.2 - PRINT AUTONOMY

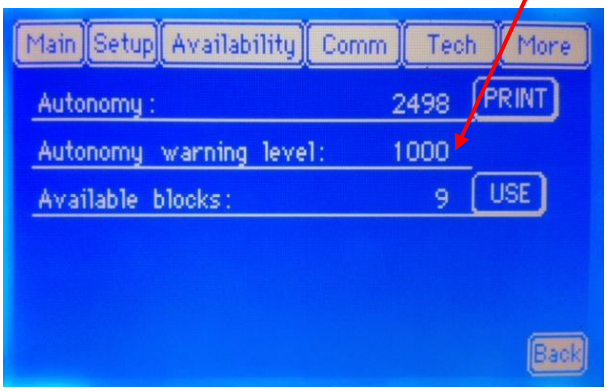
Pressing "**PRINT**", the instrument will print out the remaining number of credits for each active parameters.



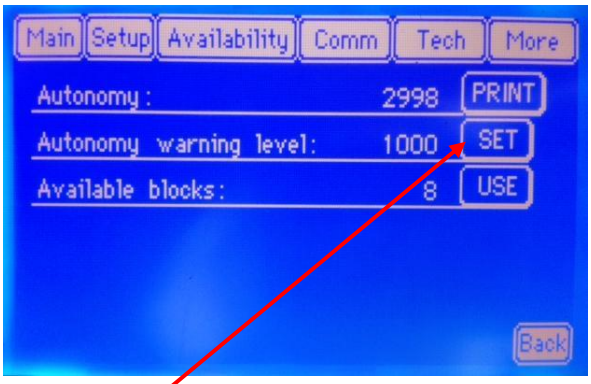
Press "**Back**" to come back to Main Screen.

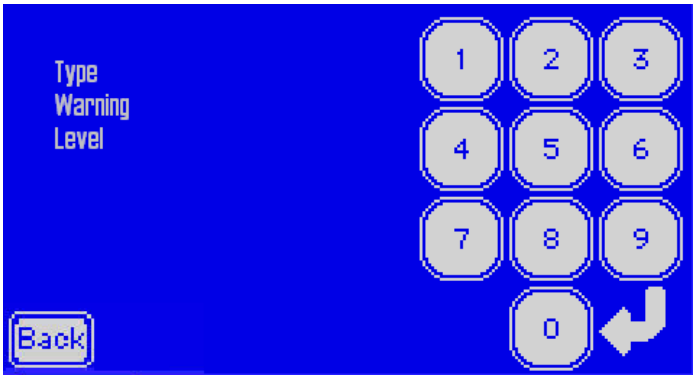
9.3.3 - AUTONOMY WARNING LEVEL

Without a password:
The instrument only show the actual value of the Autonomy Warning Level (1000 by default):



With a User Password (after logged, please see **chapter 15.1**):
The instrument will display:

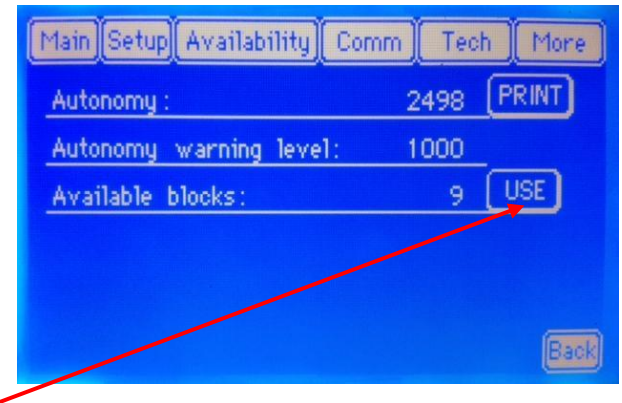




Pressing "**SET"** the instrument allow to modify threshold level (from 5 to 63000) using the keyboard, so to increase availability type the desired warning value, then press the "**Left Arrow**" to confirm or "**Back**" to exit without change anything, in both cases, the instrument will display again the previous screen with the new warning reference. Then press "**Back**" to go back to Main Screen

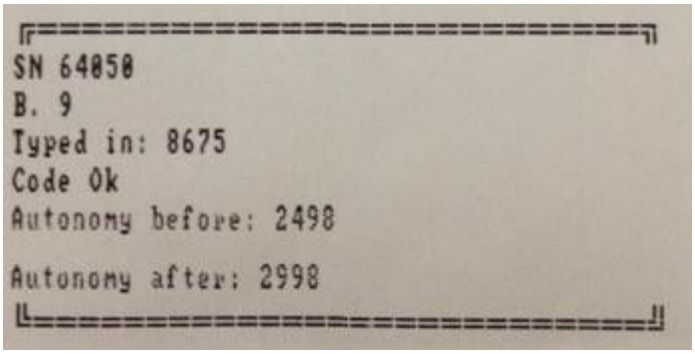
9.3.4 - CARD WITH DIVISIBLE CREDIT

If a card with divisible credit has been loaded, pressing "**USE**" it is possible to use one by one the special codes, for increase the availability in blocks of 500 credits (till to 4500 credits for each card).



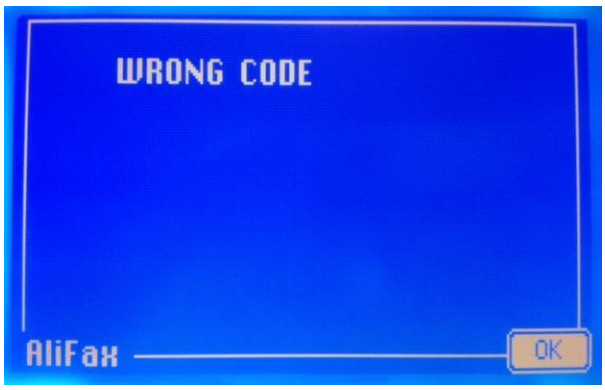
After pressing "**USE**" button, the instrument will show this screen:

Where in base of the Serial Number (**SN**) of the card and the number of the block (**B.**), typing the correct code is possible to load the 500 credits. Then after typed the code, press "**Left Arrow**" to confirm or "**Back**" to exit without change anything. The instrument controls the code and if is correct, it loads the 500 credits and prints this:



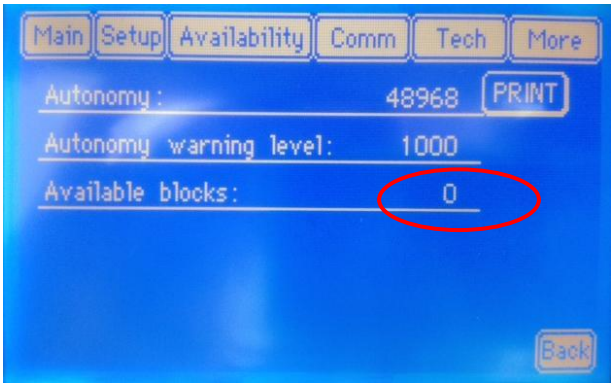
Then it comes back to Availability Menu.

Otherwise, if the code is wrong the instrument shows this:



Then press "**OK**" to come back to Availability Menu, and try again to type the code.

When the number of blocks become '0' (zero), the button "**USE**" become invisible, and is no longer possible to load the credits, until a new card with divisible credit is loaded.



Pressing "**Back**" it is possible to go back to Main Screen.

9.4 – COMM MENU (Technical password required)

9.5 – TECH MENU (Technical password required)

10.0 – NEEDLE REPLACE

The photos below show the quick needle replacing procedure

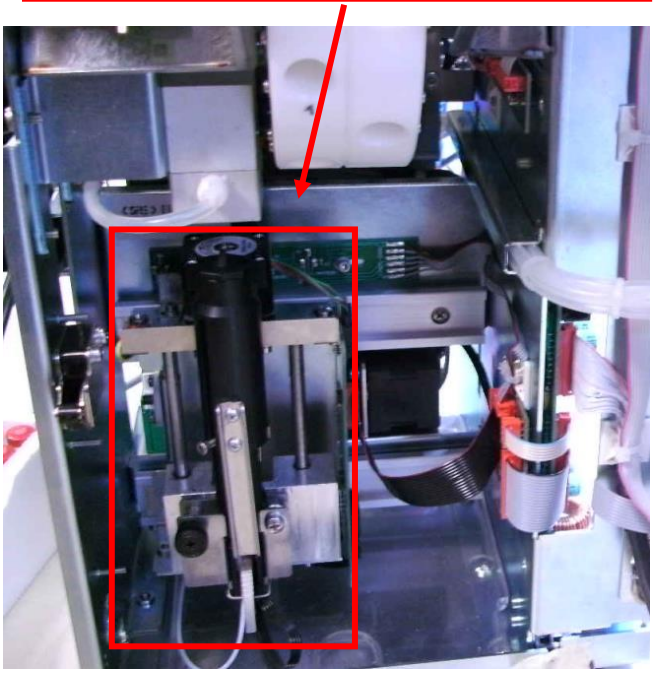
WARNINGS:

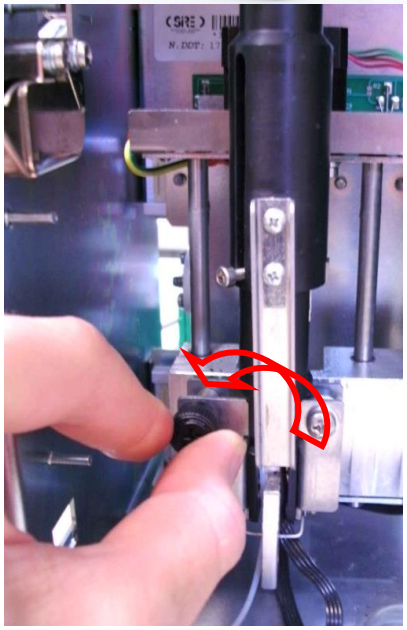
- **Verify the instrument is switched off**
- **During the needle replacing operations, it is mandatory the use of gloves and protective glasses, to avoid any contact with potentially infected biological material.**
- **Avoid absolutely to touch the top of the syringe piston, because also a light pressure 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

Open the front door pushing it till you ear the “click” of the latch .

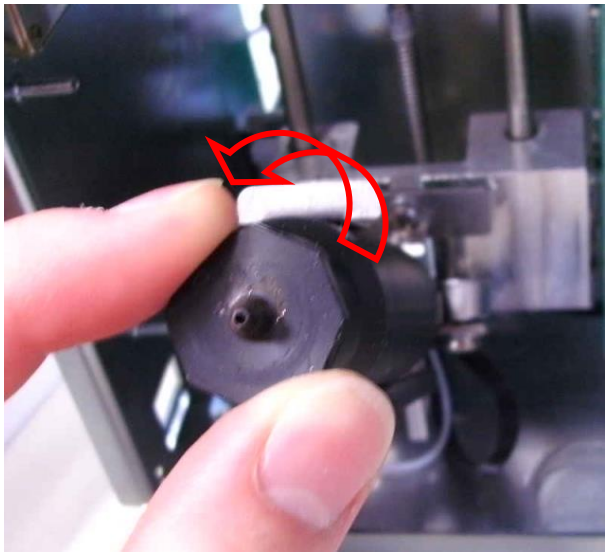
Localize the piston group(displayed in the photo):

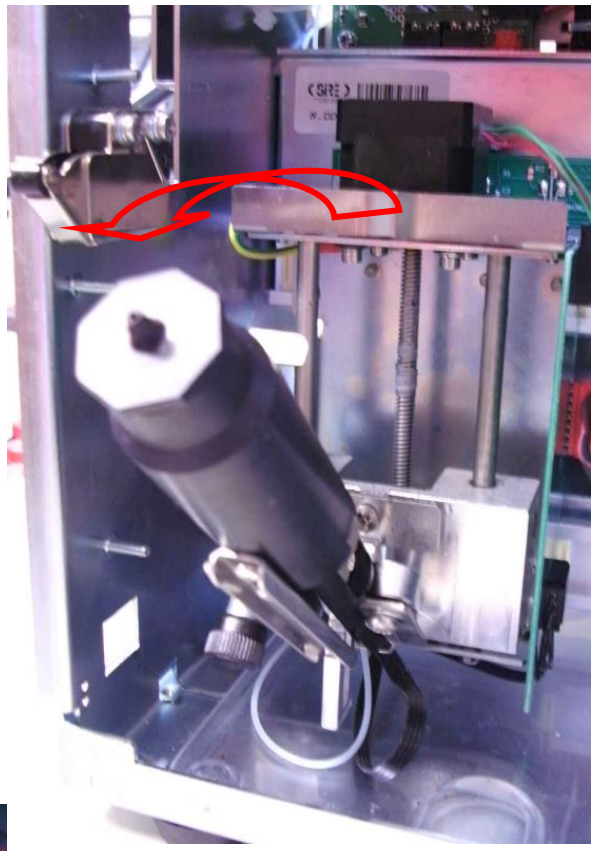


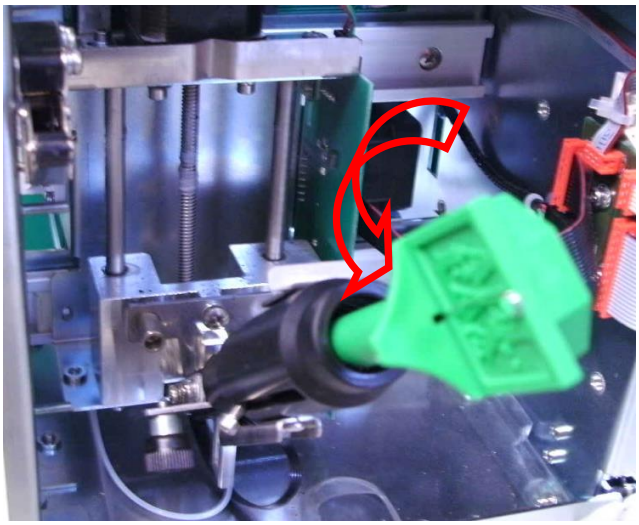


Unscrew the fixing screw

Pull the CBC adapter (piston) that will tilt to 45°.

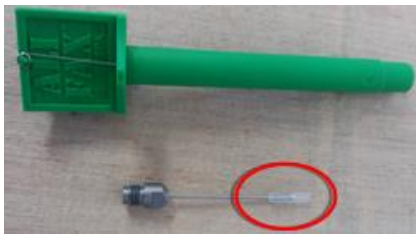


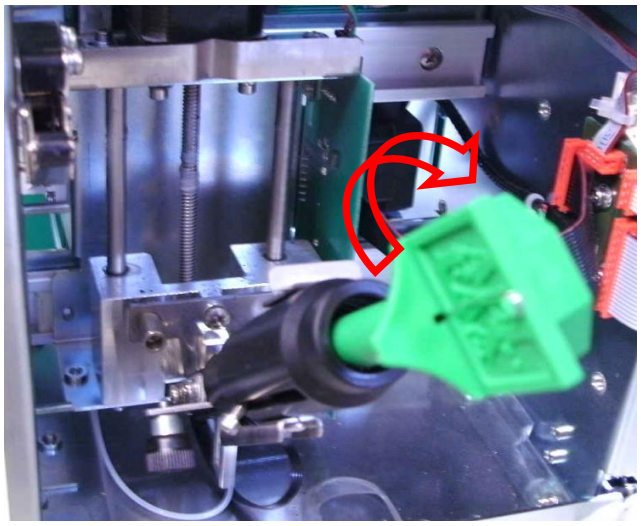




Unscrew the upper side of the piston (as shown in the photo.
This procedure allows to access the piston's internal side.

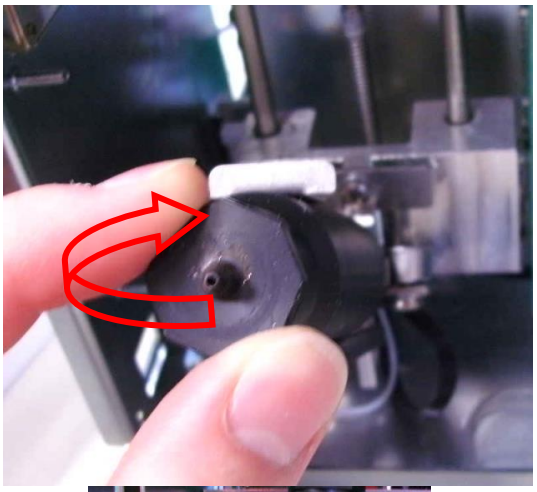
Insert the green tool (supplied) inside the piston, unscrew completely the needle and remove it. This operation has to be done in safety. Discard the replaced needle.



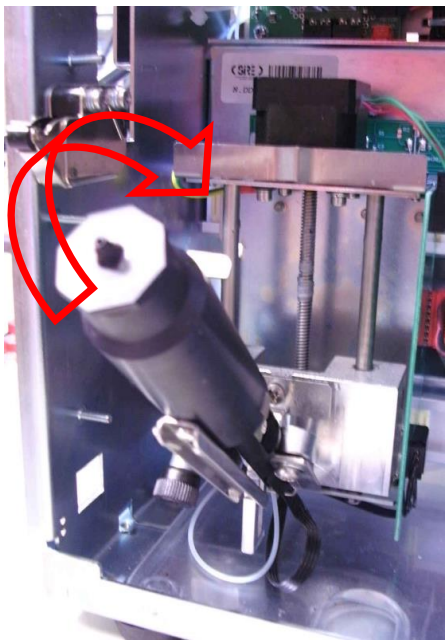


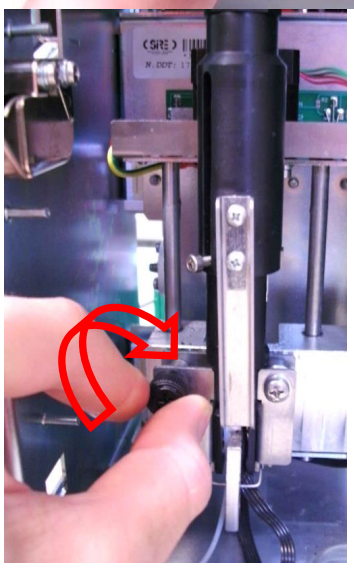
Take the new kit (SI 195.077), remove the needle from the green tool, remove the protective rubber from needle's tip, insert again the needle inside the plastic tool and insert it into the piston The ord. code for the new needle is
SI 1955077

Insert the tool with the new needle inside the piston body and tight the needle, paying attention do not tight excessively to avoid the thread damage.



Apply again the piston's tip, screw in to the right side (as shown in the photo).





Push back the piston and screw the fixing screw

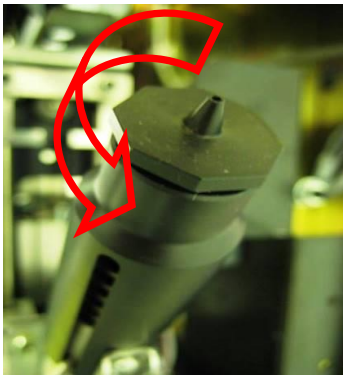
Note: After needle replacement is suggest to do a washing routine.

NEEDLE CLEANING PROCEDURE

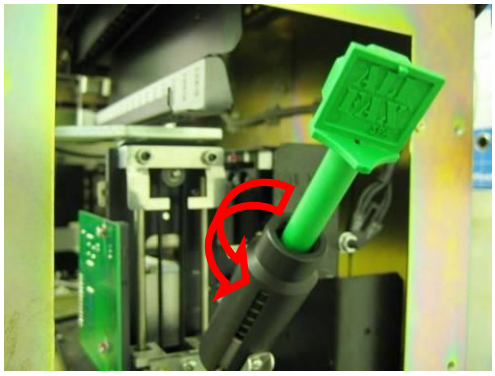
PROCEDURE:

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

Unscrew the blocking screw (blue circled) of the needle (if present) and pull the piston towards you, as shown in the picture.



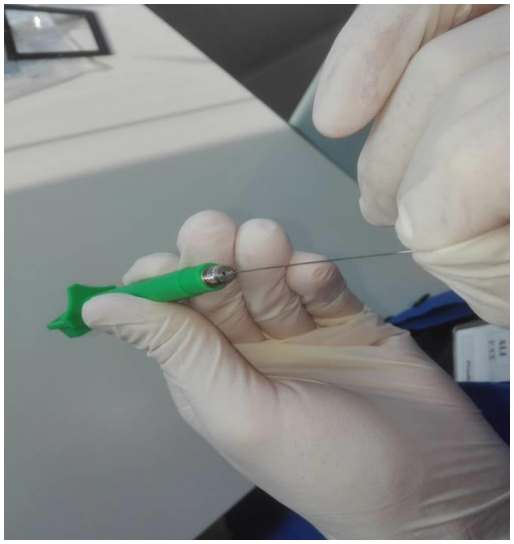
Carefully unscrew the cap of the piston, using the tool in the picture, NEVER USE HANDS, in order to avoid contact with the needle.



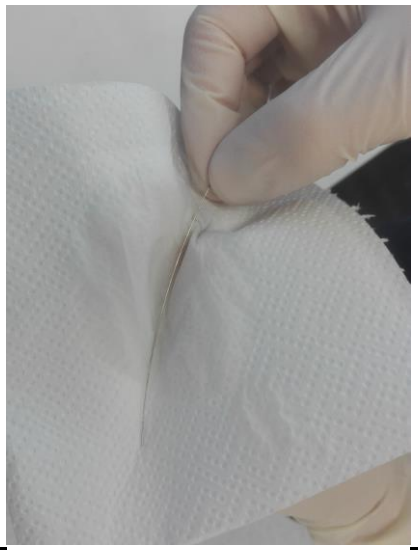
Carefully insert the tool as in picture, until you find the right connection point with the needle, and start to unscrew the needle..
Extract the key, keeping the needle inside it.

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.



11.0 – ERROR LIST

ERRORS THAT CAUSE INSTRUMENT'S BLOCKAGE:

Note			
E	X	X	Switch off the instrument, wait 10 seconds and switch on again
E	L	A	
E	E	X	
E	N	D	
E	0	0	
E	0	1	Rotor's home sensor not detected, check if square magnet is present on the rotor
E	0	2	Syringe's home sensor not detected, check if square magnet is present on the piston, check if sensor detects magnet presence
E	0	3	Carriage home sensor not detected, check if square magnet is present on the carriage, check if sensor detects magnet presence
E	0	4	Not detected home sensor for peristaltic pump even after three complete rotations, check if square magnet is present on the pump's rotor.
E	0	5	Not detected home sensor for external probe, check if square magnet is present on the manual syringe
E	0	6	Carriage position 1 sensor not detected, check if square magnet is present on the carriage, check if sensor detects magnet presence
E	0	7	Carriage position 2 sensor not detected, check if square magnet is present on the carriage, check if sensor detects magnet presence
E	0	8	Not Used
E	0	9	Not detected out sensor for external probe, check if square magnet is present on the manual syringe
E	1	0	Not Used
E	1	1	Not Used
E	1	2	Not Used
E	1	3	Not Used
E	1	4	CPS. Internal Serial Communication Protocol error, switch off the instrument, wait 10 seconds and switch on again
E	1	5	EXT_EEprom. Error during external eeprom access, switch off the instrument, wait 10 seconds and switch on again
E	1	6	RTC – Error during internal communication, switch off the instrument, wait 10 seconds and switch on again
E	1	7	UI (Unit Interface) – error during writing process on Unit Interface flash memory, switch off the instrument, wait 10 seconds and switch on again
E	1	8	COMM. Error during internal data transmission, switch off the instrument, wait 10 seconds and switch on again
E	1	9	COMM. Error in the internal protocol, switch off the instrument, wait 10 seconds and switch on again
E	2	0	Timeout during SPI transmission to MOTOR switch off the instrument, wait 10 seconds and switch on again

E	2	1	MOTOR. More than one *carriage* position sensor detected (active) at the same time (physically impossible!) switch off the instrument, wait 10 seconds and switch on again
E	2	2	MOTOR. (*syringe*) Both sensors sirup and sirdown active at the same time (physically impossible!) switch off the instrument, wait 10 seconds and switch on again
E	2	3	MOTOR. *Syringe* in sirdown and piston's sensor not detected. Switch off the instrument, wait 10 seconds and switch on again
E	2	4	MOTOR. (*manual syringe*) Both sensors sirmanout and sirmanin active at the same time (physically impossible!) switch off the instrument, wait 10 seconds and switch on again
E	2	5	Missing ACK of executed command from Hydraulic Selection
E	2	6	MOTOR.: Appears after 3 failed attempts to execute the required movement (request by other board or by operator), switch off the instrument, wait 10 seconds and switch on again
E	3	0	CPS.: Error E30 refers to a problem of missing communication between CPS and UI board during initial start-up. In the event this error is issued CPS must be replaced
E	3	1	MOTOR. (*peristaltic pump*) During movement of the pump there are detected motor stalls. (limited to CPS-MC Module), switch off the instrument, wait 10 seconds and switch on again
E	3	2	COMM Error in the internal communication with the cryptographic module; switch off the instrument, wait 10 seconds and switch on again
E	3	3	COMM Error timeout in the internal communicating with the cryptographic module¸ switch off the instrument, wait 10 seconds and switch on again
E	3	4	COMM Error in the decreasing of availability of tests inside the cryptographic ,module in the internal communicating with the cryptographic module¸ switch off the instrument, wait 10 seconds and switch on again

In case one of the mentioned errors is reported, for don't lose the current session, press the "**OK**" button. When "OK" button is pressed, the instrument automatically try again the last operation (move again the motor) and if this time the error not occurred, continue with the analysis.

The voices: **MOTOR, COMM, CPS, RTC, UI, EXT Eeprom** belongs to the electronic board that compose the instrument. This electronic boards contains parts and electronics components that **CAN NOT BE ADJUSTED BY THE LOCAL FIELD ENGINEER.** It is possible just to check the presence/absence of the square magnets on the syringe, carriage and peristaltic pump.

12.0 - 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 Sanitization Form (appendix B)

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.

Note: we suggest to make a copy of the appendix A at each sanitization and to fill it according to the sanitization procedure.

13.0 - SWITCHING OFF

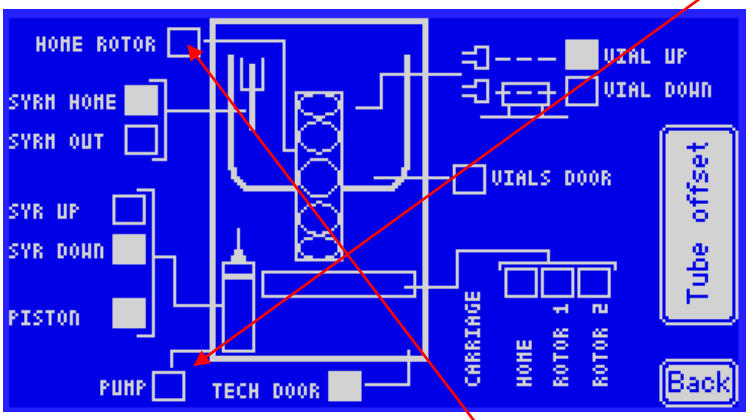
Before switching OFF the instrument it is mandatory to use the WASHING procedure.

Then the instrument can be switched OFF using the back side push-button.

When the instrument is switched ON if the washing was done previously, the instrument prints out **WASHING PERFORMED** , on the contrary the message will be **WASHING NOT PERFORMED** . These messages are useful to start correctly the analytical cycle only if the washing procedure was performed.

14.0 PROGRAMMED MAINTENANCE PROCEDURE

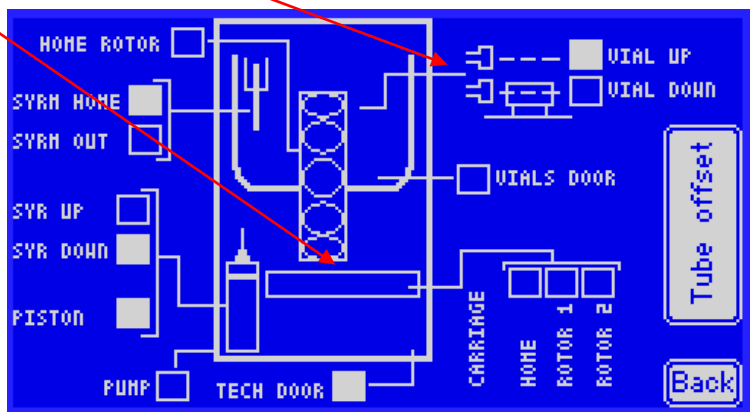
Frequency	Part to check	Description of checks (please fill in the checks done)
30.000 TEST		
	Carriage (X axis R20PN)	□ Clean the slides from eventual grease residuals and lubricate again with a PTFE grease or spray with silicone grease.
	Syringe (Z axis)	□ Check the status and the tension of belt, in particular the point of lockage to the syringe carriage, replace it if damaged. □ Clean and lubricate as explained for carriage (X axis). □ Check the status of the cable of piston sensor, replace it if damaged or folded.
	Needle	□ Check for any damage of the needle and replace it if damaged.
	Withdrawal piston	□ Remove grease residuals in the inner part of piston on the needle support. □ Lubricate the needle support, clean the steel flag on the side facing the sensor.
	Pump tube	□ Replace it, even if it seems not damaged.
	PTFE tubing	□ Check the status of PTFE tubing from syringe to the reading block and from the pump to waste tank, replace the tubing if deformed or damaged . □ Check if blood flow is normal and regular.
	Pump	□ Check the rotation of pump, pay attention to rolls are regularly rolling. □ Verify the regularity of pressure of rolls due to springs. If some squeaking is heard while the rolls operate, lubricate the rolls spraying them with a bit of silicon oil. □ Check if the magnets stuck on the head of pump are present, check the sensor, and look if the sensor, on the commands panel, is lighted when the magnets face the sensor during rotation.
	Rotor and Sensor	□ Check if the Home sensor is distant less than 2 mm from the magnet (the optimal distance is 1 mm) and check if it is detected. □ Adjust, if necessary the distance moving the sensor toward the rotor. □ Check the status of belt tension of motor eventually adjust the tension of belt . Remember that an excessive tension of belt enhances the motor noise level during rotation.
	Alignment	□ Align the syringe group (carriage) with the motor group, use the racks



carriage-rotor that are used by customer. The procedure of alignment of carriage with the rotor is described in the previous chapters.

Front door and Technical door

- □ Check the correct open/close of front door (open and close the doors), check if the movement on the hinges is not altering the correct detection of closed door by the sensor. If opening or closing of door is not correctly detected by the sensors, check the distance between the door frame and the sensor mechanical lever, Eventually add a small thin layer of plastic or rubber in order to allow the door (when closed) to push down the mechanical lever.



CPS block

- □ Check its calibration as described in the previous chapter 9.1.3
- □ The calibration can be adjusted using the calibration kit SI 305.400, composed by a series of optical filters and the calibration procedure.

Reset of counters

- □ When all the described checks are performed at the level of 30.000 test, reset the Maintenance Counter (Chapter 9.2.7.5). When reset, the instrument will alert the operator when other 30.000 test are performed, to call technical service. To reset the counter, enter in RESET MENU

60.000 TEST **Perform all checks reported for the 30.000 test as above described and also:**

Pump speed reducer

- □ Check the oscillation of the reduction gear shaft into the bearings. If the oscillation is higher than 0,5 mm evidencing also a grease leakage, replace the reduction gear.

Repeatability check

- □ Execute this test loading a certain number of samples available (max 60), repeat the analysis three cycles consecutively.
- □ Compare the results to verify the instrument repeatability.

15.0 - ALIFAX – REFERENCES

Manufacturer: **ALIFAX S.r.l.**

Production Site:
Via Merano 30 33045 Nimis (UD) Italy
Tel +39 0432 547454
Fax +39 0432 547378

Legal Site:
via F. Petrarca 2
Isola dell'Abbà
35020 Polverara (PD)
Tel. +39-049-0992000
e-mail info@alifax.com
web **www.alifax.com**
VAT: IT04337640280

The instrument is CE certified
According to directive 98/79/EC relative to In Vitro Diagnostic Medical Devices

The instrument is ETL certified for the North American market by Intertek

ETL LISTED
CONFORMS TO
UL STD 61010-1
CERTIFIED TO
CSA STD C22.2 # 61010-1
CSA STD C22.2 # 61010-2-081

APPENDIX A (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:

Too low

- 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:

OK

- 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.

Too high

- 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 B (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 (refer to page **37**) and the successive analysis cycle.

APPENDIX C - IMPROVEMENTS ON SOFTWARE VERSIONS from 5.00A

Version 5.00A

- Universal Software for R20-PN and R20-MC.
- Handling of the new smart card reader

Version 5.00B

- Fixed a minor bug of the syringe movement during washing cycles

Version 5.00C

- Fixed a minor bug of the smart card reader module

APPENDIX D – SANITIZATION FORM

This module must be filled by the Laboratory / Technical Service Engineer before shipping the instrument.
This document MUST be attached to the instrument.

Description of sanitization procedures to be done by the Laboratory:

Switch ON the instrument:

	OK	NOK
➢ Execute the Internal washing procedure		
Perform a first wash using two tubes filled with distilled water	☐	☐
Perform a second wash using one tube filled with water and one tube filled with sodium hypochlorite	☐	☐
➢ If the instrument is a Roller 10PN or Roller 20PN execute also the external washing procedure		
Perform a first wash using two tubes filled with distilled water	☐	☐
Perform a second wash using one tube filled with water and one tube filled with sodium hypochlorite	☐	☐
Remove the waste tank and dispose it following he 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 Internal washing procedure		
Perform a first wash using two tubes filled with distilled water	☐	☐
Perform a second wash using one tube filled with water and one tube filled with sodium hypochlorite	☐	☐
➢ If the instrument is a Roller 10PN or Roller 20PN execute also the external washing procedure		
Perform a first wash using two tubes filled with distilled water	☐	☐
Perform a second wash using one tube filled with water and one tube filled with sodium hypochlorite	☐	☐
Remove the waste tank and dispose it following he 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 OFF the instrument and unplug it from the power supply cable.

➢ If some part inside the instrument are contaminated with blood:		
Spray the parts with a disinfectant (cationic surfactants).	☐	☐
Collect liquid from the sprayed parts with absorbing paper towels.	☐	☐
Wash with water and dry with paper	☐	☐
For the disposal of the contaminated effluents and the Waste Tank, 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	☐	☐
For the disposal of the contaminated effluents and the Waste Tank content, follow the standard safety procedures in use in the laboratory	☐	☐

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 DATASHEET (PTDS)

ESR_PTDS_SIR20-PN_PTDS

PRODUCT TECHNICAL DATASHEET

ROLLER20-PN

Rev.2.4 – Valid from 2021 Jul 22

NAME: **Roller 20 PN**

REF Code: **SI R20 PN**

INTEDED USE: Automatic analyzer for Erythrocyte Sedimentation Rate (ESR) determination.

DESCRIPTION: Model with 2 rotors for 20 samples total equipped with an automatic washing system and manual external withdrawal tip for pediatric test-tubes and for test tubes that can be uncapped.

ANALYSIS PRINCIPLE: 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±0.5°C (98.6±0.9°F)

RESULTS: Given in mm/h in the range from 2 to 120 mm/h.

SAMPLE REQUIREMENTS: 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 section "method limitations" paragraph 2.

- the sample must be of whole blood collected in EDTA anti-coagulant.
- the blood sample must be neither coagulated nor hemolyzed.
- 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.
- The use of sample tubes with different volumes could affect the performance of the instrument

Automatic withdrawal:

- the minimum blood volume for the withdrawal is 800 microliters
- In the event paediatrics samples with **internal withdrawl** method the minimum volume suggested is 500 uL,
- the minimum blood working volume required for the analysis is about 175 microliters except for the first two samples from which supplementary 116 microliters are approximately withdrawn for priming. In total from the first two samples around 232 microliters are withdrawn. In case there is only one sample, the amount withdrawn for priming is around 232 microliters.
- samples separation inside the capillary by air bubble.

Manual withdrawal:

- the minimum blood working volume required for the analysis is about 100 microliters, except for the first sample from which supplementary 100 microliters are approximately withdrawn for priming.
- samples separation inside the capillary by air bubble.

TUBE REQUIREMENTS: Test-tubes 13x75 mm (0,512 x 2,953 inches) like BD Vacutainer® or BD Microtainer® or Greiner Bio-one or with 13 mm (0,512 inches)diameter and from 75 to 83 mm (2,953 – 0,3268 inches) high, cap included like, for example, the Sarstedt tubes that measure 11,5x66 mm (0,4528x0,2598 inches) without cap.
Compatible also with test tubes Terumo Venoject II® models VP-DK052K, VP-DK052K05 and VJ-DK052E004

- It is possible to use "BD Microtainer MAP®" tubes directly (also in conjunction with other 13x75, 0,512 x 2,953 inches tubes) 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" tubes; 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

PRODUCT TECHNICAL DATASHEET
ROLLER20-PN

PEDIATRIC TUBE COMPATIBILITY **For tubes not listed here, please contact you Alifax Distributor**	**Roller20-PN** With mixer, internal and external withdraw 	**Roller20-MC** Without mixer, external withdrawn only 
 Sarstedt S-Monovette EDTA 1.2 ml pediatric tube and SI195595 Tube Adapter	Internal mixing Internal withdraw External withdraw also	External mixing External withdraw only
 Tapval pediatric tube and SI195590 Tube Adapter	Internal mixing Internal withdraw External withdraw	External mixing External withdraw only
 BD Vacutainer pediatric tube and SI195593 Tube Adapter	Internal mixing Internal withdraw External withdraw	External mixing External withdraw only
 BD Microtainer MAP from 250 to 500 uL pediatric cuvette into 13x75mm tube with pierceable cap No tube adapter required	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 rotor	External mixing External withdraw only
 Sarstedt Microvette 500 K3E Code 20.1341.100 Capillary pediatric test tube for 500uL and SI205052 Tube Adapter	Internal mixing (use centrifuged mixing) **Internal withdraw (minimum 300uL)** External withdraw (less than 300 uL)	External mixing External withdraw only

 Sarstedt Microvette 200 K3E Code 20.1288.100 Capillary pediatric Test tube for 200uL and SI205052 Tube Adapter	Internal mixing (use centrifuged mixing) **No internal withdraw** **(too few blood 200uL)** External withdraw (200 uL is enough)	External mixing External withdraw only

Please notice all above tubes, have been tested mechanically to check compatibility with the instrument rotor and piercing system. There is not available any specific comparative performance information about them.

OPERATIVE PERFORMANCES

Operative performances:

- New design with thermoplastic cover, front door for easy access to waste and washing tanks and needle.
- Simplified and safe needle replacing procedure.
- Simplified Smart Card downloading.
- Photometer check after each washing, to ensure continuous control of the instrument.
- New photometer (CPS) with three detectors for ESR analysis and blood flow management.
- New automatic washing programmable at the end of each cycle.
- New withdrawal tip for pediatric test-tubes and for test tubes that can be uncapped.
- To compare the ESR testing between manual and automatic procedure performed with Roller 20 PN it is mandatory to open the cap of the tube both for automatic - manual procedure and vice versa
- Management of Latex Controls kits for TEST1 family analyzers **(Ord. code SI 305.100-A/SI 305.102-A and SI 305.300-A/ SI 305.302-A).**

Automatic withdrawal:

- Start the analysis within 2-4 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, after that, test should be executed within 4 hours
- In the event paediatrics samples with **internal withdrawal** method the minimum volume suggested is 500 uL,
- Instrument offers three mixing speeds (60 rpm, 32 rpm, 24 rpm); it is recommended to configure a speed of 32 rpm and 140 cycles for an adequate homogenization of the samples.
- Minimum volume required is 800 uL
- First result available after 4,4 minutes (mixing) and 30 seconds (analysis), the other results are given every 30 seconds each; 20 samples processed in about 10 minutes (120 samples per hour) without considering the time taken for loading and unloading of test-tubes from the instrument.
- The above throughput could be delayed in case of connection to the Host Computer with reply output time more than 1 second.
- verify 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.

- It is suggested the sample volume should not exceed the 50-60% of the total volume of the test-tube.
- In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following suggestions:
  1. Using the gain of the instrument during correlation with lab reference method
  2. Increasing the mixing time (this can be obtained using an external mixer before the ESR analysis or/and increasing the mixing time of the ESR analyzer).
  3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis.

Manual withdrawal:

- Start the analysis within 2-4 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, after that, test should be executed within 4 hours.

- Minimun volume required is 100 uL except for the first sample from which supplementary 100 microliters are approximately withdrawn for priming.
- verify 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.
- In case of external mixing of the samples, use a rotating wheel or a tilting bed set at speed of 32 rpms and 140 cycles of mixing to allow a suitable homogenization of the samples.
- In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following tips:
    1. Using the gain of the instrument during correlation with lab reference method
    2. Increasing the mixing time (this can be obtained using an external mixer before the ESR analysis or/and increasing the mixing time of the ESR analyzer).
    3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis.

Error notice:
The instrument in case of error or malfunction, reports this situation with a specific message on the screen plus with an acoustic intermittent signal of 62,5 dBA.

CAPACITY: max 20 samples/session

ANALYTICAL PERFORMANCES (obtained with 3 ml test-tubes):

Agreement with TEST1: **R^2 = 0.91**

Repeatability: mean CV% = 5.7% on the whole range 2 - 120 mm/h
Reproducibility: mean CV% = 5.1% on the whole range 2 - 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 (39.2°F) and some others at room temperature, have been analysed 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 (39.2°F) (r=0.980). Those stored at room temperature did not correlate quite as well as those stored at 4 °C (39.2°F), but still had very good correlation (r=0.917)[(1)].

METHOD LIMITATIONS:

1. The erythrocyte sedimentation rate is a phenomenon confined to fresh blood and transient[(2)], not a hematic matrix component (at corpuscular / molecular level). The procedures used to determine the ESR cannot be calibrated as they are susceptible to a variety of errors (temperature, hematocrit, erythrocyte mean corpuscular volume, plasma viscosity, etc.)[(2)]. Based on the acquired experience,TEST1 family instruments (TEST1, MicroTEST1, Roller20LC, Roller20PN, Roller20MC, Roller10PN and JO-PLUS), are limitedly affected by these variables. For this reason it is possible to observe instrument performances deviations compared to other procedures if the above variables are not taken into account.

2. Erythrocyte sedimentation remains an only partly understood phenomenon….is a nonspecific reaction (from a clinical point of view)… [(2)] that is affected by several technical aspects [(3)]. The ESR is often normal in patients with cancer...[(3)].

International guidelines for diagnosis and management of multiple myeloma do not mention the Erythrocyte Sedimentation Rate [(4)]. It is then necessary to point out that even though TEST1 analytical performances have been confirmed in patients affected by multiple myeloma [(5,6)], there have been some cases of patients affected by multiple myeloma in which TEST1 has reported clinically negative ESR values in comparison to other methods. Based on this experience there could be cases in which Roller gives low ESR results likewise TEST1 in presence of Multiple Myeloma.

Furthermore in presence of this disease and/or other oncological pathologies it is possible to observe deviations form 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 the 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. The use of such tubes optimizes the mixing phase and consequently the results reproducibility.

ENVIRONMENTAL AND PHYSICAL SPECIFICATIONS

Permissible environment conditions for operation:

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

Permissible environment conditions for transportation and storage:

Temp.: from -20÷70°C (-4÷158°F)
Humidity : from 5% to 95% - no dew

Size and weight:

[L] Length: 24 cm (9.4488 inches)
[W] Width: 39 cm (15.354 inches)
[H] Height: 46 cm (18.11 Inches)
Weight: 16 Kg (35.274 Lb)

Packaging: Cardboard box

[L] Length: 65 cm (25.591 inch)
[W] Width: 34 cm (13.386 inch)
[H] Height: 50 cm (19.685 inch)
Gross Weight: 20 Kg (44.092 Lb)
Volume: 0,1105)m^3 (3,902 F^3)
Pallet: No

ELECTRICAL SPECIFICATIONS

Voltage: 115 / 230 Vac (For USA and Canada 115 VAC only)

Power consumption: 115 VA
Switch on cons: 132 W

Frequency: 50/60 Hz

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

OTHER OPERATIVE SPECIFICATIONS:

Heat dissipation in the environment: about 230 BTU/hour

Noise: at low speed mixing: 55,0 db(A)
at high speed mixing: 50,6 db(A)

Maximum rated altitude: 3000 mt asl

Communication: 2 serial RS232 ports located on the rear side of the instrument:
Port 1 (DB25) is dedicated to connect an external scanner
Port 2 (DB) is dedicated to connect the instrument to an Host Computer
1 USB serial ports (for future applications)

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: Indoor user appliance

Rated pollution degree: Grade 2

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

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 TEST1 family analyzers allow the control of the calibration stability of TEST1, MicroTEST1; Roller10, Roller20LC, Roller20PN, Roller20MC, Roller10PN and JO-PLUS.

They are available in two kinds of test tubes:

- ♦ 13x75 mm Greiner: **Latex Controls (6 tests) - code SI 305.100-A;** **Latex Controls (30 tests) – code SI 305.300-A**
- ♦ 11,5x66 mm Sarstedt: **Latex Controls (6 tests) - code SI 305.102-A;** **Latex Controls (30 tests) - code SI 305.302-A**

CONSUMABLES

Printer Paper: Thermal roller paper 58 ±1/mm (0.2283 inch ± 0.004inch) x Max 32 mm(0.126 inch)

Smart Card: Conform to ISO 7816-1 specifications – 85.6 x 54 x 0.8 mm (33.7 x 21.26 x 0.315 inch)
Coded using Alifax proprietary algorithm.
Available for 1,000 (Ord. code SI 195.901) - 4,000 (Ord. code SI 195.904) - 10,000 (Ord. code SI 195.910) - 20,000 (Ord. code SI 195.920) tests / Universal Card; furthermore from Sw. version 5.00 it is available also the 5,000 test (SI 195.950) Multicode Card for TEST1 family analysers (TEST1, MicroTEST1, Roller20LC, Roller20PN, Roller20MC, Roller10PN

Waste Tank: 500 ml plastic tank with screw cap to collect blood and washing effluents. **SI205801**

Wash Tank: 500 ml plastic tank with screw cap for the water used to wash the instrument. (Available only on SI R20 PN Model) **SI195145**

OPTIONAL AVAILABLE TOOLS

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

REGULATORY INFORMATIONS:

Classification	IVD	
EAN13 Code	805604014034	
CND Code	W02029001	Not Applicable
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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5. Ajubi et al.: “Determination of the lenght of sedimentation reaction in blood using the TEST1 system: comparison with the Sedimatic 100 method, turbidimetric fibrinogen levels, and the influence of M-proteins”, Clin Chem Lab Med 2006; 44 (7): 904-906
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