



OPERATING MANUAL

Software Release N°2.33

Rev. 1.0 issued on December 2012

*Automatic laboratory device for the determination
of the erythrocyte sedimentation rate (ESR)
(Patented)*





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Issued on December 2012

(Total Pages: 109).

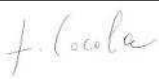
Standard applied in this document:

UNI EN ISO 18113-3:2010

CEI EN 61010-1 II Edition File 6290 (November 2001)

CEI EN 61010-2-101 I Edition File 7134 (November 2003)

LIST OF MANUAL REVISIONS
















REVISION MANUAL	DESCRIPTION OF MODIFICATIONS	APPROVED BY
1.0 of 12/2012	Official version	 R&D director

APPLICATION OF THE MANUAL

This manual applies to the following models of the VES-MATIC CUBE 200:

DIESSE Code	Model description
10370/S	VES-MATIC CUBE 200 intended for SYSMEX rack
10370/A	VES-MATIC CUBE 200 intended for ADVIA [®] BAYER rack
10370/AB	VES-MATIC CUBE 200 intended for ABX rack
10370/BC	VES-MATIC CUBE 200 intended for BECKMAN COULTER rack
10370/BC5	VES-MATIC CUBE 200 intended for BECKMAN COULTER rack (5 positions)

SYMBOLS

Legend of graphic symbols used on the instrument.	
	Instrument satisfying requirements of European directive on in vitro diagnostic medical devices (98/79/EC).
	In vitro diagnostic medical device.
	Date of manufacturing of the unit.
	Serial number of the unit.
	Manufacturer data.
Legend of Electrical and Safety symbols used on the instrument.	
	Protective conductor terminal.
	RAEE: Electric-Electronics Instrument – Separate compulsory collection of waste under D.L. 25/07/2005 n° 151 (Italy), implementation of 2002/96/EC and 2003/108/EC Directives.
	Warning, read the Manual and <u>pay attention to the safety symbols</u> .
	Warning, risk of electric shock.
	Warning, biohazard.
	Warning, laser beam.
Legend of symbols used in this document.	
	ATTENTION, potential hazard of personal injuries, all conditions indicated in the text have to be read and understood before proceeding.
	CAUTION, potential danger of damage to the machine, all conditions indicated in the text have to be read and understood before proceeding.
	NOTE, important information
	BIOHAZARD, danger of contamination with possibly infected materials.



Instrument satisfying CSA standards for the Canadian and U.S.A. market.

WARNINGS AND LIMITS

Before installation and use of the instrument, **for proper and safe use**, it is advised to **carefully read** the warnings and instructions contained in this user manual. It is important that this user manual is stored together with the instrument for future reference.

In case of sale or transfer make sure that this manual accompanies the Ves-Matic Cube 200 to allow new users to be informed about the instrument functionality and the related warnings.

Use of this instrument is advised only to **qualified and able personnel**. The installation has to be carried out by an authorized Diesse Diagnostica Senese S.p.A. technician who will create an **Installation Report** supplied separately with the Installation Check Guide.




This report has to be transmitted to the Diesse Diagnostica Senese S.p.a. Technical Service Department to allow the possibility for more effective technical interventions and assistance after installation.



The safety requirements and instrument performance are no longer guaranteed if to power the machine, a model of cable other than the supplied one (compatible with the voltage of the country of installation) is used .



BIOHAZARD

	<p>Potentially infected material is handled.</p> <p>When an analysis system like the Ves-Matic Cube 200 is used, all precautions have to be used regarding biological risks. The samples do not require preparation. The samples have to be disposed off in accordance with the laboratory instructions and with local laws.</p> <p>Observe the individual and collective security measures as appropriate for the operator and for the working spaces. Comply with directives in security matters and with the current legal regulations</p>
	<p>In case of leakage of biological material, during the working cycle, clean external surfaces of the instrument using appropriate laboratory safety procedures in order to assure personnel safety (see paragraph 5.2)</p>
	<p>All supplied materials have to be disposed off in accordance with the local laws.</p>

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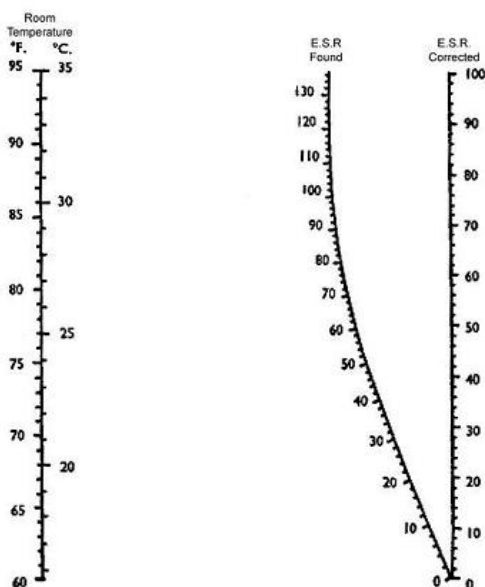
CHAPTER 1

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1.1. PRESENTATION OF THE INSTRUMENT

The Ves-Matic Cube 200 is an automatic bench top analyzer designed and programmed to determine the Erythrocyte Sedimentation Rate (ESR) on whole blood samples anti-coagulated with EDTA. It can analyze up to 190 blood samples per hour. The instrument performs the analysis making use of the full blood count samples that are loaded in the machine in the rack of the cell counter in use in the laboratory. ESR and non-ESR samples are automatically sorted by the system through bar-code reading and host query. The system accepts any kind of brand/model of top lavender tubes available in the market; it's therefore neither necessary to use a dedicated Citrate tube nor to transfer the blood from the tube inside the instrument. The exam is executed in complete automation (mixing of the samples and reading of the results) and the results, obtained in only 20 minutes, are comparable to those obtained with the Westergren method in 1 hour (60 minute sedimentation performed at 18°C using dedicated glass pipettes of 200 mm, with an internal bore with a diameter of 2 mm). The maximum throughput of the system is 190 results/hour. The main innovation of the system is that the sedimentation of red cells in autologous plasma is read directly in the original EDTA tubes used for the full blood count, by means of a specially designed optical system. Due to this feature, no part of the system comes in contact with or consume any of the blood samples during its operation. As a result, there is no transfer of blood from the original tube into any part of the analyzer and no production of waste fluids. The system is therefore designed to maximize the operator safety and protection. The Ves-Matic Cube 200 is environmentally friendly since it eliminates the possibility of biological contamination of the environment via biological waste and reduces the amount of plastic tubes that have to be disposed of thus decreasing the laboratory costs.

The instrument, which is designed with the temperature correction always activated, relates the results to a temperature of 18°C according to Manley's Nomogram (graphic 1.1). Never the less it is possible to de-select the temperature correction for laboratory needs.



Grafic1.1 Manley's Nomogram

Clinical concept of the ESR

The Erythrocyte Sedimentation Rate test (ESR) is performed measuring the distance travelled by red cells in autologous plasma over a fixed period of time. In normal conditions, red cells tend to repel each other by virtue of the negative membrane net charge, due to the presence of numerous sialic acid residues at the level of membrane glycoproteins.

When the protein composition of the plasma is changed, with the production of so-called "acute phase proteins", as a result of an inflammatory process or tissue damage, thanks to the binding of these proteins (fibrinogen, immunoglobulins) to the surface of red blood cells, the negative charge of membrane potential (Z) is altered and the red blood cells can pile-up, to form the so-called rouleaux, which then aggregate to form microspheres of uniform radius, that begin to sediment when their density exceeds that of the plasma in which they are immersed. The value of the ESR is then increased in all of those situations in which there is an increase in acute phase proteins and in particular fibrinogen (which is thought to contribute for 70% to the total phenomenon of sedimentation) and immunoglobulins (that will increase in case of onco-hematological diseases and acute infections). ESR is therefore an indirect not specific measure of an inflammatory state and is elevated in various pathological conditions such as inflammatory diseases (infections, rheumatic diseases), relative/absolute increase of globulins (nephrotic syndrome, myeloma), tissue necrosis (myocardial infarction, tumors). ESR is useful for predicting the prognosis of some diseases such as polymyalgia rheumatica, giant cell arteritis, rheumatoid arthritis and Hodgkins disease and is useful as a marker of treatment efficacy in many diseases such as rheumatoid arthritis, vasculitis, collagenosis, septic arthritis.

The erythrocyte sedimentation rate is usually higher in females than males and is increased in pregnancy and it has also a tendency to increase in both sexes with increasing age.

In the classical formulation of Westergren the test is performed on blood anti-coagulated with citrate, in the proportion of 4 parts blood to one part of anticoagulant. The diluted blood is then aspirated inside a special graduated pipette with inner diameter of 2.5 mm held vertically in a stand; the level of sedimentation of the erythrocytes is recorded after one hour, measuring the distance between the lower face of the meniscus of the plasma and the upper face of the layer of sedimented red blood cells. In the system Ves-Matic Cube 200, the results of sedimentation of red blood cells in EDTA anti-coagulated plasma are recalculated using the formula described in the 1993 ICSH document to transform them into values of sedimentation in citrate, in order to provide ESR results in full accordance with international guidelines.

General functions of the instrument

The blood obtained in the test tube for the CBC (cell blood count) exam, is accurately mixed by the instrument; the samples then remain at rest for a predetermined amount of time, to allow the sedimentation to occur.

Through analogical sensors (optic-electronic groups) the instrument automatically determines the sedimentation level of the red cells at time zero and after 20 minutes, subsequently the information is extrapolated and then automatically printed or shown on the display (in case of a Host connection, please read paragraph 7.2).

Normal values of ESR (Westergren citrate)

According to the scientific literature, normally ESR values are between 1 and 10 mm/h for men and between 1 and 15 mm/h for women; in pathological conditions they can increase to values of up to 100 mm/h and above.

Approximate normal range of the Ves-Matic Cube 200 instrument:

MEN up to 10 mm/h

WOMEN up to 15 mm/h

These values have to be considered as entirely approximate and vary in function of age and gender. According to international guidelines, each laboratory should determine its own normal ranges based on gender and divided by decades of age.

1.2. GENERAL DESCRIPTION OF THE INSTRUMENT



Fig. 1.2.1 "front view closed"

Legend Fig. 1.2.1 "front view closed":

- ① Instrument control unit with display equipped with Touch Screen 'Tablet PC'
- ② Printer
- ③ Lid of the rack introduction compartment
- ④ Opening for the introduction of the sample holder rack into the classifier module



Fig. 1.2.2 "front view open"

Legend fig. 1.2.2 "front view open":

- ① Sample rack introduction compartment
- ② Internal barcode reader
- ③ Test tube withdrawal clamp



Fig. 1.2.3 "back view"

Legend fig. 1.2.3 "back view":

- ① External connection panel
- ② Power supply box



Fig. 1.2.4 "Detail connection panel"

Legend fig. 1.2.4 "Detail connection panel":

- ① RS232 connector (for connection to the Host Computer)
- ② EXTERNAL BARCODE connector
- ③ USB_HOST connector



Fig. 1.2.5 "Detail power supply box"

Legend fig. 1.2.5 "Detail power supply box":

- ① Switch " I " [ON] / " O " [OFF]
- ② Filtered outlet with fuse holder lodging

1.2.1. MODELS VES-MATIC CUBE 200

There are currently five models of the Ves-Matic Cube 200 available that are designed to be compatible with various blood cell counter rack types present in the laboratory.

The available models are as follows:

Ves-Matic Cube 200 predisposed for blood cell counter SYSMEX/MINDRAY

Ves-Matic Cube 200 predisposed for blood cell counter ADVIA[®] BAYER

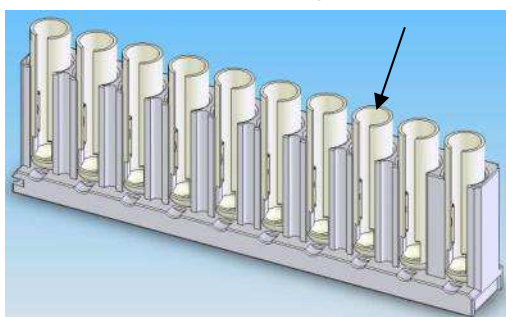
Ves-Matic Cube 200 predisposed for blood cell counter ABX

Ves-Matic Cube 200 predisposed for blood cell counter BECKMAN COULTER

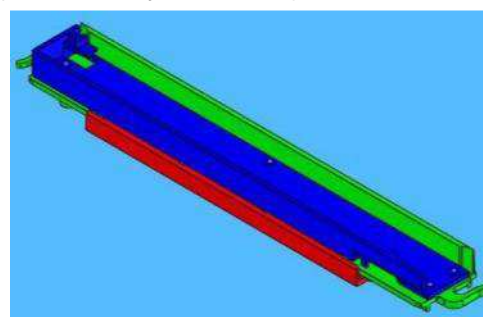
Ves-Matic Cube 200 predisposed for blood cell counter BECKMAN COULTER (5 positions)

Ves-Matic Cube 200 predisposed for blood cell counter SYSMEX [Code 10370/S]:

Rack SYSMEX: white colored 10 positions with outer cover (indicated by the arrow).



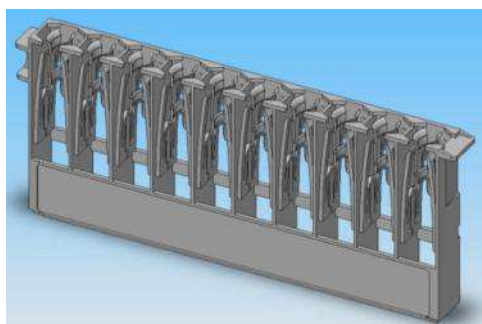
Rack Sysmex



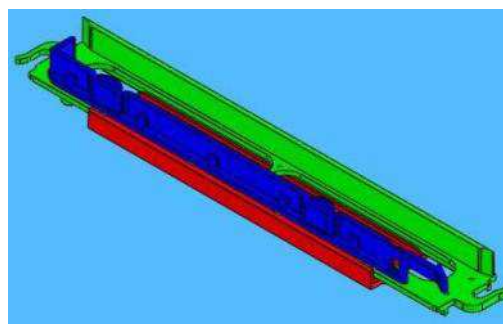
Rack Holder Sysmex

Ves-Matic Cube 200 predisposed for blood cell counter ADVIA[®] BAYER [Code 10370/A]:

Rack ADVIA[®] BAYER: grey colored 10 positions racks



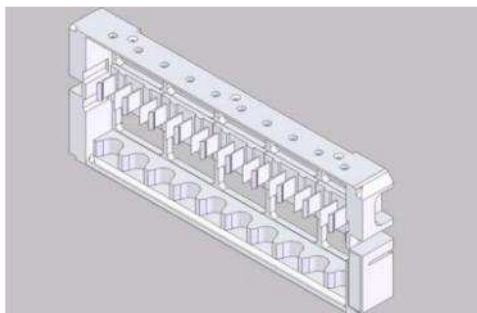
Rack Advia[®] Bayer



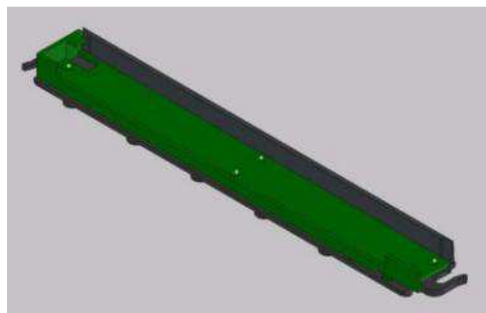
Rack Holder Advia[®] Bayer

Ves-Matic Cube 200 predisposed for blood cell counter ABX [Code 10370/AB]:

Rack ABX: white colored 10 positions rack



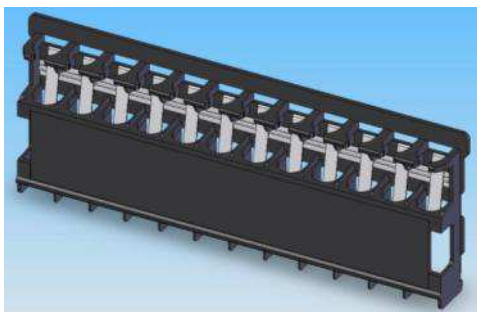
Rack ABX



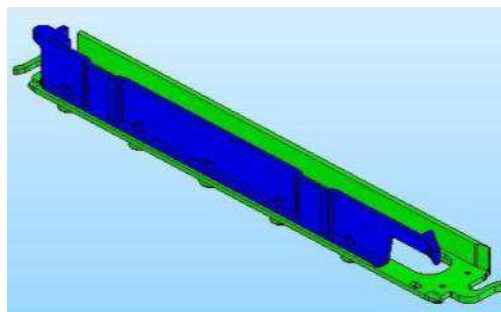
Rack Holder ABX

Ves-Matic Cube 200 predisposed for blood cell counter BECKMAN COULTER [Code 10370/BC]:

Rack BECKMAN COULTER: black colored 12 positions rack



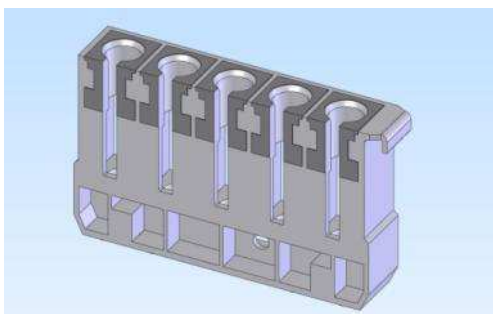
Rack Beckman Coulter



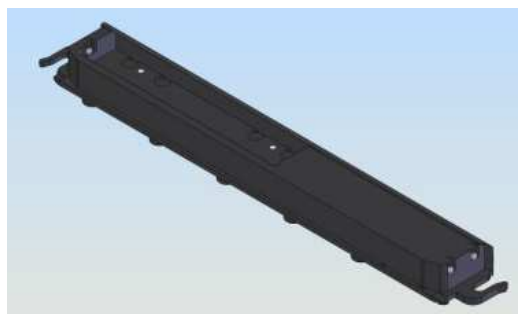
Rack Holder Beckman Coulter

Ves-Matic Cube 200 predisposed for blood cell counter BECKMAN COULTER - 5 positions [Code 10370/BC5]:

Rack BECKMAN COULTER: grey colored 5 positions rack





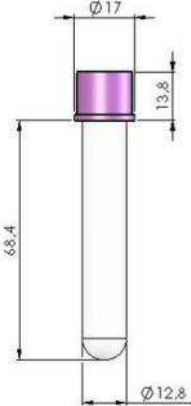
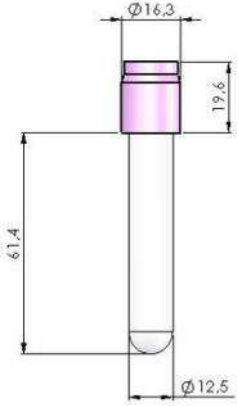
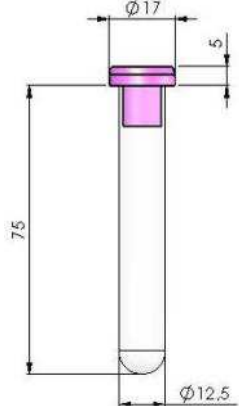
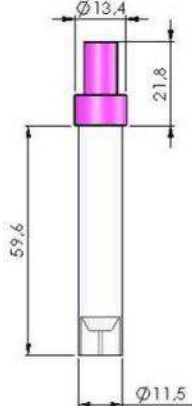


Rack Beckman Coulter (5 Positions)



Rack Holder Beckman Coulter (5 Positions)

1.2.2. COMPATIBILITY WITH TEST TUBES USED FOR THE CBC TEST

	VACUETTE (GREINER BIO-ONE) AND SIMILAR	VACUTAINER (BD) AND SIMILAR (VACUTEST KIMA, VENOSAFE TERUMO, VACUTRUST ETC.)	'RUBBER' [RUBBER CAP, BD, TERUMO]	'SARSTEDT' (see foot note!)
Models				
Dimensionis (mm)				

All produced models of the Ves-Matic Cube 200 are configured to use the same test tubes coming from the blood cell counter present in the laboratory. As a reminder: it is not possible to use two different types of test tubes simultaneously. Their varying dimensions, in particular the height, can interfere with the movement of some mechanical parts of the instrument.

The height of the test tubes conditions the regulation and the movement of the groups of internal mechanical parts, so it is fundamental, at the moment of the installation, to set the model of test tubes used in the Service menu; this intervention on the configuration software is allowed only to technicians authorized by DIESSE Diagnostica Senese S.p.A.



The instrument WILL NOT WORK if different models of test tubes are used simultaneously.

If the type of test tube being used is not displayed in the above examples, it is possible to request that the instrument be programmed to render it compatible with the desired test tube type. This modification has to be executed only by a specialized technician, authorized by DIESSE Diagnostica Senese S.p.A.




For the use of Sarstedt test tubes some mechanical adjustments are necessary to parts of the instrument: to the expulsion group and to the inserter tube (where the addition of a nestable guide is requested); furthermore the use of specific mails of the analytical chain is needed (for explanation please contact a specialized technician authorized by DIESSE Diagnostica Senese S.p.A.)

1.3. MATERIAL SUPPLIED WITH THE INSTRUMENT

The Ves-Matic Cube 200 is supplied with the following materials:

Q.ty	Description	Code	Image
1	Operating Manual (on paper)	R30600541	-----
2	Lifting handles	R10340531	-----
2	Sample holder racks	R30003650	
2	Rack input extensions	R10338870	
2	Microswitch keys V.2	R10345960	
1	Roll of thermal paper H.mm L=57 D=50	R12300000	
2	Delayed 5x20 mm UL fuse blocks 5A	R20400070	
1	Power cable 3x0.75 L=2m SCHUKO 90°-C13	R21890040	
1	Power cable SVT PLUG USA/OUTLET VDE 2MT UL	R21890370	

Q.tY	Description	Code	Image
1	BARCODE READER Z-3010 + CABLE 171-10R435-200 (VES-CUBE)	R20550510	
1	Final Inspection report	NA	-----

Based on the product model the following accessories are supplied:

With Ves-Matic Cube 200 models 10370/S, for blood cell counters SYSMEX

- n°1 Rack holder Sysmex (*with model CODE 10370/S*) [Ref.: R30207890]
- n° 1 CCD&LASER SCAN MODULE [ZEBEX] - CD – USER MANUAL [Ref.: R30650110]

With Ves-Matic Cube 200 models 10370/A, for blood cell counters Advia® Bayer

- n°1 Rack holder Bayer (*with model CODE 10370/A*) [Ref.: R30207900]
- n° 1 CCD&LASER SCAN MODULE [ZEBEX] - CD – USER MANUAL [Ref.: R30650110]

With Ves-Matic Cube 200 models 10370/AB, for blood cell counters ABX

- n°1 Rack holder ABX (*with model CODE 10370/AB*) [Ref.: R30207930]
- n° 1 CCD&LASER SCAN MODULE [ZEBEX] - CD – USER MANUAL [Ref.: R30650110]

With Ves-Matic Cube 200 models 10370/BC, for blood cell counters Beckman Coulter

- n°1 Rack holder BeckC (*with model Code 10370/BC*) [Ref.: R30207910]
- n° 1 DS 1100-2110 [DATALOGIC] - CD – USER MANUAL [Ref.: R30650060]

With Ves-Matic Cube 200 models 10370/BC5, for blood cell counters Beckman Coulter with 5 positions

- n°1 Rack holder BeckC Five (*with model Code 10370/BC5*) [Ref.: R30214090]
- n° 1 CCD&LASER SCAN MODULE [ZEBEX] - CD – USER MANUAL [Ref.: R30650110]

Consumables:

Check-Device Transponder RF 1K per VES-MATIC CUBE 200 (1000 tests) [Ref.: 10292]

Check-Device Transponder RF 5K per VES-MATIC CUBE 200 (5000 tests) [Ref.: 10291]

Check-Device Transponder RF 10K per VES-MATIC CUBE 200 (10000 tests) [Ref.: 10290]

ESR Control 2x9 mL (2 Bottles Normal + 2 Bottles Abnormal) [Ref.: 10430]

ESR Control 4x9 mL (1 Bottle Normal + 1 Bottle Abnormal) [Ref.: 10434]

Thermal paper for printer (1pc) [Ref.: 10403]



The safety requirements and instrument performance are no longer guaranteed if to power the machine, a model of cable other than the supplied one (compatible with the voltage of the country of installation) is used.



The safety and performance requirements of the instrument are not guaranteed whenever the instrument is used with materials different from the ones supplied and reported below: external barcode reader, the sample holder rack, the input extension rack, the delayed fuse block 5A 5x20mm UL, the programming guide for the internal barcode reader, the rack holder compatible with the supplied model of the Ves-Matic Cube 200.

1.4. TECHNICAL SPECIFICATIONS

POWER SUPPLY	EUROPE: 230Vac@50Hz USA/CANADA: 110-120Vac@60Hz	
ABSORBED ELECTRICAL POWER	265VA	
FUSES	2 x 5,0 A T (5 x 20 mm) UL	
DIMENSIONS	650 x 680 x 690 mm (l x h x d)	
WEIGHT	70 Kg (154 lbs)	
AMBIENT TEMPERATURE	Operational	from +15 to +35°C
	Storage	from + 5°C to + 45°C
RELATIVE HUMIDITY THRESHOLD	from 20 to 80% without condensation	
NOISE LEVEL	78 dBa	
EMBEDDED CONTROLLER	Microprocessor Freescale i.MX31 ARM11; Flash 128MB NAND; 128MB DDR RAM	
DISPLAY	TFT 800x 600 colour with Touch Screen	
CONTROL UNIT PERIPHERALS	Microprocessor card on owner bus	
INTERNAL ANALYTIC SECTION	89 position chain for the appropriate test tube	
STEP PROGRESS CHAIN	19 seconds in the normal functioning	
SAMPLE INPUT SECTION	10 + 10 slides for reception and transport of the typical haematology racks.	
ANALYZED SAMPLES COLLECTION SECTION	Sample holder rack with 8x14 positions for storage of the processed test tubes	
OPTICAL UNITS	Two couples of optic-electronic elements (Led & analogical sensor).	
PRINTER	Alfanumerica a carta termica larga 58 mm, 36 caratteri per linea, velocità 20 mm/sec.	
INTERFACE	2 x RS232C, 2 USB Host, 1 USB Client, 1 Slot Compact Flash	
PROTECTION CATEGORY	CLASSE I	
SAFETY STANDARDS	CEI EN 61010-1 (Ed.2001-11); CAN/CSA-C22.2 Nr.61010-1-04 (Ed.2004-07); UL61010-1 (Ed.2004-07)	
EMC STANDARDS	CEI EN 61326 (Ed.2004-08)	
INSTALLATION CATEGORY	II	



The safety and performance requirements of the instrument cannot be guaranteed anymore whenever for the powering of the instrument, a cable model different from the one supplied, compatible with the net power of the country of installation is used.

1.5. TECHNICAL DESCRIPTION OF THE INSTRUMENT

The "Selection Module" consists of:

- 'TABLET PC'- CENTRAL UNIT

Herein resides the application software that controls, manages and receives data, via serial connection from the single peripheral microprocessor boards where reside EEPROM with all parameters of the instrument memorized.

It is fitted with:

- Display (Fig.2.1) that allows the visualization and the interaction (by means of a touch screen) with all the software functions.

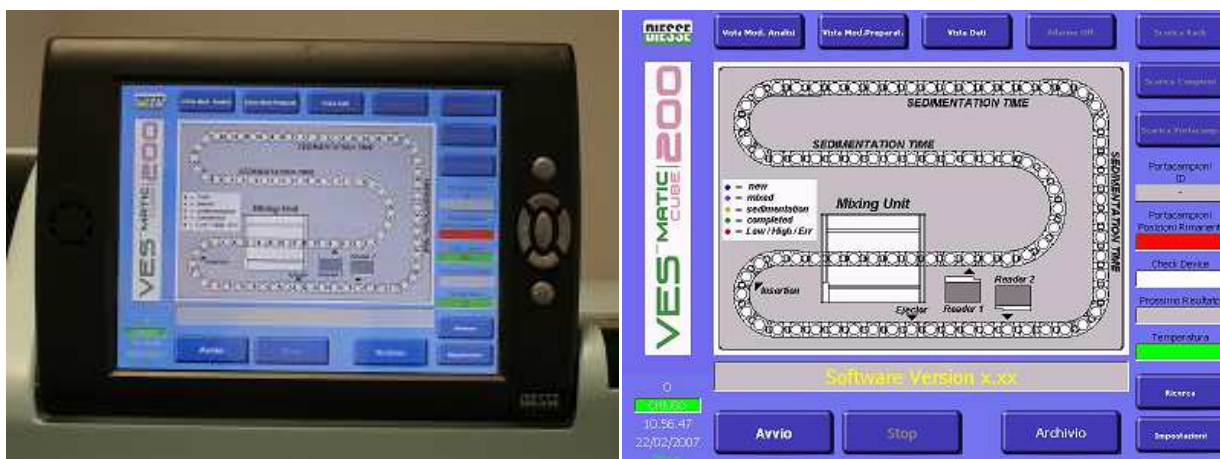
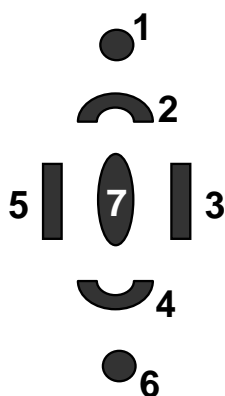


Fig. 2.1

- Keyboard (fig.2.2) situated on the frame of the Tablet PC



Description of button commands:

- 1 and 6 not active
- 2 the cursor moves up
- 3 the cursor moves right
- 4 the cursor moves down
- 5 the cursor moves left
- 7 "enter"

Fig. 2.2

- and an acoustic alarm situated on the frame of the Tablet PC which has the function to attract the operator's attention during specific phases of the work cycle and advises the operator in case of error conditions.

- **PRINTER**

Prints the information regarding the processed test tubes (sample code, ESR result) contained in the sample holder rack and all useful information regarding the working cycle (date, hour, temperature). For a detailed description see paragraph 3.4.

- **RACK MOVEMENT UNIT**

Standard hematology racks are inserted in the front part of the instrument in the appropriate locations (10+10 slides total, 9 slides accessible for the operator).

By means the combined movement of two *transfers* and of two *traslators* the racks rotate anti-clockwise inside the module to be transferred to the barcode scanning position and subsequently to the position where the test tube is withdrawn from the *preparer*.

- **RACK PRESENCE DETECTION UNIT**

A LED system allows the operator to know racks can be removed (green LED) and which racks are still waiting to be processed (red LED); this allows for random and continuous loading of the system.

- **BARCODE READER UNIT**

This unit executes the barcode reading of each sample so that the instrument can execute a Host Query to select the test tubes that have to be processed for ESR and that have to be transferred to analysis module.

The samples which do not require ESR evaluation are left in the rack which is subsequently removed together with them.

- **CLAMP UNIT**

This unit takes the test tube from the haematology rack and transfers it to the inserter tube.

- **INSERTER UNIT**

Connection unit between preparer module and analysis module which guides the test tubes to be processed in the chain of analysis module.

The "Analysis Module" consists of:

- **TEST TUBE HOLDER CHAIN**

The sample holder chain consists of 89 links in which the samples are inserted; with the help of two traction wheels the chain rotates clockwise inside the analysis module, transferring the samples to the shaking groups and after to the reading groups.

The speed of the chain movement is controlled to allow the samples to settle for a period of 20 minutes before the last reading will be executed.

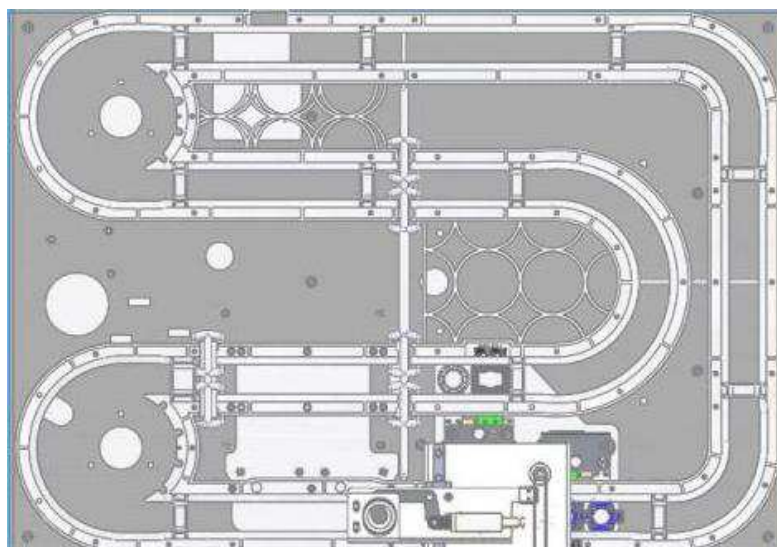


Fig. 2.3

- **MIXING GROUP**

Unit in charge of the execution of the inclination and rotation by 150° of the sample holder chain for a track of 5 test tubes, to guarantee the homogenous settling of the red blood cells.

- **READING GROUP 1 & 2**

In each group a motor executes the lift of the reading group that, by means of the help of an optical sensor, verifies the suitability of the sample contained in the test tube and detects the level of sedimentation.

- **TEMPERATURE SENSOR**

Measures the temperature inside the instrument and is positioned in the analysis module. The value of the temperature is visible in the 'temperature window' on the display.

- **EJECTOR GROUP**

Allows the expulsion of the test tube from the analytical chain of the analysis module and the transfer to the sample holder rack present in the classifier module.

The "Classifier module":

At the end of the analytical procedure, the expulsion group removes the test tube from the rack by pushing it up, and inserts it into the tube of the transfer test tube group, specifically positioned above the chain.

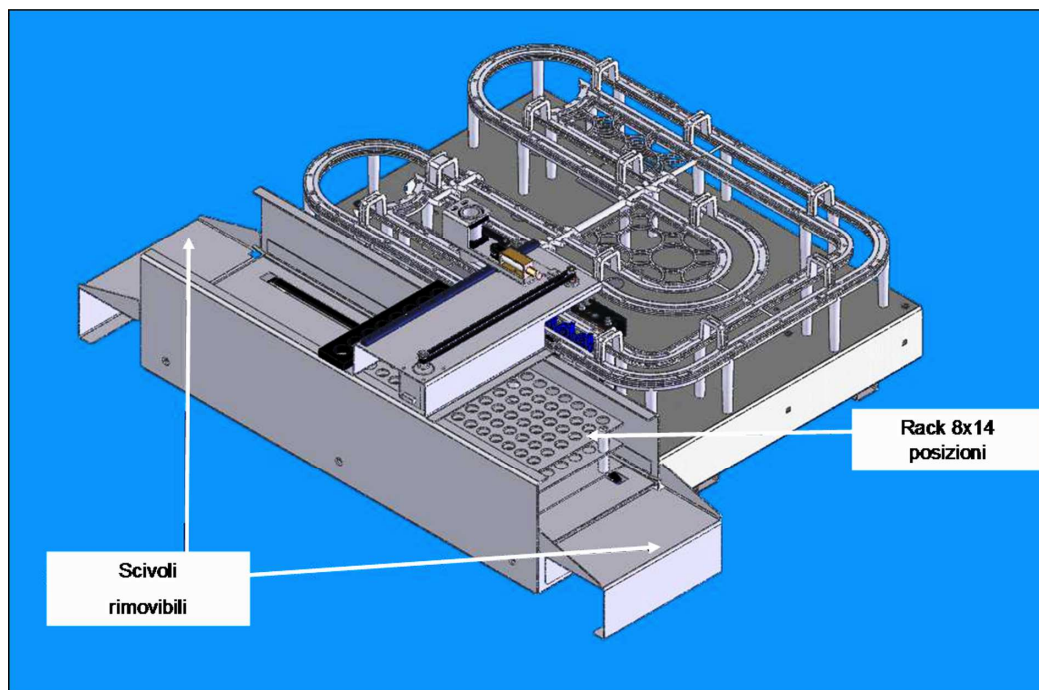


Fig. 2.4

The classifier module consists of:

- **TEST TUBE TRANSFER GROUP**

Unit in charge of removing test tubes that have completed the analysis protocol, from inside the analysis module to the sample holder rack with 112 available positions.

- **RACK PULLING GROUP**

This group moves, with the help of belts positioned on the base, the sample holder rack along and the module to allow the transfer test tube group to occupy all empty positions in the rack.

The sample holder racks ejected from the instrument have to be refrigerated.

Locating a specific sample is easy with the Ves-Matic Cube 200. The sample and location coordinates are provided for each sample in the sample holder rack, which itself is identified by a specific identifier.

1.6. INFORMATION ABOUT DISPOSAL

The Ves-Matic Cube 200 instrument relies on the use of an electrical power source and therefore, in compliance with the European Directive 2002/96/CE of 27 January 2003 and successive modifications of the European parliament, it is classified as Electrical-Electronic Equipment. [D.L.25/07/2005 n°151 (Italy)]

Therefore:

Disposal of the device in the normal solid waste is **strictly prohibited by law**. Doing so could incur legal sanctions against the violator.

At the end of the product lifecycle it is necessary to carry out **separate waste collection** of the product: contact the manufacturer or the distributor for the disposal or the redelivery of the instrument.

For the USA market

At the end of the product lifecycle it is necessary to carry out **separate waste collection** of the product: contact the manufacturer or the distributor for the disposal or the redelivery of the instrument.

CHAPTER 2

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2.1. PREPARATION AND CHECKS BEFORE INSTALLATION

The following conditions must be enforced for the safety of the instrument and the operator:



The power network (installation category II) must be compatible with the electrical requirements, specifications and current indicated on the electric power plate supplied with the instrument; it is advised that the efficiency of the electrical system is periodically verified. The network and relative outlets have to be out-fitted with an efficient ground connection following the laws in force in the matter of electrical systems.



Before making the connections with external instruments (pc, external barcode reader), remember to always do this while the instrument is switched off, it is necessary to verify compatibility (see the relative user manual) with the specifics indicated in chapter 7 and verify that the ground connection between them is uninterrupted. Connection with an external PC is possible with specific software (Microsoft Activesync®).



The operator has to be trained to ensure awareness of proper procedures, restrictions and warnings indicated in this manual in addition to the required individual laboratory safety procedures.



The material for the security of the operator (gloves, container for the disposal of the consumables used, cleaning and disinfectant solutions for the cleaning and the disinfection of the instrument, see ph 5.2) has to be always available.



The collocation of the instrument has to follow the guidelines indicated in paragraph 2.2.



IT IS ABSOLUTELY PROHIBITED to remove or modify the security and protection devices of the instrument.



INSTALLATION must be performed by a technician authorized by Diesse Diagnostica Senese SpA and it should be declared in the installation report. Refer to the Installation Check guide.



Decommissioning and shipment of the system have to be performed by personnel authorized by DIESSE Diagnostica Senese SpA

2.2. PLACEMENT

The environment intended for this instrument is the analysis laboratory.

For safety reasons and given the type of exams that it executes, the instrument has to be placed far from sources of heat, in zones non accessible to liquids, in environments free from dust and on perfectly flat work benches that are not subject to shocks or vibrations. The Ves-Matic Cube 200 has turned out to be conform the directives regarding the electromagnetic emissions, it's nevertheless advised that, when possible, the Ves-Matic Cube 200 is placed far from possible generators of Electromagnetic waves (for example fridges, laboratory centrifuges) and from instrumentation without the CE mark, since they could occasionally interfere with the functioning of the instrument.

It is advised that a proper table be used that can support the weight of the instrument. The table or bench top should not exceed 80 cm in height, to guarantee an ergonomically correct position for the operator during the input of the commands on the Tablet PC and the introduction and the extraction of the sample holder racks in the preparer module.



Fig.2.2.1 frontal view with the extensions for rack input

The table or bench top where the instrument will be placed, should allow enough space, about 40 cm, on the sides of the instrument for the operator to easily introduce and extract the sample holder rack in the classifier module (fig. 2.2.1, fig. 2.2.2 and fig. 2.2.3).

Furthermore, to be able to reach the connectors on the rear of the instrument and, most of all, to be able to quickly access the switch and the power cable in case of emergency, it is necessary to maintain a safe distance from the wall of at least 20 cm from the back side of the instrument.

For operator safety, do not place any materials or objects such as paper or containers on or near the instrument.



Fig. 2.2.2 left side of the Ves-Matic Cube 200 (exiting sample holder rack)



Fig. 2.2.3 right side of the Ves-Matic Cube 200 (entering sample holder rack)

Choose a position close to an undisturbed outlet free from electrical fluctuations.



Never move the instrument after it is properly installed. Should movement or relocation of the instrument be necessary, a re-verification of the conditions listed in this paragraph would be required before using the instrument again. Whenever the instrument will not be used or an extended period of time it is suggested that it is disconnected from the power source and protected from dust.



To move the instrument apply, always, the supplied handles to the instrument to execute the transfer of the instrument, as shown in sequence (fig. 2.2.4, a, b, c).



Fig.2.2.4.a



Fig.2.2.4.b

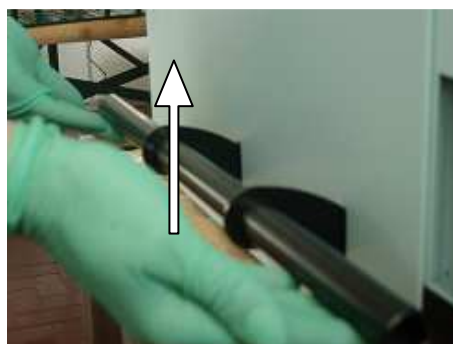


Fig.2.2.4.c



During the movement of the device avoid blows and excessive inclination that could damage the instrument.

Commissioning the system:

1. Assure that the **power switch is in the OFF <<0>>** position before continuing.
2. Executed connections with the external instruments (see paragraph 2.1).
3. Install the rack insert extension as show in the photographic sequence.



4. Check that the network power is compatible with what is specified on the label on the back of the instrument.
5. Connect the plug of the power cable (use the cable that is supplied with the instrument) to the outlet on the right side of the general power switch on the instrument itself (as shown in fig. 2.2.5 and 2.1.5). Connect the plug of the power cable to the power network.



Fig.2.2.5

6. Switch the instrument on changing the power supply switch, on the left of the power supply cable on the back of the instrument, in the « I » position (fig. 2.2.5).
7. At the start of the application program, assure that the instrument is configured to process the test tubes used in the laboratory, (the configuration rack/test tube is displayed on switch-on of the instrument, see 3.2.1 and fig. 3.2.a) otherwise contact the technical assistance for a correct configuration accessing the setup from the Service Menu.
8. To execute a test cycle and subsequently an analytical cycle, check chapter 4 of this manual. Also after a long period of not using the instrument it is advised to contact technical assistance to verify the good functioning.
9. Test cycle: Insert a rack with test tubes, with labels and start the analytical procedure. At the end of the analyses check that: the instrument executes the initial "reset" in a correct manner, that the procedure concludes correctly without interruptions, that the barcodes attached to the processed test tubes have been acquired by the instrument correctly (the print concerning the executed analytical cycle facilitates this verification operation).

2.3. LIMITATIONS AND WARNINGS



- **IN CASE OF FIRE OR GENERAL DANGER, TURN OFF THE INSTRUMENT AND UNPLUG THE POWER CABLE.**
- **DISCONNECT** the machine from the power source, before any technical intervention or in case of malfunctioning of the instrument.
- **It is forbidden to OPERATE** on the lower part of the machine while parts are moving (it is only allowed to key in commands on the touch screen and/or introduce and remove racks from the upper part).
- **ATTENTION: NEVER MANUALLY move the translators in the racks.**
- The safety and performance requirements of the instrument cannot be guaranteed anymore whenever for the powering of the instrument, a cable model is used different from the one supplied, compatible with the net power of the country of installation.
- Improper use and no or incorrect maintenance could seriously jeopardize the analytical process.



- **Limitations regarding the Check Device (consumable to be purchased for the use of the instrument):** the instrument is provided with special '**Check Device Transponder RF**' (see paragraph 1.3) destined to refill the "test counter" ("Check Device") of the instrument (see paragraph 3.3).

All **Check Device test tubes** supplied can be used only once and can't be used again.

All **Check Device test tubes** are electronic devices and when exhausted have to be disposed of according to the laws in force.

- **Reagents and consumables**

Any materials and/or accessories supplied for the Ves-Matic Cube 200 are specially designed and cannot be replaced with other types of materials or supplies. Using other types of materials can seriously jeopardize the performance of the instrument.

Diesse Diagnostica Senese S.p.A. declines every responsibility for the performance of the product if original reagents and materials are not used.



Potentially infected material is treated.

When the Ves-Matic Cube 200 is used all precautions regarding the biological risk have to be assumed.

The consumables have to be disposed of according to the laboratory instructions and the laws in force.

Observe individual and general security measures planned for the operator and appropriate for the work environment. Comply with the instructions in security matter and with the laws in force.



In case of leakage of biological material, during the working cycle, clean external surfaces of the instrument using appropriate laboratory safety procedures in order to assure personnel safety (see paragraph 5.2)

All supplied materials have to be disposed off in accordance with the local laws.



Samples that are not treated correctly cannot guarantee a good end result.

CHAPTER 3

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3.1. SWITCHING ON THE INSTRUMENT

Switching on

After verification of the installation of the instrument as described in chapter 2, make sure the window is closed and move the power switch, situated on the left of the power cable on the back of the instrument, to the on position « I » (fig.2.5).

Start of the system

Once switched on, push the “Start” button; the instrument executes an initial Check (“Reset”). This operation is essential and allows for verification of the proper functioning of all internal units and controls and that the moving parts are in the correct positions.



During the initial checks, when the instrument is switched on, the Software Version installed and subsequently the indications “RESET IN PROGRESS” are shown on the display.

3.2. DESCRIPTION OF THE SOFTWARE

3.2.1. MAIN MENU

At the start of the instrument, for about 3 seconds, the configuration of the type of test tube and the type of rack is shown (*in the example Rack/Tube Selection a Rack BECKMAN and test tube VACUTAINER BD are displayed*).



The type of tube or rack cannot be changed in this screen; this modification on the configuration software is permitted only to specialized technicians licensed by DIESSE Diagnostica Senese SpA.



Fig. 3.2.a

From the Main Menu (Fig.3.2.b), using the function buttons, it is possible to:

- start the analysis with the Ves-Matic Cube 200
- access the service menu
- modify the display mode (for example: "Analysis Mod view", "Loader Mod View", "Data View")
- unload samples that remained in the analytical chain of the Analysis Module
- unload the sample holder racks
- unload the haematology racks, if present, from the Selection Module.
- access the archives of the instrument

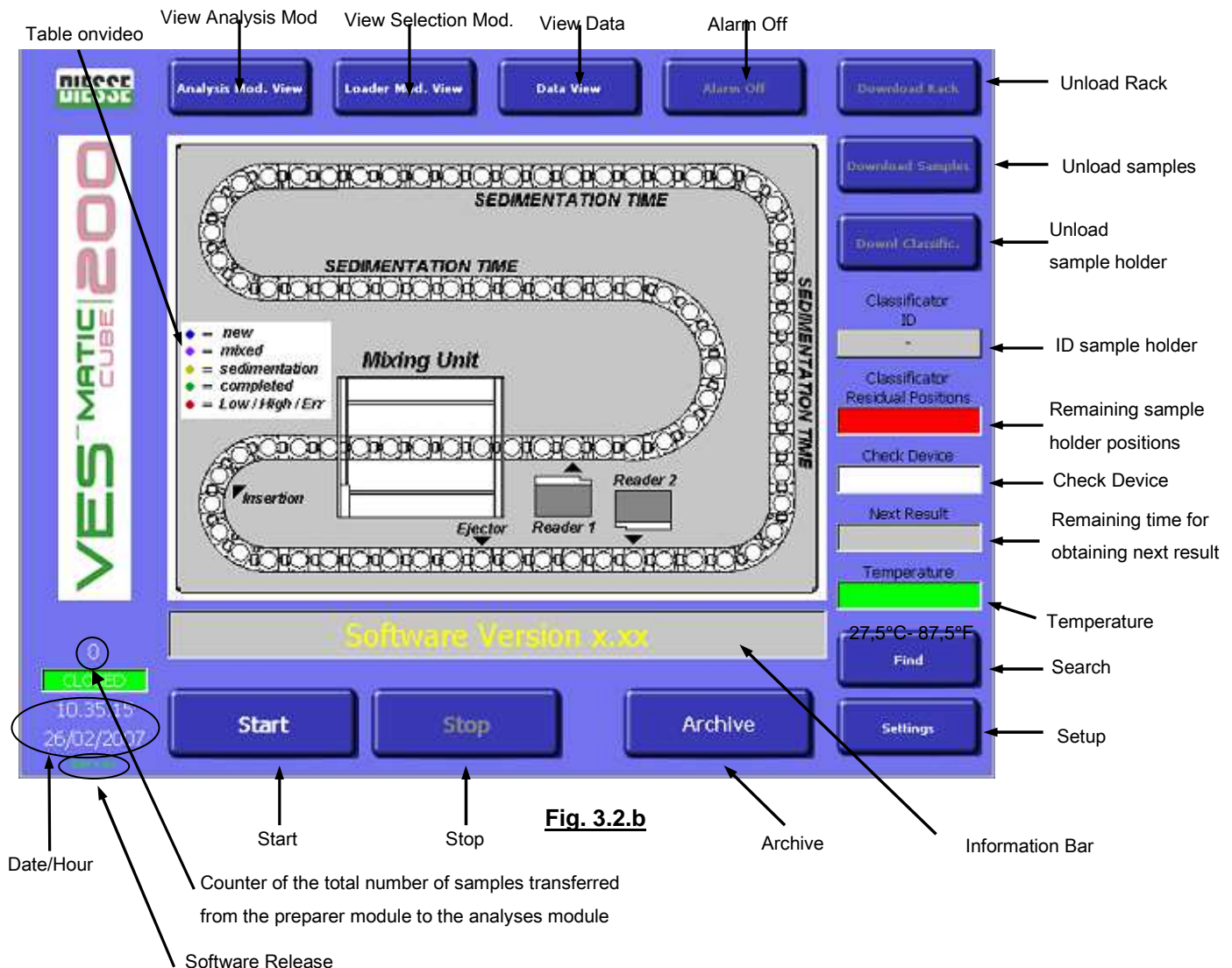


Fig. 3.2.b

3.2.1.1 DESCRIPTION OF THE COMMANDS AND INFORMATION COMMON TO THE 3 MODALITIES

Start: starts cycle of analysis

The Start command allows the initialization of the instrument for the analytical procedures.

Once Start is selected it executes a Reset of the instrument after which it will be possible to insert the samples and proceed with the analysis cycle.

Stop: interrupts the activity of the instrument.

The Stop command interrupts the analytical procedures of the instrument and allows the saving all analyzed sample data. At the end of a normal daily routine and **before** turning of the instrument, it is recommended that users press the Stop button in order to allow to remove any samples still present in the classifier module.

If the Stop button is pushed during the analytic cycle, a request of confirmation of the stop will automatically appear on the screen with the following message “Stop analysis: are you sure? NO YES (fig. 3.2.c). This avoids unwanted interruptions of the analytic cycle.



Fig. 3.2.c

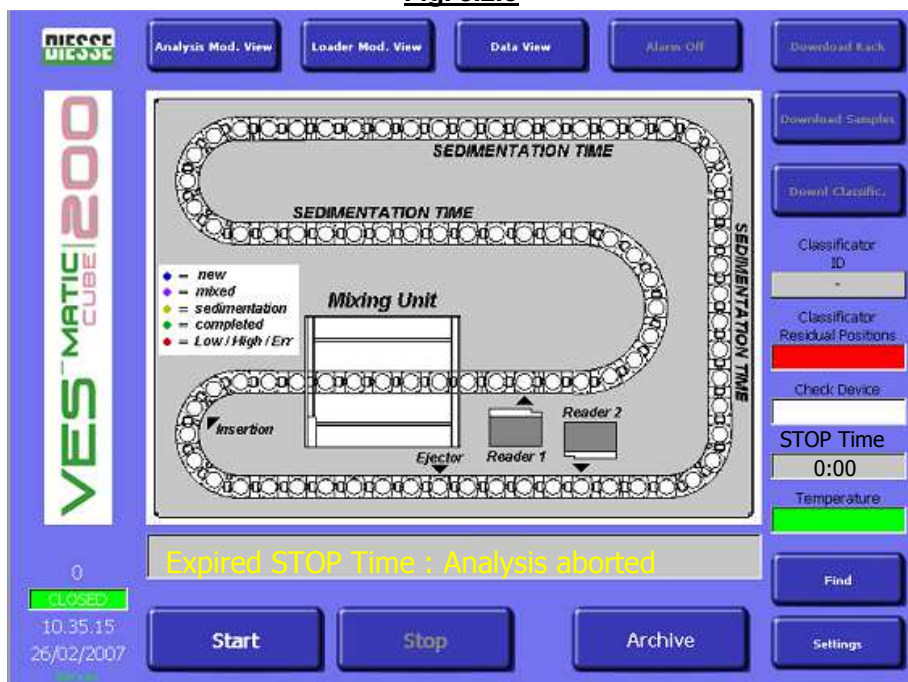


Fig. 3.2.d

Moreover the confirmation of the “YES” button automatically activates a counter of the stop time (decreasing second counter, with the duration of 90 seconds). This maximum interruption time allows the operator rapid interventions with minimal influence on the final ESR value recorded by the instrument. The time passed in “STOP” appears in the “Next result” window which will be renamed “STOP Time”. At the end of the intervention, that has to take less than 90 seconds, it is enough to push the “START” button and the instrument will resume its analytical activity.

If the analysis isn't restarted within 90 seconds, the analytical run will be cancelled and, after the pushing of the "START" button, the samples present in the chain are not ejected, but sent to a new analytical cycle (shaking, first reading, sedimentation, second reading, ejection) without a decrease of the check device. In the information bar the message "Expired STOP time: Analysis aborted" will appear, to disappear at the next "Reset", after pushing the "Start" button (fig. 3.2.d).

Archive: allows access to the database of the instrument.

Set-up: allows access to the configuration menu of the instrument (see paragraph "Setup Menu").

Search: allows the search for a sample within the instrument.

View Analysis mod: allows the graphical display of the processes inside the Ves-Matic Cube 200 regarding the analysis module.

View Loader mod: allows the graphical display of the processes on the upper side of the Ves-Matic Cube 200 regarding the module of the loading of the rack (preparer module) from the blood cell counter.

View data: allows the display of the data of the samples present in the cycle of analysis.

Alarm OFF: deactivates the sound alarms of the instrument.

ID Classifier: indicates the identification number (bar code) of the used sample holder rack.

Remaining sample holder positions: indicates how many positions in the sample holder rack are still available.

Check Device: indicates the number of test still executable on the instrument. The green color of the window indicates that more than 1000 tests are available, the orange colour indicates an availability between 1000 and 500 executable tests, the yellow colour indicates that from 500 to 0 tests remain available, while the red colour indicates that the number of available tests is exhausted. This leads to the automatic block of the transfer of the samples from the preparer module to the analysis module. The samples already present in the analysis module are nevertheless read and the relative ESR results are displayed. With the test counter at "0" the instrument is blocked, so to execute other test it will be necessary to recharge the Check Device (see paragraph **Errore. L'origine riferimento non è stata trovata.**).

Next Result: indicates the waiting time for the next analytical result.

Temperature: indicates the temperature on the inside of the instrument in °C and in °F.

Information bar: shows important information such as the error code (see the table in paragraph 6.1 "Trouble shooting").

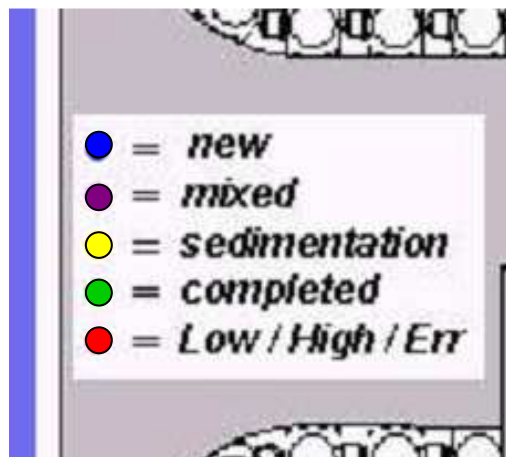
Counter of the total number of samples transferred from preparer module to analyses module: indicates the total number of samples transferred from the preparer module to the analyses module. To display the total number of tests executed by the instrument during its 'life' span it is necessary to contact a technician authorized by DIESSE Diagnostica Senese S.p.A

Window OPEN/CLOSED: (OPEN with red background, CLOSED with green background) indicates the status of the sensor present in the lid of the Preparer Module. To allow the normal execution of the analytical cycle, when the lid is closed, this window has to display the writing 'closed'.

Date/Time: indicates date and time.

SW X.XX: indicates the Software version installed on the instrument.

Table on video: In addition to the commands and information described in the previous paragraph, it is also possible to see an online animation, on the display screen, of the status of the test tubes in terms of position, reported to the various components of the instrument; this information can also be obtained by visual observation of the various colours of the individual samples, as explained in the following image.



- = new (new sample to analyse)
- = mixed (sample being mixed)
- = sedimentation (sample in sedimentation)
- = completed (sample analyzed with success)
- = Low/High/Error (sample for which an problem was encountered: blood level too low, too high or an error, for further explanations see paragraph 3.4)
- = recover sample (recupero Zero Chain Link, special fixed tube palced in position n. 1 in th chain) . Not shown in the table; it is visualized at the end of the reset operation when cirrcetly identified by the readers.

Table on video

New label introduced from SW release 2.30
(paragraph 3.2.1.9)

Unload rack: brings rack from the back of the loading module to the front for unloading. At each pressure of the unload rack button, the rack is translated one position, press the button more times to reach the desired position.

Unload samples: scans the chain of sample holders to automatically identify and unload samples selected for unloading. The procedure is useful for example in case of a forced interruption of the analytical cycle.

Unload sample holder: ejects the sample holder rack.

3.2.1.2 UNLOAD RACK PROCEDURE

The unload rack procedure recovers the racks located at the back of the loading zone; for example recovering an urgent sample or in the case of a forced interruption of the analytical cycle.

SEQUENCE OF THE OPERATIONS

1. The instrument has to display STOP
2. Push several times the UNLOAD RACK button until the rack that has to be unloaded is positioned at the front side of the loading space (selection module)
3. Remove the rack and repeat phase 1 and 2 if necessary.

3.2.1.3 UNLOAD SAMPLES PROCEDURE

The “Unload samples” procedure recovers automatically all test tubes present in the analytical zone of the instrument, for example recovering an urgent sample or in the case of a forced interruption of the analytical cycle.

SEQUENCE OF OPERATIONS IN CASE OF FORCED INTERRUPTION OF ANALYTICAL CYCLE

1. Push the START button.
2. At the end of the reset insert a sample holder rack in the dedicated zone (fig.2.4.3).
3. Push the STOP button.
4. Push the UNLOAD SAMPLES button and wait for the end of the procedure.

IN CASE OF AN UNLOAD OF SAMPLES WITHOUT BLACKOUT, FOLLOW THE PROCEDURE FROM POINT 3 (if necessary insert a sample holder rack).

3.2.1.4 SAMPLE HOLDER EMPTYING PROCEDURE

The sample holder emptying procedure allows the automatic recovery of all test tubes present in the rearrangement zone of the instrument (sample holder rack); this for example to recover an urgent sample or in case of a block of the instrument due to a forced interruption of the analytical cycle.

SEQUENCE OF THE OPERATIONS

1. Push the STOP button.
2. Push the “UNLOAD SAMPLE HOLDER” button and wait for the end of the procedure.

3.2.1.5 DESCRIPTION OF THE COMMANDS AND INFORMATION IN THE VIEW PREPARER MODULE MODE

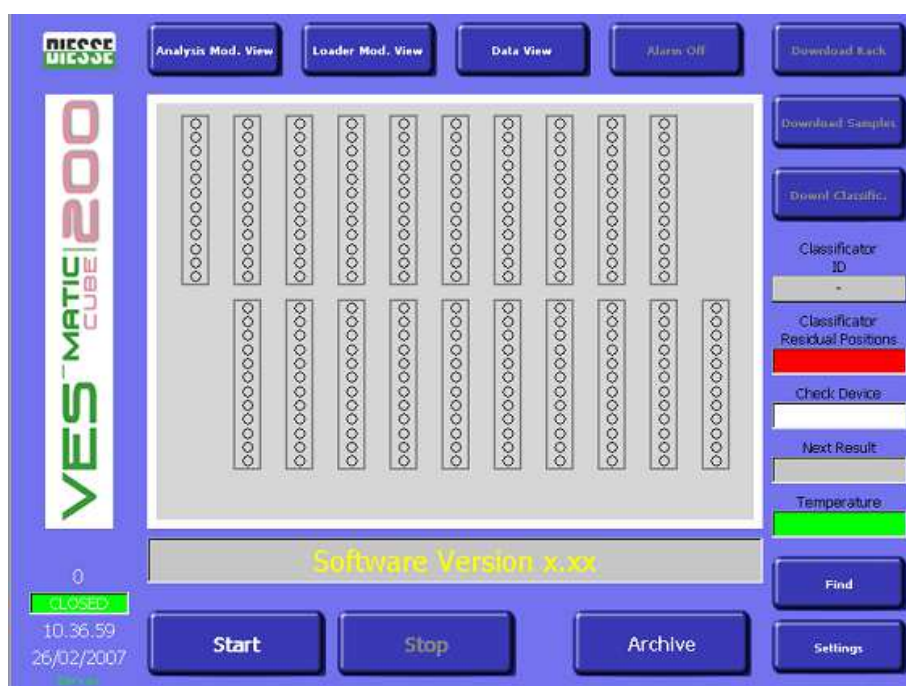
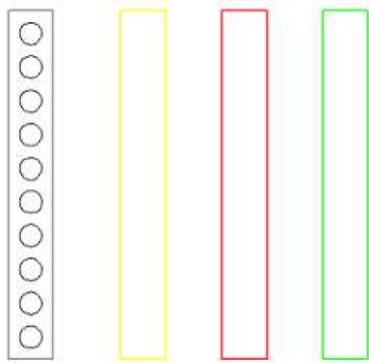


Fig. 3.2.e

Besides the buttons described in the previous paragraph, there is also an online animation of the status load and unload racks module (fig. 3.2.e).

3.2.1.6 COLOUR CODE OF RACKS IN VIEW LOADER MODULE MODE



- GREY: Empty position.
- YELLOW: New rack before the test tube barcodes are read.
- RED: Rack waiting to be processed after the test tube barcodes are read.
- GREEN: Rack already processed and ready to be removed.



ATTENTION! In the preparer mode, a LED is present in correspondence to every rack holder; if it is green this indicates a free position (fig 4.1.a) or a processed rack, if it is red (fig.4.1.e) this indicates a rack to be processed (and thus not to be removed).



ATTENTION! The introduction of a new rack containing samples to be processed has to follow what is specified on the yellow label on the left front part of the preparer module (see fig. 3.2. bis):

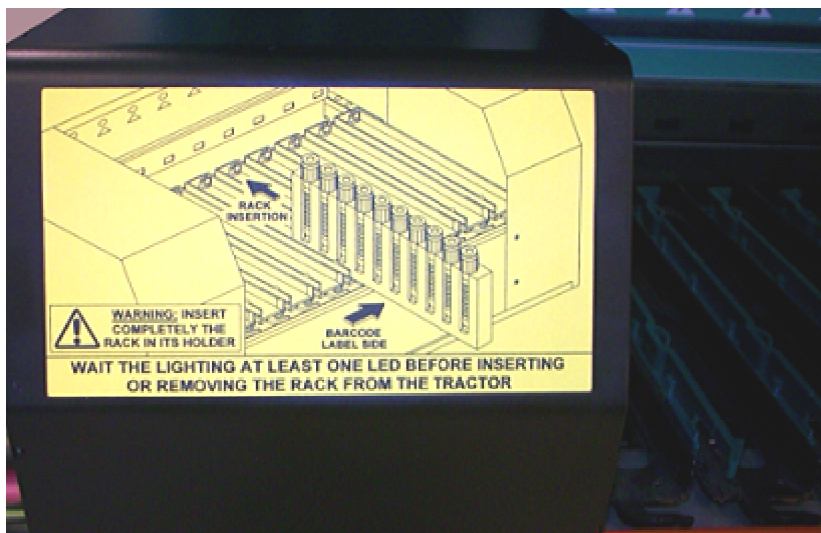
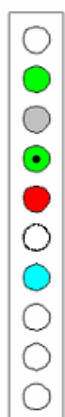


Fig. 3.2.e- bis:

Insert the rack completely into its rack holder, the barcodes of the test tubes have to be turned to the left side of the instrument; furthermore wait until the rack holders are in stop position. Before inserting or removing a rack wait for the lighting of at least one led, this condition indicates that the rack holders are in the stop position.

Fig. 3.2.e-bis

3.2.1.7 COLOUR CODE OF POSITIONS IN THE RACK IN VIEW LOADER MODULE MODE



- WHITE: Empty position.
- GREEN: Test tube waiting to be processed after the reading of the barcode and authorization of the Host computer.
- GREY: Test tube not to be processed, after the reading of the barcode and the lack of authorization of the Host computer
- GREEN+GREY: Test tube waiting to be processed, with authorization of the Host computer but without a barcode or with one not readable.
- RED: Test tube that should have been processed, but that wasn't because of mechanical problems.
- TURQUOISE: Test tube found in the rack following the search sample procedure.

3.2.1.8 DESCRIPTION OF THE COMMANDS AND INFORMATION IN VIEW DATA MODE

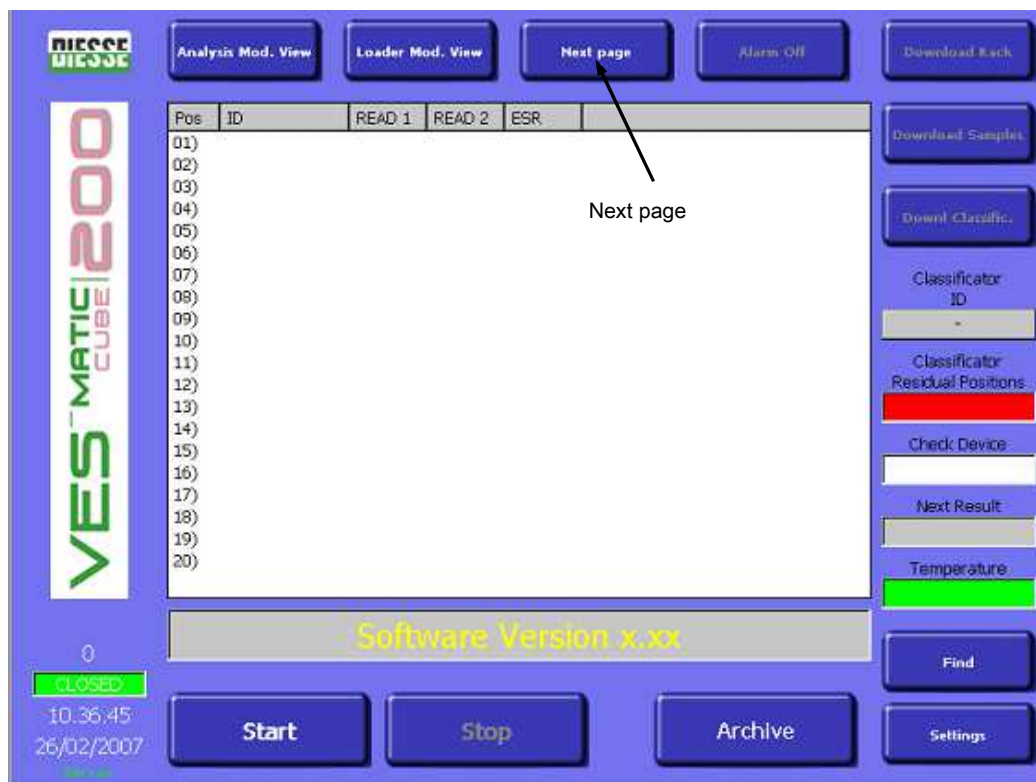


Fig. 3.2.f

Next page: allows the display of the next pages.

Besides the buttons described in the previous paragraph, it is possible to have information about the samples being analyzed. For this in the window are displayed (fig 3.2.f):

POS: position of the sample.

ID: identification code of the sample.

READ1: reading 1, corresponding to the level of the total blood column after mixing (time zero of sedimentation), this information can be displayed only after input of the special access code (The access to this information is allowed only to personnel authorized by DIESSE Diagnostica Senese S.p.A.).

READ2: reading 2, corresponding to the level of the red blood cells after sedimentation, this information can be displayed only after input of the special access code (The access to this information is allowed only to personnel authorized by DIESSE Diagnostica Senese S.p.A.).

ESR: Result of the ESR.

3.2.1.9 SEARCH FUNCTION



Fig. 3.2.g

The search button allows the detection of a sample on the inside of the Ves-Matic Cube 200 and the possible recovery of it by insertion of its bar code number (fig. 3.2.g) using the keyboard and pressing the **OK** button. Furthermore it is possible to display the position where the sample is situated. The following indication will appear on the display screen:

SAMPLE FOUND IN MODULE "-----"

List of possible wording of the description of the module:

Loader (Preparer)

Analyzer

Classifier

Once the sample is found, the software shows it on the display highlighted in **TURQUOISE** (special colour code) indicating the position occupied by the tube either in the cell counter rack (if in the Preparer Module), or in the moving chain (if in the Analyzer Module) or in the Sample holder rack (if in the Classifier Module). The **OK** button is replaced by the buttons "**YES**" and "**NO**" to provide the ability to respond to the proposed option (regarding the removal of the sample).

Removal of the sample

Pushing the "**YES**" button will start the recover sample procedure.



ATTENTION! The procedure for the recovery of samples generates different actions, depending on the module involved, where the process the sample is located:

Loader module

If the test tube is located in the PREPARER module, the analysis of the sample **will not be interrupted to allow the sample to be recovered**. The action that results from trying to recover a sample in this location is the cancellation of all the withdrawal operations of test tubes from loaded

racks; the Ves-Matic Cube 200 will move all racks to the front loading zone to allow the removal of the sought test tube.

Analyzer module

If the test tube is found in the ANALYZER module, the **analysis of the samples will be interrupted!** The action that results from it determines the cancellation of all the withdrawal operations of test tubes from the loaded racks and from the analysis. The Ves-Matic Cube 200 will launch the Unload Samples procedure and subsequent Unload sample holder to allow the removal of the sought test tube.

Classifier module

If the test tube is found in the CLASSIFIER module, the analysis of the samples **will not be interrupted**. The action that results from it determines however the ejection of the sample holder rack to allow the removal of the sought test tube

More over the instrument will ask for the introduction of a new, empty sample holder rack.

3.2.1.10 ZERO CHAIN LINK /REFERENCE TUBE - RECOVERY FUNCTION

The recovery function is present starting from SW release 2.29 and following and to make it effective it has to be activated by a Service Engineer autohorized by Diesse Diagnostica Senese S.p.A.

The Zero Chain Link (or reference tube) is recognized by the system as a "landmark" through which it is possible to bind the patient's ID (bar-code) to the ring of the chain which it is plugged in. **In this way it is eliminated the potential mismatch result/sample ID that could take place should the chain lose steps** (e.g. in case of intervention of the operator following a jam of the chain).

At machine start-up, at least one complete turn of the moving chain is performed (slow speed) for the reference search and to mark any sample tubes already present in the analysis chain.

The zero chain link ass'y contains a metallic element shaped as a normal top lavender tube bearing two windows that make it recognizable as the "reference tube" when it is read by Reader1 and Reader2 of the analysis module of the instrument, thanks to the characteristic graph of light intensity that is generated that cannot be confused with the graph of a "normal" sample. The zero chain link is also recognized by means of the reflection photocells located under the ejector; the identification by the pair of photocells involves detecting the presence of the reference tube beneath the zero chain link ass'y and detecting that the upper part of the sample tube is empty (without a "cap"). Once the search of the sample tubes is completed, the reference indexes of the chain are repositioned (putting the reference sample tube at number 1) and the analysis cycle is started.

The readers read the zero chain link ass'y at each round during the cycle of analysis, in order to keep under constant control the correct functioning of the readers and the correct movement of the chain.

If the presence of the tube reference is not confirmed, the instrument alerts the operator of a possible jam in the analysis module: the instrument beeps and the screen displays the following message.

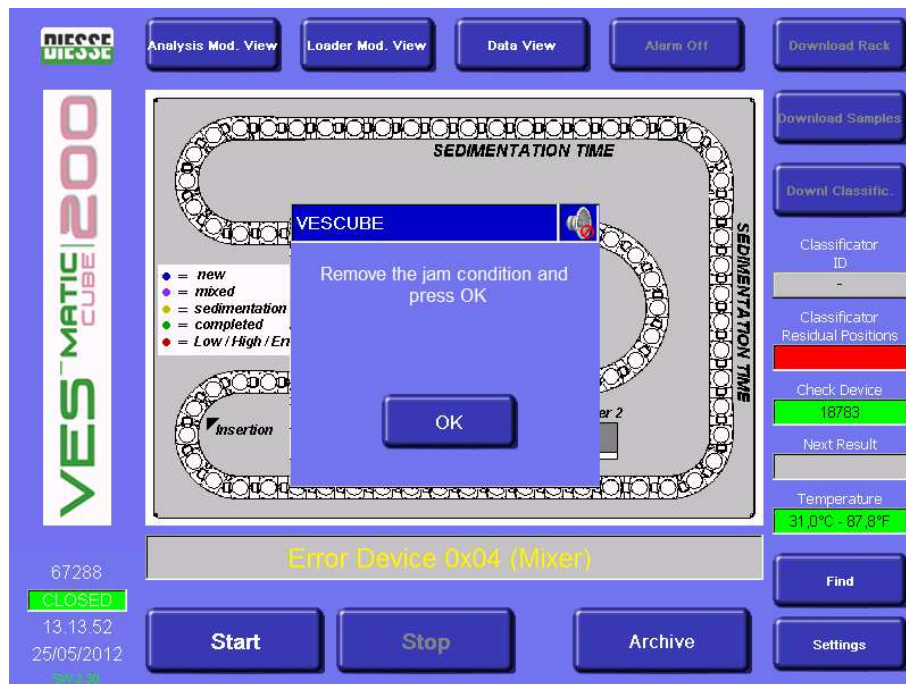


Fig. 3.2.h

In the information bar the group in which has been originated the jam in the chain is indicated.

The operator shall access the module, removing the covering panels, recover the jam, replace the panels and press OK.

In case of jamming in a device other than the moving chain, the following message will be shown on the display:

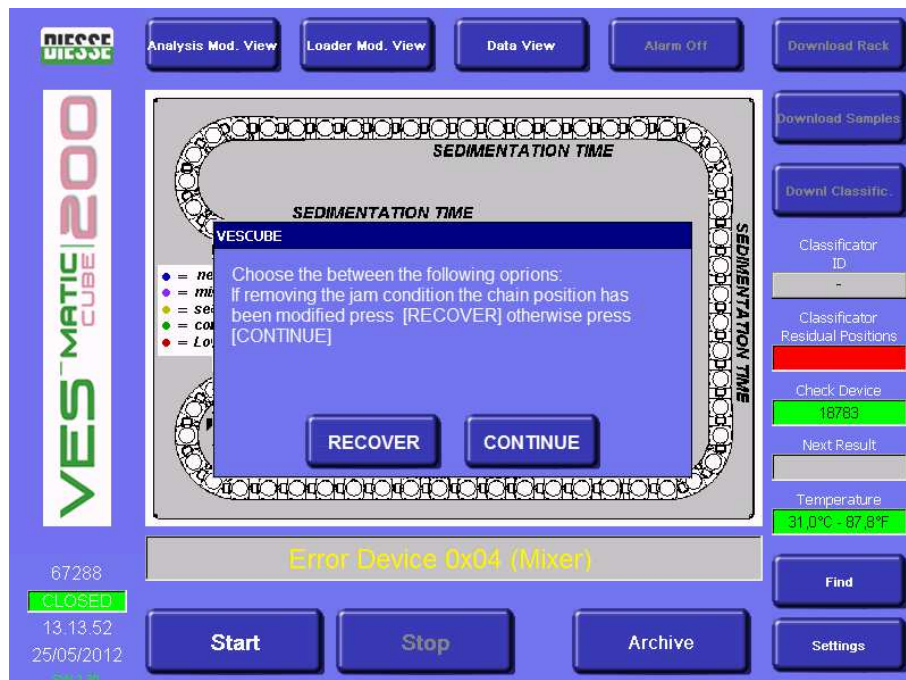


Fig. 3.2.i

The operator can choose either to start the recovery procedure or to continue the analysis in case if the operator did not need to manually move the chain in order to resolve the blocking of the chain or the previous positions were not altered.



- Press **RECOVER** if the operator needs to manually move the chain in order to resolve the blocking of the chain. The operator is then asked to perform one of the operations described in point g.
- Press **CONTINUE** to restart the test without performing a reference search cycle if the operator did not need to manually move the chain in order to resolve the blocking of the chain or the previous positions were not altered.

If the error pertains to the movement of the chain, the operator is asked to make one of the following choices:

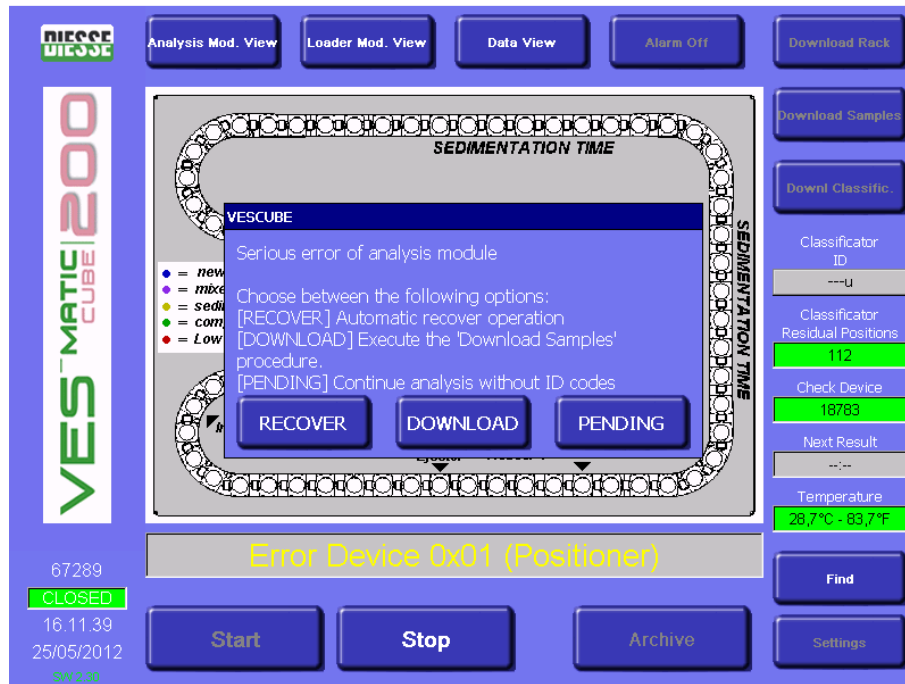


Fig. 3.2.I



- **Recover** the sample position and internal codes for the chain: perform the reference search sequence. The chain's updated state is compared with the previous state, reassigning the codes and informing the user of any changes. This function is disabled if there are no sample tube codes inside the chain.
- **Unload samples** in the chain: perform the reference search sequence. If a sample tube without cap, besides that of the reference sample tube, is present at the end of the unloading cycle, the error is displayed which informs the operator to manually extract the sample tube.
- **Pending:** Insertion of samples in the chain in the **Pending** tables: perform the reference search sequence. All the sample tubes currently in the chain will be retested without recovery of the codes which will then be inserted manually by the user into the pending database.

At the end of the recovery procedure, the software will automatically confirm the arrangement of the samples in the chain if does not detect any variation with respect to the previous one.

At the end of the recovery procedure, if the software detects variations in the arrangement of the samples, will ask the operator for a confirmation for every tube added (Fig.3.2.m) or removed (Fig.3.2.n) from the chain.

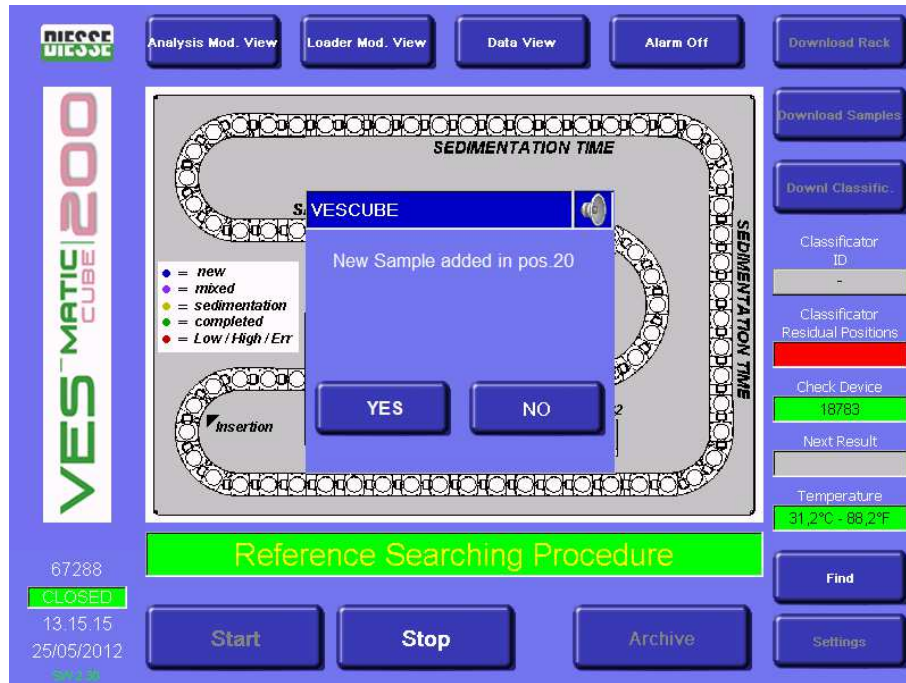


Fig. 3.2.m

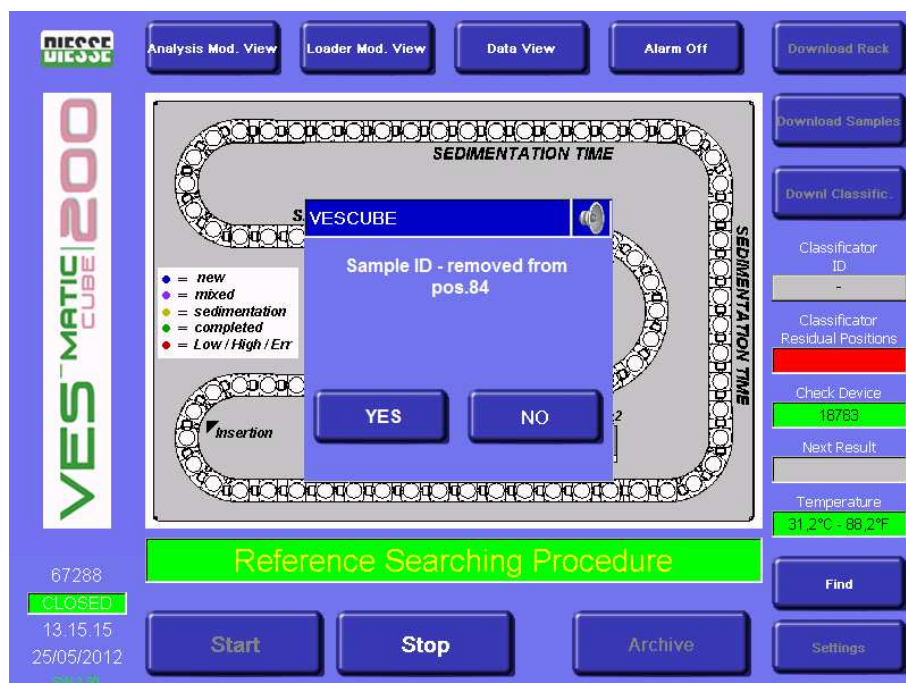


Fig. 3.2.n

The operator can choose to validate the change and continue (YES button) or to stop (NO button).

Blockage error during a movement outside the analysis cycle. Any samples in the chain will be cancelled.

Example: Blockage during a movement made from the user menu.

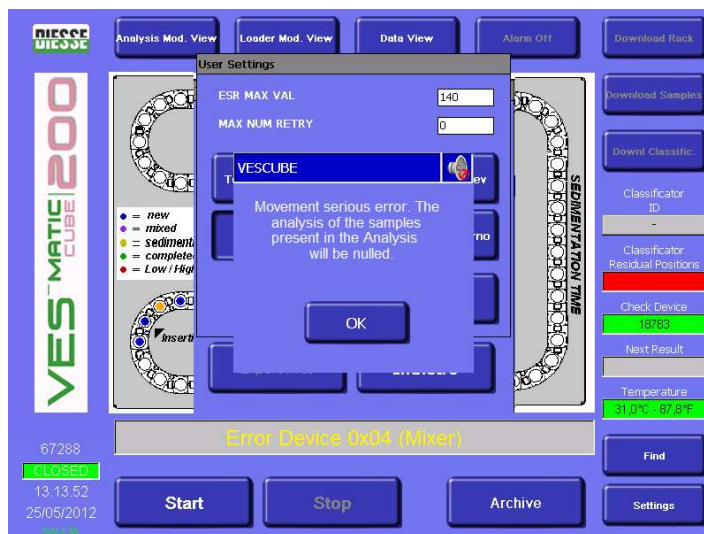


Fig. 3.2.o

Example: Conflict error of a device involved in the movement of the chain.

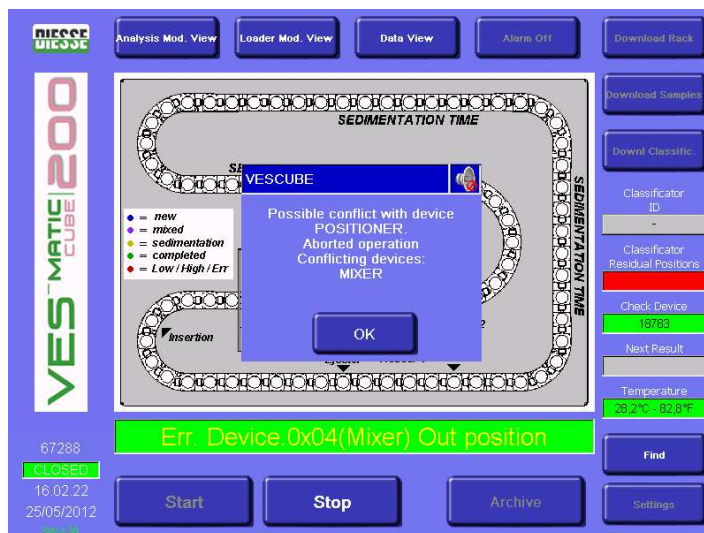


Fig. 3.2.p

Example: Sample tube without cap error detected during the sample unloading procedure, to remove it manually.

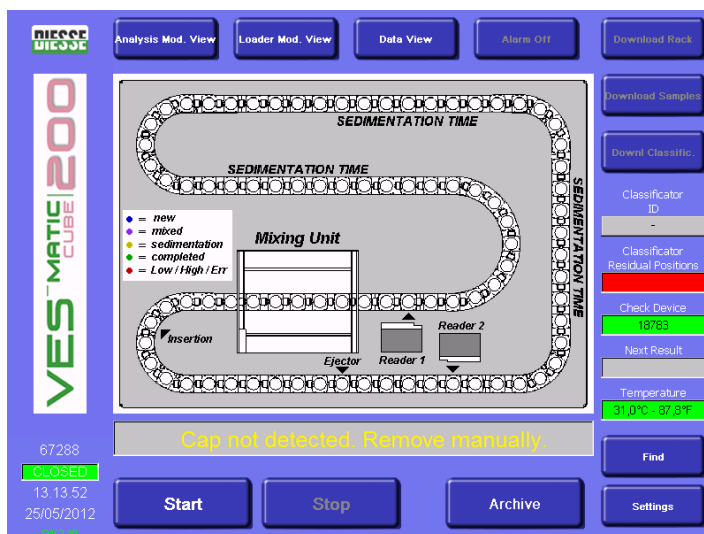


Fig. 3.2.q

3.2.2. ARCHIVE MENU

Choosing the **ARCHIVE** command in the main menu, the functions of the ARCHIVE Menu are accessed (Fig.3.2.h).

Historical DB: allows access to the historical archive of the samples present in the database.

Pending DB: allows access to the archive of the pending samples present in the database. The pending samples are those that are not yet sent to the Host or any way are not save in the historical archive.

Quality Check DB: allows access to the historical archive of the Quality check samples present in the database.

Back: returns to the Main Menu.

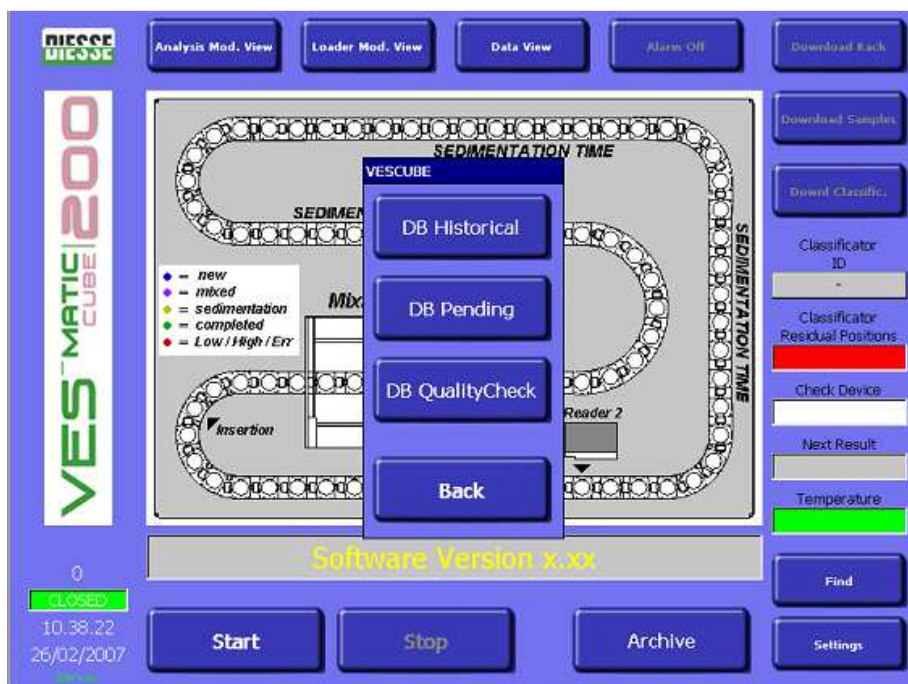


Fig.3.2.h

DATABASE (ARCHIVE)

The **historical database** (Fig.3.2.i) stores up to a maximum of 10.000 samples managed in a circular mode. In it will save only those samples for which the Host computer, or the operator, will have authorized the analysis. Only for these it will be possible to see, print and send the results to the Host. Only for these results will the check device counter be diminished. In the display page of this database the results sent to the Host will be highlighted with an asterisk (Fig. 3.2.1).

The **Pendings database** (Fig. 3.2.j) stores:

1. The samples already processed that have not yet received authorization from the Host to execute their analysis (and as such defined "pending"). The results of these samples cannot be displayed. The presence of a sample in this database is limited to 72 hours (the date/time field of the sample itself is considered as the beginning) (Fig.3.2.1), after which all information about the sample will be removed. The instrument, during the stand-by period, will try to communicate to the Host to know which pending samples have to be saved and rendered available to the operator and which ones have to be removed. The operator can force the authorization for one or more sample manually; he can in fact select the sample and push "Send to host". This forcing maneuver

determines the passing of the data regarding the sample to the host, the move of them from the pending archive to the historical archive and the decrease of the test counter of the check device.

2. Samples with barcodes that are impossible to read will also be inserted into this archive; in this case the operator has to open the Pendings archive to insert the missing codes (this can be done with the external barcode reader or manually with the virtual Windows CE keyboard). In this way the instrument will be able to ask authorization to the Host also for these samples.

If the instrument works without a host connection in this archive the samples will be present of which it has not been possible to read the bar code. Opening the pendings archive, for these samples the position in the sample holder rack and the result of the ESR will be displayed. The relative missing codes have to be inserted by the operator using the external barcode reader or manually with the virtual windows CE keyboard, as indicated in the paragraph “Description of the commands and the information in the pending archive mode”.

The **Quality Check database** (Fig. 3.2.k) contains the historic data regarding the results of the “ESR Control” samples; this database has a autonomic management regarding the other archives.

3.2.2.1 DESCRIPTION OF THE COMMANDS AND INFORMATION IN HISTORICAL ARCHIVE MODE

Fig.3.2.i

Show all (List all): all samples present in the historical archive of the database are listed.

FIND: equals an “enter”, has the function of sample search based on the code number, to be edited in the homonymous field

FIND: equals an “enter”, has the function of sample search based on the date, to be edited in the homonymous field **From [dd/mm/yy] to [dd/mm/yy]:** the automatic presence of the current day facilitates the search of samples analyzed in that day. To search for samples analyzed in other days it

is necessary to insert in the corresponding range in which one wants to execute the search, or us the code search field.

Select all: immediate selection of all present samples.

De-select all: immediate de-selection of all samples present.

Send to Host: send to Host the sample(s) selected.

Eliminate: eliminate the selected sample(s).

Print: print the list of the samples that are selected by means of the check box.

Arrow UP: executes a multiple selection of samples scrolling the list up the list.

Arrow Down: executes a multiple selection of samples scrolling down the list.

Exit: returns to the main menu.

In addition to the buttons described in the previous paragraph, there is additional information available:

Number of records in the archive: total number of samples present in the historical archive of the database.

Number of records in the list: number of samples present in the list that is displayed.

Error legend: interpretation of the letters indicated in an error code.

Furthermore the following is also visible on the display screen:

Code: code of the sample and relative check box to allow the selection of that sample.

Host: if an [*] is present near the alphanumeric identification code of the sample, this means the sample is already sent to the Host.

Date: execution date analysis.

Time: execution time analysis.

ESR: Result of the ESR.

Errors: Error codes

Rack ID: identification of the sample holder rack.

R Pos: position of the sample in the sample holder rack (identified by an alphanumeric code).

3.2.2.2 DESCRIPTION OF THE COMMANDS AND THE INFORMATION IN PENDING ARCHIVE MODE

The samples defined as "**PENDING**" refer to all those results that have not been downloaded to the Host computer (for example; because of temporary absence of connection) or that are not present in the Historical Archive.



ATTENTION!

1. As a reminder, a **PENDING** sample, if the instrument is connected to a Host, does not display the **ESR** results!
2. Every time the Ves-Matic Cube 200 sends a result to the Host and/or the historical archive the counter of the executable test is decreased (visible on the Check Device window in the View Analysis Mod. and the View Loader Mod.)

Fig.3.2.i

Show all (List all): lists all samples present in the Pending archive of the DataBase.

Find: search function of samples based on code or date.

Select all: immediate selection of all present samples.

De-select all: immediate de-selection of all present samples.

Update code: allows the input of a bar code by means of the WindowsCE keyboard, in case it is not read automatically by the instrument, the keyboard will appear automatically inserting the desired barcode into the field above this command.

Read barcode: allows the input of a bar code by means of the external barcode reader, in case it is not read by the reader inside the instrument

Send to Host: sends the sample(s), selected by means of the checkbox, to the Host.

Eliminate: eliminates the sample(s) selected.

Arrow Up: executes a multiple selection of samples scrolling the list up the list.

Arrow Down: executes a multiple selection of samples scrolling down the list.

Exit: returns to the main menu.

In addition to the buttons described in the previous paragraph, the following information is presented:

Number of records in the archive: total number of samples present in the Pending archive of the database.

Number of records in the list: number of samples present in the list that is displayed.

Error legend: interpretation of the letters indicated in an error code.

Furthermore the following is also visible on the display screen:

Code: code of the sample.

Date: execution date analysis.

Time: execution time analysis.

Rack ID: identification of the sample holder rack.

R Pos: position in the sample holder rack (identified by a alphanumeric code).

3.2.2.3 DESCRIPTION OF THE COMMANDS AND INFORMATION IN QUALITY CHECK ARCHIVE MODE



ATTENTION: As a reminder, a **quality** sample is managed in a different manner.

Fig.3.2.k

Show All (List all): lists all samples present in the database of the Quality check archive.

Find: search function of samples based on code or date.

Select all: immediate selection of all present samples.

De-select all: immediate de-selection of all present samples.

Send to Host: sends the selected sample(s) to the Host.

Eliminate: eliminates the sample(s) selected.

Print: print the list of the samples that are selected by means of the check box.

Export DB QC: allows to export the Database of the QC archive in text format.

Arrow Up: executes multiple selections of samples by scrolling the list up the list.

Arrow Down: executes multiple selection of samples by scrolling down the list.

Exit: returns to the main menu.

In addition to the buttons described in the previous paragraph, the following information is presented.

Number of records in the archive: total number of samples present in the quality archive of the database.

Number of records in the list: total number of samples present in the list that is displayed.

Error legend: interpretation of the letters indicated in an error code.

Furthermore the following is also visible on the display screen:

Code: code of the sample.

Host: if an [*] is present near the alphanumeric identification code of the sample, this means the sample is already sent to the Host.

Date: execution date analysis.

Time: execution time analysis.

ESR: ESR result.

Errors: error code.

Rack ID: identification of the sample holder rack.

R Pos: position in the sample holder rack (identified by a alphanumeric code).

Lot num: the lot number of the QC sample.

Exp date: expiring date of the QC sample.

Val Min: the minimum value obtainable with the QC sample.

Val Max: the maximum value obtainable with the QC sample.

3.2.3. SETUP MENU

Description of the commands and information of the Setup menu

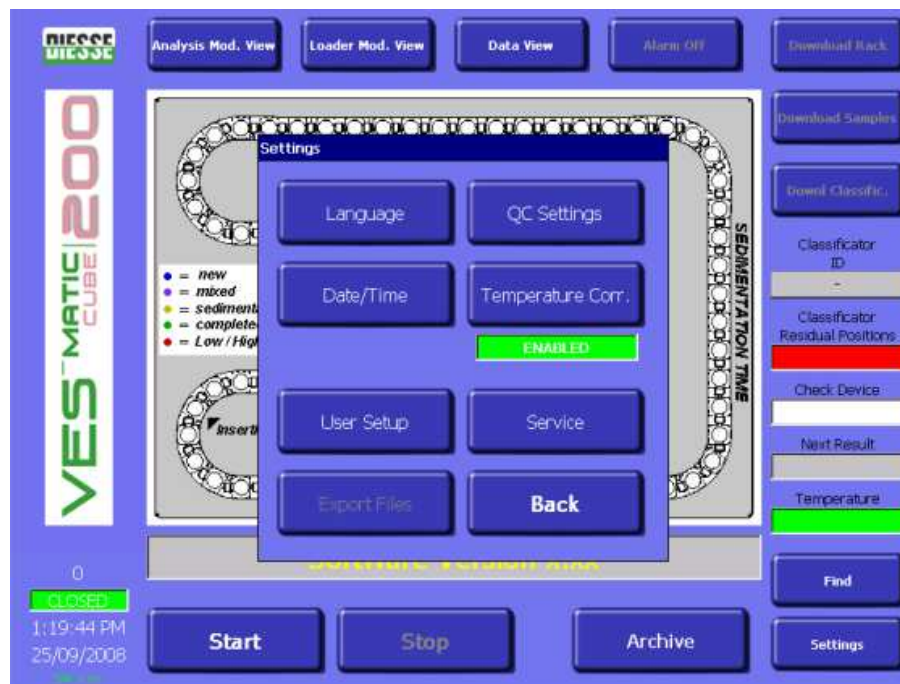


Fig.3.2.l

This function allows to access some update and service procedures (Fig.3.2.l):

Language, Qc Setting, SW Update, Date/time, Temperature Corr., User Setup, Service, Export Files.

3.2.3.1 LANGUAGE

Allows for language selection; this command will cause the **Select language** (fig 3.2.m) window to appear (Fig. 3.2.m). To set the selected language in the instrument, press the corresponding button on the display.

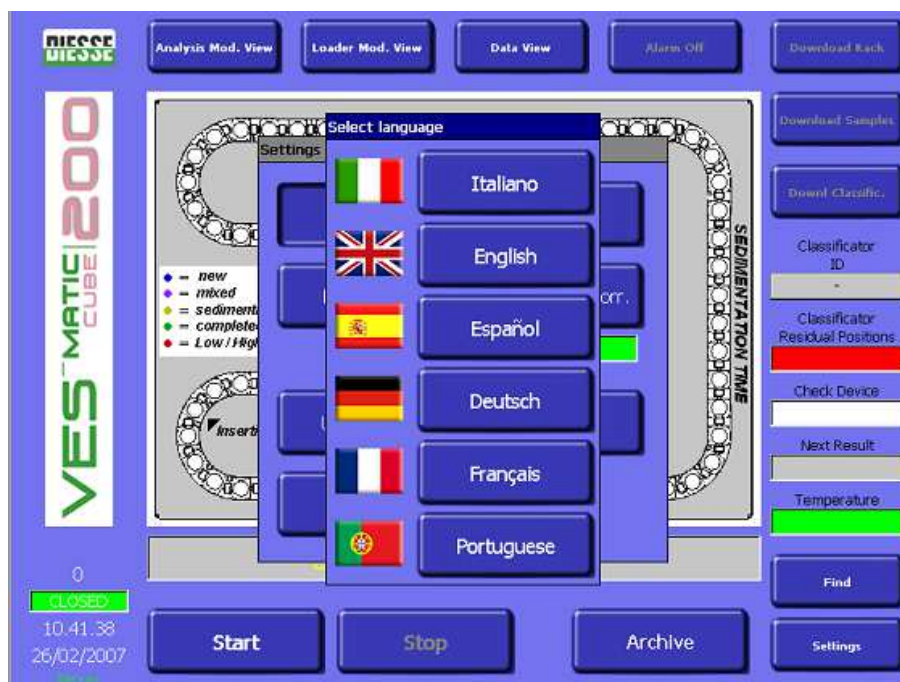


Fig.3.2.m

3.2.3.2 QC SETTINGS (QUALITY CONTROL)

Fig.3.2.n

The quality control settings window allows the set-up of all parameters for the QC samples, so that the Ves-Matic Cube 200 can recognize them and store them separated from the normal samples.

To enter the data for the batch of ESR Control in use, just scan the label barcode applied to the bottle: all the fields on the page will be automatically filled in. The data can also be entered manually by pressing on the various white fields (a virtual keyboard pops up).

EXPLANATION OF THE SECTIONS:

Normal level: area reserved for the QC parameters for a normal ESR value (refer to the technical instructions supplied with the control sample).

Abnormal level: area reserved for the QC parameters for abnormal/pathological ESR value (refer to the technical instructions supplied with the control sample).

EXPLANATION OF THE FIELDS:

Bar code: insert bar code present on the test tube(s) of the QC sample(s).

Lot num: insert the lot number of the QC sample, traceable on the package.

Expiration date: insert expiring date of the QC sample, traceable on the package.

Val.Min: insert the minimum value obtainable with the QC sample, traceable in the technical instructions.

Val.Max: insert the maximum value obtainable with the QC sample, traceable in the technical instructions.

COMMANDS in the Quality Control setup window:

Confirm: saves the data inserted or modified

Back: returns to the main menu (that is "SET UP").

3.2.3.3 DATE/TIME

It allows to select the format of the date and to set Date and Time of the system. Pressing this button the **Set Date/Time** window (Fig.3.2.o) will appear.

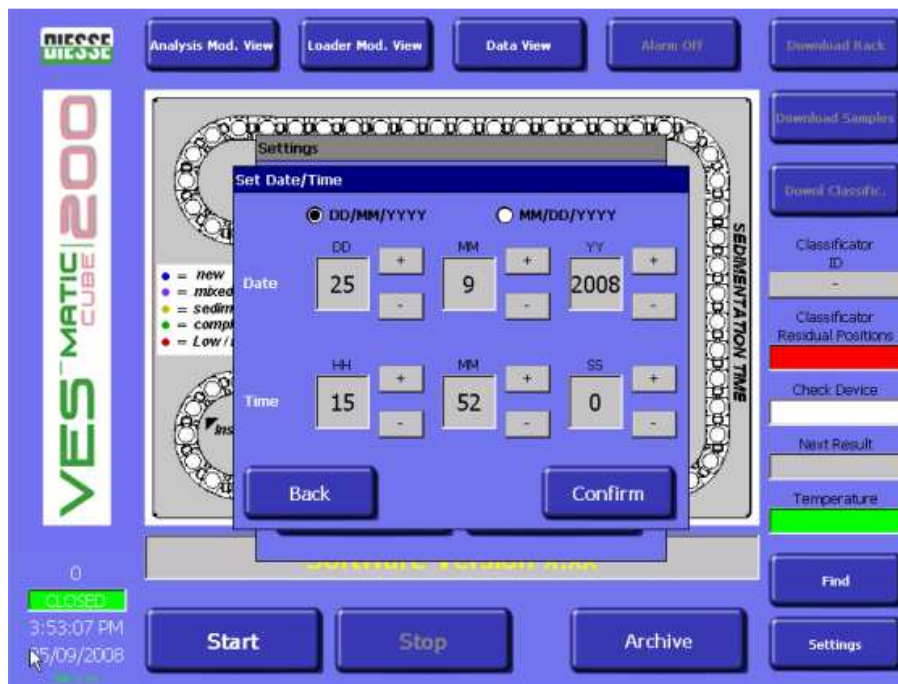


Fig.3.2.o

EXPLANATION OF EACH SECTION:

Date:

Set up date format:

DD/MM/YYYY: format with day/month/year

MM/DD/YYYY: format with month/day/year

To complete the Data format selection confirm the operation with the appropriate “Confirm” button, return to “Analysis Mod View”, turn general switch of the instrument Off and On. After this operation the date will be displayed in the selected format.

EXPLANATION OF THE FIELDS:

Setup of the Date:

DD: set up the day, using the buttons + and –

MM: setup the month using the buttons + and –

YYYY: setup the year using the buttons + and –

Setup of the Time:

HH: set the hour of the day using the buttons + and –

MM: set the minutes using the buttons + and –

SS: set the seconds using the buttons + and –

COMMANDS of the Setup Date/Time window:

Confirm: saves the data inserted or modified.

Back: returns to the main menu (that is “SET UP”).

3.2.3.4 TEMPERATURE CORRECTION

Temperature corr: allows the activation/deactivation of the automatic correction of the results in function of the temperature (when the automatic correction of the temperature is activated the relative window is coloured green and displays the writing ‘ACTIVE’, when it is deactivated the window is red and shows the writing ‘DEACTIVATED’).

3.2.3.5 USER SETTINGS

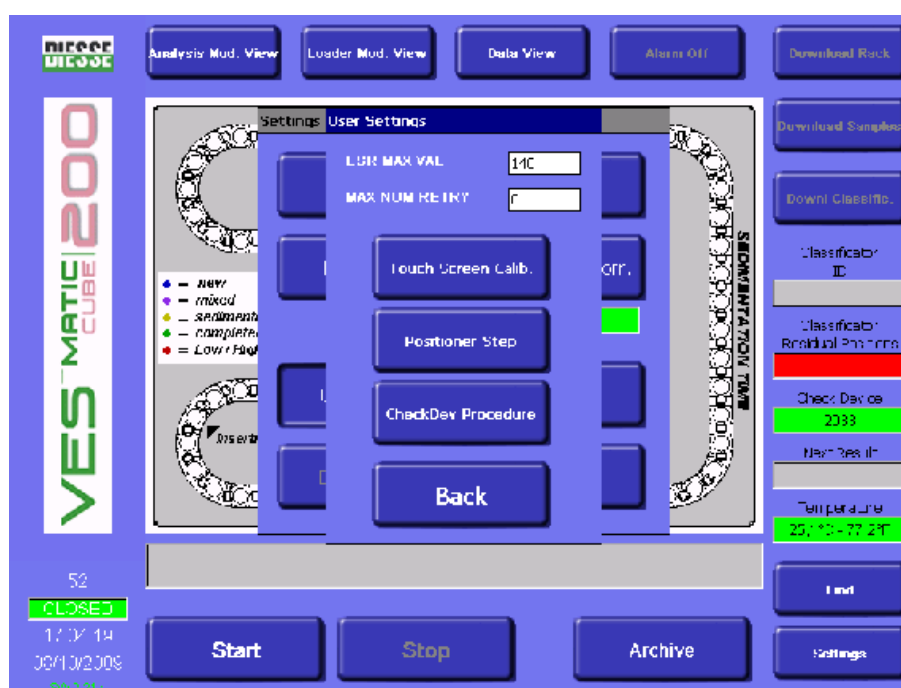


Fig.3.2.p

DESCRIPTION OF THE FIELDS:

ESR MAX VAL: this field allows the user, based on specific needs, to set up the ESR value (“ESR MAX VAL”) beyond which one desires to repeat a new analytic cycle (“RETRY”). All samples with ESR results higher than the inserted value, will be automatically exposed to a new analytic cycle.

MAX NUM RETRY: This field allows to set the number of repetitions of the analytic cycle (“MAX NUM RETRY”) regarding those samples which ESR is higher than the set value; the maximum number of repetitions allows for each sample is three.

DESCRIPTION OF THE COMMANDS:

Touch screen calibration: the pressure of this button allows to adjust, temporarily, the calibration of the tabled PC. The procedure to follow is guided and at the end of it the new “User settings” will appear. The obtained calibration is only temporary, in fact it will be lost at the switch off with the general switch.

Positioner step: this command, which should be used by expert operators only, allows to retrieve quickly a test tube from the analytical chain. After opening the front panel of the instrument and

inserting the appropriate microswitch key to avoid its complete stop, it is possible to determine, pressing several times this button, the advancement of the desired test tube up to the point in which manual access for the removal of it is allowed.

CheckDev Procedure : This button allows you to initiate the recharge of the check device (see section 3.3)

Back: returns to the MAIN menu (that is “SET UP”).

3.2.3.6 EXPORT FILES AND SERVICE BUTTONS

Export Files: the pressing of this button allows to copy the following files on the SD card: COUNTERS (INI.File), ERRORLOG (TXT.File), EVENTS (TXT.File), LOG (TXT.File), Vescube (DB.File), Vescube (INI.File). The procedure is the following: insert the SD card in the relative slot, as shown in the figure 3.2.q, the button “Export Files” will activate, illuminating the command in white, then press the button and await the end of operation before removing the SD card.



Fig. 3.2.q

Service: allows the access, by means of a password, to the service menu of the instrument.



Access to this function is only allowed to personnel authorized by DIESSE Diagnostica Senese S.p.A.

Back: returns to the main menu (that is “Setup”).

3.3. CHECK DEVICE

The "check device" is an electronic device that allows the instrument to have a defined number of executable tests available. For every result the check device will automatically undergo a decrease of the number of available tests. Once the load of tests is exhausted, it is necessary to reload the instrument using the special "Check Device Transponder RF" tube (Fig.3.3.a) (see paragraph 1.3). The check device has the dimensions and appearance of a normal hemocrome test tube.



Fig. 3.3.a "Check Device Transponder RF" tube

To perform the recharging of the Check Device it is necessary to remove the front cover panel (paragraph 6.2.1); the charging device is located beside the left side panel (Fig.3.3.b). The new "Check Device Transponder RF" tube must be inserted completely with the cap-first (directed inside) (Fig.3.3.c).



Fig.3.3.b



Fig.3.3.c

After placing the "Check Device Transponder RF" tube in the slot, in the user settings **CheckDev Procedure** should be chosen (Fig 3.2.p). After the delay of few seconds a message will appear in the dialog bar: "Refill check device executed" if the outcome of the recharge is positive; "Error in refill check device " in case of a negative result (in this case it is advised that the operator retrieves the "Check Device Transponder RF" tube and repeats the operation from the beginning).

At the end of the procedure the "Check Device Transponder RF" tube is empty and cannot be reused. It should be retrieved from the slot and disposed in accordance with current legislation.

Functioning of the check device:

1. When the result of a sample is saved on the historical database, and possibly printed, the counter of the check device is decreased.
2. In case the instrument works without a Host connection all results are saved on the historical database, printed, displayed and for each one the counter of the check device is decreased. The results regarding samples with a not readable bar code are saved in the pendings archive (see Pendings Archive in 3.2.2).
3. If the instrument is configured to work connected to a Host, only the samples for which the Host computer has requested the analysis will be analysed, then the results printed, displayed, saved on the historical archive and sent to the Host and, consequently, the counter of the check device is decreased. All others will not be analyzed.
4. In case of a temporary absence of a Host connection, the instruments proceeds as follows:
 - a. The test tubes will all be processed and the data saved temporarily (72 hours) in the so called Pendings database. The data of these test tubes are all displayed, except the analytic result.
 - b. In the moment of the positioning of the tube in the sample holder rack only the bar code and the position of the tube in the sample holder rack will be printed, the result of the analysis will not be printed.
 - c. At the end of the analytical cycle the instrument, with regular intervals and for a maximum of 72 hours, will continue to interview the Host to know which pending samples already analyzed were actually requested.
 - d. The results regarding the tubes requested by the Host are transferred and saved in the historical archive and sent to the Host. The counter of the check device will be decreased in consequence. The results of the samples not requested by the Host will be removed from the Pendings Database.
 - e. If it is not possible to re-activate the connection with the Host, the operator can enter in the Pendings archive and manually force the acceptance of one or more samples, the data of which have to be printed right away, sent to the Host (possible) and saved in the historical archive.
 - f. After a stay of 72 hours in the Pendings archive the data of the test tubes will be removed.
 - g. If, caused by the missed connection to the Host, the instrument is not able to send the results of the accepted test tubes, they are copied and memorized in the historical archive. The instrument will try cyclically to send them to the Host for 72 hours, after which the data are only available in the historical archive.
 - h. The operator can execute the re-send to the Host of the data of one or more samples present in the historical database. In this case the instrument will try cyclically to sent the data of those samples to the Host for an maximum of 72 hours.
5. In case the number of executable tests finishes during the analytic activity the instrument will save, for 72 hours and in a virtual archive, all data regarding the analyzed samples (up to a maximum of 3.000 data), the relative results will not be displayed until the test counter will be reloaded. This temporary saving (72 hours) allows to finish the analytic activity, to not lose the data regarding the analyzed samples and thus to not have to repeat them. Contemporaneously the laboratory will have sufficient time to provide for a new transponder to reload the test counter. The number of the tests available in the instrument is indicated in the dedicated window (Fig. 3.2.b), and furthermore its colour informs the user of the remaining availability of the tests; in fact the green colour indicates the possibility to execute more than 1000 tests, orange indicates that the number of

available tests is between 1000 and 500, the yellow colour indicates that the tests available are less than 500, while the colour red indicates the number of executable tests is exhausted.

3.4. GUIDED READING OF THE RESULTS PRINT

The Ves-Matic Cube 200 prints the results regarding each sample in real time.

The print including its header of the results regarding the 112 samples present in a sample holder rack (classifier) is obtained in two cases:

- 1) when the sample holder rack (classifier) is complete. In this case the instrument will slide the sample holder rack automatically until the exit, positioned at the lower left side of the instrument (Fig. 2.2.2), from this position it is possible to extract the sample holder rack completely. At the same time the printer will complete the print of the results of the samples present in that sample holder rack that will appear as described in Fig. 3.4.a and 3.4.b.
- 2) when at the end of the day the analytical routine has finished and after having pressed the "Stop" button, to not lose the data regarding the analyzed samples. In this case the sequence of operations is the following: pressing of the "Stop" button, activation and pressing of the "Unload sample holder" which allows to slide the sample holder rack to the exit and to have the print of the results regarding the samples contained in that sample holder rack, which will appear as described in fig. 3.4.a.

In both cases a header will appear where can be read in to this order: the name of DIESSE, the name of the instrument, the release of the software (V. X.xx), the writing "EDTA" for results expressed in Westergren EDTA/1h units or no specification for results expressed in Westergren citrate/1h units (see fig. 3.4.a and 3.4.b) depending on the set up selected in the laboratory at the moment of the installation (see paragraph **Errore. L'origine riferimento non è stata trovata.**), the serial number of the instrument (SN), the temperature detected inside the instrument (in °C – °F), the correction of the temperature (active = 'ON', not active = 'OFF'), the date (DD/MM/YYYY or MM/DD/YYYY, see paragraph **Errore. L'origine riferimento non è stata trovata.**) and the time (HH/MM/SS) of the execution of the analyses, the barcodes, the corresponding ESR value and the position of the sample in the sample holder rack (classifier) identified by a alphanumeric code (POS NUM). At the end of the list of samples and their relative data (there are maximum 112 samples) the barcode of the sample holder (COD SAMPLE HOLDER) will appear. If the samples contained in that sample holder are less than 112 (the case in point 2 of this paragraph) only the number of samples contained in the rack and there data will be reported.

When a control sample is used (see paragraph 3.2), the following writings will appear (fig. 3.4.a) in the printed results: QC PASS xx/xx, N. Lot xxxx, Expiring date DD/MM/YY, xxxxxxxx (QC barcode) the ESR value read for that control sample and its position in the sample holder rack. To evaluate the obtained result refer to the technical instructions supplied with the control sample.

DIESSE S. p. A

VES MATIC CUBE 200 V. 2.21

SN: 2007- 01- 00XX

TEMPERATURE : XX°C – XX°F

TEMPERATURE CORRECTION : ON

DATE : DD/MM/YYYY (MM/DD/YYYY)

TIME : HH/MM/SS

ID	WEST	POS
BarCode	1H	NUM
QC PASS	1/12	
N. Lotto xxxxx	Scadenza :	DD/MM/YYYY
QC ID Bar Code	5	C1
QC PASS	38/64	
N. Lotto xxxxx	Scadenza :	DD/MM/YYYY
QC ID Bar Code	45	B8
53435661	57	B7
90087006	6	B6
99887788	43	B5
65432211	9	B4
65443297	17	B3
43325544	HIGH	B2
76554888	29	B1
65334567	LOW	A8
53435661	55	A7
90087006	5	A6
99887788	ERR	A5
65432211	10	A4
.....	19	A3
44332255	14	A2
53435543	43*	A1

COD. PORTACAMPIONI : 1234

Fig.3.4.a

When in the column "ID BarCode" a sequence of points appears, this means that the internal barcode reader did not read that code, but that the sample, of which the position is indicated in the respective sample holder rack, was analyzed anyway (in the example of fig. 3.4.a, in B1 the result is displayed because there is no Host connection active, in case of an active Host connection, see description in 3.2.2 "Archive Menu"); the data regarding this sample are stored in the Pending Archive. At this point the operator can continue as described in 3.2.2 "Archive Menu: Historic DB and Pending Archive DB."

In the column "WEST 1H" the following messages can be present:

"ERR": means that the instrument has not been able to reveal any "characteristic point" useful for the readings, thus it is advised to observe the sample and, after excluding problems of label, coagulates etc. to repeat the analysis.

"LOW": means that the quality of blood of the sample is insufficient (\leq than 1,5 mL). Verify the level of the sample, in case this is lower than 1,5 mL, repeat blood draw.

"HIGH": means that the quantity of blood of the sample is excessive ($>$ 4 mL). Verify that a space of air exists between the end of the cap and the level of the sample. If the level of the test tube results in fact excessive, remove, after mixing, about 500 μ L of blood and repeat the test.

"xx*": a value of ESR with an asterisk (for example "43*" as in fig. 3.4.a) means that the instrument has read a value, but advises the operator that the state of the sample does not correspond to what is specified in 4.2.2 (figure 4.2.2.a, 4.2.2.b, 4.2.2.c). The operator is advised to verify the sample to exclude problems with labels, coagulates etc. and to decide whether to validate the obtained result or to repeat the analyses.

HIGH	
Test tube with sample level to high: above 4,5 mL.	Verify that a space of air exists between the end of the cap and the level of the sample. If the level in the tube is in fact excessive, remove, after mixing, about 500uL of blood and repeat the test.
LOW	
Test tube with sample level low: under 1,5 mL.	Verify the level of the sample. In case this is under 1,5 mL, repeat the blood draw.

CHAPTER 4

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4.1. GENERIC DESCRIPTION OF AN ANALYTIC CYCLE ESR IN THE VES-MATIC CUBE 200

ESR Erythrocyte sedimentation rate 1h.

Supplies the results in accordance with the Westergren citrate method with reading after an hour; the total duration of the **analysis** of the first sample is of **24-26** minutes (24' for the models Sysmex, Advia Bayer and ABX, 26' for the model Beckman Coulter), after that the result exit with a cadence of **19 seconds**.

Description of the test cycle:

- At the beginning of the analysis the unit executes a recognition round of the upper part (fig. 4.1.a) where the racks are inserted with the test tubes coming from the CBC test and at the same time executes the reading of the identification code of each sample. Insert the samples in the rack so that the bar code is presented to the internal bar code reader, as shown in fig. 4.1 b, c, d, e. (Attention: at the moment of the insertion of the samples in the rack check that the label present on each test tube corresponds to the specification described in 4.2.2, to reduce the possibility of mechanical or opto-electronic obstructions).



Fig. 4.1 a



Fig. 4.1 b

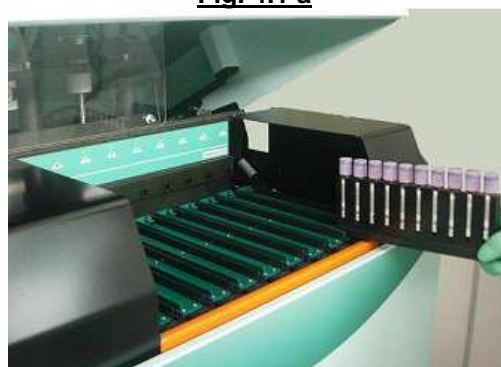


Fig. 4.1 c



Fig. 4.1 d



Fig. 4.1 e

- At this point for each sample a 'Host query' is executed (if an connection with a Host is active), to recognize if for the identified sample is also requested the execution of the ESR.
- After the recognition of the sample codes, the racks are translated into the zone of the withdrawal clamp that will extract only the test tubes selected for ESR from every rack, ignoring the ones for which no ESR test is requested. The samples for ESR are inserted one by one in the underlying chain of the analysis module and translated, with a step time of 19", to the mixing zone. Entered in the mixing zone, 5 mails long, every sample is rotated by 150° for 3 times every step, for a total of 15 inversions.
- At the exit from the shaking zone, the instrument will execute the first reading for the determination of the total blood level.
- Every test tube is then translated with a step time of 19" until the second sensor (employing for this route a global time of 20').
- The instrument then executes a second reading, for the determination of the level of the red blood cells, after the sedimentation, all data is processed and the results are referred the ESR in Westergren citrate units.
- The analyzed test tubes are removed one by one from the chain, by means of an expulsion system and positioned in a sample holder rack in positions identified by the alphanumeric coordinates.



ATTENTION! Before inserting a new rack containing samples to be processed, carefully read the specification on the yellow label present on the left front part of the loader module (figure 3.2 bis).

4.2. DETAILED DESCRIPTION

4.2.1. INITIAL POWER UP

After the installation of the instrument as indicated in chapter 2 , assure that the window is closed and change the power switch, situated on the left of the power cable on the back of the instrument, into the ON position « I ».



It is reminded that it is **absolutely forbidden** to translate the rack lodging area manually



At the first power up, to verify the status of the instrument and the efficiency of the Optical Reading Group, to the following is advised to introduce the blood of the Normal ESR control and the blood of the Abnormal ESR control in two test tubes that are normally used in the haemachrome laboratory, position them in the racks and start an analytic cycle. At the end of the test verify that the results obtained correspond to the expected values (refer to what is written in the technical instructions supplied with the ESR Control package).

Quality control test

The performance of the Ves-Matic Cube 200 instrument is verifiable at any moment using the ESR control.

The ESR control is constituted of a stable material that allows the determination of the precision of the Ves-Matic Cube 200 and of the total Ves-Matic line for measurement of the erythrocyte sedimentation rate.

The expected values, different per type of instrument, are reported in the information leaflet inside the packaging of the ESR control (see paragraph 1.3.).



For the conservation, the preparation and the modality of use of the control blood refer to the information leaflet inside the packaging of the control blood.

4.2.2. PREPARATION OF THE SAMPLE

No special preparation of the test tubes is required, since the Ves-Matic Cube 200 uses the ones coming from another analytical system (CBC exam); it is advised not the less to comply with the norms related by the ICSH, of which we cite the most important ones:

- The blood should be obtained by means of a drawn of the maximum duration of 30 seconds and without excessive venous stagnation.
- The blood can be gathered in both vacuum test tubes with EDTA as well as non-vacuum tubes with EDTA. It is reminded that the Ves-Matic Cube 200 uses the test tubes directly from the blood cell counter.
- Mix the blood immediately after the drawing with at least 2 complete inversions of the test tube.

Suitability of the sample

The sample can be considered suitable when:

- the test is executed within 4 hours of the drawing.
- the test is executed on the blood sample conserved at 4° for a maximum period of 24 hours. In this case assure that the sample is reported to room temperature before inserting it into the instrument for the analytic cycle.
- always invert the tube before inserting it into the instrument (ATTENTION: during this operation no clots should be found).



ATTENTION: Verify that the tube is **hermetically** closed.

Filling of the test tube

For a correct execution of the ESR exam by the Ves-Matic Cube 200 instrument, the level of blood in the test tube is fundamental. The instrument itself will verify the correct filling of the tube, measuring the level and comparing it with the preset tolerance values of maximum and minimum level.



In case of excessive (above 4 mL) or insufficient filling (below 1,5 mL) the instrument will print an error message. If the filling is excessive, it signals “HIGH”, if the filling is insufficient it signals “LOW”. In both cases the analysis has to be repeated with a proper quantity of blood. In the results print the same message type will appear.

Check of test tube labelling:

Sample labelling method and compatibility with the number of labels

Ves Matic Cube 200 models are designed to work with a maximum of two labels attached to the same sample tube, but not be overlapping (Fig. 4.2.2.a).

The internal barcode reader, placed inside the Loader Module, is mechanically set to read labels attached to the tube at least 3 mm above the start of bottom roundness (Fig.4.2.2.a ①); Furthermore it is programmed to read barcodes placed at 90° degrees compared to the reading rays, that is the barcode must be placed to cross horizontally the tubes vertical axis (Fig. 4.2.2.a ②). The reader nevertheless can correctly read barcodes sloping (corrected) by $\pm 5^\circ$ (fig. 4.2.2.a ③).

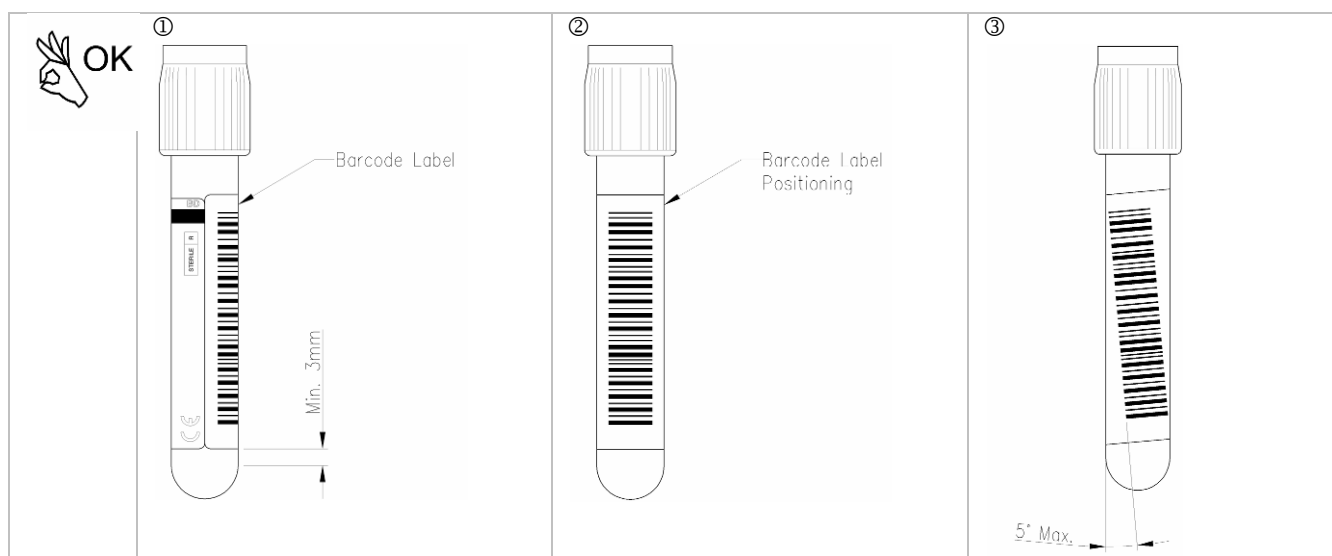


Fig.4.2.2 a Correct height of application label on test tube

The reading group sensors are able to detect correctly the sedimentation rate inside each sample, following the reading axis, reading through a maximum of three layers of paper: Thus are allowed only two labels attached to the tube which must be staggered at least of 90° degrees (Fig.4.2.2 b).

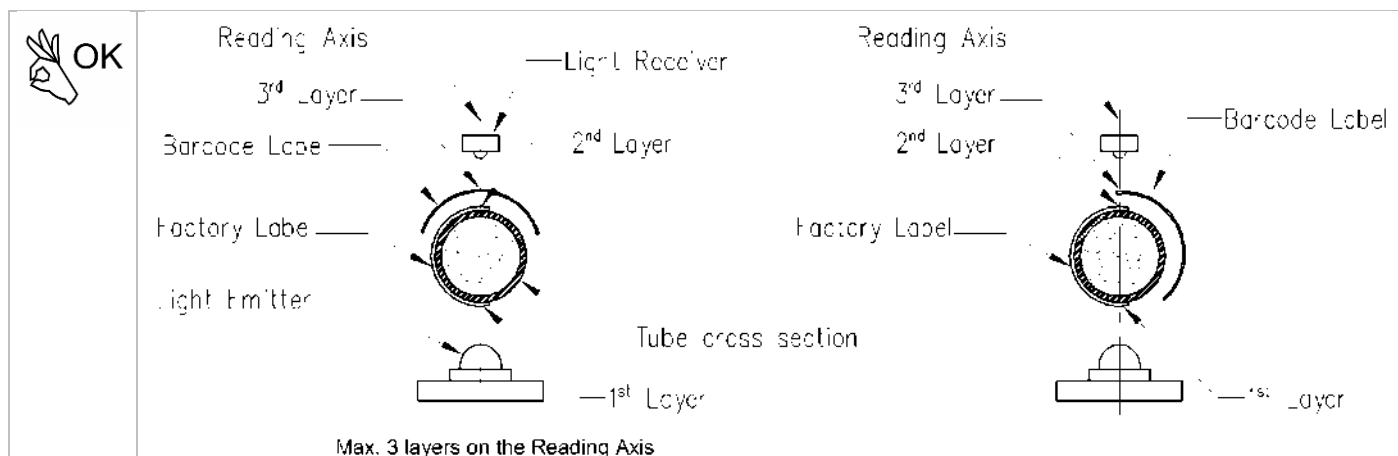


Fig.4.2.2 b Maximum number of label layers attached to test tube and accepted by the Ves Matic Cube 200



It is important to verify, before loading the instrument, that the labels adhere perfectly to the tubes: the adhesive parts, if unattached, could cause frictions during the mechanical movements of the groups (inserter, ejector, sorter), creating inserting and ejecting problems in the analytical chain and possible blocks of the reading sensors.

In fig. 4.2.2c some “INCORRECT” labelling examples are displayed. An incorrect labelling could cause mechanical blocks and/or reading problems to the Opto-Electronic Sensors.

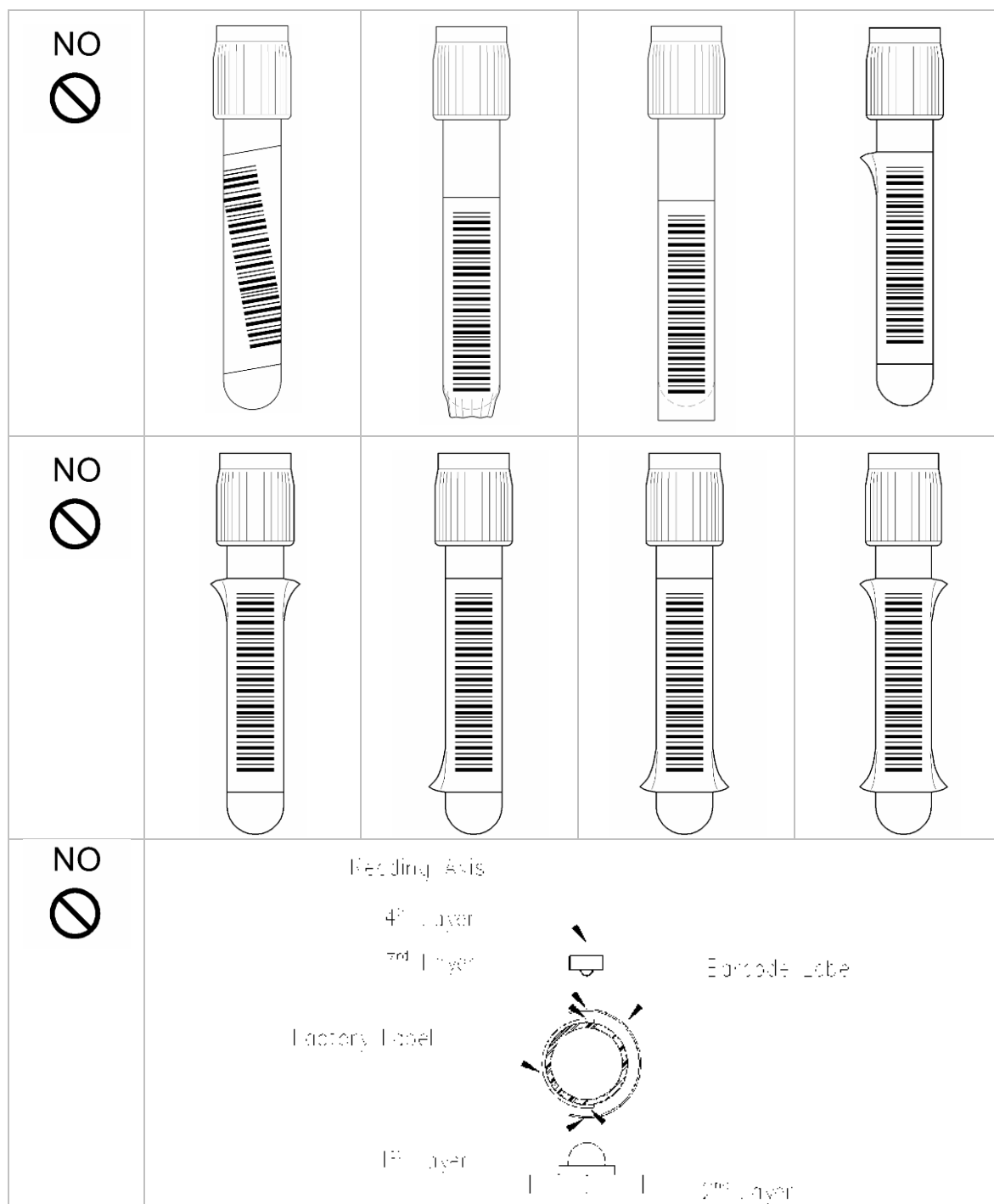


Fig.4.2.2.c Incorrect sample labeling

4.2.3. WARNINGS AND LIMITATIONS



Before starting an analysis procedure assure that in the preparer module the 20 rack holders are inserted correctly: 10 in the front part (the only part accessible of the preparer module (Fig. 4.1a) and 10 in the back part of the same module.

Insert the sample holder racks (or sample holders) for the classification of the analyzed test tubes, on the right side ("R") of the instrument as indicated by the arrow (Fig. 4.2.3.a,c and 4.2.3 c).



Fig. 4.2.3.a

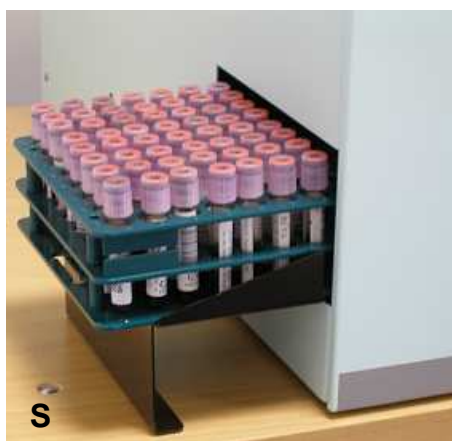


Fig. 4.2.3 b left side



Fig. 4.2.3.c right side

On the left side of the instrument a rack loading extension is present for the exiting sample holder racks, containing the analyzed samples (Fig. 4.2.3.b). The sample holder rack slides from right to left.



- Do not turn off the instrument during the working phases or during the Reset procedure.
- **Powering off** must occur **ONLY AFTER** pressing the **STOP** button on the display, awaiting the end of the movements.



The positions in which manual access by the operator is allowed in the Preparer Module are exclusively the positions 1 to 9 (Fig. 4.2.3 d). The racks in the positions protected by the two lateral black lids and all racks in the back of the instrument should NOT be touched to not falsify the automatic movement and to not alter the positions established by the instrument.

The extraction of the processed racks (in the positions 1-9 of the preparer module) should only be performed when the instrument is stopped and in the following manner:

1. Free the rack from the hook "T" holding it (fig.4.2.3 e and 4.2.3 f).
2. Slide the rack horizontally in the direction of the operator **WITHOUT LIFTING IT** (Fig 4.2.3.g).



ATTENTION

	<p>Before starting an analysis procedure make sure that 20 rack holders are inserted correctly in the preparer module (fig. 4.1.a and 4.2.d). Insert the sample holder rack (for the storage of the processed test tubes) on the right side of the instrument (fig. 4.2.3.c).</p>
	<p>Do not switch off the instrument during the working phases or during the Reset procedure. For the safeguard of the database it is advisable that the turning off occurs EXCLUSIVELY after pushing the STOP button on the display, waiting the completion of the movements.</p>
	<p>The positions in which manual access is allowed by the operator in the preparer module are exclusively the positions from 1 to 9. The rack in the positions protected by the two black lateral covers and all racks on the rear end of the instrument should NOT be touched to not falsify the automatic movements and to not change the placements assigned by the instrument. The extraction of the processed rack (in the positions 1-9 of the preparer module, fig 4.2.3.d) has to occur when the instrument is on halt and in the following way:</p> <ol style="list-style-type: none"> 1. Free the rack from the retaining hook "T" (fig.4.2.3.e and fig. 4.2.3.f) 2. Slide the rack horizontally in the direction of the operator <u>without lifting</u> (fig.4.2.3.g).

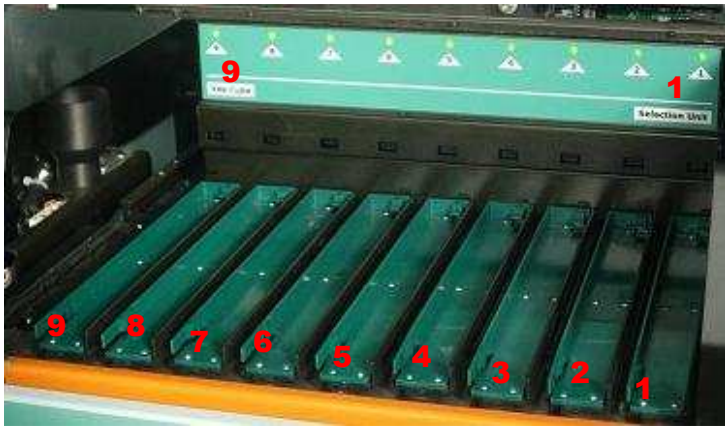


Fig. 4.2.3.d

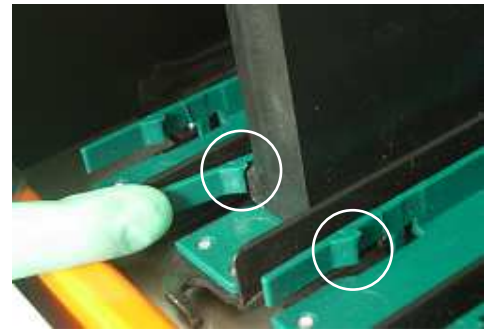


Fig. 4.2.3.e

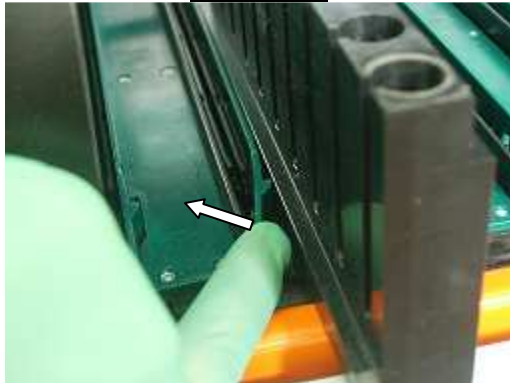


Fig. 4.2.3.f

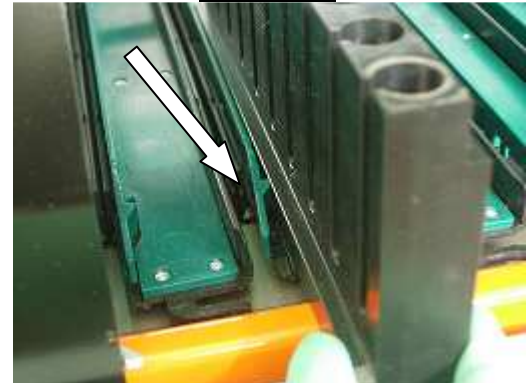


Fig. 4.2.3.g

4.2.4. PREPARATION SEQUENCE FOR A TEST

Loading procedure of the samples:

- Press the START button; wait the execution of the Reset after which raise the window (visible in fig. 4.2.4.a indicated with number 2) lifting it until the upper click.
- Introduce the racks in the appropriate lodgings (visible in fig. 4.2.4.b and fig. 4.2.4.a indicated by number 1) taking care to follow as specified on the label present on the internal left side.
- Insert the sample holder rack and insert the relative bar code (with the external barcode reader or using the virtual Windows CE keyboard pressing the grey button "Classifier ID").

At the end of the loading of the instrument, close the window; the racks will be automatically sent for barcode reading and subsequently to the analytic cycle.



It is possible at any time to open the upper compartment to insert new racks. This will not interrupt the analytic cycle.

To interrupt the analysis, press the STOP button.



Fig. 4.2.4.a



Fig. 4.2.4.b

4.2.5. CONCLUSION OF THE ANALYTICAL CYCLE

An analytic cycle regarding a single sample is finished when:

1. the sample is present and identifiable, by the corresponding alphanumeric coordinates, in the sample holder rack that holds it.
2. the relative result is present in the result print regarding the sample holder rack that holds it.

Every time a sample holder rack is complete, the instrument will complete the print of the results regarding the test tubes of the samples in it; furthermore on the print is indicated the code of the sample holder rack, the date, the time and the temperature at which the analytic cycle is executed, the installed software version and the serial number of the instrument (paragraph 3.4).

4.2.6. CONCLUSION OF THE DAILY ANALYTIC ACTIVITY

At the end of the daily analytic activity and every time one desires to access the archive it is necessary to press the 'Stop' button. This operation allows to make active ('illuminated') the 'Archive' button and at the same time to save all data obtained until that moment.

It is advised to ALWAYS press the 'Stop' button before turning the instrument off (see paragraph 3.2.1 for a description of the function 'Stop' button).

CHAPTER 5

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5.1. GENERAL RECOMMENDATIONS

The Ves-Matic Cube 200 is designed and constructed to request only a minimum maintenance.



For any intervention:

- disconnect the power from the instrument.
- use the individual protection features, expected during the functioning.
- do not remove barriers and do not elude the security devices.



In case of leaking of biological material inside the instrument, of contamination of its external surfaces or of those internal, accessible to the operator, use the expected features for the sanitation and execute as expected in the appropriate instructions described in paragraph 5.2.

5.2. CLEANING/DISINFECTION OF THE INSTRUMENT

Attention: to execute this procedure use the devices as foreseen in the norms in force in case of biological hazard.

Cleaning and sanitation of the external surfaces of the instrument

1. All described operations have to be executed with the instrument stopped.
2. Prepare a solution of Virkon (registered trade mark) of 1% in a container with spray: 10 g of powder in 1 litre of water. Dissolve the powder by shaking the container. For complete and detailed information of the properties of Virkon® visit the internet site: www.virkon.it.
3. Use a wet cloth with the Virkon® solution on the external surfaces of the instrument that are to be cleaned and decontaminated, taking care to apply with what is foreseen in the norms in force in the matter of biological hazard. Distribute the decontamination solution on the entire surface and execute the cleaning operation avoiding any contact with the internal parts of the instrument containing the electronic boards.
4. Let to dry. Repeat the operations described in 2 and 3 and at the end of these the cleaning and decontamination operations of the external surfaces of the instrument are finished.

Cleaning and sanitation of the internal parts of the instrument

All operations have to be executed only by personnel authorized by Diesse Diagnostica Senese S.p.A. and have to be done with the instrument turned off and totally open in all of its parts.

1. Prepare a solution of Virkon® of 1%: in a container dissolve 10 g of powder in 1 litre of water, shaking accurately to obtain a homogenous solution. For complete and detailed information of the properties of Virkon® visit the internet site: www.virkon.it.
2. Use a wet cloth with the Virkon® solution on the internal surfaces of the instrument that are to be cleaned and decontaminated, taking care to apply with what is foreseen in the norms in force in the matter of biological hazard. Distribute the decontamination solution on the entire surface and execute the cleaning operation between the electronic cards, avoiding any contact with the electronic cards.
3. The internal electronic cards that result contaminated by the biological samples have to be substituted with newly installed equivalent cards. The contaminated cards have to be gathered in a plastic bag which is to be sealed and sent to the disposal according to the norms in force.

5.3. REPLACEMENT OF PRINTER PAPER

Procedure:

- Stop the instrument and disconnect from the power network.
- Lift the printer window.
- Remove the paper bolt.
- Substitute the old paper role with a new one.
- Lift the printer head, raising the appropriate lateral lever (indicated with A by the arrow in Fig. 5.3.a and b). Insert the end of the paper strip in the entrance of the paper guide, taking care to level it precisely with a pair of scissors and respecting the rotating direction of the paper.

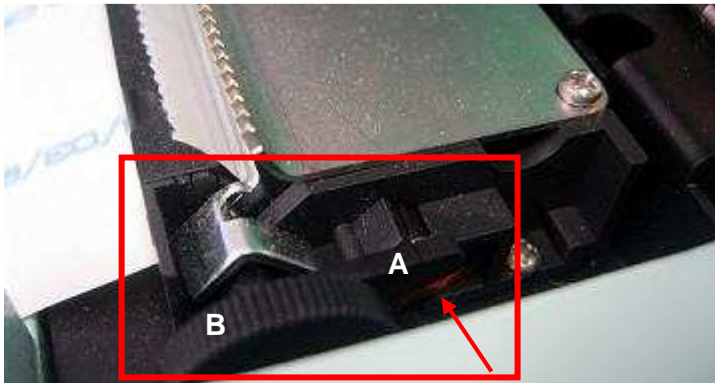


Fig. 5.3.a

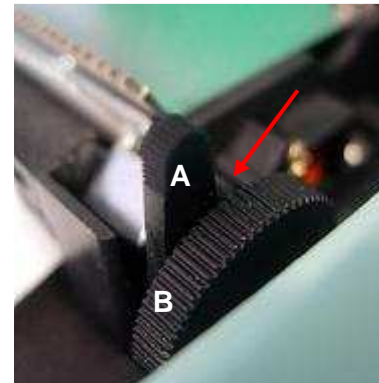


Fig. 5.3.b

- Connect the instrument to the power network and switch on.
- Push the paper until self-loading begins (fig. 5.3.c). To help the loading it is possible to use a dented role indicated by B (fig. 5.3.a, b).

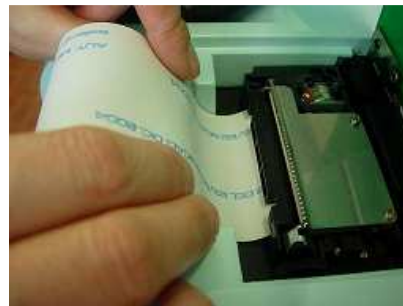


Fig. 5.3.c

- Lower the head lever.
- Let the paper move forward until exiting from the front part (fig.5.3 d, e)



Fig. 5.3.d

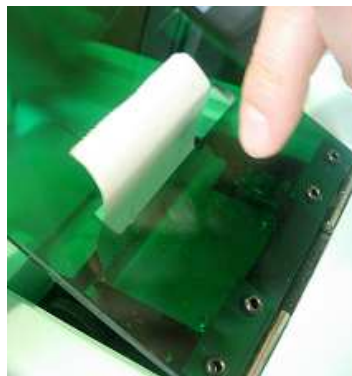


Fig. 5.3.e



Fig. 5.3.f

- Pull the paper to the extern to cut it, close the window and rip the paper that comes out of the front (fig.5.3 f).

5.4. SUBSTITUTION OF THE FUSES

When it is necessary to substitute the fuses, the procedure to follow is the described here after. Disconnect the power of the instrument. Render accessible the lid of the lodging of the fuses (“Filtered outlet with fuse holder lodging” fig. 5.4.a) which is located on the back of the instrument beneath the general power supply cable (fig. 5.4.a).



Fig. 5.4.a



Fig. 5.4.b

Insert a screwdriver with flat head in the point shown in fig. 5.4.b, than push the right tab to the left, as indicated by the white arrow in fig. 5.4.c, repeat the operation with the left tab that, in this case, is pushed to the right as indicated by the red arrow in fig. 5.4.c.

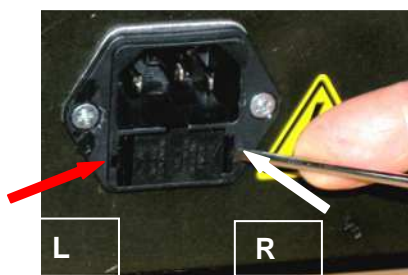


Fig. 5.4.c



Fig. 5.4.d



Pressing the tabs between thumb and forefinger it is possible to extract the fuse holder lodging completely from the filtered outlet (fig. 5.4.d) and to procede with the substitution of fuse(s) as shown in fig. 5.4.e.



Fig. 5.4.e



Fig. 5.4.f



Fig. 5.4.g

Insert the fuse holder into its lodging (fig 5.4.f) pressing down in the way indicated by the arrow in fig. 5.4.g, until the tabs return with a click into their original position.

CHAPTER 6

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6.1. TROUBLESHOOTING

The Tablet PC, besides performing command operations and control of the peripherals, constantly checks the most important parts of the instrument.

When an anomaly is encountered the process in progress is automatically interrupted and a sound signal is sent, at the same time on the screen the type of breakdown or hitch encountered is displayed.

The following messages are the followings:

MESSAGE AND FAULT	CAUSE AND SOLUTION
Error Device 0x01 (Positioner)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Error of the chain movement.	
Error Device 0x03 (Ejector chain)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph 6.2)
Error in the tube ejection device of the chain	
Error Device 0x04 (Mixer)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service
Error in mixer device of the tube in the analysis module.	
Error Device 0x05 e0x06 (Reader 1 o 2)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Errors in the reader devices of the optical sensors.	
Error Device 0x07 (Sample holder))	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service
Error in the device that moves the test tubes from the chain to the sample holder rack	
Error Device 0x07 (Ph Sorter)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service
Error caused by a test tube not detected by the removal device from the chain at the end of the cycle.	

Error Device 0x08 (Sample holder) Error in the movement of the sample holder rack.	Press the STOP button to interrupt the analysis cycle and let the rack exit by selecting "Unload sample holder rack" If the problem persists, contact technical service.
Error Device 0x09 (Ejector clamp) <i>Only in Bayer models</i> Malfunctioning of the mechanism that pushes the tube from the rack to allow the clamp to take it (only for Bayer models)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Error Device 0x10 (Clamp Hor.) Error in the movement, along the horizontal axis, of the clamp that withdraws the tube (in the upper loading zone, preparer module)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Error Device 0x11 (Clamp Vert.) Error in the movement, along the vertical axis, of the clamp that withdraws the tube (in the upper loading zone, preparer module)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Error Device 0x12 (Front Tractor) Error in the movement of the rack movement group at the front side of the preparer module (in front of the rack withdrawal rack group)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Error Device 0x13 (Detection Racks) Error in the system that identifies the rack during the loading of the Ves-Matic Cube 200.	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Error Device 0x14 (Back Tractor) Error in the movement of the rack movement group at the back side of the preparer module (behind of the rack withdrawal rack group)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Error Device 0x15 (Left Transferer) Error in the rack transfer system, in the zone behind the front of the loading compartment, preparer module	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.

Error Device 0x16 (Inserter)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Error in the inserter device of test tubes in the chain.	
Error Device 0x18 (Barcode Ejecter) Only for Beckman Coulter modules	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service
Malfunctioning of the mechanism that lifts the tube from the rack to allow the bar code reader to execute the scan of the label.	
Error Device 0x20 (Transponder)	Contact technical service.
Error of the refill device of the Check Device	
Error Device 0x30 (Dual Serial Port)	Contact technical service
Error in the communication device.	
Error tube absent (Ph Inserter)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service
The system does not detect the expected test tube for the chain in the inserter tube (pre-load)	
Error tube absent (Ph Chain)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph 6.2) If the problem persists, contact technical service.
The system does not detect a expected test tube in the chain.	
Misalignment Tractors/Trasfers!	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph Independent Management of some problems) If the problem persists, contact technical service.
Page 29 SM	
Check Device running out	Recharge the instrument
The test counter is running out, the instrument has no more then 500 hits available (box is yellow)	If the problem persists at the end of the refill, contact technical service.
Check Device ran out	Recharge the instrument
The test count has run out (box is red)	If the problem persists at the end of the refill, contact technical service.
Error in refill Check Device	Insert a different refill in the instrument.
Problems in the refill of the hit counter.	If the problem persists at the end of the refill, contact technical service.

Verify front left microswitch	Verify the correct positioning of the front carter on the indicated side of the micro-switch.
Error in left microswitch of the front panel.	If the problem persists, contact technical service.
Verify front right microswitch	Verify the correct positioning of the front carter on the indicated side of the micro-switch.
Error in right microswitch of the front panel.	If the problem persists, contact technical service.
Timeout Host	Verify the correct connection of the cable on the back side of the Ves-Matic Cube 200.
Error of connection line to Host computer.	Verify the correct functioning of the IT network of the laboratory.
Printer: out of paper	Insert a new role of paper in the printer see (paragraph 5.3)
Printer paper ran out.	If the problem persists, contact technical service.
Printer head up	Lift the lid of the printer and lower the head, acting on the black lever on the right side of the head.
The printer head is lifted.	If the problem persists, contact technical service.
Printer: communication error	Verify the presence of paper and the head position.
Communication error between printer and Tablet PC.	If the problem persists, contact technical service.
Error Device 0x07	Besides possible electric defects, there can be mechanical obstructions that are to be removed (see paragraph about independent management of some problems)
Error generate by a test tube raised by 2/3 mm above the chain that remained stuck on the sorter tube or generated by a malfunction of the test tube presence photocell of the tube	If the problems persists, contact technical service .
File <u>EVENTS</u> RESET PROC – SORTER STEPS ERROR	
No error displayed Event registered in the Events file only	If the problems persists, contact technical service.
Loss of steps of the left transferor during the transfer of the samples from the preparer module to the analysis module of a rack with a high probability of error in the match between bar code and sample. The codes of the test tubes in the rack are cancelled and the processed samples are transferred to the pendings archive.	
File <u>EVENTS</u> : TRANSFER_LEFT MAX STEPS ERROR	



After any **ERROR** signal, it is advisable to repeat the whole operation at least one time, to assure that the error isn't caused by external factors, like the momentary interruption or variation of the electric power.

Switch the instrument off and wait some seconds; turn the instrument on again and restart the cycle in the prescribed mode (at the start of the analysis procedure the instrument executes a reset of all internal groups).

6.2. INDEPENDENT MANAGEMENT OF SOME PROBLEMS



ATTENTION: The described procedures have to be executed strictly while the instrument is switched off. Before reactivating the instrument it is necessary to restore all security covers.

6.2.1. PROCEDURE FOR THE ACCESS TO THE CLASSIFIER MODULE

1. Remove the two Rack inserting extensions sliding them for about 1 cm up and moving them to the outside to free them from the holding buttons (Fig. 6.2.1.a).



Fig. 6.2.1.a

Push up the rack inserting extension and move it outwards, following the order of the arrows (Fig. 6.2.1.a).

2. Open the lid of the preparer module and lift the front cover, pushing down in vertical direction for about 1 cm, making it slide from down upwards (as indicated in the sequence 1, 2 in fig. 6.2.1.c), freeing it from the four blocking points on the frame as indicated by the black arrows in fig. 6.2.1.b, c.



Fig. 6.2.1.b

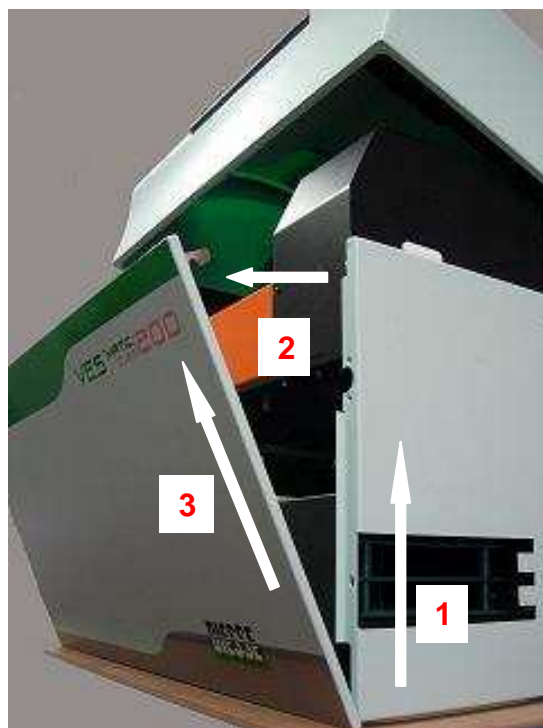


Fig. 6.2.1.c

3. Remove the front cover as indicated by the sequence of the arrows in fig. 6.2.1.c. Verify if there are any test tubes that cause a block and remove them.

4. For the reassembling follow the opposite procedure as the one described until the alignment of the upper part of the cover with the lateral panels.

6.2.2. PROCEDURE OF PARTIAL ACCESS TO THE ANALYSIS MODULE

1. Follow the procedure described in paragraph 6.2.1 Locate the unlocking switches (left and right) colored yellow with the writing "PUSH TO OPEN" fig. 6.2.2.a.

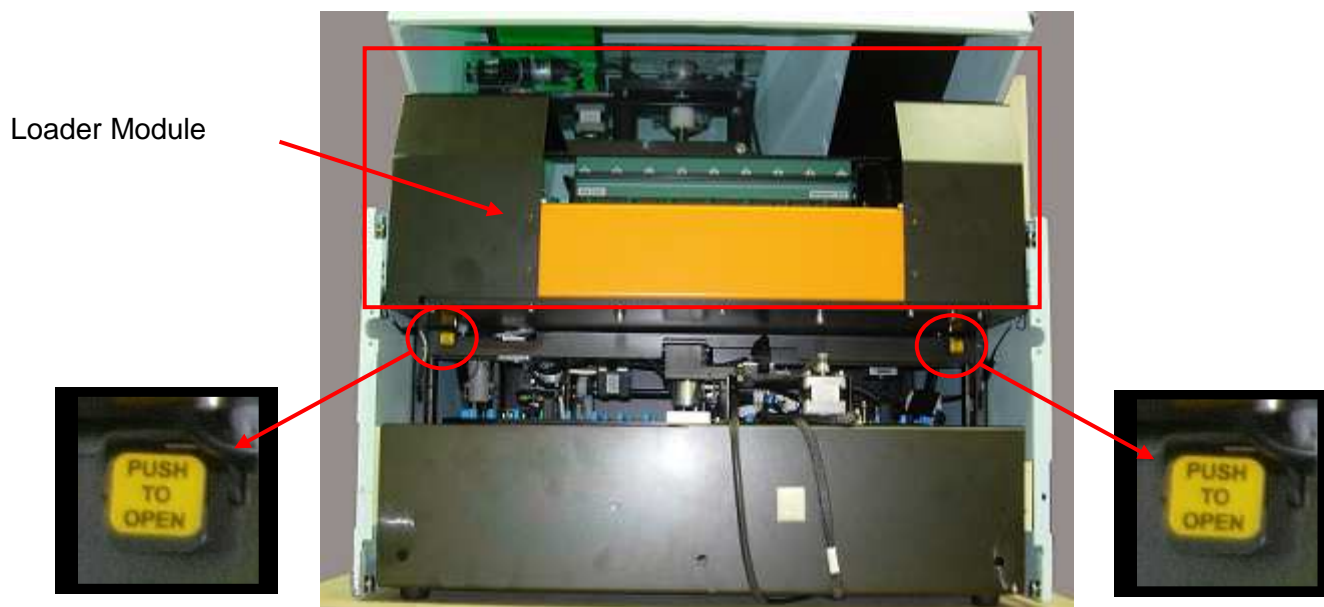
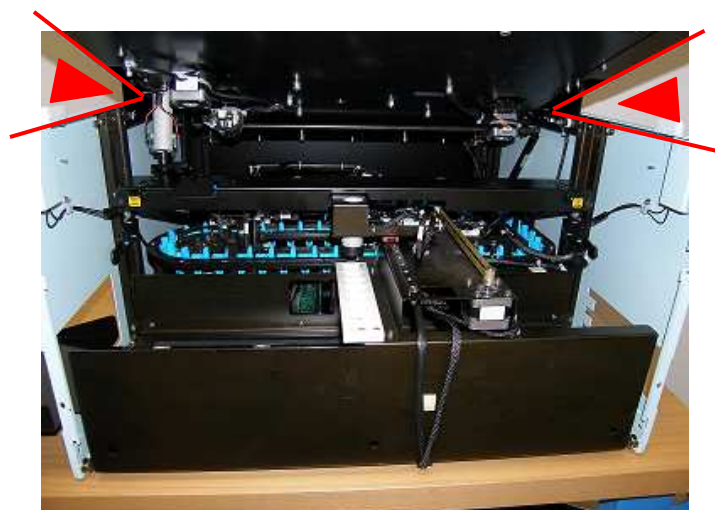


Fig. 6.2.2.a

2. Act contemporaneously with front-back pressure on the two unlocking switches under the plate of the preparer module close to the left and right side of it (fig. 6.2.2.a).
3. The preparer module (pointed out by the rectangle in fig. 6.2.2.a) will lift automatically by means of two gas springs for the allowed run (about 20°) (fig. 6.2.2.b).



Upwards opening of the Preparator module, the opening angle (20°) in respect to the Analyses Module is indicated by the red triangles

Fig. 6.2.2.b

Verify whether or not there are any test tubes that cause a block and remove them.

4. For the reinstatement push down the preparer module, acting with both hands on the orange front part, until the click of the two hooks left and right on the blocking staff. Assure that both hooks click correctly, guaranteeing the block in place of the preparer module.

6.2.3. LIST OF SOME ERROR MESSAGES AND THEIR SOLUTION

When the instrument is in the “View Analyses module” or “View Preparer module” mode, it can indicate error messages on the screen in the “information bar” (see fig. 3.2.b). Some error messages and the operating instructions for their solution by the operator are reported below.

Verify front left microswitch: in this case it is advised to verify, without necessarily switching off the instrument, the correct application of the front cover.

Error Device 0x04(Mixer): the normal movement of the mixer is blocked.

It is advised to access the analyses module following, with the instrument turned off, the procedure described in 6.2.1 and 6.2.2, verify whether there are any mechanical blocks, then remove the sample near the mixer, switch the instrument on, press “Start” and verify that the “reset” (indicated in the information bar) occurs regularly.

Error tube absent (Ph. Chain): this error can occur:

1. in case of the Sysmex model of the instrument, the rack is inserted into the Preparator Module incorrectly (see fig. 3.2 bis). The consequence of an incorrect insert is the transfer of the sample to the Analyses module, inclusive of “sleeve”.
2. when the sample remains blocked in the tube for a friction caused by an incorrect labeling of the test tube (see paragraph 4.2.2).

In both cases to remove the block follow, with the instrument turned off, the procedures described in the paragraph 6.2.1 and 6.2.2. Switch the instrument on again, press “Start” and execute “Unload Samples” to recover all samples present in the analytical chain and insert them into a new rack in the preparator module.

Error device 0x03 (Ejector chain): this error occurs when a sample remains blocked in the mail of the chain. This resolving intervention has to be executed by expert operators only. To remove the sample it is not necessary to switch the instrument off. Proceed as described in the following: remove the front panel (6.2.1), interrupt the cycle by pressing the “Stop” button and then press “Start”. At the end of the “Reset” the instrument will indicate an incorrect positioning of the test tube in the mail. At this point, after verification of the labeling of the sample (see 4.2.2.), put the sample correctly in the mail and press “Start” again.

Error device 0x07 (Ph. Sorter): this error occurs when the test tube has not entered in the sample holder rack (classifier). This resolving intervention has to be executed by expert operators only. The operator, without turning off the instrument, can solve this problem as follows: remove the front panel as described in 6.2.1, detect the test tube and, after verification of the labeling of the sample (see 4.2.2), insert it manually into the sample holder rack and in the end press “Start”.

Error Device 0x08 (Sample holder): when this message appears at the start of an analytical cycle, this means that the introduction of the sample holder rack was done on the contrary, thus even if the sample holder advances in the classifier module it is not able to position itself correctly in front of the ejector group of the Analysis module. Even though the introduction of the sample holder rack in the classifier module is guided by the outline of the opening for the introduction present in the side panel, it

is important to that the right direction of introduction of the sample holder rack occurs as indicated by the yellow arrow (A) in fig. 6.2.3.a, to verify the following conditions:

1. the label of the barcode of the sample holder rack has to be turned towards the operator and high-placed on the right side of the rack.
2. the notches present in the positions "A1, B1, C1, D1, E1, F1, G1, H1, I1, J1, K1, L1, M1, N1" (some indicated in the detail "C" in fig. 6.3.2. red arrows) have to be turned towards the back of the instrument.
3. the hollow notch at the inferior border of the sample holder rack, indicated by arrow "D" in fig. 6.2.3, has to be always on the right side in the lowest position.

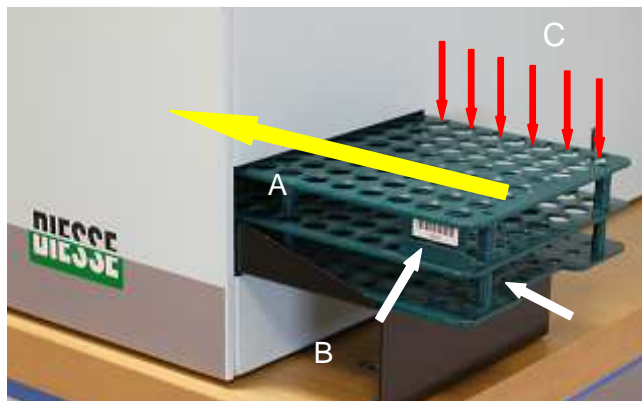
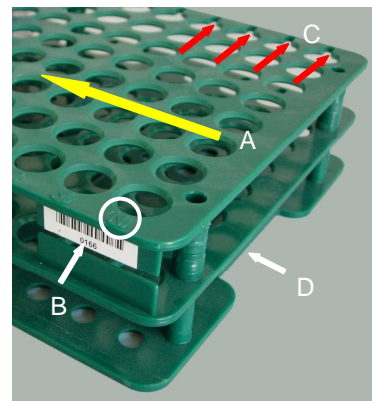


Fig. 6.2.3



Particolare di fig. 6.2.3.

The absence of one or more of these conditions represents a reason for a mechanical block of the instrument.

CHAPTER 7

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7.1. EXTERNAL BARCODE READER

The recording of the identification number of the sample holder rack can only occur by means of the external BAR CODE READER, supplied with the instrument.

GENERAL SPECIFICATIONS OF THE CONNECTION:

Before connecting the external Barcode Reader verify that:

- this is out-fitted with a cable with female connector DB9 in DTE configuration with current of 5Vdc on 9 pins (refer to the instruction manual of the barcode reader),
- the signals on the female connector DB9 are compatible with the connector placed on the back of the instrument to which it is connected:

DB9 Male External barcode	
PIN	SIGNAL
2	Tx data to reader (not used)
3	Rx data from reader
5	GND
9	+ 5 V

TECHNICAL INFORMATION:

- The electric levels of the signals or of type standard RS232
- The communication is one-way from the barcode reader to the machine.
- The transmission speed is 9600 bit/s, the format of the data is of the type 8 bit of data, 1 stop bit and no parity bit.
- The communication protocol is of the type ASCII; the read barcode has to be finished by the Carriage return (0x0d) character.

The reader has to be connected, WHILE THE INSTRUMENT IS TURNED OFF, to the appropriate DB9 male placed on the back of the Lid Unit.

During the turning on of the instrument, if it's connected correctly, the reader will emit an acoustic signal. A similar signal is sent every time the reader obtains a barcode.

7.2. CONNECTION TO THE HOST COMPUTER

Serial Protocol for communication with the Host Computer

7.2.1. PREFACE: TECHNICAL INFORMATION

- The electric levels of the signals are of the standard type RS232C.
- Transmission speed is 9600 bit/s, the data format is 8 bit of data, 1 stop bit and no parity bit.

- The DB9 Male “RS232C” connector on the back panel of the Ves-Matic Cube 200 reflects the following pin-out:

PIN	SIGNAL
2	Rx data from Host
3	Tx data to Host
5	GND

7.2.2. PREFACE: HEXADECIMAL ASCII (HEX-ASCII) REPRESENTATION

In the protocol described below many of the parameters and data are represented in Hexadecimal ASCII (HEX-ASCII) format, in other words:

a byte with a value of 0x7A is represented by two ASCII characters: ‘7’ (0x37) and ‘A’ (0x41), the first represents the most significant nibble and the second, the least significant.

Examples:

Original Byte Hexadecimal value	Representation HEX-ASCII	
	H characters	L characters
0x45	‘4’ (0x34)	‘5’ (0x35)
0xC8	‘C’ (0x43)	‘8’ (0x38)
0x6F	‘6’ (0x36)	‘F’ (0x46)
0x10	‘1’ (0x31)	‘0’ (0x30)

As can be noticed, this type of representation means that two ASCII characters are necessary for the representation of the value of one byte.

7.2.3. GENERAL REMARKS: DELAY IN REPLYING

To allow the machine time to activate the reception mode it is necessary to enter a delay of 1 second on the reply.

7.2.4. MESSAGE REQUESTING TUBES TO BE PROCESSED: CONTROL 0x50

This message is sent by the Ves-Matic Cube 200 to the Host computer. It contains a list of the barcodes from the samples inserted in each rack. The Host computer must reply to this message with a similar message containing only the barcodes for the samples that require ESR testing (that is codes that have already been accepted by the Host) and in case codes that have not yet been accepted by the Host (thus unknown).

The management of the samples to execute because accepted on the Host and that of the samples to execute although ‘unknown’ to the Host, is based on an attribute (the terminator of the bar code) contained in the reply message of the Host (see 7.2.5).

Example 1 (WITHOUT management 'unknown' codes):

The Ves-Matic Cube 200 sends to the Host 10 bar codes, the Host returns only 4 of the 10 received codes, that is only those that have to be analyzed by the Ves-Matic Cube 200 (the other 6 samples will not be processed by the instrument).

Example 2 (WITH management 'unknown' codes):

The Ves-Matic Cube 200 sends to the Host 10 barcodes, the Host returns 4 codes with the attribute ESR to execute + 2 codes with the attribute "unknown code". The instrument will execute the 6 samples, at the end of the analysis it will send the results of the 4 codes with ESR to execute, while the other 2 'unknown' codes will stay in the pendings database.

7.2.4.1 REQUEST: VES-MATIC CUBE 200 SENDS THE FOLLOWING FRAME:

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	H-LEN	L-LEN	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x30)	Data-1	...	Data-n	ETX (0x0D)	H-CHK	L-CHK
---------------	-----------------	-----------------	--------------	--------------	-----------------	-----------------	-----------------	-----------------	---------------	-----	---------------	---------------	--------------	--------------

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print, are variable, and are described below:

7.2.4.1.1. H-LEN / L-LEN: length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum Value 'F' (0x46) / 'F' (0x46). This is the effective number of bytes contained in the **Data** field. In fact, the maximum number of bytes contained in the Data field is 255.

7.2.4.1.2 Data-1 . Data-n: Data field. The data field for the message code 0x50 consists of the following:

H-NUM / L-NUM (2 bytes HEX-ASCII)	BarCode-1 (ASCII string max. 15 characters)	Terminator of the string Barcode-1 (0x10)	BarCode-2 (ASCII string max. 15 characters)	Term. of the string Barcode-2 (0x10)	BarCode-n (ASCII string max. 15 characters)	Term. of the string Barcode-n (0x10)
--	---	---	---	--	-------	---	--

H-NUM / L-NUM: Number of barcodes contained in the message, represented in HEX-ASCII.

BARCODE-n: ASCII string with a variable length, maximum of 15 characters allowed. This is the barcode, as it is read by the Ves-Matic Cube 200 barcode reader.

Terminatore: Each string of the barcodes is terminated with the byte 0x10. This is because the length of the string is variable.

The number of Barcodes contained in the data field is limited by the fact that the data field itself may contain up to a maximum of 255 bytes, nevertheless the barcodes are never cut off, but are always complete with terminator.

7.2.4.1.3 H-CHK / L-CHK: CheckSum of the message, represented in HEX-ASCII. The Checksum is calculated by carrying out the OR-exclusive of all the sent bytes from STX to ETX inclusive. The resulting hexadecimal value is then converted into HEX-ASCII and the two characters that represent it are sent.

ATTENTION: for debugging purposes it is possible to disable the checksum control, replacing the H-COM bytes with the value of 0x44 instead of 0x35. In this case the two bytes of the checksum are still sent but their value will be insignificant. The Host computer must also manage any possible cases in which the checksum is disabled.

7.2.4.2 REPLY FROM THE HOST COMPUTER

Upon receiving the message, the Host computer has to first send an ACK message to acknowledge correct receipt and interpretation of the message; meaning that all the fields have the correct values and the checksum is correct, or a NACK message to indicate that the message contains one or more errors: inexact checksum, incorrect length of the data field, etc...

7.2.4.2.1 ACK Message

ACK (0x06)	H-ADD (0x30)	L-ADD (0x31)	ETX (0x0D)
---------------	-----------------	-----------------	---------------

Timeout on ACK Message: 2 Sec.

7.2.4.2.2 NACK Message

NACK (0x15)	H-ADD (0x30)	L-ADD (0x31)	H-ERR	L-ERR	ETX (0x0D)
----------------	-----------------	-----------------	-------	-------	---------------

where: **H-ERR / L-ERR** are the HEX-ASCII representation of the error code defined according to the following table:

Error code	H-ERR Value	L-ERR Value	Meaning
0x00	0x30	0x30	General Error
0x04	0x30	0x34	Checksum Error
0x05	0x30	0x35	Field Error value H-LEN / L-LEN
0x06	0x30	0x36	Data field Length Error

Timeout on NACK Message: 2 Sec.

7.2.4.2.3. Reply Message with 0x50 Control Data

After having sent the ACK message, the Host computer must send the real reply to the 0x50 message. This reply will be identical to the message send by the Ves-Matic Cube 200 (see paragraph 7.2.4.1), with the difference that the barcodes sent will be only those that have to be processed by the Ves-Matic Cube 200 and another difference of the terminator 0x11 for the “unknown” codes (that is not yet accepted by the Host computer and thus equally to be processed) Therefore, the **H-LEN / L-LEN** and **H-NUM / L-NUM** fields may be different.

If none of the barcodes have to be processed, the **data** field will only contain the H-NUM / L-NUM (0x30 / 0x30 value) field and H-LEN /L-LEN will be equal to 0x30 / 0x32.

The data field of the message cod. 0x50 is composed as follows:

H-NUM / L-NUM (2 bytes HEX-ASCII)	BarCode-1 (String ASCII max 15 characters)	Terminator of the string Barcode-1 (0x10/0x11)	BarCode-2 (String ASCII max 15 characters)	Terminator of the string Barcode-2 (0x10/0x11)	BarCode-n (String ASCII max 15 characters)	Terminator of the string Barcode-n (0x10/0x11)
--	--	--	---	--	-------	---	--

H-NUM / L-NUM: Number of bar codes contained in the message, represented in HEX-ASCII.

BARCODE-n: ASCII string of variable length, maximum 15 characters allowed. This is the bar code as it is read by the bar code reader of the Ves-Matic Cube 200.

Terminator: Every string of the bar code is terminated by a 0x10 byte of a 0x11 byte (for “unknown” codes). This to allow the management of the variable length of the codes as well the management of “unknown codes”.

The number of bar codes contained in the data field is limited by the fact that the data field itself can contain a maximum of 255 bytes, in any case the bar codes are never truncated, but always complete with terminator.

If the string of the bar code terminates with a 0x10 byte; this means that the sample has to be processed by the Ves-Matic Cube 200, at the end of the exam the result will be printed and stored in the Historic Database.

If the string of the bar code terminates with a 0x11 byte, this means the code of the sample is unknown; in this case the Ves-Matic Cube 200 will process the sample but at the end of the exam the result will not be printed and it will be stored in the Database of the Pendings.

Timeout on Message with Data: 5 Seconds.

7.2.4.3 **ERROR ON REPLY MESSAGE WITH DATA**

If the Ves-Matic Cube 200 detects an error in the receipt of the message it will repeat the transaction from the beginning and resend the request message indicated in paragraph 7.2.4.1.

7.2.5. MESSAGE FOR SENDING RESULTS: 0x51 CONTROL

This message is sent by the Ves-Matic Cube 200 to the Host computer. The message contains the results of the analyses carried out on one or more tubes. The Host computer must reply to this message only with a message of the ACK or NACK type to notify the successful receipt of the results or the presence of errors in the message.

NB: the samples that were analyzed by the instrument with the attribute “unknown code” are not send automatically at the end of the analysis process but can be send exclusively manually by the operator by means of the command “Send to Host” from the Menu of management of the Pending Database.

7.2.5.1 CONTROL: VES-MATIC CUBE 200 SENDS THE FOLLOWING FRAME:

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	H-LEN	L-LEN	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x31)	Data-1	...	Data-n	ETX (0x0D)	H-CHK	L-CHK
---------------	-----------------	-----------------	--------------	--------------	-----------------	-----------------	-----------------	-----------------	---------------	-----	---------------	---------------	--------------	--------------

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print are variable and are described below:

7.2.5.1.1 H-LEN / L-LEN: Length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum value 'F' (0x46) / 'F' (0x46). This is the effective number of bytes contained in the data field. The maximum number of bytes contained in the data field is in fact 255.

7.2.5.1.2 Data-1 .. Data-n: Data field. The data field for the message code 0x51 consists of the following:

H-PRO / L-PRO (2 bytes HEX-ASCII)	Record Tube-1	Record Tube -n
---	----------------------	-------	-----------------------

H-PRO / L-PRO: Number of Tube records contained in the message, represented in HEX-ASCII.

The Tube Record number contained in the data field is limited by the fact that the data field itself is able to contain up to a maximum of 255 bytes, in any case the tube records are never cut off.

RECORD TUBE:

Barcode (ASCII string max 15 characters)	Terminator of the string Barcode (0x10)	ANALYSIS DATE ASCII string 6 characters	ANALYSIS TIME ASCII string 4 characters	ESR ASCII string 4 charact.	H-FLAGS	L-FLAGS	RACK ID ASCII string 4 charact.	POSITION ASCII string 2 charact.
--	--	---	---	--------------------------------------	---------	---------	--	--

BARCODE: ASCII string with variable lengths, maximum of 15 characters allowed. This is the barcode as it is read by the Ves-Matic Cube 200 Barcode Reader.

- Terminator:** Each string of the barcodes is terminated with the byte 0x10.
This is because the length of the string is variable.
- ANALYSIS DATE:** String of 6 characters without terminator, “**DDMMYY**” where:
“DD” = day of the month, from “01” to “31” ASCII.
“MM” = Month of the year, from “01” to “12” ASCII.
“YY” = Year of the century, from “00” to “99” ASCII.
- ANALYSIS TIME:** String of 4 characters without terminator, “**hhmm**” where:
“hh” = hour of the day, from “00” to “23” ASCII.
“mm” = Minutes, from “00” to “59” ASCII.
- ESR:** Value of the ESR measured, ASCII string without terminator:
from “ 0” (3 spaces + ‘0’) transmitted in the case of an error, to “ 140” (1 space + “140”). If the result is higher of 140 the string will be “>140”.
EXAMPLES, see following table:

ESR value	String sent	Bytes of the string
1	“ 1”	0x20, 0x20, 0x20, 0x31
100	“ 100”	0x20, 0x31, 0x30, 0x30
>140	“>140”	0x3E, 0x31, 0x34, 0x30

H-FLAGS / L-FLAGS: Bitmap with 8-bit of the sample errors, represented in HEX-ASCII. The following table illustrates the errors:

Bit	Error	Description
0	Sample High	Blood column too high
1	Sample Low	Blood column too low
2	Sample Absent	Tube Empty
3	Reading Error	General reading error
4	QC PASS	Reserved for samples with control blood
5	QC FAIL	Reserved for samples with control blood
6-7	-	Reserved

EXAMPLES:

- In the case of a “Sample High” error the Bit 0 (least significant) will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x01 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x31.
- In the case of a “Sample Absent” error the Bit 2 will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x04 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x34.

Management UNCERTAIN RESULT:

- If a Tube record is sent with an ESR value equal to 0 and with an error flag active (Bit 3 set to 1), the result (ESR=0) has to be interpreted by the Host as ‘Reading error of the sample’.
- IF a Tube record is sent with an ESR value different from 0 and with an error flag active (Bit 3 set to 1), the result (ESR different from 0) has to be interpreted by the Host as ‘Uncertain Result’, in the report the result is printed and indicated with an asterisk.

RACK ID: String of 4 characters without terminator, identifies the sample holder rack in which the sample has been repositioned.

POSIZIONE: String of 2 characters without terminator, identifies the coordinates of the position in which the sample has been repositioned in the sample holder rack.

7.2.5.1.3 H-CHK / L-CHK: CheckSum of the message, represented in HEX-ASCII. The checksum is calculated by carrying out the OR-exclusive of all the bytes sent from STX to ETX inclusive. The resulting hexadecimal value is then converted into HEX-ASCII and the two characters that represent it are sent.

ATTENTION: for debugging purposes it is possible to disable the checksum control, replacing the H-COM bytes with the value of 0x44 instead of 0x35. In this case the two bytes of the checksum are still sent but their value will be insignificant. The Host computer must also manage any possible cases in which the checksum is disabled.

7.2.5.2 REPLY FROM THE HOST COMPUTER

Upon receiving the message, the Host computer must send an ACK message to acknowledge correct receipt and interpretation of the message; meaning that all the fields have the correct values and the checksum is correct, or a NACK message to indicate that the message contains one or more errors: inexact checksum, incorrect length of the data field, etc...(see paragraph 7.2.4.1)

7.2.6. MESSAGE FOR SENDING QC (QUALITY CONTROL) SAMPLE DATA: CONTROL 0x52

This message is sent from the Ves-Matic Cube 200 to the Host computer. The message contains the results of the analysis performed on one or more samples. The Host computer must only reply to this message with an ACK or NACK type message to notify the successful receipt of the results or the presence of errors in the message.

7.2.6.1 CONTROL: VES-MATIC CUBE 200 SENDS THE FOLLOWING FRAME:

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	H-LEN	L-LEN	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x32)	Data-1	...	Data-n	ETX (0x0D)	H-CHK	L-CHK
---------------	-----------------	-----------------	--------------	--------------	-----------------	-----------------	-----------------	-----------------	---------------	-----	---------------	---------------	--------------	--------------

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print are variable and are described below:

7.2.6.1.1 H-LEN / L-LEN: Length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum Value 'F' (0x46) / 'F' (0x46). This is the effective number of bytes contained in the data field. In fact, the maximum number of bytes accepted in the Data field is 255.

7.2.6.1.2 Data-1 .. Data-n: Data field. The Data field for the message code 0x52 consists of the following:

QC data	QC Sample Record
---------	------------------

QC DATA:

Batch No (ASCII string 6 characters)	EXPIRE DATE ASCII string 6 characters	H-VALMIN	L-VALMIN	H-VALMAX	L-VALMAX
---	---	----------	----------	----------	----------

BATCH No.: ASCII string of 6 characters. Identifies the production batch of the control blood.

EXPIRE DATE: string of 6 characters without terminator, “DDMMYY” where:
“DD” = day of the month, from “01” to “31” ASCII.
“MM” = Month of the year, from “01” to “12” ASCII.
“YY” = Year of the century, from “00” to “99” ASCII.

H-VALMIN / L-VALMIN: The minimum value of the acceptable range for the control blood, represented in HEX-ASCII.

H-VALMAX / L-VALMAX: The maximum value of the acceptable range for the control blood, represented in HEX-ASCII.

QC SAMPLE RECORD:

Barcode (ASCII string max 15 characters)	Terminator of the Barcode string (0x10)	ANALYSIS DATE ASCII string 6 characters	ANALYSIS TIME ASCII string 4 characters	ESR ASCII string 4 characters	H-FLAGS	L-FLAGS	RACK ID ASCII string 4 characters	POSIZIONE ASCII string 2 characters
--	---	--	--	--	---------	---------	---	---

BARCODE: ASCII string with variable length, maximum of 15 characters allowed. This is the barcode as it is read by the Ves-Matic Cube 200 Barcode Reader.

Terminator: The string of barcodes terminates with the 0x10 byte. This is because the length of this string is variable.

ANALYSIS DATE: String of 6 characters without terminator, “DDMMYY” where:
“DD” = day of the month, from “01” to “31” ASCII.
“MM” = Month of the year, from “01” to “12” ASCII.
“YY” = Year of the century, from “00” to “99” ASCII.

ANALYSIS TIME: String of 4 characters without terminator, “hhmm” where:
“hh” = hour of the day, from “00” to “23” ASCII.
“mm” = Minutes, from “00” to “59” ASCII.

ESR: Value of the VES measured on the QC sample, ASCII string without terminator:
from “ 0” (3 spaces + ‘0’) transmitted in the case of an error, to
“140” (1 space + “140”). If the result is higher than 140 the string will be “>140”.

EXAMPLES: See following table:

ESR Value	String sent	Bytes of the string
1	" 1"	0x20, 0x20, 0x20, 0x31
100	" 100"	0x20, 0x31, 0x30, 0x30
>140	">140"	0x3E, 0x31, 0x34, 0x30

H-FLAGS / L-FLAGS: Bitmap with 8-bit of the sample errors, represented in HEX-ASCII. The following table illustrates the errors:

Bit	Error	Description
0	Sample High	Blood column too high
1	Sample Low	Blood column too low
2	Sample Absent	Tube Empty
3	Abnormal	Error in acquisition of height
4	QC PASS	The VES of the QC measured is within the acceptability range
5	QC FAIL	The VES of the QC measured is outside the acceptability range
6-7	-	Reserved

EXAMPLES:

- In the case of a "Sample High" error the Bit 0 (least significant) will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x01 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x31.
- In the case of a "QC Fail" error the Bit 5 will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x20 hexadecimal value and its HEX-ASCII representation will be 0x32 / 0x30.

RACK ID: String of 4 characters without terminator, identifies the sample holder rack in which the sample has been repositioned.

POSIZIONE: String of 2 characters without terminator, identifies the coordinates of the position in which the sample has been repositioned in the sample holder rack.

7.2.6.2 REPLY FROM THE HOST COMPUTER

Upon receiving a message, the Host computer must send an ACK message to acknowledge correct receipt and interpretation of the message, meaning that all the fields have the correct values and the checksum is correct; or a NACK message to indicate that the message contains one of more errors: inexact checksum, incorrect length of the DATA field, etc...(see paragraph 7.2.4.1).

7.2.7. EXAMPLE OF SERIAL PROTOCOL

7.2.7.1 EXAMPLE FOR THE REQUEST ESR ANALYSIS ON TWO SAMPLES (TWO BARCODES, SEE 7.2.4.1)

ATTENTION: The non printable characters (<0x20) are represented with their hexadecimal value between brackets [0x..].

Ves-Matic Cube 200 TX:

>001401500201091053[0x10]20586743[0x10][0x0D]36

STX	H/L BLK	H/L LEN	H/L ADD	H/L COM	H/L NUM	SAMPLE 1 BARCODE+ TERMINATOR	SAMPLE 2 BARCODE+ TERMINATOR	ETX	H/L CHK
>	00	14	01	50	02	01091053[0x10]	20586743[0x10]	[0x0D]	36

STX : [0x3E] '>'.
H/L BLK : fixed value '00'.
H/L LEN : number of characters present in the data field (14 hex = 20 characters: 2 for H/L NUM + 9 SAMPLE 1 BARCODE + TERMINATOR + 9 SAMPLE CODE 2 BARCODE + TERMINATOR)
H/L ADD : fixed value '01'
H/L COM : command code "for request sample code to process": '50'.
H/L NUM : number of barcode included in this message (02 hex = 2 bar codes).
SAMPLE 1 BARCODE + TERMINATOR
SAMPLE 2 BARCODE + TERMINATOR
ETX : character [0x0D].
H/L CHK : "xor" of all characters from STX to ETX included.

7.2.7.2 EXAMPLE OF THE AUTHORIZATION REQUEST TO HOST FOR TWO BAR CODES OF TWO SAMPLES AND THE AUTHORIZATION REPLY FOR THE ANALYSIS OF ONLY THE SECOND (SEE 7.2.4.2.2.)

ATTENTION: The non printable characters (<0x20) are represented with their hexadecimal value between brackets [0x..].

Request Ves-Matic Cube 200 TX:

>001401500201091053[0x10]20586743[0x10][0x0D]36

Message Host TX ack:

[0x06]01[0x0D]

Reply Host TX:

>000B01500120586743[0x10][0x0D]5D

STX	H/L BLK	H/L LEN	H/L ADD	H/L COM	H/L NUM	SAMPLE 2 BARCODE+ TERMINATOR	ETX	H/L CHK
>	00	0B	01	50	01	20586743[0x10]	[0x0D]	5D

STX : [0x3E] '>'.

H/L BLK : fixed value '00'.

H/L LEN : number of characters present in the data field (0B hex = 11 characters: 2 for H/L NUM + 9 SAMPLE CODE 2 BARCODE + TERMINATOR)

H/L ADD : fixed value '01'

H/L COM : command code "for request sample code to process": '50'.

H/L NUM : number of barcode included in this message (01 hex = 1 bar code).

SAMPLE 2 BARCODE + TERMINATOR

ETX : character [0x0D].

H/L CHK : "xor" of all characters from STX to ETX included.

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Attachment A: EC COMPLIANCE CERTIFICATE

EC DECLARATION OF CONFORMITY

In accordance with 98/79/EEC regulation regarding In-Vitro Medical Diagnostics Devices



DIESSE Diagnostica Senese S.p.A.

DIESSE DIAGNOSTICA SENESE S.p.A. with head office in Milan, Via A. Solari 19 sc. 6

certifies

that the design, type of manufacture of the in vitro medical-diagnostics device described hereafter and the version distributed on the market,

conforms

to the

“ 98/79/EEC directive relevant to the In Vitro Medical-Diagnostics Devices (IVD)”

through the accomplishment to the Annex III (except section 6) and the essential requirements of Annex I.

This certificate will lose its validity in the event of:

- modifications made to the machine in question without our authorization
- incorrect use of the instrument
- technical interventions performed by unauthorized personnel
- installation of non-original spare parts.

Product: **Automatic instrument for ESR analysis**

Type: **VES-MATIC CUBE 200**

Technical data: **110/120/230 Vac (56–60 Hz)**

conforms

as a whole and in its parts, with the following standards and their amendments:

EN 61010-1 (CEI 66-5)	“Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements”. The instrument is classified in Class I.
EN 61010-2-101	“Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for In vitro diagnostic (IVD) medical equipment”.
EN 61326-1	“Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements – Part 1: General requirements
EN 61326-2-6	“Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements – Part 2-6: In vitro diagnostic (IVD) medical equipment”

And therefore meets the minimum requirements of the following Community directives and their amendments:

Low Voltage Directive (2006/95/EEC)

Electromagnetic Compatibility Directive (2004/108/EEC)

Place, date of issue:

Monteriggioni, 02 AUGUST 2012



Signature:

Francesco Cocola
General Manager

Attachment B: ASSISTANCE REQUEST FORM

Form Requesting Assistance		DATE 																
Product: _____ Serial N°: _____ SW Release: _____ T.D. _____ Date _____ Guarantee YES <input type="checkbox"/> NO <input type="checkbox"/>	Client: _____ Referee: _____ Address: _____ Phone: _____ Fax: _____ E-mail: _____																	
LAST TECHNICAL INTERVENTION on the product: Carried out by: _____ On: _____																		
<div style="background-color: #e0f7fa; text-align: center; padding: 2px;">DETAILED DESCRIPTION OF THE PROBLEM</div> <div style="border: 1px solid black; height: 150px; margin-top: 5px;"></div>																		
<div style="text-align: center; padding: 5px;">ANY CUSTOMER REMARKS</div> <div style="border: 1px solid black; height: 80px; margin-top: 5px;"></div>																		
<div style="background-color: #e0f7fa; text-align: center; padding: 2px;">INTERNAL USE</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; vertical-align: top;"><i>Type of complaint:</i></td> <td style="width: 10%; text-align: center;"> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </td> <td style="width: 40%; vertical-align: top;"> Supply Product Technical Service Sales Office Technical Dpt. Purchase Office Quality Ass. _____ </td> <td style="width: 20%; vertical-align: top;"> _____ _____ _____ _____ </td> </tr> <tr> <td style="vertical-align: top;"><i>Notice to be forwarded to:</i></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="vertical-align: top;"><i>Reply time</i></td> <td></td> <td> <input type="checkbox"/> BY _____ days <input type="checkbox"/> URGENT </td> <td></td> </tr> <tr> <td style="vertical-align: top;"><i>Return</i></td> <td></td> <td></td> <td> Fax: _____ E-mail: _____ </td> </tr> </table>			<i>Type of complaint:</i>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Supply Product Technical Service Sales Office Technical Dpt. Purchase Office Quality Ass. _____	_____ _____ _____ _____	<i>Notice to be forwarded to:</i>				<i>Reply time</i>		<input type="checkbox"/> BY _____ days <input type="checkbox"/> URGENT		<i>Return</i>			Fax: _____ E-mail: _____
<i>Type of complaint:</i>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Supply Product Technical Service Sales Office Technical Dpt. Purchase Office Quality Ass. _____	_____ _____ _____ _____															
<i>Notice to be forwarded to:</i>																		
<i>Reply time</i>		<input type="checkbox"/> BY _____ days <input type="checkbox"/> URGENT																
<i>Return</i>			Fax: _____ E-mail: _____															
NB.: To better understand and troubleshoot the fault reported we recommend: 1. Filling out this form in all its parts 2. Attaching the following to this form (if available): - the documentation supplied by the client (e.g. printing report; photos; etc...) - the documentation supplied by the Service Staff (e.g. printout of the settings; reports; etc...)																		
FIRMA _____		DATA _____																
<div style="border: 1px solid black; display: inline-block; padding: 2px 10px;">Pag. 1 di</div>																		

Attachment C: ACCESSORIES, SPARE PARTS AND CONSUMABLES

The Ves-Matic Cube 200 is supplied with the following materials:

n°2 Sample holder racks	[Ref: R30003650]
n°2 Microswitch keys	[Re: R10343131]
n°1 Roll of thermal paper h.mm l=57 D=50	[Re: R12300000]
n°2 Delayed 5x20mm UL fuse blocks 5A	[Re: R20400070]
n°1 Power cable 3x0.75 L =2m SCHUKO 90°-C13	[Re: R21890040]
n°1 Power cable SVT PLUG USA/OUTLET VDE 2MT UL	[Re: R21890370]
n°1 Barcode reader Z-3080+Cabke CAB50607-R9	[Re: R20550510]
n°1 Rack holder Sysmex (with model code 10370/S)	[Re: R30207890]
n°1 Rack holder Bayer (with model code 10370/A)	[Re: R30207900]
n°1 Rack holder ABX (with model code 10370/AB)	[Re: R30207930]
n°1 Rack holder BeckC. (with model code 10370/BC)	[Re: R30207910]
n°1 Rack holder BeckC Five. (with model code 10370/BC5)	[Re: R30214090]

Consumables

Check-Device Transponder RF 1K for VES-MATIC CUBE 200 (1000 tests)	[Ref.: 10292]
Check-Device Transponder RF 5K for VES-MATIC CUBE 200 (5000 tests)	[Ref.: 10291]
Check-Device Transponder RF 10K for VES-MATIC CUBE 200 (10000 tests)	[Ref.: 10290]
ESR Control 9 mL (2 Bottles Normal + 2 Bottles Abnormal)	[Ref.: 10430]
ESR Control 9 mL (1 Bottle Normal + 1 Bottle Abnormal)	[Ref.: 10434]
Thermal paper for printer (4pcs)	[Ref. 10403]

Attachment D: REQUEST FORM; ACCESSORIES, SPARE PARTS AND CONSUMABLES

Fill out and sent a readable copy of the following from to:

Part request form			
INSTRUMENT _____	MODEL _____	SN# 200 <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>	
CLIENT / COMPANY _____			
ADDRESS _____			
CITY _____	CAP _____	STATE _____	
Doc. n° <input style="width: 80px;" type="text"/> of <input style="width: 80px;" type="text"/>			
Note _____			
Code	Description	Conf.	Requested quantity
<div style="display: flex; justify-content: space-between;"> Date _____ . Signature _____ . </div>			

Attachment E: MANUAL METHOD ACCORDING TO THE WESTERGREN TECHNIQUE

MANUAL METHOD ACCORDING TO WESTERGREN'S TECHNIQUE FOR DETERMINING THE ESR.

In order to measure ESR according to Westergren's technique follow the recommendations of the International Committee for Standardization in Haematology (ICSH) (bibliog. Ref.12/13), outlined below.

Materials

Blood collected not more than three hours earlier with EDTA-K2 (1.5 ± 0.25 mg per mL of blood) or with EDTA-K3 (1.7 ± 0.3 mg per mL of blood). The haematocrit value must be found between 30 and 36% (PCV - packed cell volume 0.33 ± 0.03).

Anticoagulant/diluent solution consisting of trisodium citrate dihydrate 109 mmol/L (3.28 g dissolved in 100 mL of distilled water).

Glass sedimentation test tubes with the following dimensions: total length 300 ± 1.5 mm, internal diameter 2.55 ± 0.15 mm with a uniformity of ± 0.05 mm, graded scale 200 ± 0.35 mm long subdivided into 10 mm steps or less with a maximum error tolerance between two consecutive divisions of 0.2 mm; before use the test tubes must be cleaned, dried and free of any residual traces of detergent.

Supporting rack for holding the test tubes in a perfectly vertical position ($\pm 1^\circ$) and structured so as to be completely stable to prevent any spilling of the blood from the test tubes in.

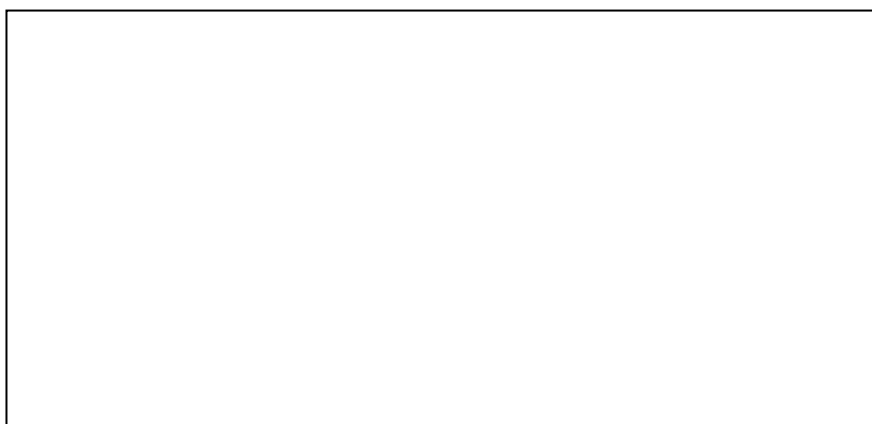
Procedure

Dilute the blood collected in EDTA, after an accurate though not too vigorous shaking, with the citrate 109 mmol/L in a proportion of 4+1 (for example, 2 mL of blood + 0.5 mL of citrate); mix the blood with the citrate accurately for a long time, but not vigorously, and draw up into Westergren test tubes; place the test tubes in the supporting rack making sure not to expose to direct sunlight, vibrations or impact; after 60 minutes exactly read the distance in mm between the lower meniscus of the plasma and the level of the column of sedimented erythrocytes.

Attachment F: QUICK-START INSTRUCTIONS **EXCERPT from this Operating Manual.**

These quick start instructions are directed only to expert users with a good level of knowledge of the entire contents of this manual.

- Turn the instrument on by the general switch, situated on the back of the instrument (fig. 2.2.5).
- Press the “Start” button, await the execution of the Reset after which raise the window (visible in fig. 4.2.4.a, indicated with number 2) lifting it until the upper click.
- Before starting an analysis procedure make sure that 20 rack holders are inserted correctly in the preparer module. Then verify that the labels adhere perfectly to the tubes: the adesive parts, if unattached, could cause frictions during the mechanical movements of the groups (inserter, ejector, sorter), creating inserting and ejecting problems in the analytical chain and possible blocks of the reading sensors.
- Blood sample level: minimum level accepted is $\geq 1,5$ mL; maximum level accepted < 4 mL.
- No special preparation of the test tubes is required, since the Ves-Matic Cube 200 uses the ones coming from another analytical system (CBC exam); it is advised not the less to comply with the norms related by the ICSH.
- Introduce the racks in the appropriate lodgings (visible in fig. 4.2.4.a and fig. 4.2.4.b indicated by number 1). The positions in which manual access is allowed by the operator in the preparer module are exclusively the positions from 1 to 9 (fig. 4.2.3 d). The racks in the positions protected by the two black lateral covers and all racks on the rear end of the instrument should NOT be touched to not falsify the automatic movements and to not change the placements assigned by the instrument.
- **ATTENTION!** Before inserting a new rack containing samples to be processed, carefully read the specification on the yellow label present on the left front part of the preparator module (fig.3.2.bis).
- Insert the sample holder rack (for the storage of the processed test tubes) on the right side of the instrument (fig. 4.2.3.c) and insert the relative bar code.
- At the end of the loading of the instrument, close the window, the racks will be automatically sent for barcode reading and subsequently to the analytic cycle.
- It is possible at any time to open the upper compartment to insert new racks. This will not interrupt the analytic cycle.
- To interrupt the analysis, press the STOP button.
- **ATTENTION!** Do not switch off the instrument during the working phases or during the Reset procedure. For the safeguard of the database it is advisable that the turning off occurs **EXCLUSIVELY** after pushing the STOP button on the display, waiting the completion of the movements.
- The extraction of the processed rack (in the positions 1-9 of the preparer module, fig 4.2.3.d) has to occur when the instrument is on halt and in the following way: free the rack from the retaining hook “T” (fig.4.2.3.e and fig. 4.2.3.f), slide the rack horizontally in the direction of the operator without lifting (fig.4.2.3.g)
- At the end of the daily analytic activity and every time one desires to access the archive it is necessary to press the ‘Stop’ button. This operation allows to make active (‘illuminated’) the ‘Archive’ button and at the same time to save all data obtained until that moment.
- It is advised to **ALWAYS** press the ‘Stop’ button before turning the instrument off (see paragraph 3.2.1, description of the function ‘Stop’ button)



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