

TEST1 2.0

Valid for Software Version 1.0.X

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



In Vitro Diagnostic Medical Device for professional use

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INDEX

1. ALIFAX ESR INSTRUMENTS PRESENTATION	5
2. TYPOGRAPHICAL CONVENTIONS	8
2.1 DISPLAY of WARNINGS and NOTES	8
2.2 USED WARNINGS SYMBOLS	8
2.3 OTHER SYMBOLS	9
3. WARNINGS FOR A CORRECT USE OF THE INSTRUMENT.....	10
3.1 GENERAL SAFETY	10
3.2 OPERATIVE SAFETY	11
3.3 MECHANICAL SAFETY	12
3.4 ELECTRICAL SAFETY	13
3.5 BIOLOGICAL SAFETY.....	14
3.6 PRIVACY AND PATENT SENSIBLE DATA HANDLING	15
4. LABELS.....	16
5. UNPACKING AND INSTALLATION.....	17
6. TEST1 2.0 PRESENTATION	18
7. INSTRUMENT FRONT SIDE OVERVIEW.....	19
7.1 INSTRUMENT FRONT SIDE VIEW (TLA VERSION)	19
7.2 INSTRUMENT INTERNAL VIEW (TLA VERSION)	19
7.3 INSTRUMENT INTERNAL VIEW COMMON TO BOTH VERSIONS	21
7.4 INSTRUMENT REAR SIDE.....	22
7.5 WATER TANK AND WASTE TANK HANDLING.....	22
8. "POWER ON" THE INSTRUMENT	23
9. TECHNICAL SERVICE LOGIN CREDENTIAL	23
10. MAINTENANCE MENU	24
10.1 NEEDLE REPLACEMENT	24
10.1.1 External probe replacement	25
10.2 CPS.....	27
10.2.1 Internal CPS Calibration	27
10.2.2 Internal CPS Calibration (TLA VERSION)	29
10.2.3 External CPS Calibration (valid for both Desk and TLA models)	30
10.2.4 Latex Errors	31
10.2.5 CPS Configuration (valid for Internal and External CPS)	32
10.2.6 CPS Latex Quality Control (valid for Internal and External CPS)	34
10.2.7 CPS "Extra" setup (valid for Internal and External CPS)	34
10.3 SETTINGS	35
10.3.1 Localization	35
10.3.2 Racks selection	35
10.3.3 Needle	36
10.3.4 System Info	36
10.3.5 Automatic Wash	37
10.3.6 Automatic Washing Timeout.....	37

10.3.7	Test - Debug.....	37
10.3.8	Latex & Priming	38
10.3.9	Users	38
10.3.10	Configuration Management	38
10.3.11	Auto-logout	39
10.3.12	Network	39
10.3.13	Remote Control	39
10.3.14	System Update.....	39
10.3.15	General Parameters	40
10.3.16	Printers	40
10.3.17	Archive Settings	41
10.3.18	Storage Settings	41
10.4	MACHINE CALIBRATION.....	42
10.4.1	Verify	42
10.4.2	Gripper	43
10.4.3	Rack Holder.....	43
10.4.4	Chassis.....	44
10.4.5	Roller.....	44
10.4.6	Roller Insertion	45
10.4.7	Test Tube Picking.....	46
10.4.8	Barcode	47
10.5	TEST FUNCTIONS	48
10.5.1	Gripper	48
10.5.2	Barcode	49
10.5.3	CPS	49
10.5.4	TEST CYCLE	49
10.5.5	SENSOR STATUS	50
10.5.6	AXIS	50
10.5.7	NEEDLE	50
10.5.8	Wash	51
10.5.9	Roller	51
10.5.10	USB	51
10.5.11	Edit Machine Info.....	51
10.6	FIRST-UP INTERNAL	52
10.6.1	FIRST-UP INTERNAL DESK VERSION MODEL.....	52
10.6.2	FIRST-UP INTERNAL TLA VERSION MODEL.....	52
10.7	FIRST-UP EXTERNAL PROBE	52
10.8	LOGS EXPORT.....	53
10.9	Export Video.....	53
10.10	TANK LEVEL (WASTE)	53
10.10.1	TANK EMPTY PROCEDURE.....	54
10.11	PARTS	54
10.11.1	Check	55
10.11.2	Service	55
10.11.3	Replacement	55
11.	RESTRICTIONS.....	57
11.1	“Service Engineer.....	57
11.2	“Laboratory manager”.....	57
11.3	Laboratory technician	57
12.	TURN THE INSTRUMENT OFF.....	57
13.	SANITIZATION PROCEDURE	57
14.	ERROR LIST.....	58
15.	SOFTWARE VERSIONS	71



SERVICE MANUAL

TEST1 2.0

16.	ALIFAX - REFERENCES.....	72
17.	APPENDIX A (how to load racks inside Desk Version instrument)	73
18.	APPENDIX B (Needle Management)	74
18.1	APPENDIX B1 (needle replacement)	74
18.2	APPENDIX B2 (External probe replacement).....	74
19.	APPENDIX C (How to create new Users).....	75
20.	APPENDIX D (NF meaning).....	76
21.	APPENDIX E (NR meaning)	76
22.	APPENDIX F (asterisk meaning)	77
23.	APPENDIX G (Wash station O-Ring replacement).....	77
24.	SANITIZATION FORM.....	78
25.	PROGRAMMED MAINTENANCE PROCEDURE	79
26.	INTERFACING INFORMATION.....	79
	ATTACHMENT 1 – PRODUCT TECHNICAL DATA SHEET	80
	ATTACHMENT 2 – ASTM LIS Interface Protocol	80
	ATTACHMENT 3 – SERIAL LIS Interface Protocol	80

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.

Neither this manual nor any parts of it may be duplicated or transmitted in any way without the written approval of Alifax S.r.l.

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 creating 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 (Westergren-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

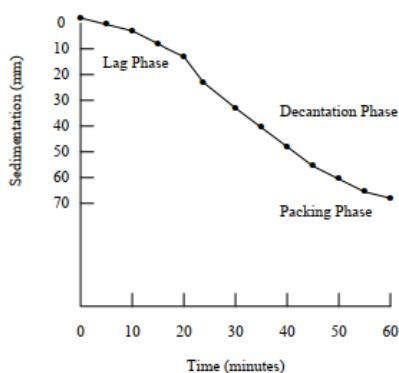


Figure 1. Sigmoid Sedimentation Curve. Evolution of the erythrocyte rouleaux formation in the different phases of ESR in a case with a high level of acute phase proteins.

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 modularity

The TEST1 2.0 instrument it is adaptable to the working needs of the laboratory, can be integrated, it can work 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 Lapic, 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."*

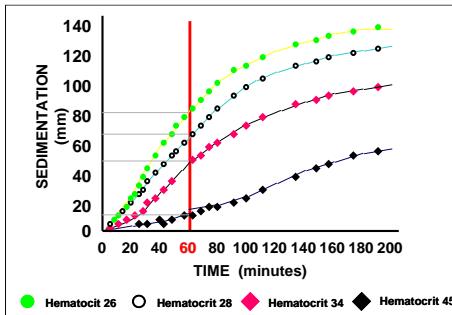
A further example is given by the following evidence:

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 Peloso 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 $p = 0.99$ 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) Explanation:**

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

3. WARNINGS FOR A CORRECT USE OF THE INSTRUMENT

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

Handling of Serious Incidents:

"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;

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.

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

Mobile Phones**WARNING**

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 ($\pm 0.5^\circ\text{C}$) / 98,6°F ($\pm 0,9^\circ\text{F}$)
- 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.
- To use the Latex Controls, please refer in any case to the IFU of the Latex.
- 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 mm² 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.

WARNING



Danger due to Improper Place of Installation

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

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

DANGER



Electrocution/Fire Hazard!

During the normal routine working please:

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

DANGER



Electrocution/Fire Hazard!

During Maintenance/ Technical Service activities be sure to:

- Immediately separate the defective system from the mains supply if a safe usage is no longer possible.

- Secure the defective system against reconnection.
- Label the defective system clearly as being defective.

WARNING



Battery Handling

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

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

- 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 username 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.

SERVICE MANUAL

TEST1 2.0

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.



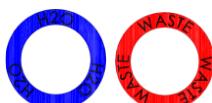
Label that stats attention and Biohazard risk and require compulsory use of gloves



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

	<p>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.</p>
--	---

5. UNPACKING AND INSTALLATION

- **Qualified to the installation personnel**

The installation of this device cannot be done by the final user. To avoid the invalidation of the guarantee, it must be done from a qualified technician authorised from the manufacturer only. In this way, each possible problem, that could jeopardize the instrument work, can be evaluated and solved by fully trained personnel for these eventualities.

- **Packing check**

The instrument comes packed in a carton box with wood socket. Before unpacking it, check the box for possible damaging, verifying sides, corners and the wood base. Any damaging part has to be reported on the installation and testing form, enclosed on the instrument documentation.

- **Packing contents check**

The pack contains even a box which contains all the scheduled accessories to a correct installation and setting of the instrument. All these accessories are exactly listed on the Packing List form and they could vary according to the instrument configuration.

The content of the packing and the accessories box has to be the following:

no. 01 TEST1 2.0 instrument

no. 01 Packing List form

no. 01 Installation and Testing form

no. 01 CE conformity declaration.

no. 01 Final Testing certificate

no. 01 External Power Supply Unit

no. 02 Waste tank (one is installed, one into the accessories box)

Note:

Refer, however, to the Packing List form for the control of the packing and accessories box contents, signalling any differences between the pack contents and those listed on the Packing List on the Installation and testing form.

- **Unpacking**

The instrument should be unpacked and handled by 4 people due to the size and the weight of the instrument.

Open the pack from the top, extract the first box that contains the accessories and then, at sides, extract the instrument using the cardboard tool that facilitates the extraction process.

Place the instrument on the floor or on a low table to remove the protective nylon foil.

Check the instrument plastic cover and report any damaged part to the "Installation and Testing" document.

Alifax recommends installing the instrument on a flat table sheltered from sun light and able to support its weight (**about 94 Kg**). On the right side it would be enough space to reach the power supply switch, located on the rear side of the instrument just above the mains cord.

Besides, provide at least **10 cm** of clearance on the rear side of the instrument to allow the connection of the mains cable and any data cable for the connection with the Lab Informative System (LIS).

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.

Before connecting the cable to the mains outlet, be sure that the mains voltage corresponds to the voltage selector located on the back of instrument, just above the mains power switch.

Before powering on the instrument, check the presence and the connection of the waste tank, opening the left side door of the instrument also and then proceed lighting the instrument.

Verify the correct initialization procedure. Any possible anomaly must be signalled on the Installation and Testing form document.

During the installation of the instrument, it is compulsory for the Field Service Engineer to fill in the specific check-list, called Installation and Operational Qualification coded as: ESR_IQOQ_SI195210THL_TEST1-2-0_SW1-0_1-0_EN and to keep it for the whole life of the device.

The Installation and Operational Qualification document is available inside the "Accessories Box" supplied together

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 samples/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



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.

SERVICE MANUAL

TEST1 2.0



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 right side

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



Please remember to fill the rack with all the necessary test tubes

Close the door and start the procedure.



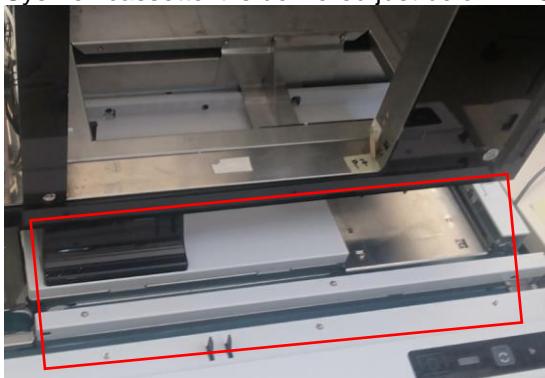
■ Water tubes

■ Hypochlorite tubes

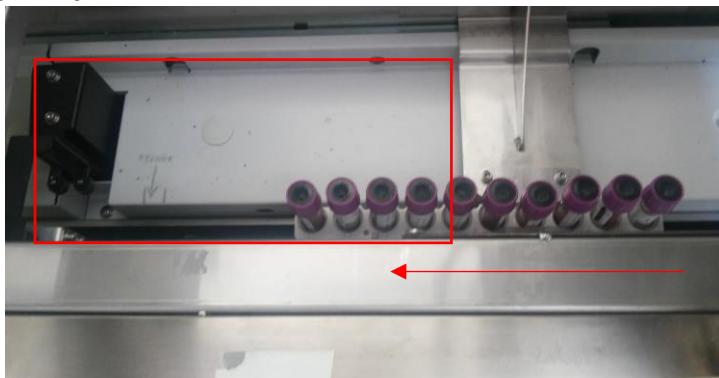
□ Latex tubes

✗ Unused slot

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

SERVICE MANUAL

TEST1 2.0

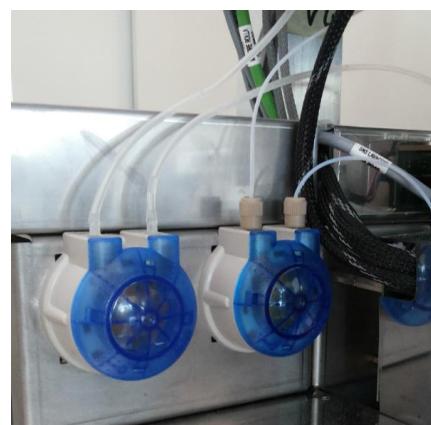
7.3 INSTRUMENT INTERNAL VIEW COMMON TO BOTH VERSIONS



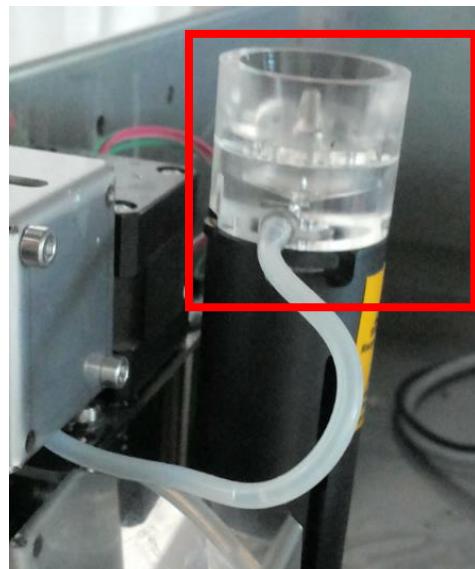
Internal Needle Zone



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

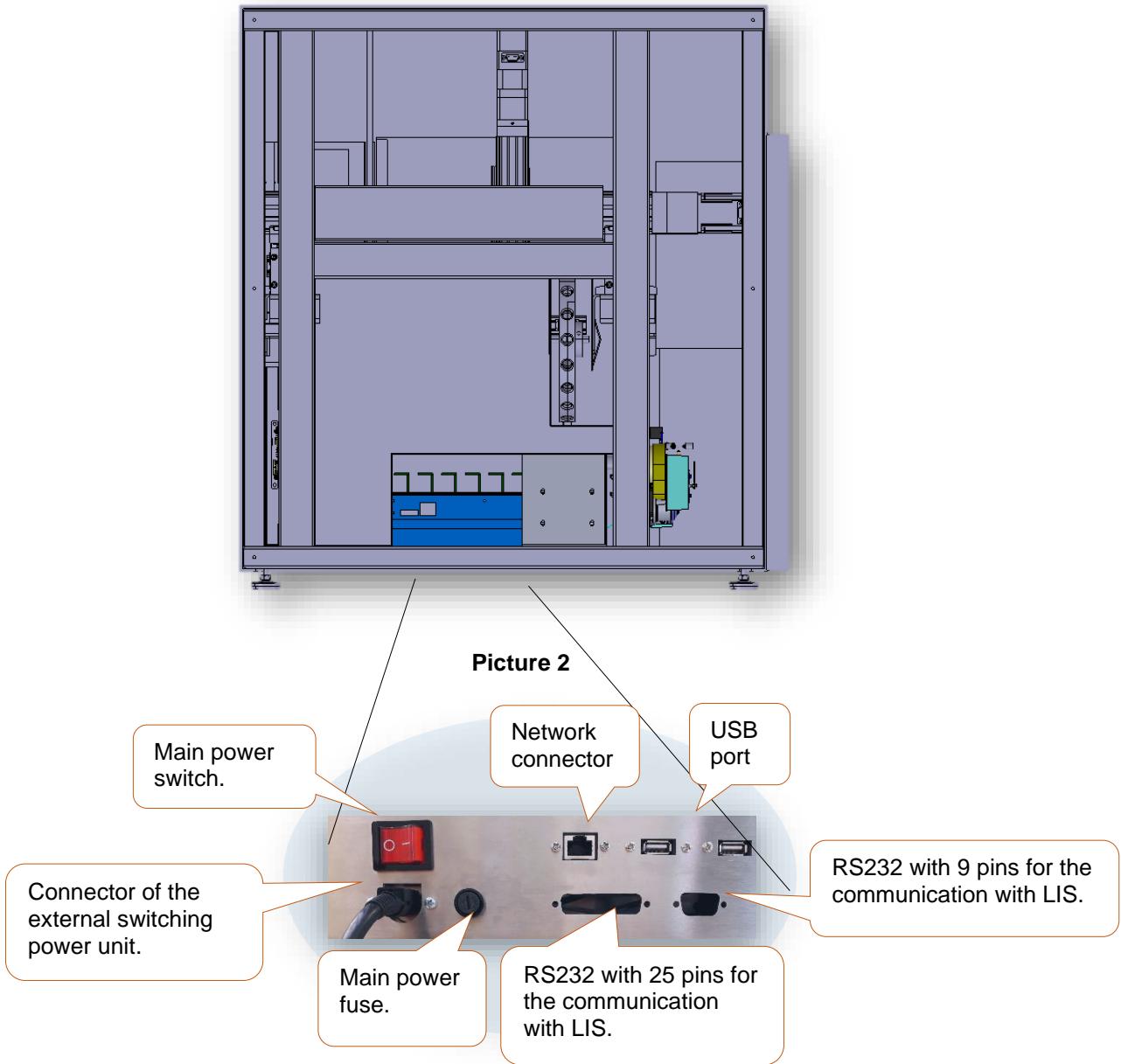


Internal BarCode Reader



Internal BarCode Reader mirror

7.4 INSTRUMENT REAR SIDE



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. TECHNICAL SERVICE 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.

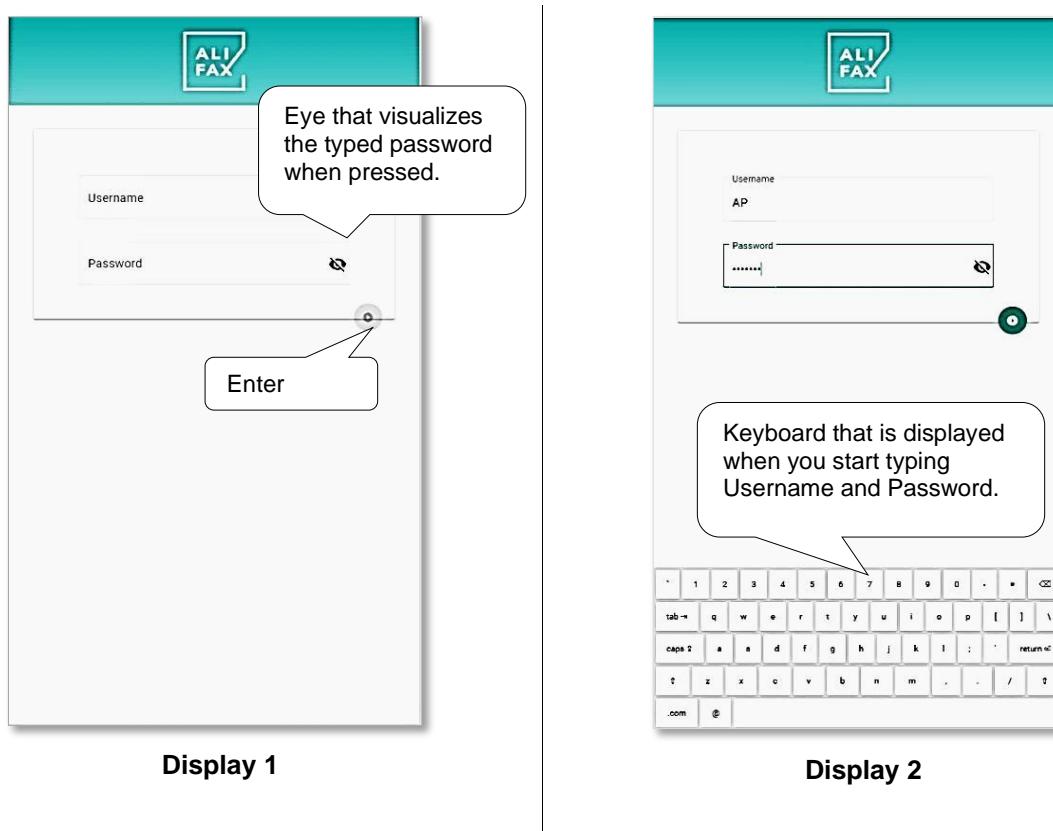
Considering this is a Service Manual, the username and password to be inserted are:

- **Username:** admin
- **Password:** admint120

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.

IMPORTANT: Being this a Service Manual, washing procedures are not explained, please refer to User Manual Chapter 11





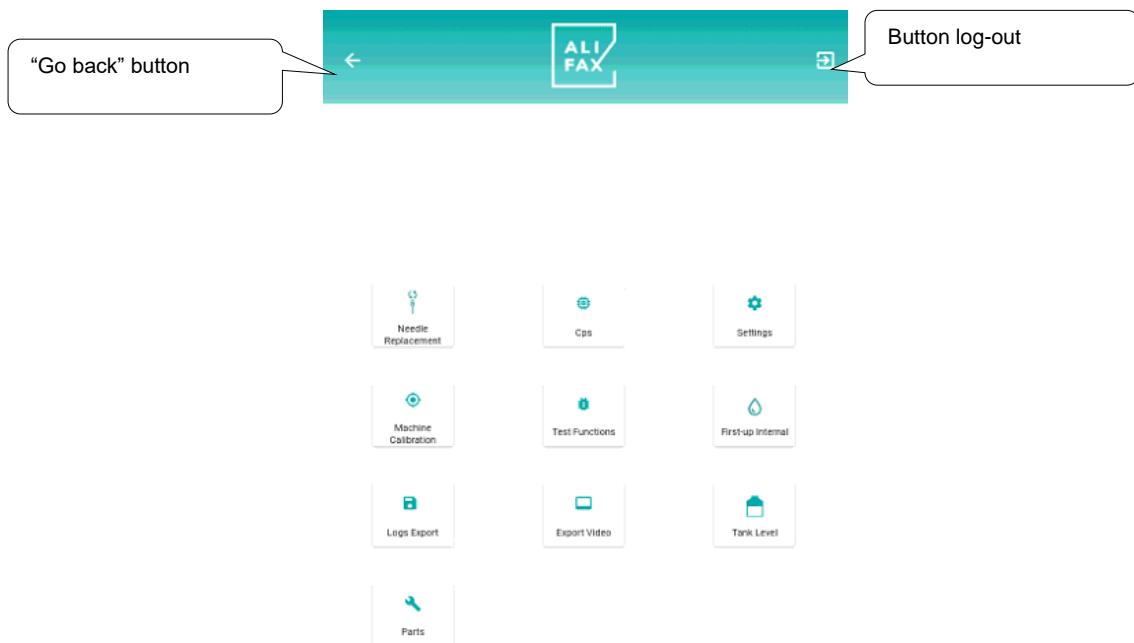
SERVICE MANUAL

TEST1 2.0

10. MAINTENANCE MENU

Once logged in, Service Engineer (from now on we use the abbreviation "SE") have full visibility and access to all the functions.

After having pressed the "**Maintenance**" icon (located on the main menu), below screenshot shows the functions available menu; the access to each one to the "functions" it is done just "pressing" the desired icon.

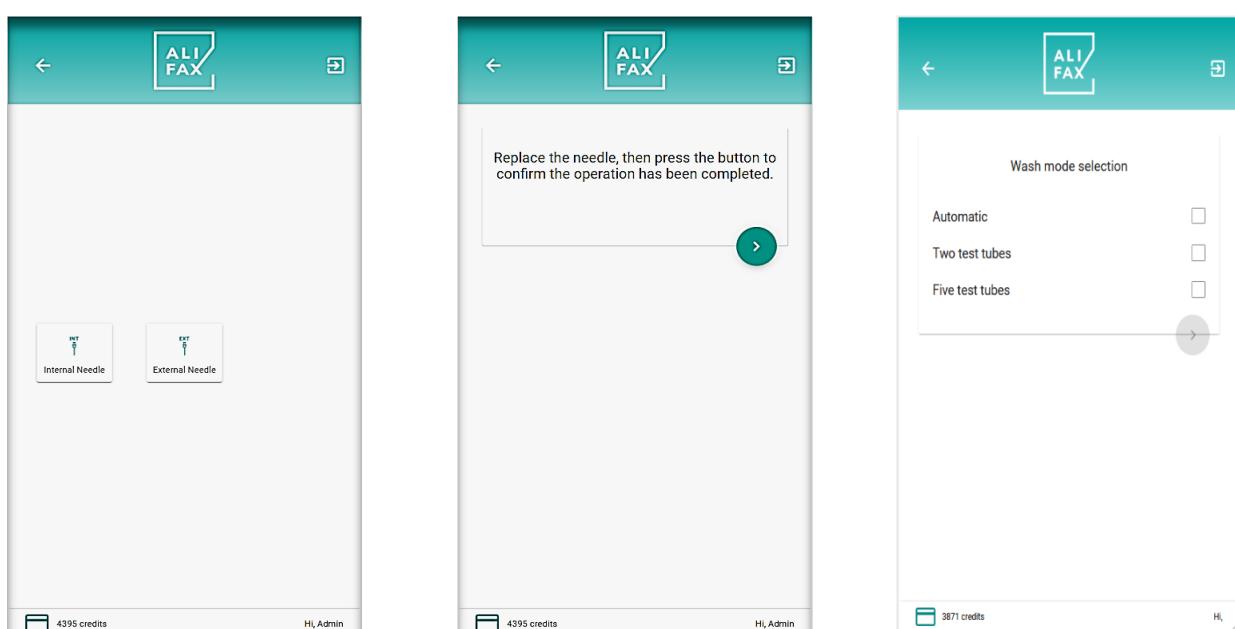


10.1 NEEDLE REPLACEMENT



The needle does not have a minimum number 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.

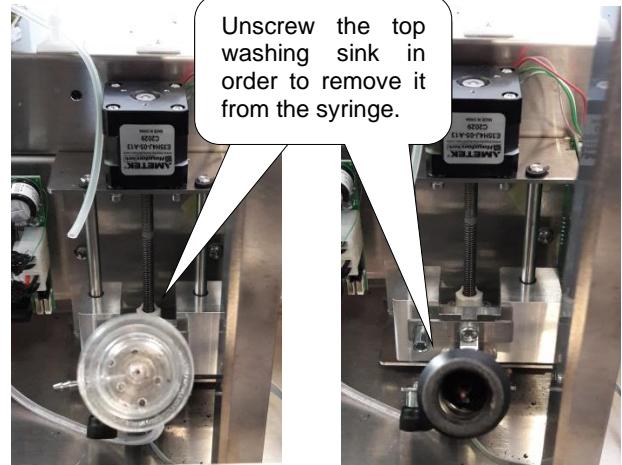
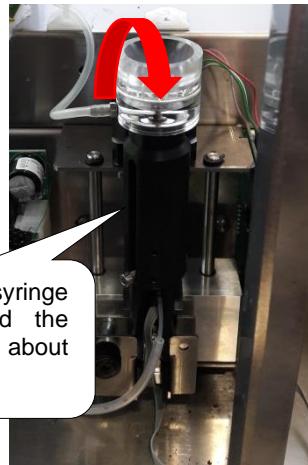


SERVICE MANUAL

TEST1 2.0

Before starting the internal needle replacement, it is necessary to perform an automatic washing (**chapter Error! Reference source not found.of user manual**). Once done refer to **chapter Error! Reference source not found. (user manual)**; press “Internal Needle”. Once pressed the button, the robotic arm is going to move far away from the syringe location to make easy the needle replacement. Lift up the front lid to accessing to the “Internal circuit compartment” as shown here below.

IT IS MANDATORY to wear protective gloves and follow the instructions below:



Pull the syringe body toward the front (it tilt about 45°)

Unscrew the top washing sink in order to remove it from the syringe.



Take the spare needle plastic tool, insert it into the syringe up the end and unscrew the syringe to remove it then up.



Take a new kit and place the new needle and tight firmly without overstressing 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

10.1.1 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”.

SERVICE MANUAL

TEST1 2.0

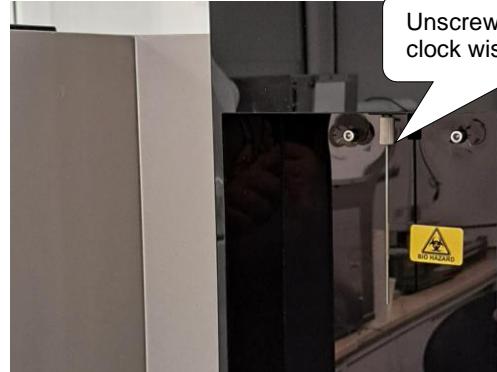
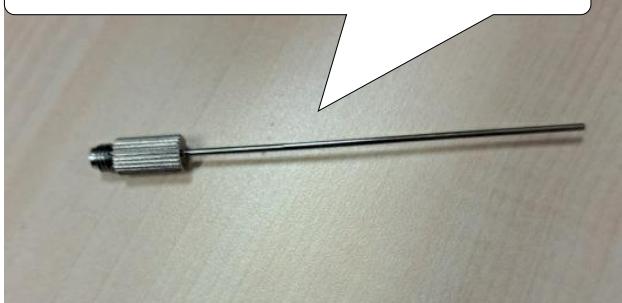
Before starting the external probe replacement, it is necessary to perform a washing (**chapter Error! Reference source not found.user manual**). Once done refer to Error! Reference source not found. press "External Needle". Open left side front door to get access to the external needle; remember **IT IS MANDATORY** to wear protective **gloves** and follow the instructions below:



Pull the left side door



Take the spare needle and install in the slot



Unscrew (rotate counter clock wise) the probe

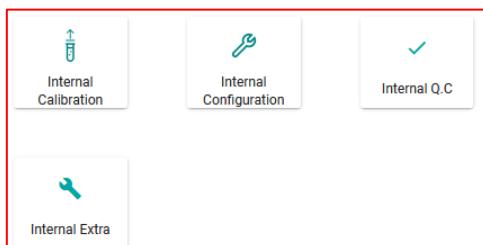


Screw in (rotate clock wise) the probe

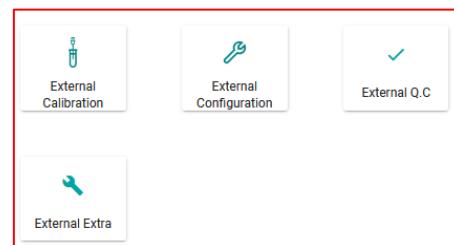
10.2 CPS



When the **CPS** button is pressed, instrument offers two alternatives: Internal or external; depending which option it is chosen, instrument will show basically the same options with the only difference in the names “internal” or “external” as visible in below images.



CPS Internal option



CPS External option

10.2.1 Internal CPS Calibration



Latex Calibration kit is a rapid tool easy to handle that enables to bring back the analyser to the original performances.

The kit is supplied in a box that can contain:

- 1 triplet Latex that allow executing a total of 6 calibrations (code **SI 305.400-A**)
- 6 set of three tubes containing water

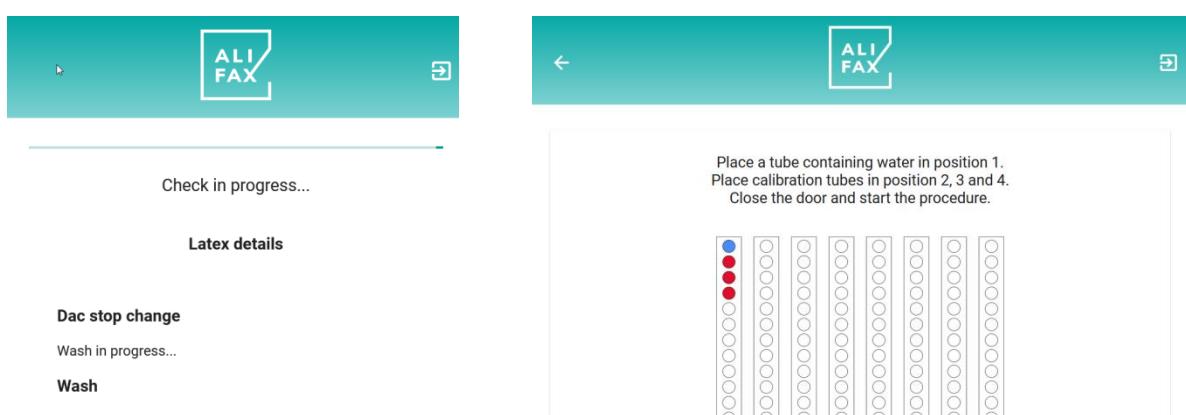
To use the Latex Calibrators, please refer in any case to the IFU of the Latex Calibrators.

Before running a Latex Calibrators, carry-out a “5 tube washing procedure” (as explained in User Manual chapter 11.2):

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

Once done the “5 tube washing” start the calibration following strictly the loading sequence as displayed:

- In position 1 (blue) must go a wash tube filled $\frac{3}{4}$ 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:



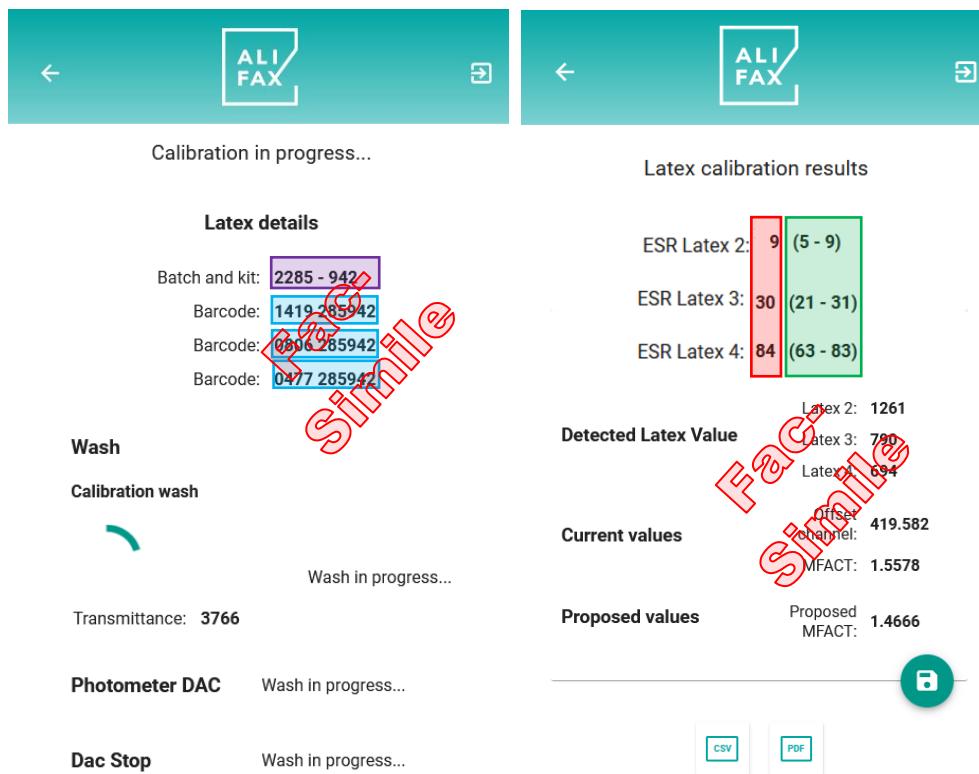
10.2.1.1 Internal / External CPS Calibration Results

Independently the Calibration it is done in the Internal CPS or in the External CPS, at the end of the Calibration 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 Calibrator Box.

If the results obtained are within the expected ranges, it means that the analyzer is calibrated correctly. On the contrary, 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 Calibration process:



Calibration in progress...

Latex details

Batch and kit: 2285 - 942
Barcode: 1419 28542
Barcode: 0906 265942
Barcode: 0477 285942

Wash

Calibration wash

Wash in progress...

Transmittance: 3766

Photometer DAC

Wash in progress...

Dac Stop

Wash in progress...

Latex calibration results

ESR Latex 2: 9 (5 - 9)
ESR Latex 3: 30 (21 - 31)
ESR Latex 4: 84 (63 - 83)

Detected Latex Value

Latex 2: 1261

Latex 3: 790

Latex 4: 694

Current values

Offset channel: 419.582

MFACT: 1.5578

Proposed values

Proposed MFACT: 1.4666

On the left side instrument shows the lot and kit number of the Latex Calibrator triplet and the code of each level

On the right side, once the 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.

Being this a Calibration procedure, the instrument displays some supplementary variables (not displayed in case of a Latex Control).

Detected Latex Value	Latex 2: 1261 Latex 3: 790 Latex 4: 694
Current values	Offset channel: 419.582 MFACT: 1.5578
Proposed values	Proposed MFACT: 1.4666

Detected latex refers to the real photometrical value measured by the CPS. This is helpful because it is a quick evidence if one or more of the three levels are degraded comparing to the expected values

Offset channel it is mainly for Manufacturing process and it is automatically calculated during latex run

The important parameter to be observed during a latex Calibration procedure it is the latex gain variable called "MFACT". The first number (in this case 1.5578) it is the current value memorized by the instrument

The Proposed MFACT it is a value calculated by the instrument comparing the expected values and the values measured.

The second number "Proposed MFACT" in (in this case 1.466) it is the new gain value that should be inserted in the instrument.

Please notice the instrument only proposed it, It does not update the value unless the FSE confirms it pressing the "save"  pushbutton.

Once saved, a resume visualization it is displayed:

IMPORTANT NOTE:

If the deviation of MFACT (difference between prior and after calibration). It is greater than 50 points, for example from 1.222 to 1.172 or 1.345 to 1.395 it should not be assumed a valid calibration and the same must be repeated verifying each time any deviations

After done at least **three calibrations** and verified that the difference is less than 50 points on the three readings, example initial MFACT 1.223, MFACT obtained during the 3 calibrations 1.276, 1.264, 1.281, 1.257, the new MFACT can be considered around the value 1.27XX and then it can be considered valid. If the values of MFACT obtained during the three or more calibrations are not within the variability allowed (**XX < 50 points**), it is advisable to verify the CPS manifold.

Once the calibration process it is finished, it is possible to:

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

10.2.2 Internal CPS Calibration (TLA VERSION)

The procedure to be done in case of "TLA Version" it is conceptually speaking the same as above explained; the only difference it is in the way rack containing latex and wash tubes it is loaded.

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

Place water tubes in position 1, 5 and 6.
 Place Latex Control tubes 2, 3 and 4 in position 2, 3 and 4,
 respectively.
 Close the door and start the procedure.



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

Water tubes must be filled up indicatively $\frac{3}{4}$ 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 calibration; the process the instrument will do it is the same explained in **chapter 10.2.1.1**



Table-columns.id	Table-columns.previous	Table-columns.current
Latex 2	1261	1261
Latex 3	790	790
Latex 4	694	694
ESR Latex 2	9	8
ESR Latex 3	30	26
ESR Latex 4	84	74
Offset channel	419.582	387.2596
MFACT	1.5578	1.4666

10.2.3 External CPS Calibration (valid for both Desk and TLA models)



The **External Calibration** procedure (as well as results visualization) it is similar than the internal one described on **chapter 10.2.1.1**. 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.

The kit is supplied in a box that can contain:

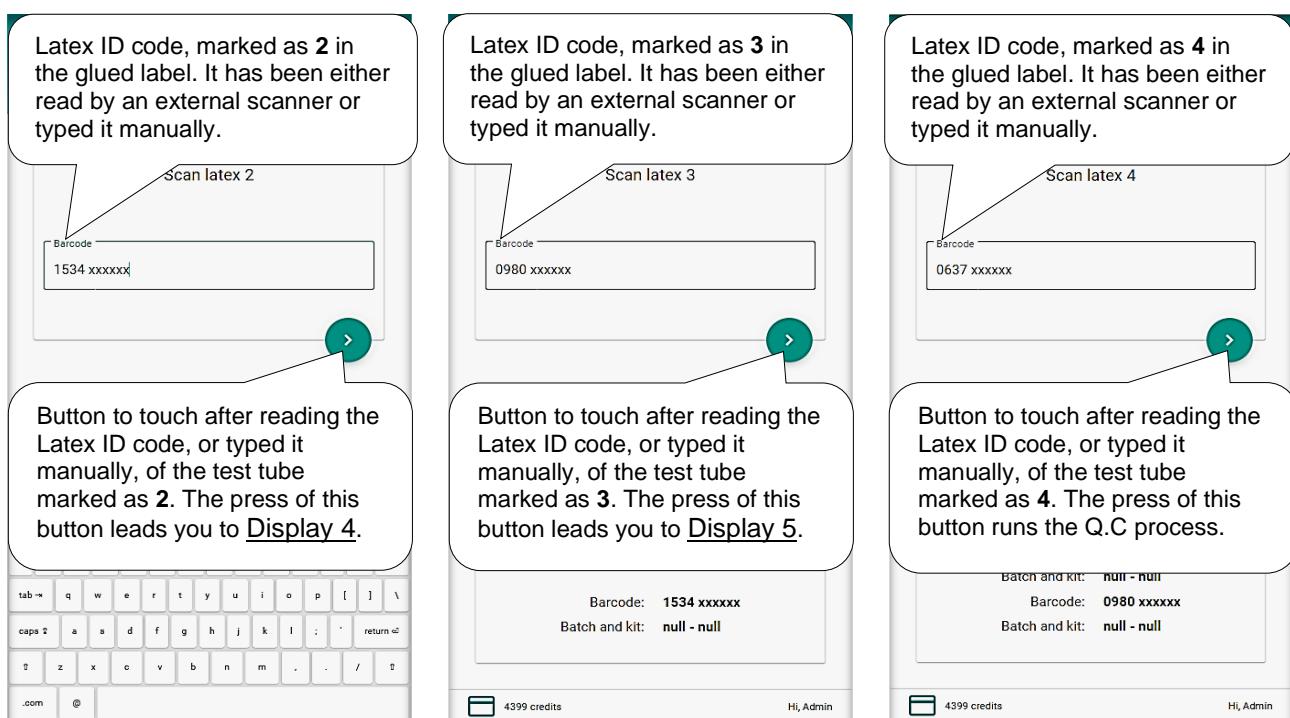
- 1 triplet Latex that allow executing a total of 6 calibration (code **SI 305.400-A**)
- 6 set of three tubes containing water

To use the Latex Calibrators, please refer in any case to the IFU of the Latex Calibrators.

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

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 User Manual):



Display 3

Display 4

Display 5

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 (this initial phase it is only to prime the circuit)
3. 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 till instrument asks to remove it emitting a beep and a video request (this phase it is the real sampling)

4. 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
5. 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
6. 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
7. 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 Calibration 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.

Result visualization it is the same as for the Internal CPS Calibration procedure explained in **chapter 10.2.1.1**

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 Calibration Box.

10.2.4 Latex Errors

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

10.2.4.1 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:



10.2.4.2 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:



10.2.4.3 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

10.2.4.4 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.



10.2.4.5 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.

Latex controls QC results

ESR Latex 2: -4 (6 - 11)

ESR Latex 3: -4 (15 - 22)

ESR Latex 4: -4 (56 - 74)



SERVICE MANUAL

TEST1 2.0

10.2.5 CPS Configuration (valid for Internal and External CPS)



Internal Configuration

The **CPS Configuration** menu it is available for both Internal and External CPS. For easiness of explanation this chapter will explain the Internal CPS configuration, but it is important to clarify the exact same description applies for the External CPS.

The description it is the same independently the model of TEST1 2.0 (Desk or TLA model).

The Internal configuration menu contains all the variable linked with the CPS setup; the menu it is divided in two columns "Read" and "Write".

The column "Read" just shows the current status of each variable, while in the column "Write" the FSE can modify the value easily just typing the desired variable value. To switch between Read and Write just click over the string "Read" or "Write"

Click over "Write" to get access to the fields where variables can be edited.

BoosterY: Used to align and correlate instrument Vs. reference method.

Selection between EDTYA or Sodium Citrate (to be configured during instrument installation by FSE)

DAC 1 **MUST NOT BE MODIFIED**

ModelFact: Used to align and correlate instrument with Latex Controls

DAC STOP **MUST NOT BE MODIFIED**

Setup of temperature of CPS. **MUST NOT BE MODIFIED**

Offset Channel automatically adjusted during latex control / calibration

Temperature inside the CPS module

All these parameters **MUST NOT BE MODIFIED**

Variable	Type	Value
Boostery edta	Read	1
Boostery citrate	Read	1
Dac 1	Read	1210
Mfact 1	Read	1.4996
Dac stop	Read	0
Target thermostat led side	Read	37
Target thermostat photometer side	Read	37
Channel offset	Read	343.1396
Current offset	Write	343.1396
Current temperature photometer side	Read	37.0355
Current temperature led side	Read	36.977
Hematocrit parameter	Read	1
Hemoglobin parameter	Read	1
Aggregation factor parameter	Read	1
Viscosity parameter	Read	1
Anemia parameter	Read	1

To modify a value, once clicked over "Write" tab, you have to click over the specific field of the variable under adjustment

A "numeric keyboard" it is displayed where the FSE can type the corresponding value. Once done press "Return" and then press the "save" pushbutton to confirm the new value

Finally press again "Read" tab to verify the new value has been acquired.



SERVICE MANUAL

TEST1 2.0

The screenshot shows a configuration interface with the following parameters:

Parameter	Type	Value
Active booster type	Read	-256
Wash result	Write	0
Transmittance detected on photometer	Read	3802
Value empty pipe on optical fork	Write	1650
Currently detected adc value on photometer	Read	1608
Currently detected adc value on fork	Write	4055
Ves extra corrector	Read	1

Annotations from the manual:

- Kind of anticoagulant among EDTA and Citrate.
- Wash executed correctly (1)
Wash not executed correctly (0).
- Transmittance value of the optical fork.
(MUST NOT BE MODIFIED)
- ADC value detected from the optical fork.
(MUST NOT BE MODIFIED)
- Transmittance value of the photometer
(MUST NOT BE MODIFIED)
- ADC value detected from the photometer.
(MUST NOT BE MODIFIED)
- Extra corrector to set the ESR point of the photometer.
(MUST NOT BE MODIFIED)

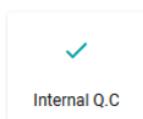
The screenshot shows a configuration interface with the following parameters:

Parameter	Type	Value
Ves extra corrector	Read	1
Ves extra offset	Write	0
Lactic offset	Read	0.7637
Blood threshold	Write	1000
Latex 2 threshold	Read	1300
Latex 3 threshold	Write	1000
Latex 4 threshold	Read	800
Offset vol	Write	2000

Annotation from the manual:

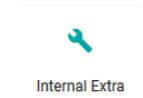
- All these parameters **MUST NOT BE MODIFIED**

10.2.6 CPS Latex Quality Control (valid for Internal and External CPS)



The **CPS Latex Quality Control** menu it is available for both Internal and External CPS. The description it is the same independently the model of TEST1 2.0 (Desk or TLA model). Being this a process normally done by end user, please refer to "User Manual" chapter "Latex Quality Control".

10.2.7 CPS "Extra" setup (valid for Internal and External CPS)



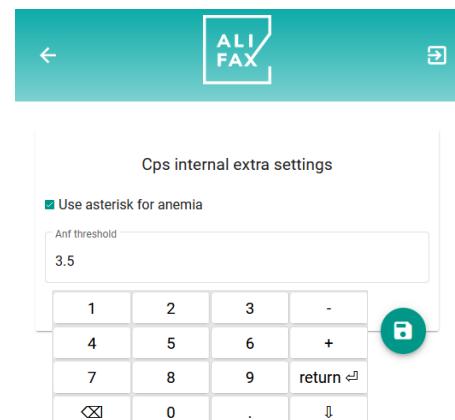
The **CPS "Extra" setup** menu it is available for both Internal and External CPS. For easiness of explanation this chapter will explain the Internal CPS configuration, but it is important to clarify the exact same description applies for the External CPS.

The description it is the same independently the model of TEST1 2.0 (Desk or TLA model).

Pressing the icon "Internal Extra" the display visualizes the following configuration window. This specific parameter that should not be modified it is used to configure the "anaemia threshold", this is, in case of blood samples with Hct indicatively lower than 30 the instrument will issue an * near the ESR result.

It is important to observe TEST1 2.0 does not measure the anaemia; in the ESR measurement process TEST1 2.0 analyses the aggregation curve and based on the behaviour of the curve TEST1 2.0 can assume a sample might be anemic and this is the reason the *it is issued only with aim to warn about of an eventual possible low haematocrit and eventual potential anaemia.

To modify the threshold value, click over the specific field of the variable under adjustment; a "numeric keyboard" it is displayed where the FSE can type the corresponding value. Once done press "Return" and then press the "save" pushbutton to confirm the new value

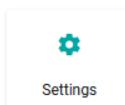




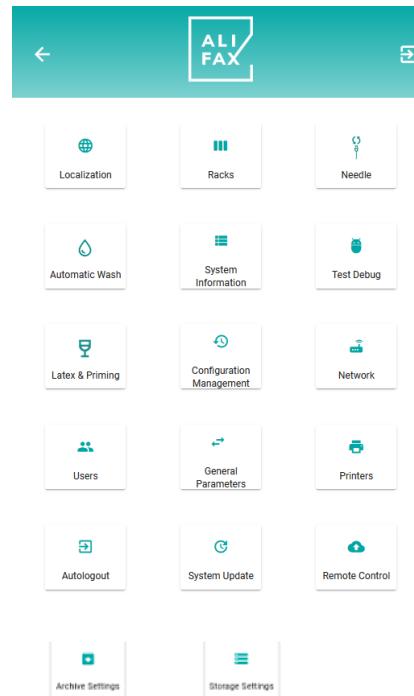
SERVICE MANUAL

TEST1 2.0

10.3 SETTINGS

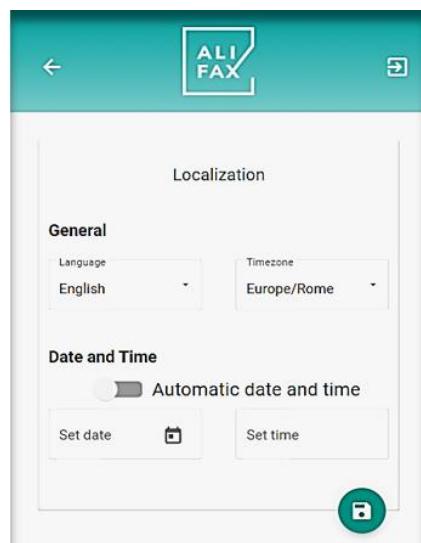


When the **SETTINGS** button it is pressed, instrument allows the FSE to get access to specific configuration functions here below displayed.



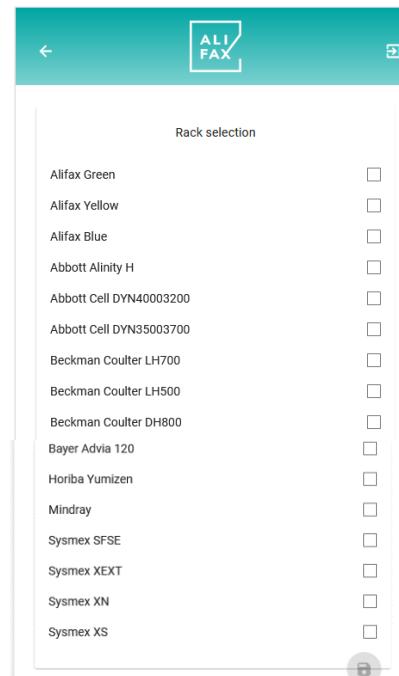
10.3.1 Localization

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



10.3.2 Racks selection

Rack selection allow to configure rack in use in the Laboratory



Important:
It can be selected only one model
of rack to be used.

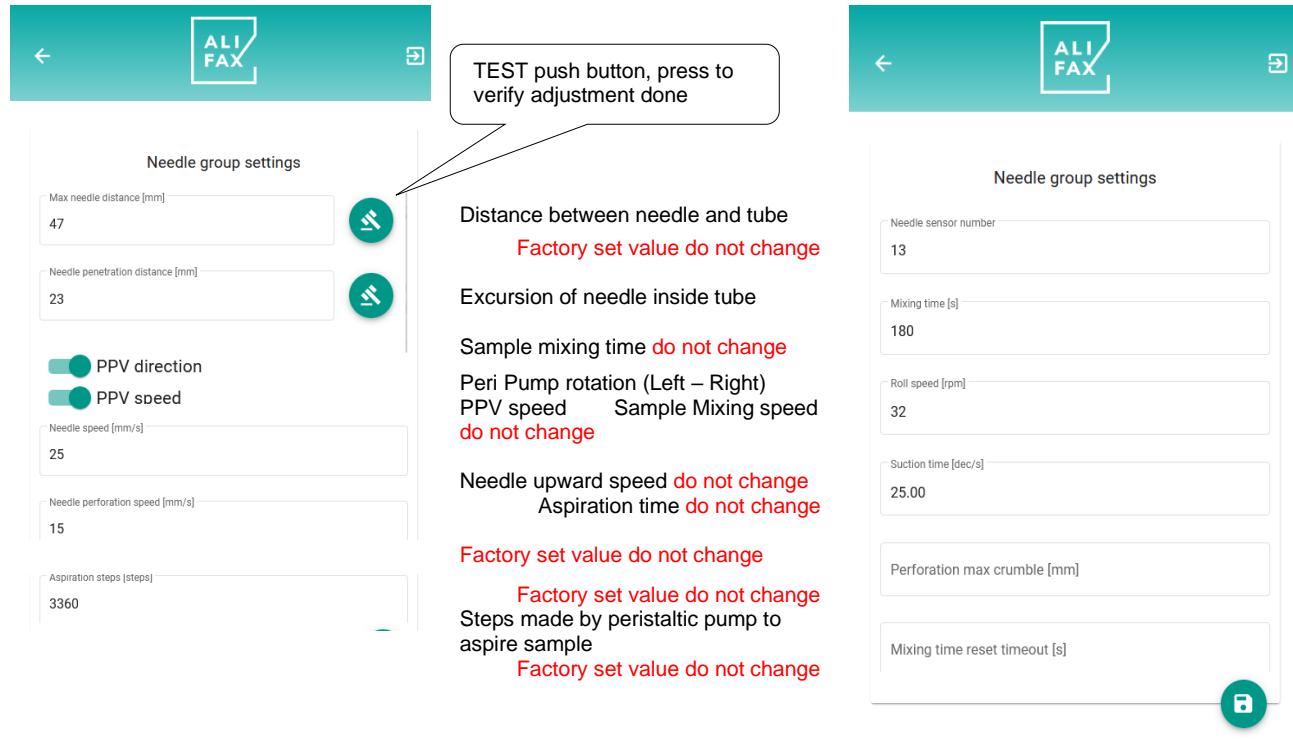


SERVICE MANUAL

TEST1 2.0

10.3.3 Needle

Pressing Needle icon instrument allows the FSE to get access to all the variables that controls the needle movements

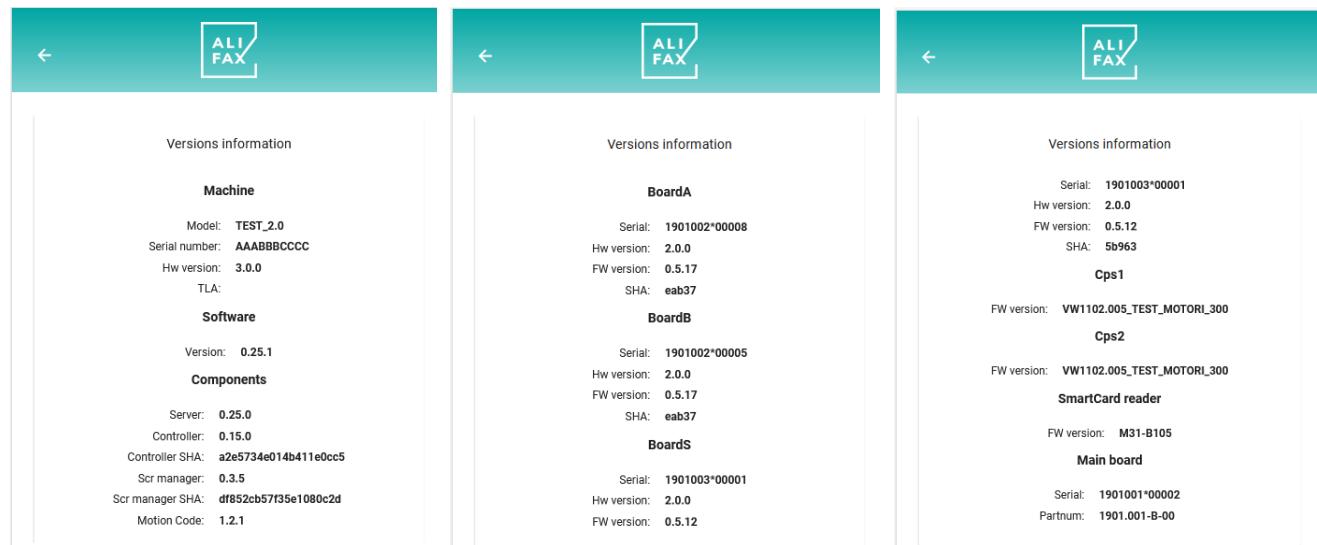


To modify a value, click over the specific field of the variable under adjustment; a “numeric keyboard” it is displayed where the FSE can type the corresponding value. Once done press “Return” and then press the “save” pushbutton to confirm the new value

1	2	3	-
4	5	6	+
7	8	9	return
	0	.	

10.3.4 System Info

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



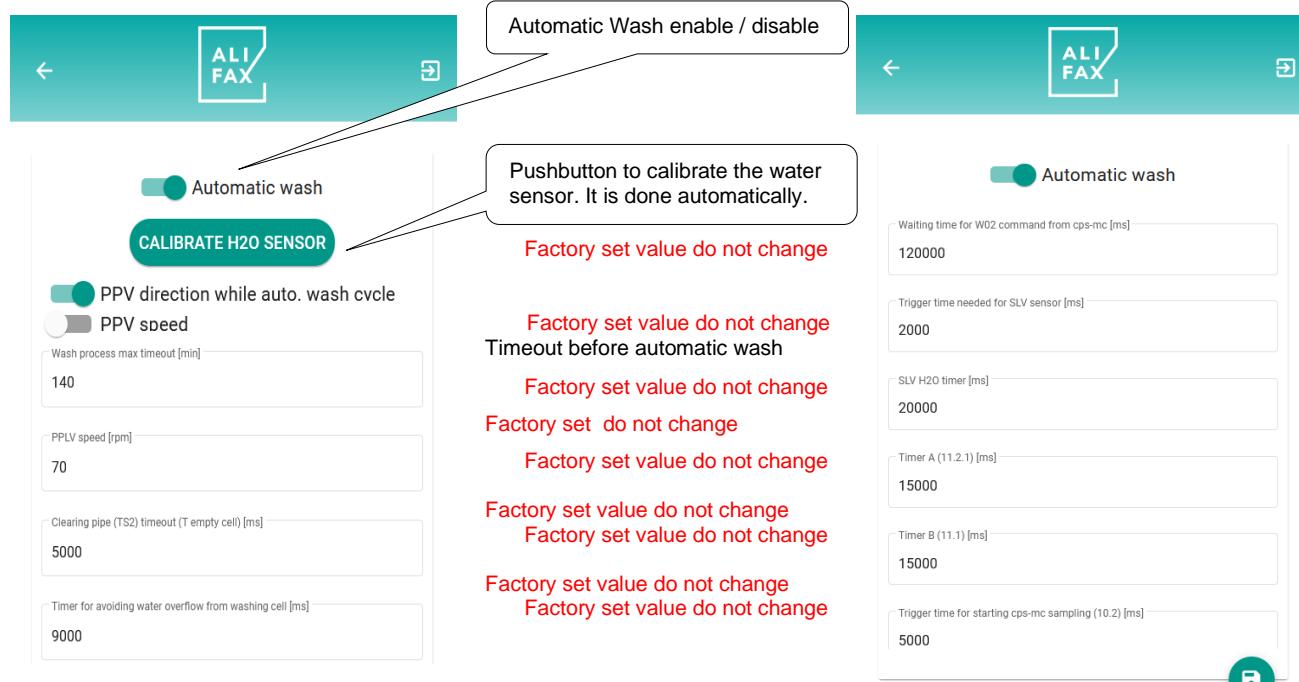


SERVICE MANUAL

TEST1 2.0

10.3.5 Automatic Wash

Pressing Automatic Wash icon instrument allows the FSE to get access to all the variables that controls the washing sequences. Inside the menu there are two icons: "Automatic Wash" and "Automatic Was Timeout". Here below we start explanation from icon "Automatic Wash".



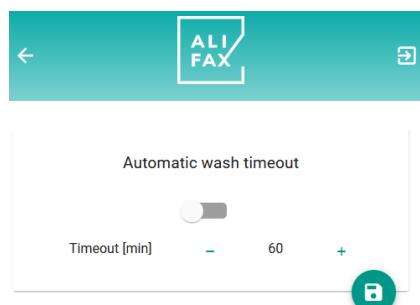
10.3.5.1 Calibrate H2O sensor.

This function it is used to recalibrate the optical fork sensor located before wash station (blue led on when water detected)

To modify a value, click over the specific field of the variable under adjustment; a "numeric keyboard" it is displayed where the FSE can type the corresponding value. Once done press "Return" and then press the "save" pushbutton to confirm the new value

1	2	3	-
4	5	6	+
7	8	9	return
	0	.	

10.3.6 Automatic Washing Timeout



The second option available inside the "Automatic Wash" menu it is the possibility to configure the timeout after which the instrument automatically washes itself (Internal probe only).

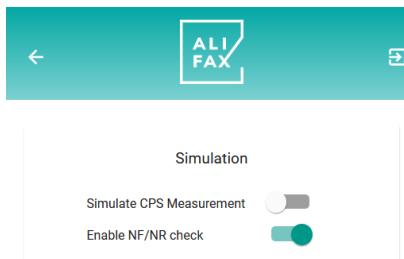
There are two options:

- Enable / Disable the timeout
- Configure the time (min) after which instrument washes itself.

To change the time just click over "-" or "+";

Once done press "Return" and then press the "save" pushbutton to confirm the new value

10.3.7 Test - Debug



In debug Mode, the FSE have basically two options:

- Simulate CPS Management (**must be and remain disabled**): this function it is used to generate ESR result (for factory purposes).
- Enable / Disable (**must be always enabled**) the printout of NR (Not Reliable) and NF (No Flow) messages

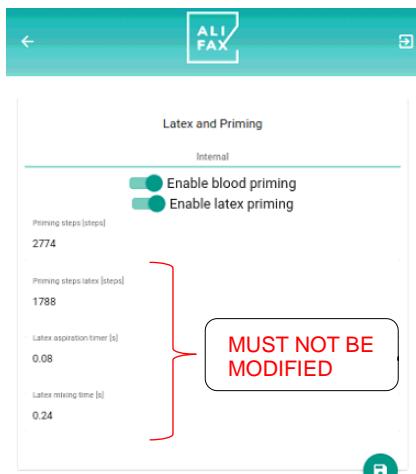
See "Appendix" D and E for more information.



SERVICE MANUAL

TEST1 2.0

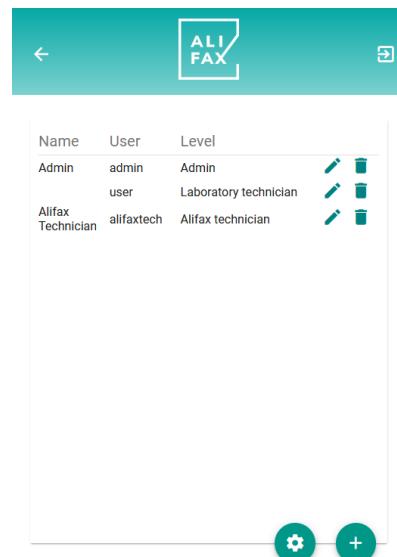
10.3.8 Latex & Priming



The priming function means that after a washing procedure (independently it is internal or external), 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.

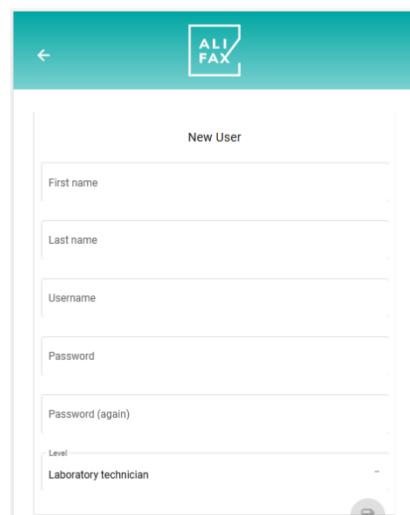
10.3.9 Users



User function allow to configure username and password for each operator, also allows to grant permissions and accessibility level.

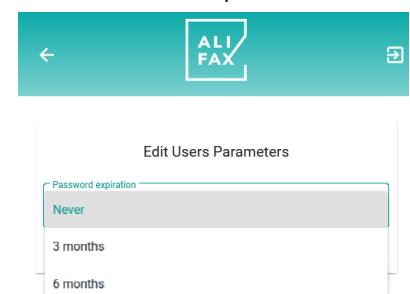
- Allows to remove an operator from the list.
- Allows to modify the right of an operators

Only Laboratory Manager or Technical Service can add or remove users from The individual user can modify its own password or erase itself



Pressing it is possible to configure a new user and its access levels

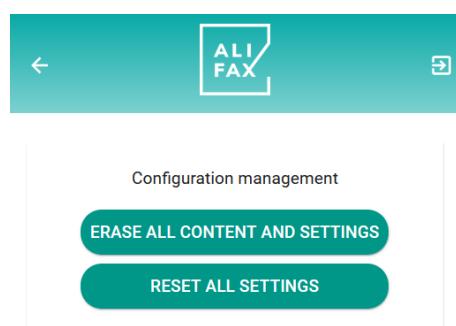
Pressing it is possible to configure the "lifetime" of the passwords.



There are 3 possibility:

- Never expire
- 3 Months validity
- 6 Months validity

10.3.10 Configuration Management



ATTENTION:

These functions are extremely dangerous indeed in case the FSE presses the "Erase All Content and Settings" and /or "Reset All Settings" the instrument will be reset to factory initial configuration.

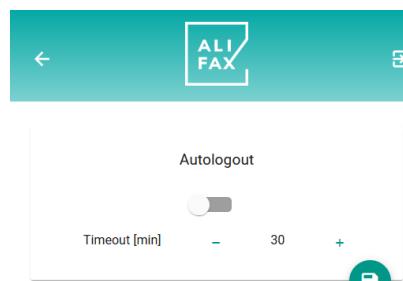
It is highly recommended to never press these two options.



SERVICE MANUAL

TEST1 2.0

10.3.11 Auto-logout

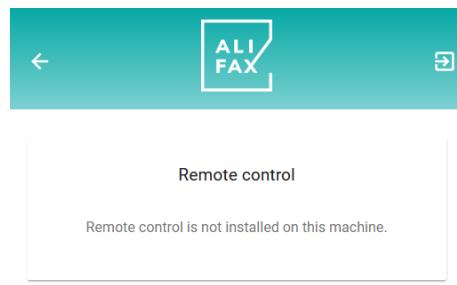


This function (if enabled) allows the instrument to automatically log out the operator currently logged in.

As visible on the screenshot, the timeout it is configurable in term of minutes.

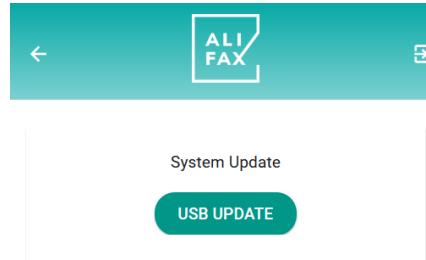
Once defined the timeout, just enable the function shifting the sliding button to the right and then save it pressing the button.

10.3.13 Remote Control



This function (if installed in the instrument software) will allow the remote control of instrument by Alifax Service Engineers from Alifax Headquarters.

10.3.14 System Update



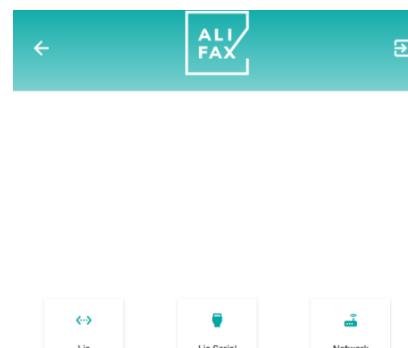
This function allows the local FSE to update the firmware of the instrument.

The update it is done by means of an USB pen drive that must be inserted in the front USB port.



Once selected the file proceed with the update.

10.3.12 Network



This function includes the 4 alternatives available to interconnect the instrument to the network to be interconnected to a LIS. User function allow to configure username and password for each.

Pressing "Network" it is possible to configure the network parameters.

Network Settings

Interface: Eth0
MacAddress: 00:21:f3:07:4c:da
IP address: 192.168.2.194
Gateway address: 192.168.2.253
Net mask: 255.255.255.0

"Send directly Auto-Generated ID" allows to send to LIS ID autogenerated in case IBCR it is not able to read barcode.

"Send also results of external withdrawal". If **active** sends embedded in the results string, the reference as Rack "0" to discriminate the sample was processed manually. By default, it is active.

Pressing "LIS" it is possible to configure the parameters to connect instrument thought ASTM protocol LAN Network

LIS ASTM

Enable ASTM protocol
Server IP: 10.202.1.105

 Enable query
 Enable missing ID
 Send directly Auto-generated IDs results to LIS

Pressing "LIS Serial" it is possible to configure the parameters to connect instrument thought LIS via RS232 Serial port.

LIS SERIAL

Enable serial protocol
 Enable ACK
Timeout UART ms: 2000

 Enable Bayer
 Enable BCI (otherwise DAT 15 is enabled)
 Enable asterisk (*)
 Enable missing ID
Unique number for multiple instrument connections: 1

 Send directly Auto-generated IDs results to LIS
 Send also results of external withdrawal

- "Enable ACK" allows instrument to increase the waiting time (default 2 sec) to a time configurable
- "Enable Bayer" allows instrument to be compatible with LIS using Bayer Protocol.
- "Enable BCI" allows the instrument to use "Query" mode to query every sample ID with LIS to verify if ESR it is required or not.
- "Use Asterisk" if enabled send an * near the ESR results to evidence an eventual anaemic state.
- "Use Missing ID" if enabled allows instrument to replace a non-read ID by IBCR with a TEST1 2.0 auto generated ID.
- "Unique Number" in this field it is necessary to type a number "univocal" used to identify TEST1 2.0 in case multiple instruments are present in the laboratory. By default it is set to 1.



SERVICE MANUAL

TEST1 2.0

10.3.15 General Parameters

Inside General Parameter menu, there are available two options: "Motion" and "Calibration".

Motion parameters

Gripper offset X [mm]: 16.48

Gripper offset Y [mm]: 7.75

X middle position for safe motions [mm]: 100

Y middle position for safe motions [mm]: 10

Z middle position for safe motions [mm]: 50

Release safety height [mm]: 3

For absolutely no reason these values must be changed

The same applies for the Calibration parameters.

Calibration parameters

Safety approach distance with ABCD ref. points of rack holder [mm]: 100

Calibration speed [mm/s]: 50

Theoretical chassis X ref position [mm]: 230

Theoretical chassis Y ref position [mm]: 26

Theoretical chassis Z ref position [mm]: 42

Calibration bar thickness [mm]: 1

All above parameters are automatically updated by the instrument every time a mechanical calibration it is carried on using the appropriate procedures explained in chapter 10.4

10.3.16 Printers



Printing Settings

Pressing "Printing Settings" is possible to configure the parameters of the variable that can be eventually printed out.

Printing Settings

Startup Test	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Errors RT	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Errors	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Device Status	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Wash Results RT	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Wash Results	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Latex Controls RT	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Latex Control tubes	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Latex Calibrators RT	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Latex Calibrators	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
ESR Result RT	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
ESR Result	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Credits RT	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
Credits	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
LIS Messages RT	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended
LIS Messages	<input type="radio"/> Disabled	<input checked="" type="radio"/> Standard	<input type="radio"/> Extended

This function includes the 3 alternatives available to interconnect the instrument to a printer.

Press "External printer" instrument allows to enable the use of an external printer.

External Printers

Printer Settings

Printer enabled

Printer available

Test Printer

Once defined the configuration, save it pressing the button.

it is possible to use only a LAN printer. **Noticer that in this case it is necessary to install the Linux drivers of the printer.**

Press "Thermal printer" instrument allows to enable the use of an USB thermal printer.

Thermal Printer

Printer Settings

Printer enabled

Printer available

Test Printer



SERVICE MANUAL

TEST1 2.0

10.3.17 Archive Settings

Archive Settings

Max number of items sendable to the LIS
50

Max number of items printable
50

This function allows to define the maximum number records to be sent to LIS or to printer.

10.3.18 Storage Settings

Storage Settings

Low storage memory warning (Mb)
300

Low storage memory error (Mb)
150

Days of database kept for (days)
365

Days of technical logs kept
180

Maximum size of the various files making up the log archive in (Mb)
10

This function allows to configure the storage of data in terms of Mb and days



SERVICE MANUAL

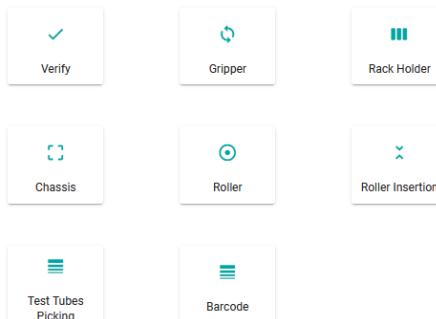
TEST1 2.0

10.4 MACHINE CALIBRATION



When the **MACHINE CALIBRATION** button is pressed, instrument allows the FSE to get access to functions specifically designed to help the FSE check all mechanical calibrations of the robotic arm over the different areas of the instrument.

Some of the functions are “blind functions” this means they are done in automatic by the arm without the necessity of the intervention of the FSE.



10.4.1 Verify

Verify performs a general check-up of the mechanical coordinates already stored in the memory of the instrument



Verify machine calibration

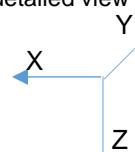
Remove all the racks and close the door, then start the calibration check.



The specific sequence foresees the arm (and more in detail the gripper) goes in the “4 corners” of the rack holder drawer and physically “touches the X, Y, Z coordinate of each one of the 4 corners.

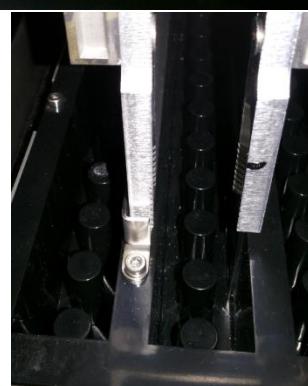
The detection is done “electrically”. Once the edge of the gripper touches the metallic frame an electric circuit is momentarily activated confirming the position it is correct.

The red numbers indicates the sequence of the corners; here below a detailed view of the gripper near the corner:



In case of verification errors, instrument issues below message

Rack holder calibration check failed

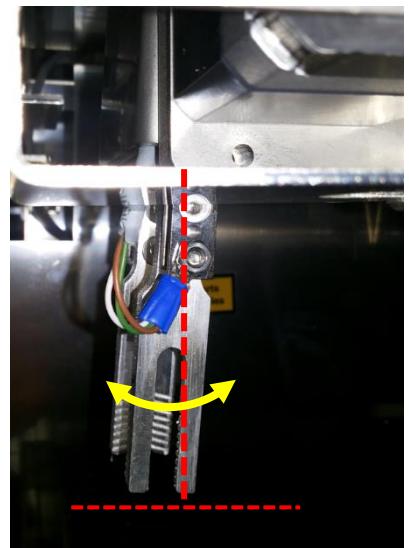
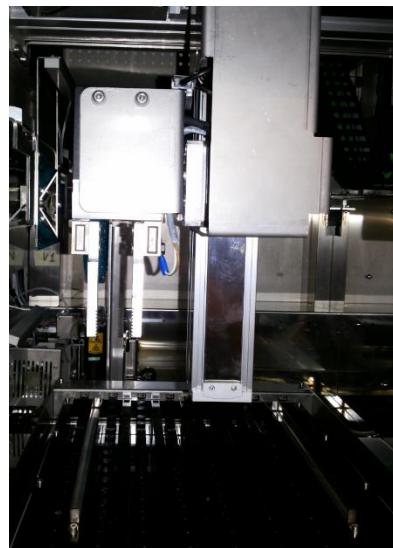


10.4.2 Gripper

Gripper performs a general check-up of the mechanical and alignment of the Gripper.



The specific sequence foresees the arm (and more in detail the griper) once pressed the button; moves in front of the working zone where the FSE can verify the 90° rotation of the Gripper unit.



- Pressing “-“ will leave the Gripper more rotated toward the left side
- Pressing “+“ will leave the Gripper more rotated toward the right side

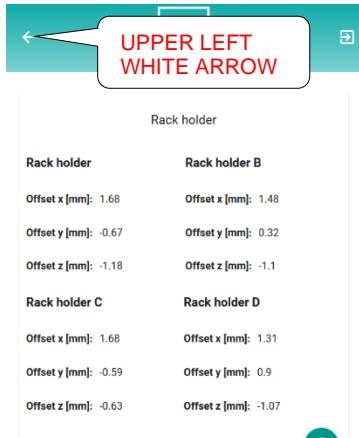
(above photo shows the gripper seen from then right lateral side)

The Gripper Rotation Offset it is nothing else that the adjustment eventually necessary to be done in case during the verification it is evident the gripper does not stop perpendicularly

Once done the adjustment, press the button to verify if the adjustment done let the Gripper stop perpendicularly. In case not, keep adjusting by means of “-“ or “+“ and repeat the check till a correct positioning it is achieved. Once got the correct adjustment, press the button to save the new coordinates.

10.4.3 Rack Holder

Rack holder it is similar to Verify performs a general check-up of the mechanical coordinates already store in the memory of the instrument.



Initially there are displayed “current coordinates”.

Then, once pressed the start button

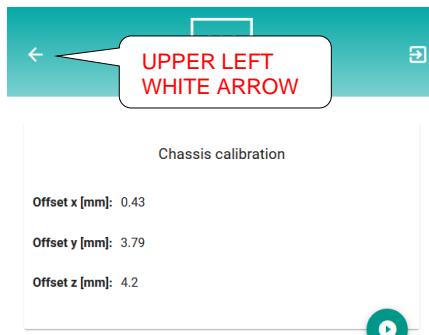


Robotic arm moves to 6 specific positions where the gripper torches the metallic references guides (every specific rack holder has its own dedicated guides embedded); the detection it is done “electrically. Once the edge of the gripper touches the metallic frame an electric circuit is momentarily activated conforming the position it is correct. The red numbers indicate the sequence of the corners; here below a detailed view of the gripper near the corner:

In case there it is a discordance between the expected positons and the detected, the system automatically readjust the coordinates “offsets” in order the gripper it is aligned with the expected references. At the end the new “offset” are visualized. To finish just press the upper left corner white arrow to return to previous menu.

10.4.4 Chassis

Chassis it is similar to Rack holder indeed performs a general check-up of the mechanical coordinates of the arm near the mirror frame where the gripper places the tube to read the barcode label.



The specific sequence foresees the arm (and more in detail the griper) once pressed the button; moves in front left side of the instrument where it is located the mirror.

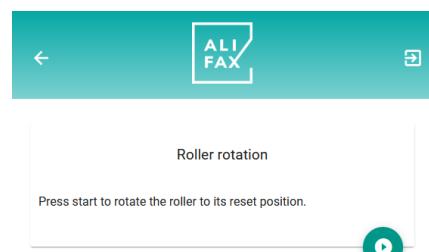


Robotic arm moves to specific positions where the gripper torches the metallic references guides the detection it is done "electrically. Once the edge of the gripper touches the metallic frame an electric circuit is momentarily activated conforming the position it is correct.

In case there is a discordance between the expected positions and the detected, the system automatically readjust the coordinates "offsets" in order the gripper it is aligned with the expected references. At the end the new "offset" are visualized. To finish just press the upper left corner white arrow to return to previous menu.

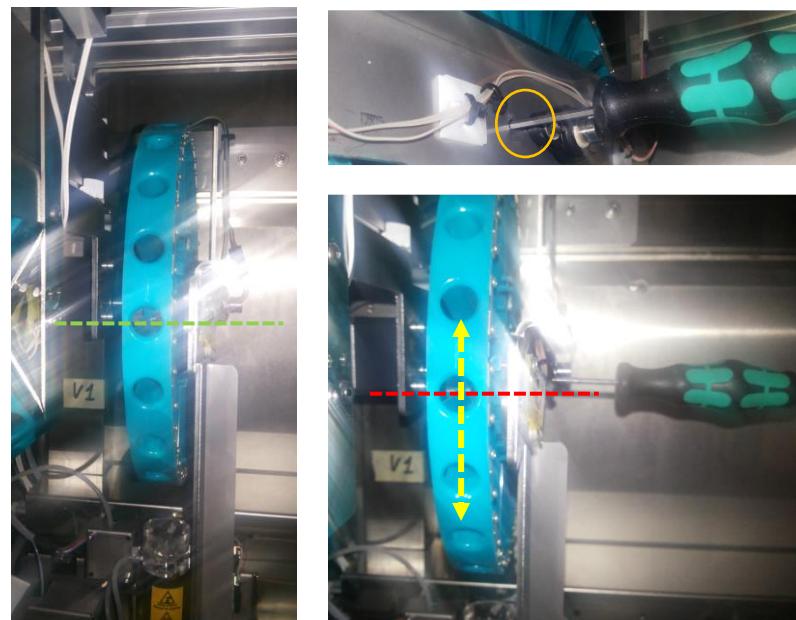
10.4.5 Roller

Roller performs a general check-up of the mechanical and horizontal alignment of the Rotor.



The specific sequence foresees the Rotor, once pressed the button; moves in home position which it is mechanically detected by a hall effect sensor. Home sensor does not mean the rotor stops perpendicularly in the position where tubes will be inserted by the Gripper.

The aim of this adjustment it is precisely to assure the position in where it stops it is correct.



Above photo (from left to right) indicates theoretical position (green line); second photo it is a detailed view of the zone where the reference (in this case a tiny screwdriver goes inserted) and last photo basically "indicates" that when the screwdriver it is "practically" horizontal, means the rotors stops in the correct position.

- Pressing “-“ will stop the Roller downward (use in case rotor stops higher than threshold)
- Pressing “+“ will stop the Roller upward (use in case rotor stops lower than threshold)

Once done the adjustment, press the button to verify if the adjustment done let the Roller stop perpendicularly;(before remove screwdriver)

In case not, keep adjusting by means of “-“ or “+“ and repeat the check till a correct positioning it is achieved.

Once got the correct adjustment, press the button save the new coordinates

10.4.6 Roller Insertion

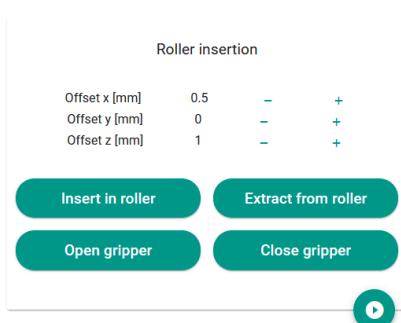
Roller Insertion performs a simulated insertion of a tube inside the Roller.
The aim of this it is to verify if the Gripper it is aligned with the Roller.



The specific sequence foresees the Gripper, once pressed the button; moves to the rack holder and takes an **empty** tube from the rack and moves near the Roller.

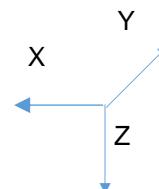
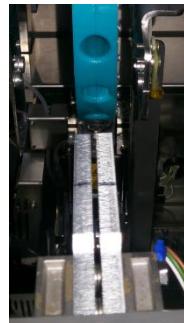
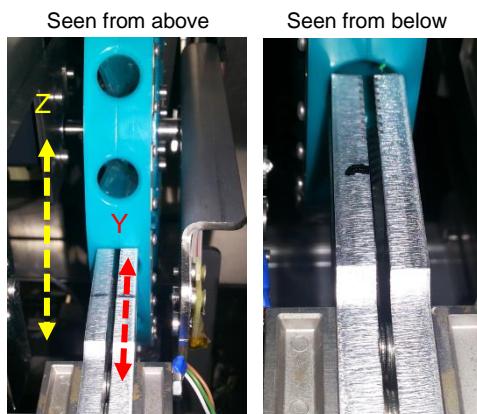


Once done, on instrument display appears a dedicate window with 4 pushbuttons which will be used to verify and eventually adjust the alignment.



The specific sequence of operations it is described here below

- 1 Press Open gripper (test tube it is released, take by hand)
- 2 Press Close gripper
- 3 Press Insert in roller (will move Gripper near the Roller simulating tube insertion) without test tube (**visually** check the alignment) take note of the eventual adjustment required.(in/out, up-down)



- 4 Press Extract from roller
- 5 Based on step 3, make the appropriate changes by means of the X, Y, Z, offset adjustments using the “-” and “+” options.

Attention:

- Y movement is used to adjust the **depth** of the test tube into the Roller. Pressing “-“ will move back the Gripper from Roller ; “+“ move the Gripper close to Roller;
- Z movement it is used to adjust the **insertion height** (vertical alignment of the Gripper to be aligned with the Roller slot) Pressing “-“ will move the Gripper upward; “+“ move the Gripper downward to Roller
- X movement it is used to adjust the **insertion height** (horizontal alignment of the Gripper to be aligned with the Roller slot) Pressing “-“ will move the Gripper Leftward; “+“ move the Gripper Rightward to Roller.

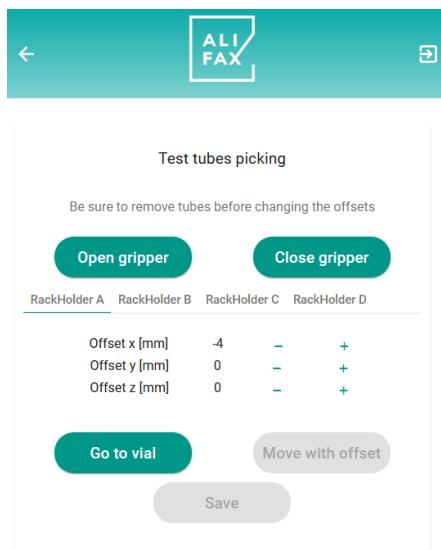
When you consider the adjustment are ok, press the button; system will acquire the new offsets.

- 6 To check if changes are OK, press **INSERT** in ROLLER, if OK press the **SAVE** button (bottom right next to the GO button (the one that looks like a floppy))
- 7 If the changes do not go well repeat from step 5 until OK.
- 8 Once got the correct adjustment, press the button to save the new coordinates
- 9 To test with a test tube, start from the beginning of this specific chapter.

10.4.7 Test Tube Picking

Test Tube Picking performs the calibration of the picking coordinates on the edge of the racks.

The aim of this it is to verify if the Gripper is vertically aligned with the racks and picks up correctly the test tubes.



The sequence must be repeated for each one of the "4 corners" of the rack holder cassette.

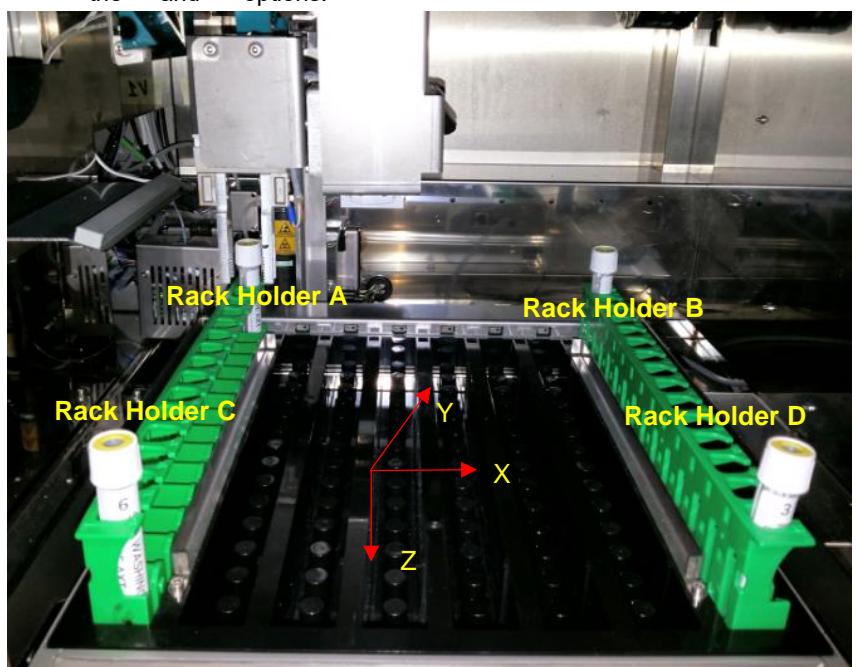
The "4 corners" are identified as:

- Rack Holder A
- Rack Holder B
- Rack Holder C
- Rack Holder D

foresees the Gripper, once pressed the button; moves to the rack holder and takes an **empty** tube from the rack and moves near the Roller.

The specific sequence of operations it is described here below

- 1 Press Rack Holder A
- 2 Press Open Gripper
- 3 Press Go To Vial (gripper will move in the corresponding position.)
- 4 Now it is necessary to adjust the three coordinates; make the appropriate changes by means of the X, Y, Z, offset adjustments using the “-“ and “+“ options.



- X movement it is used to adjust the horizontal alignment of the Gripper to be aligned with the test tube. Pressing “-“ will move the Gripper Leftward; “+“ move the Gripper Rightward.
- Y movement is used to adjust the back – front alignment of the Gripper to be aligned with the test tube. Pressing “-“ will move backward the Gripper ; “+“ move the Gripper frontward;
- Z movement it is used to adjust the vertical alignment of the Gripper over the test tube. Pressing “-“ will move the Gripper upward; “+“ move the Gripper downward to the test tube.
For the Z alignment be sure the back mark matches the cap of the tube



- 5 To verify the correctness of each single adjustment press Move With Offset; if it is OK press Save

Repeat steps 1 to 5 also for position Rack Holder B, C and D



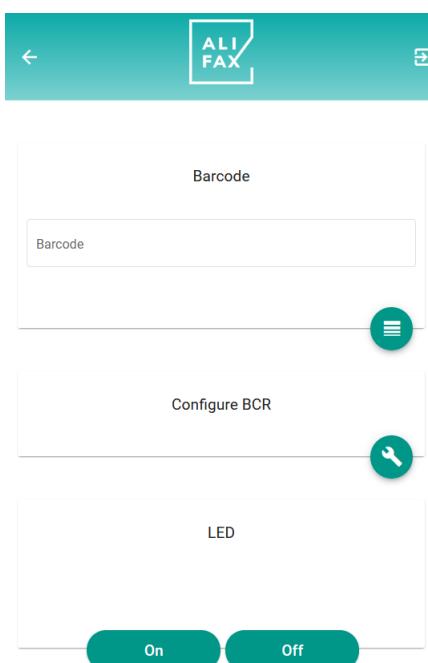
SERVICE MANUAL

TEST1 2.0

10.4.8 Barcode

Barcode it is used to perform the verification of the alignment and reading of the test tube barcode labels.

Changes on configuration are not required, please avoid to apply any change.

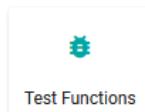




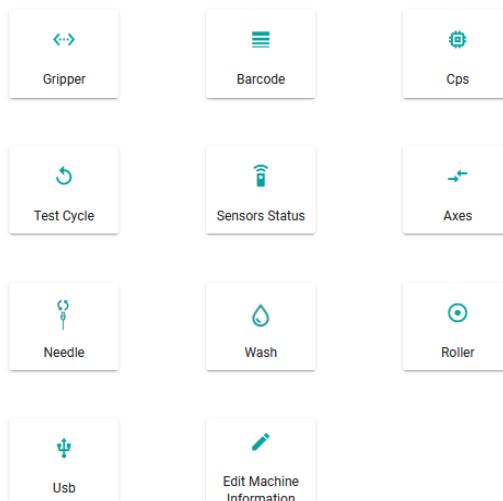
SERVICE MANUAL

TEST1 2.0

10.5 TEST FUNCTIONS



When the **TEST FUNCTIONS** button is pressed, instrument allows the FSE to get access to functions specifically designed to help the FSE verify each instrument component working and status of the sensors directly linked to the component.



10.5.1 Gripper

Verify performs a general check-up of the mechanical coordinates already stored in the memory of the instrument

Pressing Open – Close it is possible to verify the effective opening and closing of the gripper.

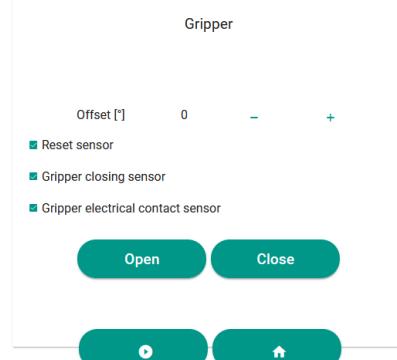
It is possible to verify the functioning of the open – close sensor:

- Gripper Open sensor check present
- Gripper fully closed sensor check not present

It is possible to make adjustments to the offset (rotation of the gripper unit) by means of "+" and "-", and pressing the it is possible to see the new position.

Notice that the adjustments made to the offset are used only to verify the movements, the offset is not saved.

Pressing returns the Gripper to its mechanical home position





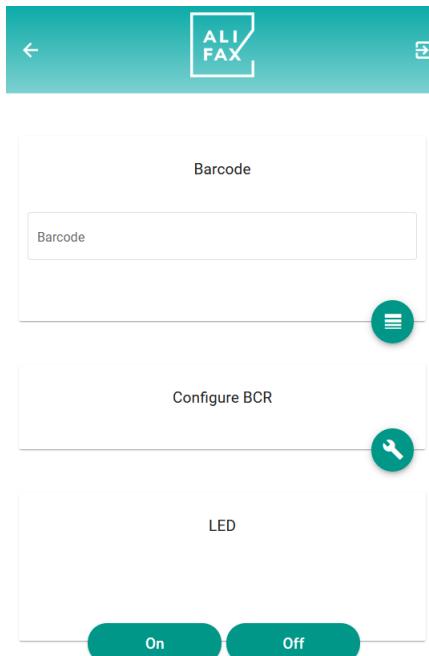
SERVICE MANUAL

TEST1 2.0

10.5.2 Barcode

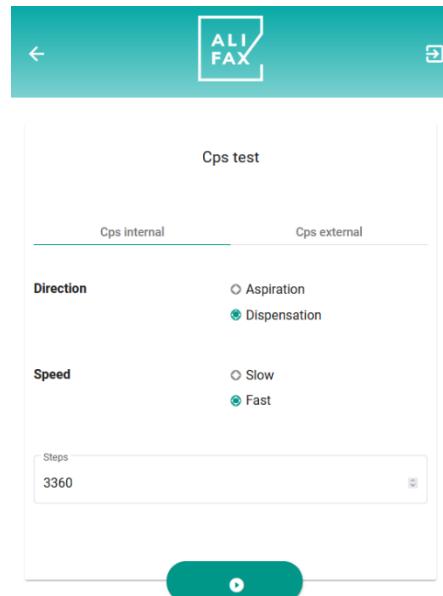
Barcode it is used to perform the verification of the alignment and reading of the test tube barcode labels.

Not yet fully implemented



10.5.3 CPS

CPS it is used to verify the movement of the peristaltic pump of the CPS. Please notice the menu contains both Internal and External CPS.



It is possible to verify the functioning of the peristaltic pump in both directions:

- Aspiration (sample taken from tube)
- Dispensation (sample inoculated in tube) conceptually Dispensation it is not used in the instrument in routine.

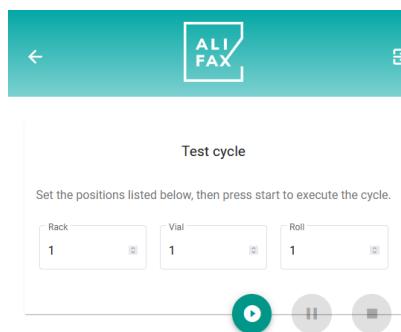
Speed can be check the rotation of the peristaltic pump in

- Slow
- Fast

Steps: it is the number of steps the pump makes during the test rotation independently the rotation direction

10.5.4 TEST CYCLE

TEST CYCLE it is used to simulate a whole movement of the robotic arm.



It is possible to select

- From which rack (1 to 8)
- From which position inside the rack (1 to 15) depending the model of rack

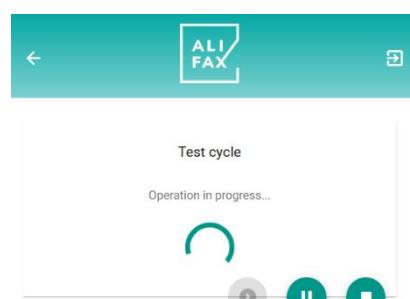
The test tube will be taken and also it is possible to select

- In which slot of the Roller the tube will be physically inserted.

To start the test cycle (once selected the above three variables) press

To pause the test cycle press

To stop the test cycle press





SERVICE MANUAL

TEST1 2.0

10.5.5 SENSOR STATUS

Sensor Status reassumes in a graphical format the status of the sensors presents inside the instrument.

In Wash visualization there it is also the possibility to calibrate the waster sensor installed near the internal needle.

This sensor it is used to detect the flow of water.

In Mobile elements visualization there it is also the possibility to verify the functioning of the front door latch pressing "Lock" "Unlock".

The screenshots show the Sensor Status interface with three tabs: Rack, Wash, and Mobile elements. In the Rack tab, there are checkboxes for Rack sensor 1 through 8. In the Wash tab, there are checkboxes for Washing tank present, Waste tank present, Tank level, and Wash sensor, along with a 'Calibrate sensor' button. In the Mobile elements tab, there are checkboxes for Drawer sensor and Door sensor, with 'Unlock' and 'Lock' buttons below.

10.5.6 AXIS

Axis has a similar function like "Gripper" it is used to verify the movement and reset of the three axis.

The process it is the same for the three cases performs a general check-up of the mechanical coordinates already store in the memory of the instrument

Axis X

The screenshot shows the Axis X interface with an 'Axes' tab. It has tabs for Axis x, Axis y, and Axis z. Under Axis x, there is an 'Offset x [mm]' slider set to 0, with '+' and '-' buttons. A 'Reset sensor' checkbox is checked. Below the slider are two buttons: a blue circle with a dot and a teal square with a house icon.

Axis Y

The screenshot shows the Axis Y interface with an 'Axes' tab. It has tabs for Axis x, Axis y, and Axis z. Under Axis y, there is an 'Offset y [mm]' slider set to 0, with '+' and '-' buttons. A 'Reset sensor' checkbox is checked. Below the slider are two buttons: a blue circle with a dot and a teal square with a house icon.

It is possible to make adjustments to the offset by means of "+" and "-", and pressing the it is possible to see the new position.

Notice that the adjustments made to the offset are used only to verify the movements, the offset it is not saved.

Pressing returns the axis to its mechanical home position

Axis Z

The screenshot shows the Axis Z interface with an 'Axes' tab. It has tabs for Axis x, Axis y, and Axis z. Under Axis z, there is an 'Offset z [mm]' slider set to 0, with '+' and '-' buttons. A 'Reset sensor' checkbox is checked. Below the slider are two buttons: a grey 'Unlock' button and a teal 'Lock' button.

In Axis Z it is also the possibility to verify the functioning of the locking module pressing "Lock" "Unlock".

10.5.7 NEEDLE

The screenshot shows the Needle interface with a 'Needle' tab. It has an 'Offset needle [mm]' slider set to 0, with '+' and '-' buttons. Below the slider are two buttons: a blue circle with a dot and a teal square with a house icon.

The same applies also for the Needle.

10.5.8 Wash

Wash it is used to verify the movement of the automatic wash pump (only internal). Please notice the menu contains both Internal and External CPS.

It is possible to verify the functioning of the peristaltic pump in both directions:

- Aspiration (sample taken from tube)
- Dispensation (sample inoculated in tube) conceptually Dispensation it is not used in the instrument in routine.

Speed can be check the rotation of the peristaltic pump in

- Slow
- Fast

Steps: it is the number of steps the pump makes during the test rotation independently the rotation direction

Wash pump

Direction	<input checked="" type="radio"/> Aspiration <input type="radio"/> Dispensation
Speed	100
Steps	100
<input checked="" type="checkbox"/> Wash pump reset sensor	

Pressing the it is possible to move the pump based on the speed and steps set.

Notice that the adjustments made are used only to verify the movements, the offset it is not saved.

Pressing returns the rotor pump home position.

10.5.9 Roller

Roller it is used to verify the movement of the Rotor as well as Gripper as well as Needle. pump of the CPS. Please notice the menu contains both Internal and External CPS.

Roll

Roll Gripper position Needle position

Use the buttons below to start, stop and reset the roll rotation.

Reset sensors

Photocell near roller
 Photocell near operator
 Roll reset
 Roll position

Roll:

Pressing rotor begins to move normally and every time it passes in front of home sensor it blinks as well as the also the other sensors.

Pressing rotor returns to home position.

Gripper:

Pressing the Roll will rotate and stops in front of the gripper.

Needle Position:

Pressing the Roll will rotate and stops just above the needle unit.

10.5.10 USB

This function it is just to verify the USB connectivity

Usb

Press the button to check usb peripherals.

10.5.11 Edit Machine Info

This function it is used mainly to configure:

- serial number,
- enable / disable Automatic Wash and External CPS
- enable / disable External CPS
- Configure reference for TLA Sysmexs track

Edit machine information

Model	TEST1_2.0
Serial number	AAABBBCCCC
Hw version	3.0.0
TLA	

Automatic wash External CPS



SERVICE MANUAL

TEST1 2.0

10.6 FIRST-UP INTERNAL

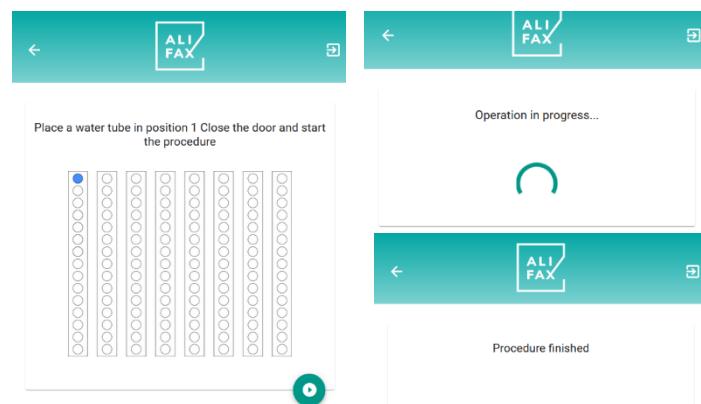


When the **FIRST-UP Internal** button is pressed, instrument will automatically perform a “calibration” of the CPS.

Please notice this specific calibration it is not linked with Latex Calibration.
The First-Up procedure it is used to “calibrate” the CPS to the water reference.

10.6.1 FIRST-UP INTERNAL DESK VERSION MODEL

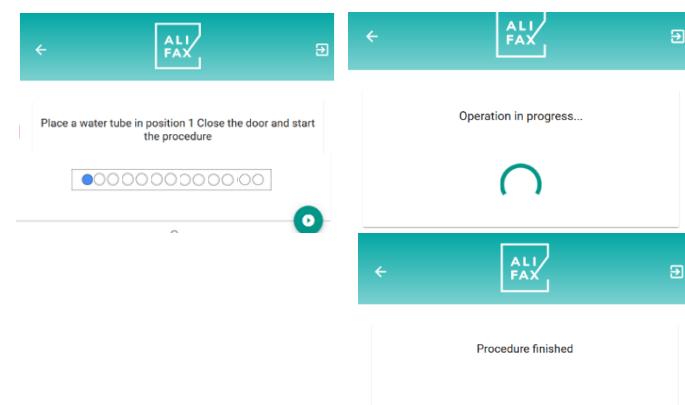
In case of TEST1 2.0 desk model, pressing First-Up Internal, the instrument will ask to place a test tube containing water in Rack 1 position 1 as here below evidenced.



Once press the procedure starts automatically and it is performed by the instrument; once finished instrument returns the test tube to the original position and informs First-Up it is completed.

10.6.2 FIRST-UP INTERNAL TLA VERSION MODEL

In case of TEST1 2.0 TLA model, pressing First-Up Internal, the instrument will ask to place a test tube containing water in Rack 1 position 1 as here below evidenced.



Once press the procedure starts automatically and it is performed by the instrument; once finished instrument returns the test tube to the original position and informs First-Up it is completed.

10.7 FIRST-UP EXTERNAL PROBE

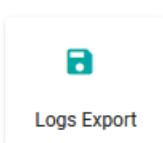
The First-Up procedure in the external probe independently it is a desk or TLA TEST1 2.0 it is the same. In this case the procedure foresees a test tube filled with water it is manually placed (and held) in the external probe. Once finished the instrument will require to remove the test tube.



SERVICE MANUAL

TEST1 2.0

10.8 LOGS EXPORT



When the **Logs Export** button is pressed, instrument will proceed to export the logs of the operation trails to an external USB memory.



The USB memory must be inserted in the front USB port.

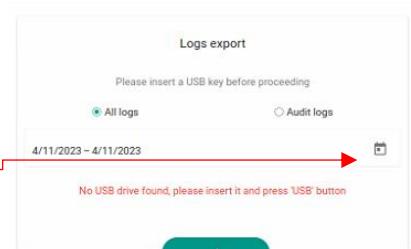
It is possible to choose between:

- All Logs
- Audit Logs (means the logs of the operators)

For both cases the operator can select the interval time for the export, just pressing over the calendar icon.

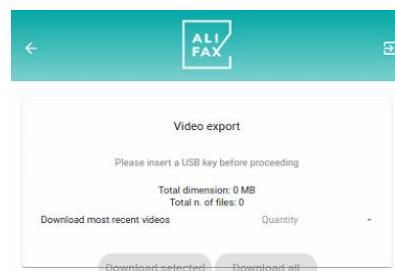


Once selected, (being sure the USB pen drive it is already plugged in in the instrument USB port, just press the “USB” symbol to download the log.



10.9 Export Video

Similar to Export Logs, Export video allows operator to download to an USB pen drive, internal videos of the robotic arm movements. This feature is only necessary in case of mechanical error or troubleshooting.



It is possible to choose between:

- A specific number of videos (from 1 to xxx)
- All videos

Notice: the videos are not stored per date, so video 1 is the one corresponding to the most recent session.

For example, selecting 10 videos, means the last 10 sessions will be exported to USB

10.10 TANK LEVEL (WASTE)

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.

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

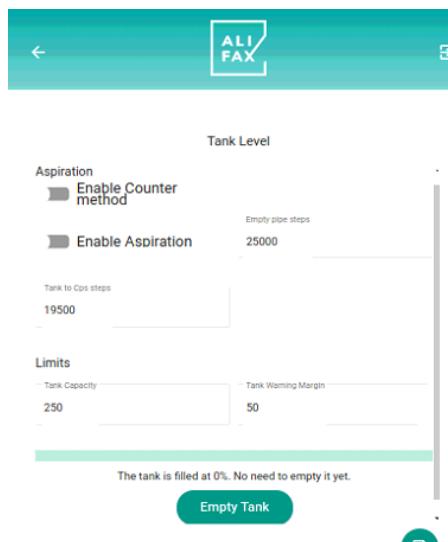
⚠ The tank is full. Please empty it. ✗

✗ Full waste tank error ✗



SERVICE MANUAL

TEST1 2.0



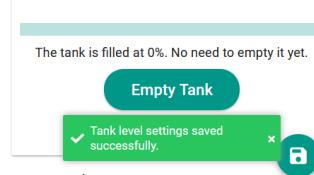
Once inside “Tank Level” it is possible to configure the aspirating steps the pump needs to do to verify the level of waste tank.
It is kindly suggested to not modify the aspiration nor the tank thresholds configures in factory.

10.10.1 TANK EMPTY PROCEDURE

In case it is needed to empty the waste tank, 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.



Once done press button to confirm tank it is empty.

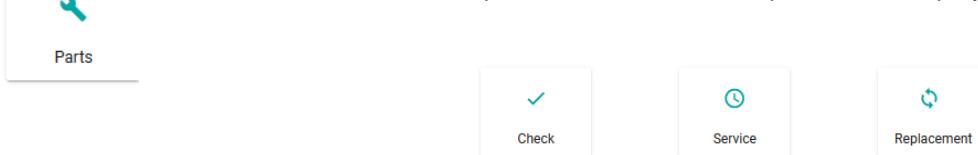
Waste tank must be disposed once it becomes full unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use.

Open left front door, pull out the loading carrier and remove waste tank cap; remove carefully the full waste tank, insert an empty waste tank, reinser 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



10.11 PARTS

When the **Parts** button is pressed, instrument will proceed to display three options:



Basically the Parts shows the status of every individual component of the instruments, indicate when it was last time it was:

- Checked
- Maintained
- Replaced

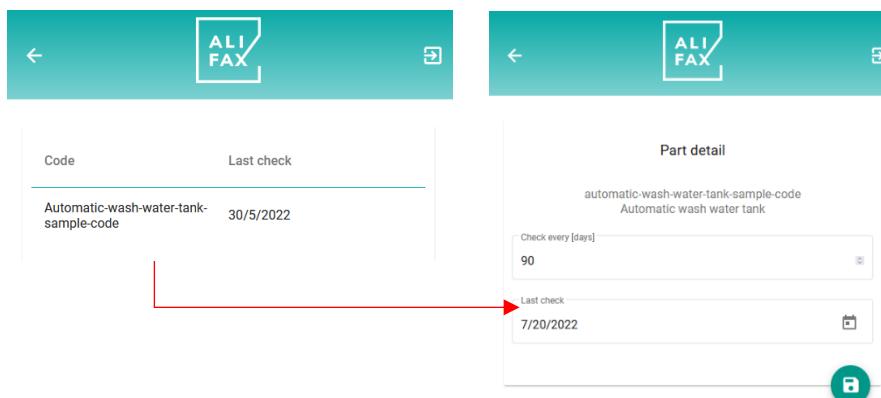


SERVICE MANUAL

TEST1 2.0

10.11.1 Check

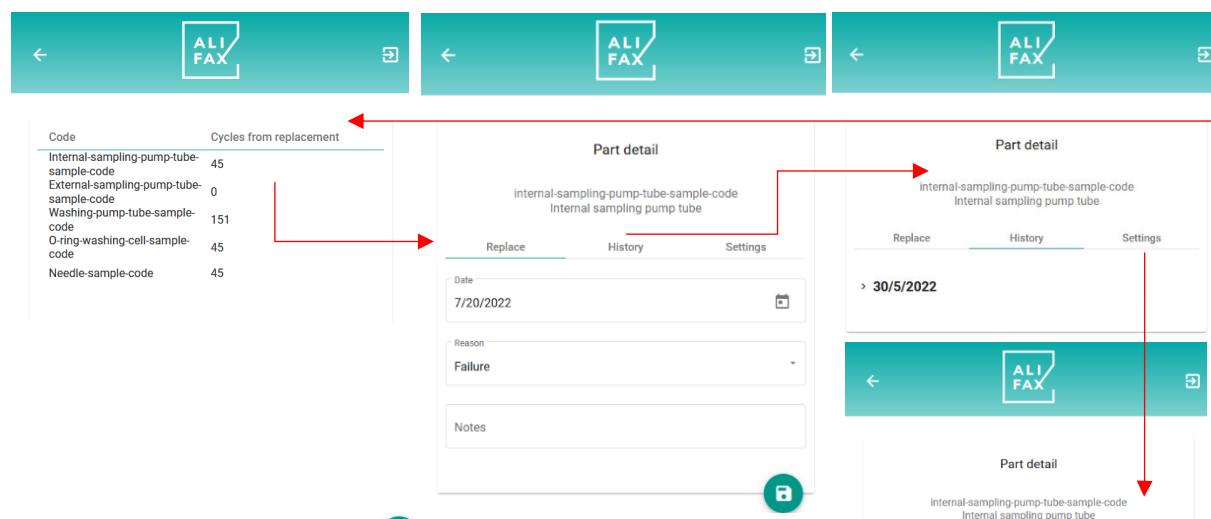
Pressing **Check** instrument display which are the parts already verified and when; clicking over the part name a detailed visualization containing more info bout the specific part it is displayed.



10.11.2 Service

Pressing **Service** instrument displays for each part how many cycles have been done since last replacement. Clicking over the part name a detailed visualization containing more info bout the specific part it is displayed; in detail:

- “Replace contains the date, reason (service or failure) and eventually notes linked to the replacement of the part.
- “History” it is a resume of the replaced parts, by date.
- “Settings” contains the pre-configured operative parameters. **It is kindly suggested to not modify the parameters / thresholds pre-configured in factory.**



Once done the updates, press button to memorize data

10.11.3 Replacement

Pressing **Replacement** instrument displays all the parts that have been eventually replaced; it is a similar concept of the above “Service” each part how many cycles have been done since last replacement. Clicking over the part name a detailed visualization containing more info bout the specific part it is displayed; in detail:

- “Replace contains the date, reason (service or failure) and eventually notes linked to the replacement of the part.
- “History” it is a resume of the replaced parts, by date.



SERVICE MANUAL

TEST1 2.0

The figure consists of three horizontal screenshots of a mobile application. Each screenshot has a teal header bar with a back arrow, the 'ALI FAX' logo, and a save icon.

- Screenshot 1:** A list of codes under the heading 'Code'. The items listed are:
 - Internal-sampling-pump-tube-sample-code
 - External-sampling-pump-tube-sample-code
 - Washing-pump-tube-sample-code
 - O-ring-washing-cell-sample-code
 - Needle-sample-code
 - Automatic-wash-water-tank-sample-code
- Screenshot 2:** A 'Part detail' screen for a 'washing-pump-tube-sample-code' (Washing pump tube). It shows a 'Replace' tab selected. The date is set to '7/20/2022' and the reason is 'Failure'. There is a note field and a save button at the bottom.
- Screenshot 3:** Another 'Part detail' screen for the same part, showing the date changed to '30/5/2022'. It also has a 'Replace' tab selected and a save button at the bottom.

A red arrow points from the 'Replace' tab in Screenshot 2 to the 'Replace' tab in Screenshot 3, indicating a change in the status or configuration of the part.

Once done the updates, press button to memorize data



SERVICE MANUAL

TEST1 2.0

11. 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.

11.1 "Service Engineer"

"Service Engineer" have access to all menus and functions.

The password of the Service Engineer MUST not be of public domain.

11.2 "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

11.3 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

12. TURN THE INSTRUMENT OFF

Before turning the instrument OFF it is essential carry-out a WASHING procedure

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.

If the shut down it is confirmed, just press ok, then switch off the instrument using the rear side main switch.

13. 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

SERVICE MANUAL

TEST1 2.0

14. ERROR 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.	1008

SERVICE MANUAL

TEST1 2.0

		Remove manually any test tubes that had remained in the roll. 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 technical 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.	1021



SERVICE MANUAL

TEST1 2.0

		Start a new measurement session. If the error persists contact Alifax technical support.	
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.	1104



SERVICE MANUAL

TEST1 2.0

		Start a new measurement session. If the error persists contact Alifax technical support.	
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



SERVICE MANUAL

TEST1 2.0

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 persists 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



SERVICE MANUAL

TEST1 2.0

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



SERVICE MANUAL

TEST1 2.0

		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



SERVICE MANUAL

TEST1 2.0

		<ul style="list-style-type: none">- 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



SERVICE MANUAL

TEST1 2.0

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



SERVICE MANUAL

TEST1 2.0

		<ul style="list-style-type: none">- Start a new measurement session.- If the error persists contact Alifax technical support. <p>B. If a warning is shown:</p> <ul style="list-style-type: none">- 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)	<p>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 funktion "Verify Machine Calibration"</p> <p>A. If no warning is shown:</p> <ul style="list-style-type: none">- Start a new measurement session.- If the error persists contact Alifax technical support. <p>B. If a warning is shown:</p> <ul style="list-style-type: none">- 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)	<p>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.</p>	1276
Rack out of holder, please verify	Rack out of rack holder error (Ex: missed rack holding system)	<p>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.</p>	1277
Failed roller insertion	Error during Test Tube insertion in the roller (Ex: collision detected during the movement)	<p>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 funktion "Verify Machine Calibration"</p> <p>A. If no warning is shown:- Start a new measurement session.- If the error persists contact Alifax technical support.</p> <p>B. If a warning is shown:- contact Alifax technical support.</p>	1278
test tube lost during extraction from rack	Test Tube lost during extracting from rack	<p>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 funktion "Verify Machine Calibration"</p> <p>A. If no warning is shown:</p> <ul style="list-style-type: none">- Start a new measurement session.- If the error persists contact Alifax technical support. <p>B. If a warning is shown:</p> <ul style="list-style-type: none">- contact Alifax technical support.	1279



SERVICE MANUAL

TEST1 2.0

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 funktion "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

SERVICE MANUAL

TEST1 2.0

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



SERVICE MANUAL

TEST1 2.0

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



SERVICE MANUAL

TEST1 2.0

15. SOFTWARE VERSIONS

Version 1.0.0

- First version released.

Version 1.0.1

- Fixed some minor bugs.

Version 1.0.2

- Fixed some minor Fw bugs.



SERVICE MANUAL

TEST1 2.0

16. 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'Abba
35020 Polverara (PD)
Tel. +39-049-0992000
e-mail: info@alifax.com
web: www.alifax.com
VAT: IT04337640280

The instrument is CE certified



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



SERVICE MANUAL

TEST1 2.0

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



Photo 1

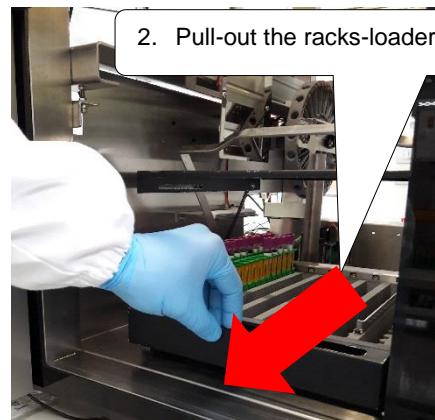


Photo 2

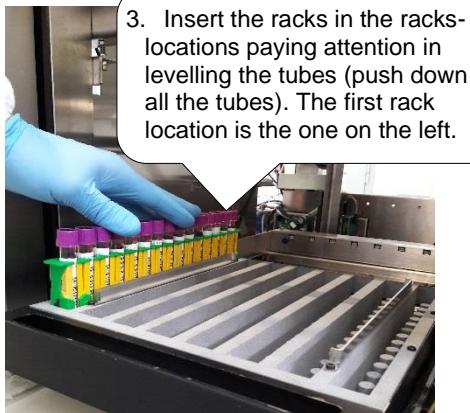


Photo 3



Photo 4

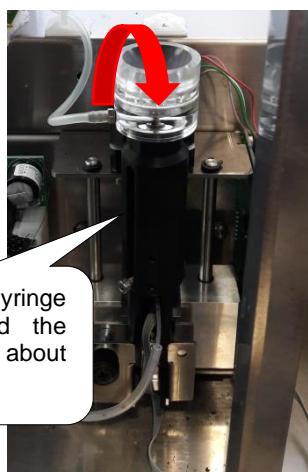
The photo of the rack it is purely indicative just to explain the way it must be loaded

Also please notice it is not necessary to verify the correct alignment of the barcode labels facing the right side of the rack.

18. APPENDIX B (Needle Management)

18.1 APPENDIX B1 (needle replacement)

Before starting the internal needle replacement, it is necessary to perform an automatic washing (**chapter** Error! Reference source not found.). Once done refer to **chapter** Error! Reference source not found.; 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:



Pull the syringe body toward the front (it tilt about 45°)

Photo 5



Unscrew the top washing sink in order to remove it from the syringe.

Photo 6



Take the spare needle plastic tool, insert it into the syringe up the end and unscrew the syringe to remove it then up.

Photo 7



Take a new kit and place the new needle and tight firmly without overstressing 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.

Photo 8

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

18.2 APPENDIX B2 (External probe replacement)

SERVICE MANUAL

TEST1 2.0

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 **Error! Reference source not found.**). Once done refer to **chapter Error! Reference source not found.**; press “External Needle”.

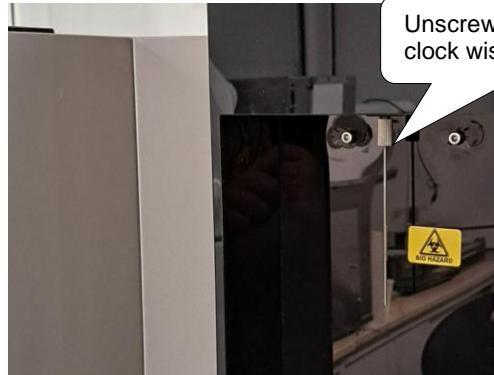
Open left side front door to get access to the external needle; remember **IT IS MANDATORY** to wear protective gloves and follow the instructions below:



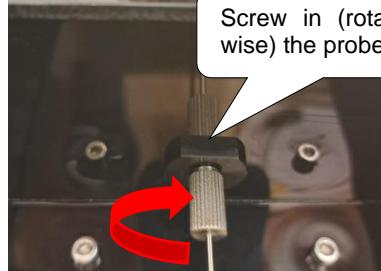
Pull the left side door



Unscrew (rotate counter clockwise) the probe



Screw in (rotate clockwise) the probe



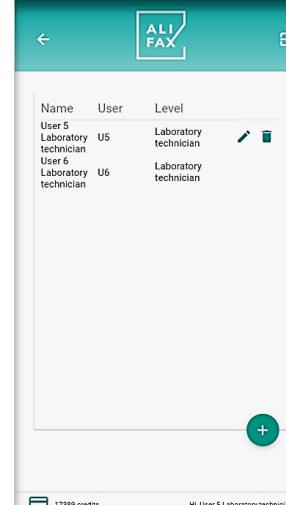
19. APPENDIX C (How to create new Users)

- * 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.

* 







20. 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.



21. 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 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.

22. APPENDIX F (asterisk meaning)

If the instrument detects a low hematocrit level, indicatively lower than 30%, along the measuring phase of the specimen, the instrument software prints out an * (asterisk) symbol near by the ESR result, this symbol warns of an eventual possible low hematocrit and eventual potential anemia.

23. APPENDIX G (Wash station O-Ring replacement)

The replacement kit part number it is SI19010107 "O-Ring for Washing Cell"

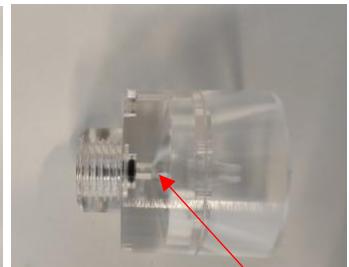
Once removed the whole wash station from the syringe group.



Using the supplied tool, unscrew the internal plastic stopper,



Using a small pliers, remove the old O-Ring from its slot, then insert the new one inside the slot till the bottom.
Be sure it fits well, using a cylindrical object such as a pen or touch



screen pencil (diameter 5 ± 1 mm) and apply a small pressure. Right side photo shows the position where the O-Ring shall be located once replaced.

Once finished, take the "new" plastic stopper supplied in the O-Ring kit, and screw in again the wash station.



24. 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:

- 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.

OK NOK

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

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.

- 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.

OK NOK

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

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

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

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 lower right side of the page (or make a photocopy) and include the tag in the shipping documents.



SERVICE MANUAL

TEST1 2.0

25. PROGRAMMED MAINTENANCE PROCEDURE

TEST1 2.0 requires a scheduled maintenance every 30.000 test performed or at least once per year (if in the year the 30.000 test threshold it is not reached).

The required parts to perform the maintenance are:

- 2 x SI19010202 Withdrawal Pump Tube (it fits both internal and external pumps)
- 1 x SI19010201 Wash Pump Tube
- 1 x SI19010107 O-Ring For Washing Cell
- 1 x SI19010101 Internal Sampling Metal Screw Needle for TEST1 2.0
- 1 x SI19010102 External Sampling Needle for TEST1 2.0
- 1 x SI305.100 Latex Quality Control Kit

Frequency	Part to check	Description (please tick in the box after checking)
30.000 test	Robotic arm (X, Y, Z axis) and Rotor	<input type="checkbox"/> Perform the verifications steps described in the ESR_IQOQ_SI195210THL_TEST1-2-0_SW1-0_1-0_EN module, from page 9 till page 12.
	Needle	<input type="checkbox"/> Check if the needle is damaged or obstructed. Change it if it is necessary.
	Pump tube (to be verified on the 3 pumps)	<input type="checkbox"/> It <u>must be replaced</u> even if it seems not damaged.
	Capillary tube (both internal and external circuits)	<input type="checkbox"/> Check the status of the capillary tube from the syringe to CPS and from CPS to the pump. Replace if it is deformed, damaged, or crouched.
	Pump (to be verified on the 3 peristaltic pumps)	<input type="checkbox"/> Check the pump rotation paying attention to the rolls rolling.

26. INTERFACING INFORMATION

A laboratory information system (LIS) is a software system that records, manages, and stores data for clinical laboratories. A LIS has traditionally been most adept at sending laboratory test orders to lab instruments, tracking those orders, and then recording the results, typically to a searchable database.

The TEST1 2.0 software shall communicate with LIS systems using standard ASTM communication protocol or the classic Serial RS232.

Please refer to the following documents in attachment in the next pages.



SERVICE MANUAL

TEST1 2.0

ATTACHMENT 1 – PRODUCT TECHNICAL DATA SHEET

ATTACHMENT 2 – ASTM LIS Interface Protocol

ATTACHMENT 3 – SERIAL LIS Interface Protocol

PRODUCT TECHNICAL DATA SHEET

TEST1 2.0

Rev.1.0 - 2022-09-27

Equipment name:	TEST1 2.0 (SI 195.210/THL).
Intended Use:	<p>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.</p> <p>TEST1 2.0 provides results to inform clinical management of serious and non-serious conditions requiring further diagnostic investigation and assessment of clinical status.</p> <p>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.</p>
Principle of measure:	<p>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 ($\pm 0.5^\circ\text{C}$) / 98.6°F ($\pm 0.9^\circ\text{F}$)</p>
Results:	ESR results are displayed (and memorized) in mm/h on the range from 2 to 120 mm/h.
Configurations:	<p>TEST1 2.0 has two withdrawal systems:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>
	<p>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.</p>
	<p>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 μl.</p>
Compatibility:	TEST1 2.0 is available in two versions: <ul style="list-style-type: none"> • 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	<p>Main feature common to both versions</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ✓ 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 Vacutette® / 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
<i>Overall CV(%)</i>		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 K₃EDTA-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 K₃EDTA-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 K₃EDTA 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 m³ (36 ft³)
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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- (1) M. Plebani, S. De Toni, M.C.Sanzari, D. Bernardi and E. Stockreiter: "The TEST1 Automated System", American Journal of Clinical Pathology, Vol. 110, 1998
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TEST1 2.0 ASTM LIS INTERFACE PROTOCOL



In Vitro Diagnostic Medical Device for professional use

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TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Index

Introduction.....	4
General informations	4
Glossary	4
Communication.....	5
TCP/IP Data Exchange.....	5
Lan connection	5
ASTM - Low level transfer protocol.....	6
Data Link layer.....	6
Establishment Phase	6
Transfer Phase	6
Termination Phase.....	7
Defective Frames.....	7
Timeouts.....	8
Restricted Characters	8
Transport Layer Sequence.....	8
ASTM – Message Layer.....	11
Message content	11
Characters	11
Maximum Field Length.....	11
Language.....	11
Date and Time	11
Record codes.....	11
Delimiters.....	12
Fields.....	12
ASTM - Record Field Contents.....	12
Records summary	12
Message Header Record (LIS02A2E chapter 6).....	13
Patient Information Record (LIS02A2E chapter 7).....	14
Test Order Record (LIS02A2E chapter 8)	16
Result Record (LIS02A2E chapter 9).....	18
Request Information Record (LIS02A2E chapter 11)	20
Message Scientific Record (LIS02A2E chapter 13).....	21
Message Comment Record (LIS02A2E chapter 10)	21
Message Manufacturer Information Record (LIS02A2E chapter 14)	21
Message Terminator Record (LIS02A2E chapter 12).....	21
ASTM - Record Field Contents more details.....	22
Message Header Record - Processing ID explain	22
General - Record Sequence Number	23
DAC15 or BCI mode.....	23
Test order record explain.....	23
Sample ID.....	23
Specimen ID	23
Universal Test ID	23
Report Type.....	23
Result Record explain	24



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Universal Test ID24
Data or Measurement Value.....	.24
Result Status25
Use cases and examples.....	.25
LIS -> Test1 2.0 or Roller 20: control query for the exam to execute.....	.25
Test1 2.0 or Roller 20 -> LIS : send valid results.....	.26
Test1 2.0 or Roller 20 -> LIS : send invalid results (NR or NF).....	.26
Test1 2.0 or Roller 20 -> LIS : send not processed record notice27
Test1 2.0 or Roller 20 -> LIS : send not processable record notice27
Test1 2.0 or Roller 20 -> LIS : send latex results28



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

1- Introduction

General informations

Test1 2.0 and Roller 20 are automatic analyzers for Erythrocyte Sedimentation Rate (ESR) determination of human blood samples in-vitro. The technology applied by Alifax's ESR instrumentation is Quantitative Capillary Photometry, which allows in just 20 seconds of analysis to obtain the ESR result of the sample, expressed in mm/hour, as per guidelines and reference method.

Test1 2.0 and Roller 20 has two withdrawal systems:

- The internal one which requires that samples in tubes are inserted in the instrument using racks
- The external one which withdraws blood from open tube that must be inserted manually in an external probe.

The second system is an optional and its measurement circuit is completely separated from the first one

A laboratory information system (LIS) is a software system that records, manages, and stores data for clinical laboratories. A LIS has traditionally been most adept at sending laboratory test orders to lab instruments, tracking those orders, and then recording the results, typically to a searchable database.

The Test1 2.0 and Roller 20 software shall communicate with LIS systems using standard ASTM communication protocol.

This manual is intended to provide detailed information on how to implement communication between Test1 2.0 or Roller 20 and a LIS system.

It should assist software house companies in creating, modifying and installing their program on the host computer.

2- Glossary

Term	Definition
[]	In message formats, brackets indicate that the enclosed group of records/segments is optional.
<CR>	Carriage Return (ASCII decimal 13).
<ENQ>	ASTM Enquiry. ASCII character 5. This control character is used to establish communication between machines.
<EOT>	ASTM End of Transmission. ASCII character 4. A control character used to mark the end of a session.
<ETB>	ASTM End of Transmission Block. ASCII character 23. This control character may be used in place of ETX to distinguish between the end of a data block at a different logical (abstraction) level.
<ETX>	ASTM End of Text. ASCII character 3. This control character denotes the end of the data (text) block.
<LF>	Line Feed (ASCII Decimal 10).
<NAK>	Negative Acknowledgment (ASCII Decimal 21).
<STX>	Start of Frame (ASCII Decimal 2).
ACK	Positive Acknowledgement. For ASTM - ASCII character 6.
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Materials. In this guide, ASTM refers to the communication protocols defined by the E-1381 and E-1394 specifications noted in the references
BCI	Software application option to indicate that if enabled, before taking an exam you must make a request query to the LIS.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

CLSI	The Clinical and Laboratory Standards Institute
DAC15	Software application option to indicate that if enabled, you can perform any exam and then send the final result to the LIS.
frame	The basic unit of communication at the Data Link Layer for ASTM protocol
LIS	Laboratory Information System. The Lab Computer together with the software that runs on it viewed as a logical unit.
MISSING ID	Software application option to indicate incorrect barcode must be replaced (value = 1) or the exam must be discarded (value = 0)
Record	In reference to the low level protocol, a record is the communications packet. If the frame length is longer than 64,000 characters, then it must be split into two parts and sent in two or more communications packets. The intermediate packet uses the <ETB> character, and the ending packet uses the <ETX> character. No single communications packet contains more than one record. In reference to the message layer, it is an aggregate of fields describing one aspect of the complete message. A record will contain one of the following codes: H (header), P (patient), O (order), R (result), L (terminator), C (comment), Q (request for information), and M (manufacturer information).
Rx	Receive(r).
Sample	The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.
Specimen	Term for Sample
Tx	Transmit, Transmission, or Send(er).

3- Communication

TCP/IP Data Exchange

Protocol: TCP/IP

Electrical Characteristics: The voltage and impedance levels for the generator and receiver circuits are as specified in the IEEE 802.3 standard.

Signal Levels: The signal levels conform to the IEEE 802.3 standard.

Interface Connections: An RJ45 connection is used. The connector contact assignments conform to the ANSI EIA/TIA 568B standard (also called the AT&T specification).

Speed: The data transmission rate for the instruments shall conform to IEEE 802.3 and operate at least 10 MB/second. A computer system using TCP/IP must have the capability to conform to a minimum speed of 10 MB/second.

Lan connection

Standard LAN Cable to connect instrument to Host (LAN port), eventually the Host side could be different, so depending the configuration on Host side, one edge could be different.
Software House has the responsibility for the cable.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

4- ASTM - Low level transfer protocol

To accomplish a successful interface between the System Manager and the laboratory computer, a compatible environment, both physical and logical, must be established. At the lowest level, the physical connections must be defined and the behavior of both the sender and receiver of information must be specified.

The Low Level Protocol to use for transferring messages between the Instrument and the laboratory computer is the Clinical and Laboratory Standards Institute (CLSI) Communication Protocol: CLSI LIS1-A (formerly NCCLS LIS1-A, formerly ASTM 1381-02).

Data Link layer

The data link layer has procedures for link connection and release, delimiting and synchronism, sequential control, error detection, and error recovery as specified in CLSI LIS1-A (formerly NCCLS LIS1-A, formerly ASTM 1381-02). There are three distinct phases in transferring information between the System Manager and the laboratory computer. The three phases assure the actions of sender and receiver are coordinated. The three phases are establishment, transfer, and termination.

The data link layer uses a character-oriented protocol to send messages between directly connected systems. The data link mode of operation is one-way transfer of information with alternate supervision. Information flows in one direction at a time. Replies occur after information is sent, never at the same time. It is a simple stop-and-wait protocol. At times the two systems are actively operating to transfer information. The remainder of the time the data link is in a neutral state.

Establishment Phase

The establishment phase determines the direction of information flow and prepares the receiver to accept information. A system, which does not have information to send, normally monitors the data link to detect the establishment phase. It acts as a receiver, waiting for the other system.

The system with information available initiates the establishment phase. After the sender determines the data link is in a neutral state, it transmits the <ENQ> transmission control character. The receiver ignores any character other than <ENQ> while in the neutral state. Sender will ignore any responses to the <ENQ> other than <ACK>, <NAK>, or <ENQ>.

Receiver State	Sender		Receiver Reply	Sender Status After Receiving Response
Receiver Ready	<ENQ>	→ ←	<ACK>	Transfer phase
Receiver Not Ready	<ENQ>	→ ←	<NAK>	Wait 10 seconds, then send <ENQ> again.
Receiver sending *1	<ENQ>	→ ←	<ENQ>	*2

*1 Line Contention condition - Receiver also has information available and sent the ENQ at the same time as the sender.

*2 If Sender is the Instrument, wait 1 second and then begin establishment phase by sending <ENQ>. If Sender is the laboratory computer, the laboratory computer goes into a neutral state for a minimum of 20 seconds or until the receive message session from the System Manager is complete.

Transfer Phase

During the transfer phase, the sender transmits messages to the receiver. The transfer phase continues until all messages are sent. Messages are sent in frames. Each frame contains a maximum of 64,000 characters (including frame overhead). Messages longer than 64,000 characters are divided between two or more frames. Multiple messages are never combined in a single frame.

Every message must begin in a new frame. There are two types of frames: intermediate and end. The intermediate frames terminate with the character <ETB>, checksum, <CR><LF>. End frames terminate with <ETX>, checksum, <CR><LF>. A message containing 64,000 characters or less is sent in a single end frame. Longer messages are sent in intermediate frames with the last part of the message sent in the end frame.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Frame Number

The frame number permits the receiver to distinguish between new and retransmitted frames. It is a single digit sent immediately after the <STX> character. The frame number is an ASCII digit ranging from 0 to 7. The frame number begins at 1 with the first frame of the Transfer phase. The frame number is incremented by one for every new frame transmitted. After 7, the number rolls over to 0, and continues in this fashion.

Checksum

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters, which are sent after the <ETB>, or <ETX> character. The checksum is computed by adding the binary values of the characters, keeping the least significant eight bits of the result. The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR><LF>. The checksum is an integer represented by eight bits; it can be considered as two groups of four bits. The groups of four bits are converted to the ASCII characters of the hexadecimal representation. The two ASCII characters are transmitted as the checksum, with the most significant character first.

N.B.: It is very important that the hexadecimal checksum value sent by the LIS to the instrument is in upper case. Eg: If the checksum is 127 in hex it must be sent with 7F (7f is considered an error in receiving the message)

Acknowledgments

After a frame is sent, the sender stops transmitting until a reply is received. The receiver replies to each frame. When it is ready to receive the next frame, it transmits one of three replies to acknowledge the last frame. This reply must be transmitted within the timeout period. (See Timeouts for additional information.) A reply of <ACK> signifies the last frame was received successfully and the receiver is prepared to receive another frame. The sender must increment the frame number and either send a new frame or terminate. A reply of <NAK> signifies the last frame was not successfully received and the receiver is prepared to receive the frame again. A reply of <EOT> signifies that the last frame was successfully received; the receiver is prepared to receive another frame, but is a request to the sender to stop transmitting.

Receiver Interrupts

The receiver interrupt is a means for the receiver to request the sender to stop transmitting messages as soon as possible. During the transfer phase, if the receiver responds to a frame with an <EOT> in place of the usual <ACK>, the sender must interpret this reply as a receiver interrupt request. The <EOT> is a positive acknowledgement of the end frame, signifies the receiver is prepared to receive next frame, and is a request to the sender to stop transmitting. The sender does not have to stop transmitting after receiving the receiver interrupt request. If the sender chooses to ignore the <EOT>, the receiver must re-request the interrupt for the request to remain valid. If the sender chooses to honor the receiver interrupt request, it must first enter the termination phase to return the data link to the neutral state. This gives the receiver an opportunity to enter the establishment phase and become the sender. The original sender must not enter the establishment phase for at least 15 seconds or until the receiver has sent a message and returned the data link to the neutral state.

Termination Phase

The termination phase returns the data link to the clear or neutral state. The sender notifies the receiver that all messages have been sent. The sender transmits the <EOT> transmission control character and then regards the data link to be in a neutral state. Upon receiving <EOT>, the receiver also regards the data link to be in a neutral state.

Defective Frames

A receiver checks every frame to guarantee it is valid. A reply of <NAK> is transmitted for invalid frames. Upon receiving the <NAK>, the sender retransmits the last frame with the same frame number. In this way, transmission errors are detected and automatically corrected. The receiver ignores any characters occurring before the <STX> or <EOT> or after the end of the block character <ETB> or <ETX> when checking the frame. A frame should be rejected because:

1. Any character errors are detected (parity error, framing error, etc.)
2. The frame checksum does not match the checksum computed on the received frame
3. The frame number is not the same as the last accepted frame or one number higher (modulo 8).

Upon receiving a <NAK> or any character except an <ACK> or <EOT> (a <NAK> condition), the sender increments a retransmit counter and retransmits the frame. If this counter shows a single frame was sent and not



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

accepted six times, the sender must abort this message by proceeding to the termination phase. An abort should be extremely rare, but it provides a mechanism to escape from a condition where the transfer phase cannot continue.

Timeouts

The sender and receiver both use timers to detect loss of coordination between them. If a reply of an <ACK>, <NAK>, or <ENQ> is not received within 15 seconds, a timeout occurs. After a timeout, the sender enters the termination phase.

During Establishment Phase

During the establishment phase, if the computer (as receiver) detects contention, it sets a timer. If an <ENQ> is not received within 20 seconds, a timeout occurs. After a timeout, the receiver regards the line to be in the neutral state.

During the Transfer Phase

During the transfer phase, the sender sets a timer when transmitting the last character of a frame.

If a reply is not received within 15 seconds, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the termination phase. As with excessive retransmissions of defective frames, the message must be remembered so it can be completely repeated.

Receiver Waiting for Frame

During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or <EOT> is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete message and regards the line to be in the neutral state.

Sender Wait on Reply

A receiver must reply to a frame within 15 seconds or the sender will timeout. A receiver can delay its reply for up to 15 seconds to process the frame. Longer delays cause the sender to abort the message.

Receivers that cannot process messages fast enough to keep up with a sender may cause message buffer overflows in the sender. A sender can normally store at least one complete message. Storage space for more than one outgoing message is desirable but optional.

Restricted Characters

The data link protocol is designed for sending character-based message text. Restrictions are placed on which characters may appear in the message text. The restrictions make it simpler for senders and receivers to recognize replies and frame delimiters. Additional characters are restricted to avoid interfering with software controls for devices such as multiplexers.

An <LF> character is not permitted to appear in the message text; it can appear only as the last character of a frame. None of the ten transmission control characters, the <LF> format effector control character, or four device control characters may appear in message text. The restricted characters are: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3>, and <DC4>.

Transport Layer Sequence

The following tables illustrate a transport layer sequence:

Normal Session	Sender	Receiver
Establishment Phase	<ENQ>	→ ← <ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR><LF> Frames continue until entire message sent	→ ← <ACK>
Termination Phase	<EOT>	→ No response Expected

TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Delay Request Session (NAK)	Sender		Receiver
Establishment Phase	<ENQ>	→	
		←	<NAK>
	(Delay 10 seconds)		
	<ENQ>	→	
		←	<ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
	frames continue until entire message sent	←	<ACK>
Termination Phase	<EOT>	→	No Response Expected

Failure Session (Max <NAK>s)	Sender		Receiver
Establishment Phase	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
Termination Phase	<EOT>	→	No Response Expected

Failure Session (No Response)	Sender		Receiver
Establishment Phase	<ENQ>	→	
	(Time-out after 15 seconds)		No Response
Termination Phase	<EOT>	→	No Response Expected

Retransmission Request (Multiple <NAK>s)	Sender		Receiver
Establishment Phase	<ENQ>	→	
		←	<ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>

TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
	frames continue until entire message sent	←	<ACK>
Termination Phase	<EOT>	→	No Response Expected

Failure Session (Max <NAK>s)	Sender	Receiver
Establishment Phase	<ENQ>	→
		← <ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
Termination Phase	<EOT>	→ No Response Expected

Failure Session (Receiver Timeout During Transfer)	Sender	Receiver
Establishment Phase	<ENQ>	→
		← <ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← No Response within 15 seconds
Termination Phase	<EOT>	→ No Response Expected

Failure Session (Sender Timeout During Transfer Phase)	Sender	Receiver
Establishment Phase	<ENQ>	→
		← <ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <ACK>
Termination Phase	No Frame sent within 30 seconds	→ No Response Discards



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

		incomplete message and assumes neutral state.
--	--	---

5- ASTM – Message Layer

This section conforms with CLSI LIS2-A (formerly NCCLS LIS2-A, formerly ASTM 1394-97). The intent of this section is to develop a complete understanding of the particular records and fields as supported by the Instrument. The low level protocol communications are separate from the message level.

Message content

Characters

All data must be represented as 8-bit, single-byte coded graphic character values, as defined in ISO 8859-1: 1987. The eight-bit values, between 0 and 127 of ISO 8859-1: 1987, correspond to the standard ASCII character set. Values from 0 to 31 are not allowed except for 7 (BEL), 9 (Horizontal Tab), 11 (Vertical Tab) and 13 (CR), where 13 is reserved as the record terminator. Values from 32 to 126 and 128 to 254 are allowed. Values 127 and 255 are not allowed. It is the responsibility of the instrument vendor and the information system vendor to understand the representation of any other extended or alternative character sets to be used. For example, the numeric value 13.5 would be sent as four-byte 13.5 or Latin-1 (49), Latin-1 (51), Latin-1 (46), and Latin-1 (53) characters.

Allowed characters: 7, 9, 11, 12, 13, from 32 to 126, from 128 to 254 Not allowed characters: from 0 to 6, 8, 10, from 14 to 31, 127, 255

In text data fields, only Latin-1 characters 32 through 126 and undefined characters 128 through 254 are allowed (excluding those used as delimiter characters in a particular transmission).

In addition, all characters used as delimiters for a particular transmission are excluded from the allowed range. The sender is responsible for screening all fields of text data to ensure that the text does not contain these delimiters. Unless otherwise indicated, the content of the data fields must be case-sensitive.

Maximum Field Length

While no maximum field length is imposed within the low level protocol mechanism, the parser restricts the fields' length because of the 64,000 byte frame limit. See the record tables in this document for specific field restrictions.

Language

Most user-entered fields will be transmitted in the localized language. All other fields that will be transmitted to and from instrument must be in English.

Further on you will find: Record Field Contents lists the acceptable values for each field.

Date and Time

In all cases, the dates must be recorded in the YYYYMMGG format as required by ANSI X3.30. December 1, 1989 would be represented as 19891201. When times are transmitted, they must be represented as HHMMSS and must be linked to dates as specified by ANSI X3.43.3. The date and time together must be specified as a 14-character string: YYYYMMGGHHMMSS.

Record codes

The following codes are required in relation to the ASTM standard:

Record name	Record code	Notes
Message Header Record	H	Fully Implemented
Patient Information Record	P	Fully Implemented
Test Order Record	O	Fully Implemented
Result Record	R	Fully Implemented
Comment record	C	Fully Implemented
Request Information Record	Q	Fully Implemented
Message Terminator Record	L	Fully Implemented
Scientific record	S	Fully Implemented
Manufacturer Information Record	M	Not implemented

Delimiters

The ASCII characters that follow the H (Header Record Identifier) define the unique field, repeat, component, and escape delimiters that are used in the message. Alphanumeric characters should not be used as delimiters because they are likely to appear within the field content.

The following are recommended delimiters for all messages.

Scope	Character	Description	Reference
Field delimiter		vertical bar	Latin 1 (124)
Repeat delimiter	\	backslash	Latin 1 (92)
Component	^	spacing circumflex accent	Latin 1 (94)
Escape delimiter	&	ampersand	Latin 1 (38)

Fields

Fields shall be identified by their position, obtained by counting field delimiters from the front of the record. This position-sensitive identification procedure requires that when the contents of the field are null, its corresponding field delimiter must be included in the record to ensure that the correct field can be found by counting delimiters. Delimiters are not included for trailing null fields or for trailing fields with data. That is, if the tenth field was the last field containing data, the record could terminate after the tenth field, and therefore would contain only nine delimiters. (Note: NULL in this context is not a character but is the lack of any characters for the field). The laboratory computer may transmit a null value for a field because:

1. it does not know the value
2. it knows the value is irrelevant to the Instrument, or
3. the Instrument defaults are to be used for the value.

6- ASTM - Record Field Contents

This section lists the following records and the fields they contain:

- Message Header Record
- Patient Information Record
- Test Order Record
- Result Record
- Request Information Record
- Message Terminator Record

Following each record is a list of the requirements and general considerations regarding the contents of one or more fields of the record.

Following field definitions apply to all records and fields:

Definition	Description
+	Mandatory filed
*	Optional field
empty	Field not used (but set to null)
TX	Transmission (from instrument to LIS)
RX	Reception from (LIS to instrument)
other characters	Exactly those characters must appear in the field
Not supported	Field not supported or implemented

Records summary

Only the records implemented/managed by the component are illustrated below; the other records foreseen by the specific (for example the C record of the comments) are not used but their possible presence is not affects the correct functioning of the system.

The TX and RX columns indicate how the corresponding field is implemented:

- the symbol "+" indicates that the field is implemented and mandatory
- the symbol "*" (asterisk) indicates that the field is optional



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

- other symbols represent the EXACT value that is expected to be present (if in RX) or will be present (if in TX), or a description of what to enter in the field
- the absence of symbols indicates that the field is not used (generally the unused fields are also indicated in gray).

The USE column explains how the corresponding field has been implemented. It can also indicate the exact value that will be transmitted or expected to be received. A very common syntax, called Backus-Naur Form, has often been used to generally describe the data received or transmitted; briefly this syntax can be explained with the following examples:

1. <surname>^<name> means that the surname and name data are present separated by the symbol “^” (example: rossi^mario)
2. <surname>^<[name]> means that the surname and the symbol “^” are certainly present but the name is optional (both valid examples: rossi^ and rossi^mario).

(For more info on this, see: https://it.wikipedia.org/wiki/Backus-Naur_Form)

Message Header Record (LIS02A2E chapter 6)

The header (Header Record) must contain the identifiers of the sender and the recipient.

The message header is a zero level record and must be followed at some point by a message terminator record before ending the session or passing another Header record. This type of record must always be the first record in a broadcast.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	RX instrument	TX instrument values	RX instrument values
Record Type ID (6.1)	H identify the record type: message header.	+	+	H	H
Delimiter definition (6.2)	These characters identify: <ul style="list-style-type: none">• the field delimiter character• the delimiter of repetitions• the component delimiter• the escape character On RX these characters are defined by the user; on TX default characters are implemented	+	+	^&	That of LIS
Message Control ID (6.3)	Supported	empty	empty		
Access Password (6.4)	Supported	empty	empty		
Sender Name Or ID (6.5)	Sender Name Or ID True True This field identifies the specific manufacturer / instrument (s) used. By using the repeat and / or component delimiter character this field can reflect the revision of the software or firmware, multiple instruments connected to the line, etc ...	+		ALIFAX^ESR^<Serial Number> <Serial Number> is the Serial Number of the instrument	



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Sender Street Address (6.6)	Supported	empty	empty		
Reserved files (6.7)	Supported	empty	empty		
Sender Telephone Number (6.8)	Supported	empty	empty		
Characteristics of Sender (6.9)	Supported	empty	empty		
Receiver ID (6.10)	Supported	empty	empty		
Comment or Special Instructions (6.11)	Supported	empty	empty		
Processing ID (6.12)	The process ID indicates how this message will be processed: P - Production: considers the message as an active message to be completed according to standard processing. T - Training: the message is initiated by a trainer and should not affect the system. D - Debug: the message is started for the purpose of a debug program. Q - Quality control: the message is initiated for the purpose of transmitting quality control / safety control or regulatory data.	+	+	P, D	P, D
Version Number (6.13)	Version level of the LIS specification (the current is LIS2-A2)	+	+	LIS2-A2	LIS2-A2
Date and Time of Message (6.14)	Date and time the message was generated (see chapter 5.6.2 of LIS02A2E).	+	*	Current date and time Format: YYYYMMDDHH MMSS	Current date and time Format: YYYYMMDDHH MSS

Patient Information Record (LIS02A2E chapter 7)

Each patient data line must start with the record type and end with a carriage return.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	RX instrument	TX instrument values	RX instrument values
Record type ID (7.1)	P identify the record of type: patient information 2.0.	+	+	P	P
Sequence number (7.2)	For the first patient transmitted it must be 1, for the second 2,... until the last one is defined (see chapter 5.6.7 of LIS02A2E).	+	+	numerical sequence	numerical sequence

Practice-Assigned Patient ID (7.3)	<p>This field must be the unique identifier assigned and used for practice to identify the patient and his results following the tests</p> <p>This identifier must be unique and used to identify the processing process number assigned to the patient by the laboratory.</p>	*	*	<ID paziente>	Equal
Laboratory-Assigned Patient ID (7.4)	Supported	empty	empty		
Patient ID Number 3 (7.5)	Supported	empty	empty		
Patient Name (7.6)	Supported	*	*	<surname> [^] <name>	Equal
Mother's Maiden Name (7.7)	Supported	empty	empty		
Birthdate (7.8)	Supported	empty	empty		
Sex (7.9)	Supported	empty	empty		
Patient Race-Etnic Origin (7.10)	Supported	empty	empty		
Patient Address (7.11)	Supported	empty	empty		
Reserved Fields (7.12)	Supported	empty	empty		
Patient Telephone Number (7.13)	Supported	empty	empty		
Attending Physician ID (7.14)	Supported	empty	empty		
Special Field 1 (7.15)	Supported	empty	empty		
Special Field 2 (7.16)	Supported	empty	empty		
Patient Height (7.17)	Supported	empty	empty		
Patient Weight (7.18)	Supported	empty	empty		
Patient's Known or Suspected Diagnosis (7.19)	Supported	empty	empty		
Patient Active Medications (7.20)	Supported	empty	empty		
Patient's Diet (7.21)	Supported	empty	empty		
Practice Field Number 1 (7.22)	Supported	empty	empty		
Practice Field Number 2 (7.23)	Supported	empty	empty		
Admission and discharge dates (7.24)	Supported	empty	empty		
Admission Status (7.25)	Supported	empty	empty		
Location (7.26)	Supported	empty	empty		
Nature of Alternative Diagnostic Code and Classifiers (7.27)	Supported	empty	empty		
Alternative Diagnostic Code and Classification (7.28)	Supported	empty	empty		
Patient Religion (7.29)	Supported	empty	empty		
Marital Status (7.30)	Supported	empty	empty		
Isolation Status (7.31)	Supported	empty	empty		
Language (7.32)	Supported	empty	empty		
Hospital Service (7.33)	Supported	empty	empty		
Hospital Institution (7.34)	Supported	empty	empty		
Dosage Category (7.35)	Supported	empty	empty		

Test Order Record (LIS02A2E chapter 8)

The test order record registration defines the attributes of a particular request for the services of a clinical instrument and contains all information about the samples. The system information will generate an order record to request a specific test, battery or test set. The information in an order record usually applies to a single sample. However, there is not necessarily a one-to-one relationship between the sample and the ordered tests. Different test groups are usually sorted into different order records even when they can be performed on a single sample. In this case, the sample information is duplicated in each of the order records that employ that sample.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	RX instrument	RX instrument values	TX instrument values
Record type ID (8.4.1)	O identify the record type: order record.	+	+	O	O
Sequence number (8.4.2)	For the first order transmitted it must be 1, for the second 2,... until the last one is defined (see chapter 5.6.7 of LIS02A2E).	+	+	numerical sequence	numerical sequence
Specimen ID (8.4.3)	This text field must represent a unique identifier for the sample assigned by the information system and returned by the instrument. If the sample has multiple components which further identify the crops derived therefrom, these component identifiers will follow the sample ID and be separated from the component delimiters. For example, the sample ID may contain the sample number followed by the isolated number, the well or the cup number (e.g. 10435A ^ 01 ^ 64).	+	+	<sample ID> or the text string "LATEX" in case of latex	Equal
Instrument Specimen ID (8.4.4)	Supported	empty	empty		
Universal Test ID (8.4.5)	This field must be used as described in the chapter 5.6.1 of LIS02A2E	+	*	^^<ExamName> ExamName allowed Value: "ESR"	Equal
Priority (8.4.6)	Supported	empty	empty		
Requested/Ordered Date and Time (8.4.7)	Supported	empty	empty		
Specimen Collection Date and Time (8.4.8)	Supported	empty	empty		

TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Collection End Time (8.4.9)	Supported	empty	empty		
Collection Volume (8.4.10)	Supported	empty	empty		
Collector ID (8.4.11)	Supported	empty	empty		
Action Code (8.4.12)	Supported	empty	empty		
Danger Code (8.4.13)	Supported	empty	empty		
Relevant Clinical Information (8.4.14)	Supported	empty	empty		
Date/Time Specimen received (8.4.15)	Supported	empty	empty		
Specimen descriptor (8.4.16)	Supported	empty	empty		
Ordering Physician (8.4.17)	Supported	empty	empty		
Physician's Telephone Number (8.4.18)	Supported	empty	empty		
User Field Number 1 (8.4.19)	Supported	empty	empty		
User Field Number 2 (8.4.20)	Supported	empty	empty		
Laboratory Field Number 1 (8.4.21)	Supported	empty	empty		
Laboratory Field Number 2 (8.4.22)	Supported	empty	empty		
Date/Time Results Reported or Last Modified (8.4.23)	Supported	empty	empty		
Instrument Charge to Information System (8.4.24)	Supported	empty	empty		
Instrument Section ID (8.4.25)	Supported	empty	empty		
Report Types (8.4.26)	Type of report code	+	+	O, Y, Z O – order record Y – no record order for this (in response to query) Z – the exam is not to be done	F, X F – final results X – order cannot be done, order cancelled
Reserved Fields (8.4.27)	Supported	empty	empty		
Location of Specimen Collection (8.4.28)	Supported	empty	empty		
Nosocomial Infection Flag (8.4.29)	Supported	empty	empty		
Specimen Service (8.4.30)	Supported	empty	empty		
Specimen Institution (8.4.31)	Supported	empty	empty		

TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Result Record (LIS02A2E chapter 9)

Result Record

FIELD NAME (LIS02A2E chap-ter)	USE	TX INSTRUMENT	TX INSTRUMENT VALUES
Record Type ID (9.1)	R identify the record type: result record.	+	R
Sequence Number (9.2)	For the first result transmitted it must be 1, for the second 2,... until the last one is defined (see chapter 5.6.7 of LIS02A2E).	+	numerical sequence
Universal Test ID (9.3)	This field must be used as described in the chapter 5.6.1 of LIS02A2E	+	In case of result, ESR measure: ^^^<ExamName> ^<measure_name> ExamName allowed Value: "ESR" Same as order: parent order Universal Test ID Measure_name: For the admitted values see chapter "<measure_name> values" In case of latex measurement result: ^^^<ExamName> ^latex^<latex lot>^<latex number>
Data or Measurement Value (9.4)	If numeric, textual or coded values, the data must be recorded in ASCII textual notation. If the data result contains qualifying elements of equal stature, they should be separated by component delimiters. This strictly applies to results of an identical nature (that is, this field may not contain implicit secondary values). The use of components within this field should be avoided whenever possible. Multiple results or values, observed, calculated or implied, for a single test order (e.g. MIC or interpretation codes from a single antibiotic sensitivity test) must be reported in separate result records with each definition uniquely defined by the field previous Universal Test ID. Consequently, this field must be sufficiently descriptive to determine the placement of the data value with reference to the original test order record and other result records associated with this test order record.	+	<measure_value> measure_value must be numeric For the admitted values and ranges see chapter "<measure_name> values"
Units (9.5)	Supported	+	mm/h for ESR measure pure number for other measures



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Reference Ranges (9.6)	Supported	+	In case of latex measurement result: <latex ESR expected value>
Result Abnormal Flag (9.7)	Supported	empty	
Nature of Abnormality Testing (9.8)	Supported	empty	
Result Status (9.9)	The following codes must be used: C - correction of previously transmitted results P - preliminary results F - final results X - the order cannot be executed I - still in the tool, waiting for results S - partial results M - this result is a MIC level R - this result has been previously passed on N - this result record contains the information necessary to execute a new order NOTE: For example, when ordering a sensitivity, the information system can download a record of results containing the type of organism or species identified in a previous test. D - this result is a response to a pending query V - result verified / approved by the operator (validated) W - attention: validity is questionable	+	F, X
Date of Charge in Instrument Normative Values or Units (9.10)	Supported	empty	
Operator Identification (9.11)	Supported	+	<first_name last_name> of logged operator or "Unknown Operator"
Date/Time Test Started (9.12)	Supported	+	Date/Time of start YYYYMMDDHHMMSS
Date/Time Test Completed (9.13)	Supported	+	Date/Time of end YYYYMMDDHHMMSS
Instrument Identification (9.14)	Supported	+	ALIFAX^ESR^<serial number>^<internal or external> <serial number> is the serial number of the product <internal or external> indicates whether the

		measurement was carried out by the external or internal cps
--	--	---

Request Information Record (LIS02A2E chapter 11)

The Request Information Record is used by the clinical tool or by the information system to request information remotely from the reciprocal system. NOTE: only one request of one record at a time can be left pending; the recipient of the record request must end the request when it has finished, by means of the message termination record, or it is the sender who must cancel the current request before sending a second logical request.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	TX instrument values
Record Type ID (11.1)	Q identify the record type: query record.	+	Q
Sequence Number (11.2)	For the first query record transmitted it must be 1, for the second 2,... until the last one is defined (see chapter 5.6.7 of LIS02A2E).	+	Numerical sequence
Starting Range ID Number (11.3)	<p>This field may contain three or more components to define a range of patient/sample/manufacturer selection criteria. The first component is the patient ID number of the information system. The second component is the sample ID number of the information system. Any additional components are defined by the manufacturer for the use of requests for additional information (i.e. a single isolated sample or a battery of samples). These components depend on the location. A list of sample IDs may be required using the repeat delimiter to separate the IDs.</p> <p>When "ALL" is entered and the information system sends the order record, it is understood that all sample results are requested by the requesting system. If the instrument is generating the order record, it means that all required demographics and tests must be sent to the instrument at this time. The request is then interpreted for that identified subset of samples and subsequently modified by the test specifications and date ranges as described below.</p> <p>This specification does not indicate how long data should be stored by an instrument, and does not require that the instrument provide you with implicit search services for some content in the fields. The appropriate response for a result request is simply to return a subset of results that are currently in memory and that can be practically retrieved.</p>	+	ALL or ^Specimen ID
Ending Range ID Number (11.4)	Supported	empty	empty
Universal Test ID (11.5)	Supported, empty	+	ALL if requesting a specific Specimen ID
Nature of Request Time Limit (11.6)	Supported	empty	empty
Beginning Request Result Date and Time (11.7)	Supported	+	Beginning of day YYYYMMHHMS S

Ending Request Result Date and Time (11.8)	Supported	empty	empty
Requesting Physician Name (11.9)	Supported	empty	empty
Requesting Physician Telephone Number (11.10)	Supported	empty	empty
User Field Number 1 (11.11)	Supported	empty	empty
User Field Number 2 (11.12)	Supported	empty	empty
Request Information Status Codes (11.13)	The following codes must be used: C - correction of previously transmitted results P - preliminary results F - final results X - impossible to get results, request canceled I - request pending results S - partial / not finalized results request M - the result is a MIC level R - this result has been previously passed on A - cancel / cancel the criteria of the last request (allows to follow a new request) N - request only for new or modified results O - request for test requests and demographics only (no results) D - request for demographic data only (e.g. patient's medical record)	+	O

Message Scientific Record (LIS02A2E chapter 13)

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	TX instrument values
All fields	Supported	empty	empty

Message Comment Record (LIS02A2E chapter 10)

FIELD NAME (LIS02A2E chapter)	USE	RX instrument	RX instrument values
All fields	Supported	empty	empty

Message Manufacturer Information Record (LIS02A2E chapter 14)

NOT IMPLEMENTED

Message Terminator Record (LIS02A2E chapter 12)

This is the last record in the message. A new Message Header Record can be sent after this record and means the start of a second message.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	RX instrument	TX instrument values	RX instrument values



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Record Type ID	L identify the record type: message terminator.	+	+	L	L
Sequence Number	This field is described in chapter 5.6.7 of LIS02A2E. (For this type of record the value of this field must always be "1")	+	+	1	1
Termination Code	This field provides the reason for the end of the session: Nil, N - normal termination T - interrupted by sender R - the receiver requested the interruption E - unknown system error Q - error in the last request for information I - there is no information available since the last query F - last request for information processed NOTE: I or Q will terminate the request and allow you to process a new one	+	+	N	N

7- ASTM - Record Field Contents more details

Message Header Record - Processing ID explain

This field can have the following values:

"P": indicates that the data to be sent and received are production data: it considers the message as an active message to be completed according to standard processing.

"D": indicates that the data to be sent and received are debug data;

Messages received with this type of communication must not contain or be obscured from any sensitive personal data.

The data do not include any of the following 18 identifiers (of the individual or his/her relatives, household members, or employers) that could be used alone or in combination with other information to identify the subject:

- Names
- Geographic subdivisions smaller than a state (including zip code)
- All elements of dates except year (unless the subject is greater than 89 years old)
- Telephone numbers
- Fax numbers
- E-mail address
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers including license plates
- Device identifiers and serial numbers (patient care devices)
- URLs
- Internet protocol addresses
- Biometric identifiers (fingerprint, retina scan)
- Full face photos and comparable images
- Any unique identifying number, characteristic, or code



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

General - Record Sequence Number

This is a required field used in record types that can appear multiple times in a single message. The number used defines the 1st occurrence of the type of record associated with a certain hierarchical level and is reset to one (lower number) each time a record with a higher hierarchical meaning is transmitted or if the same record is used at a different one hierarchical level.

Example:

```
H|&||Alifax TEST1 2.0 123456|||||P|LIS2-A2|20191202112454
P|1|PAT-268-OH||Azzan^Rudy||19781210|M
O|1|347845992OB||^ESR||||||||||F
R|1|^ESR^ESR|52|mm/h|||F|mario
rossi|20210706125024|20210706125316|ALIFAX^ESR^123456
R|2|^ESR^ lowHematocrit|0| |||F|mario
rossi|20210706125024|20210706125316|ALIFAX^ESR^123456
.....
P|2|PAT-269-OH||Ceschia^Marco||19761012|M
O|1|747839192OB||^ESR||||||||||F
R|1|^ESR^ESR|97|mm/h|||F|mario
rossi|20210706125224|20210706125616|ALIFAX^ESR^123456
R|2|^ESR^ lowHematocrit|0| |||F|mario
rossi|20210706125224|20210706125616|ALIFAX^ESR^123456
.....
L|1|N
```

DAC15 or BCI mode

As for the serial protocol, it will be possible to set the machine in DAC15 or BCI mode.

In BCI mode the machine will query the host before taking an exam. In DAC15 mode, on the other hand, no query will be made but at the end of the examination the results will still be sent to the LIS.

Test order record explain

Sample ID

Test 1 2.0 or Roller 20 identifies the sample or the latex by its barcode value.

Specimen ID

In the case of an order concerning an ESR measurement, this is the barcode of the tube. In case of a measurement result relating to latexes, the text string 'LATEX' will always be.

Universal Test ID

The Test1 2.0 or Roller 20 expects to receive an Order Record with TestID that contains at least 1 component with value = "ESR" (not case sensitive)
"^^ESR"

Report Type

Value	Description	Direction
F	We are sending the results found to the LIS	TX
X	Order cannot be done or cancelled	TX
O	Used for transmission of the Order record from the LIS after the query request	RX
Y	No record order for this (in response to query)	RX



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Z	Record found but the exam is not be done	RX
---	--	----

N.B.: In case the record order contains Report Type "X" in TX direction the "Result record" messages containing cycle, position and rack number data will still be sent.

The "Result Status" field of "Result record" will contain the value "X".

Result Record explain

Universal Test ID

The Test1 2.0 or Roller 20 uses the parent Order Record Test ID appending to it (adding 1 component to the Test ID) the name of the measured value.

In case of result, ESR measure:

"^^ESR^<measure_name>"

<measure_name> values

Measure type	Description	Max range value	Min range value	Notes
esr	The esr measure value	120	2	Special admitted values - 2 NR (Not Readable), -4 NF (No flow)
lowHematocrit	Indicates the presence of anemia if it is 1	1	0	value 1 means true, value 0 means false
position	Sample position in the rack	15	1	
rackNumber	Sample rack number	8	1	
cycle	Sample cycle number	99	1	
latex	(only in the case of latex measurement) The esr measure value	120	2	

In case of latex measurement result will be "latex" with the current lot number and the current latex number next to it:

"^^ESR^latex^<latex lot>^<latex number>"

<latex lot>

Identification code of the latex lot.

<latex number>

Identification number of the latex tube. It can be: 1, 2 or 3.

NOTE: In case of control with latexes the results will be sent at the end with a single message containing three "R" records.

Data or Measurement Value

<measure_value>

All results reported to LIS by Test1 2.0 or Roller 20 are numerical values, as reported by the test unit.

The only measure with a measurement unit is the ESR value (mm/h). The other measures are pure numbers, except in the case of "Low Hematocrit".

The result with "measure name" = "ESR" returns a numerical value "measure value" ranging from 2 to 120 except in two cases that indicate the following anomalies in the measure:

"-2": for NR (Not Readable) error:

It means that it is not possible to carry out the test due to problems with the processing of the sample (it has processed it but has not obtained a valid ESR value).

"-4": for NF (No flow) error:

It means it didn't find the blood, as if there was an empty or partial test tube.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

The result with "measure_name" = "lowHematocrit" can have the values "measure_value" 1 ("true") or 0 ("false") which indicate that a sample has a very low hematocrit value and therefore we are in the presence of anemia. If "lowHematocrit" is 0 this record can also be omitted from the result transmission.
All the values of "measure_value" are of numeric type.

Result Status

Value	Description	Direction
F	The result is valid and ready for the LIS	TX
X	If the barcode has not been read correctly and the machine is set in MISSING ID = 0 mode, the exam is not performed and the LIS is notified via this parameter	TX

Use cases and examples

LIS -> Test1 2.0 or Roller 20: control query for the exam to execute

This situation occurs in response to the Test1 2.0 or Roller 20 request for the test record with a certain unique identifier.

1. Test1 2.0 or Roller 20 requests a test records to LIS sending: Message Header Record, Request Information Record and Message Terminator Record

ASTM Message	Record
H ^\& 5026 ALIFAX^ESR^12345 P LIS2-A2 20220210142127	Message Header Record
Q 1 ^41c5624116 ALL 20220210000000 O	Request Information Record
L 1 N	Message Terminator Record

2. LIS replies with data sending to Test1 2.0 or Roller 20: Message Header Record, Patient Information Record, Test Order Record, Message Terminator Record

ASTM Message	Record
H ^\& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1 782 Jerde^Roberto	Patient Information Record
O 1 41c5624116 ^^^ESR O	Test Order record
L 1 N	Message Terminator Record

3. If the order is not found, the LIS replies with this data sending to Test1 2.0 or Roller 20: Message Header Record, Patient Information Record, Test Order Record, Message Terminator Record

ASTM Message	Record
H ^\& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

P 1	Patient Information Record
O 1 41c5624116 Y	Test Order record
L 1 N	Message Terminator Record

4. If the order is found, but the exam is not to be done the LIS replies with this data sending to Test1 2.0 or Roller 20: Message Header Record, Patient Information Record, Test Order Record, Message Terminator Record

ASTM Message	Record
H \^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1	Patient Information Record
O 1 41c5624116 Z	Test Order record
L 1 N	Message Terminator Record

Test1 2.0 or Roller 20 -> LIS : send valid results

This situation occurs when Test1 2.0 or Roller 20 successfully identifies the sample.

Case 1: result is valid

ASTM Message	Record
H \^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1 782 Jerde^Roberto	Patient Information Record
O 1 41c5624116 ^\^ESR F	Test Order record
R 1 ^\^ESR^esr 39 mm/h F Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 2 ^\^ESR^lowHematocrit 0 F Admin 20220720122514 20220720122600 ALIFAX^ESR^12345^internal R 3 ^\^ESR^position 2 F Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 4 ^\^ESR^rackNumber 1 F Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 5 ^\^ESR^cycle 5 F Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal	Result Record
L 1 N	Message Terminator Record

Test1 2.0 or Roller 20 -> LIS : send invalid results (NR or NF)

This situation occurs when Test1 2.0 or Roller 20 fails to identify the sample

Case 2: result invalid



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

ASTM Message	Record
H \^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1 782 Jerde^Roberto	Patient Information Record
O 1 41c5624116 ^\^ESR F	Test Order record
R 1 ^\^ESR^esr - 2 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12345^internal Or R 1 ^\^ESR^esr - 4 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12345^internal ...	Result Record
L 1 N	Message Terminator Record

Test1 2.0 or Roller 20 -> LIS : send not processed record notice

This record is sent in the event of a machine process error such as a failed roll insertion.

Case 3: process error

ASTM Message	Record
H \^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1 782 Jerde^Roberto	Patient Information Record
O 1 41c5624116 ^\^ESR X	Test Order record
R 3 ^\^ESR^position 2 X Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 4 ^\^ESR^rackNumber 1 X Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 5 ^\^ESR^cycle 5 X Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal	Result Record
L 1 N	Message Terminator Record

Test1 2.0 or Roller 20 -> LIS : send not processable record notice

This record is sent if the barcode has not been read correctly and the machine is set in MISSING ID = 0 mode to warn that the exam has not been performed.

Case 4: process error

ASTM Message	Record
H \^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1	Patient Information Record
O 1 41c5624116 ^\^ESR X	Test Order record
R 1 ^\^ESR X Admin 20220211114835 20220211114910 ALIFAX^ESR^12345^internal	Result Record



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

L 1 N	Message Terminator Record
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Test1 2.0 or Roller 20 -> LIS : send latex results

This situation occurs when Test1 2.0 or Roller 20 successfully identifies the 3 latex ESR values.

Case 5: latex results

ASTM Message	Record
H \^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1	Patient Information Record
O 1 LATEX ^~^LATEX F	Test Order record
R 1 ^~^LATEX^875^1 123 005 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12 345^internal R 2 ^~^LATEX^875^2 123 036 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12 345^internal R 3 ^~^LATEX^875^3 123 083 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12 345^internal	Result Record
L 1 N	Message Terminator Record



Rev 1.0 – Effective from: 16 Feb 2023

TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL



In Vitro Diagnostic Medical Device for professional use

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TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

Index

1- Introduction	3
Purpose	3
Scope	3
Overview	3
General information	3
2- Glossary	4
3- Serial port physical interface and configuration	4
4- Serial cable pin connections to connect Test1 2.0 or Roller 20 to PC-LAB	4
5- Test1 2.0 or Roller 20, RS232 ports features	5
6- Messages	5
Overview	5
Common parts	5
Buffer delimiter characters	5
Checksum	5
Fields encoding	6
Patient ID	6
Query	6
Response	7
Result exam	7
Result latex	8
7- Test1 2.0 or Roller 20 protocol explain	9
DAC15 or BCI	9
Barcode	9
Bayer and Cycle	9
Rack number	9
Configuration for the correct Query protocol functioning	10
8- Query Protocol flow description valid for all Test1 2.0 or Roller 20	10
<u>Warnings</u>	11
Example	11
9- Test1 2.0, Roller 20 Multiple connections	12
10- Appendix	12
Exam result state diagram (BCI mode) seen from the instrument side	12
Exam result state diagram (BCI mode) seen from the LIS side	13
Exam result state diagram (DAC15 mode) seen from the instrument side	13
Exam result state diagram (DAC15 mode) seen from the LIS side	14
Useful tools for debugging	14

1- Introduction

Purpose

This document specifies the LIS interface used by the Alifax ESR Line instruments.

Scope

This documents applies to the following instruments Test1 2.0 with software version 1.0.2 only and Roller 20 with software version 1.0.x

Overview

Its serial based protocol. It is used to enable the instruments to query the LIS if a sample needs processing or not, send the result of an analysis of blood or latex to the LIS.



General information

Alifax ESR Line instruments are automatic analyzers for Erythrocyte Sedimentation Rate (ESR) determination of human blood samples in-vitro. The technology applied by Alifax's ESR instrumentation is Quantitative Capillary Photometry, which allows in just 20 seconds of analysis to obtain the ESR result of the sample, expressed in mm/hour, as per guidelines and reference method.

Test1 2.0 or Roller 20 has two withdrawal systems:

- The internal one which requires that samples in tubes are inserted in the instrument using racks
- The external one which withdraws blood from open tube that must be inserted manually in an external probe.
- The second system is an optional and its measurement circuit is completely separated from the first one

A laboratory information system (LIS) is a software system that records, manages, and stores data for clinical laboratories. A LIS has traditionally been most adept at sending laboratory test orders to lab instruments, tracking those orders, and then recording the results, typically to a searchable database.

The Test1 2.0 or Roller 20 software shall communicate with LIS systems using custom Alifax serial communication protocol.

This manual is intended to provide detailed information on how to implement communication between Test1 2.0 or Roller 20 and a LIS system.

It should assist software house companies in creating, modifying and installing their program on the host computer.



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

2- Glossary

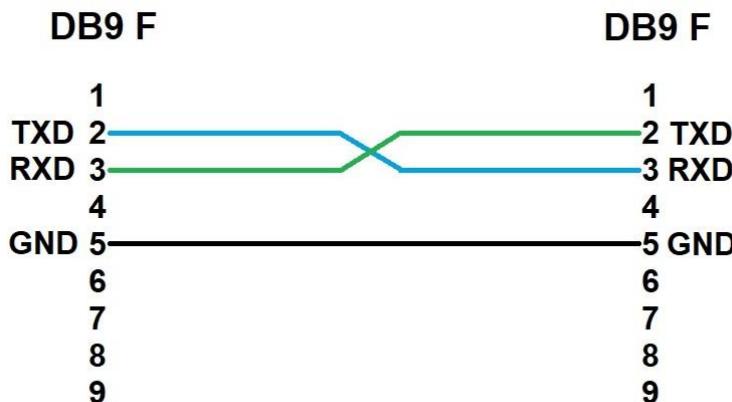
Term	Definition
<CR>	Carriage Return (ASCII decimal 13).
<LF>	Line Feed (ASCII Decimal 10).
<NAK>	Negative Acknowledgment (ASCII Decimal 21).
<STX>	Start of (text) block (ASCII Decimal 2).
ACK	Positive Acknowledgement. ASCII character 6.
ASCII	American Standard Code for Information Interchange
CHECKSUM	XOR calculation of part of R received message to check the correctness of it. See: Checksum
CLSI	The Clinical and Laboratory Standards Institute
<ETX>	End of Text. ASCII character 3. This control character denotes the end of the data (text) block.
LIS	Laboratory Information System. The Lab Computer together with the software that runs on it viewed as a logical unit.
Rx	Receive(r).
Sample	The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.
Specimen	Term for Sample
Tx	Transmit, Transmission, or Send(er).

3- Serial port physical interface and configuration

A standard cable to connect two personal computers via serial port.
This cable must have, D-type 9 pin female connector at the instrument side.

4- Serial cable pin connections to connect Test1 2.0 or Roller 20 to PC-

LAB





TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

5- Test1 2.0 or Roller 20, RS232 ports features

Communication ports parameters are fixed and cannot be modified.

Parameter name	Value
Baud rate	9600
Parity	N
Data bit number	8
Stop bit	1

6- Messages

Overview

The protocol uses four messages Query, Response, Result exam, Result latex as specified in this section. Each message has common structure comprising:

- a binary header
- a body
- a binary terminator
- a binary checksum.

Common parts

Buffer delimiter characters

<STX> ASCII character (❶ symbol) in the serial transmission is represented by 0x02 hex value and represents the beginning of the message.

<ETX> ASCII character (❷ symbol) in the serial transmission is represented by 0x03 hex value and represents the end of the message.

Checksum

Checksum value is the result of Exclusive OR (XOR) of all characters of the message, excluded STX, ETX and Checksum. If the Checksum value calculated by the analyser is 03 (corresponding to ETX), or 02 (corresponding to STX), or 00 (corresponding to NULL), the value will be automatically replaced with 7F hex value.

Software House must adopt the same procedure when calculating checksum of the strings received from the analyser. In the transmission protocol, hexadecimal characters like 0x13 (DC3 character), 0x14 (DC4 character), and 0x17 (ETB character), are not transmitted unless used as checksum.

TypeScript example to get the checksum byte

```
1. const NUL = 0x00;
2. const STX = 0x02;
3. const ETX = 0x03;
4. const DEL = 0x7f;
5.
6. checksum(data: Buffer) {
7.   let integrityChar = 0;
8.
9.   integrityChar = data
```



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

```
10. .slice(0, 1) // Remove first STX byte from data buffer
11. .slice(0, -2) // Remove last checksum and EXT byte from data buffer
12. .reduce(
13.   (acc, byte) => acc ^ byte, integrityChar // perform XOR of all characters
14. );
15.
16. // It checks if the resulting byte is among those not allowed and if so it replaces it with 7F
17. if ([ETX, STX, NUL].some((ch) => ch === integrityChar)) {
18.   integrityChar = DEL;
19. }
20.
21. return integrityChar;
22. }
```

Fields encoding

ASCII Encoded Integer 00-99 (zero padded)

All most significant byte which are not used to indicate the expected value are replaced by char "0" (zero) with hexadecimal value 0x30.

For example, to identify workstation number three we will write the following pair of bytes:

Text value: "03"
->
Byte value: 0x30 0x33

Patient ID

In the case of the "Patient ID", all less significant byte which are not used to indicate the expected value are replaced by the char " " (space) with hexadecimal value 0x20.

Text value: "27201999159 "
<-
Byte value: 0x32 0x37 0x32 0x30 0x31 0x39 0x39 0x39 0x31 0x35 0x39 0x20 0x20 0x20 0x20

Query

This is the structure of message query that is send from instrument to LIS.

Byte Index	Field	Length	Type [Value (hex)]	Notes
0	Header	1	byte [0x02]	This is the <STX> ASCII character
1	Message Type	1	byte [0x51]	This is the "Q" ASCII character
2-3	Workstation Number	2	ASCII Encoded Integer 00-99 (zero padded)	Identification number of the instrument if connected to the network together with others
4-18	Patient ID	15	ASCII String	See Patient ID for the specification



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

19-22	Reserved	4		This field should be ignored
23	Checksum	1	byte	See Checksum for the specification
24	Terminator	1	byte [0x03]	This is the <ETX> ASCII character

Response

This is the structure of message response that is send from LIS to instrument.

Byte index	Field	Length	Type [Value (hex)]	Notes
0	Header	1	byte [0x02]	This is the <STX> ASCII character
1	Message Type	1	byte [0x54]	This is the "T" ASCII character
2-3	Workstation number	2	ASCII Encoded Integer 00-99 (zero padded)	Identification number of the instrument if connected to the network together with others
4-18	Patient ID	15	ASCII String	See Patient ID for the specification
19-22	Result	4	bytes [0x30,0x30,0x30,0x30] or bytes [0x30,0x30,0x30,0x31]	In the first case the examination must not be done. In the second case, however, the examination must be done
23	Checksum	1	byte	See Checksum for the specification
24	Terminator	1	byte [0x03]	This is the <ETX> ASCII character

Result exam

This is the structure of message result exam that is send from instrument to LIS.

Byte index	Field	Length	Type [Value (hex)]	Notes
0	Header	1	byte [0x02]	This is the <STX> ASCII character
1	Message Type	1	byte [0x52]	This is the "R" ASCII character
2-3	Workstation number	2	ASCII Encoded Integer 00-99 (zero padded)	Identification number of the instrument if connected to the network together with others
4-18	Patient ID	15	ASCII String	See Patient ID for the specification
19-20	Rack number	2	ASCII Encoded Integer 00-99 (zero padded)	Number of rack containing the sample See: Rack number If there is no rack as in the case of external sampling, we use the value 00



TEST1 2.0 SERIAL LIS

INTERFACE PROTOCOL

21-22	Position	2	ASCII Encoded Integer 01-99 (zero padded)	Position of the sample in the rack
23-24	Cycle/Bayer	2	ASCII Encoded Integer 01-99 (zero padded)	See: Bayer and Cycle
25-28	Result	4	ASCII Encoded Integer 0000-9999 (zero padded) Or ASCII Encoded Integer *000-*999 (zero padded) Or ASCII Encoded Integer 0-04 or -004 (zero padded) Or ASCII Encoded Integer 0-02 or -002 (zero padded) Or ASCII Encoded Integer 0-01 or -001 (zero padded)	ESR measured value See: Flow description
29	Checksum	1	byte	See Checksum for the specification
30	Terminator	1	byte [0x03]	This is the <ETX> ASCII character
Total length		31 bytes		

Result latex

When the instrument runs latex controls, it is possible to send the results to host computer. This is the structure of message result latex that is send from instrument to LIS.

Byte index	Field	Length	Type [Value (hex)]	Notes
0	Header	1	byte [0x02]	This is the <STX> ASCII character
1	Message Type	1	byte [0x52]	This is the "R" ASCII character
2-3	Workstation number	2	ASCII Encoded Integer 00-99 (zero padded)	Identification number of the instrument if connected to the network together with others
4-12	LATEX0XYZ	9	ASCII String "LATEX0" + ASCII Encoded Integer 000-999 (zero padded)	Is the identification of the latex and the Lot to which they belong
13	Field 1	1	ASCII Encoded Integer 1-3 (zero padded)	Can be 1, 2 or 3 and identifies level 1, 2 and 3 of latex
14-16	ESR Value	3	ASCII Encoded Integer 000-999 (zero padded)	This is the expected Latex ESR value
17-18	Space	2	[0x20,0x20]	Two spaces
19-20	Field 2	2	ASCII Encoded Integer 00-99 (zero padded)	01 for internal cps, 00 for external cps
21-22	Field 3	2	ASCII Encoded Integer 00-99 (zero padded)	The same as Field 1



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

23-24	Field 4	2	ASCII Encoded Integer 00-99 (zero padded)	Priming cycle (the first priming, resets every midnight of the day)
25-28	ESR Value	4	ASCII Encoded Integer 000-999 (zero padded)	This is the detected Latex ESR value
29	Checksum	1	byte	See Checksum for the specification
30	Terminator	1	byte [0x03]	This is the <ETX> ASCII character

Latex examples

```
<0x2>R01LATEX08451005 0101010002<0x19><0x3>
<0x2>R01LATEX08452036 0102010034<0x1c><0x3>
<0x2>R01LATEX08453083 0103010071<0x13><0x3>
```

7- Test1 2.0 or Roller 20 protocol explain

DAC15 or BCI

The instrument can be configured in DAC15 mode which is unidirectional or in BCI mode which is bidirectional in Query Host.

Independently Test1 2.0 or Roller 20 is set on DAT 15 or BCI the protocol description for the result string "R" sent to HOST is exactly the same.

If the customer is not interested in working with Query Host, leave instrument set on BCI mode and configure ACK option set to OFF.

DAT15 and the BCI option mode can be chosen from the serial LIS network configuration menu.

Barcode

It works by an internal (IBCR) or external bar code reader (EBCR). It accepts the maximum patient identity code with 15 characters of length.

Bayer and Cycle

This field take care of the Cycle number. This field could be relating to Bayer parameter setting it by software. If Bayer is 0, the field deals with the number of Cycle otherwise if Bayer is 1, the field will contain '01' (hex 30 and 31) to maintain the Bayer protocol compatibility.

Rack number

In case of sampling and analysis on external CPS, the byte to be used is 0x00 in case of internal CPS a byte from 0x01 to 0x08 must be set which indicates the number of the rack in which the sample being analyzed is located.



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

Configuration for the correct Query protocol functioning

Option	Description
Enable ACK	If this option is enabled, the instrument waits for the ACK character when transmitting messages according to the waiting time set on the "Timeout UART " field
Timeout UART	Set the waiting time (from 2 to 99 seconds) if the increasing of the waiting time to receive "T" message and the confirmation byte (ACK) for having received "R" message is requested. The maximum time to receiving "T" message and the confirmation byte (ACK) for having received "R" message remain set to 2 seconds keeping it to OFF. If within this time no message comes in, the instrument will go ahead. This option works if ACK option, is enabled.
Enable bayer	Enable it to guarantee the Bayer protocol specifications (field Cycle/Bayer = 01). If Bayer protocol is not requested this option must be kept disable.
BCI or DAC15	If we are in BCI mode, the query is made first and then the result data is transmitted to the LIS. If we are in DAC15 mode the query is not executed but only the results data are transmitted.
Use asterisk to highlight anemia	Enable the asterisk character transmission to the host. It works when a analysed sample gives a low value of hematocrit
Use missing id	Allow the analysis of samples with an auto generated ID in case IBCR is not able to read the barcode label. Keeping it disable, these samples won't be analysed.
Unique number for multiple instrument connections	A number between 01 to 99 on each instrument can be assigned by this option if multiple instruments connections to Host computer is required

8- Query Protocol flow description valid for all Test1 2.0 or Roller 20

Following protocol is the same independently it is set the option DAT 15 or BCI.

1. The internal scanner reads the bar code (patient ID) from the label stuck on the tube, the instrument creates "Q" message and sends it to HOST computer through RS232 serial port (or to PC LAB PC if it is connected like a bridge).

```
<STX>Q01123456789 0000a<ETX>
```

2. HOST computer verifies if the patient identity code is present in the working list and, accordingly, it replies with "T" message. TEST1 waits to receiving it within two seconds and then it goes ahead. If ACK option is off, TEST1 is going to remain waiting up to 2 seconds for receiving it, otherwise if it is on, TEST1 is going to wait for all the set time (TIMEOUT from 2 to 99 seconds). "Timeout UART" time and ACK are selectable in the serial network settings menu. "T" message is going to have the result field filled with "0001", if the sample requires the analysis. The result field will be filled with "0000" if the sample doesn't require the analysis.

```
<STX>T01123456789 0001e<ETX>  
<STX>T01123456789 0000d<ETX>
```

3. After measuring (24 seconds about), Test1 2.0 or Roller 20 sends "R" message to host replacing the result field value (0001) with the ESR read value which should be between 0002 and 0120 or negative. Errors messages are reported like: -001 for SM (Sample missing), -002 for NR (Not Readable) error and -004 for NF (No flow) error.

```
<STX>R01123456789 0103050012f <ETX>  
<STX>R01123456789 010305-0041 <ETX>
```

4. Host computer should send ACK confirmation byte (♣ symbol displayed on the HyperTerminal program) to Test1 2.0 or Roller 20 for having accepted "R" message. Test1 2.0 and Roller 20 will ignore it, if ACK



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

is off. Otherwise it will wait for all the set time (TIMEOUT from 2 to 99 seconds) if ACK is On.

ACK = Hexadecimal code 06

Warnings

1. If a patient identity (ID) read by the Test1 2.0 or Roller 20 scanner doesn't find its own correspondent code in the Host computer working list, "T" message will be replaced by <NAK> message(§ symbol displayed on the HyperTerminal program). The sample will be however analysed and "R" message sent to host.

(NAK Message) Hex code 21

2. If a particular sample has a very low hematocrit (around 20% and less) and * option in the communication menu is enabled, the result field of "R" message, sent to the host, will contains an asterisk set in the first position on the left and its own ESR result

<STX>R01123456789 010305***015**[<ETX>

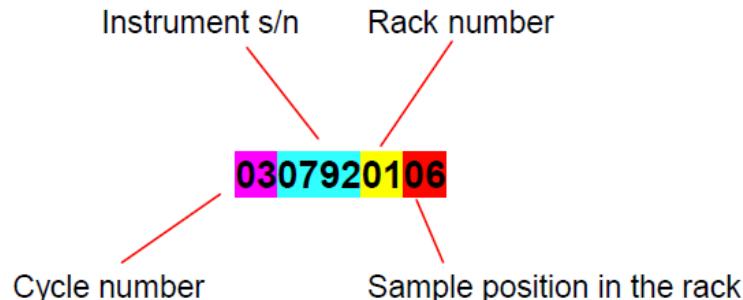
If the analysis of a particular sample generates an error and * option in the communication menu is enabled, ESR result field will contain 0 in the first left position, “-” (minus) in the second and the error code

<STX>R01123456789 010305**0-04**\<ETX>

3. If the internal scanner cannot read the patient ID and "MISS ID" option in the serial network menu setup is 0, "Q" message won't be created. The sample without its own patient identity won't be processed.
4. If the internal scanner cannot read the patient ID and "MISS ID" option in the serial network menu setup is 1, "Q" message won't be created. The sample without its own patient identity will be, however, processed and "R" message sent to host with an identity code generated by the instrument itself. The new patient ID, in this case, will be composed by 10 characters: cycle number (from 01 to 99) (2 characters), instrument s/n (4 characters), rack number (from 00 to 08 - 2 characters) sample position in the rack (from 01 to 15 - 2 characters).

Note: Rack number 00 is used for sampling and analysis on an external CPS

Example



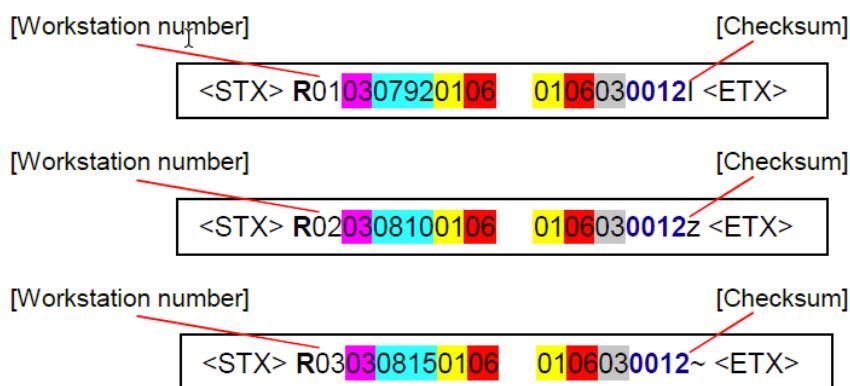
A complete "R" string for the transmission could be:

[Workstation number] [Instrument s/n] [Rack number] [ESR] [Checksum]
<STX>R01**0307920106** **010603****0012f** <ETX>
[Cycle number] [Sample position] [Cycle number (Note 2)]

9- Test1 2.0, Roller 20 Multiple connections

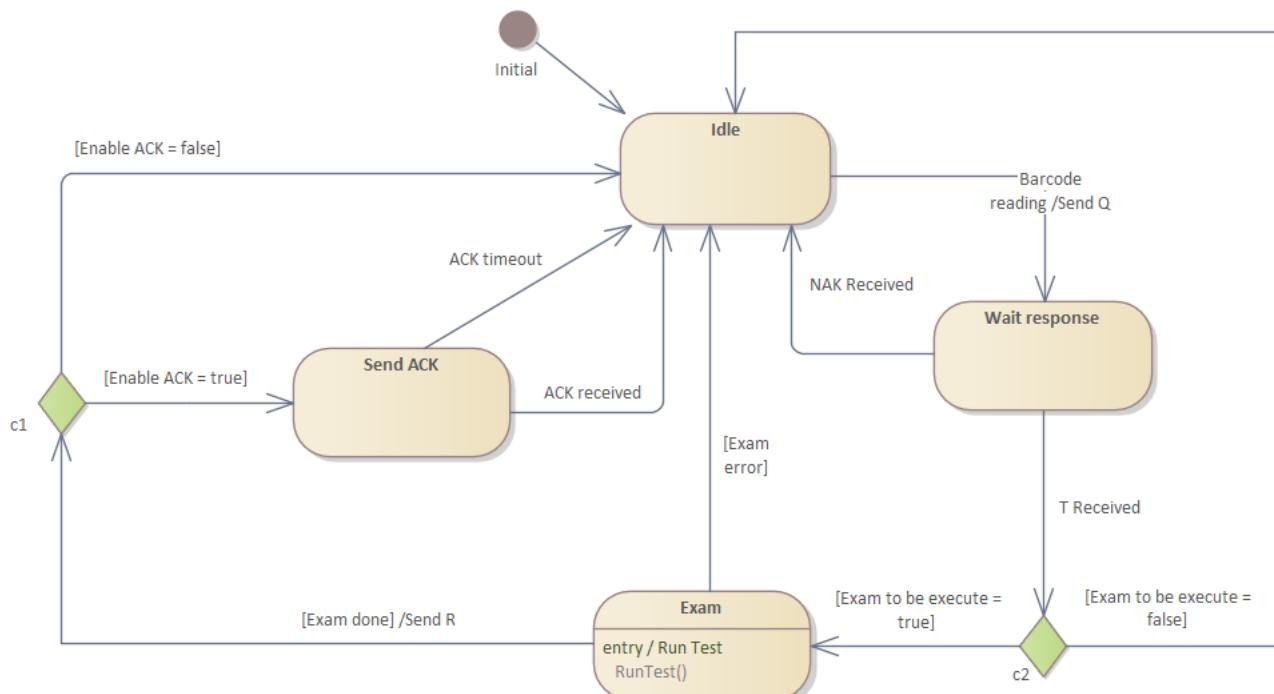
Query protocol is able to manage multiple connections by using the same PC-LAB with multiple serial ports. In that case every instrument connected to the PC-LAB has to have an identification number different for each and the PC-LAB the same number of serial ports as the instruments.

Our instruments have an option: Test1 number in the COMMUNICATION menu for Test1 2.0 models Instruments" family" to assign a different identification number to each instrument, "R" message should be different for each like in the following example:



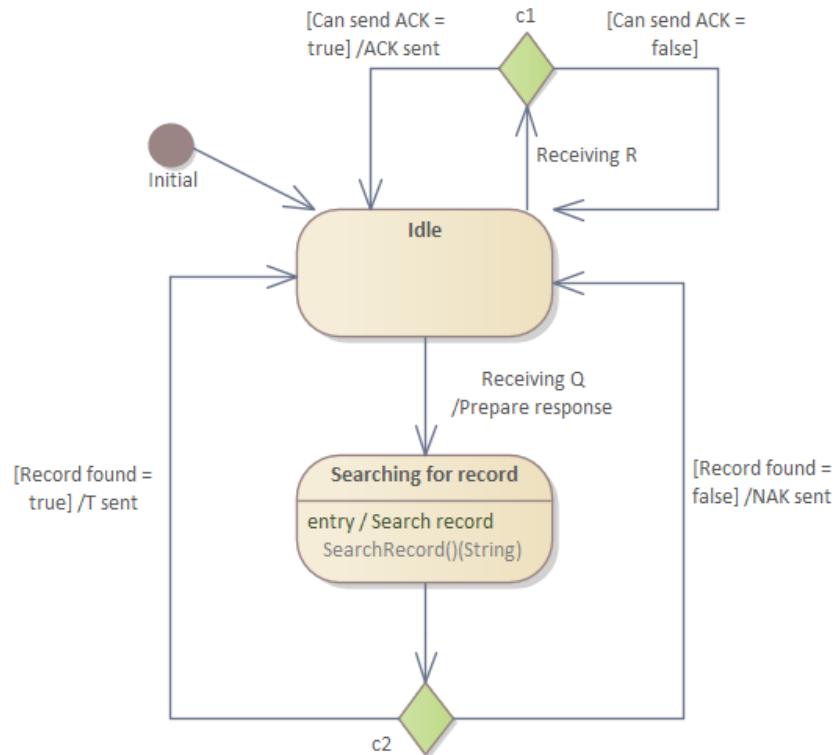
10- Appendix

Exam result state diagram (BCI mode) seen from the instrument side

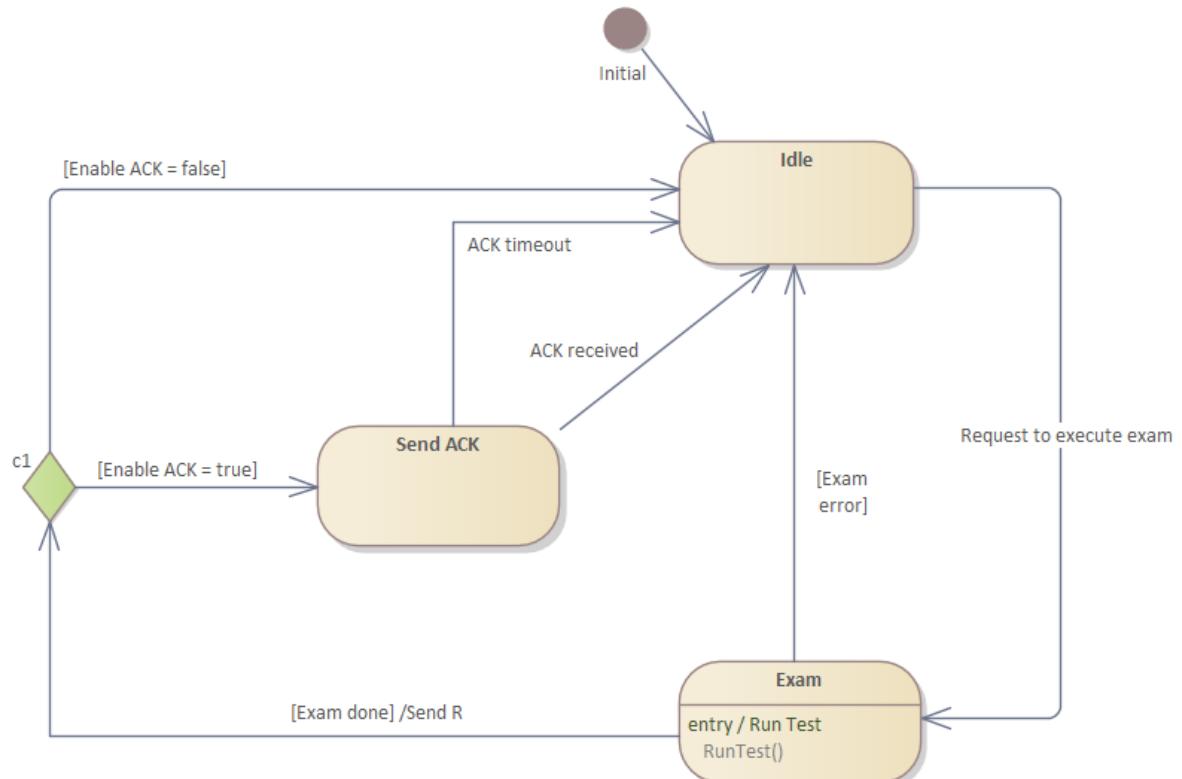


TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

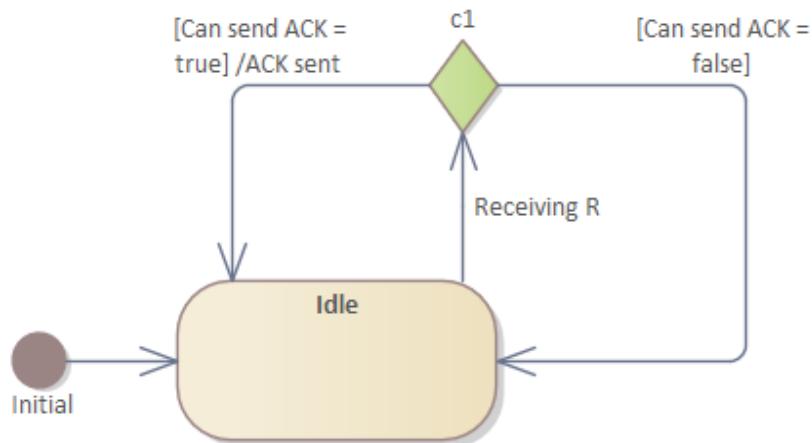
Exam result state diagram (BCI mode) seen from the LIS side



Exam result state diagram (DAC15 mode) seen from the instrument side



Exam result state diagram (DAC15 mode) seen from the LIS side



Useful tools for debugging

A PC computer with a communication program installed (like HyperTerminal of Windows) to test the instrument communications.

HyperTerminal allows the technician to check the communication messages byte by byte.

To run it follow the path: start, all programs, accessories, communication, HyperTerminal; run it and choose new connection. Type a preferred name e.g. Test1, press OK and then EXIT.

Open the curtain menu pressing File on the left upper side of HyperTerminal window and Property; a new window will be opened. Press Connection and choose the serial port where the serial cable has been connected: e.g. COM1.

Press Configuration and choose the speed which should be 9600Bps. Press OK twice.

PRODUCT TECHNICAL DATA SHEET

TEST1 2.0

Rev.1.0 - 2022-09-27

Equipment name:	TEST1 2.0 (SI 195.210/THL).
Intended Use:	<p>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.</p> <p>TEST1 2.0 provides results to inform clinical management of serious and non-serious conditions requiring further diagnostic investigation and assessment of clinical status.</p> <p>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.</p>
Principle of measure:	<p>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 ($\pm 0.5^\circ\text{C}$) / 98.6°F ($\pm 0.9^\circ\text{F}$)</p>
Results:	ESR results are displayed (and memorized) in mm/h on the range from 2 to 120 mm/h.
Configurations:	<p>TEST1 2.0 has two withdrawal systems:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>
	<p>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.</p>
	<p>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 μl.</p>
Compatibility:	TEST1 2.0 is available in two versions: <ul style="list-style-type: none"> • 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	<p>Main feature common to both versions</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ✓ 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 Vacutette® / 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
<i>Overall CV(%)</i>		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 K₃EDTA-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 K₃EDTA-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 K₃EDTA 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 m³ (36 ft³)
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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TEST1 2.0 ASTM LIS INTERFACE PROTOCOL



In Vitro Diagnostic Medical Device for professional use

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TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Index

Introduction	4
General informations	4
Glossary.....	4
Communication.....	5
TCP/IP Data Exchange	5
Lan connection	5
ASTM - Low level transfer protocol	6
Data Link layer.....	6
Establishment Phase.....	6
Transfer Phase	6
Termination Phase	7
Defective Frames	7
Timeouts	8
Restricted Characters.....	8
Transport Layer Sequence	8
ASTM – Message Layer	11
Message content.....	11
Characters	11
Maximum Field Length	11
Language.....	11
Date and Time	11
Record codes.....	11
Delimiters.....	12
Fields	12
ASTM - Record Field Contents.....	12
Records summary	12
Message Header Record (LIS02A2E chapter 6).....	13
Patient Information Record (LIS02A2E chapter 7).....	14
Test Order Record (LIS02A2E chapter 8)	16
Result Record (LIS02A2E chapter 9).....	18
Request Information Record (LIS02A2E chapter 11)	20
Message Scientific Record (LIS02A2E chapter 13).....	21
Message Comment Record (LIS02A2E chapter 10)	21
Message Manufacturer Information Record (LIS02A2E chapter 14)	21
Message Terminator Record (LIS02A2E chapter 12)	21
ASTM - Record Field Contents more details	22
Message Header Record - Processing ID explain	22
General - Record Sequence Number	23
DAC15 or BCI mode	23
Test order record explain	23
Sample ID	23
Specimen ID	23
Universal Test ID	23
Report Type	23
Result Record explain	24



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Universal Test ID	24
Data or Measurement Value.....	24
Result Status	25
Use cases and examples.....	25
LIS -> Test1 2.0 or Roller 20: control query for the exam to execute	25
Test1 2.0 or Roller 20 -> LIS : send valid results	26
Test1 2.0 or Roller 20 -> LIS : send invalid results (NR or NF).....	26
Test1 2.0 or Roller 20 -> LIS : send not processed record notice.....	27
Test1 2.0 or Roller 20 -> LIS : send not processable record notice.....	27
Test1 2.0 or Roller 20 -> LIS : send latex results	28

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.

Neither this manual nor any parts of it may be duplicated or transmitted in any way without the written approval of Alifax S.r.l.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

1- Introduction

General informations

Test1 2.0 and Roller 20 are automatic analyzers for Erythrocyte Sedimentation Rate (ESR) determination of human blood samples in-vitro. The technology applied by Alifax's ESR instrumentation is Quantitative Capillary Photometry, which allows in just 20 seconds of analysis to obtain the ESR result of the sample, expressed in mm/hour, as per guidelines and reference method.

Test1 2.0 and Roller 20 has two withdrawal systems:

- The internal one which requires that samples in tubes are inserted in the instrument using racks
- The external one which withdraws blood from open tube that must be inserted manually in an external probe.

The second system is an optional and its measurement circuit is completely separated from the first one

A laboratory information system (LIS) is a software system that records, manages, and stores data for clinical laboratories. A LIS has traditionally been most adept at sending laboratory test orders to lab instruments, tracking those orders, and then recording the results, typically to a searchable database.

The Test1 2.0 and Roller 20 software shall communicate with LIS systems using standard ASTM communication protocol.

This manual is intended to provide detailed information on how to implement communication between Test1 2.0 or Roller 20 and a LIS system.

It should assist software house companies in creating, modifying and installing their program on the host computer.

2- Glossary

Term	Definition
[]	In message formats, brackets indicate that the enclosed group of records/segments is optional.
<CR>	Carriage Return (ASCII decimal 13).
<ENQ>	ASTM Enquiry. ASCII character 5. This control character is used to establish communication between machines.
<EOT>	ASTM End of Transmission. ASCII character 4. A control character used to mark the end of a session.
<ETB>	ASTM End of Transmission Block. ASCII character 23. This control character may be used in place of ETX to distinguish between the end of a data block at a different logical (abstraction) level.
<ETX>	ASTM End of Text. ASCII character 3. This control character denotes the end of the data (text) block.
<LF>	Line Feed (ASCII Decimal 10).
<NAK>	Negative Acknowledgment (ASCII Decimal 21).
<STX>	Start of Frame (ASCII Decimal 2).
ACK	Positive Acknowledgement. For ASTM - ASCII character 6.
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Materials. In this guide, ASTM refers to the communication protocols defined by the E-1381 and E-1394 specifications noted in the references
BCI	Software application option to indicate that if enabled, before taking an exam you must make a request query to the LIS.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

CLSI	The Clinical and Laboratory Standards Institute
DAC15	Software application option to indicate that if enabled, you can perform any exam and then send the final result to the LIS.
frame	The basic unit of communication at the Data Link Layer for ASTM protocol
LIS	Laboratory Information System. The Lab Computer together with the software that runs on it viewed as a logical unit.
MISSING ID	Software application option to indicate incorrect barcode must be replaced (value = 1) or the exam must be discarded (value = 0)
Record	In reference to the low level protocol, a record is the communications packet. If the frame length is longer than 64,000 characters, then it must be split into two parts and sent in two or more communications packets. The intermediate packet uses the <ETB> character, and the ending packet uses the <ETX> character. No single communications packet contains more than one record. In reference to the message layer, it is an aggregate of fields describing one aspect of the complete message. A record will contain one of the following codes: H (header), P (patient), O (order), R (result), L (terminator), C (comment), Q (request for information), and M (manufacturer information).
Rx	Receive(r).
Sample	The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.
Specimen	Term for Sample
Tx	Transmit, Transmission, or Send(er).

3- Communication

TCP/IP Data Exchange

Protocol: TCP/IP

Electrical Characteristics: The voltage and impedance levels for the generator and receiver circuits are as specified in the IEEE 802.3 standard.

Signal Levels: The signal levels conform to the IEEE 802.3 standard.

Interface Connections: An RJ45 connection is used. The connector contact assignments conform to the ANSI EIA/TIA 568B standard (also called the AT&T specification).

Speed: The data transmission rate for the instruments shall conform to IEEE 802.3 and operate at least 10 MB/second. A computer system using TCP/IP must have the capability to conform to a minimum speed of 10 MB/second.

Lan connection

Standard LAN Cable to connect instrument to Host (LAN port), eventually the Host side could be different, so depending the configuration on Host side, one edge could be different.
Software House has the responsibility for the cable.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

4- ASTM - Low level transfer protocol

To accomplish a successful interface between the System Manager and the laboratory computer, a compatible environment, both physical and logical, must be established. At the lowest level, the physical connections must be defined and the behavior of both the sender and receiver of information must be specified.

The Low Level Protocol to use for transferring messages between the Instrument and the laboratory computer is the Clinical and Laboratory Standards Institute (CLSI) Communication Protocol: CLSI LIS1-A (formerly NCCLS LIS1-A, formerly ASTM 1381-02).

Data Link layer

The data link layer has procedures for link connection and release, delimiting and synchronism, sequential control, error detection, and error recovery as specified in CLSI LIS1-A (formerly NCCLS LIS1-A, formerly ASTM 1381-02). There are three distinct phases in transferring information between the System Manager and the laboratory computer. The three phases assure the actions of sender and receiver are coordinated. The three phases are establishment, transfer, and termination.

The data link layer uses a character-oriented protocol to send messages between directly connected systems. The data link mode of operation is one-way transfer of information with alternate supervision. Information flows in one direction at a time. Replies occur after information is sent, never at the same time. It is a simple stop-and-wait protocol. At times the two systems are actively operating to transfer information. The remainder of the time the data link is in a neutral state.

Establishment Phase

The establishment phase determines the direction of information flow and prepares the receiver to accept information. A system, which does not have information to send, normally monitors the data link to detect the establishment phase. It acts as a receiver, waiting for the other system.

The system with information available initiates the establishment phase. After the sender determines the data link is in a neutral state, it transmits the <ENQ> transmission control character. The receiver ignores any character other than <ENQ> while in the neutral state. Sender will ignore any responses to the <ENQ> other than <ACK>, <NAK>, or <ENQ>.

Receiver State	Sender		Receiver Reply	Sender Status After Receiving Response
Receiver Ready	<ENQ>	→ ←	<ACK>	Transfer phase
Receiver Not Ready	<ENQ>	→ ←	<NAK>	Wait 10 seconds, then send <ENQ> again.
Receiver sending *1	<ENQ>	→ ←	<ENQ>	*2

*1 Line Contention condition - Receiver also has information available and sent the ENQ at the same time as the sender.

*2 If Sender is the Instrument, wait 1 second and then begin establishment phase by sending <ENQ>. If Sender is the laboratory computer, the laboratory computer goes into a neutral state for a minimum of 20 seconds or until the receive message session from the System Manager is complete.

Transfer Phase

During the transfer phase, the sender transmits messages to the receiver. The transfer phase continues until all messages are sent. Messages are sent in frames. Each frame contains a maximum of 64,000 characters (including frame overhead). Messages longer than 64,000 characters are divided between two or more frames. Multiple messages are never combined in a single frame.

Every message must begin in a new frame. There are two types of frames: intermediate and end. The intermediate frames terminate with the character <ETB>, checksum, <CR><LF>. End frames terminate with <ETX>, checksum, <CR><LF>. A message containing 64,000 characters or less is sent in a single end frame. Longer messages are sent in intermediate frames with the last part of the message sent in the end frame.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Frame Number

The frame number permits the receiver to distinguish between new and retransmitted frames. It is a single digit sent immediately after the <STX> character. The frame number is an ASCII digit ranging from 0 to 7. The frame number begins at 1 with the first frame of the Transfer phase. The frame number is incremented by one for every new frame transmitted. After 7, the number rolls over to 0, and continues in this fashion.

Checksum

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters, which are sent after the <ETB>, or <ETX> character. The checksum is computed by adding the binary values of the characters, keeping the least significant eight bits of the result. The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR><LF>. The checksum is an integer represented by eight bits; it can be considered as two groups of four bits. The groups of four bits are converted to the ASCII characters of the hexadecimal representation. The two ASCII characters are transmitted as the checksum, with the most significant character first.

N.B.: It is very important that the hexadecimal checksum value sent by the LIS to the instrument is in upper case. Eg: If the checksum is 127 in hex it must be sent with 7F (7f is considered an error in receiving the message)

Acknowledgments

After a frame is sent, the sender stops transmitting until a reply is received. The receiver replies to each frame. When it is ready to receive the next frame, it transmits one of three replies to acknowledge the last frame. This reply must be transmitted within the timeout period. (See Timeouts for additional information.) A reply of <ACK> signifies the last frame was received successfully and the receiver is prepared to receive another frame. The sender must increment the frame number and either send a new frame or terminate. A reply of <NAK> signifies the last frame was not successfully received and the receiver is prepared to receive the frame again. A reply of <EOT> signifies that the last frame was successfully received; the receiver is prepared to receive another frame, but is a request to the sender to stop transmitting.

Receiver Interrupts

The receiver interrupt is a means for the receiver to request the sender to stop transmitting messages as soon as possible. During the transfer phase, if the receiver responds to a frame with an <EOT> in place of the usual <ACK>, the sender must interpret this reply as a receiver interrupt request. The <EOT> is a positive acknowledgement of the end frame, signifies the receiver is prepared to receive next frame, and is a request to the sender to stop transmitting. The sender does not have to stop transmitting after receiving the receiver interrupt request. If the sender chooses to ignore the <EOT>, the receiver must re-request the interrupt for the request to remain valid. If the sender chooses to honor the receiver interrupt request, it must first enter the termination phase to return the data link to the neutral state. This gives the receiver an opportunity to enter the establishment phase and become the sender. The original sender must not enter the establishment phase for at least 15 seconds or until the receiver has sent a message and returned the data link to the neutral state.

Termination Phase

The termination phase returns the data link to the clear or neutral state. The sender notifies the receiver that all messages have been sent. The sender transmits the <EOT> transmission control character and then regards the data link to be in a neutral state. Upon receiving <EOT>, the receiver also regards the data link to be in a neutral state.

Defective Frames

A receiver checks every frame to guarantee it is valid. A reply of <NAK> is transmitted for invalid frames. Upon receiving the <NAK>, the sender retransmits the last frame with the same frame number. In this way, transmission errors are detected and automatically corrected. The receiver ignores any characters occurring before the <STX> or <EOT> or after the end of the block character <ETB> or <ETX> when checking the frame. A frame should be rejected because:

1. Any character errors are detected (parity error, framing error, etc.)
2. The frame checksum does not match the checksum computed on the received frame
3. The frame number is not the same as the last accepted frame or one number higher (modulo 8).

Upon receiving a <NAK> or any character except an <ACK> or <EOT> (a <NAK> condition), the sender increments a retransmit counter and retransmits the frame. If this counter shows a single frame was sent and not



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

accepted six times, the sender must abort this message by proceeding to the termination phase. An abort should be extremely rare, but it provides a mechanism to escape from a condition where the transfer phase cannot continue.

Timeouts

The sender and receiver both use timers to detect loss of coordination between them. If a reply of an <ACK>, <NAK>, or <ENQ> is not received within 15 seconds, a timeout occurs. After a timeout, the sender enters the termination phase.

During Establishment Phase

During the establishment phase, if the computer (as receiver) detects contention, it sets a timer. If an <ENQ> is not received within 20 seconds, a timeout occurs. After a timeout, the receiver regards the line to be in the neutral state.

During the Transfer Phase

During the transfer phase, the sender sets a timer when transmitting the last character of a frame.

If a reply is not received within 15 seconds, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the termination phase. As with excessive retransmissions of defective frames, the message must be remembered so it can be completely repeated.

Receiver Waiting for Frame

During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or <EOT> is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete message and regards the line to be in the neutral state.

Sender Wait on Reply

A receiver must reply to a frame within 15 seconds or the sender will timeout. A receiver can delay its reply for up to 15 seconds to process the frame. Longer delays cause the sender to abort the message.

Receivers that cannot process messages fast enough to keep up with a sender may cause message buffer overflows in the sender. A sender can normally store at least one complete message. Storage space for more than one outgoing message is desirable but optional.

Restricted Characters

The data link protocol is designed for sending character-based message text. Restrictions are placed on which characters may appear in the message text. The restrictions make it simpler for senders and receivers to recognize replies and frame delimiters. Additional characters are restricted to avoid interfering with software controls for devices such as multiplexers.

An <LF> character is not permitted to appear in the message text; it can appear only as the last character of a frame. None of the ten transmission control characters, the <LF> format effector control character, or four device control characters may appear in message text. The restricted characters are: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3>, and <DC4>.

Transport Layer Sequence

The following tables illustrate a transport layer sequence:

Normal Session	Sender	Receiver
Establishment Phase	<ENQ>	→ ← <ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR><LF> Frames continue until entire message sent	→ ← <ACK>
Termination Phase	<EOT>	→ No response Expected

TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Delay Request Session (NAK)	Sender		Receiver
Establishment Phase	<ENQ>	→	
		←	<NAK>
	(Delay 10 seconds)		
	<ENQ>	→	
		←	<ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
	frames continue until entire message sent	←	<ACK>
Termination Phase	<EOT>	→	No Response Expected

Failure Session (Max <NAK>s)	Sender		Receiver
Establishment Phase	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
	<ENQ>	→	
	(Delay 10 seconds)	←	<NAK>
Termination Phase	<EOT>	→	No Response Expected

Failure Session (No Response)	Sender		Receiver
Establishment Phase	<ENQ>	→	
	(Time-out after 15 seconds)		No Response
Termination Phase	<EOT>	→	No Response Expected

Retransmission Request (Multiple <NAK>s)	Sender		Receiver
Establishment Phase	<ENQ>	→	
		←	<ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
		←	<NAK>



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→	
	frames continue until entire message sent	←	<ACK>
Termination Phase	<EOT>	→	No Response Expected

Failure Session (Max <NAK>s)	Sender	Receiver
Establishment Phase	<ENQ>	→
		← <ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <NAK>
Termination Phase	<EOT>	→ No Response Expected

Failure Session (Receiver Timeout During Transfer)	Sender	Receiver
Establishment Phase	<ENQ>	→
		← <ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← No Response within 15 seconds
Termination Phase	<EOT>	→ No Response Expected

Failure Session (Sender Timeout During Transfer Phase)	Sender	Receiver
Establishment Phase	<ENQ>	→
		← <ACK>
Transfer Phase	<STX> [frame number] [DATA] <ETX> [C1] [C2] <CR> <LF>	→
		← <ACK>
Termination Phase	No Frame sent within 30 seconds	→ No Response Discards



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

		incomplete message and assumes neutral state.
--	--	---

5- ASTM – Message Layer

This section conforms with CLSI LIS2-A (formerly NCCLS LIS2-A, formerly ASTM 1394-97). The intent of this section is to develop a complete understanding of the particular records and fields as supported by the Instrument. The low level protocol communications are separate from the message level.

Message content

Characters

All data must be represented as 8-bit, single-byte coded graphic character values, as defined in ISO 8859-1: 1987. The eight-bit values, between 0 and 127 of ISO 8859-1: 1987, correspond to the standard ASCII character set. Values from 0 to 31 are not allowed except for 7 (BEL), 9 (Horizontal Tab), 11 (Vertical Tab) and 13 (CR), where 13 is reserved as the record terminator. Values from 32 to 126 and 128 to 254 are allowed. Values 127 and 255 are not allowed. It is the responsibility of the instrument vendor and the information system vendor to understand the representation of any other extended or alternative character sets to be used. For example, the numeric value 13.5 would be sent as four-byte 13.5 or Latin-1 (49), Latin-1 (51), Latin-1 (46), and Latin-1 (53) characters.

Allowed characters: 7, 9, 11, 12, 13, from 32 to 126, from 128 to 254 Not allowed characters: from 0 to 6, 8, 10, from 14 to 31, 127, 255

In text data fields, only Latin-1 characters 32 through 126 and undefined characters 128 through 254 are allowed (excluding those used as delimiter characters in a particular transmission).

In addition, all characters used as delimiters for a particular transmission are excluded from the allowed range. The sender is responsible for screening all fields of text data to ensure that the text does not contain these delimiters. Unless otherwise indicated, the content of the data fields must be case-sensitive.

Maximum Field Length

While no maximum field length is imposed within the low level protocol mechanism, the parser restricts the fields' length because of the 64,000 byte frame limit. See the record tables in this document for specific field restrictions.

Language

Most user-entered fields will be transmitted in the localized language. All other fields that will be transmitted to and from instrument must be in English.

Further on you will find: Record Field Contents lists the acceptable values for each field.

Date and Time

In all cases, the dates must be recorded in the YYYYMMGG format as required by ANSI X3.30. December 1, 1989 would be represented as 19891201. When times are transmitted, they must be represented as HHMMSS and must be linked to dates as specified by ANSI X3.43.3. The date and time together must be specified as a 14-character string: YYYYMMGGHHMMSS.

Record codes

The following codes are required in relation to the ASTM standard:

Record name	Record code	Notes
Message Header Record	H	Fully Implemented
Patient Information Record	P	Fully Implemented
Test Order Record	O	Fully Implemented
Result Record	R	Fully Implemented
Comment record	C	Fully Implemented
Request Information Record	Q	Fully Implemented
Message Terminator Record	L	Fully Implemented
Scientific record	S	Fully Implemented
Manufacturer Information Record	M	Not implemented



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Delimiters

The ASCII characters that follow the H (Header Record Identifier) define the unique field, repeat, component, and escape delimiters that are used in the message. Alphanumeric characters should not be used as delimiters because they are likely to appear within the field content.

The following are recommended delimiters for all messages.

Scope	Character	Description	Reference
Field delimiter		vertical bar	Latin 1 (124)
Repeat delimiter	\	backslash	Latin 1 (92)
Component	^	spacing circumflex accent	Latin 1 (94)
Escape delimiter	&	ampersand	Latin 1 (38)

Fields

Fields shall be identified by their position, obtained by counting field delimiters from the front of the record. This position-sensitive identification procedure requires that when the contents of the field are null, its corresponding field delimiter must be included in the record to ensure that the correct field can be found by counting delimiters. Delimiters are not included for trailing null fields or for trailing fields with data. That is, if the tenth field was the last field containing data, the record could terminate after the tenth field, and therefore would contain only nine delimiters. (Note: NULL in this context is not a character but is the lack of any characters for the field). The laboratory computer may transmit a null value for a field because:

1. it does not know the value
2. it knows the value is irrelevant to the Instrument, or
3. the Instrument defaults are to be used for the value.

6- ASTM - Record Field Contents

This section lists the following records and the fields they contain:

- Message Header Record
- Patient Information Record
- Test Order Record
- Result Record
- Request Information Record
- Message Terminator Record

Following each record is a list of the requirements and general considerations regarding the contents of one or more fields of the record.

Following field definitions apply to all records and fields:

Definition	Description
+	Mandatory filed
*	Optional field
empty	Field not used (but set to null)
TX	Transmission (from instrument to LIS)
RX	Reception from (LIS to instrument)
other characters	Exactly those characters must appear in the field
Not supported	Field not supported or implemented

Records summary

Only the records implemented/managed by the component are illustrated below; the other records foreseen by the specific (for example the C record of the comments) are not used but their possible presence is not affects the correct functioning of the system.

The TX and RX columns indicate how the corresponding field is implemented:

- the symbol "+" indicates that the field is implemented and mandatory
- the symbol "*" (asterisk) indicates that the field is optional



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

- other symbols represent the EXACT value that is expected to be present (if in RX) or will be present (if in TX), or a description of what to enter in the field
- the absence of symbols indicates that the field is not used (generally the unused fields are also indicated in gray).

The USE column explains how the corresponding field has been implemented. It can also indicate the exact value that will be transmitted or expected to be received. A very common syntax, called Backus-Naur Form, has often been used to generally describe the data received or transmitted; briefly this syntax can be explained with the following examples:

1. <surname>^<name> means that the surname and name data are present separated by the symbol “^” (example: rossi^mario)
2. <surname>^[<name>] means that the surname and the symbol “^” are certainly present but the name is optional (both valid examples: rossi^ and rossi^mario).

(For more info on this, see: https://it.wikipedia.org/wiki/Backus-Naur_Form)

Message Header Record (LIS02A2E chapter 6)

The header (Header Record) must contain the identifiers of the sender and the recipient.

The message header is a zero level record and must be followed at some point by a message terminator record before ending the session or passing another Header record. This type of record must always be the first record in a broadcast.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	RX instrument	TX instrument values	RX instrument values
Record Type ID (6.1)	H identify the record type: message header.	+	+	H	H
Delimiter definition (6.2)	These characters identify: <ul style="list-style-type: none">• the field delimiter character• the delimiter of repetitions• the component delimiter• the escape character On RX these characters are defined by the user; on TX default characters are implemented	+	+	^&	That of LIS
Message Control ID (6.3)	Supported	empty	empty		
Access Password (6.4)	Supported	empty	empty		
Sender Name Or ID (6.5)	Sender Name Or ID True True This field identifies the specific manufacturer / instrument (s) used. By using the repeat and / or component delimiter character this field can reflect the revision of the software or firmware, multiple instruments connected to the line, etc ...	+		ALIFAX^ESR^<Serial Number> <Serial Number> is the Serial Number of the instrument	



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Sender Street Address (6.6)	Supported	empty	empty		
Reserved files (6.7)	Supported	empty	empty		
Sender Telephone Number (6.8)	Supported	empty	empty		
Characteristics of Sender (6.9)	Supported	empty	empty		
Receiver ID (6.10)	Supported	empty	empty		
Comment or Special Instructions (6.11)	Supported	empty	empty		
Processing ID (6.12)	The process ID indicates how this message will be processed: P - Production: considers the message as an active message to be completed according to standard processing. T - Training: the message is initiated by a trainer and should not affect the system. D - Debug: the message is started for the purpose of a debug program. Q - Quality control: the message is initiated for the purpose of transmitting quality control / safety control or regulatory data.	+	+	P, D	P, D
Version Number (6.13)	Version level of the LIS specification (the current is LIS2-A2)	+	+	LIS2-A2	LIS2-A2
Date and Time of Message (6.14)	Date and time the message was generated (see chapter 5.6.2 of LIS02A2E).	+	*	Current date and time Format: YYYYMMDDHH MMSS	Current date and time Format: YYYYMMDDHH MSS

Patient Information Record (LIS02A2E chapter 7)

Each patient data line must start with the record type and end with a carriage return.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	RX instrument	TX instrument values	RX instrument values
Record type ID (7.1)	P identify the record of type: patient information 2.0.	+	+	P	P
Sequence number (7.2)	For the first patient transmitted it must be 1, for the second 2,... until the last one is defined (see chapter 5.6.7 of LIS02A2E).	+	+	numerical sequence	numerical sequence

TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Practice-Assigned Patient ID (7.3)	<p>This field must be the unique identifier assigned and used for practice to identify the patient and his results following the tests</p> <p>This identifier must be unique and used to identify the processing process number assigned to the patient by the laboratory.</p>	*	*	<ID paziente>	Equal
Laboratory-Assigned Patient ID (7.4)	Supported	empty	empty		
Patient ID Number 3 (7.5)	Supported	empty	empty		
Patient Name (7.6)	Supported	*	*	<surname> [^] <name>	Equal
Mother's Maiden Name (7.7)	Supported	empty	empty		
Birthdate (7.8)	Supported	empty	empty		
Sex (7.9)	Supported	empty	empty		
Patient Race-Etnic Origin (7.10)	Supported	empty	empty		
Patient Address (7.11)	Supported	empty	empty		
Reserved Fields (7.12)	Supported	empty	empty		
Patient Telephone Number (7.13)	Supported	empty	empty		
Attending Physician ID (7.14)	Supported	empty	empty		
Special Field 1 (7.15)	Supported	empty	empty		
Special Field 2 (7.16)	Supported	empty	empty		
Patient Height (7.17)	Supported	empty	empty		
Patient Weight (7.18)	Supported	empty	empty		
Patient's Known or Suspected Diagnosis (7.19)	Supported	empty	empty		
Patient Active Medications (7.20)	Supported	empty	empty		
Patient's Diet (7.21)	Supported	empty	empty		
Practice Field Number 1 (7.22)	Supported	empty	empty		
Practice Field Number 2 (7.23)	Supported	empty	empty		
Admission and discharge dates (7.24)	Supported	empty	empty		
Admission Status (7.25)	Supported	empty	empty		
Location (7.26)	Supported	empty	empty		
Nature of Alternative Diagnostic Code and Classifiers (7.27)	Supported	empty	empty		
Alternative Diagnostic Code and Classification (7.28)	Supported	empty	empty		
Patient Religion (7.29)	Supported	empty	empty		
Marital Status (7.30)	Supported	empty	empty		
Isolation Status (7.31)	Supported	empty	empty		
Language (7.32)	Supported	empty	empty		
Hospital Service (7.33)	Supported	empty	empty		
Hospital Institution (7.34)	Supported	empty	empty		
Dosage Category (7.35)	Supported	empty	empty		

Test Order Record (LIS02A2E chapter 8)

The test order record registration defines the attributes of a particular request for the services of a clinical instrument and contains all information about the samples. The system information will generate an order record to request a specific test, battery or test set. The information in an order record usually applies to a single sample. However, there is not necessarily a one-to-one relationship between the sample and the ordered tests. Different test groups are usually sorted into different order records even when they can be performed on a single sample. In this case, the sample information is duplicated in each of the order records that employ that sample.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	RX instrument	RX instrument values	TX instrument values
Record type ID (8.4.1)	O identify the record type: order record.	+	+	O	O
Sequence number (8.4.2)	For the first order transmitted it must be 1, for the second 2,... until the last one is defined (see chapter 5.6.7 of LIS02A2E).	+	+	numerical sequence	numerical sequence
Specimen ID (8.4.3)	This text field must represent a unique identifier for the sample assigned by the information system and returned by the instrument. If the sample has multiple components which further identify the crops derived therefrom, these component identifiers will follow the sample ID and be separated from the component delimiters. For example, the sample ID may contain the sample number followed by the isolated number, the well or the cup number (e.g. 10435A ^ 01 ^ 64).	+	+	<sample ID> or the text string "LATEX" in case of latex	Equal
Instrument Specimen ID (8.4.4)	Supported	empty	empty		
Universal Test ID (8.4.5)	This field must be used as described in the chapter 5.6.1 of LIS02A2E	+	*	^^<ExamName> ExamName allowed Value: "ESR"	Equal
Priority (8.4.6)	Supported	empty	empty		
Requested/Ordered Date and Time (8.4.7)	Supported	empty	empty		
Specimen Collection Date and Time (8.4.8)	Supported	empty	empty		



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Collection End Time (8.4.9)	Supported	empty	empty		
Collection Volume (8.4.10)	Supported	empty	empty		
Collector ID (8.4.11)	Supported	empty	empty		
Action Code (8.4.12)	Supported	empty	empty		
Danger Code (8.4.13)	Supported	empty	empty		
Relevant Clinical Information (8.4.14)	Supported	empty	empty		
Date/Time Specimen received (8.4.15)	Supported	empty	empty		
Specimen descriptor (8.4.16)	Supported	empty	empty		
Ordering Physician (8.4.17)	Supported	empty	empty		
Physician's Telephone Number (8.4.18)	Supported	empty	empty		
User Field Number 1 (8.4.19)	Supported	empty	empty		
User Field Number 2 (8.4.20)	Supported	empty	empty		
Laboratory Field Number 1 (8.4.21)	Supported	empty	empty		
Laboratory Field Number 2 (8.4.22)	Supported	empty	empty		
Date/Time Results Reported or Last Modified (8.4.23)	Supported	empty	empty		
Instrument Charge to Information System (8.4.24)	Supported	empty	empty		
Instrument Section ID (8.4.25)	Supported	empty	empty		
Report Types (8.4.26)	Type of report code	+	+	O, Y, Z O – order record Y – no record order for this (in response to query) Z – the exam is not to be done	F, X F – final results X – order cannot be done, order cancelled
Reserved Fields (8.4.27)	Supported	empty	empty		
Location of Specimen Collection (8.4.28)	Supported	empty	empty		
Nosocomial Infection Flag (8.4.29)	Supported	empty	empty		
Specimen Service (8.4.30)	Supported	empty	empty		
Specimen Institution (8.4.31)	Supported	empty	empty		



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Result Record (LIS02A2E chapter 9)

Result Record

FIELD NAME (LIS02A2E chap-ter)	USE	TX instrument	TX instrument values
Record Type ID (9.1)	R identify the record type: result record.	+	R
Sequence Number (9.2)	For the first result transmitted it must be 1, for the second 2,... until the last one is defined (see chapter 5.6.7 of LIS02A2E).	+	numerical sequence
Universal Test ID (9.3)	This field must be used as described in the chapter 5.6.1 of LIS02A2E	+	In case of result, ESR measure: ^^<ExamName> ^<measure_name> ExamName allowed Value: "ESR" Same as order: parent order Universal Test ID Measure_name: For the admitted values see chapter "<measure_name> values" In case of latex measurement result: ^^<ExamName> ^latex^<latex lot>^<latex number>
Data or Measurement Value (9.4)	If numeric, textual or coded values, the data must be recorded in ASCII textual notation. If the data result contains qualifying elements of equal stature, they should be separated by component delimiters. This strictly applies to results of an identical nature (that is, this field may not contain implicit secondary values). The use of components within this field should be avoided whenever possible. Multiple results or values, observed, calculated or implied, for a single test order (e.g. MIC or interpretation codes from a single antibiotic sensitivity test) must be reported in separate result records with each definition uniquely defined by the field previous Universal Test ID. Consequently, this field must be sufficiently descriptive to determine the placement of the data value with reference to the original test order record and other result records associated with this test order record.	+	<measure_value> measure_value must be numeric For the admitted values and ranges see chapter "<measure_name> values"
Units (9.5)	Supported	+	mm/h for ESR measure pure number for other measures



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Reference Ranges (9.6)	Supported	+	In case of latex measurement result: <latex ESR expected value>
Result Abnormal Flag (9.7)	Supported	empty	
Nature of Abnormality Testing (9.8)	Supported	empty	
Result Status (9.9)	The following codes must be used: C - correction of previously transmitted results P - preliminary results F - final results X - the order cannot be executed I - still in the tool, waiting for results S - partial results M - this result is a MIC level R - this result has been previously passed on N - this result record contains the information necessary to execute a new order NOTE: For example, when ordering a sensitivity, the information system can download a record of results containing the type of organism or species identified in a previous test. D - this result is a response to a pending query V - result verified / approved by the operator (validated) W - attention: validity is questionable	+	F, X
Date of Charge in Instrument Normative Values or Units (9.10)	Supported	empty	
Operator Identification (9.11)	Supported	+	<first_name last_name> of logged operator or "Unknown Operator"
Date/Time Test Started (9.12)	Supported	+	Date/Time of start YYYYMMDDHHMMSS
Date/Time Test Completed (9.13)	Supported	+	Date/Time of end YYYYMMDDHHMMSS
Instrument Identification (9.14)	Supported	+	ALIFAX^ESR^<serial number>^<internal or external> <serial number> is the serial number of the product <internal or external> indicates whether the

		measurement was carried out by the external or internal cps
--	--	---

Request Information Record (LIS02A2E chapter 11)

The Request Information Record is used by the clinical tool or by the information system to request information remotely from the reciprocal system. NOTE: only one request of one record at a time can be left pending; the recipient of the record request must end the request when it has finished, by means of the message termination record, or it is the sender who must cancel the current request before sending a second logical request.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	TX instrument values
Record Type ID (11.1)	Q identify the record type: query record.	+	Q
Sequence Number (11.2)	For the first query record transmitted it must be 1, for the second 2,... until the last one is defined (see chapter 5.6.7 of LIS02A2E).	+	Numerical sequence
Starting Range ID Number (11.3)	<p>This field may contain three or more components to define a range of patient/sample/manufacturer selection criteria. The first component is the patient ID number of the information system. The second component is the sample ID number of the information system. Any additional components are defined by the manufacturer for the use of requests for additional information (i.e. a single isolated sample or a battery of samples). These components depend on the location. A list of sample IDs may be required using the repeat delimiter to separate the IDs.</p> <p>When "ALL" is entered and the information system sends the order record, it is understood that all sample results are requested by the requesting system. If the instrument is generating the order record, it means that all required demographics and tests must be sent to the instrument at this time. The request is then interpreted for that identified subset of samples and subsequently modified by the test specifications and date ranges as described below.</p> <p>This specification does not indicate how long data should be stored by an instrument, and does not require that the instrument provide you with implicit search services for some content in the fields. The appropriate response for a result request is simply to return a subset of results that are currently in memory and that can be practically retrieved.</p>	+	ALL or ^Specimen ID
Ending Range ID Number (11.4)	Supported	empty	empty
Universal Test ID (11.5)	Supported, empty	+	ALL if requesting a specific Specimen ID
Nature of Request Time Limit (11.6)	Supported	empty	empty
Beginning Request Result Date and Time (11.7)	Supported	+	Beginning of day YYYYMMHHMS S



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Ending Request Result Date and Time (11.8)	Supported	empty	empty
Requesting Physician Name (11.9)	Supported	empty	empty
Requesting Physician Telephone Number (11.10)	Supported	empty	empty
User Field Number 1 (11.11)	Supported	empty	empty
User Field Number 2 (11.12)	Supported	empty	empty
Request Information Status Codes (11.13)	The following codes must be used: C - correction of previously transmitted results P - preliminary results F - final results X - impossible to get results, request canceled I - request pending results S - partial / not finalized results request M - the result is a MIC level R - this result has been previously passed on A - cancel / cancel the criteria of the last request (allows to follow a new request) N - request only for new or modified results O - request for test requests and demographics only (no results) D - request for demographic data only (e.g. patient's medical record)	+	O

Message Scientific Record (LIS02A2E chapter 13)

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	TX instrument values
All fields	Supported	empty	empty

Message Comment Record (LIS02A2E chapter 10)

FIELD NAME (LIS02A2E chapter)	USE	RX instrument	RX instrument values
All fields	Supported	empty	empty

Message Manufacturer Information Record (LIS02A2E chapter 14)

NOT IMPLEMENTED

Message Terminator Record (LIS02A2E chapter 12)

This is the last record in the message. A new Message Header Record can be sent after this record and means the start of a second message.

FIELD NAME (LIS02A2E chapter)	USE	TX instrument	RX instrument	TX instrument values	RX instrument values



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

Record Type ID	L identify the record type: message terminator.	+	+	L	L
Sequence Number	This field is described in chapter 5.6.7 of LIS02A2E. (For this type of record the value of this field must always be "1")	+	+	1	1
Termination Code	<p>This field provides the reason for the end of the session:</p> <p>Nil, N - normal termination T - interrupted by sender R - the receiver requested the interruption E - unknown system error Q - error in the last request for information I - there is no information available since the last query F - last request for information processed</p> <p>NOTE: I or Q will terminate the request and allow you to process a new one</p>	+	+	N	N

7- ASTM - Record Field Contents more details

Message Header Record - Processing ID explain

This field can have the following values:

"P": indicates that the data to be sent and received are production data: it considers the message as an active message to be completed according to standard processing.

"D": indicates that the data to be sent and received are debug data;

Messages received with this type of communication must not contain or be obscured from any sensitive personal data.

The data do not include any of the following 18 identifiers (of the individual or his/her relatives, household members, or employers) that could be used alone or in combination with other information to identify the subject:

- Names
- Geographic subdivisions smaller than a state (including zip code)
- All elements of dates except year (unless the subject is greater than 89 years old)
- Telephone numbers
- Fax numbers
- E-mail address
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers including license plates
- Device identifiers and serial numbers (patient care devices)
- URLs
- Internet protocol addresses
- Biometric identifiers (fingerprint, retina scan)
- Full face photos and comparable images
- Any unique identifying number, characteristic, or code



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

General - Record Sequence Number

This is a required field used in record types that can appear multiple times in a single message. The number used defines the 1st occurrence of the type of record associated with a certain hierarchical level and is reset to one (lower number) each time a record with a higher hierarchical meaning is transmitted or if the same record is used at a different one hierarchical level.

Example:

```
H|^&|||Alifax TEST1 2.0 123456|||||P|LIS2-A2|20191202112454
P|1|PAT-268-OH|||Azzan^Rudy||19781210|M
O|1|347845992OB|^^^ESR||||||||||||||F
    R|1|^^^ESR^ESR|52|mm/h|||F|mario
rossi|20210706125024|20210706125316|ALIFAX^ESR^123456
    R|2|^^^ESR^ lowHematocrit|0| |||F|mario
rossi|20210706125024|20210706125316|ALIFAX^ESR^123456
.....
P|2|PAT-269-OH|||Ceschia^Marco||19761012|M
O|1|747839192OB|^^^ESR||||||||||||||F
    R|1|^^^ESR^ESR|97|mm/h|||F|mario
rossi|20210706125224|20210706125616|ALIFAX^ESR^123456
    R|2|^^^ESR^ lowHematocrit|0| |||F|mario
rossi|20210706125224|20210706125616|ALIFAX^ESR^123456
.....
L|1|N
```

DAC15 or BCI mode

As for the serial protocol, it will be possible to set the machine in DAC15 or BCI mode.

In BCI mode the machine will query the host before taking an exam. In DAC15 mode, on the other hand, no query will be made but at the end of the examination the results will still be sent to the LIS.

Test order record explain

Sample ID

Test 1 2.0 or Roller 20 identifies the sample or the latex by its barcode value.

Specimen ID

In the case of an order concerning an ESR measurement, this is the barcode of the tube. In case of a measurement result relating to latexes, the text string 'LATEX' will always be.

Universal Test ID

The Test1 2.0 or Roller 20 expects to receive an Order Record with TestID that contains at least 1 component with value = "ESR" (not case sensitive)
"^^^ESR"

Report Type

Value	Description	Direction
F	We are sending the results found to the LIS	TX
X	Order cannot be done or cancelled	TX
O	Used for transmission of the Order record from the LIS after the query request	RX
Y	No record order for this (in response to query)	RX
Z	Record found but the exam is not be done	RX



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

**N.B.: In case the record order contains Report Type "X" in TX direction the "Result record" messages containing cycle, position and rack number data will still be sent.
The "Result Status" field of "Result record" will contain the value "X".**

Result Record explain

Universal Test ID

The Test1 2.0 or Roller 20 uses the parent Order Record Test ID appending to it (adding 1 component to the Test ID) the name of the measured value.

In case of result, ESR measure:

"^^^ESR^<measure_name>"

<measure_name> values

Measure type	Description	Max range value	Min range value	Notes
esr	The esr measure value	120	2	Special admitted values - 2 NR (Not Readable), -4 NF (No flow)
lowHematocrit	Indicates the presence of anemia if it is 1	1	0	value 1 means true, value 0 means false
position	Sample position in the rack	15	1	
rackNumber	Sample rack number	8	1	
cycle	Sample cycle number	99	1	
latex	(only in the case of latex measurement) The esr measure value	120	2	

In case of latex measurement result will be "latex" with the current lot number and the current latex number next to it:

"^^^ESR^latex^<latex lot>^<latex number>"

<latex lot>

Identification code of the latex lot.

<latex number>

Identification number of the latex tube. It can be: 1, 2 or 3.

NOTE: In case of control with latexes the results will be sent at the end with a single message containing three "R" records.

Data or Measurement Value

<measure_value>

All results reported to LIS by Test1 2.0 or Roller 20 are numerical values, as reported by the test unit.

The only measure with a measurement unit is the ESR value (mm/h). The other measures are pure numbers, except in the case of "Low Hematocrit".

The result with "measure name" = "ESR" returns a numerical value "measure value" ranging from 2 to 120 except in two cases that indicate the following anomalies in the measure:

"-2": for NR (Not Readable) error:

It means that it is not possible to carry out the test due to problems with the processing of the sample (it has processed it but has not obtained a valid ESR value).

"-4": for NF (No flow) error:

It means it didn't find the blood, as if there was an empty or partial test tube.



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

The result with "measure_name" = "lowHematocrit" can have the values "measure_value" 1 ("true") or 0 ("false") which indicate that a sample has a very low hematocrit value and therefore we are in the presence of anemia. If "lowHematocrit" is 0 this record can also be omitted from the result transmission.
All the values of "measure_value" are of numeric type.

Result Status

Value	Description	Direction
F	The result is valid and ready for the LIS	TX
X	If the barcode has not been read correctly and the machine is set in MISSING ID = 0 mode, the exam is not performed and the LIS is notified via this parameter	TX

Use cases and examples

LIS -> Test1 2.0 or Roller 20: control query for the exam to execute

This situation occurs in response to the Test1 2.0 or Roller 20 request for the test record with a certain unique identifier.

1. Test1 2.0 or Roller 20 requests a test records to LIS sending: Message Header Record, Request Information Record and Message Terminator Record

ASTM Message	Record
H ^\& 5026 ALIFAX^ESR^12345 P LIS2-A2 20220210142127	Message Header Record
Q 1 ^41c5624116 ALL 20220210000000 O	Request Information Record
L 1 N	Message Terminator Record

2. LIS replies with data sending to Test1 2.0 or Roller 20: Message Header Record, Patient Information Record, Test Order Record, Message Terminator Record

ASTM Message	Record
H ^\& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1 782 Jerde^Roberto	Patient Information Record
O 1 41c5624116 ^\^ESR O	Test Order record
L 1 N	Message Terminator Record

3. If the order is not found, the LIS replies with this data sending to Test1 2.0 or Roller 20: Message Header Record, Patient Information Record, Test Order Record, Message Terminator Record

ASTM Message	Record
H ^\& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1	Patient Information Record



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

O 1 41c5624116 Y	Test Order record
L 1 N	Message Terminator Record

4. If the order is found, but the exam is not to be done the LIS replies with this data sending to Test1 2.0 or Roller 20: Message Header Record, Patient Information Record, Test Order Record, Message Terminator Record

ASTM Message	Record
H ^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1	Patient Information Record
O 1 41c5624116 Z	Test Order record
L 1 N	Message Terminator Record

Test1 2.0 or Roller 20 -> LIS : send valid results

This situation occurs when Test1 2.0 or Roller 20 successfully identifies the sample.

Case 1: result is valid

ASTM Message	Record
H ^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1 782 Jerde^Roberto	Patient Information Record
O 1 41c5624116 ^^^ESR F	Test Order record
R 1 ^^^ESR^esr 39 mm/h F Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 2 ^^^ESR^lowHematocrit 0 F Admin 20220720122514 20220720122600 ALIFAX^ESR^12345^internal R 3 ^^^ESR^position 2 F Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 4 ^^^ESR^rackNumber 1 F Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 5 ^^^ESR^cycle 5 F Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal	Result Record
L 1 N	Message Terminator Record

Test1 2.0 or Roller 20 -> LIS : send invalid results (NR or NF)

This situation occurs when Test1 2.0 or Roller 20 fails to identify the sample

Case 2: result invalid

ASTM Message	Record
--------------	--------



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

H ^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1 782 Jerde^Roberto	Patient Information Record
O 1 41c5624116 ^ESR F	Test Order record
R 1 ^ESR^esr - 2 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12345^internal Or R 1 ^ESR^esr - 4 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12345^internal ... L 1 N	Result Record
L 1 N	Message Terminator Record

Test1 2.0 or Roller 20 -> LIS : send not processed record notice

This record is sent in the event of a machine process error such as a failed roll insertion.

Case 3: process error

ASTM Message	Record
H ^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1 782 Jerde^Roberto	Patient Information Record
O 1 41c5624116 ^ESR X	Test Order record
R 3 ^ESR^position 2 X Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 4 ^ESR^rackNumber 1 X Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal R 5 ^ESR^cycle 5 X Admin 26101005125455 26101005125455 ALIFAX^ESR^12345^internal L 1 N	Result Record
L 1 N	Message Terminator Record

Test1 2.0 or Roller 20 -> LIS : send not processable record notice

This record is sent if the barcode has not been read correctly and the machine is set in MISSING ID = 0 mode to warn that the exam has not been performed.

Case 4: process error

ASTM Message	Record
H ^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1	Patient Information Record
O 1 41c5624116 ^ESR X	Test Order record
R 1 ^ESR X Admin 20220211114835 20220211114910 ALIFAX^ESR^12345^internal	Result Record



TEST1 2.0 ASTM LIS

INTERFACE PROTOCOL

L 1 N	Message Terminator Record
-------	---------------------------

Test1 2.0 or Roller 20 -> LIS : send latex results

This situation occurs when Test1 2.0 or Roller 20 successfully identifies the 3 latex ESR values.

Case 5: latex results

ASTM Message	Record
H \^& ALIFAX^ESR^12345 P LIS2-A2 20191114121443	Message Header Record
P 1	Patient Information Record
O 1 LATEX ^~^LATEX F	Test Order record
R 1 ^~^LATEX^875^1 123 005 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12 345^internal R 2 ^~^LATEX^875^2 123 036 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12 345^internal R 3 ^~^LATEX^875^3 123 083 F Admin 20220211114835 20220211114910 ALIFAX^ESR^12 345^internal	Result Record
L 1 N	Message Terminator Record



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TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL



In Vitro Diagnostic Medical Device for professional use

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TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

Index

1- Introduction	3
Purpose	3
Scope	3
Overview	3
General information	3
2- Glossary	4
3- Serial port physical interface and configuration	4
4- Serial cable pin connections to connect Test1 2.0 or Roller 20 to PC-LAB	4
5- Test1 2.0 or Roller 20, RS232 ports features	5
6- Messages	5
Overview	5
Common parts	5
Buffer delimiter characters	5
Checksum	5
Fields encoding	6
Patient ID	6
Query	6
Response	7
Result exam	7
Result latex	8
7- Test1 2.0 or Roller 20 protocol explain	9
DAC15 or BCI	9
Barcode	9
Bayer and Cycle	9
Rack number	9
Configuration for the correct Query protocol functioning	10
8- Query Protocol flow description valid for all Test1 2.0 or Roller 20	10
Warnings	11
Example	11
9- Test1 2.0, Roller 20 Multiple connections	12
10- Appendix	12
Exam result state diagram (BCI mode) seen from the instrument side	12
Exam result state diagram (BCI mode) seen from the LIS side	13
Exam result state diagram (DAC15 mode) seen from the instrument side	13
Exam result state diagram (DAC15 mode) seen from the LIS side	14
Useful tools for debugging	14

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.

Neither this manual nor any parts of it may be duplicated or transmitted in any way without the written approval of Alifax S.r.l.

1- Introduction

Purpose

This document specifies the LIS interface used by the Alifax ESR Line instruments.

Scope

This documents applies to the following instruments Test1 2.0 with software version 1.0.2 only and Roller 20 with software version 1.0.x

Overview

Its serial based protocol. It is used to enable the instruments to query the LIS if a sample needs processing or not, send the result of an analysis of blood or latex to the LIS.



General information

Alifax ESR Line instruments are automatic analyzers for Erythrocyte Sedimentation Rate (ESR) determination of human blood samples in-vitro. The technology applied by Alifax's ESR instrumentation is Quantitative Capillary Photometry, which allows in just 20 seconds of analysis to obtain the ESR result of the sample, expressed in mm/hour, as per guidelines and reference method.

Test1 2.0 or Roller 20 has two withdrawal systems:

- The internal one which requires that samples in tubes are inserted in the instrument using racks
- The external one which withdraws blood from open tube that must be inserted manually in an external probe.
- The second system is an optional and its measurement circuit is completely separated from the first one

A laboratory information system (LIS) is a software system that records, manages, and stores data for clinical laboratories. A LIS has traditionally been most adept at sending laboratory test orders to lab instruments, tracking those orders, and then recording the results, typically to a searchable database.

The Test1 2.0 or Roller 20 software shall communicate with LIS systems using custom Alifax serial communication protocol.

This manual is intended to provide detailed information on how to implement communication between Test1 2.0 or Roller 20 and a LIS system.

It should assist software house companies in creating, modifying and installing their program on the host computer.



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

2- Glossary

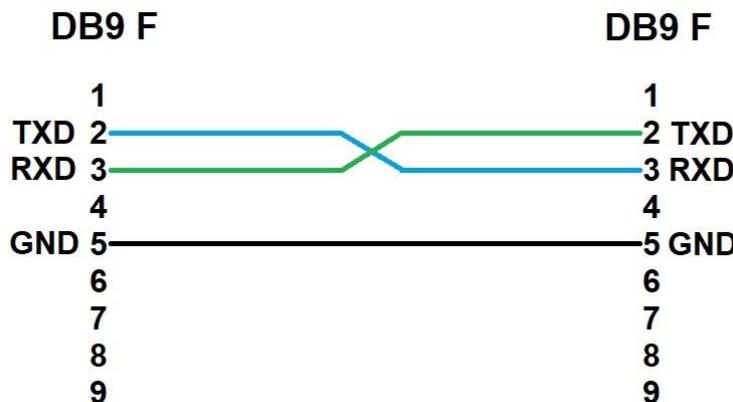
Term	Definition
<CR>	Carriage Return (ASCII decimal 13).
<LF>	Line Feed (ASCII Decimal 10).
<NAK>	Negative Acknowledgment (ASCII Decimal 21).
<STX>	Start of (text) block (ASCII Decimal 2).
ACK	Positive Acknowledgement. ASCII character 6.
ASCII	American Standard Code for Information Interchange
CHECKSUM	XOR calculation of part of R received message to check the correctness of it. See: <u>Checksum</u>
CLSI	The Clinical and Laboratory Standards Institute
<ETX>	End of Text. ASCII character 3. This control character denotes the end of the data (text) block.
LIS	Laboratory Information System. The Lab Computer together with the software that runs on it viewed as a logical unit.
Rx	Receive(r).
Sample	The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.
Specimen	Term for Sample
Tx	Transmit, Transmission, or Send(er).

3- Serial port physical interface and configuration

A standard cable to connect two personal computers via serial port.
This cable must have, D-type 9 pin female connector at the instrument side.

4- Serial cable pin connections to connect Test1 2.0 or Roller 20 to PC-

LAB





TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

5- Test1 2.0 or Roller 20, RS232 ports features

Communication ports parameters are fixed and cannot be modified.

Parameter name	Value
Baud rate	9600
Parity	N
Data bit number	8
Stop bit	1

6- Messages

Overview

The protocol uses four messages Query, Response, Result exam, Result latex as specified in this section. Each message has common structure comprising:

- a binary header
- a body
- a binary terminator
- a binary checksum.

Common parts

Buffer delimiter characters

<STX> ASCII character (❶ symbol) in the serial transmission is represented by 0x02 hex value and represents the beginning of the message.

<ETX> ASCII character (❷ symbol) in the serial transmission is represented by 0x03 hex value and represents the end of the message.

Checksum

Checksum value is the result of Exclusive OR (XOR) of all characters of the message, excluded STX, ETX and Checksum. If the Checksum value calculated by the analyser is 03 (corresponding to ETX), or 02 (corresponding to STX), or 00 (corresponding to NULL), the value will be automatically replaced with 7F hex value.

Software House must adopt the same procedure when calculating checksum of the strings received from the analyser. In the transmission protocol, hexadecimal characters like 0x13 (DC3 character), 0x14 (DC4 character), and 0x17 (ETB character), are not transmitted unless used as checksum.

TypeScript example to get the checksum byte

```
1. const NUL = 0x00;
2. const STX = 0x02;
3. const ETX = 0x03;
4. const DEL = 0x7f;
5.
6. checksum(data: Buffer) {
7.   let integrityChar = 0;
8.
9.   integrityChar = data
```



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

```
10. .slice(0, 1) // Remove first STX byte from data buffer
11. .slice(0, -2) // Remove last checksum and EXT byte from data buffer
12. .reduce(
13.   (acc, byte) => acc ^ byte, integrityChar // perform XOR of all characters
14. );
15.
16. // It checks if the resulting byte is among those not allowed and if so it replaces it with 7F
17. if ([ETX, STX, NUL].some((ch) => ch === integrityChar)) {
18.   integrityChar = DEL;
19. }
20.
21. return integrityChar;
22. }
```

Fields encoding

ASCII Encoded Integer 00-99 (zero padded)

All most significant byte which are not used to indicate the expected value are replaced by char "0" (zero) with hexadecimal value 0x30.

For example, to identify workstation number three we will write the following pair of bytes:

Text value: "03"
->
Byte value: 0x30 0x33

Patient ID

In the case of the "Patient ID", all less significant byte which are not used to indicate the expected value are replaced by the char " " (space) with hexadecimal value 0x20.

Text value: "27201999159 "
<-
Byte value: 0x32 0x37 0x32 0x30 0x31 0x39 0x39 0x39 0x31 0x35 0x39 0x20 0x20 0x20 0x20

Query

This is the structure of message query that is send from instrument to LIS.

Byte Index	Field	Length	Type [Value (hex)]	Notes
0	Header	1	byte [0x02]	This is the <STX> ASCII character
1	Message Type	1	byte [0x51]	This is the "Q" ASCII character
2-3	Workstation Number	2	ASCII Encoded Integer 00-99 (zero padded)	Identification number of the instrument if connected to the network together with others
4-18	Patient ID	15	ASCII String	See Patient ID for the specification



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

19-22	Reserved	4		This field should be ignored
23	Checksum	1	byte	See Checksum for the specification
24	Terminator	1	byte [0x03]	This is the <ETX> ASCII character

Response

This is the structure of message response that is send from LIS to instrument.

Byte index	Field	Length	Type [Value (hex)]	Notes
0	Header	1	byte [0x02]	This is the <STX> ASCII character
1	Message Type	1	byte [0x54]	This is the "T" ASCII character
2-3	Workstation number	2	ASCII Encoded Integer 00-99 (zero padded)	Identification number of the instrument if connected to the network together with others
4-18	Patient ID	15	ASCII String	See Patient ID for the specification
19-22	Result	4	bytes [0x30,0x30,0x30,0x30] or bytes [0x30,0x30,0x30,0x31]	In the first case the examination must not be done. In the second case, however, the examination must be done
23	Checksum	1	byte	See Checksum for the specification
24	Terminator	1	byte [0x03]	This is the <ETX> ASCII character

Result exam

This is the structure of message result exam that is send from instrument to LIS.

Byte index	Field	Length	Type [Value (hex)]	Notes
0	Header	1	byte [0x02]	This is the <STX> ASCII character
1	Message Type	1	byte [0x52]	This is the "R" ASCII character
2-3	Workstation number	2	ASCII Encoded Integer 00-99 (zero padded)	Identification number of the instrument if connected to the network together with others
4-18	Patient ID	15	ASCII String	See Patient ID for the specification
19-20	Rack number	2	ASCII Encoded Integer 00-99 (zero padded)	Number of rack containing the sample See: Rack number If there is no rack as in the case of external sampling, we use the value 00



TEST1 2.0 SERIAL LIS

INTERFACE PROTOCOL

21-22	Position	2	ASCII Encoded Integer 01-99 (zero padded)	Position of the sample in the rack
23-24	Cycle/Bayer	2	ASCII Encoded Integer 01-99 (zero padded)	See: Bayer and Cycle
25-28	Result	4	ASCII Encoded Integer 0000-9999 (zero padded) Or ASCII Encoded Integer *000-*999 (zero padded) Or ASCII Encoded Integer 0-04 or -004 (zero padded) Or ASCII Encoded Integer 0-02 or -002 (zero padded) Or ASCII Encoded Integer 0-01 or -001 (zero padded)	ESR measured value See: Flow description
29	Checksum	1	byte	See Checksum for the specification
30	Terminator	1	byte [0x03]	This is the <ETX> ASCII character
Total length		31 bytes		

Result latex

When the instrument runs latex controls, it is possible to send the results to host computer. This is the structure of message result latex that is send from instrument to LIS.

Byte index	Field	Length	Type [Value (hex)]	Notes
0	Header	1	byte [0x02]	This is the <STX> ASCII character
1	Message Type	1	byte [0x52]	This is the "R" ASCII character
2-3	Workstation number	2	ASCII Encoded Integer 00-99 (zero padded)	Identification number of the instrument if connected to the network together with others
4-12	LATEX0XYZ	9	ASCII String "LATEX0" + ASCII Encoded Integer 000-999 (zero padded)	Is the identification of the latex and the Lot to which they belong
13	Field 1	1	ASCII Encoded Integer 1-3 (zero padded)	Can be 1, 2 or 3 and identifies level 1, 2 and 3 of latex
14-16	ESR Value	3	ASCII Encoded Integer 000-999 (zero padded)	This is the expected Latex ESR value
17-18	Space	2	[0x20,0x20]	Two spaces
19-20	Field 2	2	ASCII Encoded Integer 00-99 (zero padded)	01 for internal cps, 00 for external cps
21-22	Field 3	2	ASCII Encoded Integer 00-99 (zero padded)	The same as Field 1



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

23-24	Field 4	2	ASCII Encoded Integer 00-99 (zero padded)	Priming cycle (the first priming, resets every midnight of the day)
25-28	ESR Value	4	ASCII Encoded Integer 000-999 (zero padded)	This is the detected Latex ESR value
29	Checksum	1	byte	See Checksum for the specification
30	Terminator	1	byte [0x03]	This is the <ETX> ASCII character

Latex examples

```
<0x2>R01LATEX08451005 0101010002<0x19><0x3>
<0x2>R01LATEX08452036 0102010034<0x1c><0x3>
<0x2>R01LATEX08453083 0103010071<0x13><0x3>
```

7- Test1 2.0 or Roller 20 protocol explain

DAC15 or BCI

The instrument can be configured in DAC15 mode which is unidirectional or in BCI mode which is bidirectional in Query Host.

Independently Test1 2.0 or Roller 20 is set on DAT 15 or BCI the protocol description for the result string "R" sent to HOST is exactly the same.

If the customer is not interested in working with Query Host, leave instrument set on BCI mode and configure ACK option set to OFF.

DAT15 and the BCI option mode can be chosen from the serial LIS network configuration menu.

Barcode

It works by an internal (IBCR) or external bar code reader (EBCR). It accepts the maximum patient identity code with 15 characters of length.

Bayer and Cycle

This field take care of the Cycle number. This field could be relating to Bayer parameter setting it by software. If Bayer is 0, the field deals with the number of Cycle otherwise if Bayer is 1, the field will contain '01' (hex 30 and 31) to maintain the Bayer protocol compatibility.

Rack number

In case of sampling and analysis on external CPS, the byte to be used is 0x00 in case of internal CPS a byte from 0x01 to 0x08 must be set which indicates the number of the rack in which the sample being analyzed is located.



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

Configuration for the correct Query protocol functioning

Option	Description
Enable ACK	If this option is enabled, the instrument waits for the ACK character when transmitting messages according to the waiting time set on the "Timeout UART " field
Timeout UART	Set the waiting time (from 2 to 99 seconds) if the increasing of the waiting time to receive "T" message and the confirmation byte (ACK) for having received "R" message is requested. The maximum time to receiving "T" message and the confirmation byte (ACK) for having received "R" message remain set to 2 seconds keeping it to OFF. If within this time no message comes in, the instrument will go ahead. This option works if ACK option, is enabled.
Enable bayer	Enable it to guarantee the Bayer protocol specifications (field Cycle/Bayer = 01). If Bayer protocol is not requested this option must be kept disable.
BCI or DAC15	If we are in BCI mode, the query is made first and then the result data is transmitted to the LIS. If we are in DAC15 mode the query is not executed but only the results data are transmitted.
Use asterisk to highlight anemia	Enable the asterisk character transmission to the host. It works when a analysed sample gives a low value of hematocrit
Use missing id	Allow the analysis of samples with an auto generated ID in case IBCR is not able to read the barcode label. Keeping it disable, these samples won't be analysed.
Unique number for multiple instrument connections	A number between 01 to 99 on each instrument can be assigned by this option if multiple instruments connections to Host computer is required

8- Query Protocol flow description valid for all Test1 2.0 or Roller 20

Following protocol is the same independently it is set the option DAT 15 or BCI.

1. The internal scanner reads the bar code (patient ID) from the label stuck on the tube, the instrument creates "Q" message and sends it to HOST computer through RS232 serial port (or to PC LAB PC if it is connected like a bridge).

```
<STX>Q01123456789 0000a<ETX>
```

2. HOST computer verifies if the patient identity code is present in the working list and, accordingly, it replies with "T" message. TEST1 waits to receiving it within two seconds and then it goes ahead. If ACK option is off, TEST1 is going to remain waiting up to 2 seconds for receiving it, otherwise if it is on, TEST1 is going to wait for all the set time (TIMEOUT from 2 to 99 seconds). "Timeout UART" time and ACK are selectable in the serial network settings menu. "T" message is going to have the result field filled with "0001", if the sample requires the analysis. The result field will be filled with "0000" if the sample doesn't require the analysis.

```
<STX>T01123456789 0001e<ETX>
<STX>T01123456789 0000d<ETX>
```

3. After measuring (24 seconds about), Test1 2.0 or Roller 20 sends "R" message to host replacing the result field value (0001) with the ESR read value which should be between 0002 and 0120 or negative. Errors messages are reported like: -001 for SM (Sample missing), -002 for NR (Not Readable) error and -004 for NF (No flow) error.

```
<STX>R01123456789 0103050012f <ETX>
<STX>R01123456789 010305-0041 <ETX>
```

4. Host computer should send ACK confirmation byte (♣ symbol displayed on the HyperTerminal program) to Test1 2.0 or Roller 20 for having accepted "R" message. Test1 2.0 and Roller 20 will ignore it, if ACK



TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

is off. Otherwise it will wait for all the set time (TIMEOUT from 2 to 99 seconds) if ACK is On.

ACK = Hexadecimal code 06

Warnings

1. If a patient identity (ID) read by the Test1 2.0 or Roller 20 scanner doesn't find its own correspondent code in the Host computer working list, "T" message will be replaced by <NAK> message(§ symbol displayed on the HyperTerminal program). The sample will be however analysed and "R" message sent to host.

(NAK Message) Hex code 21

2. If a particular sample has a very low hematocrit (around 20% and less) and * option in the communication menu is enabled, the result field of "R" message, sent to the host, will contains an asterisk set in the first position on the left and its own ESR result

<STX>R01123456789 010305***015**[<ETX>

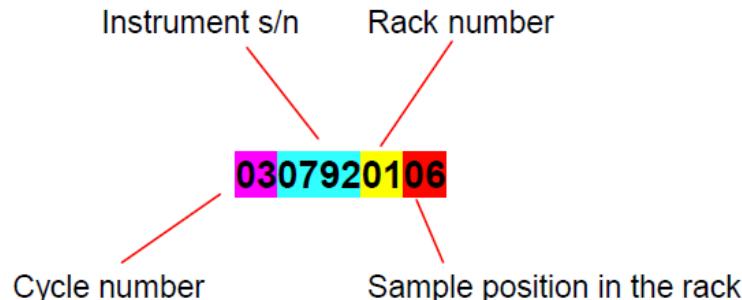
If the analysis of a particular sample generates an error and * option in the communication menu is enabled, ESR result field will contain 0 in the first left position, “-” (minus) in the second and the error code

<STX>R01123456789 010305**0-04**\<ETX>

3. If the internal scanner cannot read the patient ID and "MISS ID" option in the serial network menu setup is 0, "Q" message won't be created. The sample without its own patient identity won't be processed.
4. If the internal scanner cannot read the patient ID and "MISS ID" option in the serial network menu setup is 1, "Q" message won't be created. The sample without its own patient identity will be, however, processed and "R" message sent to host with an identity code generated by the instrument itself. The new patient ID, in this case, will be composed by 10 characters: cycle number (from 01 to 99) (2 characters), instrument s/n (4 characters), rack number (from 00 to 08 - 2 characters) sample position in the rack (from 01 to 15 - 2 characters).

Note: Rack number 00 is used for sampling and analysis on an external CPS

Example



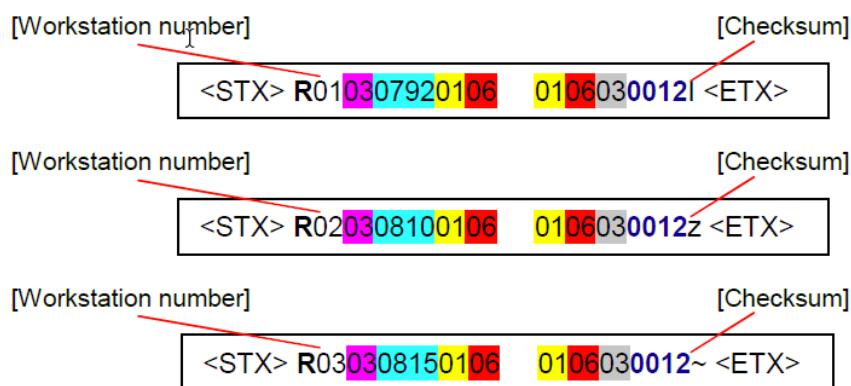
A complete "R" string for the transmission could be:

[Workstation number] [Instrument s/n] [Rack number] [ESR] [Checksum]
<STX>R01**0307920106** **010603****0012f** <ETX>
[Cycle number] [Sample position] [Cycle number (Note 2)]

9- Test1 2.0, Roller 20 Multiple connections

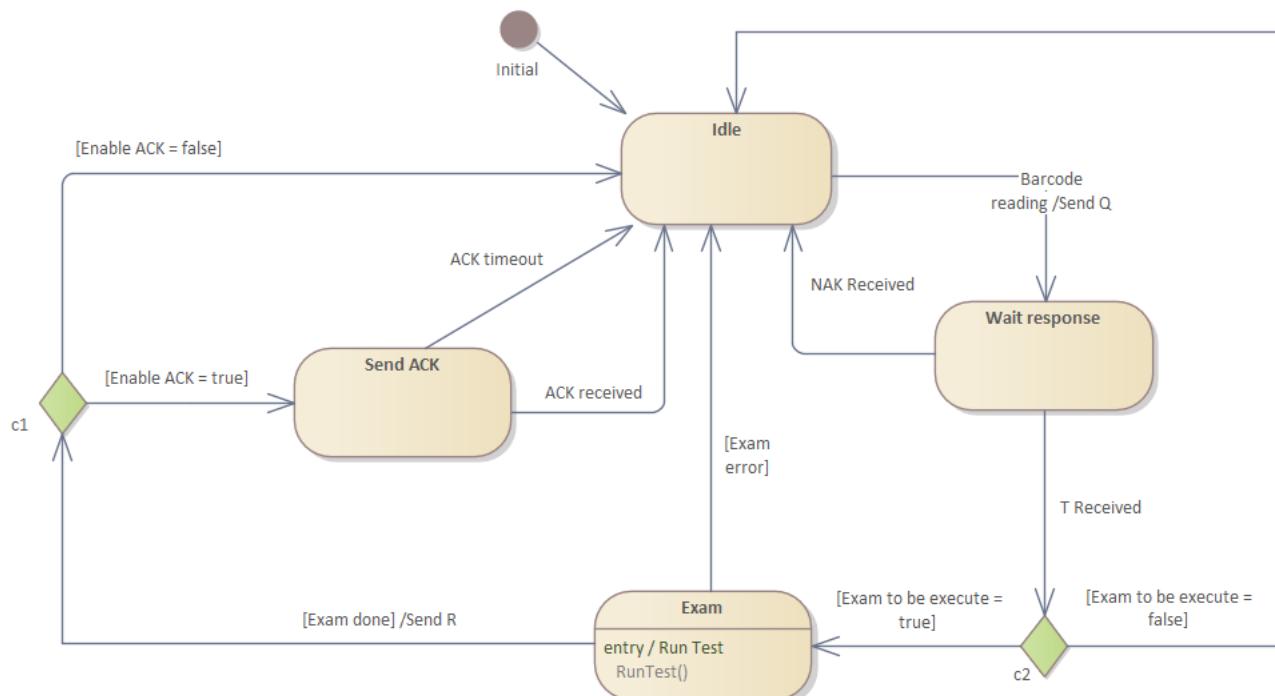
Query protocol is able to manage multiple connections by using the same PC-LAB with multiple serial ports. In that case every instrument connected to the PC-LAB has to have an identification number different for each and the PC-LAB the same number of serial ports as the instruments.

Our instruments have an option: Test1 number in the COMMUNICATION menu for Test1 2.0 models Instruments" family" to assign a different identification number to each instrument, "R" message should be different for each like in the following example:



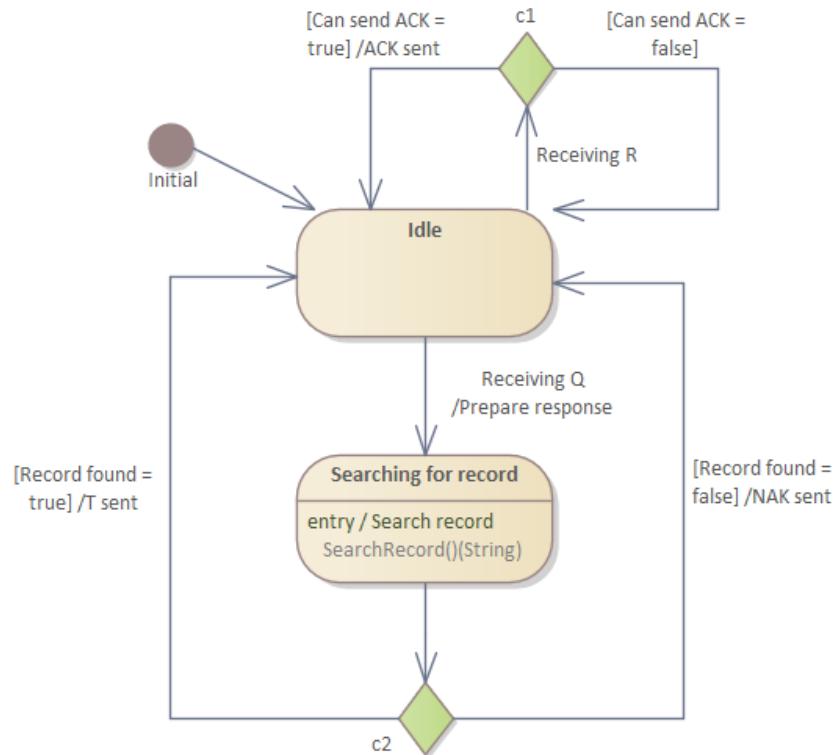
10- Appendix

Exam result state diagram (BCI mode) seen from the instrument side

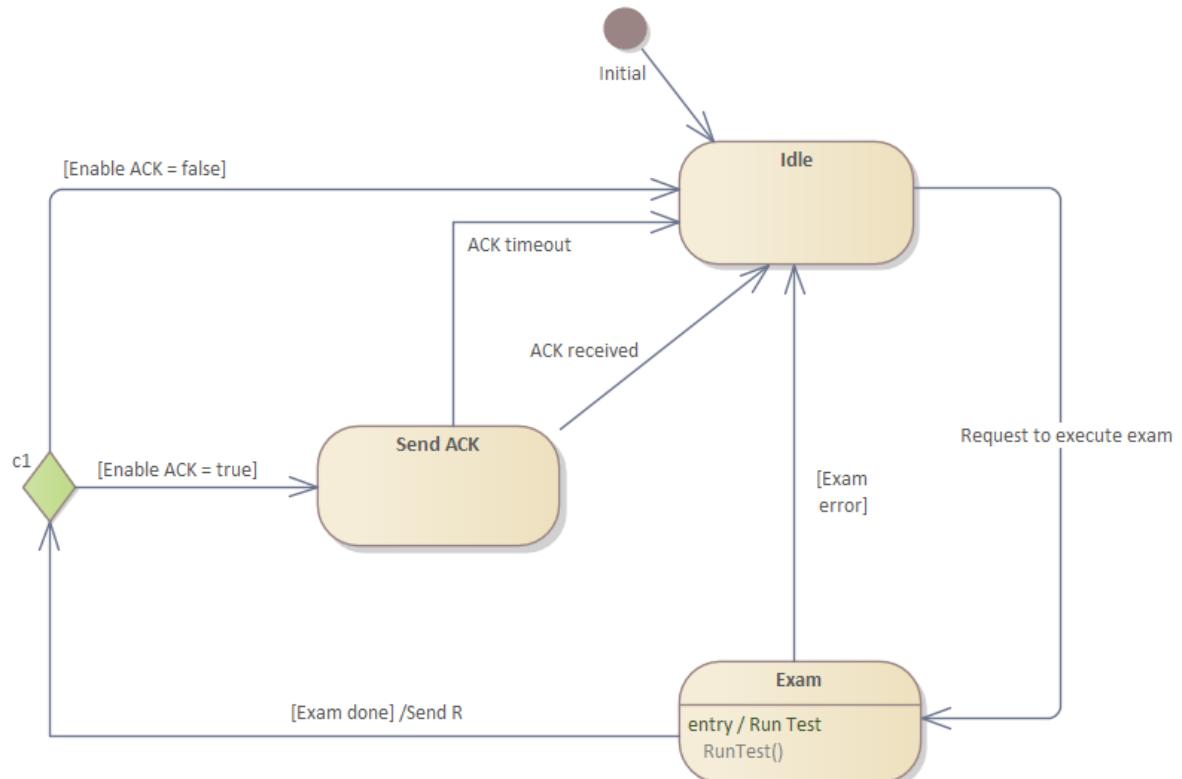


TEST1 2.0 SERIAL LIS INTERFACE PROTOCOL

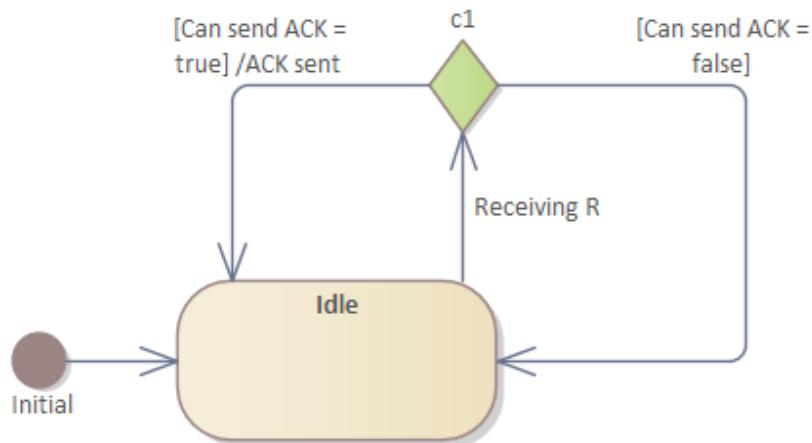
Exam result state diagram (BCI mode) seen from the LIS side



Exam result state diagram (DAC15 mode) seen from the instrument side



Exam result state diagram (DAC15 mode) seen from the LIS side



Useful tools for debugging

A PC computer with a communication program installed (like HyperTerminal of Windows) to test the instrument communications.

HyperTerminal allows the technician to check the communication messages byte by byte.

To run it follow the path: start, all programs, accessories, communication, HyperTerminal; run it and choose new connection. Type a preferred name e.g. Test1, press OK and then EXIT.

Open the curtain menu pressing File on the left upper side of HyperTerminal window and Property; a new window will be opened. Press Connection and choose the serial port where the serial cable has been connected: e.g. COM1.

Press Configuration and choose the speed which should be 9600Bps. Press OK twice.