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TEST1 2.0

Valid for Software Version 1.0.x

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

CE IVD

In Vitro Diagnostic Medical Device for professional use

INDEX

Note:

Parts written in blue colour, point-out an update or modification in the manual as regards the previous version.

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

1. ALIFAX ESR INSTRUMENTS PRESENTATION

Dear Customer,

Thank You 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 laboratory determination of erythrocyte sedimentation rate (ESR) in human blood samples with EDTA from adult and pediatric patients 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 human 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, anemia, 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 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

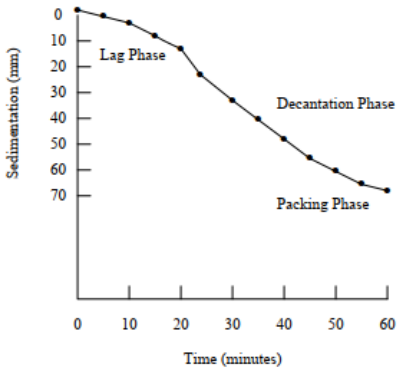


Figure 1. Sigmoid Sedimentation Curve. Evolution of the erythrocyte rouleaux formation in the different phases of ESR in a case with a high level of acute phase proteins.

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 18.5 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 18.5 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.

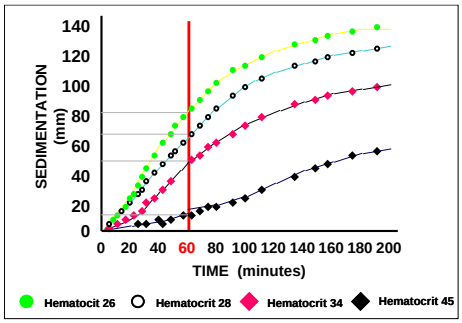
Adaptability to laboratory workflows
The operator loads the samples into the instrument using the same racks coming from the cell counter, in continuous access, without any manipulation of the single tube by the operator. The racks and tubes will be returned by the instrument in the same order in which 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 2.0 instrument it is adaptable to the working needs of the laboratory, can be integrated, it can works as a stand alone instrument or be integrated in a T.L:A. (Sysmex® track), 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 (18.5 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.



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:
- The 30 test kit consists of 15 test tubes containing 3 ml of synthetic latex solution:

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 ρ =0.99 with p<0.001, according to Passing-Bablok linear regression analysis:
Y= -0.28 + 1.04x , intercept A -0.28 , [95% C.I.: -1.17 to -0.10].
The article is available at http://dx.doi.org/10.1515/cclm-2019-0204

2. TYPOGRAPHICAL CONVENTIONS

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

2.1 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).

2.2 USED WARNINGS SYMBOLS

Caution, risk of danger to person or damage to equipment!

Biohazard!

Caution, moving parts inside!

Electrical hazard!

Mechanical hazard!

Ground!

Cut injury / sharp hazard!

Consult instructions for use!

Automatic start-up!

2.3 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] Length, [W] Width, [H] Height

NOTE The following label the reference serial number of the instruments

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

3. WARNINGS FOR A CORRECT USE OF THE INSTRUMENT

The following safety instructions must be observed at all times, both before and during operation and during maintenance.
The warnings, notes and symbols described hereafter are used in the current manual, on the instrument and on its packaging.

WARNING

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.
- The instructions for use manual must be accessible to the user at any time.

TEST1 2.0 system is designed and manufactured in accordance with the safety requirements for electronic and medical systems. If the law issues regulations concerning the installation and/or operation of the instrument, then it is the operator's responsibility to adhere to them.
The manufacturer have done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The systems are tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

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

3.1 GENERAL SAFETY

WARNING

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.

WARNING

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.
- If the unit is used in a manner not specified by manufacturer the degree of protection may be impaired.
- In the event any available data stored in the instrument it is eventually downloaded, the person that have done the action becomes automatically the only responsible of the download data.

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.

3.2 OPERATIVE SAFETY

WARNING

Mobile Phones

Do not use a mobile phone next to a running system. It is possible to affect the correct function of the system.

Do not use mobile phones in proximity of the device.

Minimum distance that must be maintained between mobile phone and device could be calculated with following formula: $d=2\times\sqrt{P}$ where d=distance [m] and P=maximum power [W].

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 2.0 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 cap 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 The minimum blood volume for the internal sampling is 800 ul and verify that the blood is not neither haemolysed nor coagulated. Use exclusively blood samples withdrawn in EDTA anticoagulant (K2 or K3).
- In case of low volume samples, the external sampling system allows to handle samples with low volume in the tube (e.g. paediatric, oncology samples, etc.), between 300 and 799 ul. The instrument's external sampling system can be used without work-flow interruption.
- 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

- It is possible to use “BD Microtainer MAP®” tubes directly (also in conjunction with other 13x75 tubes) but could be necessary to verify the needle offset.
- 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 (or Calibration) that must be stored in the refrigerator at + 4÷8 °C (+39,2 / +46,4 °F); To use the Latex Controls, please refer in any case to the IFU of the Latex Control.
- 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.

3.3 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 authorized by the manufacturer.
- Switch off the system, separate it from the mains supply and protect it against restarting.
- For your safety, if any part should be damaged, ask for the immediate replacing with original spare parts, specially for the parts connected to mains (power cord, fuse-holder and mains switch …)
- Use only original spare parts supplied by the manufacturer.
- Use only peripherals authorized by the Manufacturer

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.

3.4 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).
- External power supply can be connected to building installation with overcurrent protective device 16 A or 20 A (US Canada).
- External power supply shall be connected to the socket outlet with grounding pin.
- 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 doing any kind of intervention on electrical parts of the instrument; also unplug power cord before connecting any external peripheral as external bar code readers, printer cables and/or RS232 serial cables and for maintenance.

Danger due to Improper Place of Installation

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

- Ensure the place of installation of the system is so that the power supply and mains switch are easily accessible and disconnectable from the power grid.
- 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.

Electrocution/Fire Hazard!

During the normal routine working please:

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

Electrocution/Fire Hazard!

During Maintenance/ Technical Service activities be sure to:

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

Battery Handling

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

- Do not attempt to recharge the battery.
- Do not expose to temperatures higher than 60°C (140°F).
- Do not disassemble, crush, puncture, short external contacts, or dispose of in fire or water.
- Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.
- Replace only with the spare designated for this product.
- Lithium battery VL 2020 type inside smart card reader.
- Lithium battery CR1620 type inside CPU board (IMX8).

NOTE

Transient Emissions and Interference Resistance

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

- This instrument can cause radio interference in domestic environment. In this case it may be required to take action to eliminate such interference.
- This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference
- Before setup and operation of the instrument, the electromagnetic environment should be evaluated.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources, deliberately operated high frequency sources), as these can interfere with proper operation
- 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

3.5 BIOLOGICAL SAFETY

DANGER

Risk of infection!

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

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

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

DANGER

Waste and Disposable procedures

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

DANGER

Maintenance
During Maintenance/ Technical Service activities be sure to:

- **use gloves to protect against 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

3.6 PRIVACY AND PATENT SENSIBLE DATA HANDLING

WARNING

Personal Data

- The software has been designed and set up to guarantee data protection through the security measures of pseudonymisation, disassociation and disconnection.
- The personal data that are processed by default by the software are the pseudonymised ID of the sample, the report of the ESR examination performed by the operator as well as the pseudonymised username created by each individual account.
- Each user must authenticate with his or her own login credentials (username and password) in order to use the software; depending on the type of profile of the specific user, different levels of functionality and processing of personal data are assigned. If the password is lost, it can be reset by the user responsible for the laboratory and a new one created later.
- The log files of each user are stored and maintained in a special mass storage and contain pseudonymised data relating to the operation of TEST1 2.0 and user use. Only with the express permission of the laboratory manager is it possible to link the pseudonymised data to a specific user.
- By default, only the user name of the user, the pseudonymised ID of the sample and the report of the ESR examination performed by the operator can be displayed on the screen.
- Other personal patient data can only be displayed after interfacing the laboratory LIS and only by the user. Only the user can view and extract a copy of the ESR report complete with the patient's personal data acquired from the LIS.
- As an additional security measure, by default the software automatically logs the user off if the instrument is inactive for more than 30 minutes. Each user can manually disable this function or change the inactivity time for disconnection.
- The instrument does not store personal patient data transmitted by the LIS and the manufacturer (Alifax) has no way of accessing this type of information.
- Once the ESR examination of the sample has been performed, the report linked to a specific pseudonymised ID is stored in a special mass memory and retained for a period of 1 year. After this period, the data is deleted.
- In the case of activation of the 'Remote Control' function, pseudonymised data related to the user, the ID of the analysed sample and the report of the ESR examination performed can be shared. Data sharing with the cloud platform is done through secure, encrypted connections authenticated with logins and passwords for users and with certificates for devices. Remote Control's cloud services are based on Google Cloud services. All data stored in the Remote Control system are backed up daily. Backup data from the last 7 days and a backup of the first day of the previous month are maintained.
- It is the sole burden and responsibility of the user or data controller to take and maintain the necessary security measures to protect users' and patients' personal data in accordance with applicable local legislation, e.g. EU Regulation 2016/679 (GDPR) in Europe.

4. LABELS

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

Instrument plate label

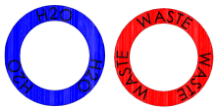
Biohazard label with compulsory use of gloves
Accidental puncture hazard label when changing the needle

Label to indicate moving parts inside the instrument.

Label that stats attention and Biohazard risk and require compulsory use of gloves

Biohazard label risk and require compulsory use of gloves

Fuse indication label



Washing tank cap identification label (BLUE) Identification label for drain tank cap (RED)

Biohazard label with indications about tank replacement

and

Washing tank label with filling information

PROCEDURE OF INSTRUMENT WASTE AT THE END OF ITS OPERATIONAL LIFE

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

5. UNPACKING, INTALLATION and FIRST START-UP

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

6. TEST1 2.0 PRESENTATION

The TEST1 2.0 is an automatic analyser developed to do ESR analysis in 18.5 seconds. The maximum capacity is **120 blood samples** (using 8 Alifax plastic racks of 15 positions each).
Different configurations are allowed according to the kind of rack used in the laboratory. In this case the management of the whole amount of test tubes containing blood samples depends on the kind of rack.

Alifax offers the new TEST1 2.0 in two versions:

1. **Version with automatic washing and external probe**. In addition to the above explained features, this version allows ESR analysis using an external probe able to aspirate one blood sample per time. The test tube is uncapped and kept by hand. This additional device is thought to analyse paediatric blood samples as well as also for urgent sample is possible to external sampling independently from internal sampling without work-flow interruption
2. **Version compatible with Sysmex® TLA track;** this is the version that can be installed directly on the Sysmex® track and have all the previous features included (automatic wash, manual, wash, external sampling).

STAT function:
For urgent samples it is possible to proceed with the external sampling unit.
The urgent sample/s must be previously mixed (ie. manually at least 16 times by complete inversion of blood tube, or using a blood mixer, to prevent eventual clots).
The external sampling unit will return the ESR result in 18.5 seconds, without interruption of the working session loaded on the automatic TEST1 2.0 unit.

Low Volume samples:
The external sampling system allows to handle samples with low volume in the tube (e.g. paediatric, oncology samples, etc.), between 300 and 799 ul

All versions contain an internal robotic arm used to transfer the test tubes from the racks holders to a rotor having 20 test tube slot capacity. Robotic arm is able to take the already processed test tubes from the rotor and return in the corresponding rack holder; this feature allows consequently a “continuous loading” process of tubes for ESR analysis.
Before inserting the tube in the rotor, robotic arm places the tube in front of the IBCR (Internal Bar Code Reader) for the identification of each tube; once identified, the tube is inserted in the rotor and automatically mixed.
First result it is available in less than 5 minutes independently the sampling it done in the automatic (internal) or manual mode.

The ESR outcome matched with the ID code will be visible on display in 18.5 seconds after the reading leading to a throughput of 195 sampes/hour (without considering loading, unloading and mixing times); in case of TEST1 2.0 over Sysmex® TLA, it is possible to process up to 180 samples/hour.
Results obtained can eventually be exported into a pen-drive inserted into a frontal USB port. The created file could then be opened and displayed into two formats which are: CSV and PDF; the analyser is also able to send to LIS the ESR outcome. The same outcomes could be printed, if an external printer (optional) it is available.

The instrument is equipped with a tank that contains distilled water (identified as Wash Tank).
This feature allows the instrument to wash automatically in the event of 3 consecutive NF or at the eventual wash timeout. Still possible to run a manual washing that requires two tubes inserted in a rack (as in the old version of TEST1).

Instrument it is exempt from Ordinary Maintenance. At the end of the day, the operator once pressed the frontal power button might choose among normal power off or the “Wash & Sleep”.
If Wash & Sleep it is selected, the instrument washes automatically and then it powers off;
Above process requires 1 second indeed once pressed the power button, the operator only needs to select the between normal power off or “Wash & Sleep”, this means practically zero hands-on work, the instrument does it all automatically in about 4 minutes.
The next day the operator finds everything clean and ready for the new routine.
Instrument can be considered “waste-free” if it is connected (where present) to the laboratory centralized waste drain line.

7. INSTRUMENT FRONT SIDE OVERVIEW

Picture 1

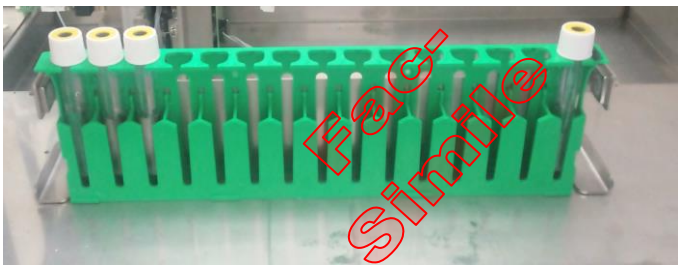
7.1 INSTRUMENT FRONT SIDE VIEW (TLA VERSION)

7.2 INSTRUMENT INTERNAL VIEW (TLA VERSION)

Below photo refers specifically to the “zone of the instrument where must be placed the rack containing the washing tubes as well as the latex ones.
As you can see, a cassette (in this specific case a green one) it is placed inside the instrument and it can contain form a minimum of 1 tube up to 15 tubes filled with distilled water.

In the same position goes the rack containing a sequence of water, hypochlorite, latex and so on in case of Latex Quality Control run.

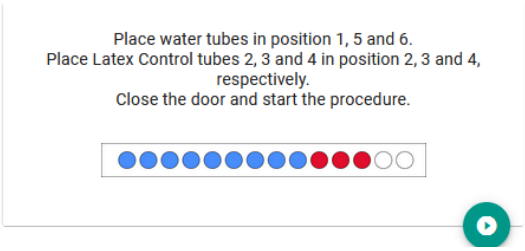
Empty Rack Station



Station with rack with 4 tube (it can contain up to 15 tubes)

Important: position N°1 it is located on the left side

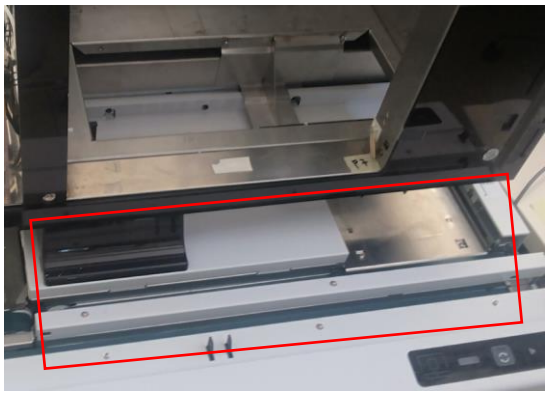
When Latex Control it is carried on, in the Rack Station it is necessary to place a rack containing in sequence



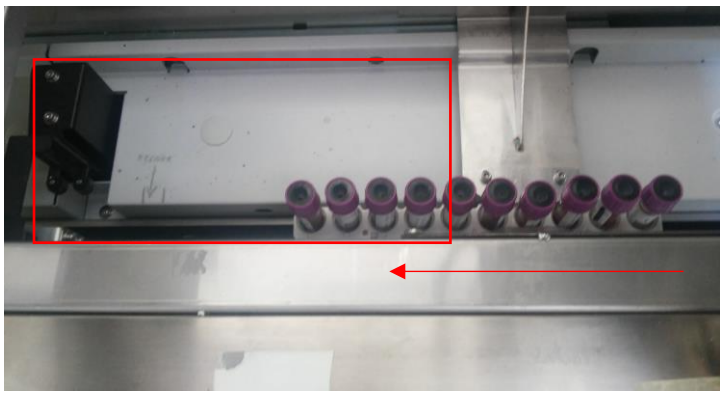
Pos 1: Water
Pos 2: Latex L2
Pos 3: Latex L3
Pos 4: Latex L4
Pos 5: Water
Pos 6: Water

Important: position N°1 it is located on the left side

Below photos shows the Sysmex® TLA track, with in detail the zone where the Sysmex cassette it is delivered just below TEST1 2.0



Sysmex® TLA track



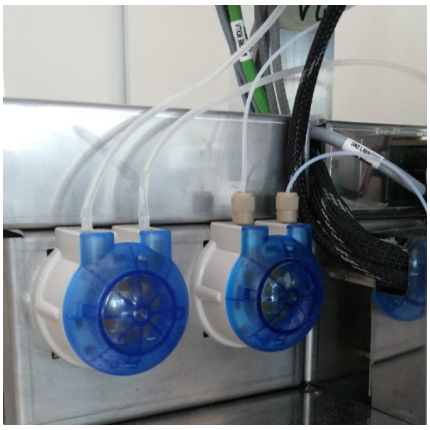
Sysmex® cassette moving to the sampling position

Sysmex® cassette in the sampling position

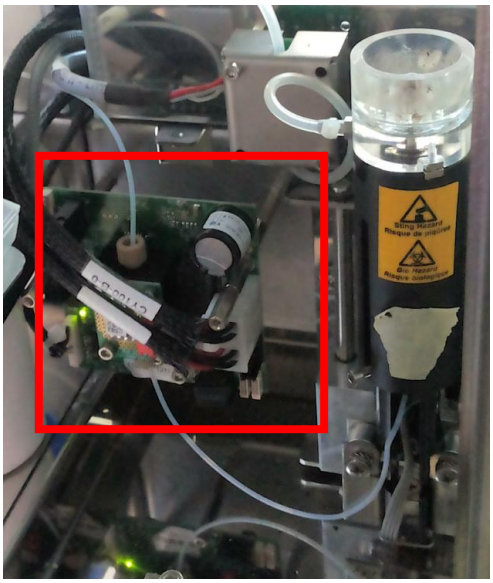
7.3 INSTRUMENT INTERNAL VIEW COMMON TO BOTH VERSIONS

Internal Needle Zone

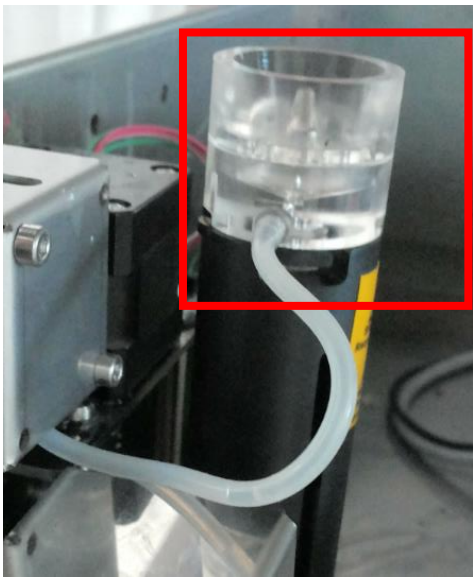
Rotor and Barcode Reader zone



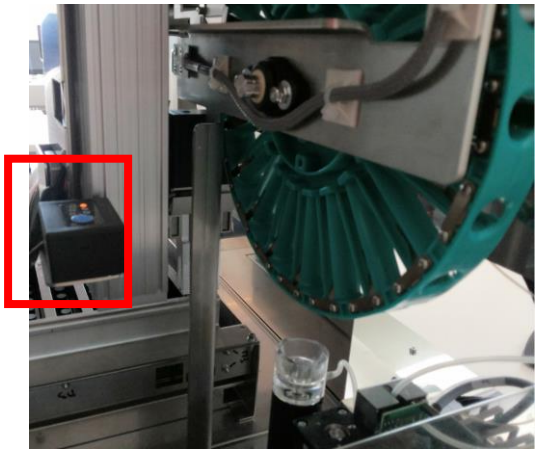
Needle Wash peristaltic pump (left)
Needle Blood peristaltic pump (right)



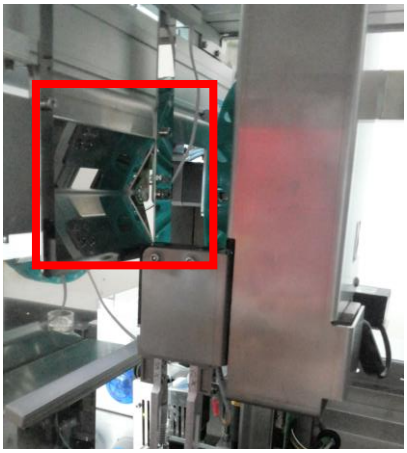
Internal CPS (Left) – Internal Piston (right)



Needle washing station details

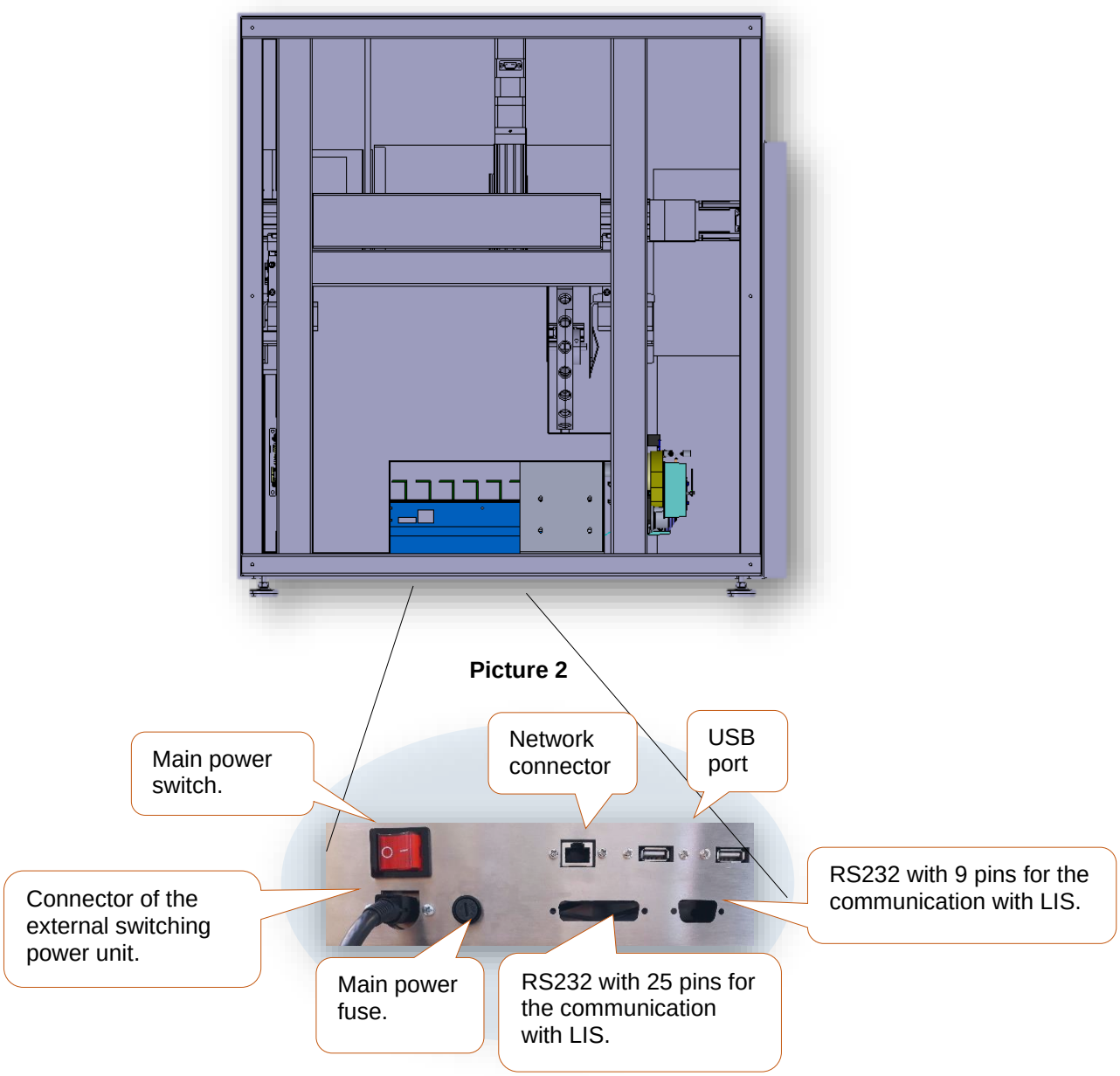


Internal BarCode Reader



Internal BarCode Reader mirror

7.4 INSTRUMENT REAR SIDE



Picture 2

7.5 WATER TANK AND WASTE TANK HANDLING

Water and Waste tanks: are located on the left side of the instrument; to get access to them just open the left side door and then pull out the sliding guide.
The Automatic Washing System requires the use of a tank containing distilled water for the cleaning of the hydraulic circuit and a waste tank.
For proper use, it is recommended to fill the wash tank on average every 2 days, making an additional check of the water level, also during the operations of replacing the drain tank. It is also recommended to remove the water tank from the instrument, wash it with hypochlorite, rinse it with water, and reinsert it (after refilling with distilled water) into the instrument. This procedure in order to avoid the formation of residue at the bottom of 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.
The photo on the right side must be intended only as an example to illustrate the process; the photo might not reflect the precise position nor the labels might be the ones applied.

8. “POWER ON” THE INSTRUMENT

The instrument is equipped by a main switch located on the rear side (see to **Picture 2,** chapter **7.4**). When you turn it ON, the instrument powers a part of the circuits present into it but it remains stand-by. To power the instrument completely there is a frontal power button (see to **Picture 1,** chapter **7**). The same button is also able to turn the instrument to stand-by after its use.

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

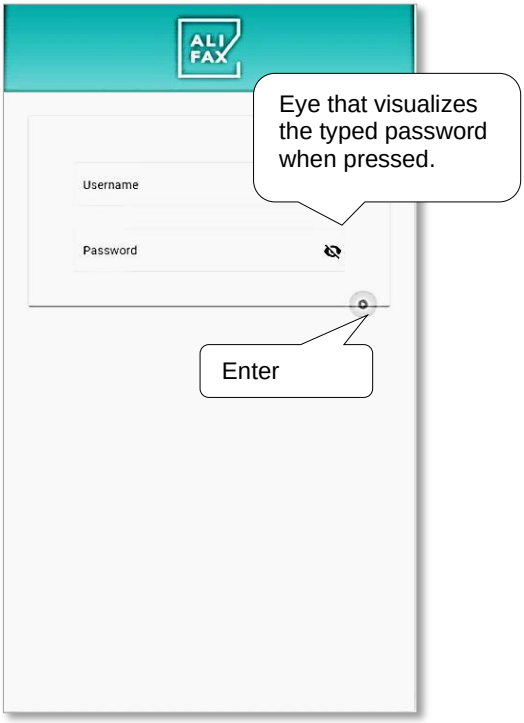
9. LOGIN CREDENTIAL

The use of the analyser and its performances is subordinate to the type of job assigned to every single person that works in the laboratory. To do that, it has been created four kinds of credentials that can be divided into:

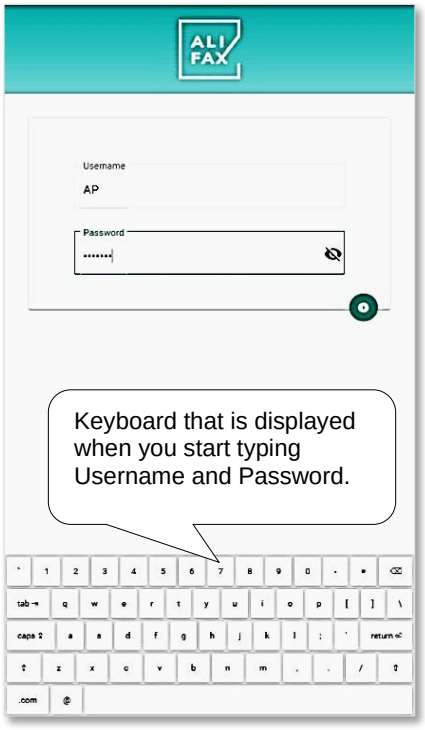
- **Laboratory manager** Medium level of credentials that allow accounts creations for laboratory technicians and can modify electronic calibrations.
- **Laboratory technician** Low level of credentials that allow doing ESR analysis, Latex Controls, washings and date and time modifications.

All operations done will be stored into an AUDIT TRIAL file.

After turning the instrument ON, the display stands on hold for the credential the user has to type according to its own activity.

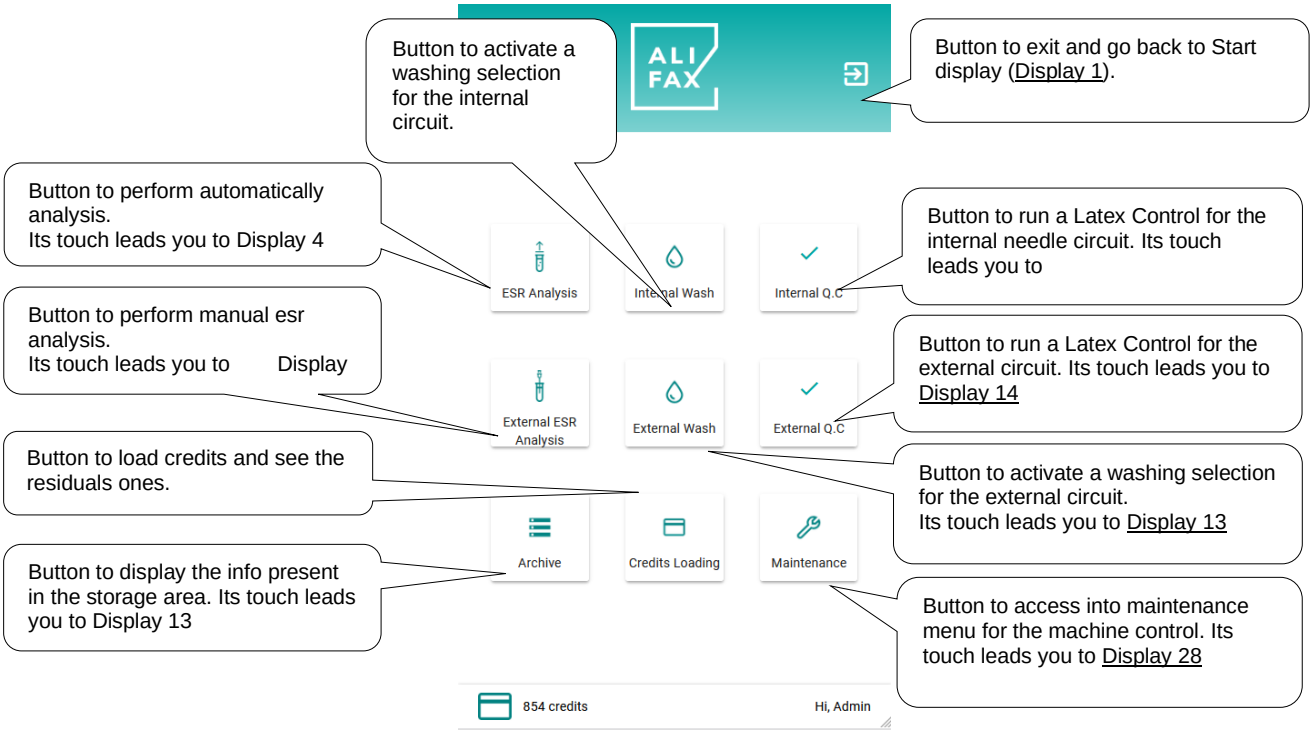


Display 1



Display 2

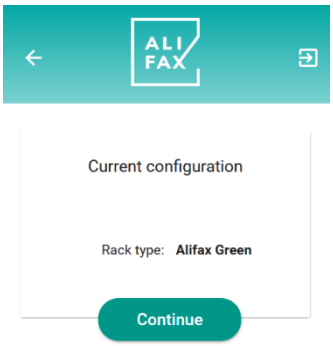
10. OPERATIONS WITH INSTRUMENT OVER DESK (NON TLA Version)



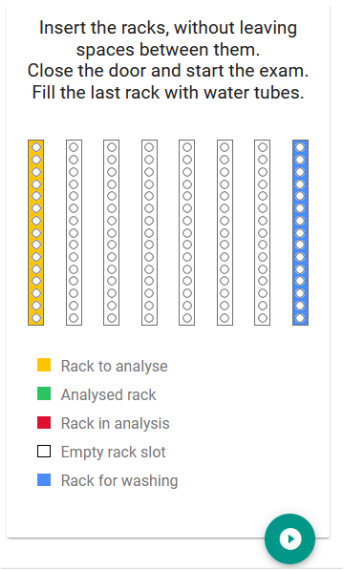
Display 3

10.1 ESR ANALYSIS

The ESR Analysis button leads you to **Display 4** where you can see the current configuration of rack adapter"; to start the analysis just press Continue**.**



Display 4



Display 5

Once press Continue, instrument will show on screen the status of the rack holder as visible on Display 5.

The first position on the left is intended to load the first rack independently the configuration. The racks slot holder therefore it is able to carry 8 racks for a total of 120 samples (assuming to use the Alifax cassette able to carry 15 tubes each).
To insert the racks into the instrument you have to follow the indication reported on "**Appendix A**" (how loading racks in the instrument).

- Orange slot = rack in waiting line for the analysis
- Blue slot = rack used to pre-load washing tubes (slot marked in blue only in case of automatic washing disabled or in case of instrument without embedded automatic washing feature). In this case when instrument will need to wash, it will use the tubes filled ¾ with water.
- It is important to verify the status of tubes (instrument in any case warns when all of them have been used and needs to be filled up again)
- Green slot = rack already analysed (it can be removed placing instrument in pause)
- Red slot = rack under current analysis (cannot be removed)
- White slot = empty and available slot

After loading the racks in the slots **(mandatory starting from most left side one)**, press the green button to start the analysis cycle.

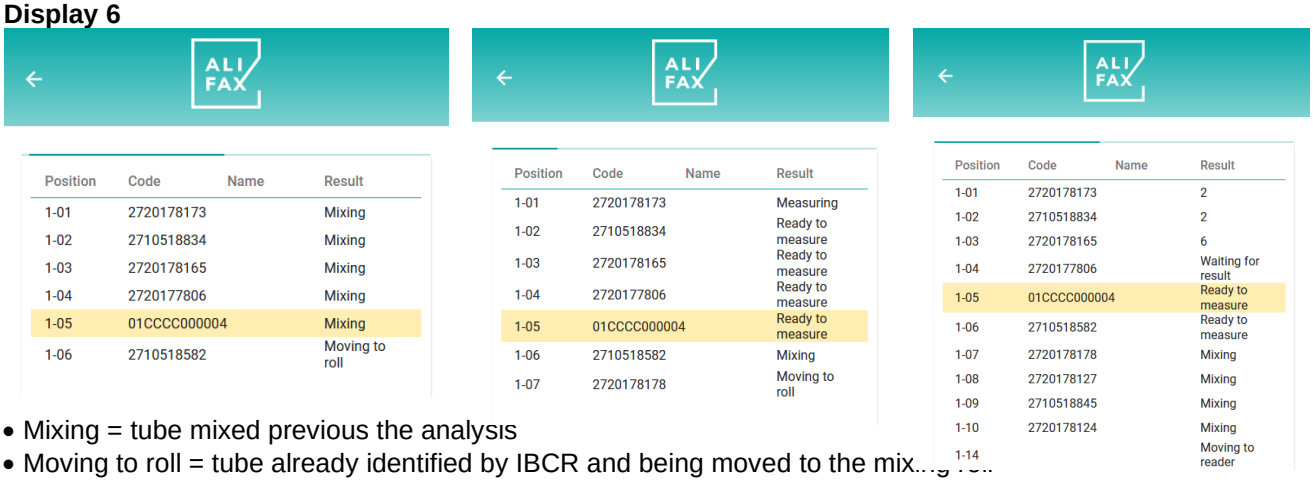
The analysis cycle includes 5 steps:

1. The robotic arm takes a test tube from a rack, identifies it by means of the Barcode Label (notice it is not necessary to verify the correct alignment of the barcode labels facing the right side of the rack) and put it into a free location of the mixing wheel.
2. The robotic arm repeats the step 1 for many times until all locations of the mixing wheel are full.
3. The mixing wheel rotates for a scheduled number of rotations and constant speed in order to homogenise the samples and so the red cells disaggregation.
4. The syringe rises towards the test tube cap, the pump then aspirates the amount of blood from the test tube and move this sample into the reading cell where then the photometer measures the aggregation phase.
5. When the measuring phase is finished and the instrument has released the ESR outcome, the robotic arm takes the test tube from the mixing wheel and move it back to the rack at the original position. If there is a free location in the wheel, the robotic arm takes next sample tube from a rack in the next slot and the process will be repeated from step 2.

10.2 ESR RESULTS

Below images represent different phases during the analysis:

Display 6



Position	Code	Name	Result
1-01	2720178173		Mixing
1-02	2710518834		Mixing
1-03	2720178165		Mixing
1-04	2720177806		Mixing
1-05	01CCCC000004		Mixing
1-06	2710518582		Moving to roll

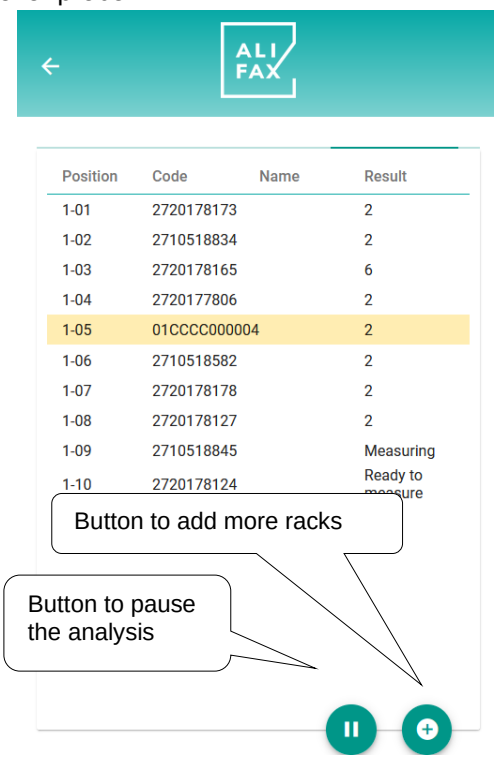
Position	Code	Name	Result
1-01	2720178173		Measuring
1-02	2710518834		Ready to measure
1-03	2720178165		Ready to measure
1-04	2720177806		Ready to measure
1-05	01CCCC000004		Ready to measure
1-06	2710518582		Mixing
1-07	2720178178		Moving to roll

Position	Code	Name	Result
1-01	2720178173		2
1-02	2710518834		2
1-03	2720178165		6
1-04	2720177806		Waiting for result
1-05	01CCCC000004		Ready to measure
1-06	2710518582		Ready to measure
1-07	2720178178		Mixing
1-08	2720178127		Mixing
1-09	2710518845		Mixing
1-10	2720178124		Mixing
1-14			Moving to reader

- Mixing = tube mixed previous the analysis
- Moving to roll = tube already identified by IBCR and being moved to the mix...
- Ready to measure =tube already mixed and waiting to be moved over probe
- Measuring = sample blood withdrawn form tube
- Waiting for result = sample under analysis
- Moving to reader = tube taken from rack in slot and being moved to the IBCR station for identification

The tube positions eventually highlighted in yellow recall the attention of the operator to the fact the patient barcode label ID was not read by the IBCR and a temporarily ID was generated by the instrument.
At the end of the session the operator must recover the specific tube and manually modify the patient ID in the instrument archive or the LIS.
Valid results are displayed and reported in the range 2-120 mm/h.
Instrument allows a "**continuous loading concept**" this means that a session can be started with only one rack loaded, then it is possible to add more rack just pressing the "add rack" button.
If necessary, it is also possible to momentarily halt the analysis pressing the "pause" button.

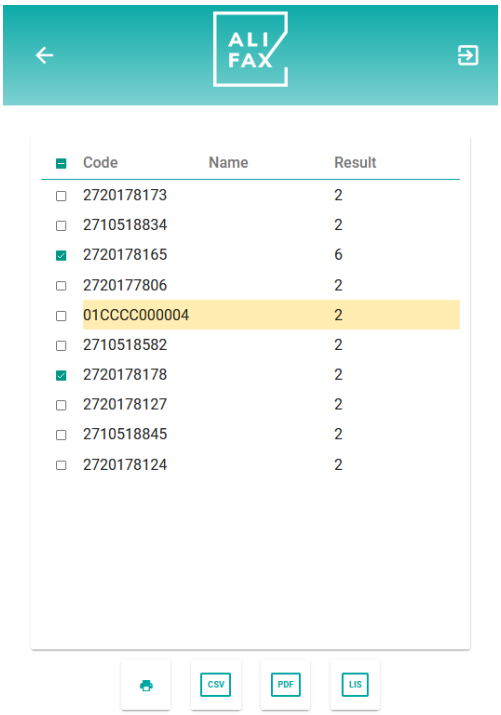
Please notice it is always possible to momentarily halt the analysis with the aim to load further racks (if there are slots available). To halt the session just press the "pause" green button, then do the required action and the press again the "pause" button to restart the session



Display 7

10.3 ESR result HANDLING

The display is going to report the outcomes as the example shown on Display 8 at the end, you have to remove all racks from the rack holder.



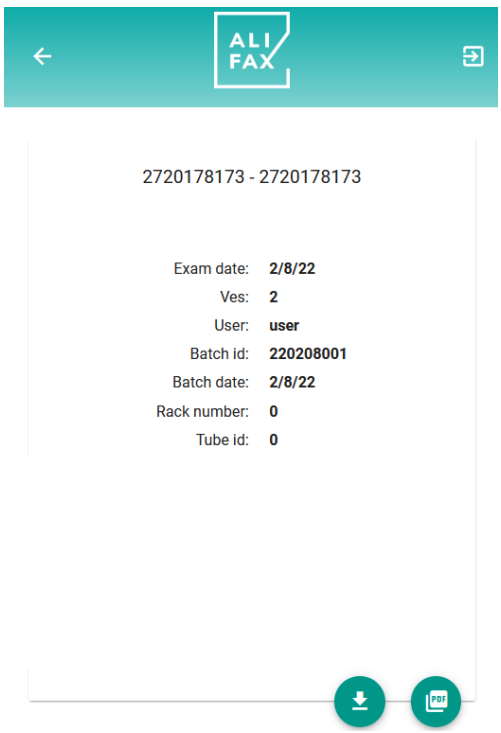
Instrument allows you to choose between following options:

- Print ESR results to a printer connected to the instrument
- Export ESR results in CVS format
- Export ESR results Send ESR results to LIS
- report in a PDF file

There it is the possibility to select only some results to be printed, other to be sent to LIS and so on; just check box near the patent ID according your necessities and then just press the corresponding icon

Remember that the instrument has an Internal Bar Code Reader (IBCR) engineered to read the patient ID barcode label. In the event the IBCR does not have the possibility to read the ID Barcode Labe, instrument will automatically assign an auto generated code to the sample (see highlighted yellow example). The code later on can be manually modified by the operator just clicking over the auto generated code and manually type the effective patient ID.
To do the barcode change please refer to **chapter 17**

Display 8



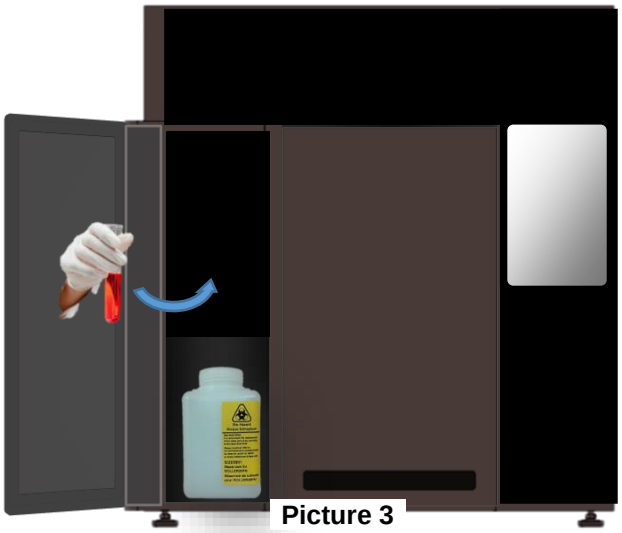
There it is also the possibility to generate a dedicated report individually, just “click” oved the patient ID number top get a detailed overview as here visible on the left side image.

In this case it is possible only to

- Export ESR results in CVS format
- Export ESR results report in a PDF file
- Send ESR results to LIS

10.4 EXTERNAL ESR ANALYSIS

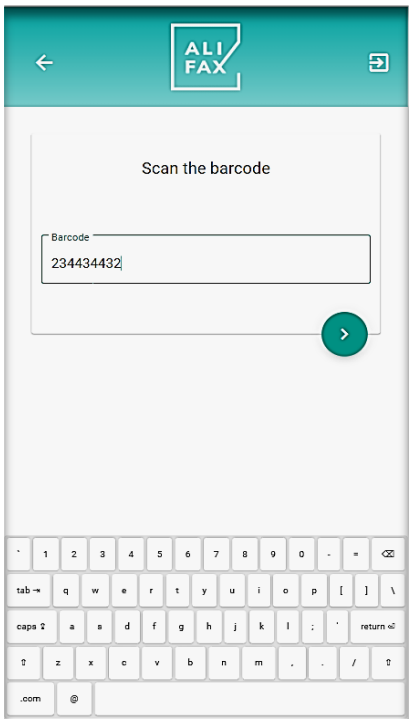
The External ESR analysis is thought to work with the external probe located on the left front side of the instrument inside a cabinet. Its configuration allows the analysis of one sample per time. The test tube is kept manually, uncapped after mixing and placed in the cabinet with the probe that sink inside the test tube.
For urgent sample is possible to external sampling independently from internal sampling without work-flow interruption



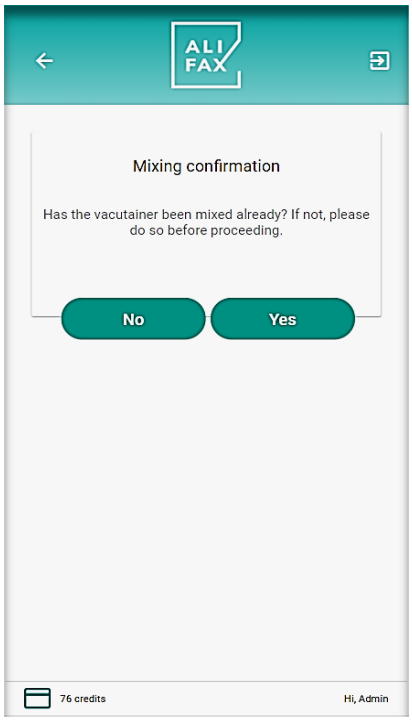
Picture 3

Pressing **External Esr Analysis** button located at Display 3 leads you to Display 9
Before placing the test tube in the cabinet with the probe inside, you have to read the ID code by an external scanner or type it manually so that it appears in the “Barcode” window. The right button will be green coloured at the barcode typing time.

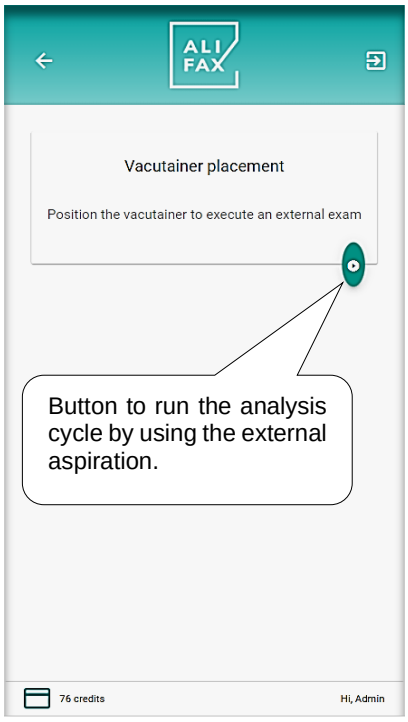
The green button touched at Display 9 leads you to Display 10 where you can choose between Yes and No; pressing Yes the instrument as to place the tube over the probe and the press start process green button



Display 9



Display 10



Display 11

11. INSTRUMENT WASHING PROCEDURE

This procedure is designed to clean the complete capillary tubing and so to set it free from blood or Latex residuals. Since along the working life Latex flow inside the Teflon tube, particles of them tend to hang on the internal walls of the capillary. This fact, accordingly, increases the capillary opacity reducing the reading scale of the ESR values.

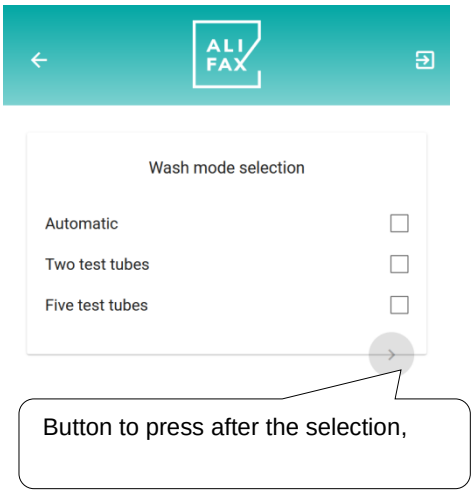
11.1 INTERNAL PROBE WASH

The **Internal Wash** button leads you to Display 12

The software allows the selection among “Automatic”, “Two test tubes”, “Five test tubes”.

11.1.1 Automatic WASH:

No tubes for washing are required. The only thing to pay attention is the water tank that should be full of distilled water and the waste tank that should be emptied. Both tanks are set inside the instrument behind the left door.



Display 12

The “Automatic” washing is normally executed:
- After 3 consecutive NFs or NRs.
- Priming error
- At the requesting time by pressing the button.

11.1.2 Two Test tubes WASH:

The washing using 2 test tubes is an alternative to the automatic washing; it can be used normally for washing the instrument.

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

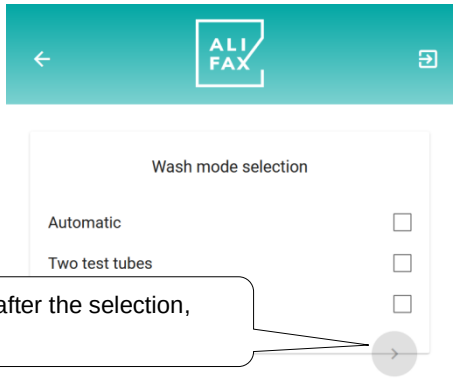
Two test tubes filled for a half with distilled water are required.

The “Two Test tubes” washing is required:
- When the automatic system is not available
- At the requesting time by pressing the button

Please notice the option “Two Test Tubes” foresees the necessity to insert a rack with tubes in position 1 and 2 of the rack.
Important: to avoid possible capillary or needle obstructions, please be sure to use maximum two times the same washing tubes

11.2 INTERNAL PROBE HYPOCLORITE WASH (5 tube wash procedure)

The procedure using five test tubes it is mandatory in preparation for the daily latex control run; this washing procedure it is also recommended as a daily maintenance to maintain the cleanings of the capillary and hydraulic circuit.



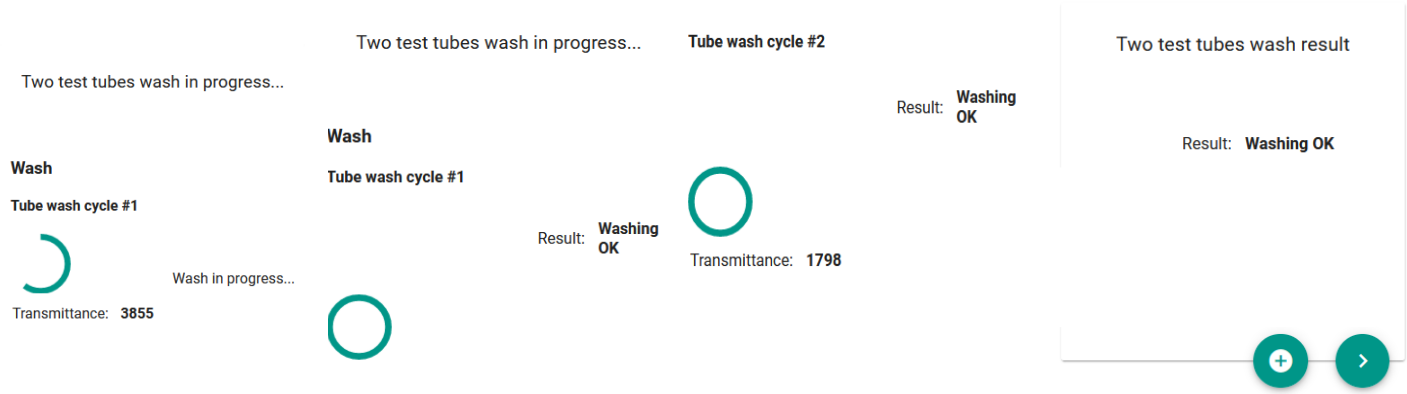
The preparation and loading procedure it is as follows:

Prepare and load in sequence:
- two test-tubes filled 3/4 with distilled water
- one test-tubes filled 3/4 with Sodium Hypochlorite (5% of dilution)
- two test-tubes filled 3/4 with distilled water

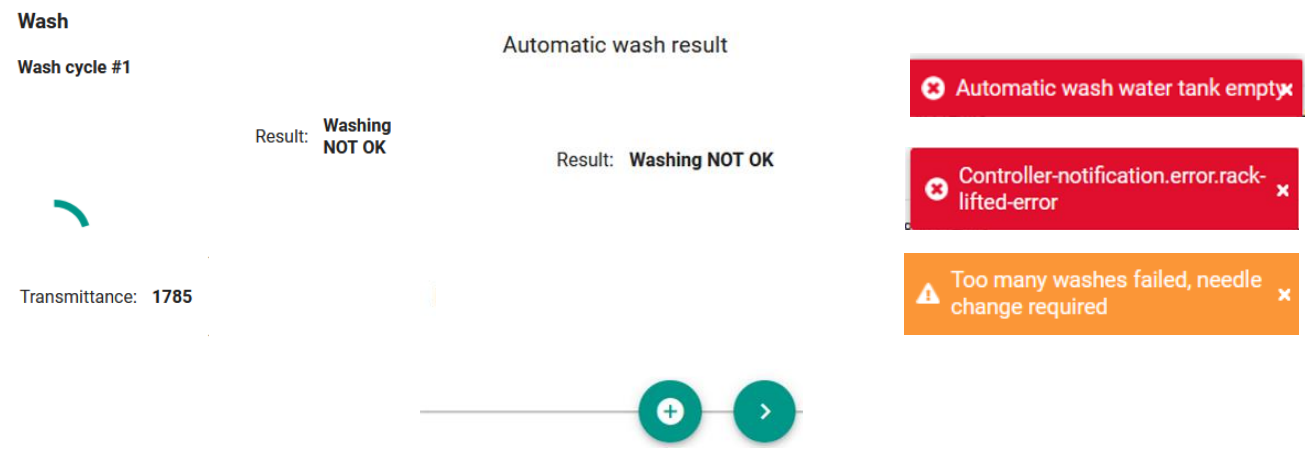
At the end you have loaded total of 5 tube sequence

Please notice the option “Five Test Tubes” foresees the necessity to insert a rack with tubes in position 1 to 5 of the rack

Once selected the washing option, instrument displays a confirmation (this example refers to the “Two test tubes” configuration) and expects the operator start the process pressing the green button.



Examples of some error messages:



11.3 EXTERNAL PROBE WASHING

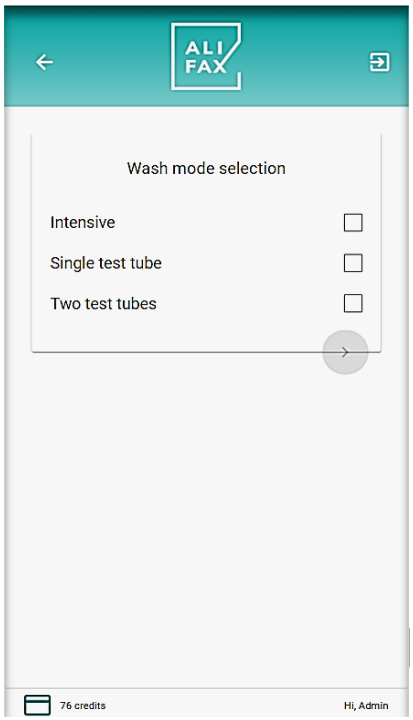
The External wash option is to clean the external probe and its liquid flow circuit. The modality of function is the same described on chapter **10.1** “INTERNAL WASH”. The unique difference is that you have to uncap the test tube to do washing and keep it manually placed in the cabinet with the probe that sinks inside the test tube (Picture 4 on page 23).

The **External Wash** button touched at Display 3 leads you to Display 13
The software allows the selection among “Intensive”, “Single test tubes”, “Two test tubes”.

Intensive washing mode
This wash foresees three steps:

- **The first step** foresees a washing with a test tube filled for a half with distilled water.
- **The second step** foresees a washing with a test tube filled for a half with Hype-Chlorite (bleach) and
- **Third step** foresees a washing with a test tube filled for a half with distilled water. .

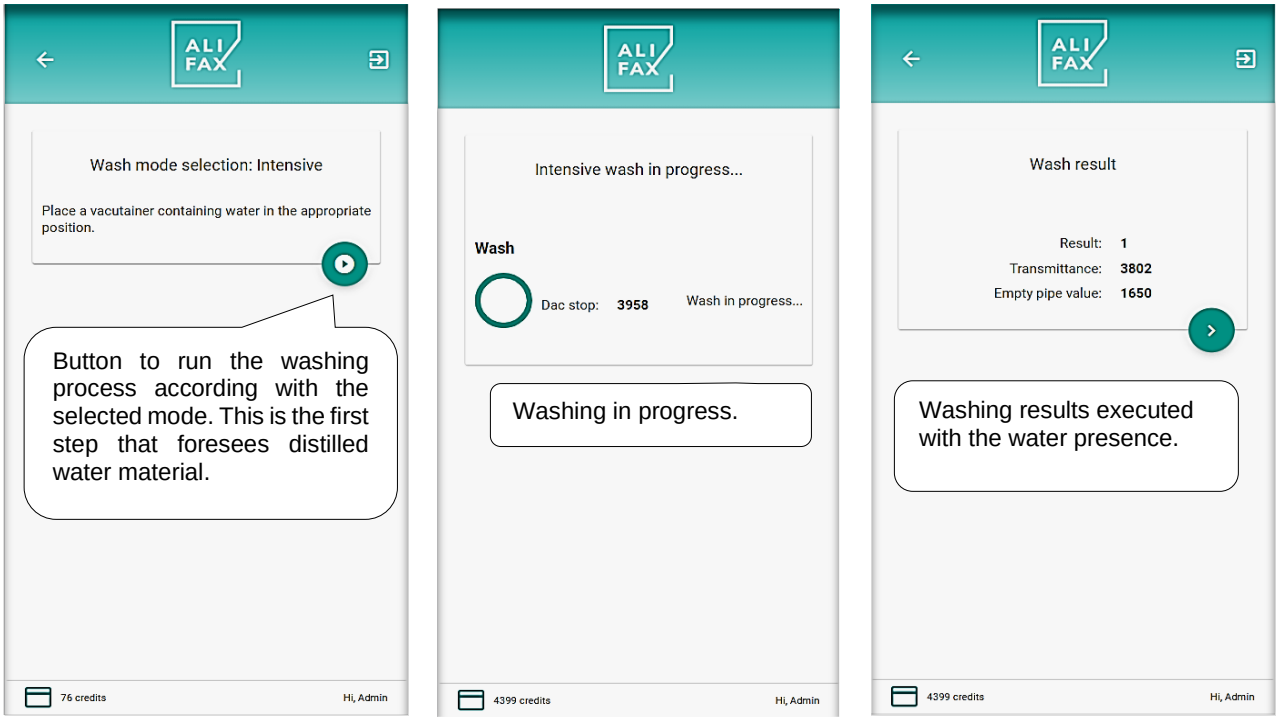
Single tube washing mode
Requires the use of only one washing tube filled half with distilled water.

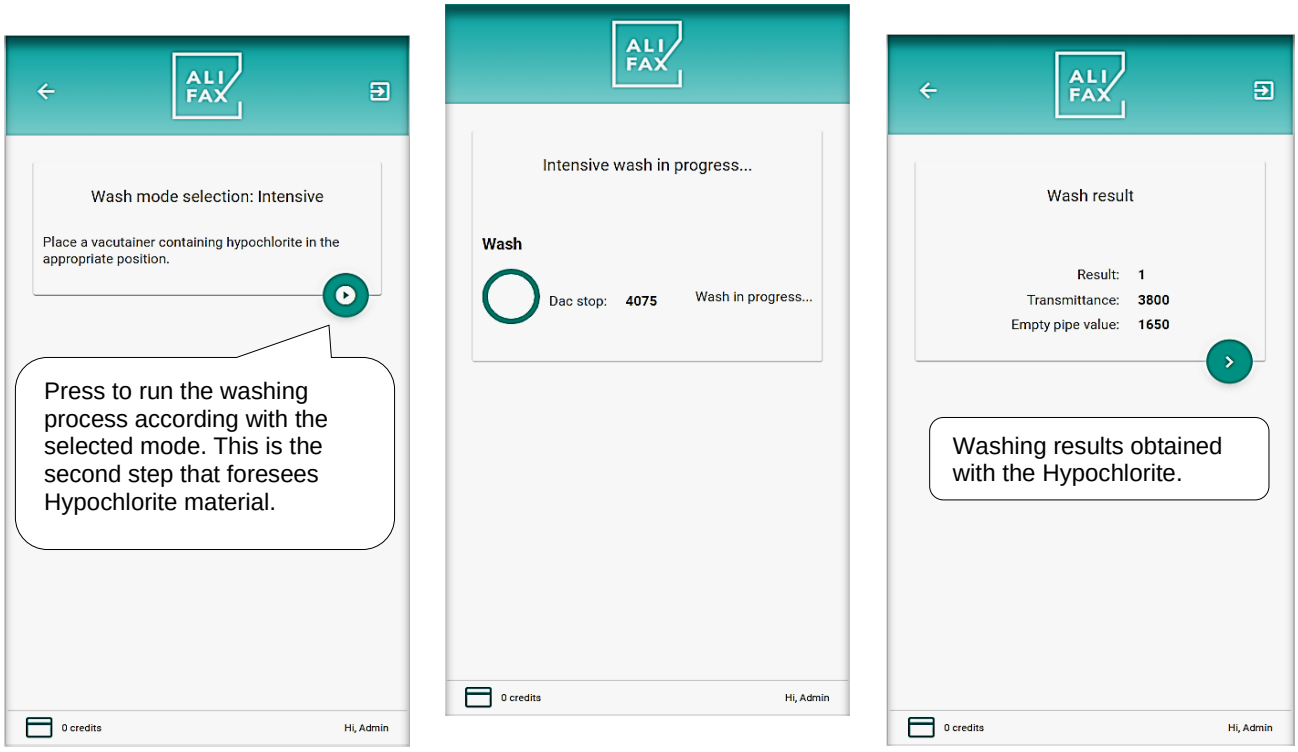


Display 13

Two test tube washing mode
Requires the use of two test tubes filled half with distilled water, this is a more intensive wash procedure in case the single washing procedure does not end successfully.

Example of Intensive Washing:





12. LATEX QUALITY CONTROL

Latex Control kit is a practical and efficient tool to check the accuracy and repeatability of the analyser during its working life.

The kit is supplied in a box that can contain:

- 1 triplet Latex that allow executing a total of 6 controls (code **SI 305.100-A**)
- 5 set of triplets Latex that allow executing a total of 30 controls (code **SI 305.300-A**).

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); remove from the box only the triplet that will be used for the checks; once used, the latexes must be returned to the refrigerator. To use the Latex Controls, please refer in any case to the IFU of the Latex Control.

12.1 LATEX QUALITY CONTROL FOR INTERNAL CIRCUIT

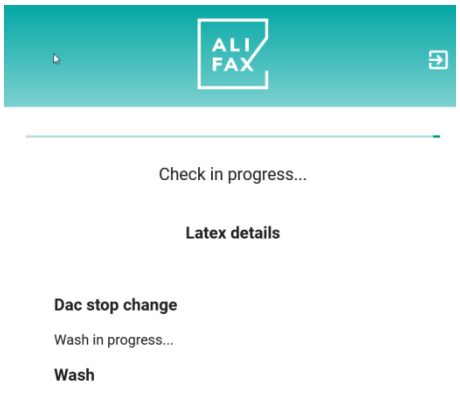
Before running a Latex Control, carry-out a "5 tube washing procedure" (refer to chapter 10.2):

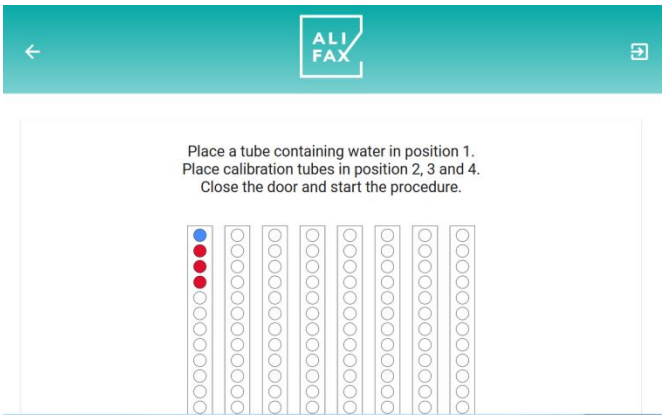
Important: to avoid possible capillary or needle obstructions, please be sure to use maximum two times the same washing tubes.

The **Internal Q.C.** button pressed at Display 3 leads to the Latex Control procedure.

Follow strictly the loading sequence as displayed:

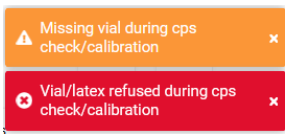
- In position 1 (blue) must go a wash tube filled ¾ with distilled water,
- In positions 2-3-4 (red) must be loaded the three latex tubes in the sequence
- NO rinsing tubes are required indeed the instrument will rinse automatically





Once loaded the tubes press the green button to start the process.

Initially the instrument will check the presence of the tubes loaded and in case of missing tube it will issue a message informing the anomaly



If presence of tubes it is confirmed, next step is the identification of the latex lot and latex triplet, followed by the washing sequence:

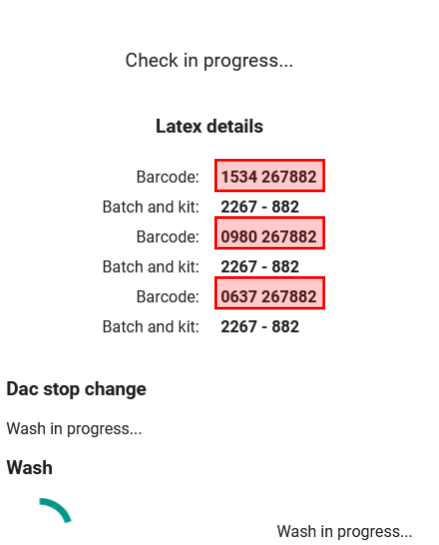
12.2 LATEX QUALITY CONTROL RESULTS FOR INTERNAL CIRCUIT

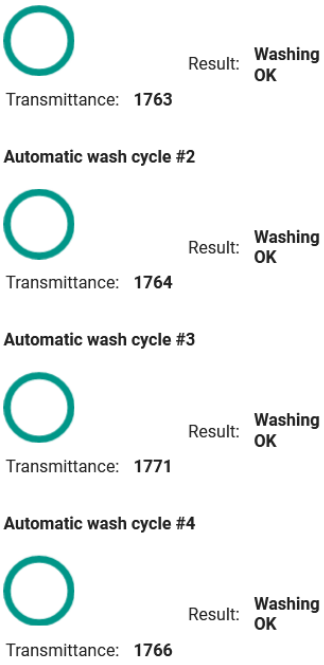
At the end of the Control process, the instrument shows the three ESR values: the first, it is designed to cover "normal" patients, the intermediate, it is designed to cover "borderline" patients and the third to cover a high level for "pathological" patients.

The effective reference ranges to be used to confirm that the instrument is "in control" are in any case those indicated on the outer label of the Latex Control Box.

If the results obtained are within the expected ranges, it means that the analyzer is calibrated correctly. On the contrary, if one or more results are out of the expected ranges, it is recommended to call the Technical Service to perform a functional verification of the analyzer and a new calibration of the analyzer.

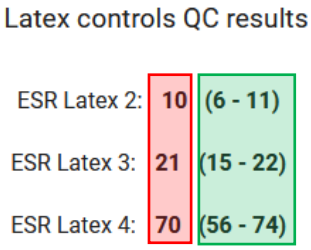
Example of the procedure with step by step displayed sequence of Latex Control process:



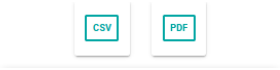


Wash in progress...

Once the Latex Control process it is finished, instrument shows the results on screen:



For each one of the three Latex Levels instrument shows the acceptable interval as well as the value measured.

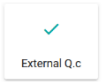


As evidenced below, at the end of the process, there it is the possibility to:

- Export Latex results in CVS format
- Generate a Latex result report in a PDF file
- Send Latex results to LIS
- Possibility to print

Please notice that CSV and PDF export procedures requires an USB pen drive must be inserted in the front USB slot of the instrument.

12.3 LATEX QUALITY CONTROL FOR EXTERNAL PROBE

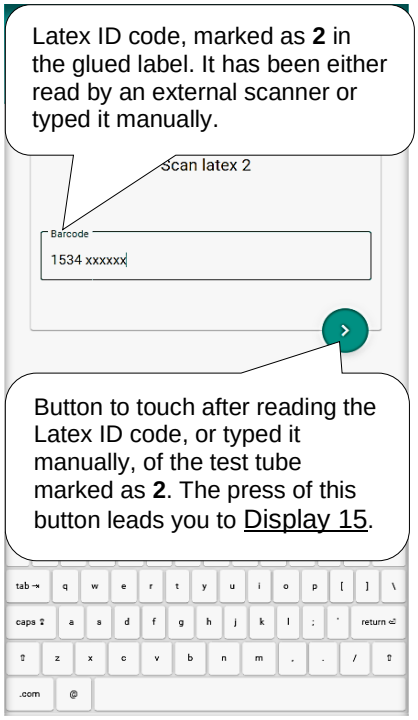


The **External Q.C** procedure (as well as results visualitation) it is similar than the internal one described on chapter **11.1**. The only difference is that you have to manually mix (or use a desk mixer) the latex tubes and then keep the test tube (following the sequence 2-3-4) by your hands uncapped and insert in the external probe.

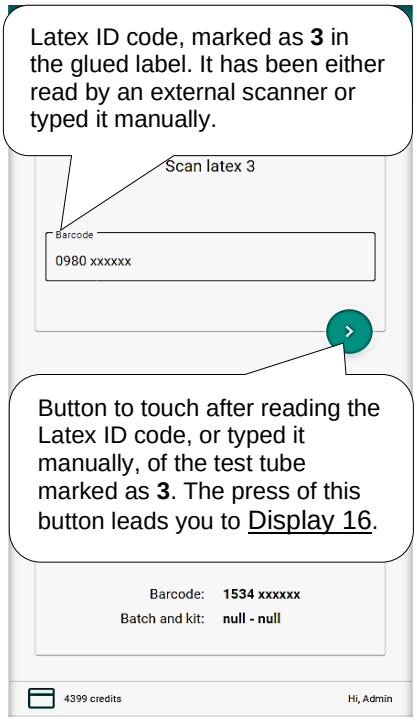
Remove from the refrigerator the box containing the Latex Control that must be stored in the refrigerator at + 4÷8 °C (+39,2 / +46,4 °F); remove from the box only the triplet that will be used for the checks; once used, the latexes must be returned to the refrigerator. To use the Latex Controls, please refer in any case to the IFU of the Latex Control.

It is extremely important to remind the latex tubes that will be used for the control of the external circuit are not mixed by the instrument, please refer to the Latex IFU for the handling of the latex in case of external sampling mode.

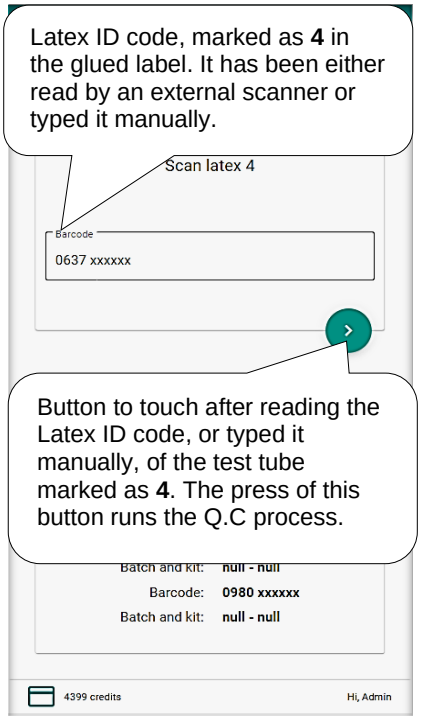
Before running a Latex Control, carry-out an "Intensive washing" procedure (refer to chapter 10.3):



Display 14



Display 15



Display 16

Note: tubes must be inserted till their bottom, this is till where the external probe touches the bottom of the tubes

The external procedure foresees a specific sequence of steps:

1. Instrument will ask to insert in the external probe a tube containing distilled water, once done press the green push button and keep the tube steady till instrument asks to remove it emitting a beep and a video request
2. Instrument will ask to insert in the external probe latex tube identified as "L2", once done press the green push button and keep the tube steady till instrument asks to remove it emitting a beep and a video request
3. (this initial phase it is only to prime the circuit)
4. Instrument will ask to insert in the external probe again latex tube identified as "L2", once done press the green push button and keep the tube steady the tube steady till instrument asks to remove it emitting a beep and a video request
5. (this phase it is the real sampling)

6. Instrument will ask to insert in the external probe latex tube identified as “L3”, once done press the green push button and keep the tube steady the tube steady till instrument asks to remove it emitting a beep and a video request
7. Instrument will ask to insert in the external probe latex tube identified as “L4”, once done press the green push button and keep the tube steady the tube steady till instrument asks to remove it emitting a beep and a video request
8. Instrument will ask to insert in the external probe a tube containing distilled water, once done press the green push button and keep the tube steady the tube steady till instrument asks to remove it emitting a beep and a video request
9. Instrument will ask to insert in the external probe one more tube containing distilled water, once done press the green push button and keep the tube steady the tube steady till instrument asks to remove it emitting a beep and a video request

At the end of the Control process, the instrument shows the three ESR values: the first, it is designed to cover "normal" patients, the intermediate, it is designed to cover "borderline" patients and the third to cover a high level for "pathological" patients.

The effective reference ranges to be used to confirm that the instrument is "in control" are in any case those indicated on the outer label of the Latex Control Box.

If the results obtained are within the expected ranges, it means that the analyzer is calibrated correctly. On the contrary, if one or more results are out of the expected ranges, it is recommended to call the Technical Service to perform a functional verification of the analyzer and a new calibration of the analyzer.

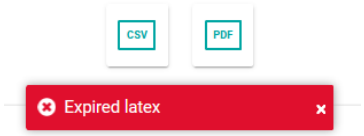
For an example of Latex results please refer to **chapter 12.2**

12.4 LATEX ERRORS

Below paragraphs explains briefly the most common errors that can be issued by the instrument during Latex Controls procedure.

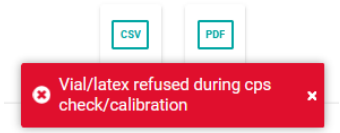
12.4.1 LATEX DATE EXPIRED ERROR

Please notice in case of latex already expired instrument will empty automatically Latex Level 2 and then inform on video about latex expired:



12.4.2 LATEX EXPIRED USED MORE THAN 6 TIMES ERROR

Please notice in case of latex already used more than 6 times, instrument will empty automatically Latex Level 2 and then inform on video about latex used more than 6 times:

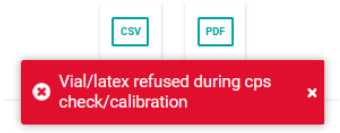


12.4.3 LATEX KIT INCONGRUENT ERROR

Please notice in case of incongruent latex triplet loaded (this is one or more of the three tubes does not match a specific lot or progressive sequence) instrument will abort the process informing with the error

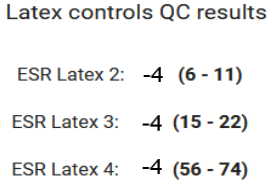
12.4.4 LATEX calibrator loaded by user ERROR

Please notice in case of latex calibrator it is mistakenly loaded in **user mode**, instrument will abort the process informing with the error



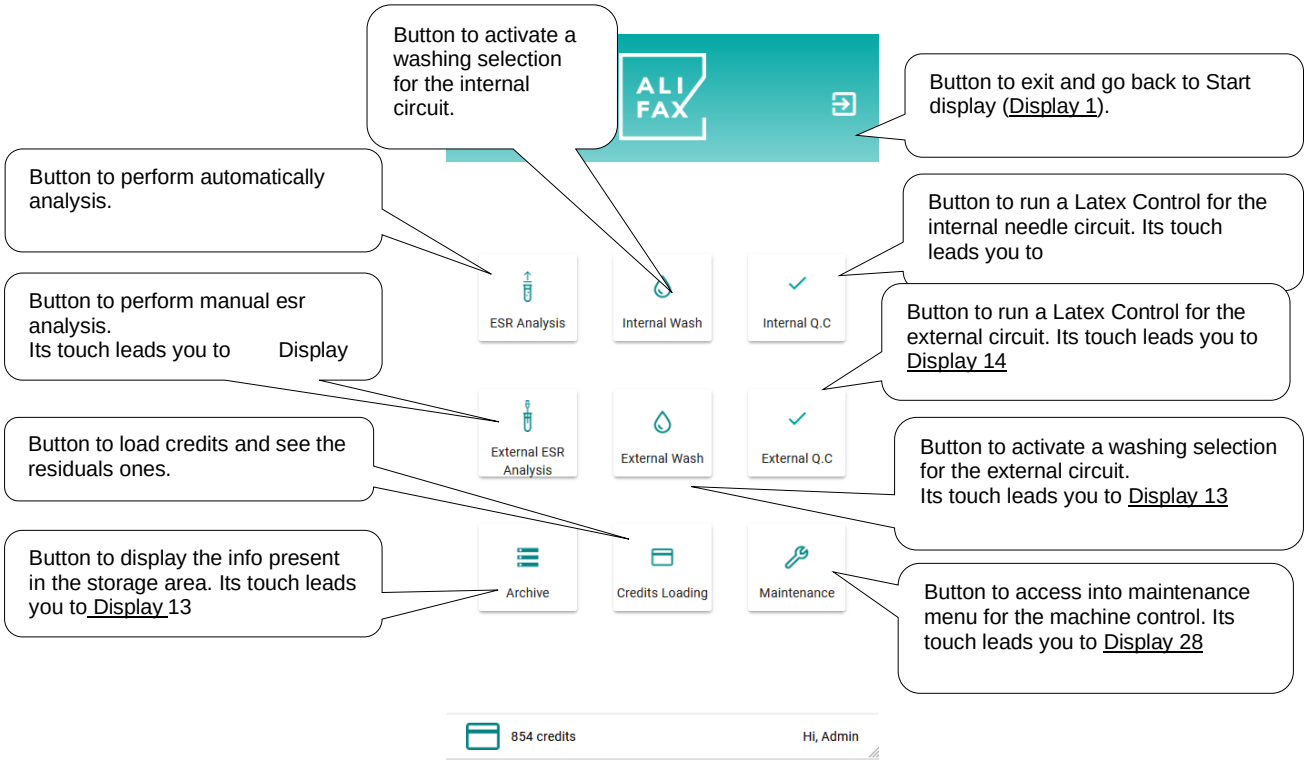
12.4.5 LATEX “Correlation NOK” ERROR

In the event during latex procedure, instrument issues the following result **(-4, -4, -4)** as displayed on the right side, means the correlation between expected latex values and real latex values obtained it is < 97%.
This means one or more of the Latex tubes reagent could be degraded.
Please also notice this could happen with a bit higher probability when performing the Latex Control procedure on the external circuit because (in absence of an External Bar Code Reade) the latex references are typed manually and this could lead to a “typo” error.



13. OPERATIONS ON INSTRUMENT INSTALLED OVER TLA TRACK

This and following chapters are specifically addressed to the use of TEST1 2.0 installed oved Sysmex® T.L.A track



Display 17

13.1 ESR ANALYSIS

In the TLA configuration, just press “ESR Analysis” to set the instrument in waiting for samples delivered by the TLA.
The ESR Analysis button allows to enable the instrument to be controlled by the TLA and to begin sending the cassettes inside the “analyses pit-lane”.

The analysis cycle includes 5 steps:

1. The robotic arm takes a test tube from the cassette in the sampling zone,
2. The sample tube it is identified by means of the Barcode Label and put it into a free location of the mixing wheel.
3. The robotic arm repeats the step 1 for many times until all locations of the mixing wheel are full.
4. The mixing wheel rotates for a scheduled number of rotations and constant speed in order to homogenise the samples and so the red cells disaggregation.
5. The syringe rises towards the test tube cap, the pump then aspirates the amount of blood from the test tube and move this sample into the reading cell where then the photometer measures the aggregation phase.
6. When the measuring phase is finished and the instrument has released the ESR outcome, the robotic arm takes the test tube from the mixing wheel and move it back to the rack at the original position. If there is a free location in the wheel, the robotic arm takes next sample tube from a rack in the next slot and the process will be repeated from step 2.

Once the cassette it is returner to the main track, the next cassette in holding position it is moved inside the sampling area and process begins again.

The ESR results are displayed in the same way as if the analysis is done on the TEST1 2.0 desk version, please refer to **chapter 10.3** and **chapter 10.4**.

13.2 EXTERNAL ESR ANALYSIS

In the event you need to perform external sampling on the instrument installed over the track, the procedure it is the same as on the desk version; please refer to **chapter 10.4**

14. WASHING PROCEDURE ON INSTRUMENT INSTALLED OVER TLA TRACK

This procedure is designed to clean the complete capillary tubing and so to set it free from blood or Latex residuals. Since along the working life Latex flow inside the Teflon tube, particles of them tend to hang on the internal walls of the capillary. This fact, accordingly, increases the capillary opacity reducing the reading scale of the ESR values.

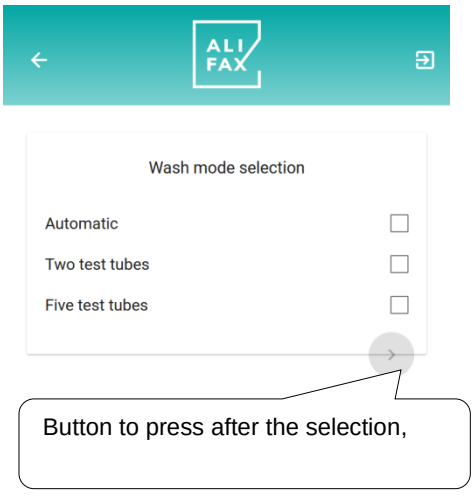
14.1 INTERNAL PROBE WASH

The **Internal Wash** button leads you to Display 18

The software allows the selection among “Automatic”, “Two test tubes”, “Five test tubes”.

14.1.1 Automatic WASH:

No tubes for washing are required. The only thing to pay attention is the water tank that should be full of distilled water and the waste tank that should be emptied. Both tanks are set inside the instrument behind the left door.



Display 18

The “Automatic” washing is normally executed:
- After 3 consecutive NFs or NRs.
- Priming error
- At the requesting time by pressing the button.

14.1.2 Two Test tubes WASH:

The washing using 2 test tubes is an alternative to the automatic washing; it can be used normally for washing the instrument.

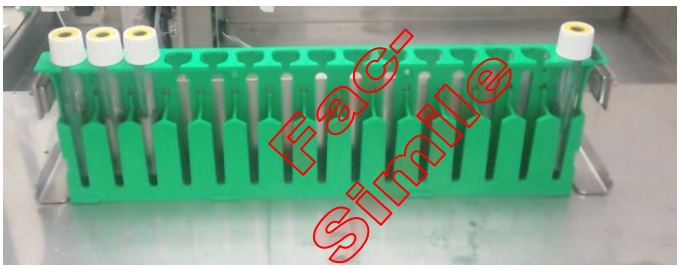
It is recommended to not use more than 2 times the same washing tubes in order to avoid possible needle and/or capillary obstructions due to rubber particle released by the washing tubes stoppers if used more than two times.

Two test tubes filled for a half with distilled water are required.

The “Two Test tubes” washing is required:
- When the automatic system is not available
- At the requesting time by pressing the button

Below photo refers specifically to the “zone of the instrument where must be placed the rack containing the washing tubes.
As you can see, a cassette it is placed inside the instrument and it can contain form a minimum of 1 tube up to 15 tubes filled with distilled water.
The right side photo must be intended only as an example of the way the rack it is loaded.

Empty Rack Station



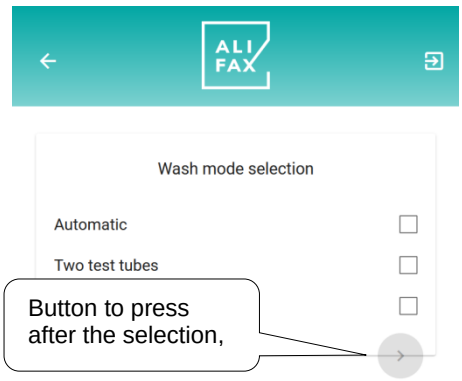
Station with rack with 4 tube (it can contain up to 15 tubes)

Important: position N°1 it is located on the left side

Please notice the photo of the rack might be intended only for explicative purpose.

14.2 INTERNAL PROBE HYPOCLORITE WASH (5 tube wash procedure)

The procedure using five test tubes it is mandatory in preparation for the daily latex control run; this washing procedure it is also recommended as a daily maintenance to maintain the cleanings of the capillary and hydraulic circuit.



The preparation and loading procedure it is as follows:

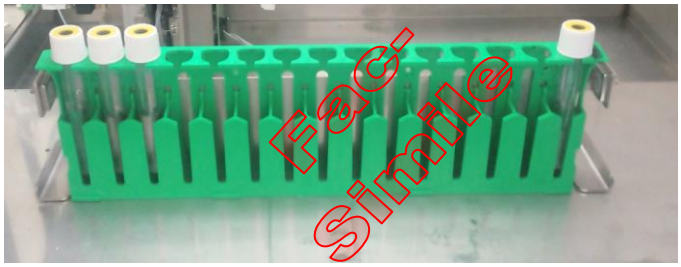
Prepare and load in sequence:

- two test-tubes filled 3/4 with distilled water
- one test-tubes filled 3/4 with Sodium Hypochlorite (5% of dilution)
- two test-tubes filled 3/4 with distilled water

At the end you have loaded total of 5 tube sequence

Below photo refers specifically to the “zone of the instrument where must be placed the rack containing the washing tubes. (the right side photo must be intended only as an example of the way the rack it is loaded and does not represent the real 5 tube sequence)

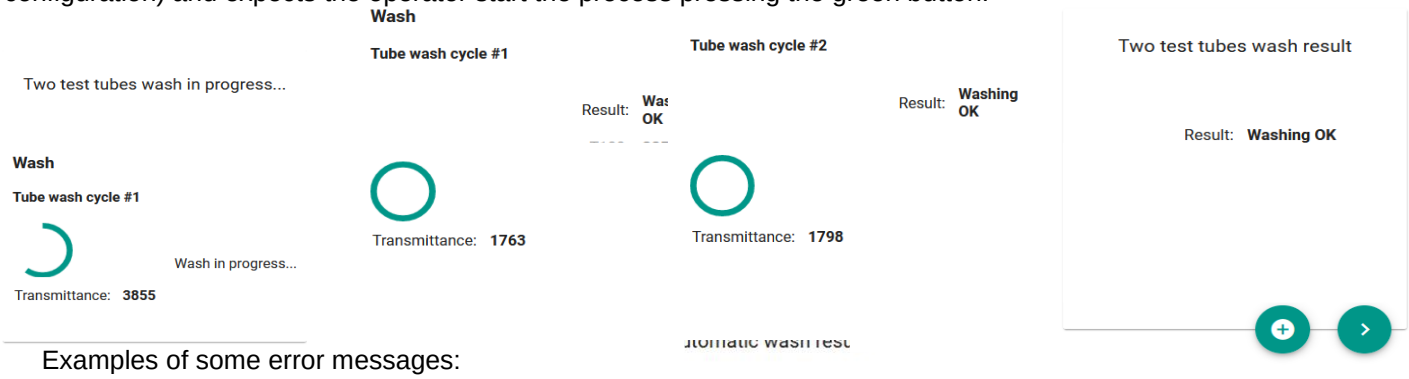
Empty Rack Station



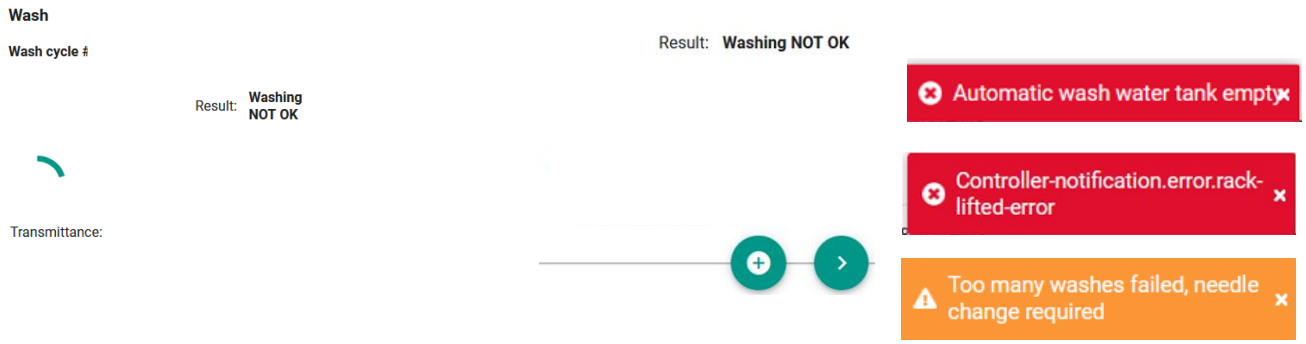
Station with rack with 4 tube (it can contain up to 15 tubes)

Important: position N°1 it is located on the left side

Once selected the washing option, instrument displays a confirmation (this example refers to the “Two test tubes” configuration) and expects the operator start the process pressing the green button.



Examples of some error messages:



14.3 EXTERNAL PROBE WASHING

The External wash option is to clean the external probe and its liquid flow circuit. The modality of function is the same described on **chapter 11.3** .

15. LATEX QUALITY CONTROL ON INSTRUMENT INSTALLED OVER TLA TRACK

Latex Control kit is a practical and efficient tool to check the accuracy and repeatability of the analyser during its working life.

The kit is supplied in a box that can contain:

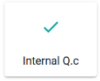
- 1 triplet Latex that allow executing a total of 6 controls (code **SI 305.100-A**)
- 5 set of triplets Latex that allow executing a total of 30 controls (code **SI 305.300-A**).

Remove from the refrigerator the box containing the Latex Control (or Calibration) that must be stored in the refrigerator at + 4÷8 °C (+39,2 / +46,4 °F); remove from the box only the triplet that will be used for the checks; once used, the latexes must be returned to the refrigerator. To use the Latex Controls, please refer in any case to the IFU of the Latex Control.

15.1 LATEX QUALITY CONTROL FOR INTERNAL CIRCUIT

Before running a Latex Control, carry-out a "5 tube washing procedure" (refer to chapter 14.2):

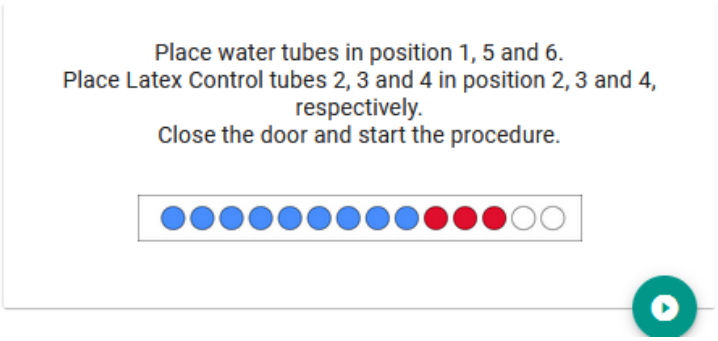
Important: to avoid possible capillary or needle obstructions, please be sure to use maximum two times the same washing tubes.



The **Internal Q.C.** button pressed at Display 3 leads to the Latex Control procedure.

When Latex Control it is carried on, in the Rack Station it is necessary to place a rack containing in sequence

Follow strictly the loading sequence as displayed:



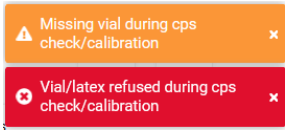
Pos 1: Water
Pos 2: Latex L2
Pos 3: Latex L3
Pos 4: Latex L4
Pos 5: Water
Pos 6: Water

Water tubes ust be filled up indicatively ¾ of its capacity with distilled water.

Important: position N°1 it is located on the left side

Once loaded the tubes press the green button to start the process.

Initially the instrument will check the presence of the tubes loaded and in case of missing tube it will issue a message informing the anomaly



If presence of tubes it is confirmed, next step is the identification of the latex lot and latex triplet, followed by the washing sequence:

For the results of the Latex Quality Control procedure, refer to **chapter 12.2**

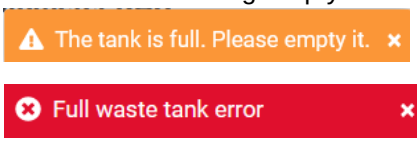
15.2 LATEX QUALITY CONTROL FOR EXTERNAL PROBE

For the Latex Quality Control on the external probe, please refer to **chapter 12.3**; the procedure as well as results and so are described in detail there.

For the explanation of the eventual Latex Errors please refer to **chapter 12.4**

16. WASTE TANK "FULL" HANDLING

At the end of every analysis cycle, and after having removed any rack from the instrument, if the quantity of discarded liquid (blood, water, Latex) reaches a value configured at 50 points below the warning empty tank threshold (set at 2000) the instrument will print out a message in orange (this is basically only a warning) informing the tank it is full and should be disposed.



Once the message displayed it is in red colour, means the instrument does not allow to perform any other operation till the tank it is disposed.

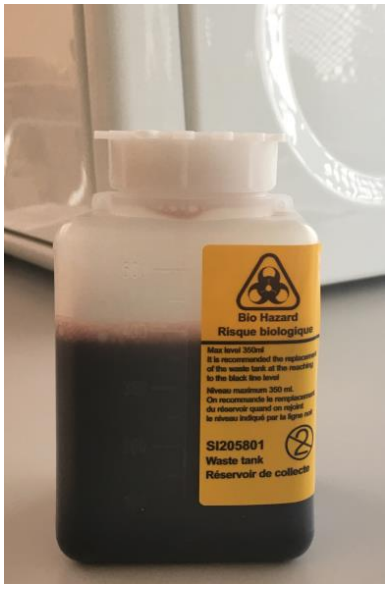
The Automatic Washing System requires the use of a tank containing distilled water for the cleaning of the hydraulic circuit and a waste tank.

For proper use, it is recommended to fill the wash tank on average every 2 days, making an additional check of the water level, also during the operations of replacing the drain tank. It is also recommended to remove the water tank from the instrument, wash it with hypochlorite, rinse it with water, and reinsert it (after refilling with distilled water) into the instrument. This procedure in order to avoid the formation of residue at the bottom of the tank.

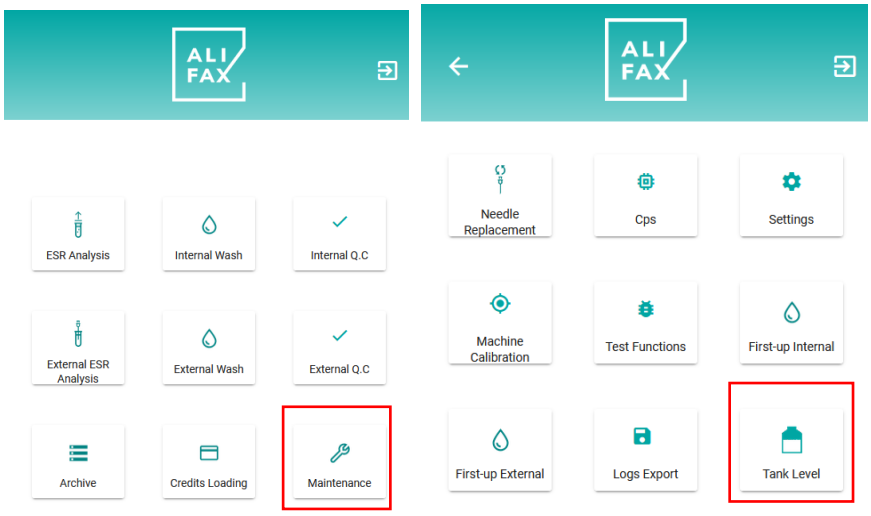
Waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use.

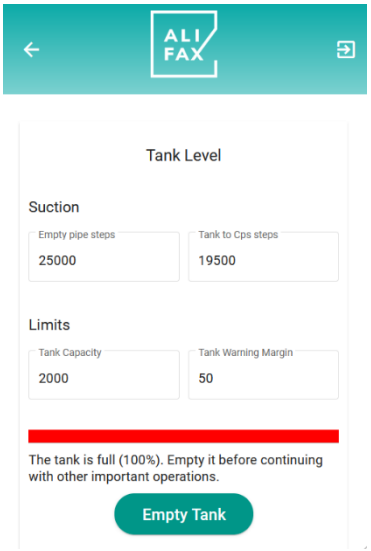
Water and Waste tanks: are located on the left side of the instrument; to get access to them just open the left side door and then pull out the sliding guide.

Open plastic front door, pull out the loading carrier and remove waste tank cap; remove carefully the full waste tank, insert an empty waste tank, reinsert the waste tank cover and finally apply the plastic screw cover to the full tank. Dispose it 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

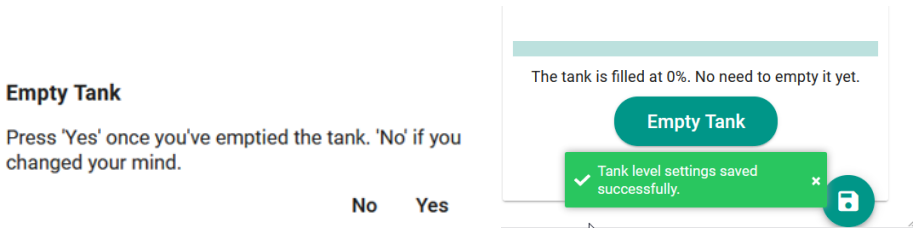


Once having physically emptied / disposed the waste tank and refilled the water one, now it is necessary to inform the instrument the tank have been “disposed”. To this, from main menu, select Maintenance and the select Tank Level



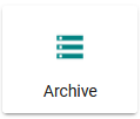


Once inside “Tank Level” just press “Empty Tank” in order to confirm the tank have been disposed, thus press “Yes”

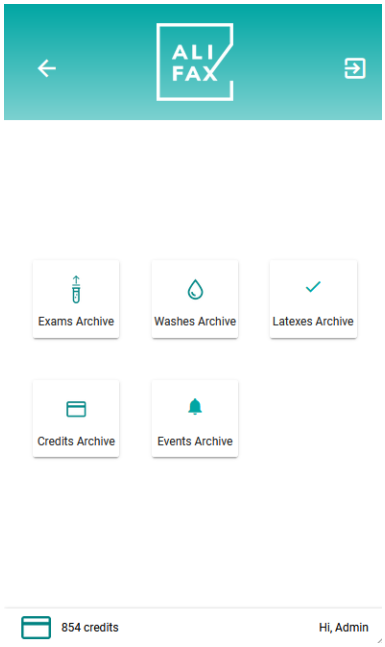


Please do not press “Empty Tank” and physically do not dispose indeed instrument will check the effectiveness of the process verifying the tank have really been emptied.

17. RESULTS DATABASE



Pressing the Archive button **(**Display 3**)** leads you to the **instrument database** where it is possible to recover all the information about, samples processed, latex quality control results, washing results and so on.



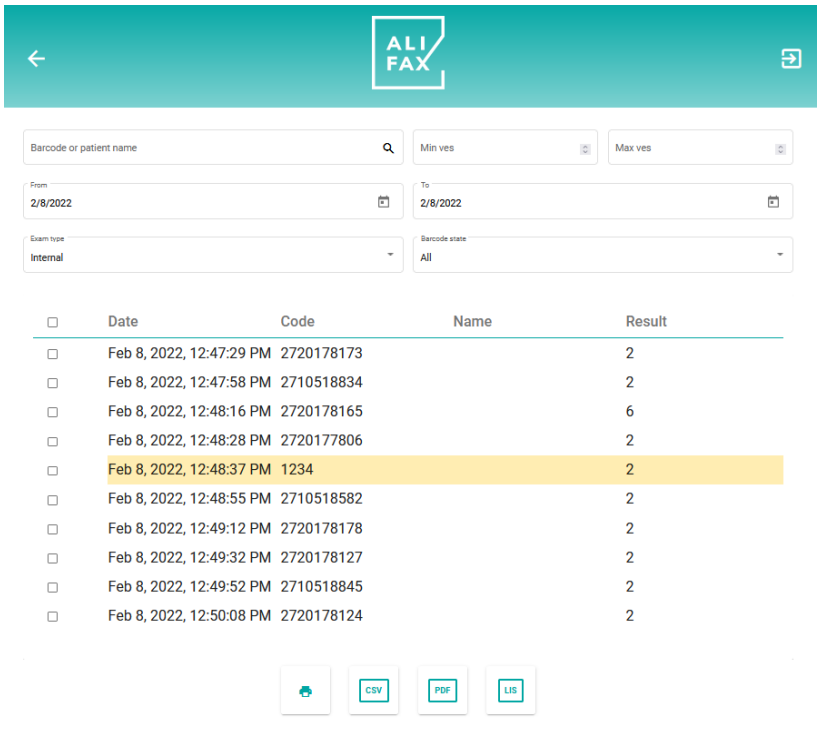
17.1 DATABASE: ESR ARCHIVES

Pressing the icon “Exams Archive” the operator can track the ESR results “filtering” the search according several options such as:

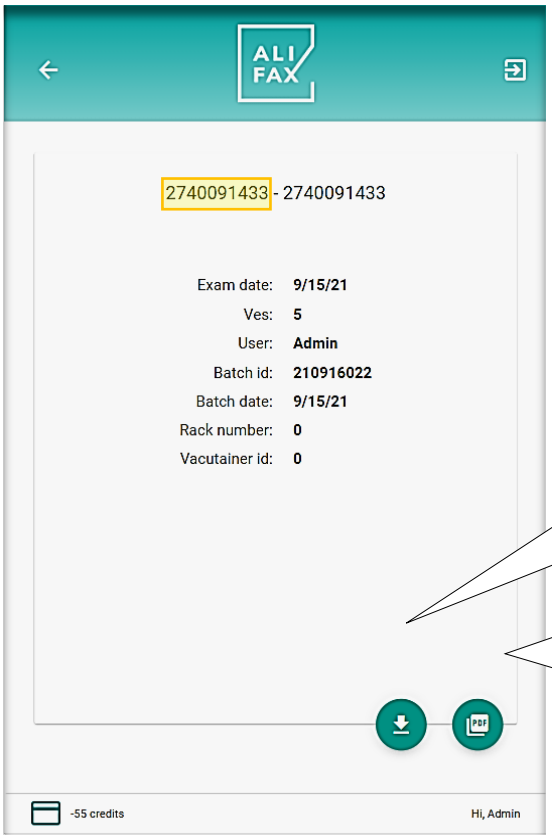
- Barcode ID or Patient Name
- Between Interval dates
- By internal or External exam
- By barcode status (original barcode or manually edited)

Based on the above filters, data it is displayed accordingly. In this example are visible the results of day Feb 2-2022.

As it is possible to see, there it is a patient whose ID barcode was not read by the IBCR and thus the instrument assigned an auto generated code (highlighted in yellow).



Display 19



Clicking over a patient number, the instrument will display a detailed info about the specific patient as visible on Display 14

In the event the operator click over a yellow highlighted code, the instrument then allows to modify the auto generated code to the original patient ID barcode present on the patient's blood tube.

Operator can easily modify the auto generated code assigning the real patient ID code simply double-clicking over the yellow highlighted field.

Button to download this information into a CSV format file to a USB key inserted in the USB slot located on the front site.

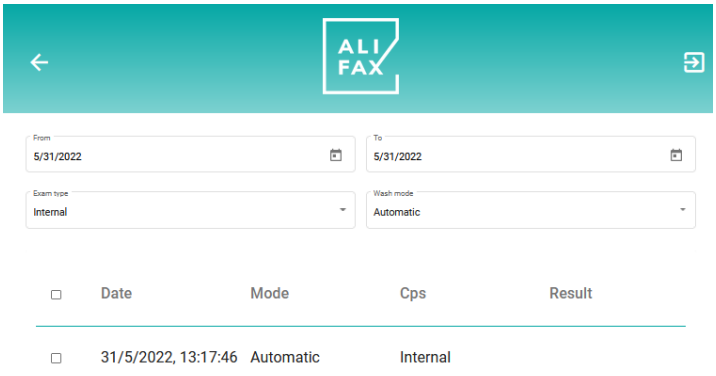
Button to download this information into a PDF format file to a USB key inserted in the USB slot located on the front site.

Display 20

17.2 DATABASE: WASHING ARCHIVES

Pressing the icon "Washing Archive" the operator can track the washing events results "filtering" the search according several options such as:

- Date (or date range)
- Internal or External circuit
- Wash mode:
  - Automatic
  - Automatic on timeout
  - Intensive
  - Single tube
  - Two tubes



Display 21

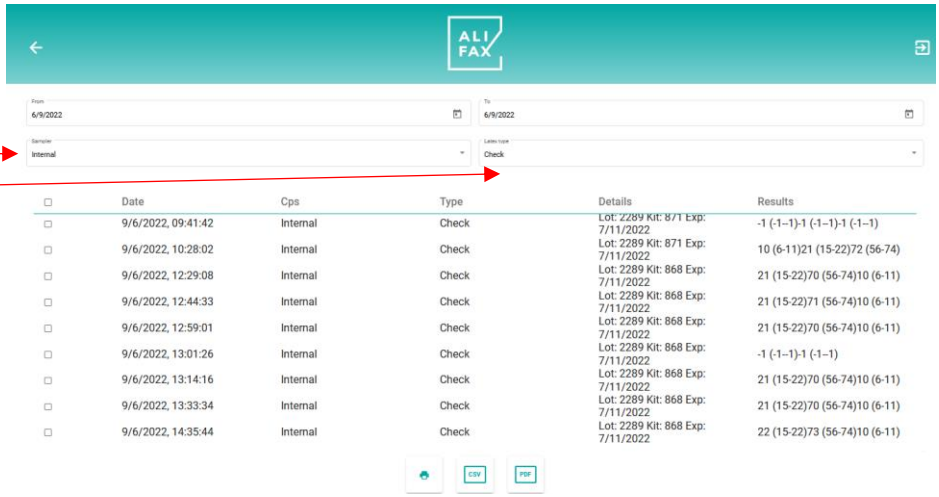
Based on the above filters, data it is displayed accordingly. In this example it is visible the result of day 31 May 2022

As it is possible to see, there it is only one wash performed in "Automatic mode" on the internal CPS.

17.3 DATABASE: LATEX (Q.C.) ARCHIVES

Pressing the icon “Latex Archive” the operator can track the latex events results “filtering” the search according several options such as:

- Date (or date range)
- Internal or External circuit
- Calibrator or Control



The results are displayed on the right side in the format X (Y-Z) where X it is the measured value while Y and Z are the lower and upper limits.

In case of latex errors such us:

- Washing errors
- Barcode not read,
- More than 6 times runs

The results are displayed in the format -1 (1—1)

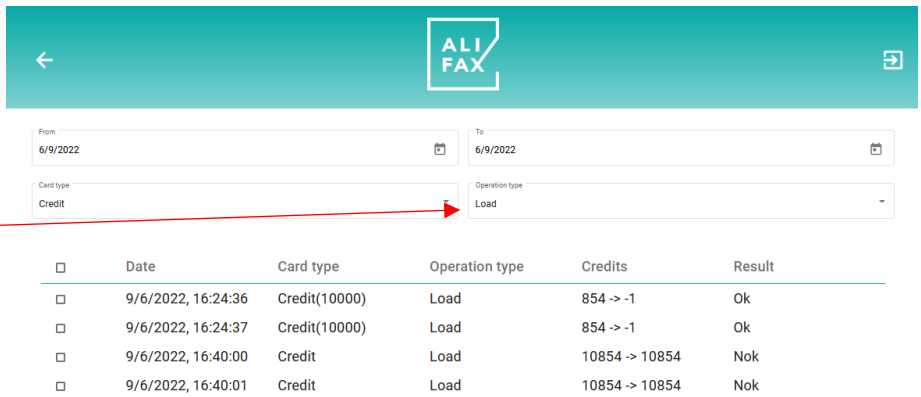
Display 22

Clicking over the date of a latex run, instrument shows a detailed visualization of the latex session

17.4 DATABASE: CREDITS (AVAILABILITY) ARCHIVES

Pressing the icon “Latex Archive” the operator can track the latex events results “filtering” the search according several options such as:

- Date (or date range)
- Kind of card
- Operation type



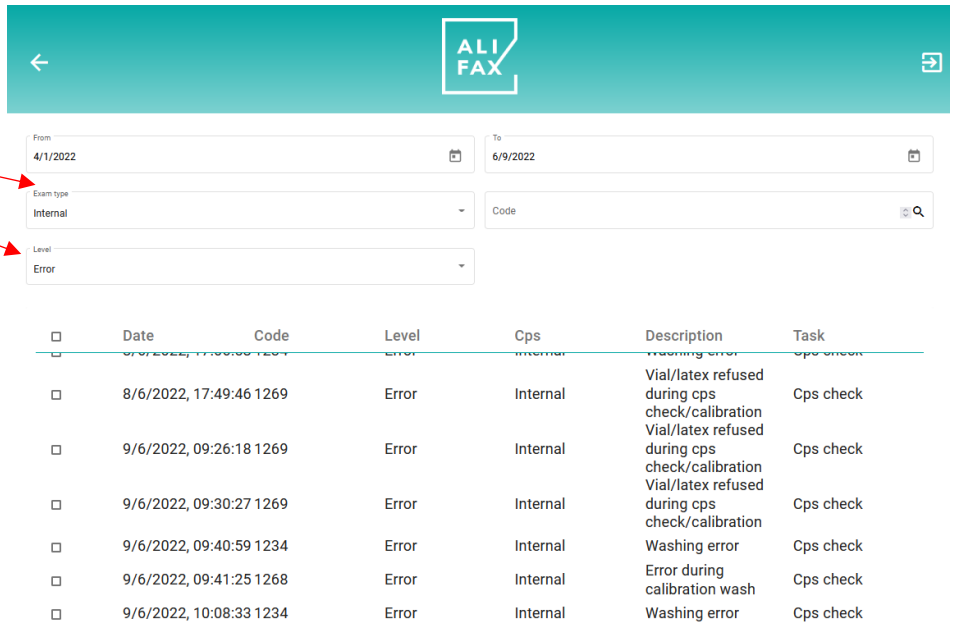
The results are displayed on the right side where it is reported the initial amount and the quantity loaded

Display 23

17.5 DATABASE: EVENTS AND ERRORS ARCHIVES

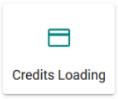
Pressing the icon “Event Archive” the operator can track the events results “filtering” the search according several options such as:

- Date (or date range)
- Internal or External circuit
- Error type
- Error Code

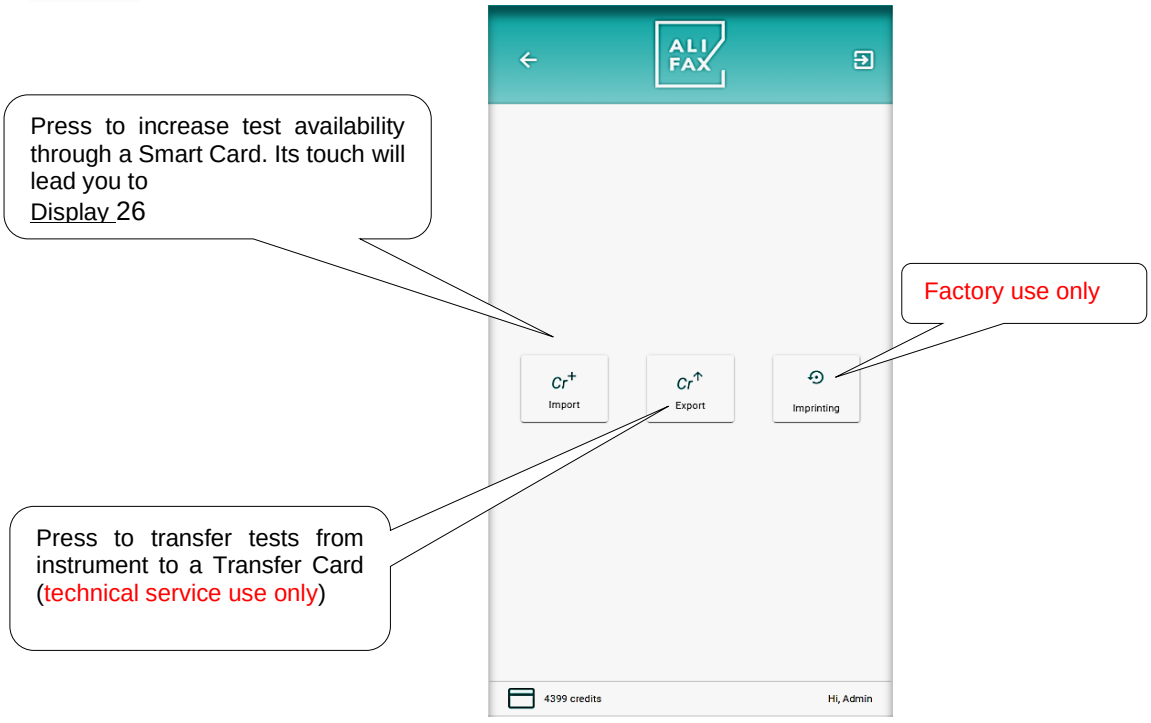


Display 24

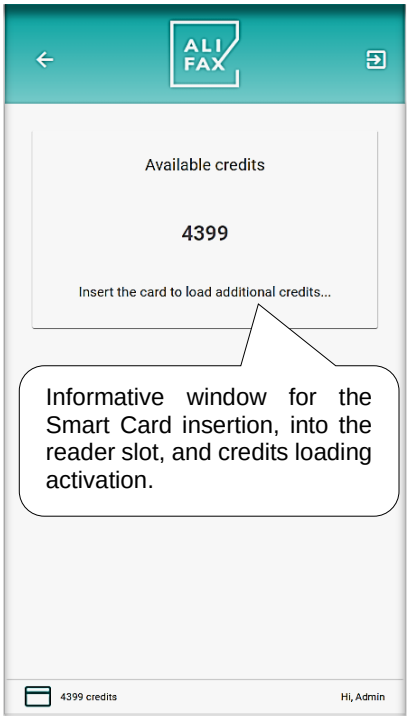
18. CREDITS LOADING



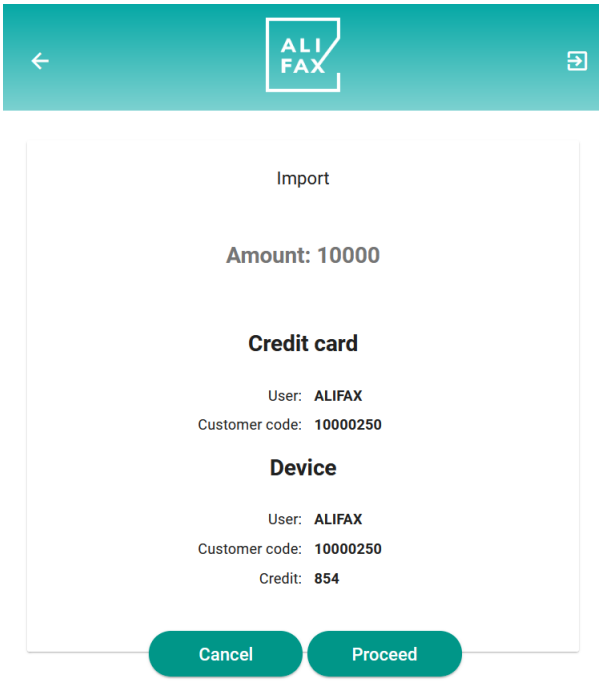
The **Credits** button pressed at Display 3 leads you to Diplay 25. The software allows the selection among **Import** (increase availability of credits), **Export** to transfer the credits from the analyser into a Transfer Card and Imprinting (last two options limited for technical service and factory)



Display 25

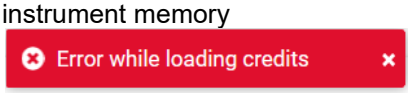


Display 26



Display 27

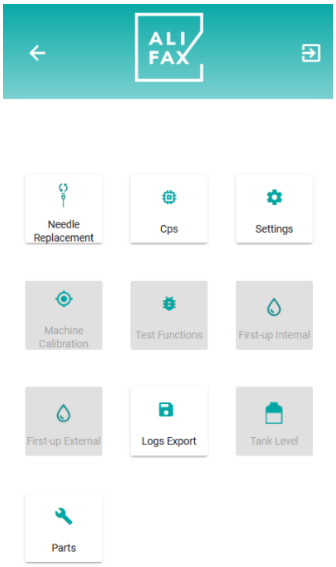
Once pressed “Proceed” instrument will transfer credits from the card to the instrument memory
In case an attempt to load an already “loaded” card the instrument issues the error:



19. "MAINTENANCE" ICON

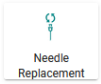
When at Display 3 you press the **Maintenance** button being logged as "**Laboratory Manager**" or "**Laboratory user**", you'll have limited functions according to the assigned rights.

19.1 Maintenance menu accessible to the "USER"



Display 28

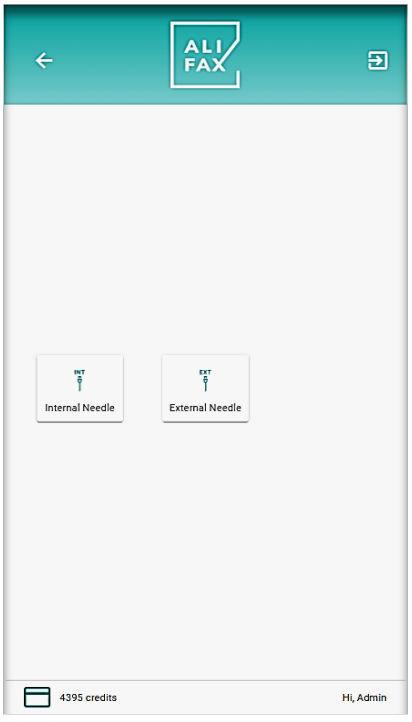
19.1.1 Needle replacement

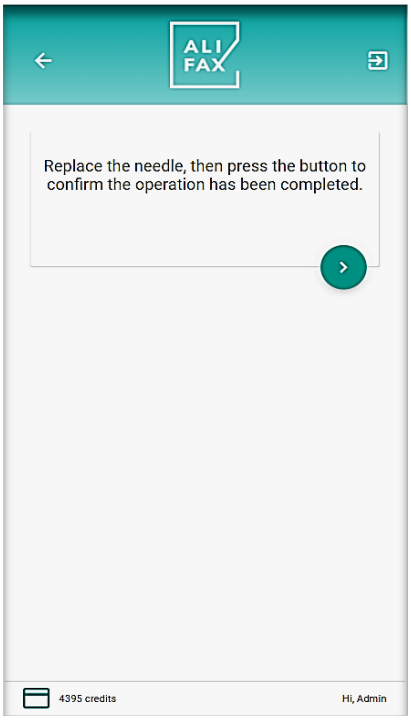


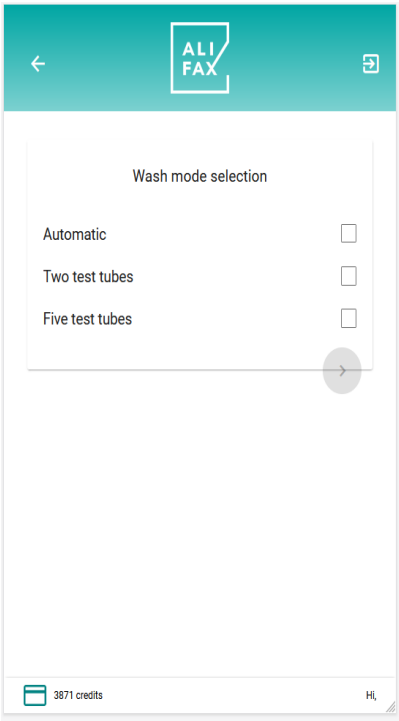
The needle does not have a minimum amount of piercings established before the replacement. The needle in use in TEST1 2-.0 it is engineered with lateral aspirating holes which allows a much more longer life span.

When the **Needle replacement** button it is pressed, instrument offers two alternatives: Internal or external

Independently which option it is chosen, a common interface message requesting the replacement of the external / internal probe it is displayed; just press the green button to start the procedure.







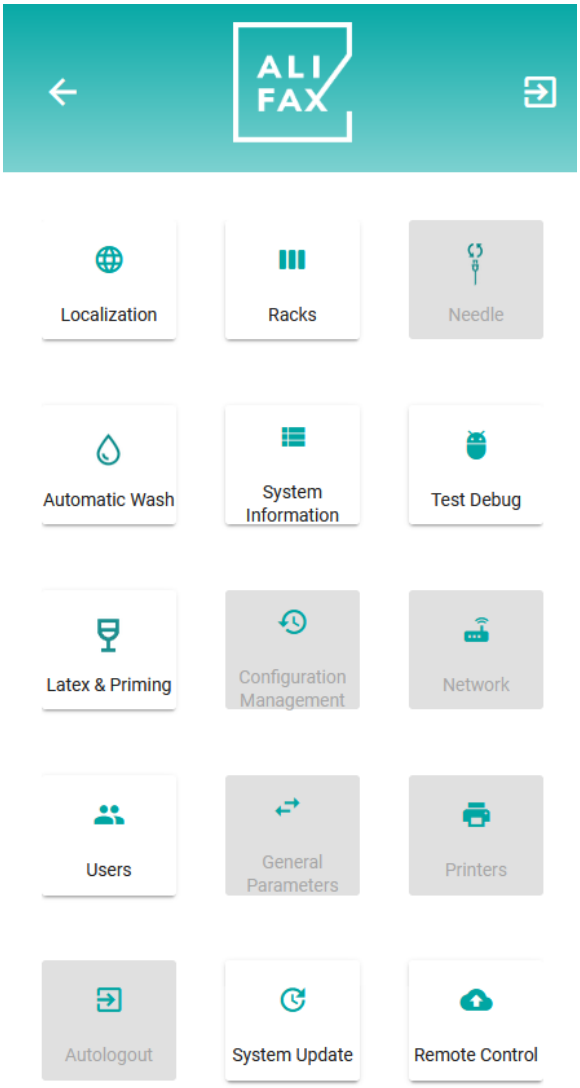
After the replacement the instrument requires to perform a washing procedure. You could select between automatic, two or five test tubes. Refer to **Appendix B** to have detailed instructions about needle replacement procedure.

19.1.2 "CPS "

This feature it is only for technical Service

19.1.3 Settings

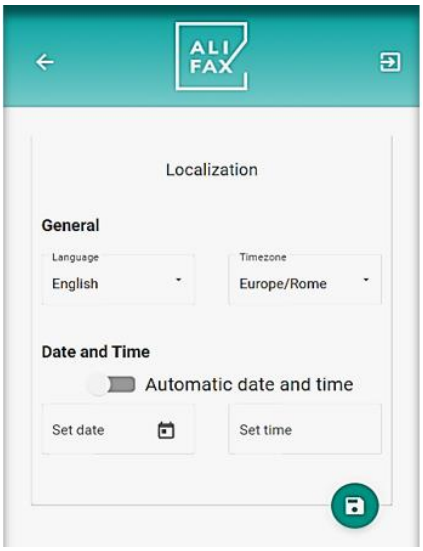
The **"SETTINGS**" button touched at Display 28 leads you to where there are other options; some of them not accessible to the user (in light gray):



Display 29

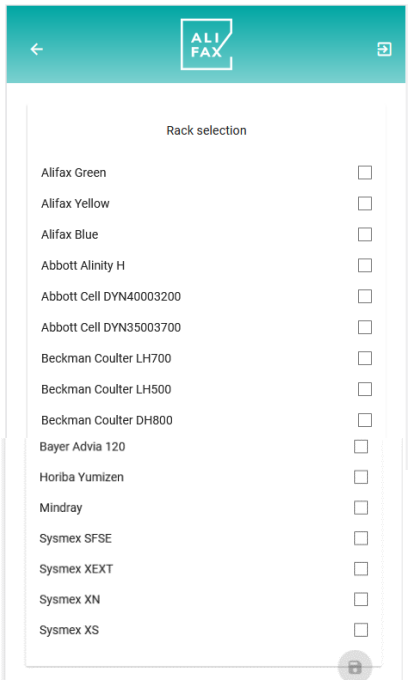
19.1.4 Localization

Location allows user to configure Language, Time Zone, Date and Time



19.1.5 Racks selection

Rack selection allow to configure rack in use in the Laboratory



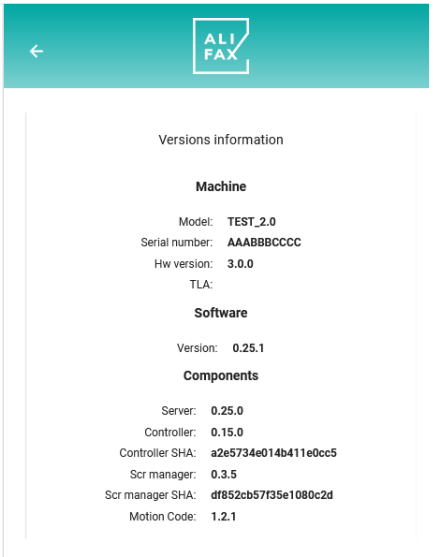
Important:
It can be defined only one kind of rack to be used.

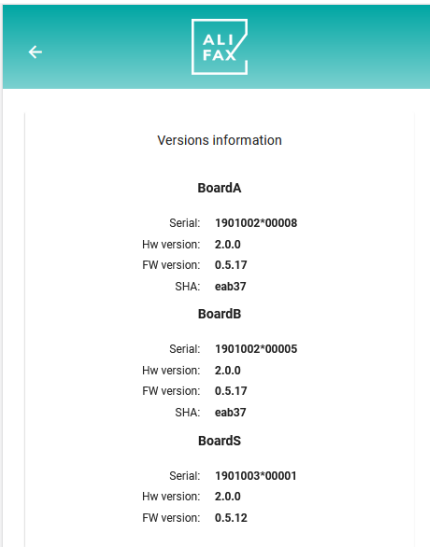
19.1.6 Automatic Wash

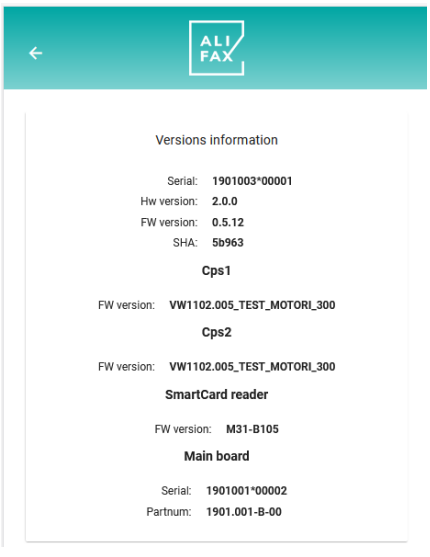
Under “User mode” Automatic Wash configuration function it is not available

19.1.7 System Info

Instrument shows the Firmware and Software configuration of the electronic boards installed





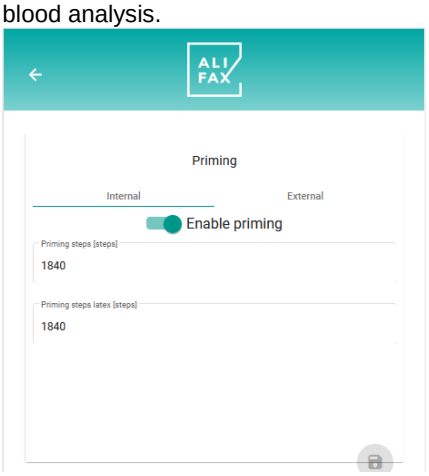


19.1.8 Test Debug

Under “User mode” Test Debug configuration function it is not available

19.1.9 Priming

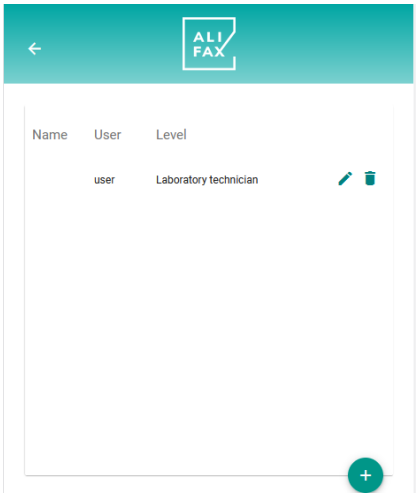
Priming allows to enable the priming for blood analysis.



Enabling the priming function means that after every washing procedure (independently it is manual or automatic), when a new analytical session it is started, instrument will take a supplementary aliquot of blood from 1st and 2nd tube loaded to prime the capillary and CPS.
Similar concept applies for latex.
Important:
Priming function MUST remain enabled.

19.1.10 Users

User function allow to configure username and password for each

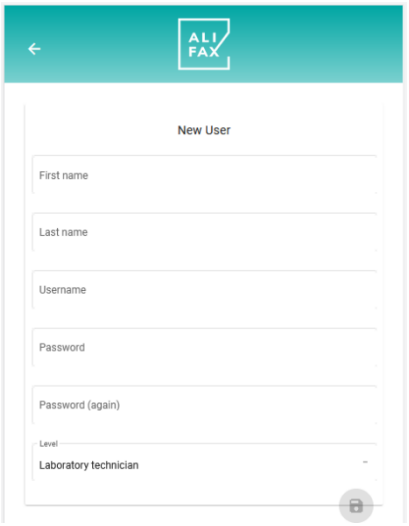


t

Allows to remove an operator from the list.

Allows to modify the right of an operators

Pressing "+" it is possible to configure a new user and its



19.1.11 System Update

Under "User mode" System Update function it is not available

19.1.12 Remote control

Under "User mode" System Update function it is not available

20. RESTRICTIONS

Instrument allows to create multiple users; from the point of view of the laboratory, it is possible to create one "Laboratory manager" and several "Laboratory technician" credentials.

20.1 "Laboratory manager"

"Laboratory manager" can create User credentials identified as "Laboratory Technicians"; the procedure to generate new Users is explained at **Appendix C.**

Laboratory manager has the right to do some operative tasks, such as:

- Increase Test availability
- Create and modify Laboratory Technicians profile

20.2 Laboratory technician

If logged as "Laboratory technician", TEST1 2.0 disables the same options of the "Laboratory manager". The only difference is that the "Laboratory technician" cannot generate another new User
If the operator forget the password, only Laboratory Manager can reset the operator password.

21. INSTRUMENT DAILY MAINTENANCE PROCEDURE

Instrument it is exempt from Ordinary Maintenance. At the end of the day, the operator once pressed the frontal power button might choose among normal power off or the "Wash & Sleep".
If Wash & Sleep it is selected, the instrument washes automatically and then it powers off.

From the point of view of the operator, above described process requires 1 second indeed once pressed the power button, the operator only needs to select the between normal power off or “Wash & Sleep”, this means practically zero hands-on work, the instrument does it all automatically in about 4 minutes.

Do not use alcohol to clean the front touchscreen panel .

22. TURN THE INSTRUMENT OFF

To switch off the instrument, the operator has only to press the power push button; the instrument will ask to select the washing as described in previous chapter.

23. INSTRUMENT PROGRAMMED MAINTENANCE

Aanalyzer, counts the executed analysis from the last maintenance time.
When, along the working days, it reaches the preset maintenance warning, which value it is set at 30000 tests, the instrument will issue a warning the maintenance it is required.

24. SANITIZATION PROCEDURE

Before shipping unit to authorized dealer for service or Transportation or disposal, perform cleaning and disinfection. Sodium hydroxide or chlorine releasing disinfectants (e.g. 20 000 ppm. Chlorine for 1hour) have been considered acceptable approaches where equipment that cannot be replaced as been exposed to potentially contaminated material.

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 at the end of the manual.

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.

25. ERRORS LIST

Message Displayed	Cause/Description	Solution	FW Error Code
Stepper Motor not enabled	Stepper Motor not enabled in machine configuration	Please contact Alifax technical support	1003
Stepper Motor error	Error in powering Stepper Motor	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1004
Stepper Motor stall error	Stepper Motor stall during the movement	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1005
Stepper Motor over temperature error	Stepper Motor stops due to over temperature shutdown	Check that the device is working inside the correct operational temperature range. Check that the ventilation holes on the device housing are not obstructed. Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll, Start a new measurement session. If the error persists contact Alifax technical support.	1006
Stepper Motor over temperature warning	Warning of over temperature in Stepper Motor	Check that the device is working inside the correct operational temperature range. Check that the ventilation holes on the device housing are not obstructed. Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll, Start a new measurement session. If the error persists contact Alifax technical support.	1007
Stepper Motor short circuit error	Stepper Motor stops due to a short circuit error	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll.	1008

		Start a new measurement session. If the error persists contact Alifax technical support.	
Stepper Motor open load error	Stepper Motor stops due to an error during load opening	Shutdown and switch the device off.Wait 30s and switch the device on.Remove manually any test tubes that had remained in the roll.Start a new measurement session.If the error persists contact Alifax technical support.	1009
Door opened during machine running	Machine stops because the loading door is detected opened during the instrument routine	Verify that during the process the door is properly close and locked. If the error persist contact Alifax techinical support.	1015
Error on axis reset	Error during axis reset	Shutdown and switch the device off. Wait 30s and switch the device on. Check that no obstacle is present inside the device that could interfere with the axis movements. Remove manually any test tubes that had remained in the roll, Start a new measurement session. If the error persists contact Alifax technical support.	1017
Error on power board	Error in board powering ON	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1018
Roll not powered error	Error in roll movement, when this is not powered	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1019
Obstacle detected while resetting roller	Obstacle detected during the roller resetting	Shutdown and switch the device off. Wait 30s and switch the device on. Check that no obstacle is present between the roll and the sensors aside of it. Remove manually any test tubes that had remained in the roll, Start a new measurement session. If the error persists contact Alifax technical support.	1020
Sensor lost during reset	Sensor not triggered during reset	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1021

Stall error	Roller motor stall error	Shutdown and switch the device off. Wait 30s and switch the device on. Check that no obstacle is present inside the device that could interfere with the roll rotation. Remove manually any test tubes that had remained in the roll, Start a new measurement session. If the error persists contact Alifax technical support.	1022
Pump not powered	Error in pump movement, when this is not powered	Shutdown and switch the device off.Wait 30s and switch the device on.Remove manually any test tubes that had remained in the roll.Start a new measurement session.If the error persists contact Alifax technical support.	1023
Pump sensor error	Error in Wash Pump sensor	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1024
Communication error with board A	Error in Communication between Main Board and Board A (ex: USB Cable disconnected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1101
Communication error with board B	Error in Communication between Main Board and Board B (ex: USB Cable disconnected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1102
Serial board communication error	Error in Communication between Main Board and Serial Board (ex: USB Cable disconnected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1103
Internal CPS communication error	Error in Communication with Internal CPS-MC Module (ex: Serial cable disconnected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1104

Barcode reader communication error	Error in Communication with BCR (ex: BCR cable disconnected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1105
External CPS communication error	Error in Communication with External CPS-MC Module (ex: Serial cable disconnected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1106
Error configuring barcode reader	Error during BCR configuration	Start a new barcode configuration. If the error persists contact Alifax technical support.	1107
Error on CV65	Error in Sysmex CV-65 Board	Shutdown and switch the device off.Wait 30s and switch the device on.Remove manually any test tubes that had remained in the roll and any rack on the CV-65.Start a new measurement session.If the error persists contact Alifax (Sysmex) technical support.	1150
CV65 not powered	Process start error in Sysmex CV-65 Board, when the board is not powered	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll and any rack on the CV-65. Start a new measurement session. If the error persists contact Alifax (Sysmex) technical support.	1151
Measure error	Procedure error happened while measure session	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1200
Error on credit decrease	Error while credit transaction decrease (ex: missing communication with the SCR Module)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1201
Barcode reading error	Error while reading barcode of the test tube (ex: barcode damaged or missing)	Read the User Manual, section "Barcode reading error"	1202

Test tube not gripped error	Error test tube not gripped on the gripper (missing tube)	Stand-alone: leave blank, the error is not notified in TLA: check potential error occurred with conveyor or the picking position, if the error persist contact Alifax technical support	1210
Test tube cap not detected error	Error test tube cap not detected on roller housing (error during test tube insertion in the roller)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1211
Test tube cap detected error	Error test tube cap detected on roller housing (error during test tube extraction from the roller)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1212
Rack removed error	A measuring rack have been removed during continuous loading process	Remove manually any test tubes that had remained in the roll.Read the User Manual, section "Continuous rack loading" Start a new measurement session.	1220
Blood not found error	After test tube measurement, blood not found for 2 times (result will be NF)	Read the User Manual, section "Blood not found error"	1230
Blood not found too many times. The session will be stopped now.	Error after 4 consecutive test tube with NF result (2 consecutive NF results for each test tube analysed) - the measure process will stop	Read the User Manual, section "Blood not found error"	1231
Priming error	Error during priming (Priming Nok)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1233
Washing error	Error during washing (Ex: empty wash tube)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1234
Test tube penetration failed	Error during test tube penetration (Ex: cable J24 damaged or disconnected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1235

Roller positioning failed	Error during Roller positioning	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1236
Restart roller rotation failed	Error during restarting the Roller rotation	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1237
Wrong initial rack sequence	Error in Rack position (process starts with the initial Rack in wrong position)	Check that the racks are in proper position. If the error persists: Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error still persists contact Alifax technical support.	1238
Front button pressed during an operation	Detected Front Button pressing during the routine	If this notification happened without pressing the front button, contact Alifax technical support.	1239
Cps calibration missing after configuration	Error in CPS-MC after configuration parameters modification without run a new calibration	Start a latex calibration process. If the error persist contact Alifax technical support	1240
Needle reset failed	Error during needle reset	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1242
Slider opened during an exam session	Detected Slider opened during routine	Check that the drawer is properly inserted in the instrument. If the error persist: Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error still persists contact Alifax technical support.	1250
Pantograph lifted during an exam session	Detected Pantograph lifted during routine	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll.	1251

		Start a new measurement session. If the error persists contact Alifax technical support.	
Full waste tank error	Error Waste Tank full	Check the liquid level in the waste liquid tank A. If the tank is full - empty it - Remove manually any test tubes that had remained in the roll. - Start a new washing session. - If the error persists contact Alifax technical support. B. If the tank is not full - Remove manually any test tubes that had remained in the roll. - Start a new washing session. - If the error persists contact Alifax technical support.	1252
Waste tank missing error	Error Waste Tank removed	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1253
Water tank missing error	Error Water Tank removed	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1254
Not enough test tube found during wash	Washing error, not enough wash tubes found for performing the washing	Insert the correct number of wash tubes.Start a new washing session.If the error persists contact Alifax technical support.	1255
Wash timeout expired	Automatic Wash timeout expired error	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new washing session. If the error persists contact Alifax technical support.	1257
wash tank empty	Automatic Wash error, Water Tank empty	Check the liquid level in the water tank A. If the tank is empty - fill it - Remove manually any test tubes that had remained in the roll. - Start a new washing session. - If the error persists contact Alifax technical support. B. If the tank is not empty - Remove manually any test tubes that had remained in the roll.	1258

		- Start a new washing session. - If the error persists contact Alifax technical support.	
Cps cleaning failed	CPS-MC washing error	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new washing session. If the error persists contact Alifax technical support.	1259
Automatic wash timer A expired	Automatic Wash timer A expired error (after 9.5 seconds water is not detected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new washing session. If the error persists contact Alifax technical support.	1260
Automatic wash timer B expired	Automatic Wash timer B expired error (water not detected within 9.5 seconds)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new washing session. If the error persists contact Alifax technical support.	1261
Pipe not detected	TS2 pipe not detected	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1262
Automatic wash: pre-aspiration failed	Automatic Wash pre-aspiration error (Ex: CPS-MC disconnected)	Shutdown and switch the device off.Wait 30s and switch the device on.Remove manually any test tubes that had remained in the roll.Start a new washing session.If the error persists contact Alifax technical support.	1263
Automatic wash: water in cps but not in pipe	Automatic Wash water detection error (detected water inside CPS-MC module but not in the pipes)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new washing session. If the error persists contact Alifax technical support.	1264
Too many washes failed, verify and clean needle	Washing error, too many (2 or more) consecutive washes failed, needle change required	Start a 5 wash tubes session. If the result is not ok change the needle and start a washing session If the result of washing is still not ok contact Alifax technical support.	1265

There is only one test tube for washing	Washing error, loaded only 1 wash tube instead of 2 (washing with 2 wash tubes)	Insert the correct number of wash tubes. Start a new washing session. If the error persists contact Alifax technical support.	1266
Expired latex	Loaded Latex expired	Insert latex tubes with correct expiration date. Start a new latex control/calibration session. If the error persists contact Alifax technical support.	1267
Error during calibration wash	Calibration wash error (Ex: calibration wash tube empty)	Check that the correct pattern of wash tube is used for calibration wash. Start a new calibration wash procedure. If the error persists contact Alifax tecnhnical support.	1268
test tube/latex refused during cps control/calibration	Incongruent Latex codes error, Latex codes inserted are wrong or coming from different triplets	Check that the correct pattern of test tube is used for control/calibration. Start a new latex control/calibration procedure. If the error persists contact Alifax tecnhnical support.	1269
No test tubes found during current procedure	Test Tubes number error, not found the correct number of test tube for the current process	Insert the test tubes needed for the execution of this procedure. Restart the procedure. If the error persists contact Alifax tecnhnical support.	1270
Automatic wash: clearing pipe failed	Automatic Wash error, clearing pipes procedure failed	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new washing session. If the error persists contact Alifax technical support.	1271
Error during first up procedure	Error during First-Up process (Ex: wash tube empty)	Insert the test tubes needed for the execution of this procedure. Restart the procedure. If the error persists contact Alifax tecnhnical support.	1272
Detected too many collisions on Y axis (roller insertion)	Y axis collision error, detected 3 consecutive collisions (during test tube insertion in the roller)	Shutdown and switch the device off.Wait 30s and switch the device on.Remove manually any test tubes that had remained in the roll.Select the funztion "Verify Machine Calibration"A. If no warning is shown:- Start a new measurement session.- If the error persists contact Alifax technical support.B. If a warning is shown:- contact Alifax technical support.	1273
Detected too many collisions on Z axis (test tube picking)	Z axis collision error, detected 4 consecutive collisions (during test tube picking from rack)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Select the funztion "Verify Machine Calibration" A. If no warning is shown:	1274

		- Start a new measurement session. - If the error persists contact Alifax technical support. B. If a warning is shown: - contact Alifax technical support.	
Detected too many collisions on Z axis (test tube delivery)	Z axis collision error, detected 4 consecutive collisions (during test tube delivery to rack)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Select the funztion "Verify Machine Calibration" A. If no warning is shown: - Start a new measurement session. - If the error persists contact Alifax technical support. B. If a warning is shown: - contact Alifax technical support.	1275
Calibration point not found during calibration	Rack Holder calibration point not found while calibration procedure (Ex: missed to mount 1 calibration bar)	Open the door and check that there isn't any evidence of damage, in case of damage contact Alifax technical support, if not: wait 30s and switch the device off. Start a new calibration check procedure. If the error persist contact Alifax technical support.	1276
Rack out of holder, please verify	Rack out of rack holder error (Ex: missed rack holding system)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1277
Failed roller insertion	Error during Test Tube insertion in the roller (Ex: collision detected during the movement)	Shutdown and switch the device off.Wait 30s and switch the device on.Remove manually any test tubes that had remained in the roll.Select the funztion "Verify Machine Calibration"A. If no warning is shown:- Start a new measurement session.- If the error persists contact Alifax technical support.B. If a warning is shown:- contact Alifax technical support.	1278
test tube lost during extraction from rack	Test Tube lost during extracting from rack	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Select the funztion "Verify Machine Calibration" A. If no warning is shown: - Start a new measurement session. - If the error persists contact Alifax technical support. B. If a warning is shown: - contact Alifax technical support.	1279

test tube lost during extraction from roller	Test Tube lost during extracting from roller	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Select the funztion "Verify Machine Calibration" A. If no warning is shown: - Start a new measurement session. - If the error persists contact Alifax technical support. B. If a warning is shown: - contact Alifax technical support.	1280
Rackholder not calibrated	Rack Holder calibration error (Rack Holder not calibrated before session start)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1282
Chassis not calibrated	Chassis calibration error (Chassis not calibrated before session start)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	1283
Rack for wash missing	Error Wash Rack not detected	Check that washing rack has been inserted Remove manually any test tubes that had remained in the roll. Start a new washing session. If the error persists contact Alifax technical support.	1284
Needle steps lost after test tube penetration	Error during test tube penetration (needle was not able to complete the movement)	Shutdown and switch the device off.Wait 30s and switch the device on.Remove manually any test tubes that had remained in the roll.Start a new measurement session.If the error persists contact Alifax technical support.	1285
A rack is blocking the calibration of the rack holder	Error during Rack Holder calibration, detected a rack inside the rack holder during the calibration phase	Remove any rack that's inside the rack holder. Start a new calibration procedure. If the error persists contact Alifax technical support.	1286
–	Server Timeout	Nothing	1287
–	Not Used	Nothing	11010
Waste tank removed	Warning - Waste Tank removed	Nothing	11023
Waste tank inserted	Warning - Waste Tank inserted	Nothing	11024
Water tank removed	Warning - Water Tank removed	Nothing	11025

Water tank inserted	Warning - Water Tank inserted	Nothing	11026
No connection with smart card reader module	Error in Communication with Smart Card Reader (ex: SCR not connected)	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	11029
Not enough credits	Availability error, not enough credits for start the analysis	Insert a smartcard with enough valid credits for the measurement session and upload new credits. If credits are not updated: Shutdown and switch the device off. Wait 30s and switch the device on. Check again the credits amount. If the error persists contact Alifax technical support.	11030
Water not found in cps-mc	Automatic Wash error, water not found inside the CPS-MC module	If the wash result is not ok, start a new washing session. If the error persist contact Alifax technical support	11031
Too many washes failed, verify and clean needle	Warning - Too many washes failed, needle change required before start a new analysis	Try to replace the needle and then run a new washing process. If the result of washing is still not ok contact Alifax technical support.	11032
Automatic wash is disabled	Automatic Wash error, called an automatic wash but the function is disabled	Enable automatic wash. Start a new washing session. If the error persists contact Alifax technical support.	11033
Missing test tube, please verify rack	Latex tubes missing during control/calibration process	Check that the correct pattern of test tube is used for control/calibration. Start a new latex control/calibration procedure. If the error persists contact Alifax tecnhnical support.	11034
Analysis process is running in simulation mode	Warning - Analysis is running in simulation mode	Disable cps-mc emulation flag. Start a new measurement session. If the error persists contact Alifax technical support.	11035
Axis steps lost after collision	Error axis steps lost, during a movement the axis lost steps due to a collision	After the measuring session start a "Verify machine calibration process" and follow the istructions given	11036
Door unlocked, remove fallen test tube and press play.	Fallen test tube error, remove the test tube and restart the session	Measuring session is paused, the door unlocked, remove the fallen test tube and press play for restarting the measuring session	11037
Door unlocked, extract test tube from roller and press play.	Test tube stuck in the roller error, extract the test tube from the roller and restart the session	Measuring session is paused, the door unlocked, remove the test tube from roller and press play for restarting the measuring session	11038

Self wash required. Now the machine is washing.	Warning - The instrument starts itself an Automatic wash after a period of inactivity	Nothing	11039
Operation not allowed. Nothing changed.	Not Used	Nothing	11040
Removed a rack instead of substituting it.	Error in continuous loading process, rack removed instead of substituted	Read the user manual, section "Continuous rack loading"	11041
The tank needs to be emptied	Waste Tank full detected	Check the liquid level in the waste liquid tank A. If the tank is full - empty it - Remove manually any test tubes that had remained in the roll. - Start a new washing session. - If the error persists contact Alifax technical support. B. If the tank is not full - Remove manually any test tubes that had remained in the roll. - Start a new washing session. - If the error persists contact Alifax technical support.	11042
Rack holder calibration check failed	Error during Rack Holder calibration check	Open the door and check that there isn't any evidence of damage, in case of damage contact Alifax technical support, if not: wait 30s and switch the device off. Start a new calibration check procedure. If the error persist contact Alifax technical support.	11043
Chassis calibration check failed	Error during Chassis calibration check	Open the door and check that there isn't any evidence of damage, in case of damage contact Alifax technical support, if not: wait 30s and switch the device off. Start a new calibration check procedure. If the error persist contact Alifax technical support.	11044
controller: waiting time for LIS answer exceeded	Error in Host communication, LIS answer waiting time expired	Contact the LIS service provider	11045
CPS MC temperature out of working range	CPS-MC temperature error, temperature out of working range	Shutdown and switch the device off. Wait 30s and switch the device on. Remove manually any test tubes that had remained in the roll. Start a new measurement session. If the error persists contact Alifax technical support.	11046

26. SOFTWARE VERSIONS

Version 1.0.0

- First version released.

27. 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

CE IVD

The instrument is MET certified for the North American market by MET Laboratories Inc.

MET Complies with UL 61010-1 CSA C22.2 NO. 61010-1
E114263

28. APPENDIX A (how to load racks inside Desk Version instrument)

Photo 1

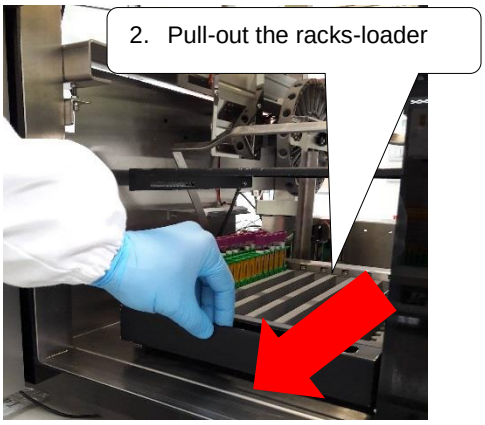


Photo 2

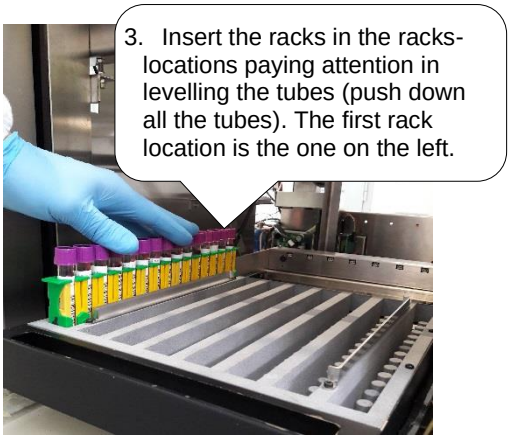


Photo 3

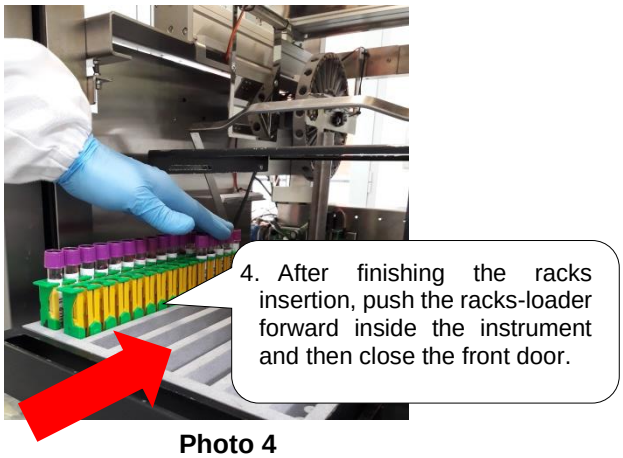


Photo 4

The photo of the rack it is purely indicative just to explain the way it must be loaded
Also please notice it is not necessary to verify the correct alignment of the barcode labels facing the right side of the rack.

29. APPENDIX B (Internal needle replacement)

Before starting the internal needle replacement, it is necessary to perform an automatic washing (**chapter 11.1.1**). Once done refer to **chapter 19.1.1**; press “Internal Needle”. Once pressed the button, the robotic arm is going to move far away from the syringe location in order to make easy the needle replacement. Lift up the front lid to accessing to the “Internal circuit compartment” as shown on Appendix A “Photo 1”**, IT IS MANDATORY** to wear protective gloves and follow the instructions below:

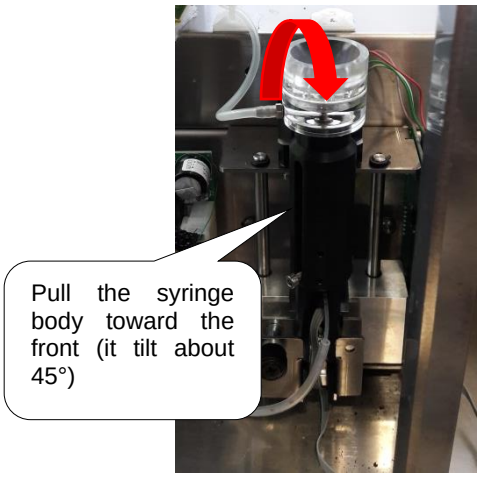


Photo 5

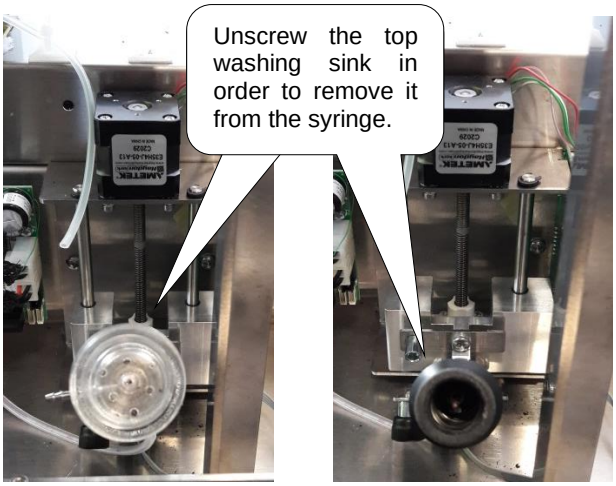


Photo 6

Photo 7

Photo 8

Take a new kit and place the new needle and tight firmly without over - stressing the tread.
After removing the plastic tool from the syringe, push back the syringe towards the original position and fix both the sink and the tube as originally set.

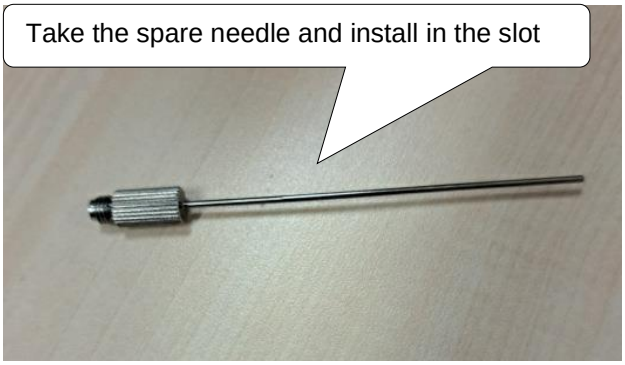
The photo of the “plastic tool” used to replace the needle it is purely indicative just to explain the way it must be used

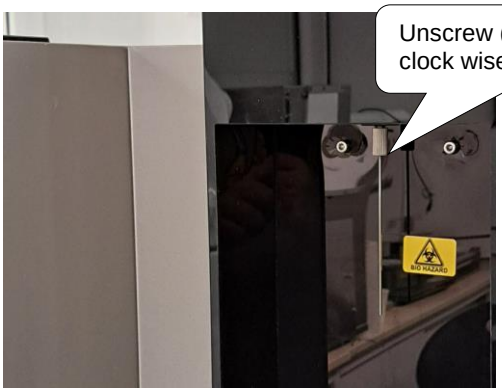
29.1 APPENDIX B1 (External probe replacement)

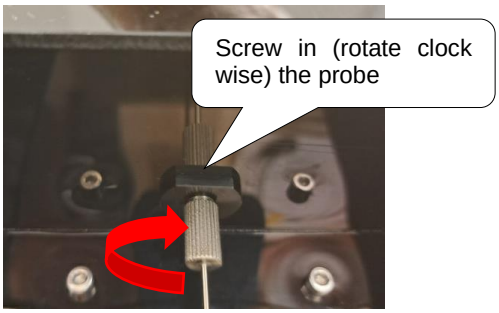
In principle the external probe should not be replaced indeed working with “uncapped” tubes, the probe does not suffer any mechanical wearing out or damage.
This procedure may be intended more as a possible way to “unclog” the probe in case of blood left during inside; this happens mainly if the operator does not wash immediately the external probe once finished the analysis.
Open the left side door and make an initial wash (as well) as the final wash done manually, you can use the option “single test tube”.

Before starting the external probe replacement, it is necessary to perform a washing (chapter 11.3). Once done refer to **chapter 19.1.1**; press “External Needle”.
Open left side front door to get access to the external needle; remember **IT IS MANDATORY** to wear protective gloves and follow the instructions below:

Pull the left side door





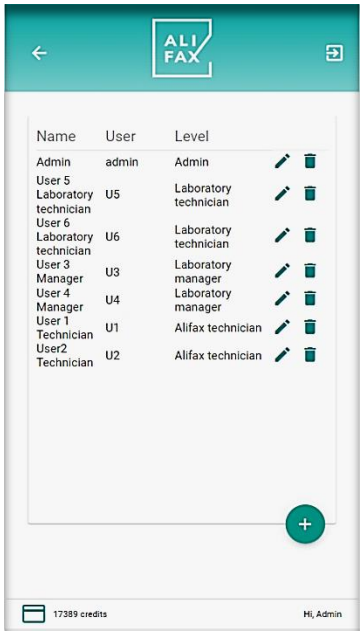


30. APPENDIX C (How to create new Users)

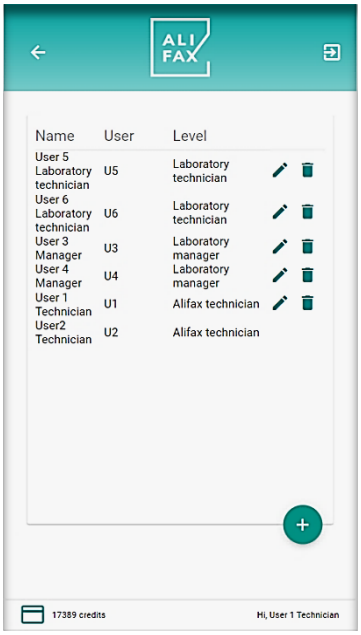
If the logged User is a “Laboratory manager”, can add new accounts or erase present one for “Laboratory managers” or “Laboratory technicians”
If the logged User is a “Laboratory Technician”, cannot add or erase new accounts

The password, in order to comply with the minimum requirements to guarantee information security, must consist of at least 8 characters and must contain characters of at least 4 different types, to be chosen from: capital letters, lower case letters, numbers, special characters (i.e. dots, hyphens, underscores, etc.).

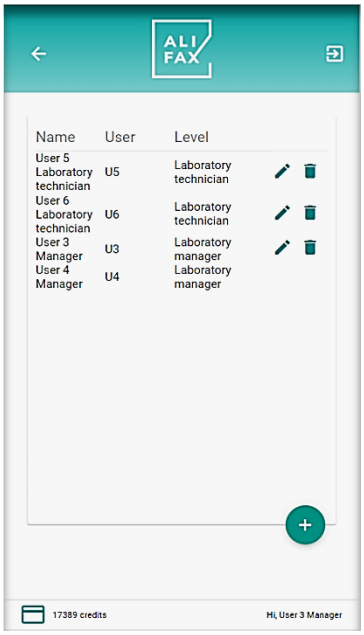
*



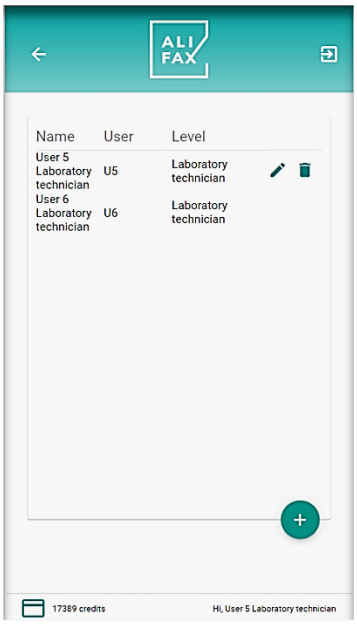
Display 30



Display 31



Display 32



Display 33

31. APPENDIX D (NF meaning)

Normally it appears when the system is not able to aspirate blood, or eventually due to a needle / capillary obstruction.

- The excursion of the needle is not enough and accordingly the needle cannot aspirate blood. If this is true, you should call the technical service in order to increase the excursion of the needle inside the test tube:

- The excursion of the needle is too high and accordingly the needle cannot aspirate blood because its tip is over the blood level. If this is true, you should call the technical service in order to reduce the excursion of the needle inside the test tube:

- Air access into the capillary during aspiration.
  If this is true, the terminal part of the capillary which touches the needle base could be ruined.
  The capillary, therefore, has to be replaced and the analogical board adjusted. To do that, call the technical service.

- The needle is obstructed partially for a limited flow. The photometer, therefore, reads blood mixed with air. Check or replace the needle.

- The pump rubber tube is not able to aspirate blood correctly. The technical service should be called in order to replace the tube.

32. APPENDIX E (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 starting of the aggregation.
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.
Please also refer to the “Limit of the Method” chapter in the PTDS.

33. SANITIZATION FORM

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

Description of sanitization procedures to be done by the Laboratory:

Switch ON the instrument:

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

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

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

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

Wear protection tools (glove and glasses).

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

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

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

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

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

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

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

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

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

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

SANITIZED

ATTACHMENT 1 – PRODUCT TECHNICAL DATA SHEET

ESR_PTDS_SI195210_TEST1-2-0

PRODUCT TECHNICAL DATA SHEET
TEST1 2.0

Rev.1.0 - 2022 -09- 27

Equipment name: **TEST1 2.0 (SI 195.210/THL)**.

Intended Use: TEST1 2.0 is an automated in vitro diagnostic analyser for the quantitative determination of erythrocyte sedimentation rate (ESR) in human blood samples with EDTA from adult and paediatric patients with suspected inflammation.
TEST1 2.0 provides results to inform clinical management of serious and non-serious conditions requiring further diagnostic investigation and assessment of clinical status.
The physician performs the assessment based on the information provided by the device using his or her professional knowledge, skills and abilities as required by local law.

Principle of measure: The technology applied by Alifax's ESR instrumentation is Quantitative Capillary Photometry, which allows in 18.5 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 analysed when this flow is suddenly interrupted (Stopped Flow): this abrupt interruption, together with the rheological characteristics of the sample itself, and the presence or absence of acute phase proteins in it, starts or not the process of aggregation by stacking red blood cells. The diagnostic algorithm of the Test 1 family instrumentation transforms the measurement performed in 18.5 seconds of analysis into a photometric quantitative data, expressed in mm/hour, without having to wait for the whole process of stacking, sedimentation and stacking of the sample. The aggregation of red blood cells (formation of RBC aggregates), the first phase of the sigmoid curve described, is strongly correlated with the end-point results of the classical Westergren method, but is not affected by the interferences that affect both the classical method and the methods based on modified Westergren. Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C) / 98,6°F (±0,9°F)

Results: **ESR** results are displayed (and memorized) in mm/h on the range from 2 to 120 mm/h**.**

Configurations: TEST1 2.0 has two withdrawal systems:

- The internal sampling which requires that samples in tubes are inserted in the instrument using racks
- The external sampling which withdraws blood from open tubes that must be inserted manually in an external probe having previously mixed it manually at least 16 times.
  The second system is an optional and its measurement circuit is completely separated from the first one and it can be used without stopping any internal sampling session.
  STAT function:
  For urgent samples it is possible to proceed with the external sampling unit.
  The urgent sample/s must be previously mixed (ie. manually at least 16 times by complete inversion of blood tube, or using a blood mixer, to prevent eventual clots).
  The external sampling unit will return the ESR result in 18.5 seconds, without interruption of the working session loaded on the automatic TEST1 2.0 unit.
  Low Volume samples
  The external sampling system allows to handle samples with low volume in the tube (e.g. paediatric, oncology samples, etc.), between 300 and 799 ul

Compatibility: TEST1 2.0 it is available in two versions:

- Stand alone “Desk Model”
- Track model: Instrument can be connected to a SYSMEX® Total Lab Automation. In that case, instrument can pick-up test-tubes directly from a conveyor that transport tubes thought various analysers.

Main Features Main feature common to both versions

- 10” colour touch screen
- Front smart card slot that accepts Alifax smart card to load credits necessary to enable ESR measurement
- Front usb port
- Front door to insert sample test tubes in racks (maximum 120 tubes in 8 racks)
- Front-lateral door to access at external withdrawal probe and water and waste tanks
- Easily adaptable to different CBC racks
- Continuous loading of samples
- IBCR The instrument is equipped with an internal Scanner programmed to read codes such:
  - ✓ CODE 39
  - ✓ 2/5 INTERLEAVED
  - ✓ CODABAR
  - ✓ CODE 128
  - ✓ EAN 128
  - ✓ ALL EAN/UPC

TEST1 2.0

Sample requirements: The sample must be whole blood collected in EDTA anti-coagulant.

- The blood sample must be neither coagulated nor haemolysed.
- It would be better to test the sample within 4-6 hours from venepuncture or within 24 hours if kept at +4/+8 °C (+39 / +46 °F), provided it is rewarmed to room temperature before testing.
- The minimum blood volume for the internal sampling is 800 microliters.
- The withdrawal volume for the internal sampling it is 175 microliters.
- After a wash make sure that the first two tubes are filled with at least 2ml of blood
- For particularly low volume samples (300-799 ul), such as paediatric, oncology etc., the instrument's external sampling system can be used without work-flow interruption.
- The withdrawal volume for the external sampling it is 30 microliters.

Tube requirements: The instrument can work with the following types of test tubes:

- Greiner Bio-one Vacuette® / BD Vacutainer® (13x75) / KIMA Vacutest® (13x75 mm) or similar tubes, with a capacity of 3 ml, diameter 13 mm and height in the range [75-83 mm] including cap
- Sarstedt or Sarstedt Monovette® (11x66 mm).
- BD Microtainer MAP® (13x75 mm)
- "Sarstedt S-Monovette® EDTA", "Tapval® pediatric tube", "BD Vacutainer® pediatric tube", only for external sampling system

Operative performances:

- Mixing takes place by completely overturning the tubes.
- Is possible to process up to 195 samples/hour (without considering loading, unloading and mixing times). Analysis time It is 18.5 seconds per sample.
- TEST1 2.0 installed over Sysmex® TLA, it is possible to process up to 180 samples/hour
- First result it is available in less than 5 minutes independently the sampling it done in the automatic (internal) or manual mode.
- 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.
- Samples separation into the capillary using air bubble.
- Audible alarm in case of error or malfunction.
- Instrument it is exempt from Ordinary Maintenance. At the end of the day, the operator once pressed the frontal power button might choose among normal power off or the “Wash & Sleep”.
  If Wash & Sleep it is selected, the instrument washes automatically and then it powers off;
  Above process requires 1 second indeed once pressed the power button, the operator only needs to select the between normal power off or “Wash & Sleep”, this means practically zero hands-on work, the instrument does it all automatically in about 4 minutes.
  The next day the operator finds everything clean and ready for the new routine.
- Instrument can be considered “waste-free” if it is connected (where present) to the laboratory centralized waste drain line.

Capacity:
Alifax Rack (code SI19010601): up to 120 samples,
Cell Blood Counter cassettes: from 80 to 96 samples

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

Intra-Assay Reproducibility (Repeatability):
The intra-assay precision has been evaluated by performing 10 replicates of 7 K3 EDTA-anticoagulated fresh whole blood samples
with ESR values ranging from 10 mm/h to 117 mm/h. The following results have been obtained [(1)]:

Sample	ESR Mean +/- SD (mm/h)	Coefficient of Variation (%)
1	10 +/- 0.86	7.52
2	15 +/- 0.49	3.28
3	23 +/- 0.87	3.77
4	33 +/- 1.48	4.49
5	46 +/- 1.51	3.29
6	56 +/- 1.51	2.70
7	117 +/- 3.32	2.83
Overall CV(%)		***3.98***

Reproducibility:
Evaluated by comparing two instruments on the whole range from 2 to 120 mm/h using the same samples (60 samples) of blood: R = 0,984, Slope: 1,0071

Correlation with ICSH reference method (Westergren in EDTA):
it has been evaluated on 158 K3 EDTA-anticoagulated fresh whole blood samples with a different range of hematocrit values. The following results have been obtained:

Y = 1.0002X + 2.02; R = 0.9761

Similar results have also been obtained in recent publications [(10)].

Stability of samples stored for 24 h at 4 °C:
It has been evaluated on 1140 K_3EDTA-anticoagulated whole blood samples comparing the results obtained within 4 hours from the sample collection and 24 hours after storage at +4 °C. The following results have been obtained [(2)]:

ESR values range (mm/h)	BIAS	Upper and Lower Limits of the Bias	95% Confidence Interval of the Bias
2-10	0.32	-3.18 – 3.82	0.13 – 0.50
11-20	1.05	-5.74 – 7.85	0.60 – 1.51
21-30	1.92	-13.29 – 17.14	0.56 – 3.3
31-40	4.32	-5.85 -14.5	3.23 – 5.42
41-50	4.18	-8.83 – 17.2	2.37 – 6.0
51-60	4.14	-12.84 – 21.13	1.16 – 7.12
61-70	5.83	-13.67 – 25.33	2.04 – 9.61
71-80	9.38	-15.28 – 34.04	4.59 – 14.16
81-90	10.17	-12.35 – 32.70	4.26 – 16.08
>90	9.55	-6.32 – 25.43	6.81 – 12.96

Stability of samples stored for 24 h at room temperature:
In order to view the effects of different methods of storage on the ESR value, 272 K_3EDTA-anticoagulated whole blood samples, some of which have been stored at 4 °C and some others at room temperature, have been analysed after 4 hrs and after 24 hrs.
Good correlation was found between the results taken at 4 hrs and those at 24 hrs on the samples stored at 4 °C (r=0.980). Those stored at room temperature did not correlate quite as well as those stored at 4 °C, but still had very good correlation (r=0.917) [(3)].

Carry-over: it has been evaluated following the CLSI H26-A2 protocol resulting in 4.2% [(10)].

Method limitations:

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

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

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

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

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

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

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

ENVIRONMENTAL AND PHYSICAL SPECIFICATIONS

Permissible environment conditions for operation:

Temp from +15 to +30°C. (+59 / +86 °F),
Humidity from 20% to 85% - no dew

Permissible environment conditions for transportation and storage:

Temp: from -20 to +60°C. (-4 to +140 °F),
Humidity: from 10% to 95% - no dew

Size and weight:

Length: 77 cm (30 in)
Width: 74 cm (29 in)
Height: 86 cm (34 in)
Weight: 94 Kg (207 lb)

Packaging:

Length:	110 cm (44 in)
Width:	87 cm (35 in)
Height:	106 cm (42 in)
Gross Weight:	133 Kg (294 lb)
Volume:	1.02 m^3 (36 ft^3)
Pallet:	Yes

ELECTRICAL SPECIFICATIONS

Input Voltage: 100 - 240 Vac ± 10% External power supply **Power cons:** 221 W **Frequency:** 50-60 Hz
Output Voltage: 48Vdc ± 10% 3A

Classification: Class III, external power supply OVC II.

OTHER OPERATIVE SPECIFICATIONS:

Noise: lower than 55 dB(A)

Maximum rated altitude: 3000 mt asl

Communication: Located on the rear side of the instrument (RS232, USB, LAN, TLA dedicated connectors)

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 to ensure a good capillary and sensor's life.

Restrictions: Indoor uses appliance

Rated pollution degree: 2

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

CONSUMABLES

Smart Card: Conform to ISO 7816-1 specifications - 85.6 x 54 x 0.8 mm (3,337 x 2,126 x 0,0321 in) - coded using Alifax proprietary algorithm.
Alifax Universal test card, sizes available: 1,000 (code **SI 195.901**) - 4,000 (code **SI 195.904**) - 10,000 (code **SI 195.910**) - 20,000 (code **SI 195.920**) tests.

Wash Tank: 500 ml plastic wash tank with screw cap (code **SI195145**).
Waste Tank: 500 ml plastic waste tank with screw cap (code **SI205801**).

INTERNAL QUALITY CONTROL

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

Latex Controls for TEST 1 family analysers allow the control of the calibration stability of the instruments. They are available in two model of test tubes:

- 13x75mm (0,512 x 2,953 in) Greiner®:

  Latex Controls (6 tests) - code SI 305.100-A; **Latex Controls (30 tests)** - code SI 305.300-A.
- 11,5x66mm (0,453 x 2,598 in) Sarstedt®:
  Latex Controls (6 tests) - code SI 305.102-A; **Latex Controls (30 tests)** - code SI 305.302-A.

Patient identification : Internal CCD bar-code reader .

OPTIONAL AVAILABLE TOOLS

External USB Thermal Printer Code SI19014001

Extraible Rack Loader for

- **Alifax rack / Beckman Coulter LH700** Code SI19010602
- **Sysmex (SF/SE/XE/XT/XS/XN)** Code SI19010603
  Horiba Yumizen racks
  Mindray racks
- **Bayer / Siemens Advia 120** Code SI19010604
- **Beckman Coulter DxH 800** Code SI19010605
- **Abbott Alinity H-Series rack** Code SI19010606

REGULATORY INFORMATION:

Classification	IVD	
UDI-DI (GTIN13)	8056040148945 TEST1 2.0	
CND Code	W02029001	APPARECCHIATURE PER VELOCITA` DI ERITRO-SEDIMENTAZIONE
FDA-CFR Code	Product code: GKB	Regulation Number: 864.5800 Automated sedimentation rate device
GIVD Code	23.09.10.01	Other_HHIHC Hardware + accessories + consumables + software
GMDN Code	56691	A mains electricity (AC-powered) laboratory instrument intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen. The device operates with minimal technician involvement and complete automation of all procedural steps
Repertorio Alifax (Only for Italian Market)	2316848	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM secondo IVDR 746/2017

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(3) E. Heverin (Galway-Mayo Institute of Technology, Ireland):” Comparison of the Westergren method versus the TEST1 technique for determining the Erythrocyte Sedimentation Rate”, May 2002, private communication

(4) NCCLS “Reference and Selected procedure for the Erythrocyte Sedimentation rate (ESR) Test; Approved Standard-Fourth Edition”, Vol. 20 No. 27

(5) Sox HC, Liang MH: “The Erythrocyte Sedimentation Rate”, Annals of Internal Medicine 1986; 105:515-523.

(6) NCCN (National Comprehensive Cancer Network) Clinical Practice Guidelines in Oncology “Multiple Myeloma” (V.I.2007)

(7) Ajubi et al.: “Determination of the length of sedimentation reaction in blood using the TEST 1 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

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

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

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

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

ALIFAX S.r.l.
via Petrarca 2/1 – 35020 POLVERARA (PD) – ITALY
Tel. +39 0490992000 e-mail: info@alifax.com
VAT: IT04337640280

ALIFAX S.r.l.
via Merano 30 – 33045 NIMIS (UD) – ITALY
Documents available on: www.alifax.com