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Rev.1.9 – 2018.10.15

JO-PLUS

USER MANUAL

From Software version 1.03.00 on ward

Unit for the Erythrocyte-Sedimentation Rate (ESR)
installed on a **LAS** (Laboratory Automation System) **.**

In Vitro Diagnostic Medical Device for professional use

Summary

Note: Paragraphs written by blue colour (as on this note) have been added or modified in regards of the previous version of the manual. Similarly, if one chapter appears in the INDEX in blue colour, it means that chapter is new or totally modified.

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

1.0 TYPOGRAPHICAL CONVENTIONS

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

DISPLAY of WARNINGS and NOTES

DANGER

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

WARNING

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

CAUTION

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

CAUTION

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

NOTE

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

USED WARNINGS SYMBOLS

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

Biohazard!

Caution, moving parts inside!

Electrical hazard!

Mechanical hazard!

Laser hazard!

Cut injury / sharp hazard!

Ground!

Automatic start-up!

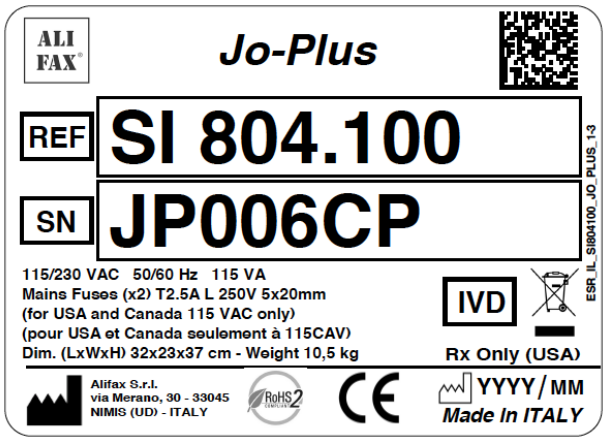
Consult instructions for use

OTHER SYMBOLS

	Manufactured by
LOT	Lot number
EXP CCYY-MM-DD	Expiration date
	Temperature limitations
CE	CE mark
REF	ID number
SN	Serial number

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.

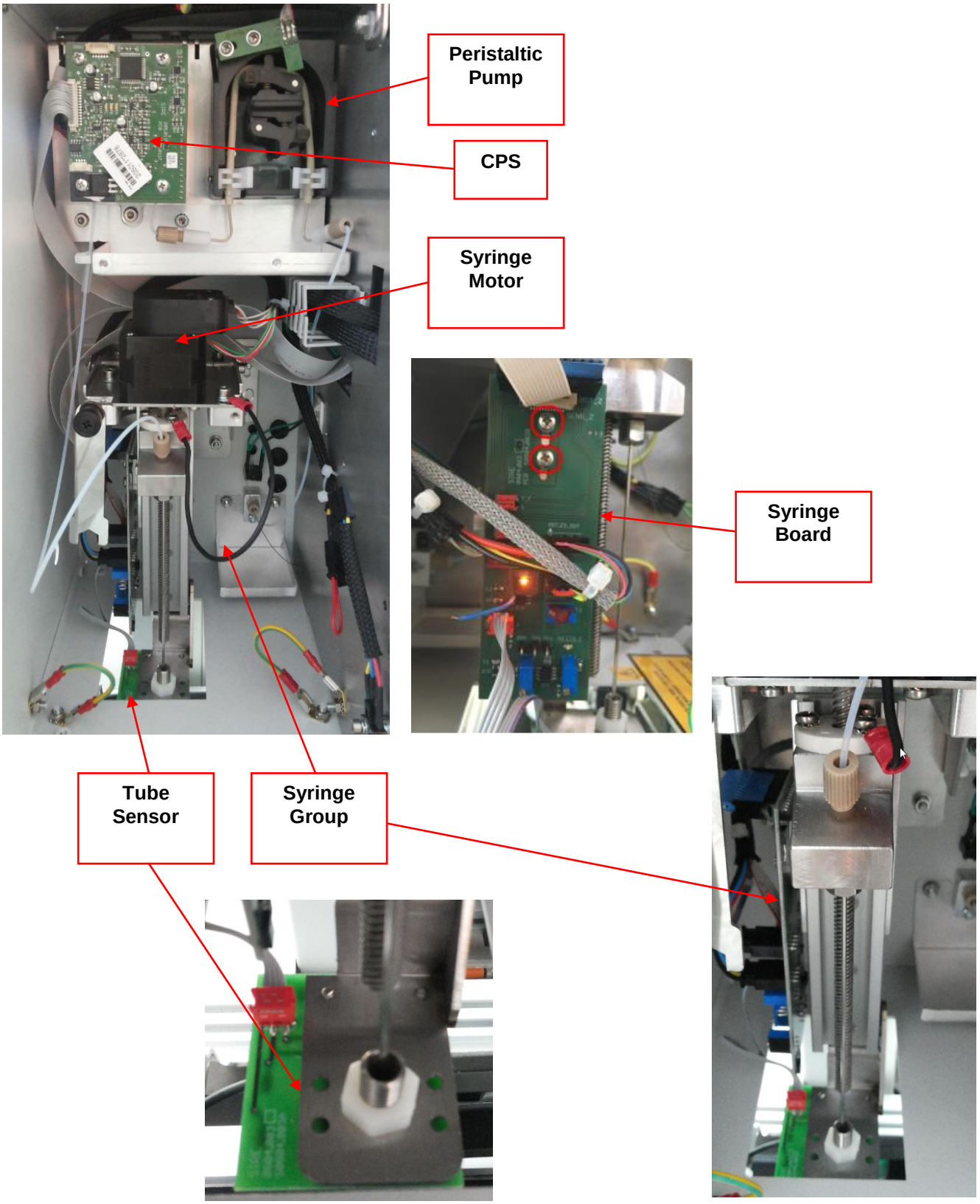
NOTE ***Following labels refers to Jo-Plus and contains between others the reference serial number of the instruments***



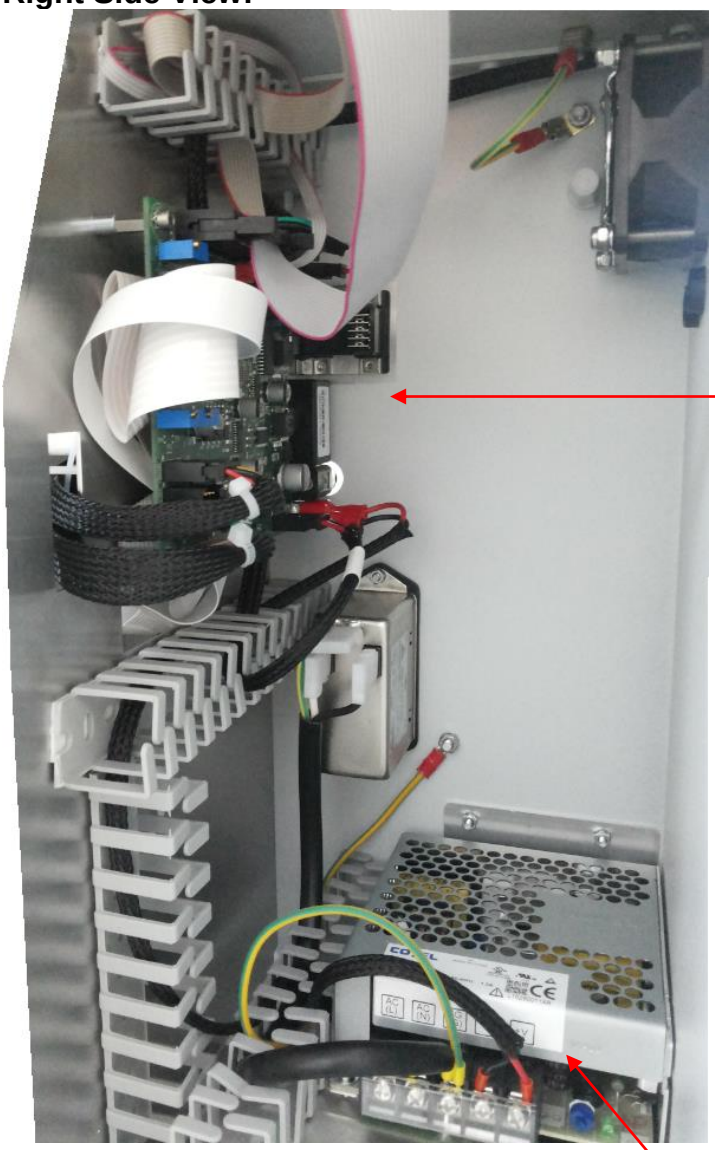
Rx Only (USA) Explantation:
Caution: U.S. Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device

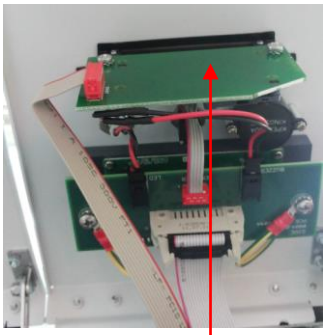
2.0 INSTRUMENT PRESENTATION

Left Side View:



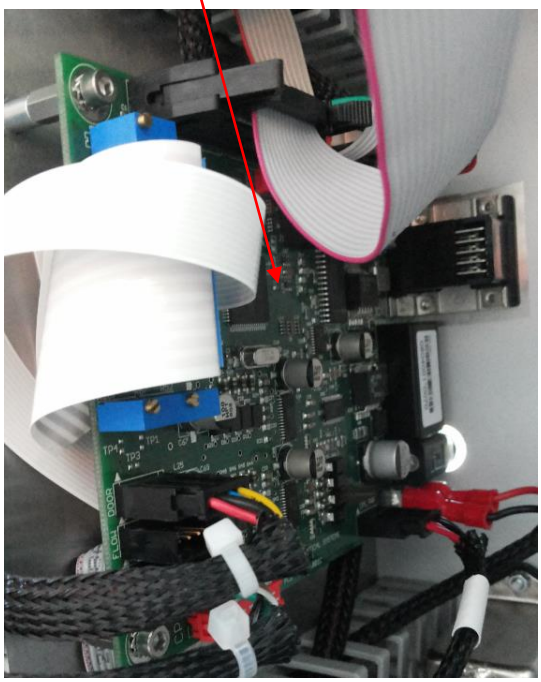
Right Side View:





Smart Card Reader

CPU



Power Supply

Rear View:

LAS Serial Port

LIS Serial Port

Waste Line Connector

3.0 INSTRUMENT DATASHEET (ESR_PTDS_SI804_JOPLUS_1-4_EN)

NAME: **JO-PLUS – code SI 804.100**

INTENDED USE: Automatic analyzer for Erythrocyte Sedimentation Rate (ESR) determination to be combined exclusively with Inpeco® Autmation Laboratory Automation System track for samples transportation with haematic samples premixing system.

ANALYSIS PRINCIPLE: Micro-photometrical capillary using stopped flow kinetic analysis.

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

SAMPLE REQUIREMENTS:

- Samples must be whole blood collected in EDTA as anti-coagulant.
- Blood samples has to be neither coagulated nor haemolysed.
- Samples has to be tested within 4 hours from venepuncture or within 24 hours if kept in a fridge at +4 / +8 °C and rewarmed them to room temperature before testing.
- The minimum blood volume (dead volume) is about 800 microliters.
- The working volume is 175 microliters (average).
  If instead the instrument was previously washed, a first withdrawn (priming) of 116 microliters is done on the first sample. This amount is then discarded and the ESR analysis is done on a second withdrawing of a first sample.
- samples are separated into the capillary by air bubbles.

TUBE REQUIREMENTS: Test-tubes 13x75 mm like BD Vacutainer® or Greiner Vacuette with 13 mm diameter and from 75 to 83 mm high, cap included.
Also 11,5x75 mm Sarstedt Monovette test-tubes can be accepted on condition that their bottom is spherical (i.e. Sarstedt Monovette EDTA/KE 2.6 ml) so that they cannot stick on LIS pallets and JO-PLUS has a suitable tube holder designed to centre test-tubes cap (code SI 804.02201 - Tube holder for Sarstedt Monovette test-tubes).
It is suggested the sample volume should not exceed the 50-60% of the total volume of the test-tube.

OPERATIVE PERFORMANCES:

- Simplified and safe needle replacing procedure.
- Simplified Smart Card downloading process.
- Photometer check after each washing, to ensure continuous checks of the instrument**.**
- Photometer (CPS) with three detectors for ESR analysis and blood flow management
- Latex Controls management for the TEST1 family analyzers (**Ord. code SI 305.100-A, SI 305.102-A or SI 305.300-A / SI 305.302-A)**
- The results are printed out every 30 seconds each; 120 samples processed in about 1 hour.
- The above throughput could be delayed in case the analyser is connected to a Host Computer (LIS) with replay output time more than 1 second.

In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following tips:

1. Using the gain of the instrument during correlation with lab reference method
2. Increasing the mixing time (this can be obtained using an external mixer before the ESR analysis or/and increasing the mixing time of the ESR analyzer).
3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis.

CAPACITY: n/a

ANALYTICAL PERFORMANCES:

they are the same of ROLLER 10 family (SI R10 PN/SI R20 PN) as JO-PLUS has the same analytical system. The ROLLER 10 performances that have been obtained using 3 ml tubes and taking the TEST 1 device as reference method, are reported hereby:
Agreement: $R^2 = 0.91$
Repeatability: mean CV% = 5.7% on the whole range 2 - 120 mm/h
Reproducibility: mean CV% = 5,1% on the whole range 2 – 120 mm/h

METHOD LIMITATIONS:

1. The erythrocyte sedimentation rate is a phenomenon confined to fresh blood and transient **(1)**, not a haematic matrix component (at corpuscular / molecular level). The procedures used to determine the ESR cannot be calibrated as they are susceptible to a variety of errors (temperature, hematocrit, erythrocyte mean corpuscular volume, plasma viscosity, etc.) **(1).** Based on the acquired experience, being JO-PLUS analyzer of the same family of TEST 1, MicroTEST 1, Roller 20 and Roller 10 instruments, is limitedly affected by these variables. For this reason it is possible to observe instrument performances deviations compared to other procedures if the above variables are not taken into account.

2. Erythrocyte sedimentation remains an only partly understood phenomenon….is a non-specific reaction (from a clinical point of view)… **(1)** that is affected by several technical aspects **(2)**. The ESR is often normal in patients with cancer...**(2).**

International guidelines for diagnosis and management of multiple myeloma do not mention the Erythrocyte Sedimentation Rate **(3)**. It is then necessary to point out that even though TEST1 analytical performances have been confirmed in patients affected by multiple myeloma **(4,5),** there have been some cases of patients affected by multiple myeloma in which TEST 1 has reported clinically negative ESR values in comparison to other methods. Based on this experience there could be cases in which JO-PLUS gives low ESR results likewise TEST 1 in presence of Multiple Myeloma.

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

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

3. Samples mixing is programmed at the beginning of the analysis with the purpose of disaggregating erythrocytes. An inefficient disaggregation or micro-clots presence can affect the result given by the instrument that in fact measures erythrocytes aggregation kinetics. For this reason the JO-PLUS must compulsorily work together with LAS track.

4. The above instrument performances have been obtained using test tubes with a capacity of 3 ml and 13x75 mm size with K_3EDTA anticoagulant. The use of such tubes optimizes the mixing phase and consequently the results reproducibility.

ENVIRONMENTAL AND PHYSICAL SPECIFICATIONS

Permissible environment conditions for operation:

Temp.: from 10 to +30°C.
Humidity: from 15% to 85% - no dew

Permissible environment conditions for transportation and storage:

Temp.: from -20 to +70°C.
Humidity : from 5% to 95% - no dew

Size and weight:

Width: 300 mm
Depth: 200 mm
Height: 340 mm
Weight: 11 Kg

Shipping Packaging: 2 Cardboard boxes

Instrument

Width: 650 mm
Depth: 500 mm
Height: 340 mm

Plastic Covers Packaging

Width: 1030 mm
Depth: 770 mm
Height: 520 mm

Total Gross Weight:
(2 packages) 34 Kg
Volume: 0,520 m^3

ELECTRICAL SPECIFICATIONS

Voltage: 115 - 230 Vac
Switch Mode Power Supply (SMPS)

Power consumption: 66 W
Switch on cons: 132 W

Frequency: 50 to 60 Hz

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

OTHER OPERATIVE SPECIFICATIONS:

Environment heat dissipation: 225 BTU/hour (operative)
450 BTU/hour (power on)

Noise: <55,0 db(A) (without considering the mixing device on LAS track)

Maximum rated altitude: 3000 mt asl

Communication: 2 serial RS232 ports located on the rear side of the instrument:
The LAS (DB9) port is dedicated to exchange data with the automation section of track
The LIS (DB9) port is dedicated to transmit results to Host.

Functioning: The instrument is designed to remain ON 24 hours a day. It is however suggested to switch it off at the end of the working day after having executed washings by at least two test tubes filled with distilled water to ensure a long operating life.

Restrictions: Indoor user appliance

Rated pollution degree: Grade 2

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

INTERNAL QUALITY CONTROL

Latex Controls: With the purpose of guarantee an always optimum performance of the instrument, the daily use of the latex control kit is recommended.
Through a Latex Controls kit it is possible to verify the calibration stability on TEST 1 family analysers (JO-PLUS, TEST 1, and Roller 20PN). The kit is available in two kinds of test tubes:

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

CONSUMABLES

Smart Card: Conform to ISO 7816-1 specifications – 85.6 x 54 x 0.8 mm
coded using ALIFAX S.r.l. proprietary algorithm.
The available Smart Card is for 20.000 credits of test only (code **SI 804.920**).

Waste Tank: **SI 804207** - 5 liters plastic waste tank with screw cap.

Needle: **SI 804005** – Needle for top piercing

Accessories: Labels to apply on the test tubes intended to wash the capillary:

- labels coded as **WASH** have to be applied on test tubes filled with distilled water.
- labels coded as **NAHCLOWASH** have to be applied on test tubes filled with bleach (Hype-Chlorite) in order to clean the capillary before doing Controls by Latex.
- Labels coded as **CALIBWASH** have to be applied on test tubes filled with distilled water to carry out a Control process by Latex for the internal Quality Control.

The labels can be purchased from Alifax separately or even in a complete kit which contains:
: **4** sheets of 52 labels coded as **WASH1, WASH2, WASH3, etc....**
1 sheets of 52 labels coded as **NAHCLOWASH**
1 sheets of 52 labels coded as **CALIBWASH**

The sale code of a Label sheet coded as WASH is	**SI804502**
The sale code of a Label sheet coded as NAHCLOWASH is	**SI804504**
The sale code of a Label sheet coded as CALIBWASH is	**SI804503**
The sale code of a complete Label kit is	**SI804501**

REGULATORY INFORMATIONS:

Classification	IVD	
EAN13 Code	805604014033	
CND Code	W02029001	APPARECCHIATURE PER VELOCITA` DI ERITRO-SEDIMENTAZIONE
FDA-CFR Code	Product code: GKB	Regulation Number: 864.5800 Automated sedimentation rate device
EDMA Code	23091001	Other_HHIHC Hardware + accessories + consumables + software
GMDN Code	35488	An automatic or semi-automatic instrument used to measure the sedimentation (sinking) velocity of red blood cells in a sample of whole blood using photometry. This is also called, erythrocyte sedimentation rate (ESR).
RoHS2 2011/65/EU	Compliant	

REFERENCES:

1. NCCLS “Reference and Selected procedure for the Erythrocyte Sedimentation rate (ESR) Test; Approved Standard-Fourth Edition”, Vol. 20 No. 27
2. Sox HC, Liang MH: “The Erythrocyte Sedimentation Rate”, Annals of Internal Medicine 1986; 105:515-523.
3. NCCN (National Comprehensive Cancer Network) Clinical Practice Guidelines in Oncology “Multiple Myeloma” (V.I.2007)
4. Ajubi et al.: “Determination of the lenght of sedimentation reaction in blood using the TEST 1 system: comparison with the Sedimatic 100 method, turbidimetric fibrinogen levels, and the influence of M-proteins”, Clin Chem Lab Med 2006; 44 (7): 904-906
5. Mercurio S. et al.: “Comparison between two methods for ESR measure in patients affected by myeloma”, 37° SIBioC National Congress, 11-14 October 2005 Rome.

4.0 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
the instructions for use 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.

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

GENERAL SAFETY

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

- Follow all warnings included in this manual.
- Follow all warnings marked on the instrument.
- 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
- 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

- **Switch to ON the instrument and wait at least 20 minutes before its use to reach the appropriate temperature inside the instrument and the thermal stabilization of the electronic circuitry.**
- 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
- 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.
- Check the waste tank level before starting the measures. Empty or replace it, if filled to security level; for the disposal of waste tank content, follow the standard safety procedures in use in the laboratory.
- Carry-out appropriate "WASHING PROCEDURES" to a good instrument maintenance
- Keep away any kind of objects, liquids, or substances not required for the instrument's use from the instrument.
- In order to avoid rubber particle coming from washing tubes could interfere with the hydraulic circuit, we recommend to use always and only new washing tubes, please do not reuse washing tubes.
- Check if the tube contains at least 1 ml 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 not exceed the 50-60% of the total volume of the test-tube in order to optimize the blood homogenization and consequently the results reproducibility.
- In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following tips:
  1. Using the gain of the instrument during correlation with lab reference method
  2. Increasing the mixing time (this can be obtained using an external mixer before the ESR analysis or/and increasing the mixing time of the ESR analyzer).
  3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis.
- Start the analysis within 2-4 hours from vein-puncture, otherwise keep the samples in refrigerator at + 4÷+8 °C for a maximum of 24 hours. If the samples have been conserved in refrigerator at + 4÷8 °C, it is necessary to leave them at room temperature at least for 30 minutes before their analysis.
- 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 vial is broken inside the instrument, it is mandatory to call the Technical Service
- An acoustic signal will be activated when the loading door remains opened. Close the door to allow the system to progress with the analysis.

MECHANICAL SAFETY

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

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

- Do not remove the panels neither camper the reading sensor.
- The internal carriage moves over a sliding guide which is an “auto lubricating” guide, so it is not necessary to lubricate or add any kind of oil or grease along the rails of the carriage guides.
- 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 …)
- In order to avoid possible mistakes in the Query-Host communication and/or the transmission of patient ID to the Host computer, it is recommended the use of bar-code codification which includes the “check-digit” option in its protocol.
- Use only original spare parts supplied by the manufacturer.
- Use only peripherals authorized by the Manufacturer

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

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

ELECTRICAL SAFETY

Electrocution/Fire Hazard!

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

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

During Installation please be sure

- Avoid improper connection of the system and the peripheral devices to mains supply can cause serious personal injury with lethal consequences and material damage (e.g. fire).
- Use only connection and extension cables with a protective conductor and sufficient capacity (performance, power) to connect the system and the peripheral devices to the mains supply.
- 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!
- Use a Smart Ups with at least 1500 VA capacity.
- 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 before connecting any external peripheral as external bar code readers, printer cables and/or RS232 serial cables

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.
- 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.
- Battery for PC Motherboard Lithium battery is BR2032 3 V.
- Battery for computer S195.001C in left drawer is Wentronic #23323 BH170-3P; Ni MH; 3,6V 230 mAh.

NOTE

Transient Emissions and Interference Resistance

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

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

BIOLOLGICAL 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 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

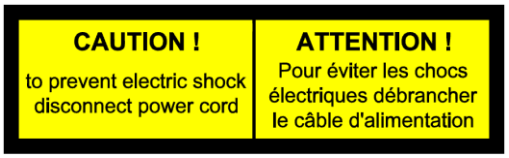
During Maintenance/ Technical Service activities be sure to:

- **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

Jo-Plus SAFETY LABELS AND TYPE LABELS

WARNING

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



PROCEDURE OF INSTRUMENT WASTE AT THE END OF ITS OPERATIONAL LIFE

As stated in the European directive 2002/ 96/CE related on waste of electrical and electronic equipment (WEEE), appropriate measures should be adopted to minimize the disposal of the instrument as unsorted municipal waste and to achieve a high level of separate collection of WEEE, according to the applicable local laws and rules.
The crossed-out wheeled bin symbol on side, placed also close to the plate of the apparatus, points out the necessity of the separate collection of the electrical and electronic equipment (WEEE).
The separate collection of this instrument at the end of its life is organized and managed by your distributor. The user who is going to get rid of it will therefore contact his distributor and follow the system that he has adopted in order to dispose the separate collection of the equipment that has reached the end of its working life.
The unauthorized disposal will be pursued according to the local laws and the rules in the nation of use. Fines will be effective, proportionate and dissuasive.

5.0 INTENDED OF USE

JO-PLUS is automatic analyzer for Erythrocyte Sedimentation Rate (ESR) determination to be combined exclusively with track for samples transportation with haematic samples premixing system.
It is designed to be installed on an Inpeco® Autmation Laboratory Automation System (LAS) and Laboratory information system (LIS) tracks.
JO-PLUS cannot be used standing alone because it has to receive hematic specimens already mixed and collected in EDTA as anticoagulant. The automation system provides to transport the test-tubes, to JO-PLUS, which contain material to be analyzed.
Its management and functioning check are mediated by a section called LAS (Laboratory Automation System) which receives and sends commands to JO-PLUS through "**RS232 LAS**" serial port present at JO-PLUS rear side. Patient ID and ESR result management, instead, is mediated by another section called LIS (Laboratory Information System) which receives and sends commands to JO-PLUS through "**RS232 LIS**" serial port present at JO-PLUS rear side too.

The JO-PLUS software is equipped with two menus:

- The "TECHNICAL" menu in which the operator can modify the available options.
- The "ADVANCED" menu in which a trained technician in charge to do maintenance service can check and configure it.

The activation of both menus which require a different password could be done pressing and rotating the navigation knob set to the front side of the module.
The options in the menus are displayed enclosed to 16 characters set on two rows.

6.0 TERMS AND DEFINITIONS

SAMPLER: analysis unit (called module also) for the value detection of the erythrocyte sedimentation rate (ESR) on entire blood.

HOST: informative system for the management of specimen result and interfacing system towards the user.

LIS: (**L**aboratory **I**nformation **S**ystem) communication for transferring results and information.

LAS: (Laboratory Automation System) robotic section reserved to the track.

TRACK: mechanic structure able to move test-tubes forward.

PIT-LANE: presentation system of specimen to analyze.

CALIBRATOR: substance or material which use is to adjust the gain in the analyzer.

CONTROL: substance or material which use is to verify the analyzer performances.

PROFESSIONAL USE: reserved to qualified personal trained to work with in vitro medical diagnostic devices.

SPECIMEN: biologic material withdrawn in order to detect or measure blood reaction (in our case the aggregation process correlated to sedimentation of erythrocytes).

ESR: erythrocyte sedimentation rate of blood.

MILLIMETERS PER HOUR: ESR measure unit (mm/h)

7.0 UNPACKING AND FIRST INSTALLATION

Please refer to chapter 6 on Service Manual.

8.0 FUNCTIONING

JO-PLUS module, called SAMPLER, has two communication lines to be connected to a Inpeco® Laboratory Automation System (LAS) and Laboratory information system (LIS) tracks.
JO-PLUS uses the LIS (laboratory information system) communication line to transfer information containing the measure report of the analyzed specimens to the informative program. TRACK is a mechanic system which transport specimens beneath JO-PLUS to be analyzed. It uses the LAS (laboratory automation system) communication line for the synchronization of the operating processes and for the recovering errors processes referred to the ESR measure. Specimens are lead to the mixing system (track section) which provides to rotate the test tubes upside-down and vice versa to a sufficient number of cycles in order to get good homogenization of blood components and so to disaggregate the red cells which join to the sedimentation phenomenon. Afterwards, one test tube per time is moved to the withdrawal place, beneath JO-PLUS, and LIS will enable the analyzer to carry-out first the withdrawal phase and then the ESR analysis. During the analysis, the scanner, set beneath JO-PLUS, reads the label applied on the test-tube. The read code, then, is going to be compared with the one present on the working list and assigned to the module. If both codes are the same, at the end of the analysis, the result will be sent to **Host** through LIS. LAS therefore, will drive TRACK in order to release the test-tube of the analyzed specimen leaving the space assigned to the withdrawal phase free for the next specimen management. If the codes are not the same, the result will not be sent to **Host** through LIS and an error message will be sent to LAS. Even in this case, LAS is going to drive TRACK in order to release the test-tube of the analyzed specimen leaving the withdrawal zone free for the next specimen management. At the end of all analysis, a counter set to **90** minutes, default value, is going to be activated to reach **0** (**zero**) so that, an alarm message to **Host** (NEED WASH) will be sent to LIS to warn the operator for the necessity to carry-out a washing procedure. If another analysis is run before the end of the scheduled time, the counter will be erased and restarted at the end of that analysis and so on. If during an analysis cycle, blood flow is not detected on three consecutive test-tubes, a new washing request will be activated.

JO-PLUS is equipped with a unit called CPS in which there are three photometers or reading units. Each of them is formed by an emitting photodiode and receiving detector. They face each other on a metallic support heated by a stable temperature of 37°C. The capillary, passing in the middle of them, attenuates the red color light and the liquid (water, Latex for the internal Quality Control, blood) which flows inside the capillary to reach the reading cells, is going to decrease (in case of water) or increase (in case of Latex or blood) the capillary opacity. Two photometers are dedicated to the reading of the liquid while the third is used to detect the end of the flow of the liquid is then to lock the peristaltic pump for all the time necessary for analysis of the liquid of the CPS. After the analysis is completed, the pump is activated to bring the biological fluid toward the waste. The two photometric signals will record the kinetics of aggregation during 10 seconds of analysis and calculate the ESR value through an appropriate algorithm.
In case of Latex, the variability will be done by the aggregation process of the particles in the liquid, in case of blood by the aggregation process of the red cells. The final ESR result is obtained from the average of the values read by the two photometers.

JO-PLUS is equipped with two factors to adjust the calibration (gains) in function of the liquid analyzed.
The first, called **Model-Fact** (**MFact**), is obtained by the calibration process done at the end if instrument assembling, or during the installation of instrument, or after the replacement of the CPS tubing carried out by an authorized service technician.
The calibration will then be checked daily using a control kit (**Latex Control Kit**) available in two formats: **SI305.100-A** (kit of a triplet of tubes that provides 6 controls) and **SI305.300-A** (kit from 5 triplets of tubes that provide 30 controls).
For more information refer to **Chapter 10** on **page 12**.
The final result, called “Latex ESR” and expressed in mm/h (millimeters/hour) will be sent to LIS.

The second gain, defined BoosterY has normally the same value as Model-Fact, in such a way as to allow adjustment of the ultimate values of VES in increase or decrease as a function of the method used in the laboratory where the instrument will be installed. At the time of installation, at least a hundred ESR analysis must be done with the laboratory method and the results should be compared with the results of the JO-PLUS. As a function of the correlation obtained, the BoosterY should be incremented or decremented manually from installer technician as described in **Chapter 13** (BoosterY) in order to obtain the best correlation with the reference method used in the lab.

9.0 TO LIGHT THE MODULE

Turn the instrument on pressing the switch set on the instrument rear side. The display is going to show the *Boot-loader* software followed by the initialization phase of the mechanic parts and then the display of the name and the operating software version installed.
Afterwards, time and date are going to be displayed while the module is waiting to receive commands from LAS.

WARNINGS:
Do not touch the withdrawal device since during the initialization phase the needle exits for a few millimeters under. The needle tip which could be contaminated by biologic materials, typically potential infected blood, could pierce the finger.

For any malfunction that occurs during the initialization phase, call the technical service.

10.0 SMART CARD

JO-PLUS works with credits loaded by Smart Card.
Alifax supplies personalized, for each customer, Smart Card programmed with 20.000 test.
To load new credits, the operator has to insert basically the Smart Card into the reader with the microchip contacts beneath and oriented towards the internal side of the instrument and wait for the end of the loading time.

Malfunctioning of the cards can generate one of these messages:

- "**ERR INSERT NOK**", card not inserted correctly or inserted upside down.
- "**ERR SIZE SMART**", credits content out of standard (20.000 test).
- "**ERR ERASE SMART**", burned error after loading credits (try to remove and reinsert)
- "**ERR SMART OPEN**", card opening error (try to remove and reinsert)
- "**ERR USED SMART**", card already downloaded. Use another card.
- "**ERR PERS NOK**", different personalization of the card.
- "**ERR ERASE AREA**", burned error after loading credits (try to remove and reinsert).
- "**ERR SEC CODE**", card opening error (try to remove and reinsert).

When one of these errors appear, the instrument remains waiting for the confirmation. Press the front knob and then extract the card from the reader.

To replace a defective Smart Card call the technical service.

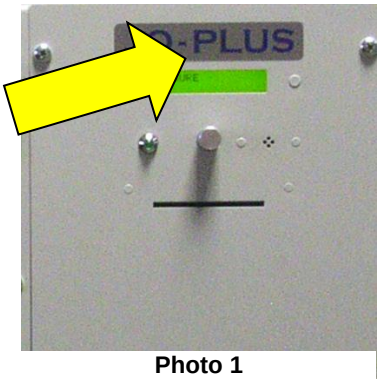


Photo 1

11.0 CHECKING PROCESS BY MEANS OF 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 Control (code **SI 305.100-A** for 6 controls) (code **SI 305.300-A** for 30 controls) is a practical and efficient control for a module functional verification. This procedure is managed completely by commands received from LAS.
The control procedure is requested by the operator which will activate TRACK to provide the tubes in the correct order for the process control.
The control results simulate three ESR values expressed in mm/hour. The first gives a low value (around 5 mm/hour) the second gives a middle value (around 20 mm/hour) and the third is set to the middle-high level (around 60 mm/hour).
Comparing the results reported on **Host** with those reported on the label of the kit box, it could be established if the module works correctly and if the analytic outcome can be reliable or not.
If the results of the analyzer comes into the values reported on the box table, it can be considered calibrated.
Otherwise, if one or more results differs from those reported on the box table, it is suggested to repeat the procedure for at least twice. If the problem remains, call the technical service for a functional verification.
By this process, the module can be maintained checked to its whole working life.

The control process is going to be activated, if the following presentation has been respected in sequence:

- ✓ **1** test-tube filled with ¾ of distilled water and labeled as **CALIBWASH**
- ✓ First test-tube filled with Latex. The test-tube has to have to be marked as **2**
- ✓ Second test-tube filled with Latex. The test-tube has to has to be marked as **3**
- ✓ Third test-tube filled with Latex. The test-tube has to has to be marked as **4**
- ✓ **2** test-tubes filled with ¾ of distilled water and labeled as **WASH……. (Note).**

In order to avoid rubber particle coming from washing tubes could interfere with the hydraulic circuit, we recommend to use always and only new washing tubes, please do not reuse washing tubes.

In this software version (1.01.00), has been implemented a new function, called priming, which aspires an amount of Latex from the first Latex test tube, marked number **2**, before the Latex sample aspiration. The aim of this function is to remove residual particles of water from the previous water aspiration in order to rise the accuracy of the Latex outcome.

Note:
References for the label to apply on test-tubes filled with water are described on APPENDIX C of page 41 "LABEL CODES FOR A CORRECT AUTOMATION"

By the attempt to remove residuals particles of blood or Latex, before starting the control process, it is recommended to carry-out the process described in the APPENDIX D of page 42 "SUGGESTIONS FOR THE USER"

12.0 TEST-TUBES LOADING IN THE IOM UNIT FOR WASHING AND CONTROL

Carry-out this procedure to load the Control Latex kit and wash test-tubes in a rack of 12 positions assigned to the Input lane of the Input/output Module (IOM) of track:

The phases to follow are:

1. Refer to the specific manufacturer track user manual to determine which kind of test-tube can be run into a lane.
2. After filling three test-tubes for ¾ with distilled water, apply a "**CALIBWASH**" (Note5) recognition code label on the test-tube intended to be inserted on the first position of TRACK and a "**WASH……** (Note5)" recognition code label on the others two test-tubes.
3. After pressing the appropriate key of the LED bar set on the front side of IOM (input/output Module of TRACK) (see at **Photo 3**) or doing the appropriate command displayed on the Graphic interface touch screen monitor of the console, using the handle, remove a 12 locations rack and free of test-tubes from a lane assigned to the rack loading of priority input (see at **Photo 5**).
   The water test-tubes and those of the Latex kit can be loaded in rack on the Input/output Module table or on another working area respecting the correct sequence described even in the document present in each box but above all following the indications described on APPENDIX D "SUGGESTIONS FOR THE USER" .

Photo 2

4. Guide the rack to a priority lane taking it by handle.

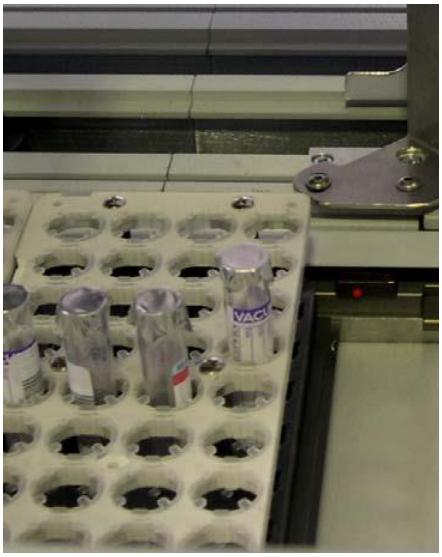


Photo 4 Priority Output loading rack

Photo 5 Priority Input loading rack view in the **IOM** unit.

WARNING pinching risk: never put the hands below of the led bar to move test-tubes.

Note: 1) Damaged racks must not be used.

2) Test-tubes must be on vertical position and centered at the inserting time.

3) Since for any error, test-tubes are lead back to the output racks, the Priority rack of Output (see at **Photo 4**) must be always loaded.

4) The test-tubes loading and unloading, to the transport lane, process, is in charge to the robotic arm present in IOM and follows the priorities of the rack columns.

5) Further information are reported on APPENDIX C "LABEL CODES FOR A CORRECT AUTOMATION".

13.0 ACCESS TO MENU

JO-PLUS software is equipped by two menus which is required a different password:

- The **technical menu** (**TECHNICAL**) which contains basic functions the operator can modify and described on page **16**
- The **advance menu** (**ADVANCE**) reserved to the technician who is in charge to do maintenance service.

The options of the menus, are displayed by means of **16** characters set on two rows of the LCD display.

To access to the TECHNICAL menu:

1) From the waiting position (when time and data appears) (**Photo 6**) Press the navigation knob (Navigator key).
2) Rotate the navigation knob to choose the desired menu. Press the knob to confirm it (**Photo 7**).
3) Type the password (**1010** matched to the TECHNICAL menu) rotating the knob and subsequently pressing it to confirm; example:

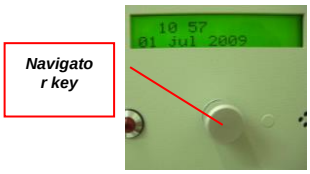


Photo 6

Photo 7

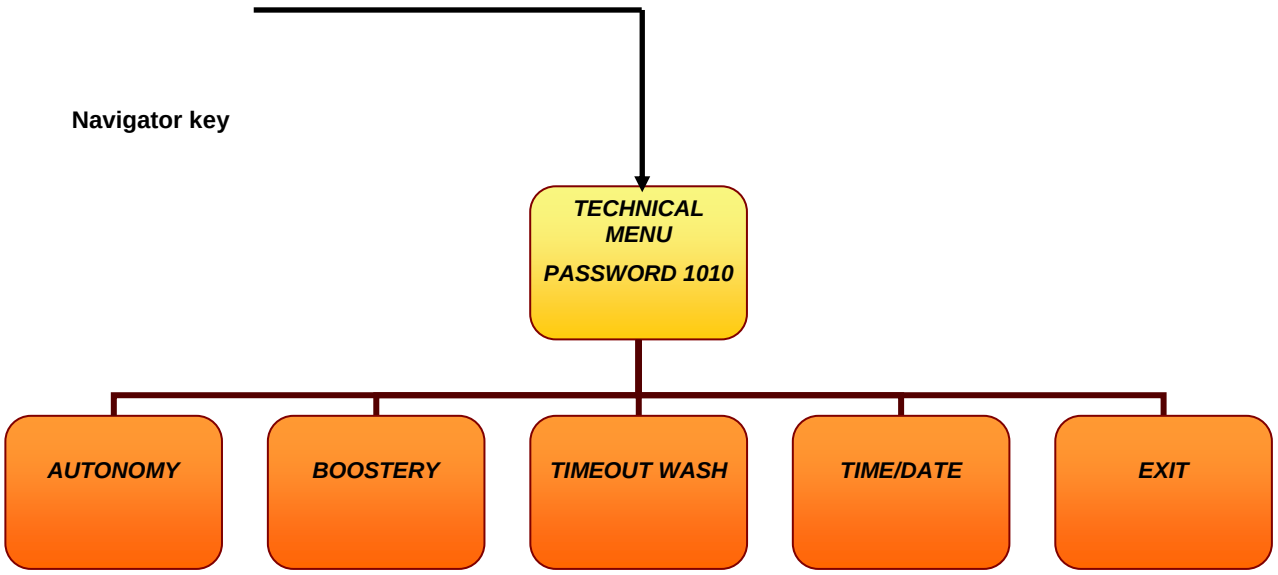
Photo 8

- 1st visualized number: rotate the knob up to obtain the first number of the password and then press it. *****
  The cursor is going to move to the second position.
- 2nd visualized number: rotate the knob up to obtain the second number of the password and then press it. *****
  The cursor is going to move to the third position.
- 3th visualized number: rotate the knob up to obtain the third number of the password and then press it. *****
  The cursor is going to move to the fourth position.
- 4th visualized number: rotate the knob up to obtain the fourth number of the password and then press it. *****

***** If rotating the knob, the assigned number is overtaken, rotate it again CW up to obtain the assigned value again.

Note:

- To exit from the menus, rotate the navigation key up to **EXIT** function and press it as confirmation.
- The TECHNICAL menu lay-out is shown on the next page



14.0 TECHNICAL MENU

The technical menu, which for the access is required the password **1010,** includes the following options:

AUTONOMY It allows the verification of the residual amount of test.

The accessing to this option is obtained pressing the navigation key when "**AUTONOMY**" inside of the **COUNTERS menu** is selected: **(>AUTONOMY).**

Figure 1

BOOSTERY BoosterY value conveys the gain, used by the module, to obtain the ESR results of hematic specimens. It is possible to adopt the gain value been obtained by the calibration process, made during the installation time, by means of Latex system. In this case the technician, in charge to do maintenance service, should report the value to BoosterY field manually.

Figure 2

If during a reproducibility trial process, analyzing at least 60 specimens, the ESR results are not correlated with those obtained by the referent method analyzing the same specimens, it is possible to increase or decrease the BoosterY value by 5 points of steps rotating the navigation key CW or CCW. Analyzing again the same specimens, it is possible to verify the BoosterY gain accuracy and so the ESR results.
The activation of this function is obtained pressing the navigation key when "**BoosterY**" inside **technical menu** (**TECHNICAL**) is selected: **(> BoosterY).**

The BoosterY range is between **0.600** to **1.400**.
The successive pressure of the key, confirms the new BoosterY value and allows exiting from this function.

Note: The table present in the **APPENDIX B** (ESR VALUES ALIGNMENT WITH THE REFERENT METHOD) helps the operator to find-out the right gain to copy in the BoosterY field.

TIMEOUT WASH At the end of every analysis cycle and if others operations are not executed, a count-down counter will be activated to calculate the elapsed time from last analysis. When the scheduled threshold time is reached, a message (NEED WASH) to require a washing will be sent to LIS.
The operator, therefore, has to carry-out a washing procedure.

Figure 3

The activation of this function is obtained pressing the navigation key when "**TIMEOUT WASH**" inside **technical menu** (**TECHNICAL**) is selected:
(> TIMEOUT WASH).
Rotating the navigation key CW or CCW a value of time into the range **0** - **99** minutes could be chosen.
Press the navigation key again to exit from this function.

NOTE: The time range to activate the alarm message can be calculated according to the frequency of time of the specimen which come in the lab. Example: if the elapsed time between an analysis cycle to another is high
(3-4 hours), for the washing request is suggested to fix a range of time low
(e.g. 30 minutes). If the elapsed time between an analysis cycle to another is low
(1-2 hours), for the washing request is suggested to fix a range of time high
(e.g. 90 minutes).

In order to avoid rubber particle coming from washing tubes could interfere with the hydraulic circuit, we recommend to use always and only new washing tubes, please do not reuse washing tubes.

TIME/DATE It allows time and data modification.
The activation of this function is obtained pressing the navigation key when "**TIME / DATE**" inside **technical menu** (**TECHNICAL**) is selected: **(> TIME / DATE)**

Figure 4

The first visualized field is **MODIFY MINUTES** (see the example of **Figure 5**)**.**
The technician can modify the minutes rotating the navigation key CW or CCW.

Figure 5

The successive fields which can be modified with the same modality are:

- Hour (see the example of **Figure 6**)
- Day (see the example of **Figure 7**)
- Month (see the example of **Figure 8**)
- Year (see the example of **Figure 9**)

Figure 6

The successive pressure of the key selects the exit from this function.

Figure 7

Figure 8

EXIT It allows exiting from technical menu.
The activation of this function is obtained pressing the navigation key.

15.0 ESR ANALYSIS

In the TRACK system, each test-tube, which contains a specimen enabled for the analysis and hold by a support called pallet, is diverted from the main lane of TRACK to a **pit lane** assigned to JO-PLUS previously.
The analysis habilitation of a specimen is determined by Query process of TRACK which compare the identity code read from the label applied on the test-tube with the one stored in the TRACK electronic node working list.
This stage is executed at the beginning of the workflow by means of the robotic arm of the track during the inserting process of the test-tube into the pallet.
Each test-tube in-fact, is matched with a label that assigns an identity code (ID) to the specimen.
Before the analysis, the test-tube diverted into the **pit lane** is shaken by means of a composed, by 10 metallic pliers, mixer in order to homogenize the blood contained in the test-tube.
At the end of all passages of the shaker, the pallet/test-tube group, is moved beneath JO-PLUS for the specimen aspiration in order to analyze it.
From this moment the system foresees the following phases:

1. SAMPLER availability request.
   - In this phase, the TRACK node requires to SAMPLER the availability for the analysis execution.
   - SAMPLER answers notifying an error (if present) which stops the process and accordingly TRACK avoids the test-tube movement to the withdrawal zone.
   - SAMPLER can notify even a warning (if present) and then the availability for the measure execution.
     If errors or warnings are not present, SAMPLER will notify the availability for the analysis execution.
     If SAMPLER is on activity status (measuring, washing, calibration/control phase), the "**BUSY status**" message will be sent to TRACK.
2. Specimens analysis request
   TRACK, releasing the identity code of the specimen (ID), requires to SAMPLER to carry-out the analysis of the specimen present on the withdrawal zone *.
3. ESR analysis
   SAMPLER aspirates the specimen to start the analysis and immediately after it notifies this to TRACK node. The analysis result, expressed in millimeter per hour (mm/h) which values fall down into a range between **2** to **120**mm/h, will be sent to **Host** through LIS.
4. Patient identity code reading by the local Scanner
   The Scanner set beneath JO-PLUS, reads the patient identity code (ID) printed-out on the label applied on the test-tube. This allows the TRACK node to identify the specimen in analysis again and after to release the test-tube from the withdrawal zone in order to position a new test-tube.
5. Confirmation for having released the specimen
   SAMPLER notifies to TRACK node the end of the analysis and so TRACK node compare the identity code present in its working list with that read by the local Scanner as described on the previous point **4**. If they correspond, then the analyzer will send the result to host at the end of the analysis. At the same time the TRACK node activates TRACK to release the test tube of the analyzed specimen.
   If the codes do not correspond, than, the result will not be sent to host. The analyzer will send the error to TRACK node and at the same time TRACK node will release the test-tube of the analyzed specimen.

*** NOTE**:
SAMPLER confirms, for the analysis, all specimens but it will process only those available on the local working list been compiled by Query process. If the specimen is not enabled for the analysis, SAMPLER will generate phase *4* and *5* in any case but with the purpose to move the specimen out from the **pit-lane** to allow then further specimen to come into the **pit-lane.**

This table reports any message can appear during the analysis process:

TRACK MESSAGES	SAMPLER MESSAGES	HOST MESSAGES
Phase 1 : Sample availability request		
>Sampler Available		
	<>**error** availability over	
	<>**error** robotics	
	<>**error** washing	
	<>**error** waste tank full	
	<>**error** calibration not executed	
	<>*warning* availability exceeded	
	<>*warning* maintenance exceeded	
	<>*warning* waste tank full	
	< Sampler Busy	
	< Sampler Available	
Phase 2: ID XXX measure request per specimen.		
>Measure Sample ID XXX		
	<>**error** availability over	
	<>**error** robotics	
	<>**error** washing	
	<>**error** waste tank full	
	<>*warning* availability exceeded	
	<>*warning* maintenance exceeded	
	<>*warning* waste tank full	
	< Measure on Sample ID xxx	
Phase 3: Specimen releasing confirmation		
	<>**error** robotics	
	<>*warning* sample missing	
	<Sample Free	
Phase 4: Specimen end of measuring confirmation		
	<>**error** robotics	
	<>*warning* no flux detect	
	<measure off sample ID	
>Sample ID YYY		
Phase 5: ID YYY result sent to LIS		
	>(IDxxx = ID YYY) ID YYY ESR result	
	(IDxxx ≠ ID YYY) <>*warning* ID mismatch	

16.0 ORDINARY MAINTENANCE

JO-PLUS has been designed to be used easily without a specific maintenance procedure the operator has to do.
Ordinary maintenance of the module requires the execution of washing cycles which maintains the hydraulic circuit internal site and needle cleaned.
The system foresees two typology of washing named **STANDARD WASH** (or simply WASH) done with distillate water and **NaHClO WASH**, done with distillate water and chlorine (bleach) . **(Note1)**
The test-tubes described below, measure 13x75mm included rubber and plastic cap and contain roughly 4 ml of distilled water or hypo-chlorite **(NaHClO-WASH)** with 5 ± 6% of dilution.
The wash liquid typology is identified by a specific ID printed-out over a label glued on the appropriate test-tube.

- **STANDARD WASH** *matched with a progressive number*, foresees that TRACK supplies to SAMPLER two test-tubes filled with distilled water.
  The washing process can be required:
  - by Host (washing request by means of the user or before a calibration/control process).
    In this modality, HOST communicates to TRACK for the necessity to supply the washing test-tubes to SAMPLER.
  - by SAMPLER to HOST in case the timer inactivity of SAMPLER goes over the scheduled threshold which could be from 60' to 180' or after a detection of systematic errors of the reading device.
    HOST will communicate to TRACK for the necessity to supply test-tubes filled with distilled water to SAMPLER.

- **NaHClO-WASH** (HARD WASH) is required by the user and foresees that TRACK supplies to SAMPLER the following test-tubes:

  N° 1 test-tubes filled with distilled water.
  N° 1 test-tube filled with **Hypo-Chlorite** (NaHClO)
  N° 2 test-tubes filled with distilled water

In case it is required a **NaHClO** wash and the capillary has not been washed previously by distilled water but it is dirty yet of residual blood and in case at a specimen measuring request the capillary contains residual parts of Hypo-Chlorite, SAMPLER is going to send an error to TRACK which will stop the process.
SAMPLER then will require to Host a standard wash with distilled water (**WASH**).

In order to avoid rubber particle coming from washing tubes could interfere with the hydraulic circuit, we recommend to use always and only new washing tubes, please do not reuse washing tubes.

***NOTE**: to avoid to jeopardize the measuring device functioning, specimens have never touch* Hypo-Chlorite*.*

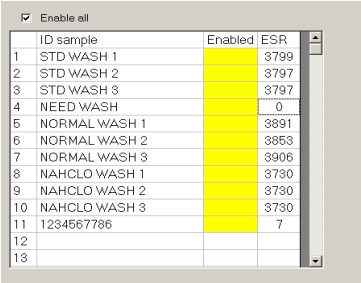
Note1: Further information are reported on APPENDIX C. of page 41 "LABEL CODES FOR A CORRECT AUTOMATION".

The **STANDARD WASH** or **WASH** or **NaHClO-WASH** process is characterized by 6 phases where it is possible to have the following casuistries:

TRACK	Analyzer (SAMPLER) reply.	
Phase 1 : Availability to run the process request.		
TRACK requires to SAMPLER for the availability to start a washing process.	Possible replies of **error**:	waste tank full robotic
	Possible warnings:	- maintenance threshold overtaken. waste tank full
	Notification	- system busy - system available
Phase 2: Wash run with H_2O request		
TRACK requires to SAMPLER for the execution of the wash with distilled water.	Possible replies of **error**:	waste tank full robotic
	Possible warnings:	- maintenance threshold overtaken. waste tank full
	Notification	- washing process run.
Phase 2: Wash run with NaHClO request		
TRACK requires to SAMPLER for the execution of the wash with Hype-Chlorite.	Possible replies of **error**:	waste tank full robotic
	Possible warnings:	- maintenance threshold overtaken. waste tank full
	Notification	- washing process run.
Phase 3: End of wash		
	Possible replies of **error**:	waste tank full robotic
	Possible warnings:	- washing not executed correctly. waste tank full
	Notification	- end of washing process
Phase 4: ID identification reading		
The TRACK scanner reads the identification ID applied on the test-tube.		- Go to the forward phase because the ID identity code corresponds to this read at the test-tube insertion in the TRACK time.
	Possible replies of **error**:	- the ID identity code does not correspond to this read at the test-tube insertion in the TRACK time.
	Notification:	- stop the test-tube releasing.
Phase 5: Result to host in contemporary to Phase 4		
	SAMPLER sends to HOST the analysis result.	➡ Successive phase.
Phase 6: Test-tube releasing		
	SAMPLER notify to TRACK that the test-tube is not longer engaged by the withdrawal device and therefore it can be moved on.	
	Possible replies of **error**:	waste tank full robotic
	Possible warnings:	- washing filed. - test-tube detection missed. - waste tank full.
	Notification	- the washing test-tube is free and so it can be moved into TRACK

17.0 RESULTS MEANING

The outcomes of the washings sent to LIS and displayed, could be similar as reported in **Figure 10**. The program which manages the displayed information is competence to track manufacturer.



	ID sample	Enabled	ESR
1	STD WASH 1		3799
2	STD WASH 2		3797
3	STD WASH 3		3797
4	NEED WASH		0
5	NORMAL WASH 1		3891
6	NORMAL WASH 2		3853
7	NORMAL WASH 3		3906
8	NAHCLO WASH 1		3730
9	NAHCLO WASH 2		3730
10	NAHCLO WASH 3		3730
11	1234567786		7
12			
13			

Figure 9

MEANINGS of the washing outcome

NEED WASH **(0)** = the module requires a washing procedure, it is a message sent to LIS for the operator. It warns him that it is necessary to wash the capillary with tubes filled with only distilled water.
The module can send it for different reasons:

1) At the “TIME-OUT WASH” expired time, starting from the end of the analysis.
2) When it is request to wash the capillary, dirty of blood, with hypo-chlorite.
3) When it is request to analyze samples with the capillary dirty of hypo-chlorite.

NORMAL WASH 1 **(3909)** = washing outcome taken from the first photometer of the reading unit. The acceptable range is between 2500-4095

NORMAL WASH 2 **(3887)** = washing outcome taken from the second photometer of the reading unit. The acceptable range is between 2500-4095

NORMAL WASH 3 **(3858)** = washing outcome taken from third photometer of the reading unit which stops the specimen for the analysis. The acceptable range is between 2500-4095

STANDARD WASH 1 **(3899)** = washing outcome taken from the first photometer of the reading unit during a calibration / control procedure. The acceptable range is between 2500-4095

STANDARD WASH 2 **(3897)** = washing outcome taken from the first photometer of the reading unit during a calibration / control procedure. The acceptable range is between 2500-4095

STANDARD WASH 3 **(3897)** = washing outcome taken from the first photometer of the reading unit during a calibration / control procedure. The acceptable range is between 2500-4095

NAHCLO WASH 1 **(3730)** = outcome taken from the **1**st photometer of the reading unit of a washing with bleach / hype-chlorite. The acceptable range is between 2500-4095

NAHCLO WASH 2 **(3730)** = outcome taken from the **2**nd photometer of the reading unit of a washing with bleach / hype-chlorite. The acceptable range is between 2500-4095

NAHCLO WASH 3 **(3730)** = outcome taken from the **3**nd photometer of the reading unit of a washing with bleach / hype-chlorite. The acceptable range is between 2500-4095

In order to avoid rubber particle coming from washing tubes could interfere with the hydraulic circuit, we recommend to use always and only new washing tubes, please do not reuse washing tubes.

MEANINGS of the ESR analysis outcome

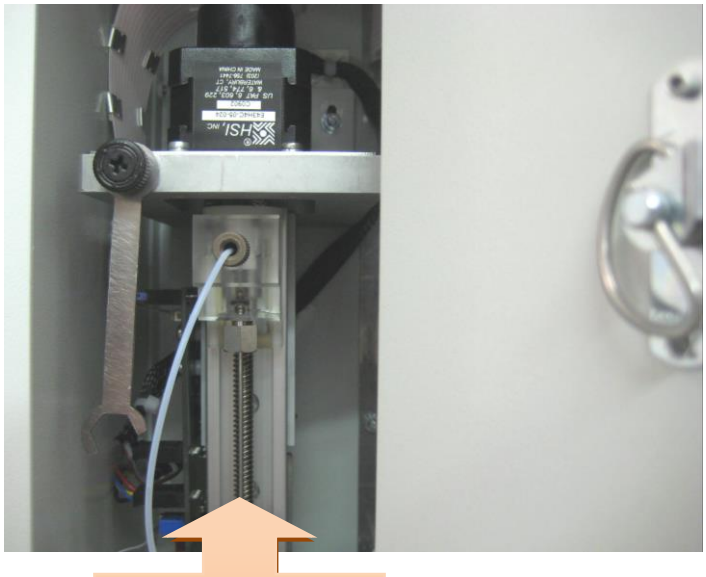
The ESR results matched with the identity code (ID), are sent to LIS and their visualization could be similar as reported on last row in **Figure 10** (**1234567786 7**).

18.0 TECHNICAL MAINTENANCE

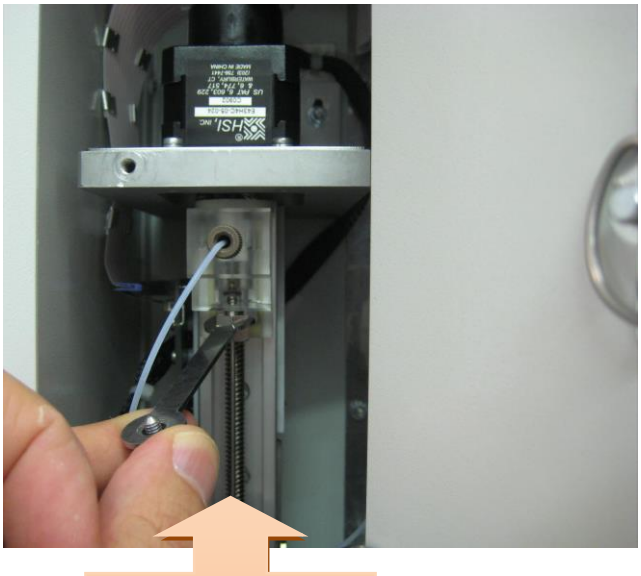
By means of an error code pointed-out to LAS, the technical maintenance is requested when the number of processed samples overtake the scheduled value of **30.000.** It is, therefore, recommended to contact the track manufacturer technical service in order to carry-out the maintenance service.

19.0 NEEDLE REPLACEMENT

At maintenance time, the needle replacement is not recommended but suggested. It depends on the condition of the needle.
To replace the needle, please see the following instructions:



1) *Open the door, take the key, set in this box, off unscrewing the fixing screw.*



2) *Unscrew the needle hexagonal base using the supplied key.*

3) *Move the needle down and unthread it from the retainer unit.*

4) *Put a new needle on repeating the operation on the reverse way.*

20.0 TURN THE INSTRUMENT OFF

Before turning the instrument off it is mandatory carrying-out a washing procedure.
The module can be turned off by pressing the switch set on the rear side of the module (see a**t** Errore. L'origine riferimento non è stata trovata.**).**

21.0 FUSES REPLACEMENT

The module has been equipped by two mains fuses of 2,5AT which have been inserted into a fuse container assigned to the mains group. Another fuse of 2AT, protects the main board (CPU).
To replace the fuses from the mains fuse container, use a Phillips screwdriver to remove the container and unthread it (see at **Photo 9-10-11**).
For the CPU fuse instead, push the fuse cover and unscrew it to ¼ of circle.
Unthread the fuse cover (see at **Photo13**).

Photo 9

Photo 10

Photo 11

Photo 12

Photo 13

22.0 SANITIZATION PROCEDURE

The following procedure must be executed before:

1) collecting/shipping of the module from laboratory after a demo or from replacement/repair.
2) technical service repair or check inside the module.

Protection tools (DPI) and suggested materials to be used:

1) Glasses.
2) Latex gloves.
3) Absorbing paper towels.

At page 35 of this manual, it has been added the SANITIZATION REPORT DOCUMENT which after a photocopy has to be filled up and matched to the analyzer.

If the sanitization cannot be executed due a failure of the washing system, contact the **Technical assistance**.

23.0 TROUBLE SHOOTING

1) Error needle sensor home (code 100).

Solutions:

S1.1 Call the technical service.

2) Error needle encoder (code 101).

Checks:

1- Verify if the connector ENC_Z set on the sensor board is plugged-in.

Solutions for any negative checks:

S1.1 Plug the connector in.
S1.2 Call the technical service.

3) Needle presence sensor malfunction (error code 101-102).

Checks:

Verify if the motor connector MOT.Z1_out set on the sensor board is plugged-in

Solutions for any negative checks:

S1.1 Plug the connector in.
S1.2 Call the technical service.

4) Malfunction of the test-tube retainer sensor (error code 103).

Checks:

1- Verify if the test-tube retainer connector set on the sensor board is plugged-in.

Solutions for any negative checks:

S1.1 Plug the connector in.
S1.2 Call the technical service.

5) Motors communication error (error code 104).

Solution:

S1.1 Call the technical service.

6) Opened door with needle or retainer down (error code 105).

Checks:

1- Verify if the door is closed well.

Solutions for any negative checks:

S1.1 Open and close the door.
S2.1 Clean the emitting sensor and the reflecting metallic part.
S2.2 Align the door sensor respecting 5-6mm of distance between the sensor emitting part and the metallic part of the door designed to reflect the sensor signal.
S2.3 Call the technical service.

7) Pump error (error code 1).

Solution:

S1.1 Call the technical service.

8) Thermostat error (error code 2).

Solution:

S1.1 Call the technical service.

9) Physic error of the Eeprom chip memory set internally of the µP (error code 3).

Solution:

S1.1 Call the technical service.

10) Precise physic error of the Eeprom chip memory set internally of the µP (error code 4).

Solution:

S1.1 Call the technical service.

11) Communication error to the Eeprom chip memory set externally of the µP (error code 5).

Solution:

S1.1 Call the technical service.

12) Eeprom chip memory set externally of the µP full of data (error code 6).

Soluzioni:

S1.1 Call the technical service.

13) Credits availability exhausted (error code 7).

Soluzioni:

S1.1 Reload the credits.
S1.2 Call the technical service.

14) Incorrect water value at the washing time (wash Not ok) (error code 8).

Checks:

1- Verify if the washing procedure has been done correctly.
2- Verify if there is water flow into the capillary during a washing procedure.

Solutions for any negative checks:

S1.1 Repeat the washing procedure.
S1.2 Replace the needle and repeat a washing procedure

15) Incorrect water value during the calibration procedure (error code 9).

Solutions:

S1.1 Call the technical service.

16) Waste Tank full (error code 10).

Checks:

1- Verify if the waste tank is full.
2- Verify that the sensor wires inside the jack are not on short circuit.

Solutions for any negative checks:

S1.1 Empty the waste tank.
S1.2 Reset the jack contacts.
S1.3 Call the technical service.

17) Calibration not executed (error code 11).

Checks:

1- Verify that the Latex kit is complete and it works.
2- Verify that the PTFE (Teflon) capillary has been washed.

Solutions for any negative checks:

S1.1 Replace the Latex kit.
S1.2 Repeat a washing procedure for few times even with Hypochlorite.
S1.3 Repeat the calibration.

18) Latex codes inconsistency (error code 12).

Checks:

1- Verify that the Latex kit has homogeneous codes.

Solutions for any negative checks:

S1.1 Replace the Latex kit.

19) Latex availability in the test-tube exceeded (error code 13).

Solution:

S1.1 Replace the Latex kit

20) Latex expiry date exceeded (error code 14).

Solution:

S1.1 Replace the Latex kit

21) Six weeks of Latex data exceeded (code 15).

Solution:

S1.1 Replace the Latex kit

22) Latex correlation NOK (below than 97%) (error code 16).

Checks:

1- Verify that the PTFE (Teflon) capillary has been washed even with Hypochlorite

Solutions for any negative checks:

S1.1 Carry-out a washing procedure even with Hypochlorite.

S1.2 Replace the Latex kit

23) Communication problems with the CPS unit (error code 17).

Solutions:

S1.1 Turn the module off and then on.

S1.2 Call the technical service.

24) Test-tube not detected (error code 18).

Checks:

1- Verify that the test-tube is available in the withdrawal zone.

2- Verify that the test-tube retainer moves down to detect the test-tube.

3- Verify that when the test-tube retainer touches the test-tube cap, the led, set on the sensor board as identifier lights.

Solutions for any negative checks:

S1.1 Carry-out a right procedure to move the test-tube to the withdrawal zone.

S2.1 Call the technical service

25) Blood detected in the tube at the washing time with Hypochlorite (error code 19).

Solutions:

S1.1 Call the technical service

26) Hypochlorite detected in the Teflon capillary analyzing blood specimens (error code 20).

Solutions:

S1.1 Call the technical service.

27) Incorrect process during the attempt to load credits (error code 21).

Solutions:

S1.1 Turn the module off and then on.
S1.2 Reload the credits using the same card.
S1.3 Load credits using a new card.

28) Smart card already used (error code 22).

Solutions :

S1.1 Turn the module off and then on
S1.2 Reload the credits using the same card.
S1.3 Load credits using a new card.

29) Smart card not programmed for JO-PLUS (error code 23).

Solutions:

S1.1 Turn the module off and then on.
S1.2 Reload the credits using the same card.
S1.3 Load credits using a new card.

30) Personalization (error code 24).

Solutions:

S1.1 Load credits using a new card personalized correctly.

.

31) Incorrect erasing card process (error code 25).

Solutions:

S1.1 Turn the module off and then on.
S1.2 Reload the credits using the same card.
S1.3 Load credits using a new card.

32) Opened door with needle and retainer at home (error code 26).

1- Verify that the door is closed well.
2- Verify that the sensor door is aligned well.

Solutions :

S1.2 Open and close the door.
S2.4 Clean the sensor emitting part and the metallic reflecting unit applied on the door.
S2.5 Align the door sensor respecting 5-6mm of distance between the sensor emitting part and the metallic part of the door designed to reflect the sensor signal.
S2.6 Call the technical service.

24.0 APPENDIX A - WASTE TANK SENSOR

The waste tank cap is equipped with two pinions (see the **Photo 14**) which are connected to the module trough electric wires tied to the discarding tube.
The two pinions work as a sensor: a wave signal is applied to one of them which is conveyed to the other when the discarded liquid level touches their base. The conveyed signal activates a counter which points out further discarded specimens. When the counter reaches **1500** discarded tests, which indicates that the level is pretty full, an acoustic alarm will be activated to warns the operator that the waste tank is full completely and needs to be emptied.
The counter, then, is going to be reset and go to **0** automatically.

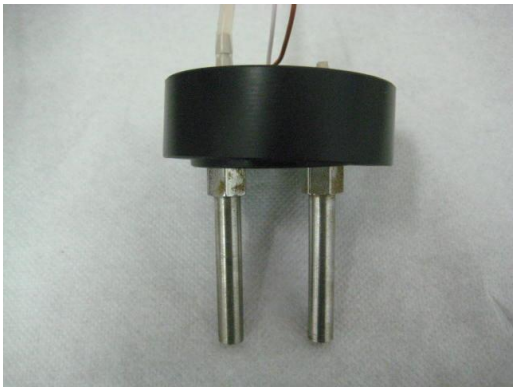


Photo 14

25.0 APPENDIX B - ESR VALUES ALIGNMENT WITH THE REFERENT METHOD

The ALIGNMENT FACTOR procedure helps to calculate a **correct value of BoosterY**.
It can be obtained reporting the associated integral value of each ESR (have a look to the **table 1**) to a table (as in the example of the **Table 2**) to calculate the **mean ratio** and multiplying the result to the present **BoosterY** value.
The calculated ALIGNMENT FACTOR can be exposed with the fourth decimal character.

ESR VALUES ASSOCIATED TO THE RELATIVE INTEGRAL VALUE

ESR	*associated integral*	ESR	*associated integral*	ESR	*associated integral*	ESR	*associated integral*	ESR	*associated integral*
0	3.4	**25**	8.5	**50**	10.9	**84**	13.3	**124**	15.7
1	4.1	**26**	8.6	**51**	11.0	**85**	13.4	**126**	15.8
2	4.6	**27**	8.7	**53**	11.1	**87**	13.5	**128**	15.9
3	4.9	**28**	8.8	**54**	11.2	**88**	13.6	**130**	16.0
4	5.2	**29**	8.9	**55**	11.3	**90**	13.7	**132**	16.1
5	5.5	**30**	9.0	**57**	11.4	**91**	13.8	**134**	16.2
6	5.7	**31**	9.1	**58**	11.5	**93**	13.9	**136**	16.3
7	5.9	**32**	9.2	**59**	11.6	**95**	14.0	**138**	16.4
8	6.1	**33**	9.3	**60**	11.7	**96**	14.1	**140**	16.5
9	6.3	**34**	9.4	**62**	11.8	**98**	14.2	**142**	16.6
10	6.5	**35**	9.5	**63**	11.9	**100**	14.3	**144**	16.7
11	6.6	**36**	9.6	**65**	12.0	**101**	14.4	**146**	16.8
12	6.8	**37**	9.7	**66**	12.1	**103**	14.5	**148**	16.9
13	6.9	**38**	9.8	**67**	12.2	**105**	14.6	**150**	17.0
14	7.1	**39**	9.9	**69**	12.3	**107**	14.7	**152**	17.1
15	7.2	**40**	10.0	**70**	12.4	**108**	14.8	**154**	17.2
16	7.3	**41**	10.1	**72**	12.5	**110**	14.9	**156**	17.3
17	7.5	**42**	10.2	**73**	12.6	**112**	15.0	**158**	17.4
18	7.6	**43**	10.3	**74**	12.7	**114**	15.1	**160**	17.5
19	7.8	**44**	10.4	**76**	12.8	**115**	15.2	**163**	17.6
20	7.9	**45**	10.5	**77**	12.9	**117**	15.3	**165**	17.7
21	8.0	**46**	10.5	**79**	13.0	**119**	15.4	**167**	17.8
22	8.1	**47**	10.6	**80**	13.1	**120**	15.5	**169**	17.9
23	8.3	**48**	10.7	**81**	13.1	**121**	15.5	**170**	18.0
24	8.4	**49**	10.8	**82**	13.2	**122**	15.6	**171**	19.0

Table 1

Method to find-out the alignment factor.
Example

Sample Number	Obtained ESR	*associated integral*	REFERENT ESR	*associated integral*	Difference between REFERENT and Otained values
1	20	7,9	25	8,5	8,5/7,9= **1.075**
2	25	8,5	31	9,1	9,1/8,5 = **1.070**
3	22	8,1	27	8,7	8,7/8.1 = **1.074**
4	36	9,6	45	10,5	10,5/9,6 = **1.093**
5	58	11,5	72	12,5	12,5/11,5 = **1.086**
6	42	10.2	53	11,1	11.1/10.2 = **1.088**
7	21	8,0	26	8,6	8,6/8,0 = **1.075**
8	51	11.0	64	12,0	12.0/11.0 = **1.090**
9	27	8,7	33	9,3	9,3/8,7 = **1,068**
10	39	9,9	48	10,7	10,7/9,9= **1,080**

Table 2

Mean value of these Alignment Factors :

(1,075+1,070+1,074+1,093+1,086+1,088+1,075+1,090+1,068+1,080) / 10 = **1.0799**

1.0799 is the value to multiply with the displayed BoosterY value.

Example 1
If the present value is e.g.1.0000, **multiply this per the obtained value** (1.0799) **=** 1,0799

Figure 10

Figure 11

Example 2
If the present value is e.g.1.0234, **multiply this per the obtained value** (1.0799) **=** 1,1051

Figure 12

Figure 13

26.0 APPENDIX C - LABELS CODE FOR A CORRECT AUTOMATION

To put more than one test-tubes into TRACK filled with water or Hype-Chlorite and therefore to allow their recognition, the labels to apply on the test-tubes have been coded by a unambiguous code.
These labels are sold by ALIFAX by the following typology and codes:

A sheet of 52 labels from ALIFAX and marked by **WASH1, WASH2, WASH3, WASH4** has purchase code as **SI804502**

A sheet of 52 labels from ALIFAX and marked by **NAHLOWASH** has purchase code as **SI804504**

A sheet of 52 labels from ALIFAX and marked by **CALIBWASH** has purchase code as **SI804503**

The complete Label kit has purchase code as **SI804501.** It contains:

- **4** sheets of 52 labels each coded as **WASH1, WASH2, WASH3, WASH4**
- **1** sheets of 52 labels coded as **NAHCLOWASH**
- **1** sheets of 52 labels coded as **CALIBWASH**

In order to avoid rubber particle coming from washing tubes could interfere with the hydraulic circuit, we recommend to use always and only new washing tubes, please do not reuse washing tubes.

27.0 APPENDIX D – SUGGESTIONS FOR THE USER

Since the user is enabled to check the module at the beginning of every new day and before starting the analysis for its **Q**uality **C**ontrol (QC) process, it should be recommended to wash the capillary following the described below procedure.
The user has to put all required test-tubes filled with distilled water, Hypo-Chlorite, and Latex to free positions of an empty rack of the track system all together assuming the right sequence is totally respected.
Once the rack is filled, he can insert it into track.
The right sequence to respect is reported just below and drown in the **Figure 15:**

- **1**st position = test-tube filled with distilled water and marked with a label which code corresponds to "**WASH1**".
- **2**nd position = test-tube filled with Hypo-Chlorite and marked with a label which code corresponds to "**NAHCLOWASH**".
- **3**rd position = test-tube filled with distilled water and marked with a label which code corresponds to "**WASH2**".
- **4**th position = test-tube filled with distilled water and marked with a label which code corresponds to "**CALIBWASH**".
- **5**th position = test-tube of the Latex kit which label is marked with the number "**2**"
- **6**th position = test-tube of the Latex kit which label is marked with the number "**3**"
- **7**th position = test-tube of the Latex kit which label is marked with the number "**4**"
- **8**th position = test-tube filled with distilled water and marked with a label which code corresponds to "**WASH3**".
- **9**th position = test-tube filled with distilled water and marked with a label which code corresponds to "**WASH4**".

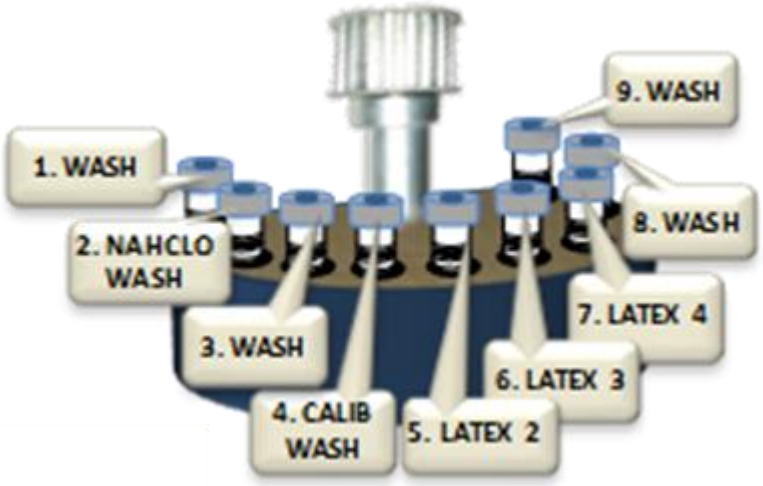


Figure 15

To a better TRACK management, it is suggested to split up the sequence in two parts. Therefore, at the preparation time we will have:

First step:
- **1**st position = test-tube filled with distilled water and marked with a label which code corresponds to "**WASH1**".
- **2**nd position = test-tube filled with Hype-Chlorite and marked with a label which code corresponds to "**NAHCLOWASH**".
- **3**rd position = test-tube filled with distilled water and marked with a label which code corresponds to "**WASH2**".

Second step:
- **1**th position = test-tube filled with distilled water and marked with a label which code corresponds to "**CALIBWASH**".
- **2**nd position = test-tube of the Latex kit which label is marked with the number "**2**"
- **3**rd position = test-tube of the Latex kit which label is marked with the number "**3**"
- **4**th position = test-tube of the Latex kit which label is marked with the number "**4**"
- **5**th position = test-tube filled with distilled water and marked with a label which code corresponds to "**WASH3**".
- **6**th position = test-tube filled with distilled water and marked with a label which code corresponds to "**WASH4**".

In order to avoid rubber particle coming from washing tubes could interfere with the hydraulic circuit, we recommend to use always and only new washing tubes, please do not reuse washing tubes.

28.0 NEW RELEASE AND IMPROVEMENTS.

SOFTWARE VERSION 0.00D: Starting software version

SOFTWARE VERSION 01.00.05:

- Credits storage in the microprocessor inside the E2prom.
- EQE Latex management
- Transferring or credits management by using a Transfer Card.
- View on display of software version and both data and time compilation.

SOFTWARE VERSION 01.00.06:

- Characters management on display improvements.

SOFTWARE VERSION 01.00.07:

- Not released version.

SOFTWARE VERSION 01.00.08:

- Beeper activation at the stop of the analysis cycle execution because the front door is open.
- High limit of BoosterY changed from 1.4 to 1.6
- Locked the possibility to modify the BoosterY value in the TECHNICAL MENU; displayed only.
- Correct a bug in the management for the credits transferring by Transfer card.

SOFTWARE VERSION 01.01.00:

- Inside “OTHER SETTINGS” menu, has been created the field “**MIN BUZ WASH**” which points out the number, in minutes, the beeper works in case of washing error activation. The missed wash will display the error message and run the LED blinking. This event can be stopped pressing the front knob.
- Inside “OTHER SETTINGS” menu, has been created the field “**SECS PRESSUR**” which points out the number, in seconds, the pump works CCW in order to inoculate air in the test tube, before water aspiration to do wash. The goal of this ploy is to avoid air bubble formation in the water flow which could jeopardize the wash outcome.
- Inside “OTHER SETTINGS” menu, has been created the field “**KIND OF CALIB.W**” which, if activated, runs FIRST-UP at half water aspiration from the test tube, at the Latex Calibration process run.
- It has been implemented the Latex priming.
- It has been implemented a control in the pump movement during wash.
- It has been implemented the OFFSETS management in the CPS field.
- Replaced **“TEMP/ADC”** with **“PARAM. CPS2”** including the OFFSET values and the possibility to modify the BY value in %.

29.0 JO-PLUS – REFERENCES

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

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

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

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

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

MET c us E114263 COMPLIES WITH UL 61010-1 CSA C22.2 NO. 61010-1

30.0 SANITIZATION REPORT DOCUMENT

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.

Sanitization procedures reserved to the Laboratory:

Turn the module on and carry-out a washing procedure: **YES** **NOK**

1. Carry-out a first wash using two tubes filled with distilled water---------- ☐ ☐
2. Carry-out a second wash using one tube filled with water and one tube filled with sodium hypochlorite---------- ☐ ☐
3. Empty and clean the Waste tank to avoid leaving residual blood.---------- ☐ ☐
   (For the disposal of the 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 .

Notes:

_____

_____

_____

DATE _____ HOSPITAL / OPERATING PLACE _____

SIGNATURE _____

Sanitization procedures reserved to the TECHNICAL SERVICE:

Wear protection devices (gloves and glasses) and remove the module cover.

If the operator has marked the washing procedure as **NO**, verify if the module is able to perform a washing procedure.

Carry-out the washing procedure as: **YES** **NOK**

1. Carry-out a first wash using two tubes filled with distilled water---------- ☐ ☐
2. Carry-out 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 residual particles of blood inside.---------- ☐ ☐
   (For the disposal of the 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, turn the module off and unplug the mains power.

If some part inside the instrument are contaminated with blood: **YES** **NOK**

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 content, follow the standard safety procedures in use in the laboratory).

If there are no parts contaminated with blood: **YES** **NOK**

1. Wash with water and dry with absorbing paper.---------- ☐ ☐
   (For the disposal of the content, follow the standard safety procedures in use in the laboratory).

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