Rev. 1.0 – Effective from: 2022 September 15

TEST 1

VALID FOR ALL MODELS

USER MANUAL

Valid for Software Version 11.00X

Usable from TEST1 serial number T17065 onward

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

MODEL WITH:
AUTOMATIC WASHING SYSTEM
CPS-MC READING MODULE

CE IVD

In Vitro Diagnostic Medical Device for professional use

USER MANUAL
TEST1

INDEX

NOTES

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

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

1-ALIFAX ESR INSTRUMENTS PRESENTATION

Dear Customer,

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

ESR Introduction

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

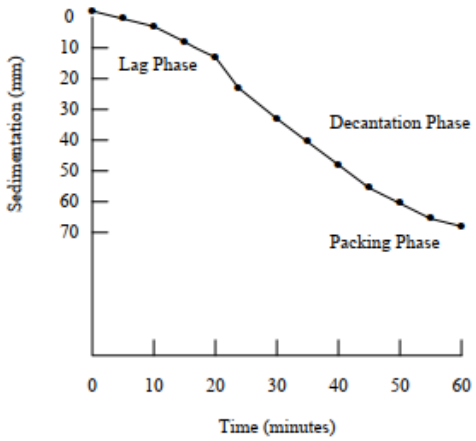


Figure 1. Sigmoid Sedimentation Curve. Evolution of the erythrocyte rouleaux formation in the different phases of ESR in a case with a high level of acute phase proteins.

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

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

Advantages of Alifax ESR instrumentation

Preparation of the suitability of the sample
-The system is structurally designed to automatically re-suspend the samples, by complete rotation of the tubes (360°) immediately before the analytical phase of each sample.
- In the **Alifax ESR** instrumentation, a great deal of attention has been paid while designing the part concerning the detection of the physical state of the samples and their correct quantity, as well as the reporting of any anomalies which allows the operator to directly verify the samples, in order to prevent an incorrect response. In fact, if there's no detection of the sample or it's insufficient or coagulated, the analysis is not performed and the problem is indicated by a special message printed and stored next to the sample identifier.
- A similar report is given for samples having a ratio between red blood cells/plasma defining an hematocrit value < 30%. For such samples, the ESR measurement performed by the **Alifax ESR** instruments is correctly performed, and the instrument prints an asterisk next to the measured value to alert the operator to the patient's potential state of anemia. A more thorough investigation of the blood parameters of the identified patient could confirm the instruments results.
- Constant thermostating of the sample analysis cell at 37 °C to ensure that the temperature influence on ESR measurement is reduced.

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

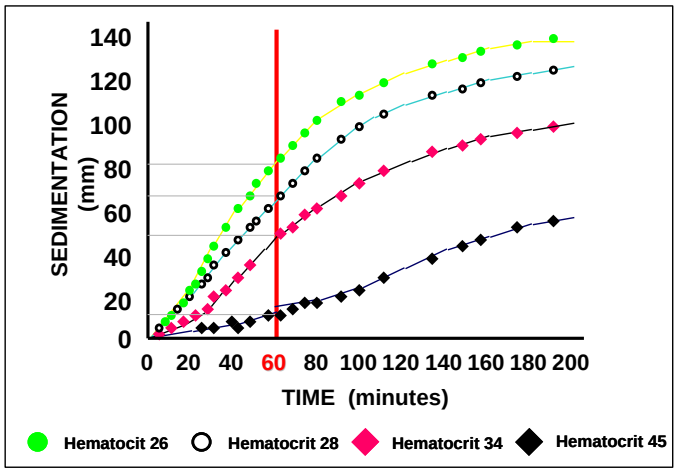
Adaptability to laboratory workflows
The operator loads the samples into the instrument using the same racks coming from the cell counter, for a total capacity of 4 racks in continuous access, without any manipulation of the single tube by the operator. The racks and tubes will be returned by the instrument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

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

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

Thanks to the technology used, (capillary quantitative photometry), **Alifax ESR** instrumentation suffers negligible interference. The very short analysis time per sample (20 seconds), and the non-sedimentation based principle of operation, do not allow the low hematocrit to influence ESR measurement by quantitative capillary photometry. This is also described in the recent publication:
Automated measurement of the erythrocyte sedimentation rate: method validation and comparison Ivana Lapić, Elisa Piva, Federica Spolaore, Francesca Tosato, Michela Pelloso and Mario Plebani Clin Chem Lab Med 2019 : "discussion – […] TEST1 with its capillary photometric kinetic method is less susceptible to variations in erythrocyte morphology or hematocrit levels. "*

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



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

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

Latex control:
The kits (Latex Controls 6 tests or 30 tests) are based on the use of three samples with known turbidity values, on which the instrument performs photometric measurements related to ESR values.
The 6 test kit consists of 3 test tubes containing 3 ml of synthetic latex solution:
1 x Level 2 Latex Test Tubes ("LATEX Test tube L 2")
1 x Level 3 Latex Test tube L 3 ("LATEX Test tube L 3")
1 x LATEX Test tube level 4 ("LATEX Test tube L 4")
The 30 test kit consists of 15 test tubes containing 3 ml of synthetic latex solution:
5 x Level 2 Latex Test Tubes ("LATEX Test tube L 2")
5 x Level 3 Latex Test tube L 3 ("LATEX Test tube L 3")
5 x LATEX Test tube level 4 ("LATEX Test tube L 4")

The three control levels, Low (level 2), Medium (level 3), and High (level 4), have narrow acceptability ranges that combined with the dedicated software ensure Accuracy and Sensitivity. Below is the reference of a scientific publication on this subject:
A new turbidimetric standard to improve the quality assurance of the erythrocyte sedimentation rate measurement
Elisa Piva, Rachele Pajola, Valeria Temporin, Mario Plebani -- Dipartimento di Medicina di Laboratorio, Università degli Studi di Padova, Azienda Ospedaliera di Padova, Padova, Italy -- Clinical Biochemistry 40 (2007) 491–495

New scientific work in 2019:

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

2-TYPOGRAPHICAL CONVENTIONS

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

DISPLAY of WARNINGS and NOTES

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

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

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

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

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

USED WARNINGS SYMBOLS

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

Biohazard!

Caution, moving parts inside!

Electrical hazard!

Mechanical hazard!

Laser hazard!

Cut injury / sharp hazard!

Ground!

Automatic start-up!

Consult instructions for use

OTHER SYMBOLS

Manufactured by

Lot number

Expiration date

Temperature limitations

CE mark

Mains in AC voltage

ID number

Weight

Serial number

Fuse

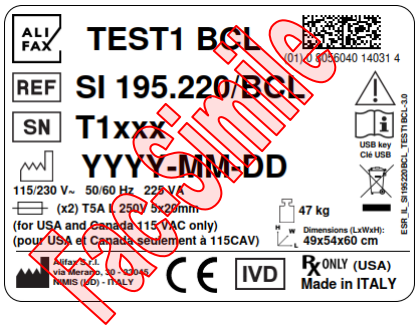
Disposal of Electrical and Electronic Equipment
In the European Union, electrical and electronic equipment must not be disposed of with other household-type waste. It must be collected separately. Please observe the relevant legal regulations effective in your country.

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

NOTE

The following label refers to TEST1THL and contains between others the reference serial number of the instruments

For the other TEST1 models the label is the same and the only difference is the second part of the REF code which depends on the instrument.
For example SI 195.xxx/yyy, where xxx is a number such as 210 or 220or 230 and soon an the part /yyy is the acronym of the instrument such as THL or BCL or SDL and so on.



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

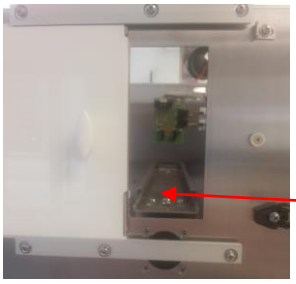
3-INTRODUCTION TO TEST1 with Automatic Washing System

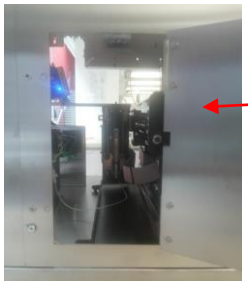
This new model represents a dramatic improvement in comparison with previous models of TEST1 family.

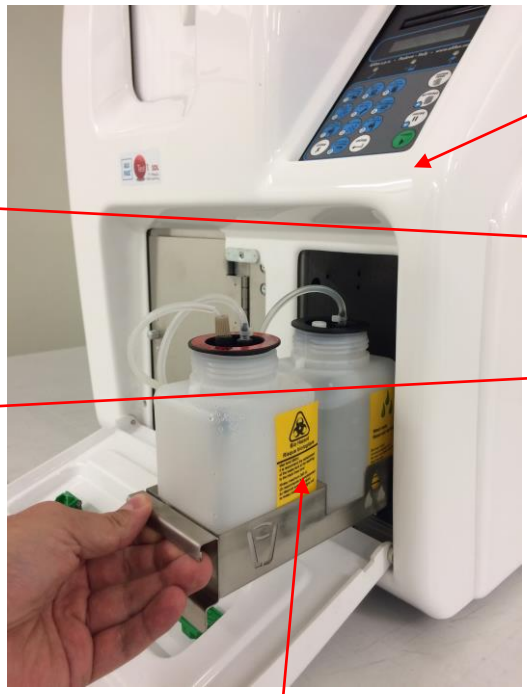
Please, read carefully this manual before starting using **TEST1** system.
You'll appreciate the functionalities and the performances of your **TEST1** system.

Following images highlight the most important improvements applied to the new **TEST1** system:

Front View:







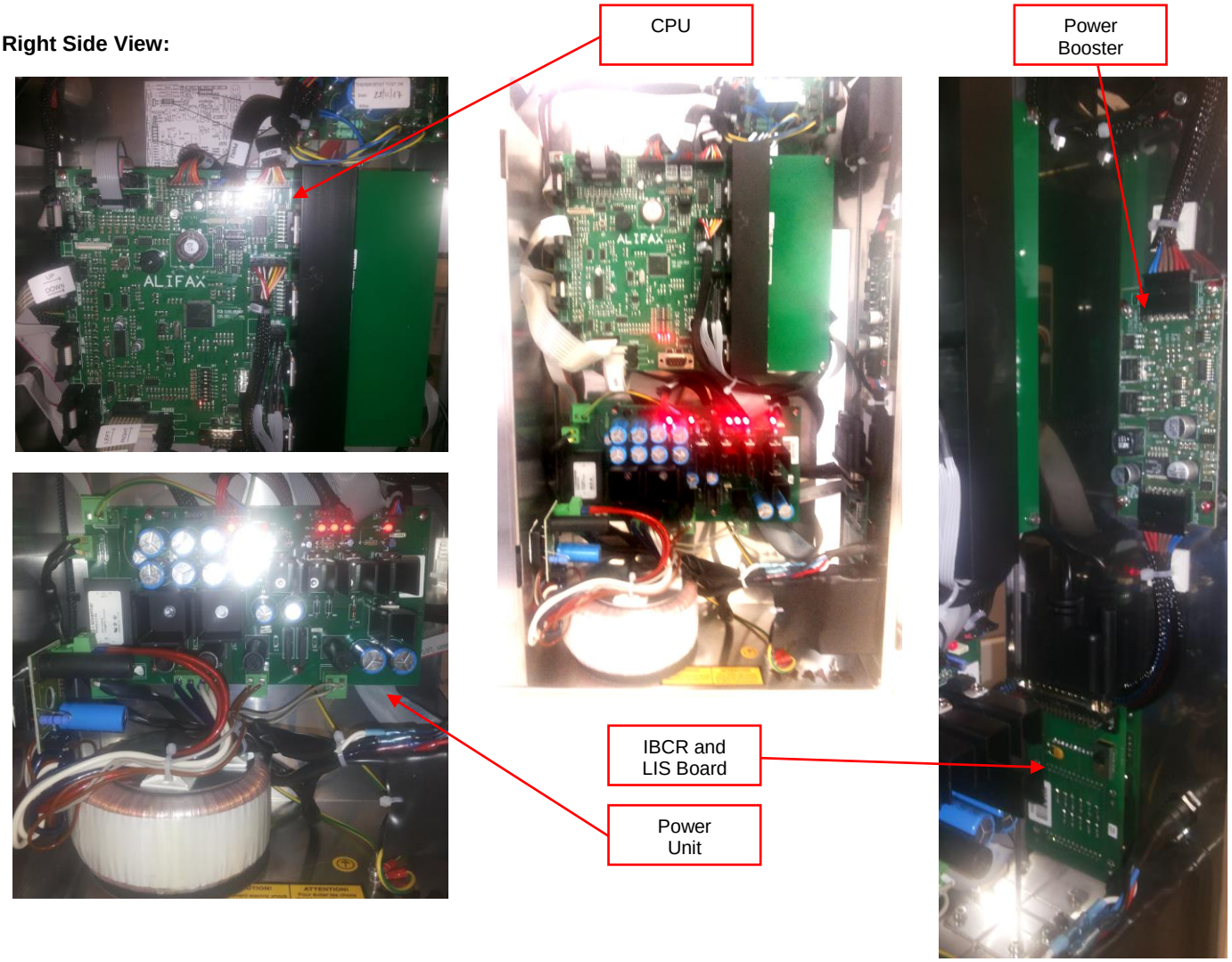
Control Panel
- Printer
- Smart Card Reader
- Display
- Keyboard

Sample Loading Door

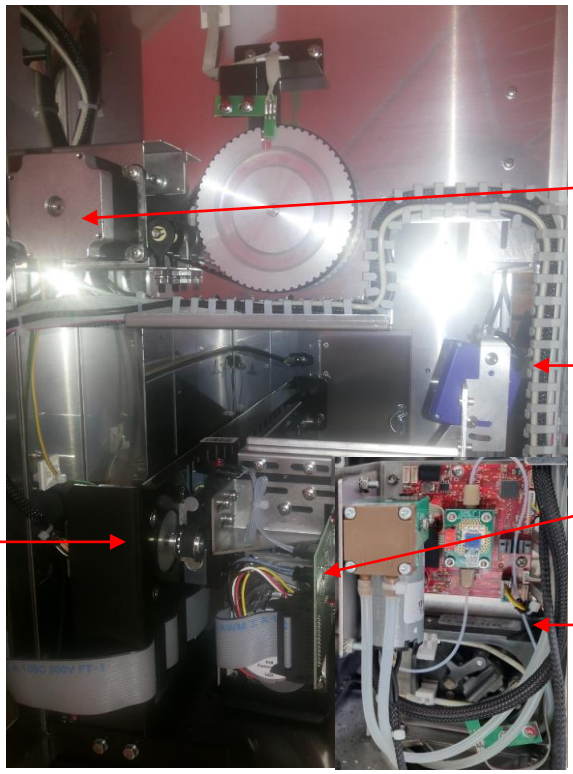
Technical Door

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

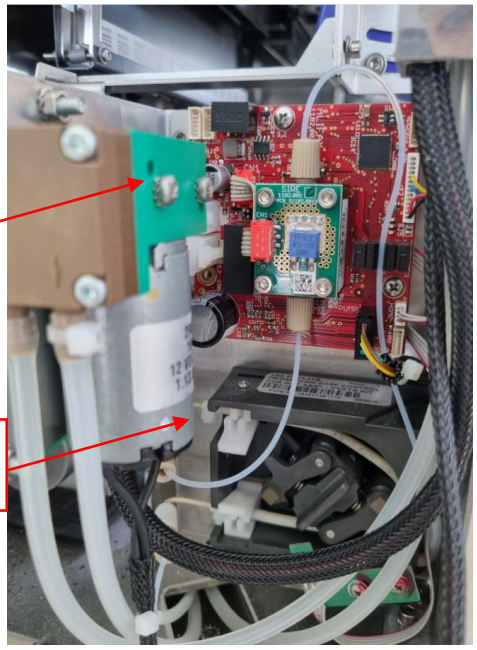
Right Side View:

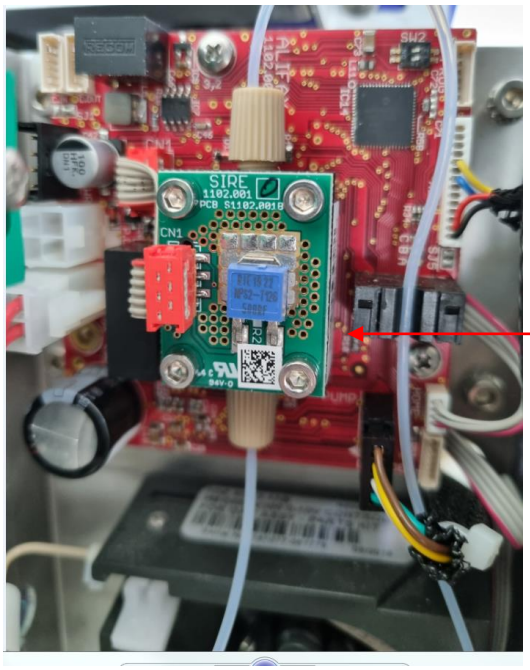


Rear View:



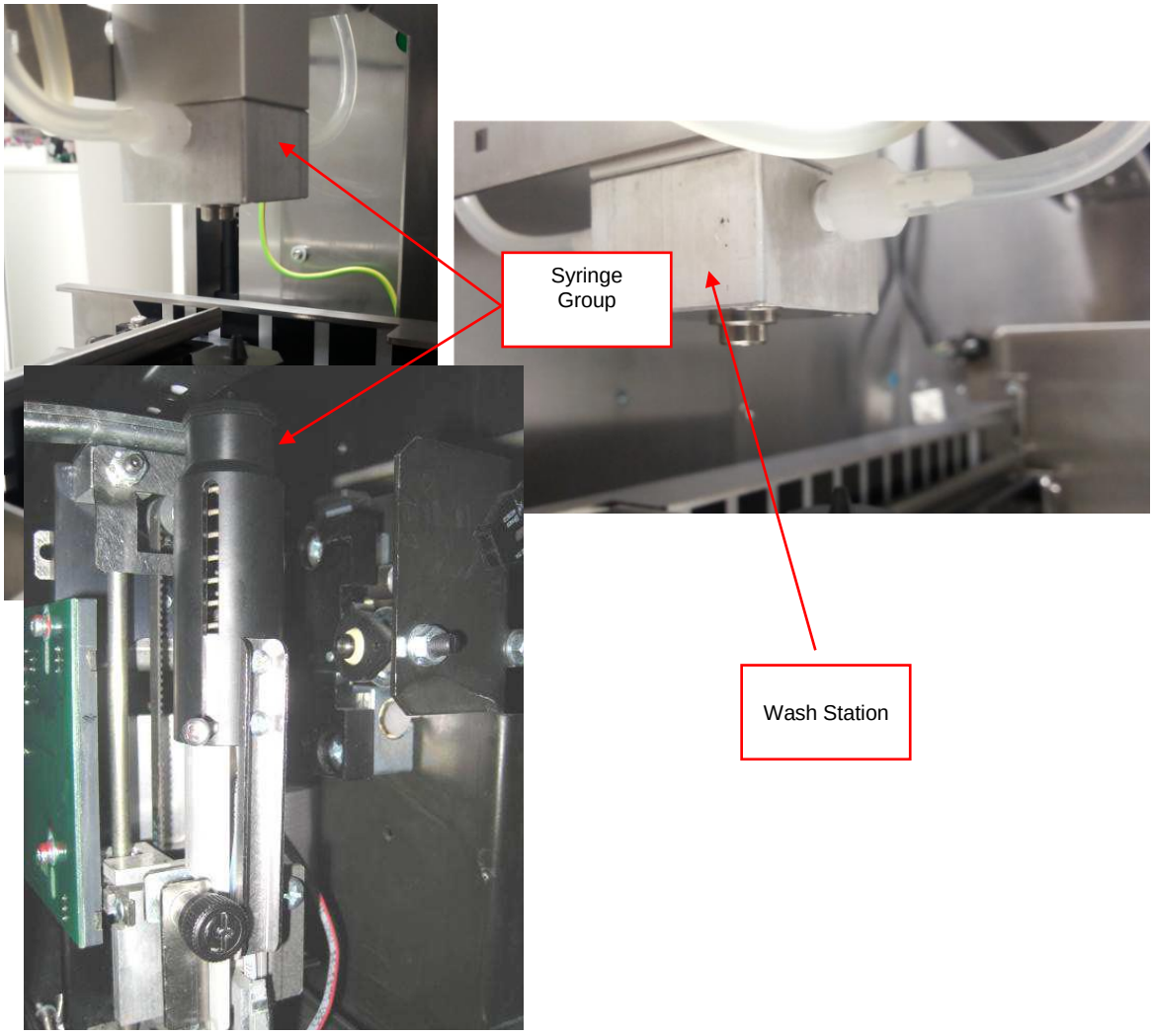
- **New CPS:** developed with the latest generation technology. This new CPS enhance highly the sensibility in the detection of the aggregation using a dedicate DSP (Digital Signal Processor) embedded inside the CPS unit.





Left Side View:

- **Automatic Washing System:** on **TEST1** Alifax have developed a washing station where needle can automatically wash (without the presence of the operator) in the event of 3 consecutive NF or NR. Also the automatic washing skips the necessity for the operator to wash the instrument at the “end of analysis time-out” because with TEST1 as soon as the time-out elapses, needle goes automatically to wash itself.
  Having the automatic washing systems enhance highly the performances of the instrument ensuring at the same time a reduction of the “instrument downs” due to capillary clogged do the presence of rubber particle generated by the reiterated use of the same washing tubes.
  Clearly the manual washing system with 2 or 3 tubes is still available.



4-WARNINGS FOR A CORRECT USE OF THE INSTRUMENT

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

Handling of Instructions for use Manual

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

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

TEST1 system is designed and manufactured in accordance with the safety requirements for electronic and medical systems. If the law issues regulations concerning the installation and/or operation of the instrument, then it is the operator's responsibility to adhere to them.

The manufacturer have done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The systems are tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

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

GENERAL SAFETY

Non-Observance of Warnings

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

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

Use of the System according to Intended Use only

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

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

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

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

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

OPERATIVE SAFETY

WARNING

Mobile Phones

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

WARNING

Instrument use in routine

- Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C) / 98,6°F (±0,9°F)
- Before starting a new session, the instrument visualizes a control check-list, is mandatory to verify all check that all the parameters in the check-list are as expected, otherwise contact the Technical Service
- TEST1 is an In Vitro Diagnostic Medical Device for professional use only. The English language knowledge is required in those countries where neither Italian nor French nor Spanish nor German is spoken.
- Use only consumables and accessories described in the user manual.
- Consumables good must be used respecting the expiration date.
- Check the level of the discharge tank before starting the measurement operation. If the tank has reached the safety level, dispose of it or empty it, following the safety regulations and procedures in the laboratory and local regulations.
- Carry-out appropriate "WASHING PROCEDURES" to a good instrument maintenance
- Important: to avoid capillary obstruction from rubber particles it is suggested to use maximum two times the same washing tubes.
- Keep away any kind of objects, liquids, or substances not required for the instrument's use.
- Check if the tube contains at least 800 uL of blood and verify that the blood is not neither haemolysed nor coagulated. Use exclusively blood samples withdrawn in EDTA anticoagulant (K_2 or K_3).
- Use preferably tubes with a capacity of 3 ml verifying that the sample volume should in any case not exceed the 50-60% of the total volume of the test-tube in order to optimise the blood homogenization.
- The mixing is done rotating completely upside-down the sample tube.
- Samples mixing is done at the beginning of the analysis with the purpose of disaggregating erythrocytes. A possible ineffective disaggregation could affect the results given by the instrument which measures system is based on the detection of the kinetics of aggregation of the red cells
- In the event paediatrics samples are used, the minimum volume suggested is 500 uL,
- It is possible to use "BD Microtainer MAP®" tubes directly (also in conjunction with other 13x75 tubes) on all TEST1 (THL, BCL, SDL, XDL, MDL, YDL) models without the use of adapter (but could be necessary to verify the needle offset adjusting its excursion in case of volumes lower than 500 uL
- Start the analysis within 4-6 hours from vein-puncture, otherwise keep the samples in refrigerator at +4÷8 °C (+39,2 / +46,4 °F), for a maximum of 24 hours. If the samples have been conserved in refrigerator at +4 ÷ 8 °C (+39,2 / +46,4 °F), it is necessary to leave them at room temperature at least for 30 minutes before their analysis, even if it

is in any case suggested to let the samples remain at room temperature preferably for about 60 minutes, then, execute the analysis within 4 hours.

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

MECHANICAL SAFETY

WARNING

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

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

- Do not remove the panels neither camper the reading sensor.
- The internal carriage moves over a sliding guide which is an “auto lubricating” guide, so it is not necessary to lubricate or add any kind of oil or grease along the rails of the carriage guides.
- Maintenance operations may only be carried out by technical personnel authorised by the manufacturer.
- Switch off the system, separate it from the mains supply and protect it against restarting.
- For your safety, if any part should be damaged, ask for the immediate replacing with original spare parts, specially for the parts connected to mains (power cord, fuse-holder and mains switch …)
- It is very important to check the tube’s height because:
  - **TEST1 BCL, SDL, YDL, MDL, XDL, cannot** use tubes with a height over than 83 mm (3,268 in) (cap included).
  - **TEST1 THL**: Can use tubes up to 95 mm (3,74 in) (cap included) but working with only 15 samples Alifax rack (code SI195500).
- 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.

ELECTRICAL SAFETY

DANGER

Electrocution/Fire Hazard!

Non-observance of rules and regulations can cause serious personal injury with lethal consequences and material damage.

National rules and legal regulations for the safe electrical operation of the system must be observed.

During Installation please be sure

- Avoid improper connection of the system and the peripheral devices to mains supply can cause serious personal injury with lethal consequences and material damage (e.g. fire).

- Use only connection and extension cables with a protective conductor and sufficient capacity (performance, power) to connect the system and the peripheral devices to the mains supply.
- Supply cord shall have cross section area at least 0,75 mm^2 or at least AWG 18
- Never interrupt the grounding contacts.
- Grounding of the system and its peripheral devices to the same protective earth potential must be ensured and it is connected to a mains socket with a Protective Earth terminal before its use
- The use of a multi plug is not allowed!
- Damaged connecting cables can cause serious personal injury with lethal consequences. Damaged connecting cables must be replaced immediately!
- No objects may be placed on the connecting cables.
- Connecting cables must be laid so that they cannot be squeezed or damaged.
- Connecting cables must be laid so that they do not lay in accessible or drivable areas.
- Switch OFF the instrument and unplug power cable before connecting any external peripheral as external bar code readers, printer cables and/or RS232 serial cables and for maintenance.

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

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

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

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

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

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

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

- Do not attempt to recharge the battery.
- Do not expose to temperatures higher than 60°C (140°F).
- Do not disassemble, crush, puncture, short external contacts, or dispose of in fire or water.
- Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.

- Replace only with the spare designated for this product.
- Lithium battery VL 2020 type inside CPU board.

NOTE

Transient Emissions and Interference Resistance

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

- This instrument can cause radio interference in domestic environment. In this case it may be required to take action to eliminate such interference.
- Before setup and operation of the instrument, the electromagnetic environment should be evaluated.
- Do not use the instrument in the vicinity of sources with excessive electromagnetic radiation (e.g. unshielded, deliberately operated high frequency sources) since they could interfere with the proper operation of the instrument
- Avoid if possible the connection to mains through plug adapters and choose an electrical outlet far from any strong impulsive voltages, usually generated from centrifuges, refrigerators, elevators and freight elevators.
- Avoid the use of the instrument near electromagnetic sources like for example cellular phones, CB's, radio transmitting units and similar
- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference

BIOLOGICAL SAFETY

DANGER

Risk of infection!

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

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

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

DANGER

Waste and Disposable procedures

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

DANGER

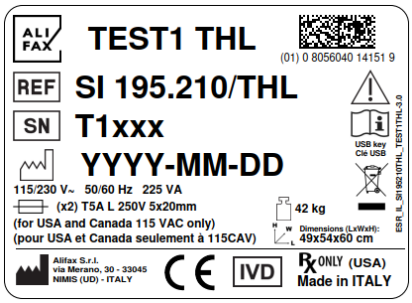
Maintenance

During Maintenance/ Technical Service activities be sure to:

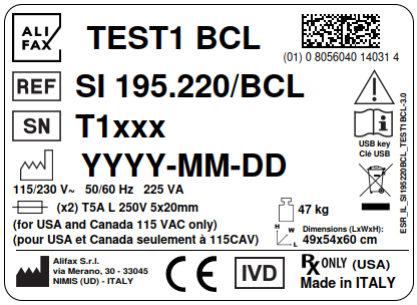
- **use gloves to protect agains any possible accidental contact with infectious materials presents inside instrument .**
- if during maintenance the instrument has been stored /moved to a cold places, wait at least 30 minutes before switching ON again the instrument for the first time in order to avoid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

5- LABELS

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

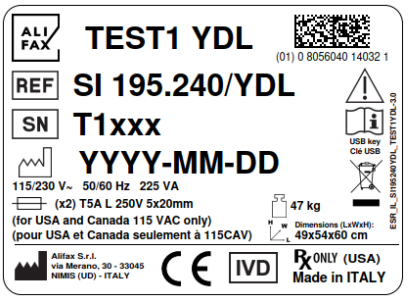


Instrument plate label THL version

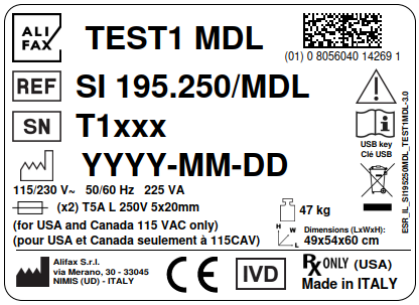


Instrument plate label BCL version

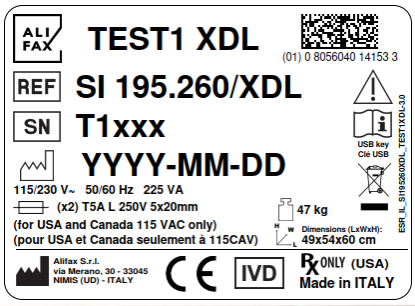
Instrument plate label SDL version



Instrument plate label YDL version

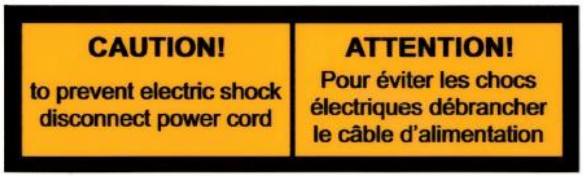


Instrument plate label MDL version



Instrument plate label XDL version

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

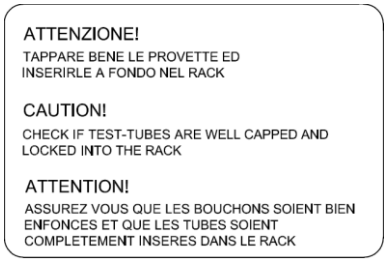


Electrical shock hazard label - disconnect the power cord

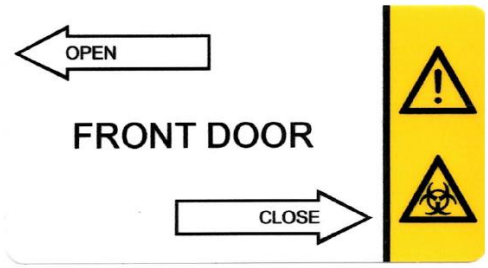
Label to indicate to collect separately from other waste.

Earthing point label

Label for technical assistance number



Caution label to the correct preparation/insertion of the tubes



Door opening label with indications of biohazard and consultation of the user manual

Biohazard label with indications about tank replacement

Washing tank label with filling information

Biohazard label

Fuse indication label

Power selector switch identification label

MET compliance label.

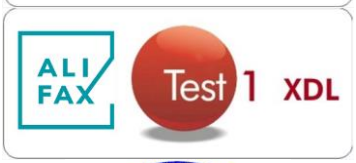
Instrument identification label THL version

Instrument identification label BCL version

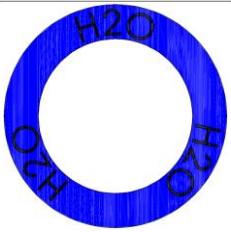
Instrument identification label SDL version

Instrument identification label YDL version

Instrument identification label MDL version

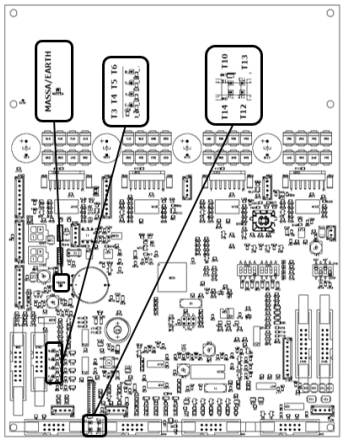


Instrument identification label XDL version



Washing tank cap identification label

Identification label for drain tank cap



CPU connection diagram label

PROCEDURE OF INSTRUMENT WASTE AT THE END OF ITS OPERATIONAL LIFE

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

UNPACKING, INSTALLATION and FIRST START-UP

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

6-VOLTAGE SELECTOR AND FUSES REPLACEMENT

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

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

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

To replace the fuses use the following procedure:

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




FUSE-FUSIBLE
T5A L 250V 5x20mm

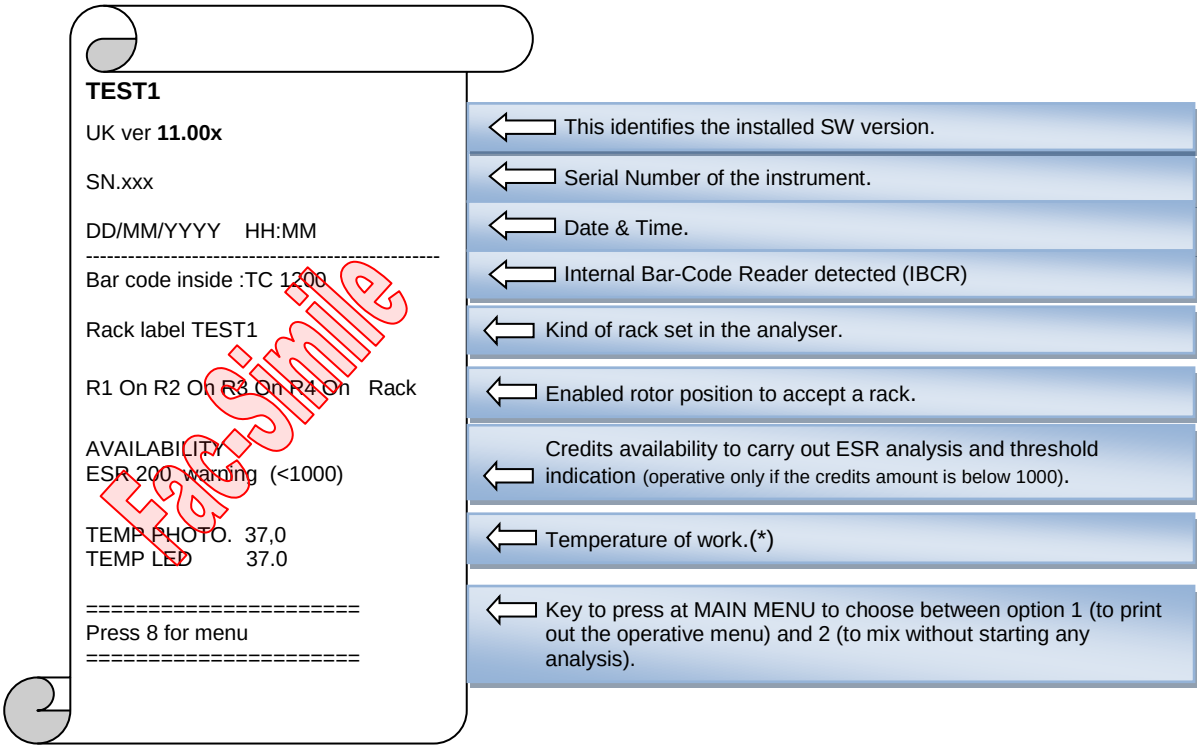
(*)
The fuse which is placed in appliance inlet shall be replaced only by a T5A L 250Vac dimensions 5x20 mm .
A T5A L fuse; it is suitable for both 115 and 230Vac.

7-TURNING THE INSTRUMENT ON

Verify whether the front door is closed, then turn the instrument on pressing the rear-side switch.

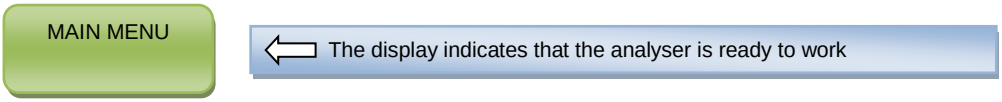
Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C) / 98,6°F (±0,9°F)

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



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

At the installation time, please check whether the configuration of the rack reported on paper is right in order to avoid mechanic and syringe group damaging.



PAPER ROLL REPLACING

The described procedure has to be done at instrument ON.

1. If the printer model is "**CUSTOM PLUS II**", press the green central key, open the paper cup lid and remove the remaining paper. If the printer model is "**Martel**", pull the lever out until the lid is released from its locking position. To avoid damaging, do not use excessive force.
2. Reel off 15 centimetres of paper roughly from a new roll. Remove the pasted part.
3. Hold approximately 5cm of paper outside the device as you place the new roll into the reservoir.

4. Close the lid by applying equal amount of pressure on each side ensuring the lid is in the locked position. Now tear the spare paper away.

5. If it is necessary to recover paper from the printer, press **PAPER FEED** over the keyboard or the key  over the printer.

Photo 1 CUSTOM PLUS II

Photo 2 Martel printer

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

SMART CARD TO LOAD CREDITS

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

UNIVERSAL CARD

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

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

8-INCREASE TEST AVAILABILITY

Pushing **0** at **MAIN MENU**, will display the following message:

MENU SMART CARD
choose

Also will be printed on paper the available choices as for the images below.

MENU SMART CARD

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

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

AVAILABILITY

ESR xxxxxxx
Card matched
Actual personalization

Loaded xxxxx tests

MENU SMART CARD

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

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

Used card
Sn yyyy
Download date xx/xx/xx

MENU SMART CARD

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

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

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

LOG SMART CARD

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

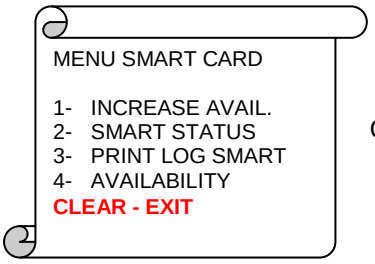
MENU SMART CARD

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

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

AVAILABILITY

ESR xxxxxx



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

SMART CARD ERRORS ALONG THE CREDITS LOADING

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

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

Error messages could appear on display like:

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

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

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

9-ANALYSIS CYCLE

PRIMING DESCRIPTION

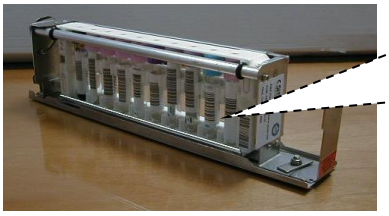
At the analysis cycle run and only whether the capillary is use washed previously, at the middle of the mixing phase, the instrument is going to withdraw a blood aliquot from the first and then from the second test-tube put into position one and two respectively of the inserted first rack. If there is only one test-tube inserted, the system is going to aspirate the same aliquot of blood twice from the first test-tube. Before discarding in the waste tank, the two aliquots of blood are moved forward and backward into the capillary for three \ four time in order to remove any residual particle of water from the Teflon capillary. This procedure is called "**priming**". The instrument then is going to continue the mixing process to complete the specimens homogenization.

10-ANALYSIS CYCLE ON TEST1 THL

DESCRIPTION

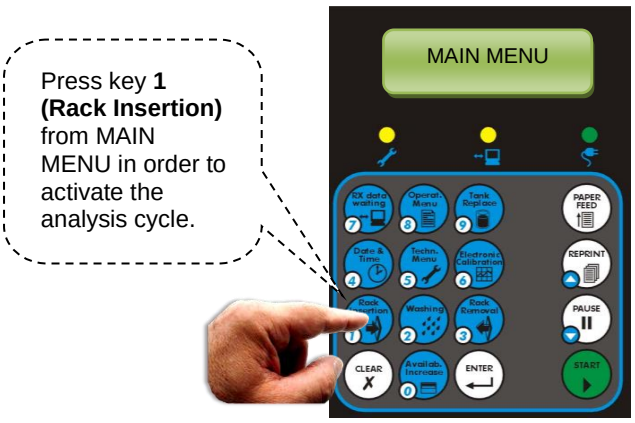
TEST1 uses an **I**nternal **B**ar **C**ode **R**eader (Scanner), to identify patients reading barcode label identification code (ID) stick on the specimen tubes. The reading is done automatically after mixing and before starting the measuring phase.
The analysis of each specimen is decided by host computer, whereas the analyser is linked with it through the serial connection. On the contrary, the ID identity code reading of each specimen and the consequent analysis run independently whereas the analyser is no linked with host computer. The analyser is able to start the analysis with one credit only and goes ahead analysing all inserted specimens. At the end of the analysis cycle announced by three acoustic beeps, having 0 or negative credits, the analyser stops working until new credits are loaded. Any negative credit will be recovered at the successive credits of test loading.

RACK PREPARATION



Like this example, insert the test tubes in a rack starting from the first position without leaving empty positions and the label bar code that exits from the slot side. Insert then the rack in use in the laboratory in the matched metallic adapter designed to support the rack.

ANALISYS START-UP



INCREASE AVAIL
Insert CARD

NOTES:

In case the message as reported on the left is displayed, it means that the residual of credits (Availability) is below than the set threshold and new credits should be loaded. References for the credits loading procedure is available at **chapter 8**

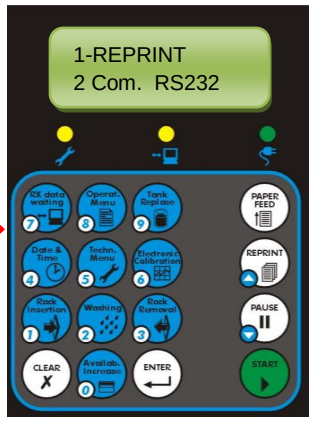
Open the front door, remove any rack that might be present in the rotor and insert the rack with the blood specimens to analyse. Close the door.
If other racks have to be inserted (up to four), open the door again insert the rack and close the door again. On the contrary press **START** to run the mixing phase followed by the analysis process.

NOTES:

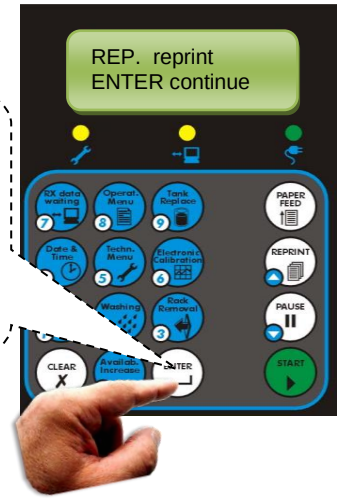
The instrument is able to manage a kind of racks between those displayed in ***APPENDIX A*** The choice depends on the Cell Blood Counter in use in the laboratory. The instrument accept four racks at maximum and runs the analysis cycle automatically after the fourth rack insertion and the door closing. In case the number of tacks to insert is between one and three, to run the analysis cycle, press **START** after closing the door.

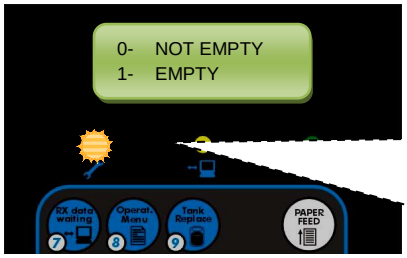
At the end of the analysis cycle announced by 3 acoustic signals, the **REPRINT** key allows to enter inside a sub-menu where is possible to reprint all the ESR of the samples analyzed, and/or resend them to the LIS if the instrument is connected to it.

Press **START** to start the analysis cycle, which allows the mixing of the samples and their consequent analysis process.



Pressing **ENTER,** the analyzer exit from the analysis procedure, asking the operator to remove every rack inserted, one by one, opening the door removing the rack and closing the door again. Once completed the removal the instrument will come back automatically to MAIN MENU.





If the display displays this message, while the left LED is blinking, it means that the tank is full of liquid. It must be disposed and the key **1** pressed to reset the counter to 0. Detailed information is present at **Section 18 TANK REPLACING**

11-ANALYTICAL CYCLE WITH DIRECT INSERTION RACK

DESCRIPTION

If the **TEST1** suffix is **BCL, SDL, MDL, YDL, XDL,** it means that the analyser is equipped by a direct insertion kit and the rack in use in the laboratory does not require rack adapters so CBC can be loaded directly inside the instrument.
Before inserting the rack in the instrument, be careful to check that all tubes have their bar code label turned to the slot side of the rack (the right side), otherwise, the **I**nternal **B**ar **C**ode **R**eader (IBCR) cannot read the ID code correctly.

PROCEDURE

The following photos show how to load the racks. This depends on the type of Direct Insertion configuration:

TEST 1 XDL

Open the loading door (Photo 11), press the guide until it is unhooked (Photo 12), pull out it until it is extracted completely (Photo 13). Insert the cassette in the guide (Photo 14) and rotate the test-tubes to allow the complete exposure of the bar codes labels from the rack slot then slide the guide inside the instrument. Push it up until the guide is hooked and close the sliding door.


Photo 11


Photo 12


Photo 13


Photo 14

TEST 1 YDL

Open the loading door (Photo 15), press the guide until it is unhooked (Photo 16) pull out it until it is extracted completely (Photo 17). Insert the cassette in the guide (Photo 18) and rotate the test-tubes to allow the complete exposure of the bar codes labels from the rack slot then slide the guide inside the instrument. Push it up until the guide is hooked and close the sliding door.


Photo 15


Photo 16


Photo 17

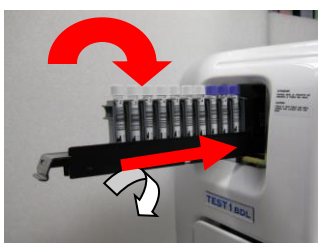


Photo 18

TEST 1 MDL:

Open the loading door (Photo 19), press the guide until it is (Photo 20), pull out it until it is extracted completely (Photo 21). Insert the racks as indicated by the (Photo 22) and then fix them pushing gently from the two extreme sides to lift the test-tubes and allow their complete exposure of the bar codes.
Slide in the guide, push it up until feel hooked and close the sliding door.


Photo 19


Photo 20


Photo 21

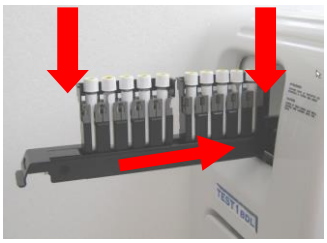


Photo 22

TEST 1 SDL:

Open the loading door (Photo 23), press the guide until it is unhooked (Photo 24), pull out it until it is extracted completely (Photo 25). Push toward right side the lever to rotate the sliding guide (Photo 26), in order to allow the cassette entering over the guide (Photo 27). Release the lever and check if the cassette fits correctly inside the sliding guide. Rotate the test-tubes to allow the complete exposure of the bar codes labels then slide the guide inside the instrument (Photo 28). Push it up until it is hooked and close the sliding door.


Photo 23


Photo 24

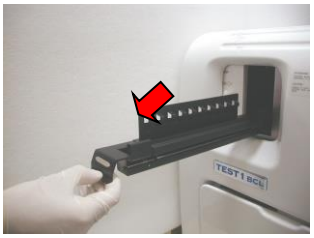


Photo 25


Photo 26

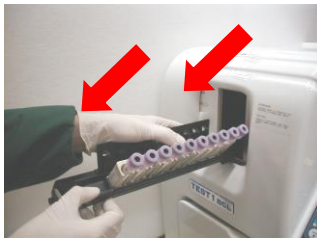


Photo 27


Photo 28

TEST 1 BCL:

Open the loading door (Photo 29), press the guide until it is unhooked (Photo 30). Accompany it up for the complete extraction (Photo 31), and insert the rack toward the inner position. Press then it on two extreme sides for lifting the test-tubes (Photo 32), and allow the complete exposure of their bar codes. Slide in the guide, push it up until it is hooked and close the sliding door.


Photo 29


Photo 30


Photo 31

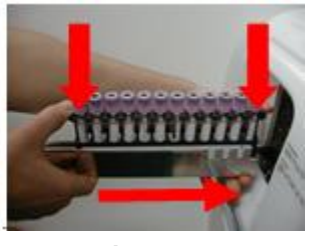
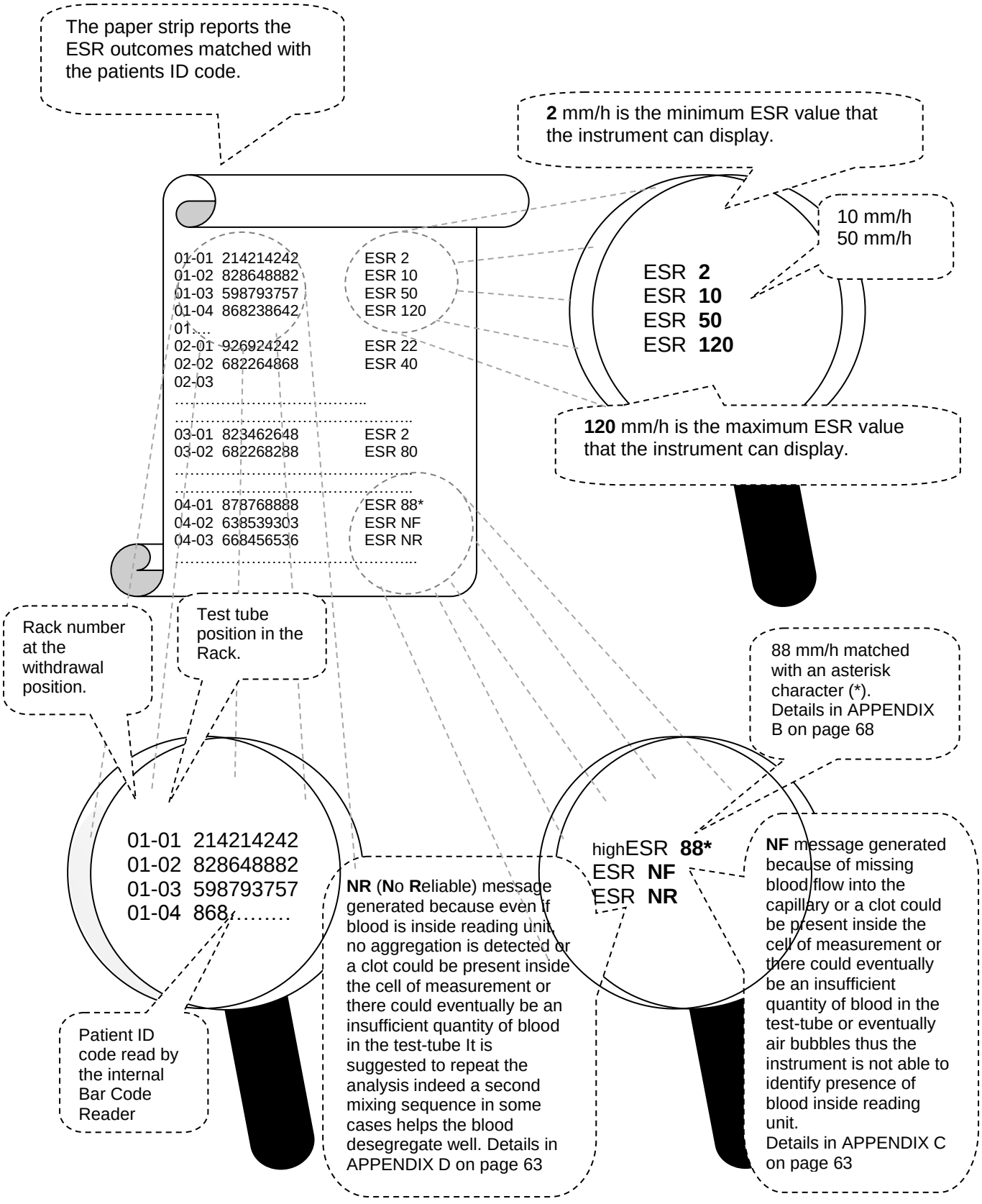


Photo 32

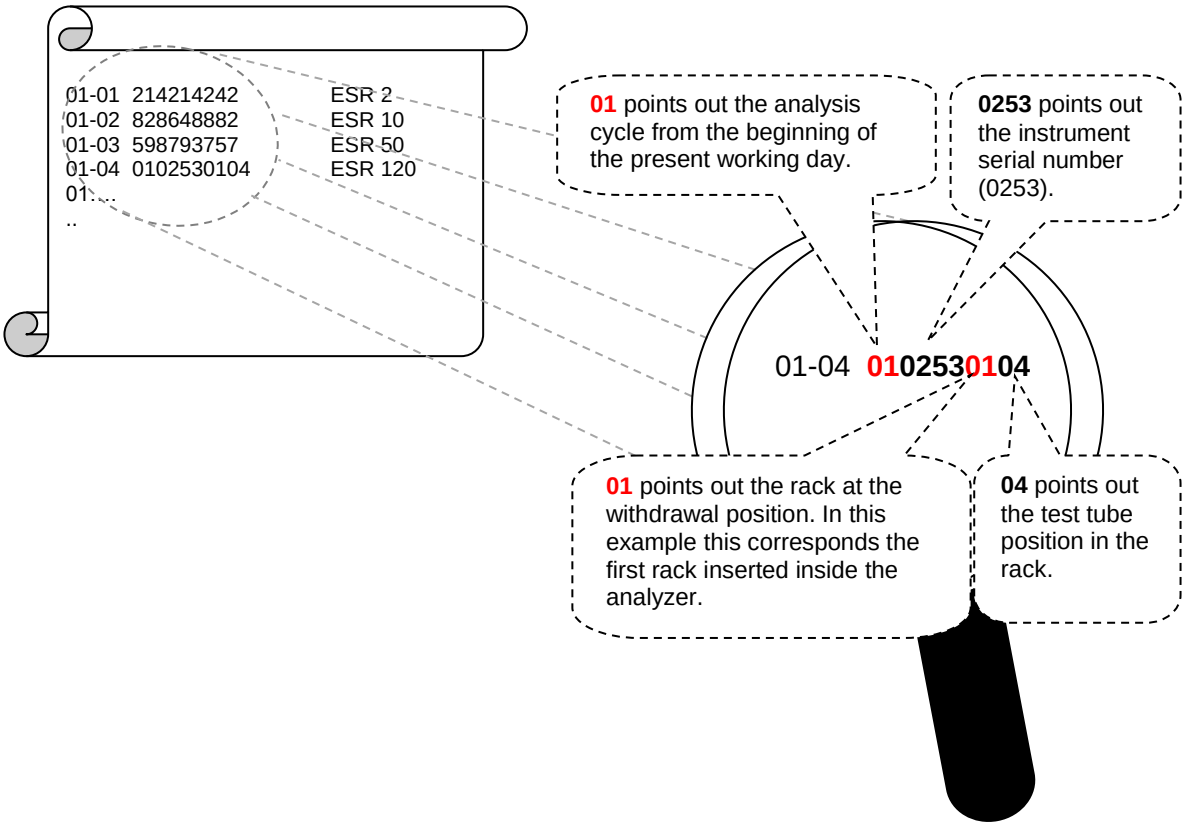
MESSAGES AND RESULTS PRINT OUT AT THE END OF THE ANALYSIS CYCLE



In case of three consecutive **N.F.**s the analysis cycle stops working and the instrument washes automatically.

ID CODE AUTOGENERATED BY THE INSTRUMENT (IF BARCODE LABEL NOT READ)

If the ID label is unreadable because ruined or no oriented properly, the TEST1 assigns an identification number autonomously which represents the cycle number running followed by the instrument serial number followed by the rack number (1÷4) followed by the position of the test tube in the rack (between 1st to 15th).

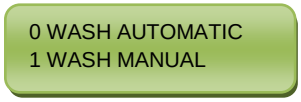


WASHING REQUESTING AT TIMEOUT

On TEST1, having installed an Automatic Washing System, at the end of the analysis cycle and having returned to MAIN MENU, a countdown timer is activated.
When the timer reaches the threshold (configured at installation time) and assuming no key on keypad was pressed to perform any other operation, the instrument moves the carriage below the washing station and automatically performs a washing cycle in order to clean the capillary and the needle.

Of course the operator can in any moment run a classical washing procedure as in the past loading 2 or 3 washing tubes on the rack following the classical washing procedure here below described.

Pressing key 2 “Washing” instrument will display the request to choose between “Automatic” and “Manual Washing” (see at Display 7)



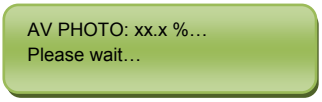
Selecting option 1 “Manual Wash” the instrument will ask to insert 2 tubes, with 3ml of distilled water in each, in the first and second position of a rack and the rack into the instrument. After closing the front door the instrument runs the washing procedure aspirating the water from the tubes. The washing execution causes the **priming** process at the successive analysis cycle run.

NOTES:

- The scheduled waiting time can be modified by the technical service; interval goes from 5 to 180 minutes.
  The choice should be configured accordingly with the specimens frequency that come in the laboratory.
  If the specimens frequency is high, than you can chose a high waiting time (example 60 minutes from the end of the lase analysis cycle) in order to avoid doing washings too much frequently.
  If the specimens frequency is low, than you can chose a low waiting time (example 10 minutes from the end of the lase analysis cycle) to avoid leaving the instrument dirty of blood for long time of inactivity.
- Every time along the waiting time a new analysis cycle is run, the counter is re-set to **0**.
- If the operator at the end of the analysis cycle carries-out a washing as described on **chapter 12** (Automatic Washing) or on page Errore. Il segnalibro non è definito. **(**Washing with 2 test tubes), the waiting time counter will be set to **0** as the instrument is able to recognize whether the capillary is cleaned or contains blood traces inside.

12-WASHING PROCEDURE

This procedure is designed to clean the complete capillary tubing and so to set it free from blood or Latex residuals. Since along the working life Latex flow inside the Teflon tube, particles of them tend to hang on the internal walls of the capillary. This fact, accordingly, increases the capillary opacity reducing the reading scale of the ESR values.
Starting from Firmware version 9.00A onwards with the introduction of the new CPS, visualization of washing cycles have been slightly modified, now on display.
Now independently the washing is done automatically or by means of test tubes filled with water, the visualization appears as here below described:



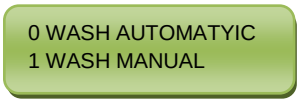
- On the first row is visible the **AV PHOTO: xx.x%** that is the ratio between the water value read and the theoretical value of the water (3800).
- On the second row is visible the phrase "**Please wait…**"

At the end of the washing cycle (independently the Automatic or the Manual one) if everything is ok, instrument will print the final values and the phrase *** PHOTOMETER OK ***.
Then it will ask to remove washing tubes / rack, if instead something goes wrong, instrument will issue a **Z** error as normally done also in the previous versions of instruments and firmware.

Next paragraphs explain the washing procedures available in the manual mode.

AUTOMATIC WASHING

Pressing key 2 "Washing" instrument will display the request to choose between "Automatic" and "Manual Washing"



Selection option 0 "Wash Automatic", instrument will perform the washing using the internal water tank as source of water; in this case it is not necessary to load any washing tube.

WASHING USING 2 TUBES

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

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

To activate the procedure prepare 2 test tubes filled for ¾ with distilled water and insert them in the position 1 and 2 of a rack. Press key **2 (Washing)** on MAIN MENU, then press option 1 "Manual Wash", insert the rack in the instrument.
Wait until MAIN MENU is displayed again which points-out the end of the process.

WASHING USING 3 TUBES

The execution of this option is suggested at the **end of the working day** to maintain the capillary cleaned during the night and for an easy way to remove residuals of blood particles from the needle and capillary tubing at the beginning of the new working day.
To activate the procedure, 3 test tubes filled for ¾ with distilled water have to be prepared and put into the first three positions of a rack and then key **2** (**Washing)** on **MAIN MENU** has to be pressed, then select Manual Washing option.
The rack has to be loaded into the instrument and then wait until "**Test 1 off**" message is displayed. The operator can chose to continue with the ordinary activities pressing "**ENTER**" or to switch the instrument off for the night. On both cases and during the washing process, the needle aspirates the content of the first and second test-tubes completely and remains filled with distilled water as well as part of the capillary inside the third test-tube. Pressing either "**ENTER**" or immediately after switching the instrument on, the needle is going to exit from the third test-tube and the instrument then goes to empty the needle and capillary.
Water and any wet residual particles of blood, will be discarded into the waste tank.

WASHING PROCEDURE FOR MAINTENANCE

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

The procedure is:

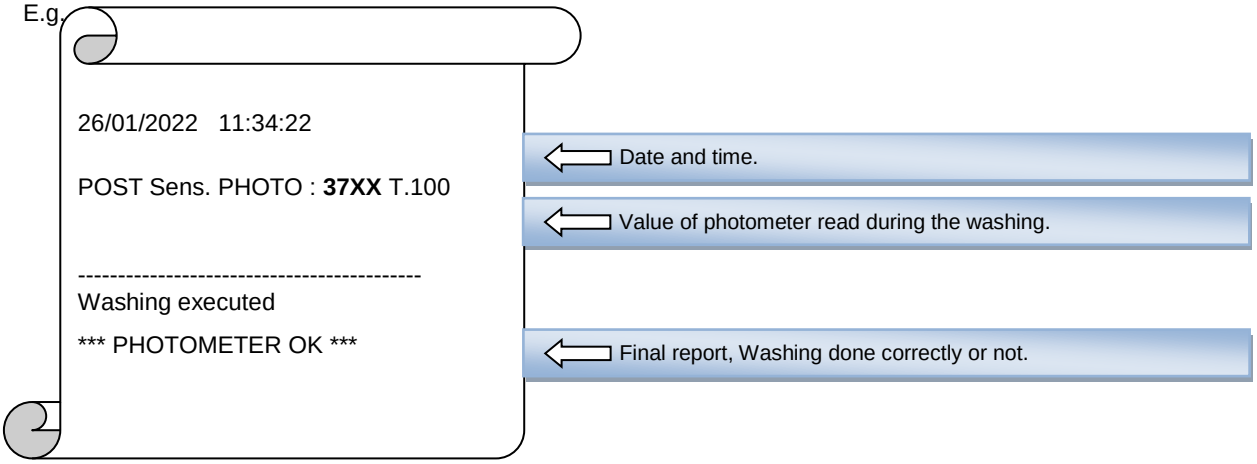
1. Prepare two test-tubes filled 3/4 with distilled water and put them in the 1st and 2nd position of a rack. Press key **2 (Washing)**, select Manual Washing option to start the procedure, insert the rack into the instrument and wait for the end of the procedure.
2. Prepare one test-tubes filled 3/4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

WASHING PROCEDURE WHEN USING LATEX CONTROLS

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

WASHING REPORT

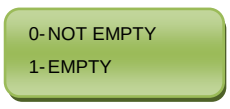
At the end of each washing procedure, the software is going to report its value matched with the suffix **T100**.
E.g.



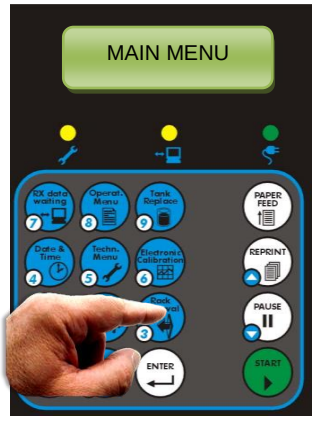
At every incorrect washing procedure, software will generate **Z** error and a new washing procedure requested.
If T. 100 tends to reach **37XX**, it means that the tubing is going to be opaque.
In this case try to carry-out the procedure explained at the chapter WASHING PROCEDURE FOR MAINTENANCE. The value then should rise at least to **3800**.
The water value is automatically corrected to a value close to 3800 every time a latex control is executed

NOTES:

- **Z** error can be differentiated to **Z-0, Z-1, Z-2, Z-3, Z-4** and **Z-5.**
  Z-0 is generate in case the calibration washing (latex procedure) fails after a fixed number of attempts
  Z-1 is generate in case of no detected or no continuous water flow
  Z-2 is generate in case the syringe is not able to detect the washing test tube or the scanner reads the code “NO”
  Z-3 is generate in case there is a mechanical problem on the instrument (example: Syringe problem)
  Z-4 is generate in case there is a problem in the CPS-MC unit (example: No communication between CPS and CPU)
  Z-5 is generate in case the washing timeout expired (Only in Debug ON mode)
- At the end of the washing procedure, in case the left LED blinks and the display shows a message like the example on the left, it means that the tank level has been exceeded. Follow the indication described at **section 18**



13-RACK EXTRACTION

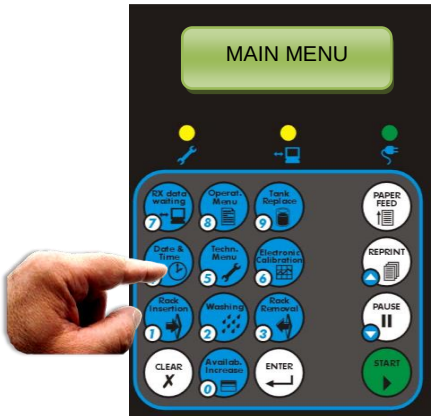


At the end of the analysis cycle the instrument activates the rack extraction process. This procedure, however, can be executed on MAIN MENU also.

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

Extract rack	Open the front door, extract the rack and close it again. If other racks have to be removed, wait a second, open the door again and extract. Repeat until the last rack is extracted.

14-CHANGE DATE & TIME



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

DD / MM / YYYY Setup DATE	where DD=Day, MM=month, YYYY=Year

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

At this point the displayed message is:

HH:MM Setup TIME	where DD=Day, MM=month, YYYY=Year

Photo 6

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

15-RESERVED FOR TECHNICAL SERVICE

16-QUALITY CHECK USING LATEX CONTROL KIT

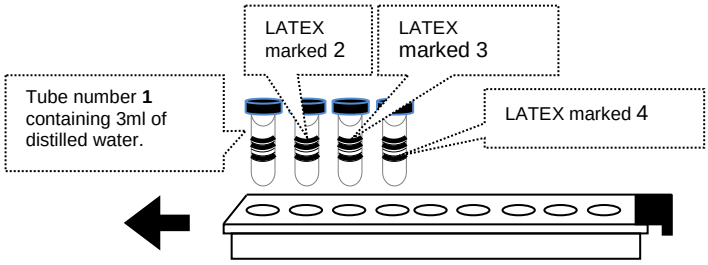
With the purpose of guarantee an always optimum performance of the instrument, the daily use of the latex control kit is recommended.

Latex Controls kit is a valid check tool to monitor the reliability of the analyser during its working life. The kit is supplied in a box. It can contain three test tubes filled with Latex that allow executing a total of 6 controls (sale code **SI 305.100-A**) or it can contain five test tubes filled with Latex that allow executing a total of 30 controls (sale code **SI 305.300-A**).

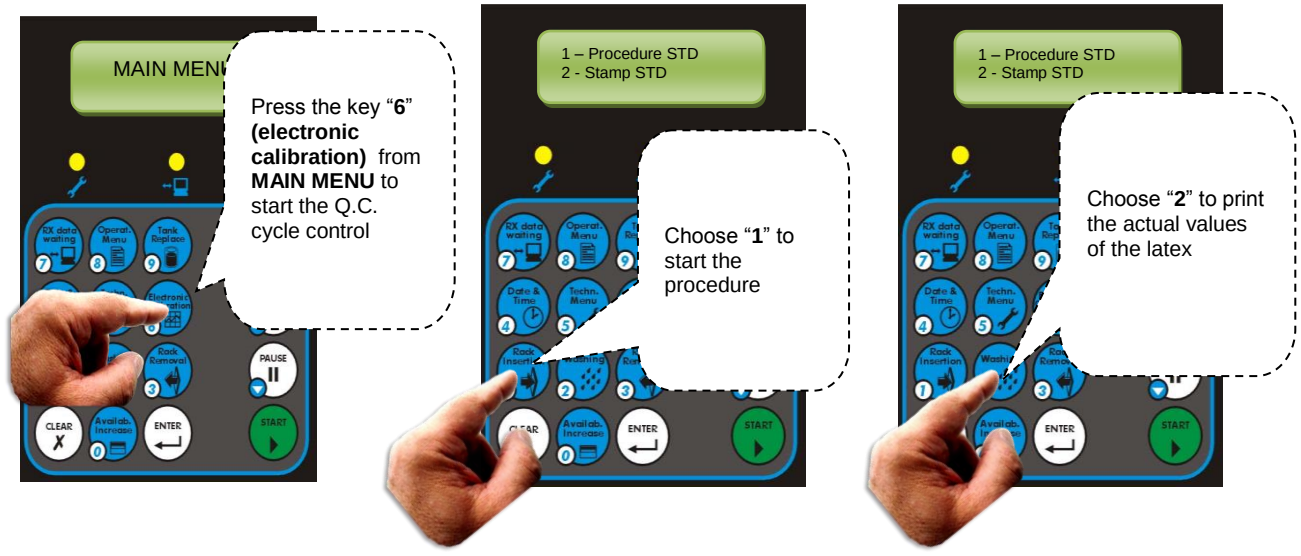
Remove from the refrigerator the box containing the Latex Control (or Calibration) that must be stored in the refrigerator at + 4÷8 °C (+39,2 / +46,4 °F); remove from the box only the triplet that will be used for the checks; once used, the latexes must be returned to the refrigerator.

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

a. Execute a first washing procedure by **2** test tubes with 3ml of distilled water in each of them. Insert them in the first and second position of the rack.
b. Execute a second washing procedure by **1** test tube with 3ml of Sodium Hypochlorite in the position 1 of the rack and **1** test tube with 3ml of distillate water in the position 2 of the rack.
c. prepare a rack with the test tubes set as the below example shows:



d. Notice that form Sw 9.00A having TEST1 the automatic washing system, it is not necessary to load anymore water tubes in position 5 and 6

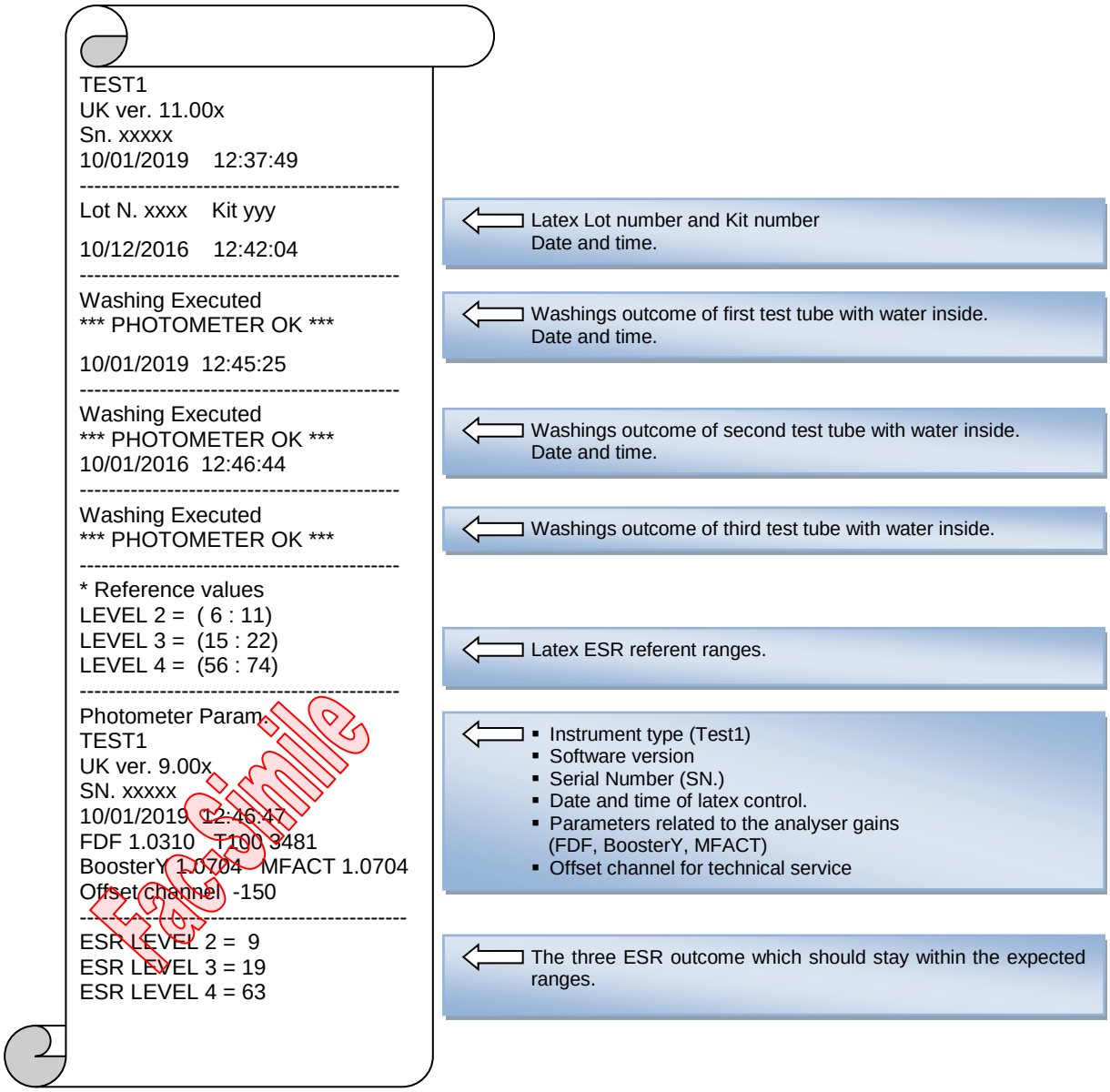


Inserire rack STD

at the request, open the door, insert the rack in the instrument and close the door. Upon having inserted the rack with the set test-tubes, the analyser is going to start mixing which, to be completed, spends one minute and half, roughly.
At the end of mixing, the controls are analysed and if the correlation between the referent values and the read ones overcome the 97% (0.97) the Control process will be completed. Otherwise, if the correlation is below

than 97%, the **"Correlation NoK, Procedure aborted**" message will be printed out on paper and the procedure aborted.

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



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

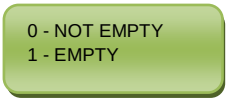
The effective reference ranges to be used to confirm that the instrument is "in control" are in any case those indicated on the outer label of the Latex Control Box.

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

Extract rack

At the end of the latex cycles, open the loading door and remove the rack. Close the front door.

- If at the MAIN MENU return, the display shows the message while the left LED blinks, it means that the tank level has been overtaken. Please follow the indication **at chapter 18 TANK REPLACING**



If after the rack introduction you get a message like **STD xxxx NX,** means that the scanner did not read the bar code on the test tubes. In this case, enter the code manually as described on "**APPENDIX E - LATEX CODES TYPED MANUALLY".**

17-KEYBOARD OPERATING FUNCTIONS

DESCRIPTION

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

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

Pressing **key 8** and then **1** and you activate the options list printing.

MAIN MENU

0-AVAILABILITY
1-MEASURE
2-WASHING
3-RACK EXTRACTION
4-DATE & TIME
5-TECHNICAL MENU
6-CALIBRATION EC
7-RS232 RX DATA
9-TO CHANGE TANK
REP-STATISTICAL DATA
CLEAR-CHANGE NEEDLE

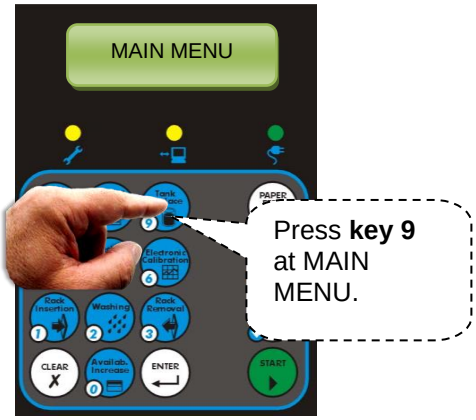
List:

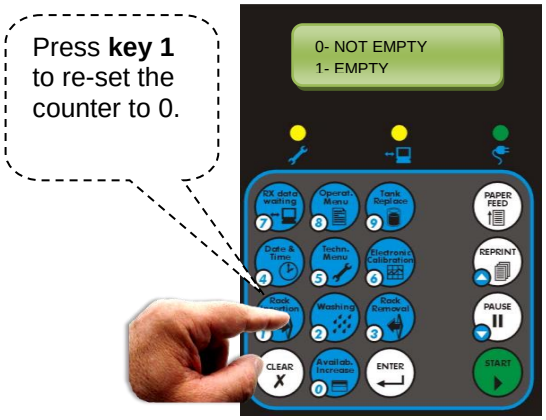
0 - (to increase the availability of credits
1 - (to run an analysis cycle)
2 - (to start a washing procedure)
3 - (to remove any rack from the instrument)
4 - (to modify date and time)
5 - (to access Technical Menu)
6 - (to start a Control process by Latex kit)
7 - (used only in absence of both internal and external scanner)
9 - (to reset the tank counter after the tank replacement)
REP-(to run the internal Quality Control)
CLEAR-(to replace the needle)

18- WASTE TANK DISPOSAL

DESCRIPTION

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 200 points below the warning empty tank threshold (set at 1500) the instrument will print out the message “TANK ALMOST FULL”. Such message warns the operator about the necessity of replacing the tank and re-set the counter to **0**.

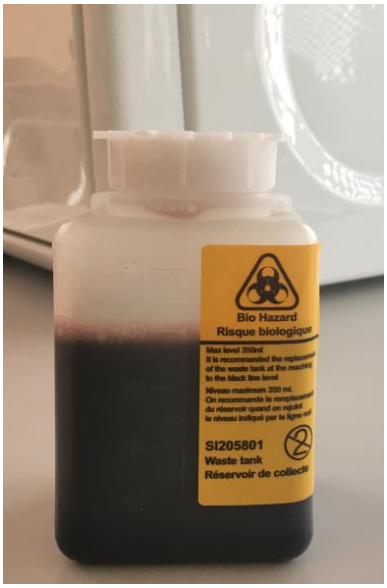




If you ignore the message “TANK ALMOST FULL” and you continue analysing specimens, at the threshold maximum level overtaken, the display will show a request to dispose the tank and the left LED above the keyboard will blink and the printer prints out “WASTE LEVEL DETECTED EMPTY THE TANK”. The instrument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

Waste tank disposing procedure

Open plastic front door, pull out the loading carrier and remove waste tank cap.



Remove carefully the full waste tank, insert an empty waste tank, reinsert the waste tank cover and finally apply the plastic screw cover to the full tank. Dispose it unless users are allowed by local government regulations to utilize laboratory policies and procedures to dispose of contaminated waste by using precautions to empty the tank and to sanitize it for re-use

Take advantage to re-fill the water tank even if it does not look empty. Fill up the 500 ml mark. If you want you can also remove the water tank to fill it up easily. Finally push in the loading guide and close the front plastic cover.

Note: 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.

19-PAPER FEED

DESCRIPTION

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

20-STATISTICAL TOOLS

In order to do keep the instrument under control, TEST1 software includes a series of tools which report and plot the instrument performances; such control tools are the following:

1. INSTRUMENT QUALITY CONTROL USING LATEX CONTROL KIT (Kit code SI 305.100 for 6 tests or code SI 305.300 for 30 test)
   - The first plot represents the Control Latex results executed daily and accordingly with the results it wants to drain a linear exposition of them or drifts.
   - The second plot drains the difference of the gain value, any Latex Control process generates, respect the referent position obtained from the Calibration process. The maximum CV allowed is 10%.

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

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

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

LATEX QUALITY CONTROL TRENDS

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

After pressing **REPRINT** at **MAIN MENU** and waiting for a couple of seconds, the following message will be displayed:

STATISTICAL DATA
ESR STD RATE (1)

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

After REPRINT, by pressing key **1** the display will show left-bottom message

1 – TREND ESR
2 – TREND FACT

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

```
ESR
   2          40          80          120
   |          |           |           |
   | *    °   |    o      |           |
   | *     °  |    o      |           |
   | *     °  |    o      |           |
   | *     °  |     o     |           |
   | *     °  |    o      |           |
   | *     °  |    o      |           |
   | *     °  |    o      |           |
   |   *     ° |      o    |           |
   |   *     ° |       o   |           |
   |   *     ° |       o   |           |
   |   *     ° |       o   |           |
```

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

```
        -20      -10       1       +10      +20
DEV%     |        |        *        |        |
         |        |        | *      |        |
         |        |        |*       |        |
         |        |        *        |        |
         |        |        |*       |        |
         |        |        | *      |        |
         |        |        |*       |        |
         |        |        | *      |        |
         |        |        | *      |        |
         |        |        |*       |        |

Dev. St. 26,15
CV% = 8,05
```

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

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

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

ESR STATISTICAL TRENDS

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

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

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

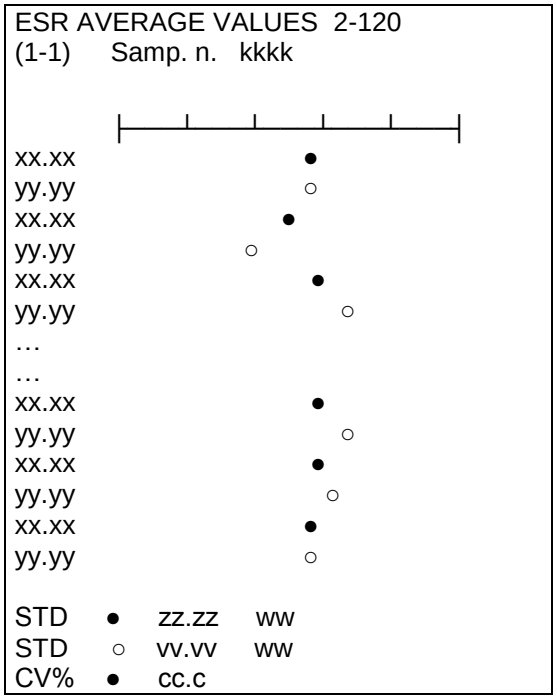
The distribution of the cumulative mean values, is undoubtedly more stable than the average values of patients on different days may come from different or particular departments, etc. This distribution, in fact, is not affected by the contribution of any abnormal samples that can be sporadically present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

STATISTICAL DATA - Graph meaning

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

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

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



Where:

kkkk = represents the whole number of analysed samples.

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

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

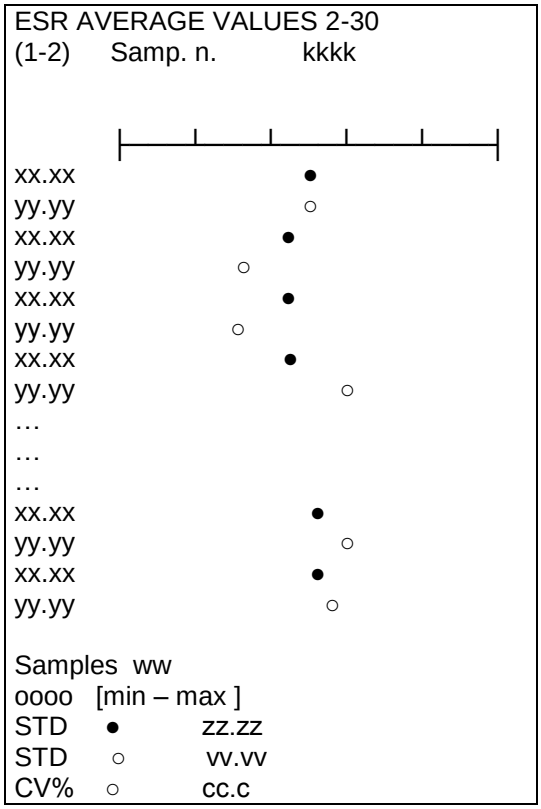
zz.zz = standard deviation of cumulative mean ESR value

vv.vv = standard deviation of daily mean ESR value

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

ww = represent the days of analysis spent to reach kkkk

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



Where:

kkkk = represents the number of analysed samples

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

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

zz.zz = standard deviation of cumulative mean ESR value

vv.vv = standard deviation of daily mean ESR value

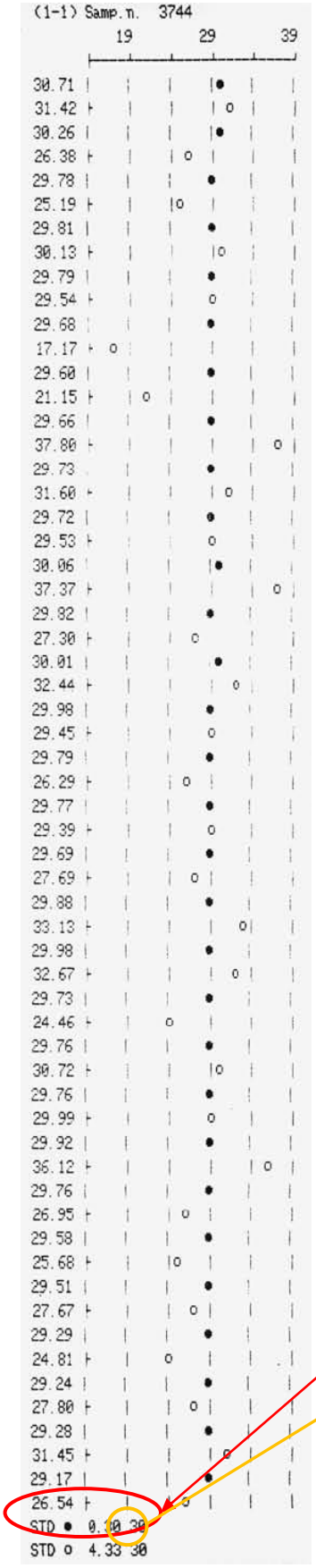
cc.c = CV% of the cumulative mean ESR value

ww = represents the days of analysis spent to reach kkkk

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

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

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



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

Example:

19 29 39

|-----|-----|-----|-----|-----|

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

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

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

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

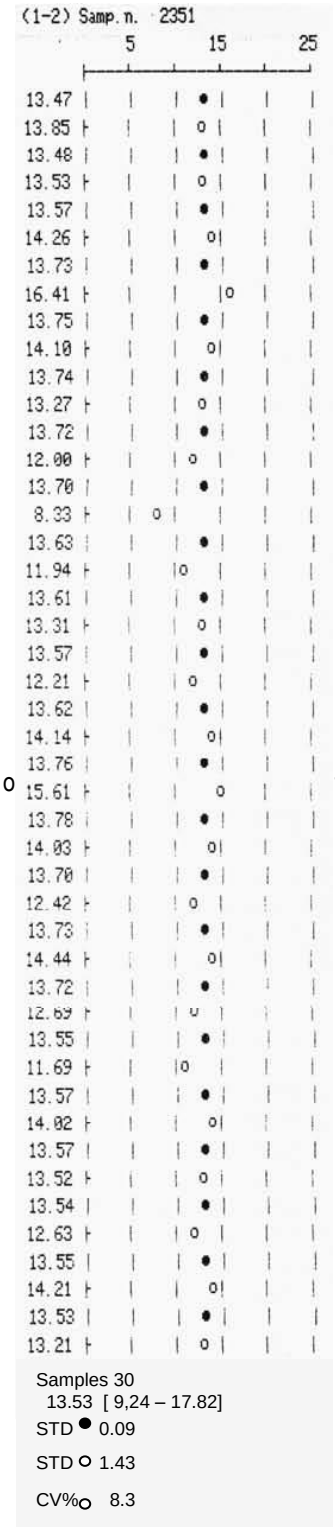
At the end of the graph, the printer prints out the Standard Deviations of both cumulative and daily average:

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

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

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

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



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

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

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

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

  5 15 25
  |-----|-----|-----|-----|-----|

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

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

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

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

In this case the last cumulative average (13.53) has to remain inside the calculated range:
([9,24 – 17,82]).

ESR DISTRIBUTION PRINTOUT

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

ESR VALUES CUMULATIVE AND DAILY DISTRIBUTION PRINTOUT

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

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

Press key 3 to activate the following sub menu.

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

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

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

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

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

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

Where:

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

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

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

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

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

Norm.               jj.jj %
```

Where:

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

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

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

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

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

Where:

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

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

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

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

Norm.               jj.jj
```

Where:

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

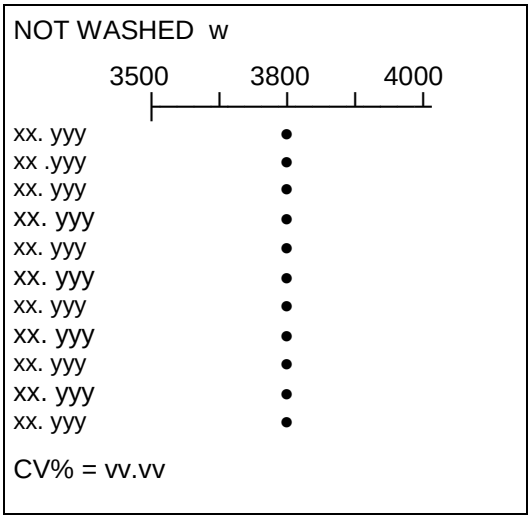
WASHING TRENDS

The print out of washing control allows to evaluate the efficiency of the TEST1 photometer (CPS). The graph visualizes the course of the washing signal, that is directly correlated to the photometrical signal. Normally, the instruments are regulated for an absolute ideal value of 3795 during the washing with distilled water. This value trends to decrease during the time, because biological residuals release deposit inside the capillary.
A daily wash using hypochlorite, will bring again the photometrical signal to an absolute value of around 3800. If this signal decreases under the value of 3500 or increases above the value of 4095, the instrument will generate Z-1 error. In this case try to repeat the washing weekly process and if the value does not come again inside the range 3500 - 4095, call to the technical service for maintenance.

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

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

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



Where:

w = Represents the missing washing number

xx.= Represents the washing progressive number

yyy = Represents the water daily value read

vv.vv = Variation coefficient.

NOTE: The correct calculation of the CV is available only after all the 30 rows are filled by data.

21-PAUSE

PAUSE key does not activate functions at MAIN MENU.

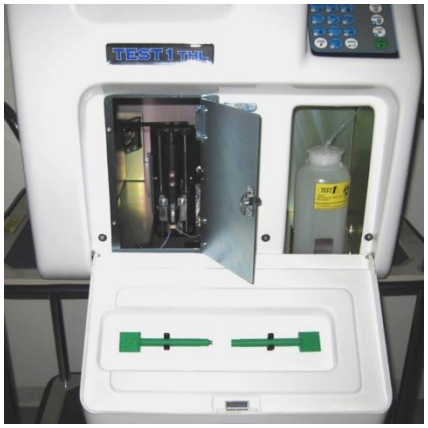
22-NEEDLE REPLACEMENT PROCEDURE

WARNINGS:

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

REPLACING PROCEDURE

With instrument powered ON, open the front door to access the waste tank and rotating the metallic knob open the metallic door to access the needle-syringe group.



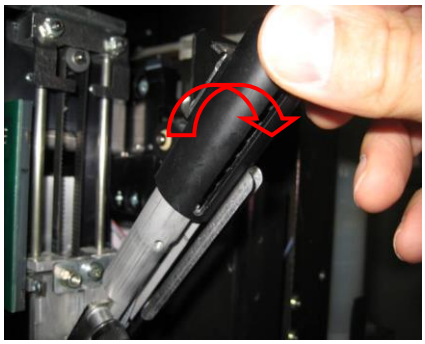
By pressing **CLEAR** key at **Main Menu**, the following message will be displayed:

CHANGE NEEDLE
ENTER continue

By pressing ENTER the syringe group will move towards the front of the instrument, to allow the best accessibility for the needle replacing.
The syringe group will stop and it will be lock to avoid any movement during the needle replacing.

During this operation the following message will be displayed:

ENTER to end



After having unscrewed the retaining screw that locks the piston assembly to the support, grasp the piston with your fingers and pull it towards you so that it will be inclined to 45°

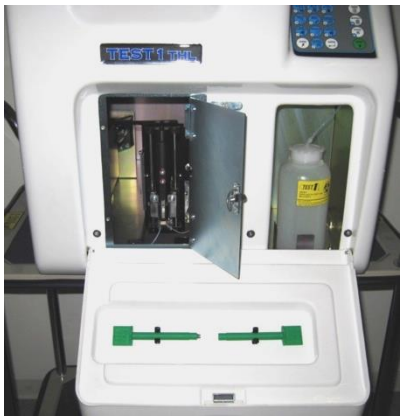
Unscrew the piston cap.
Use the supplied tool if it is necessary.

Take the green tool applied over the plastic flap internal side and insert it into the piston hole and unscrew to remove the needle.

Take the new kit (SI 195077), remove the needle from the green tool, remove the protective rubber from needle's tip, insert again the needle inside the plastic tool and insert it into the piston hole and thigh it.

After removing the green tool re-cap the piston aiding even with the tool if it is necessary.

Push the piston assembly gently inside the instrument up the square magnets retains it vertically and lock the piston assembly twisting the retaining screw.



Press **ENTER** to reset the piston assembly to home position and close the doors.

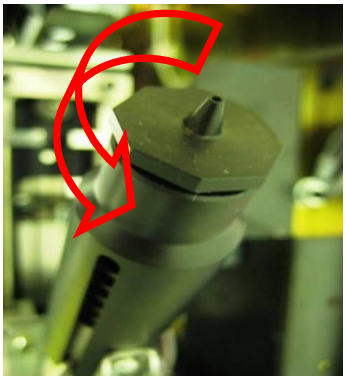
In case of needle replacement is necessary to waste the old needle within the green tool, following the laboratory disposing.

23-NEEDLE CLEANING PROCEDURE

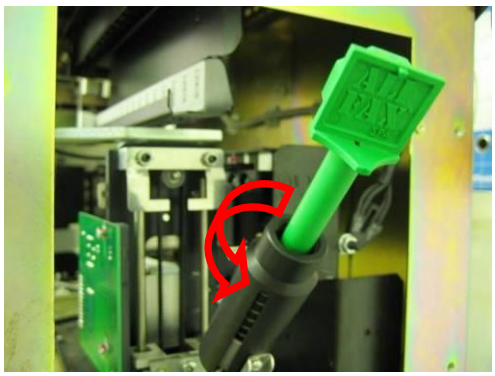
PROCEDURE:

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

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



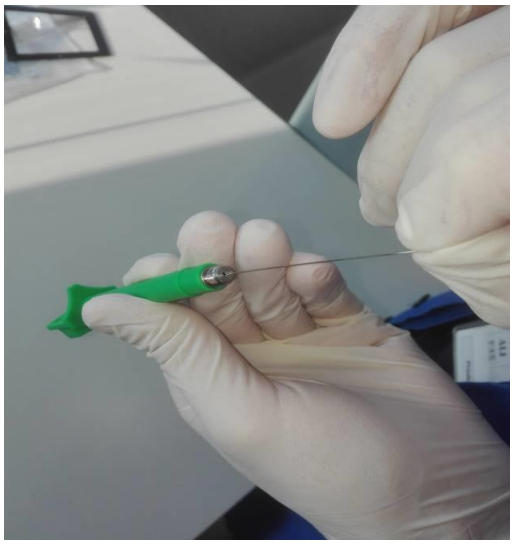
Carefully unscrew the cap of the piston, using the tool in the picture, NEVER USE HANDS, in order to avoid contact with the needle.



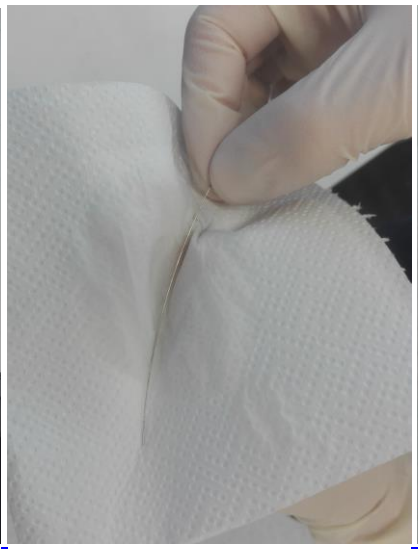
Carefully insert the tool as in picture, until you find the right connection point with the needle, and start to unscrew the needle.. Extract the key, keeping the needle inside it.

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

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



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

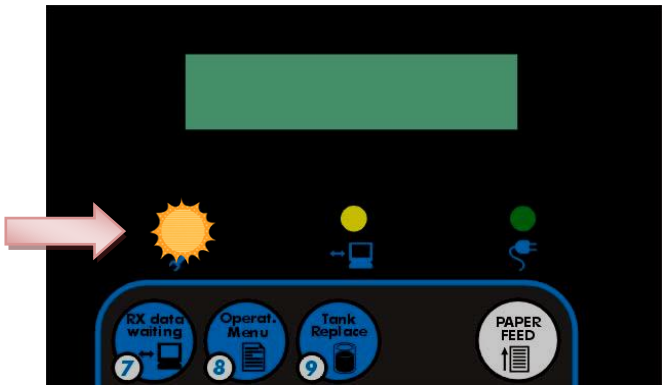


24-TURN THE INSTRUMENT OFF

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

25-MAINTENANCE PROCEDURE

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



26-SANITIZATION PROCEDURE

The following procedure must be executed before:

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

Protection tools and suggested materials to be used:

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

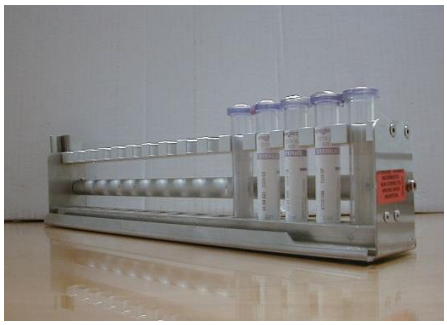
For the description of sanitization procedures of a working instrument: refer to the Sanitization Form at the end of the manual.

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.

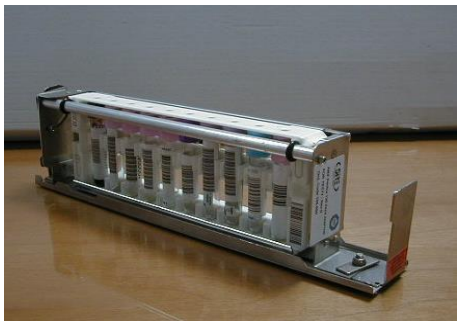
27-APPENDIX

APPENDIX A (TEST1 THL rack adapters)

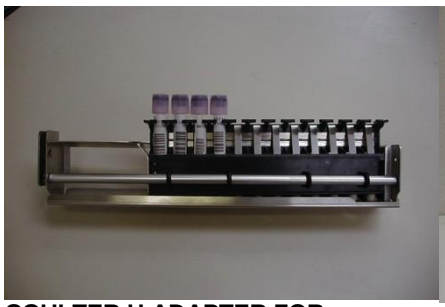


TEST1 RACK (does not require any adapter)

ADAPTER FOR ABBOTT CELL Dyn 3500-3700 / SYSMEX sf-se-xe RACK

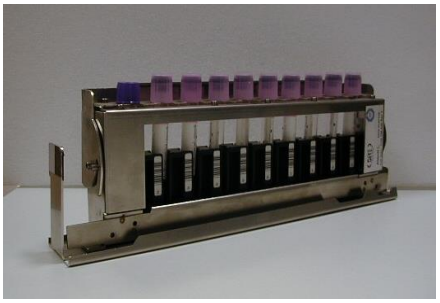


ADAPTER FOR ABX Pentra 120 RACK

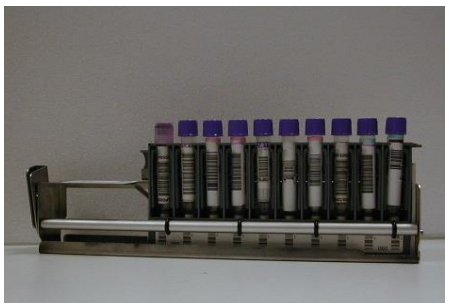


COULTER H ADAPTER FOR COULTER LH700 RACK

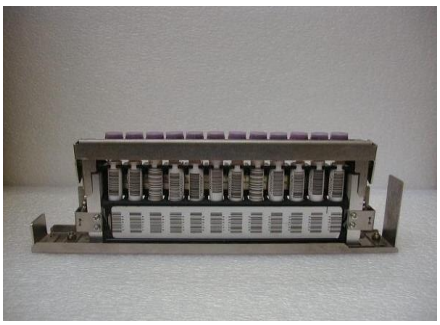
COULTER M ADAPTER FOR COULTER LH500 RACK



ADAPTER FOR ABBOTT CELL Dyn 3200-4000 (Abbott Long)



BAYER ADAPTER FOR Bayer Advia 120 RACK



COULTER RT ADAPTER FOR COULTER LH700 RACK

APPENDIX B (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.

APPENDIX C (NF meaning)

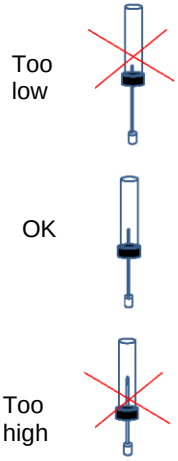
It appears when the system is not able to aspirate blood.
It could be possible:

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

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

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

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



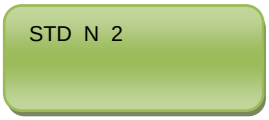
- The pump rubber tube is not able to aspirate blood correctly. The technical service should be called in order to replace the tube.

APPENDIX D (NR meaning)

NR is a printed out message which warns the operator that the result is no reliable.
The reading unit detects the transition between air (empty capillary) and blood, but not the aggregation starting. Sometimes this is could be caused by a poor mixed blood. or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube. Consequently ESR result is flagged as NR because not reliable.
A possible solution is in the pre-mixing of the specimen (reference in **section 17** Pre-mixing paragraph) and the successive analysis cycle.

APPENDIX E (latex ID codes typed manually)

If the scanner cannot read one or more of the three codes, maybe the label was ruined, each missed code could be typed manually **(*)**.
If this occurs, before mixing the display should show a messages like:



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

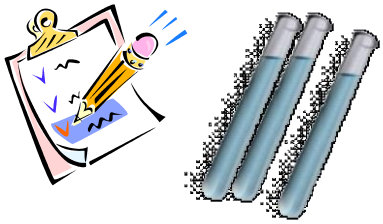
STD N 3

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

STD N 4

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

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



APPENDIX F (note for analysis cycles and washings)

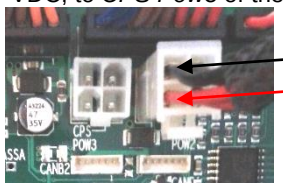
1. Tubes must be inserted and locked tightly in the rack.
2. Insert the rack along the slide completely in case of TEST1 THL. Insert deeply the rack in the guide in case of TEST1 equipped with direct insertion kit.
3. The analytical cycle cannot be interrupted to insert others rack of samples to analyse.
4. Four racks as maximum can be inserted in the same cycle.
5. Upon introduced the fourth rack and closed the door, the analysis cycle starts automatically.
6. If the function has been enabled, at every new analytical cycle run, the drawer or the rack guide that has accepted the rack on the previous cycle, will be rotated to 90°. The rack considered as first could be inserted on the successive position. In this way, there will be a controlled rotation of the drawers or rack guides in order to uniform the mechanical parts wearing.
7. If the availability of credits is below than the scheduled and stored, in the setup, threshold, beyond the real availability the printer is going to print out even a warning near by the reported availability.
   E.g. ESR **200 warning (<1500).**

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

28-ERRORS LISTS

GENERIC ERRORS

Error / Situation	Symptoms and Verifications	Checks & Solutions
Instrument does not turn ON	➢ Is the power cable connected to the mains group of the instrument? ➢ Is the power cable connected to the electricity plug? ➢ Is the switch at ON? ➢ Are the main fuses OK?	**S1** Turn the instrument off and unplug the power cable. **S2** By a tiny cross screw-driver, lift the external fuses box retaining tongue, remove the fuses box and check the efficiency of the fuses. If they are burned, go to **S3**; otherwise if they are not, go to **S5**. **S3** Replace the fuses (250VAC 2.5AT (T=time-lag)). **S4** Reinsert the fuses box into the lodgement, plug the power cable in and turn the instrument on. **S5** By a V-meter set to AC, check if J4 (on power supply board) is powered by 220VAC. If it is and the red LEDs are dark, then go to **S5.a**, otherwise if it is not, go to **S5.b** **S5.a** Turn the instrument off, replace the power supply board and turn the instrument on again. **S5.b** -Turn the instrument off, replace the power selector and turn the instrument on again. **S6** Verify the power cable efficiency connecting it to another instrument or checking the power by a V-meter. **S7** If the fuses burn again (solution **S3**), identify which part is on short-circuit, unplug the power connectors from each board and one by one plug them in again turning the instrument on after each connection
Instrument turns ON but no messages appears on display	➢ Try to turn the instrument OFF, wait for 10 seconds and turn it again. ➢ If the display is light without characters, go to **S1** of **Solutions**; if it has characters, go to **S2**.	**S1** Replace the CPU board. **S2** Identify the correctness of the information
Instrument turns on but "Error F-0" message appears on display	➢ One key could be pressed during the lighting of the analyser. ➢ The keyboard could be damaged; turn the instrument off, unplug J1 (Keyboard) and on again. ➢ If "ERROR F-0" message is still present, then go to **S1** of **Solutions**; if it is not, go to **S2**	**S1** Replace the CPU board. **S2** Replace the keyboard.
During the initialization phase, the piston assembly	➢ Have a look at the power supply board if the LED, marked F1, which points-out the presence of 8VDC, is dark. If it is, go to **S1** of	**S1** Turn the instrument off, replace the fuse of 250V 1AT marked F1 and try again.

of the instrument generates noise	**Solutions**; if it is not, go to **S2** of **Solutions**.	**S2** Replace the carriage cabled sensor and check the right position of it by DIAGNOSTIC option: **S2.a** Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5. **S2.b** Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door. **S2.c** Close the door. **S2.d** Press key 6; the carriage assembly is going to move toward to all positions of the linear encoder printing a couple of values for each vertical black and silver colour of the linear encoder. **S2.e** Move the sensor towards or away from the linear encoder and press 6 again. **S2.f** Repeat the alignment process until the black and silver bars give values close to the thresholds; e.g. Black = 40.
Stable low temperature message on display	➢ **Case 1**: In the diagnostic field the temperature remains stable to room temperature. ➢ **Case 2**: The power is present.	**S1** The 33VDC are missed: **S1.a** Turn the instrument off. **S1.b** If the fuse works, go to **S1.c**, otherwise if the fuse is burned, replace it and check again. **S1.c** Turn the instrument on and plug the probes, of a V-meter set to VDC, to *CPS Pow3* of the CPU board  **CPS Pow3** = 33VDC **S1.d** Check if the V-meter measure a value around 33Vdc. If they are not, check F3 on the *Power supply board* or change the complete board. If they are not again go to **S1.b** If they are present, then change the booster power board set on the right metallic wall. **S1.e** Check the mains transformer AC powers or change it. **S2** Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5. Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door. Press PAUSE key and check the status on display; the information of the first line points-out: **S2.a** The temperature (it should be around 20÷25); e.g. T **25**. **S2.b** The differences in temperature to reach the scheduled 37°C;

		e.g. **– 12**. **S2.c** If the thermostat works or not; e.g. **1**. **S3** Change the CPS unit. **S4** Change the CPU board.

INSTRUMENT ERRORS

Error Code	Symptoms and Verifications	Checks & Solutions
A – 0	➢ Message that occurs after 3 consecutive NFs with debug OFF	**S1** Check the needle and capillary functioning. **S2** Carry out a complete washing procedure even with Hype-Chlorite **S3** Check the correct alignment between carriage and rack/cassette
A – 1	➢ Message that occurs after 3 consecutive errors of syringe movement (the motor lose more than 250 steps at rising up)	**S1** Check the mechanical parts of the syringe assembly. **S2** Check the toothed belt.
B – 0	➢ During the analysis cycle the carriage assembly creates noise	**S1** Run a new analysis cycle and verify if the carriage assembly hits the beginning of the carriage support. If yes have a look at the power supply board. If the LED, marked F1, which points-out the presence of 8V-DC, is dark, replace the fuse of 250V 1AT. Otherwise if it lights, take a V-meter set to DC, plug the black colour probe to ground and the red one to the left external pin of the sensor connector set on the carriage board to feel if +8V-DC are present. If they are OK, otherwise go to **S3** **S2** Turn the instrument off and move the carriage assembly manually towards the front side of the instrument. **S3** Replace the cabled sensor and check the right position of it by DIAGNOSTIC option. **S3.a** Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5. **S3.b** Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door. **S3.c** Press key 6; the carriage assembly is going to move towards to all positions of the linear encoder printing a couple of values for each vertical black and silver colour of the linear encoder; **S3.d** Approach the sensor to the linear encoder or move it away from the linear encoder and press 6 again. **S3.e** Repeat the alignment until the printed out message of the white lines reports a value closed to 40. **S4** Turn the instrument off, check and (if it necessary) replace the flat cable which links the carriage board to the CPU board. **S5** Check the carriage assembly connector and its wires.

		S6 Repeat the test from **S2** to **S3**.
B – 1	➢ Home carriage error	**S1** Check or replace the carriage home sensor.
C – 0	➢ The syringe group does not go up and down correctly	**S1** Turn the instrument off and move the carriage assembly manually towards the front side of the instrument. **S2** Check the piston sensors glued on the carriage board and the presence of the square magnet glued on the piston support. **S3** Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5. Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door. Pressing key 3; the syringe assembly should move to the nearest positions of the tube cap. The piston's tooted belt could be ruined and so it needs to be replaced. The syringe motor could not work correctly cause an incorrect driving of it; the CPU board needs to be replaced. Repeat the test for many times to see if now it is working well.
C – 1	➢ Excessive friction between mechanic parts during the syringe movement	**S1** Turn the instrument off and move the carriage assembly manually towards the front side of the instrument. **S2** Remove the syringe motor and separate the belt from the pulley. **S3** Take a tiny flat head screwdriver and separate the washer and seger to 1mm from the pulley. Rotate the pulley manually and check if this rotate free of friction. **S4** Have a look if the belt, set on the support, if it is aligned vertically to the better way. If it is necessary, rotate a little bit the retaining square washer. **S5** Surround the pulley motor and pulley guide with the belt again, reinsert the pinions guides into the appropriate holes and set again all metallic parts as set originally. **S6** Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5. Press key 2 to access DIAGNOSTIC and insert a rack in after having opened the door; close the door. Pressing key 3; the syringe assembly should move to the nearest positions of the tube cap. If it cannot and during the piston movement a noise is heard, the piston tooted belt could be ruined and so it needs to be replaced. If the syringe motor does not work correctly cause an incorrect driving of it; the CPU board has to be replaced.
C – 2	➢ Analysis cycle blockage for Syringe sensor error	**S1** Change the Syringe sensors board. **S2** Replace the CPU board
C – 3	➢ The Syringe is not at home position	**S1** Change the Syringe sensors board. **S2** Check the square magnet set at the syringe external side **S3** Replace the CPU board.
C – 9	➢ The Syringe is not at home position and the rack is different than "*Coulter RT*"	**S1** Change the Syringe sensors board.

	or "*Sysmex RT*"	**S2** Check the square magnet set at the syringe external side **S3** Replace the CPU board.
D – 0	➢ Eeprom error	**S1** Press ENTER ones or twice. If "Err. MicroTEST1/TEST1, not initialized" is displayed, then press START. The instrument will display "Are you sure?, 0=NO | 1=YES". Press "1" and then "99" as password. If the problem appears again, replace the CPU board.
D – 1	➢ Database version error respect the firmware installed version	**S1** Turn the instrument off, wait for a few seconds and turn it again. If the problem appears again, re-install the firmware.
D – 2	➢ Writing error on Eeprom	**S1** Turn the instrument off, wait for a few seconds and turn it again. If the problem appears again, re-install the firmware or replace the CPU board.
D – 3	➢ Correctness verification of the writing phase on Eeprom	**S1** Turn the instrument off, wait for a few seconds and turn it again. If the problem appears again, re-install the firmware or replace the CPU board.
D – 8	➢ Saving error on Eeprom of the Smart Card log	**S1** Turn the instrument off, wait for a few seconds and turn it again. If the problem appears again, re-install the firmware or replace the CPU board.
D – 9	➢ Initialization phase error	**S1** Turn the instrument off, wait for a few seconds and turn it again. If the problem appears again, re-install the firmware or replace the CPU board.
E – 0	➢ The rotor doesn't rotate correctly for sensor or motor malfunctions. Sometimes this error is also due to the front door that is not closed well or the Door Sensor does not see well the metallic reflecting plate	**S1** Check the rotor sensor alignment respect to the magnet glued on the rotor pulley. **S2** Check if the distance between the reflecting metallic tongue set on the front door and the door sensor is 5 - 6mm. **S3** Clean the reflecting metallic tongue set on the front door.
E – 1	➢ The rotor doesn't rotate correctly for sensor or motor malfunctions. Sometimes this error is also due to the front door that is not closed well or the Door Sensor does not see well the metallic reflecting plate	**S1** Check the rotor sensor alignment respect to the magnet glued on the rotor pulley. **S2** Check if the distance between the reflecting metallic tongue set on the front door and the door sensor is 5 - 6mm. **S3** Clean the reflecting metallic tongue set on the front door.
E – 2	➢ The rotor doesn't rotate correctly for sensor or motor malfunctions. It occurs after three failed attempts, of the CPU board, to correct the incorrect positions of the rotor respect the withdrawal position. It could occur even whether the loading door has been opened frequently during mixing (voluntary or by mistake or due to door sensor vibrations)	**S1** Check the label code functioning applied on the test tube. **S2** Check the correct position of the scanner and the laser beams respect the centre of the label code. **S3** Check the correct position of the rotor at the withdrawal time.
E – 3	➢ Error because all 4 racks have been disabled	**S1** Enable at least 1 rack.
F – 1	➢ Error at the start-up phases because the CPS-MC not connected to the CPU board but selected by dipswitch JS2 and JS4 of DS1	**S1** Check if JS2 and JS4 of DS1 are set to OFF **S2** Replace the CPS-MC board. **S3** Replace the CPU unit.
F – 2	➢ The instrument does not communicate with the Peristaltic Pump at start-up	**S1** Check the connection of the peristaltic pump.

	➢ Peristaltic Pump is not working correctly	**S2** Try to rotate the pump head manually to feel if it is locked, if yes go to **S3**, if not go to **S4**. **S3** Remove the pump head and have a look if the plastic spacer is inserted on the pump motor pinion. **S4** Replace the pump motor. **S5** Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5, then press key 2 to access DIAGNOSTIC and insert a rack. Finally press key 9 to move the pump CW/CCW and see if the pump works correctly. **S6** Check the presence of the 2 square magnet glued on the pump head. **S7** Re-install the complete firmware. **S8** Replace the CPS board. **S9** Replace the CPU unit.
F – 3	➢ Reading error at the Latex Calibration/Control phase	**S1** Turn the instrument OFF and then ON and repeat the process again. **S2** Change the Calibration/Control kit and try again
F – 4	➢ FIRST-UP error	**S1** Repeat the FIRST-UP for two – three times. **S2** Check that the water flow is fluent along the aspiration and repeat the FIRST-UP for two – three times.
F – 5	➢ The CPS does not measure the blood sample at the analysis cycle	**S1** Turn the instrument OFF and then ON and repeat the analysis again. **S2** Check that the blood flow is fluent along the aspiration phase. **S3** Try to perform a washing procedure
G – 0	➢ The cycle's number of the day has reached its maximum value (250) and it has been reset	**S1** Verify that the Patient IDs, not read from the IBCR, are correct according by "**cn**"-"**isn**"-"**rk**"-"**pn**" where **cn = cycle number**, **isn = instrument serial n°**, **rk = rack**, **pn = position**. **S2** Press ENTER to continue.
H – 0	➢ "*Washing not executed xx*" printed-out message where xx is the number of missing washings. Appears when the date change and the instrument hasn't be washed	**S1** Instrument will perform an Automatic Washing
K – 0	➢ Piston position is not recognized	**S1** At MAIN MENU press CLEAR; the piston assembly should move towards the front side. **S2** Check if the piston's sensor wires are broken or the sensor is out of its position. **S3** Have a look if the square magnet glued on the external side of the piston is present. If yes OK, otherwise go to S4. **S4** Seek the square magnet (probably it is fallen down on the instrument bottom) and glued it again on the piston external side right position. **S5** Check or replace the internal sensor.
M – 0	➢ The syringe motor does not lift up, the piston is still on the low position	**S1** Turn the instrument off. **S2** Check the sensors of the syringe board and the magnet glued on the piston

& **N – 0**		assembly support. **S3** Check the syringe motor cables and connector. **S4** Check the flat cable connectors, which link the carriage board to the CPU board. **S5** Turn the instrument on and within 2 seconds after hearing two beeps sound press key 5, then press key 2 to access DIAGNOSTIC and insert a rack. Plug the probes of a V meter between ground and the wires (one by one) of the syringe motor connector to detect if it measures a value between 13/18 V. If the voltages are right, go ahead to **S6**. **S6** Press key 2 to move the piston up and the syringe inside the tube. Have a look to the complete movement of the piston unit during its movement to see if it works right. If there is any problem: Turn the instrument off, replace the CPU board and go back to **S5**.
R – 1	➢ The availability of credit has not been increased on TEST1 memory	**S1** Keep it checked during the successive loadings. If any malfunctions are repeated again, replace: **S1.1** The Smart Card Reader. **S1.2** The CPU Board.
S – 0	➢ Generic error during data transferring from CPU to new type TRANSFER CARD	**S1** Try again. **S2** Change the new type TRANSFER CARD. **S3** Change the CPU board.
S – 1	➢ Reading error of the old type TRANSFER CARD after the ESR transferring process	**S1** Change the old type TRANSFER CARD. **S2** Change the CPU board.
T – 0	➢ REAL TIME CLOCK error	**S1** Turn the analyzer OFF and then ON. **S2** Update the software to latest version. **S3** Change the CPU board.
T – 1	➢ It occurs when you attempt to transfer credits from an old type TRANSFER CARD to the CPU despite the set threshold of credits, for the old type TRANSFER CARD, have been exceeded	**S1** Load credits by using a new type TRANSFER CARD.
X – 0	➢ Checksum calculation error of the communication protocol	**S1** Turn the analyzer OFF and then ON. **S2** Update the software to latest version. **S3** Change the CPU board.
X – 1	➢ Expiry date verification error of the Latex Control/Calibration kit	**S1** Check and correct data and time of the instrument **S2** Erase the Latex datalogger. **S3** Update the software to latest version.
Y – 8	➢ Writing error in the flash memory	**S1** Turn the analyzer OFF and then ON. **S2** Update the software to latest version. **S3** Change the CPU board.

Y – 9	➢ Erasing error in the flash memory	**S1** Turn the analyzer OFF and then ON. **S2** Update the software to latest version. **S3** Change the CPU board.
Z – 0	➢ During the latex Control/Calibration procedure, the Calibration Washing failed consecutively too much times (respect the value of the '*Calibwash error threshold*' parameter)	**S1** Check the water level inside the first tube, these must be filled about ¾ of the tube, not less and no more. **S2** Perform a FIRST-UP procedure **S3** Check the value of the '*Calibwash error threshold*' parameter, this must be set to 10
Z – 1	➢ Error during Automatic/Manual Washing (PHOTOMETER NOK)	**S1** Check the water level inside the Wash Tank. **S2** Check the water level inside the tubes used for the washing, these must be filled about ¾ of the tube, not less and no more. **S3** Do a washing procedure with Hypo Chlorite. **S4** Perform a FIRST-UP procedure. **S5** Check the needle which could have obstructions caused by rubber particles unglued from the test tube cap and assessed into the needle during aspiration. Train your customer about the test tubes for water: they must not be used more than twice. **S6** Check the DC pump, if this during the automatic wash is ON or not. **S7** Check the tubing and click's seal connectors which could have misalignments. **S8** Check peristaltic pump tube. **S9** Check the alignment between syringe and rack positions. **S10** Check the alignment between syringe and Washing Cell.
Z – 2	➢ Error during Manual Washing (tube not detected or 'NO' label has been read)	**S1** Check if the test tube is dropped down. **S2** Check if the syringe is vertically aligned respect the test tube. **S3** Rotate or set the test tube on a way the label 'NO' applied on the rack container is covered. **S4** Check the IBCR alignment.
Z – 3	➢ Error during Automatic/Manual Washing (Mechanical issue)	**S1** Check the alignment between syringe and rack positions. **S2** Check the alignment between syringe and Washing Cell. **S3** Check the correct working of the Syringe Group.
Z – 4	➢ Error during Automatic/Manual Washing (CPS-MC issue)	**S1** Check the connection between CPU Board and CPS-MC Board. **S2** Check the correct working of the Peristaltic Pump.
Z – 5	➢ Washing Timeout expired (Only in DEBUG ON)	**S1** Check the same things of Error **Z-1**

ESR & LATEX ERRORS

Error / Message	Causes	Checks & Solutions
NF is printed instead of ESR value	The blood flow was not regular, or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube	If this message begins to appear frequently, it is suggested to execute a washing cycle before proceeding with further analysis.
NR (Not Reliable) is printed instead of ESR value	The reading unit detects the transition between air (empty capillary) and blood, but not the aggregation starting. Sometimes this is also due to a poor mixed blood or a clot could be present inside the cell of measurement or there could eventually be an insufficient quantity of blood in the test-tube	Try to mix again the blood and repeat the measure
CM = SM (Sample Missing) is printed instead of ESR value	This error appears when test tube has slipped out from the rotor. Instrument is expecting to find a tube (because it has recognized it when loaded) but at the analysis time, the tube is not physically present in the rotor.	Check tubes loaded are in conformity with technical data sheet of the instrument
On display appears the following message: **Increase Avail.** **Insert CARD**	The test availability is under the set threshold. The instrument alerts the customer that is necessary to increase the test availability.	Press Enter to by-pass. To avoid the message, it's necessary to increase availability inserting a new TEST1 CARD.
The following message is printed at power up: **Waste level detected** **EMPTY the tank**	The waste tank counter has reached the value of tank alarm threshold. The instrument enters automatically in waste tank replacing procedure (9)	Replace the waste tank, then press key "**1- empty**" to advice the instrument that the tank has been replaced. The waste tank counter is so put to zero.
The following message is printed at power up **Maintenance Request**	The maintenance counter has reached the value of maintenance alarm (30000 by default). Maintenance is required.	Carry out the ordinary maintenance and then reset the counter to 0.
The following message is printed: **Exceed expiry date** **Procedure aborted**	The three control tubes are expired, the calibration control could be unreliable, thus the procedure is aborted.	Check the expiry date of the kit, if it is expired replace it with a new one and repeat the control procedure.
The following message is printed: **Exceed control availability**	The three control tubes were used more than 6 times. The calibration control could be unreliable thus the procedure aborted.	The number of controls for one Latex kit is limited to six to avoid excessive piercing of the rubber cap which allow air to enter in causing Latex damaging. Repeat the control with a new kit.

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

29-CHANGE-LOG & SOFTWARE VERSIONS

Version 11.00A (TEST1 all models)

- Version released for compatibility with the new CPS-MC part number SI195148

ALIFAX - REFERENCES

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

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VAT: IT04337640280

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

SANITIZATION FORM

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

Description of sanitization procedures to be done by the Laboratory:

Switch ON the instrument:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SANITIZED

ATTACHMENT 1 – PRODUCT TECHNICAL DATA SHEET

ESR_PTDS_SI195_TEST1

PRODUCT TECHNICAL DATA SHEET
TEST1

Rev.3.0 – Effective from 2022 May 25

OPERATIONAL SPECIFICATIONS

Equipment name:

TEST1 THL (SI 195.210/THL) - Model with thermoplastic white cover and Latex Control management.

TEST1 BCL (SI 195.220/BCL) - Model with thermoplastic white cover, Latex Control management and configured with direct insertion of **Beckman Coulter LH 700 SERIES cassettes and Alifax green plastic racks.**

TEST1 SDL (SI 195.230/SDL) - Model with thermoplastic white cover, Latex Control management and configured with direct insertion of **Sysmex SF/SE/XE/XT/XSXN, cell counter rack Mindray, cell counter rack Horiba Yumizen** and Alifax yellow plastic racks**.**

TEST1 YDL (SI 195.240/YDL) - Model with thermoplastic white cover and Latex Control management. and configured with direct insertion of **BAYER/SIEMENS ADVIA 120** Cell Blood Counter cassettes **and Alifax blue plastic racks**.

TEST1 MDL (SI 195.250/MDL) - Model with thermoplastic white cover and Latex Control management and configured with direct insertion of **Beckman Coulter LH500** Cell Blood Counter cassettes.

TEST1 XDL (SI 195.260/XDL) - Model with thermoplastic white cover and Latex Control management and configured with direct insertion of **Beckman Coulter DxH 800** Cell Blood Counter cassettes.

Intended Use:

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

Principle of measure:

The technology applied by Alifax's ESR instrumentation is Quantitative Capillary Photometry, which allows in just 20 seconds of analysis to obtain the ESR result of the sample, expressed in mm/hour, as per guidelines and reference method. Quantitative Capillary Photometry studies the dynamic behavior of red blood cells (RBCs). The blood sample flows in a transparent capillary inside the instrument and the reactivity of the red blood cells is 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 only 20 seconds of analysis into a photometric quantitative data, expressed in mm/hour, without having to wait for the whole process of stacking, sedimentation and stacking of the sample. The aggregation of red blood cells (formation of RBC aggregates), the first phase of the sigmoid curve described, is strongly correlated with the end-point results of the classical Westergren method, but is not affected by the interferences that affect both the classical method and the methods based on modified Westergren. Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37°C (±0.5°C) / 98,6°F (±0,9°F)

Results:

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

Sample requirements:

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

- The blood sample must be neither coagulated nor hemolyzed.
- It would be better to test the sample within 4-6 hours from venipuncture or within 24 hours if kept at +4/+8 °C (+39,2 / +46,4 °F), provided it is rewarmed to room temperature before testing.
- The minimum blood volume (dead volume) is 800 microliters.
- The working volume is 175 microliters (average).
- After a wash make sure that the first two tubes are filled with at least 2ml of blood
- Samples separation into the capillary using air bubble of about 530 mm (255 microlitres).
- If paediatric samples are used, the minimum recommended volume is 500 uL
- In case of use of sample coming from patients affected by an oncological pathology, we remark that ESR result of those samples could be eventually NOT reliable as explained in chapter “method limitations” paragraph 2.

Tube requirements:

- Test-tubes 13x75 mm (0,512 x 2,953 in) like BD Vacutainer® or Greiner Bio-one Vacuette® or with 13 mm diameter and from 75 to 83 mm (2,953 to 3,268 in) high, cap included (like for example the Sarstedt Monovette® tubes that measure 11,5x66 mm. (0,453 x 2,598 in) without cap).
- Tubes with 95 mm (3,74 in) can be used with the Alifax 15 positions metal rack (code SI195500) only on TEST1 THL.
- It is possible to use "BD Microtainer MAP®" tubes directly (also in conjunction with other 13x75 tubes (0,512 x 2,953 in) on all TEST1 (THL, BCL, SDL, XDL, MDL, YDL) models without the use of adapter (but could be necessary to verify the needle offset adjusting its excursion in case of volumes lower than 500 uL

 BD Microtainer MAP from 250 to 500 uL pediatric cuvette into 13x75mm tube with pierceable cap it does not require any tube adapter	Can be used on all models (THL, BCL, SDL, XDL, MDL, YDL) together with other 13x75 mm (0,512 x 2,953 in),test-tubes if the blood volume is at least 250uL and the following shrewdness: turn upside down each tube and give a tap to the cap for bring down the blood towards the cap just before loading the tube into the rack.

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

Operative performances:

- Mixing takes place by completely overturning the tubes.
- Is possible to process **150** samples/hour. Analysis time is 20 seconds.
- Samples mixing is done at the beginning of the analysis with the purpose of disaggregating erythrocytes. A possible ineffective disaggregation could affect the results given by the instrument which measures system is based on the detection of the kinetics of aggregation of the red cells.
- Audible alarm in case of error or malfunction: The instrument emits a series of 62,5dBA sounds until the error is solved.
- The instrument is equipped by an internal Scanner programmed to read codes such:
  - CODE 39
  - 2/5 INTERLEAVED
  - CODABAR
  - CODE 128
  - EAN 128
  - ALL EAN/UPC

Capacity:

TEST1 THL: **Standard TEST1 racks**, up to 60 samples / session,
Cell Blood Counter adapters, from 40 to 48 samples / session.

TEST1 BCL: ALIFAX green plastic racks, up to 60 samples / session,
CBC Beckman Coulter LH 700 SERIES cassettes, 48 samples / session.

TEST1 SDL: ALIFAX yellow plastic racks, up to 40 samples / **Sysmex SF/SE/XE/XT/XSXN, /cell counter rack Mindray, cell counter rack Horiba Yumizen** session, up to 40 samples

TEST1 YDL: UP to 40 samples / session with **BAYER/SIEMENS ADVIA 120** Cell Blood Counters cassettes. ALIFAX blue plastic racks, up to 40 samples / session.

TEST1 MDL: Up to 40 samples / session with Beckman Coulter **LH500** Cell Blood Counters cassettes.

TEST1 XDL: UP to 40 samples / session with **Beckman Coulter DxH 800** Cell Blood Counters cassettes.

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

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

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

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

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

Y = 1.0002X + 2.02; R = 0.9761

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

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

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

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

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

Method limitations:

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

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

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

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

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

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

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

ENVIRONMENTAL AND PHYSICAL SPECIFICATIONS

Permissible environment conditions for operation:

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

Permissible environment conditions for transportation and storage:

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

Size and weight:

Width: 49 cm (19,29 in)
Depth: 54 cm (21,26 in)
Height: 60 cm (23,62 in)
Weight: 47 Kg (42 Kg THL Only)
103,6 lb (92,59 lb THL Only)

Packaging: Cardboard box

Width: 75 cm (29,53 in)
Depth: 62 cm (24,41 in)
Height: 92 cm (36,22 in)
Gross Weight: 56 Kg (123,5 lb)
Volume: 0,428 m^3 (15,11 ft^3)
Pallet: Yes

ELECTRICAL SPECIFICATIONS

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

Power cons: 150 VA, circa 83W
Switch on cons: 225 VA, circa 135 W

Frequency: 50 or 60 Hz ± 2 Hz

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

OTHER OPERATIVE SPECIFICATIONS:

Heat dissipation in the environment: about 300 BTU/hour

Noise: at low speed mixing: 62,6 dB(A)
at high speed mixing: 58,2 dB(A)

Maximum rated altitude: 3000 mt asl

Communication: 2 serial RS232 DB 25 ports located on the rear side of the instrument:
Port 1 is dedicated to connect an external scanner
Port 2 is dedicated to connect the instrument to a Host Computer
Note: if the Internal Bar Code Reader (IBCR) is used, it is not possible to connect an external scanner unless a technical setup is done inside the instrument.

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

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

Rated pollution degree: Grade 2

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

CONSUMABLES

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

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

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 TEST1 (TEST1, MicroTEST1, Roller20LC, Roller20PN, Roller20MC, Roller10PN and JO-PLUS. They are available in two kinds of test tubes:

- 13x75mm (0,512 x 2,953 in) Greiner:
  Latex Controls (6 tests) - code SI 305.100-A;
  Latex Controls (30 tests) - code SI 305.300-A.
- 11,5x66mm (0,453 x 2,598 in) Sarstedt:
  Latex Controls (6 tests) - code SI 305.102-A;
  Latex Controls (30 tests) - code SI 305.302-A.

Patient identification : Internal CCD bar-code reader (**SI195126**).

OPTIONAL AVAILABLE TOOLS

ADAPTERS (for TEST1 THL only):

SI195500	**TEST1 -** Standard rack for **TEST1** with Internal Bar Code Reader (IBCR) (15 positions)
SI195510	**BAYER/SIEMENS -** Adapter for **Bayer/Siemens Advia 120** Cell Blood Counter racks (10 positions)
SI195540	**ABBOTT L -** Adapter for **Abbott Cell-Dyn 4000/3200** CBC racks (long type - 10 positions)
SI195541	As the previous, but with retaining comb for **Sarsted** test-tubes
SI195542	**ABBOTT -** Adapter for **Abbott Cell-Dyn 3500/3700** CBC racks (short type) or for **Sysmex SF/SE/XE/XT/XSXN, /cell counter rack Mindray, cell counter rack Horiba Yumizen,** CBC racks or for **ABX Pentra 80** CBC racks (short type - 10 positions)
SI195543	As the previous, but with retaining comb for **Sarsted** test-tubes
SI195550	**ABX -** Adapter for **ABX Pentra 120** Cell Blood Counters racks (10 positions)
SI195580	**COULTER M -** Adapter for **Beckman Coulter LH 500** CBC (keeps 2 racks of 5 positions each)

VARIOUS / OTHER FEATURES

Common features:

- New design with thermoplastic cover, front door for easy access to waste tank and needle.
- Simplified needle replacing procedure with magnetic unlocking and screw needle.
- Simplified Smart Card downloading using a single operation.
- Automatic washing programmable between 5 and 180 minutes from the last processed sample.
- Photometer check during each washing, to ensure continuous control of the instrument.
- Management of Latex Controls Kit for TEST1 family analysers **SI 305.100-A/SI 305.102-A** (6 tests) – **SI 305.300-A/SI 305.302-A** (30 tests): for the control of the calibration stability of the instrument.
- New latex controls management algorithms for a best equalization of different instruments.
- New priming procedure that withdraws the blood from the first two available test-tubes, half cutting in this way the volume that previously was withdrawn only from the first test tube.

Specific features:

TEST1 BCL: This model is set mechanically and also from software point of view, to receive and handle directly, without any kind of adapter, Beckman Coulter **LH 700 SERIES** CBC cassettes and without further modifications, also the new ALIFAX green plastic rack for 15 positions (code **SI19550501**).

TEST1 SDL: This model is set mechanically and also from the software point of view, to receive and handle directly, without any kind of adapter, **Sysmex SF/SE/XE/XT/XSXN, /cell counter rack Mindray, cell counter rack Horiba Yumizen,** CBC cassettes and without further modifications, also the new ALIFAX yellow plastic rack for 10 positions (code **SI19550601**).

TEST1 YDL: This model is set mechanically and also from the software point of view to receive and handle directly, without any kind of adapter **BAYER/SIEMENS ADVIA 120** cassettes.

TEST1 MDL: This model is set mechanically and also from the software point of view, to receive and handle directly, without any kind of adapter **Beckman Coulter LH500** cassettes.

TEST1 XDL: This model is set mechanically and also from the software point of view, to receive and handle directly, without any kind of adapter **Beckman Coulter DxH 800** cassettes.

REGULATORY INFORMATION:

Classification	IVD	
UDI-DI (GTIN14)	08056040141519 TEST1 THL 08056040140314 TEST1 BCL 08056040141526 TEST1 SDL 08056040140321 TEST1 YDL 08056040142691 TEST1 MDL 08056040141533 TEST1 XDL	
CND Code	W02029001	APPARECCHIATURE PER VELOCITA` DI ERITRO-SEDIMENTAZIONE
FDA-CFR Code	Product code: GKB	Regulation Number: 864.5800 Automated sedimentation rate device
GIVD Code	23.09.10.01	Other_HHIHC Hardware + accessories + consumables + software
GMDN Code	56691	A mains electricity (AC-powered) laboratory instrument intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen. The device operates with minimal technician involvement and complete automation of all procedural steps

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

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

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

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

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

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

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

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