VES MATIC CUBE 200

OPERATING MANUAL

Release software N° 2.20

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

DIESSE

INNOVATIVE CLINICAL DIAGNOSTIC SYSTEMS

MANUFACTURER/AGENT

DIESSE DIAGNOSTICA SENESE SpA
Via delle Rose 10, 53035 Monteriggioni (SI), Italy
Tel. ++39 0577 587111 Fax. ++39 0577 318690
www.diesse.it

LEGAL REPRESANTATIVE

MANAGING DIRECTOR
Sig.ra Aurelia Merini Gorini
REGISTERED AND ADMINISTRATIVE OFFICE
Via S. Vittore 36/1, 20123 MILANO, Italy
Tel. ++39 02 4859121 Fax. ++39 02 48008530

SERVICE ASSISTANCE

CUSTOMER CARE
Via del Pozzo 5, 53035 Monteriggioni (SI), Italy
Tel. ++39 0577 319556 Fax. ++39 0577 319020
e-mail: customercare@diesse.it

For the USA

DIESSE INC.
1690 W 38 Place, Unit B1 Hialeah, FL 33012, U.S.A.
Phone: (305) 827-5761 | 1-877-DIESSE-3 | Fax: (305) 827-5762
e-mail : salesoffice@diesse.us

SERVICE ASSISTANCE

DIESSE INC.
1690 W 38 Place, Unit B1 Hialeah, FL 33012, U.S.A.
Phone: 800 582 1937

TECNICAL ASSISTANCE

DIESSE INC. - CUSTOMER CARE
CUSTOMER CARE
1690 W 38th Place, Unit Bi Hialeah, FL 33012
Tel. 1 (877) 343-7733 Fax. (305) 827-5762
e-mail: customercare@diesse.us

Printed in 2006 (Total pages: 101)

ATTENTION this manual consists of 101 pages. It is to be use only when complete. If not, DIESSE Diagnostica Senese S.p.A. declines every responsibility. It is possible to request a new copy at Servizio Customer Care - Via del Pozzo 5, 53035 Monteriggioni (SI), Italy. Tel. ++39 0577 319556 Fax. ++39 0577 319020; e-mail: customercare@diesse.it.

Norms applied to the present document
UNI EN 591 II Edition (November 2001)
CEI EN 61010-1 II Edition Fascicolo 6290 (November 2001)

LIST OF GUIDE REVISIONS

REVISION GUIDE	DESCRIPTION MODIFICATIONS	APPR.
1.0 del 11/2006	Official version	**R&D director**
2.0 del 05/2007	Official version	**R&D director**

Application of the guide

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/BC	VES-MATIC CUBE 200 intended for BECKMAN COULTER rack

SYMBOLS

Legend of graphic symbols used on the instrument (European Norm: EN980:2003].

Instrument that fulfils the requirements of the European directive on in vitro diagnostic devices (98/79/EC)

Instrument complies with CSA standards for the Canadian and US market

IVD — In vitro diagnostic medical device

manufacturing date

SN — Serial number

Legend of electric symbols and of security assumed for the instrument.

Caution, electrical shock danger

Attention, read the guide, observe the symbols regarding the security

WEEE - Waste from Electrical and Electronic Equipment - Obligation of separate waste collection according to D.L.25/07/2005 n°151(Italy), enforcement of the directives 2002/96/CE and 2003/108/CE

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.

NOTA, important information.

BIOHAZARD, danger of contamination with possibly infected materials

LIMITATIONS AND WARNINGS

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 Repor**t.

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.

	It is important that this user manual is stored together with the device for future reference.
	In case of sale or transfer make sure that this manual accompanies the Ves-Matic Cube 200 to allow the new users to be informed about the instrument functionality and its relative warnings.
	The Ves-Matic Cube 200 instrument has to be used by qualified laboratory personnel previously trained by Diesse _Diagnostica Senese S.p.A. or by companies nominated by it.
	IN CASE OF FIRE OR OF 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.
	Only use **finger pressure** to key in the commands of the display and/or the keyboard
	**It is PROHIBITED to operate** on the machine while any parts are moving (users are only permitted to key in commands on the keyboard).
	ATTENTION: **NEVER MANUALLY** move the translators in the racks.

	**Reagents and consumables** Any materials and/or accessories supplied for the Ves-Matic Cube 200 are specially designed and can not 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.
	For any maintenance intervention: - unplug the machine from the power source - use the individual protection devices provided by current regulations - do not take away the barrier and do not avoid the security devices
	Samples that are not treated correctly can not guarantee a good end result
	Improper use and no or incorrect maintenance could seriously jeopardize the analytical process.
	The safety and performance requirements of the instrument can not 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.

BIO-CONTAMINATION HAZARD

	Potentially infected material is handled. 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. 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
	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.

INDEX

1 CHAPTER 1:

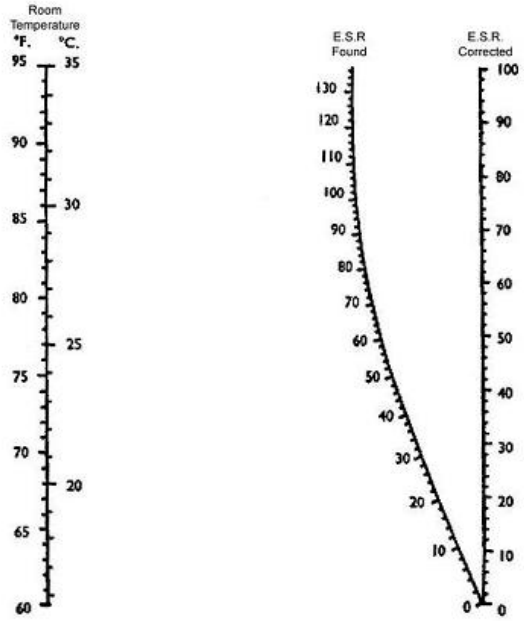
1.1 PRESENTATION OF THE INSTRUMENT

The Ves-Matic Cube 200 is a bench top instrument designed and programmed to determine the Erythrocyte sedimentation rate (ESR); it has continuous and random loading. It is able to analyze up to a maximum of 180 blood samples every hour.

The instrument executes the analysis of the samples directly from test tubes being used on the blood cell counter in the laboratory, it is therefore not necessary to do a double drawing nor a transfer of biological material.

The instrument is managed by a table top pc and its functionality will be described in more detail in the upcoming paragraphs.

The exam is executed completely automatically (shaking and reading) and the results, obtained in only 20 minutes, are comparable to those obtained with the Westergren method in 1 hour. (ref. 1-10); 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-selection the temperature correction for laboratory needs.



grafic1.1 Manley's Nomogram

Clinical concept of the ESR

The instrument supplies information about the Erythrocyte Sedimentation Rate (ESR) which reflects the speed with which the erythrocytes settle. The ESR value measured in a specific moment is influenced by the concentration in the plasma of some proteins, these concentration results change in inflammatory situations and also in the presence of certain pathologies, for example some neoplasms.
Furthermore the ESR value is affected by certain properties of the erythrocytes and by the hematocrit value.
Very high values of ESR are characteristic of multiple myeloma,. leukaemia, lymphoma, breast and lung carcinoma, rheumatoid arthritis, SLE, pulmonary infarct.
It is high in infections of any type, in carcinomas in presence of liver metastasis, in acute and chronic inflammations.

Normal values of ESR (Westergren; citrate)

Normally ESR values are between 1 and 10 mm for men and between 1 and 15 mm for women; in pathological conditions they can increase to values of up to 100mm and above.

Normal Range of the Ves-Matic Cube 200 instrument (blood in EDTA)

MEN	up to 10 mm
WOMEN	up to 15 mm

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 erythrocytes; 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)

The analytical results are obtained from the internal processing of the readings; the obtained values are correlated with the Westergren (citrate) reference method.

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 compartement
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 withdrawel 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 'Particolare Pannello Connessioni'

① RS232 connector (for connection to the Host Computer)

② EXTERNAL BARCODE reader connector

③ USB_CLIENT connector

④ 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]

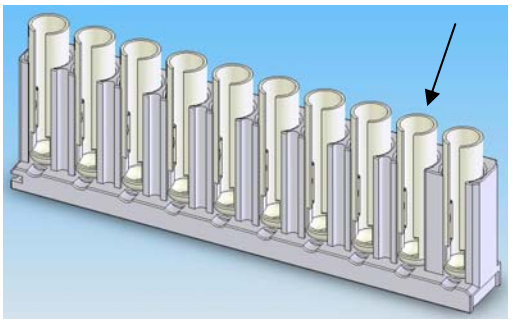
② Filtered outlet with fuse holder lodging

1.2.1 Models

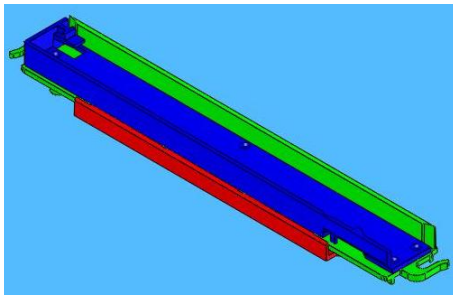
There are currently three models of the Ves-Matic Cube 200 available that are designed to be compatible with varoius blood cell counter rack types present in the laboratory:

The available models are as follows:
Ves-Matic Cube 200 predisposed for blood cell counter Sysmex
Ves-Matic Cube 200 predisposed for blood cell counter Advia Bayer
Ves-Matic Cube 200 predisposed for blood cell counter Beckman Coultier

Ves-Matic Cube 200 predisposed for blood cell counter Sysmex [Code 10370/S]
which uses
Rack Model Sysmex: white coloured rack with 10 positions with “liner” (indicated with arrow)

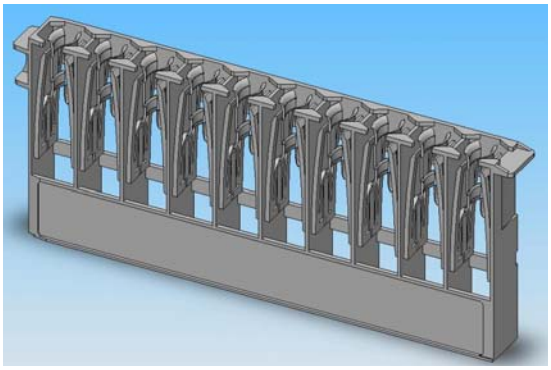


Rack Sysmex

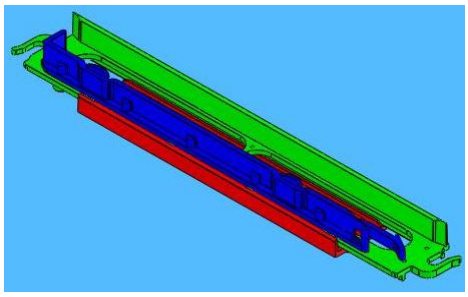


Rack holder Sysmex

Ves-Matic Cube 200 predisposed for blood cell counter Advia Bayer [Code 10370/A]
which uses
Rack Model Advia Bayer: grey coloured rack with 10 positions

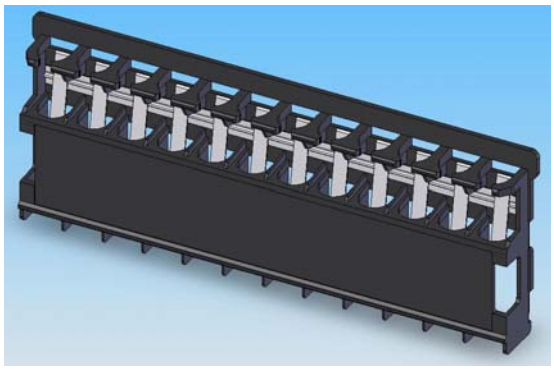


Rack Advia® Bayer

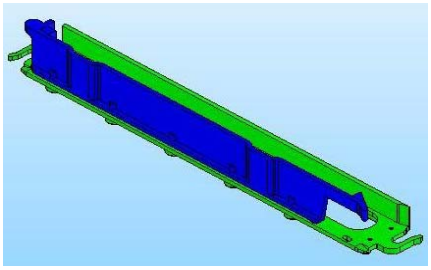


Rack holder Advia® Bayer

<u>Ves-Matic Cube 200 predisposed for blood cell counter Beckman Coultier [Code 10370/BC]</u>
which uses
Rack Model Beckman Coulter: black coloured rack with 12 positions



Rack Beckman Coulter



Rack holder Beckman Coulter

1.2.2 Compatibiliy with test tubes used for the haemachromocytometric test

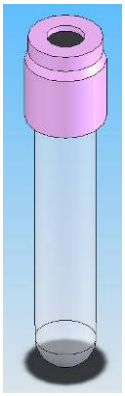
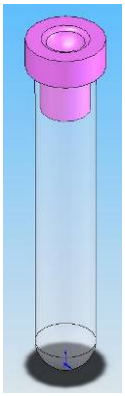
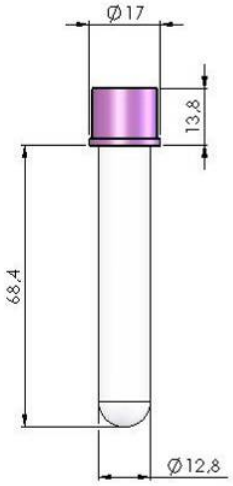
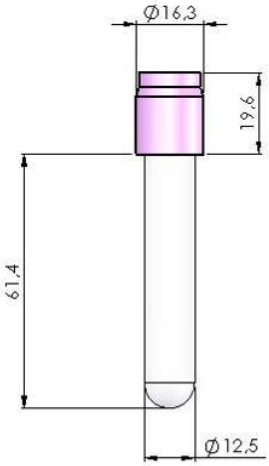
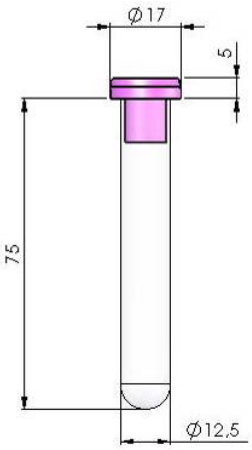
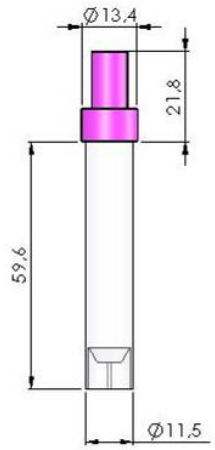
	VACUETTE (GREINER BIO-ONE)	VACUTAINER (BD)	'RUBBER' [RUBBER CAP, BD, TERUMO]	'SARSTEDT' (See Note !)
Models				
Dimensions (mm)				

fig. 1.2.2.1

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 compatible test tubes are those described in fig. 1.2.2.1

The described test tube models in the figure1.2.2.1 are essentially different in height.

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 explusion group and to the inserter tube (where the addition of a nestable guide is requested) besides the use of new mails of the chain (for explanation please contact a specialized tecnician 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:

- n°1 Operating Manual, in ENGLISH (on paper) [Ref.: R30600540]
- n°1 CD “Ves-Matic Cube 200 Multilingual user manual” [Ref.: R30650030]
- n°2 Sample holder racks [Ref.: R30003650]
- n°2 Rack input extensions [Ref.: R10338870]
- n°2 Lifting handles [Ref.: R10340531]
- n°2 Microswitch keys V.2 [Ref.: R10345060]
- n°1 Roll of thermal paper h.mm l=57 D=50 [Ref.: R12300000]
- n°2 Delayed 5x20 mm UL fuse blocks 5A [Ref.: R20400070]
- n°1 Power cable 3x0.75 L =2m SCHUKO 90°-C13 [Ref.: R21890040]
- n°1 Power cable SVT PLUG USA/OUTLET VDE 2MT UL [Ref.: R21890370]
- n°1 Barcode reader Z-3080+Cable CAB50607-R9 [Ref.: R20550510]
- n°1 Packing-list
- n° 1 Installation guide
- n° 1 Warranty Card
- n° 1 Final Inspection report

Based on the product model the following accessories are supplied

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

- n°1 Rack holder Sysmex (*with model code 10370/S*) [Ref.: R30207890]
- n° 1 Programming guide ALPHA-60M [ZEBEX] [Ref.: R30600560]

With Ves-Matic Cube 200 model10370/A, for blood cell counters ADVIA® BAYER

- n°1 Rack holder Bayer (*with model code 10370/A*) [Ref.: R30207900]
- n° 1 Programming guide ALPHA-60M [ZEBEX] [Ref.: R30600560]

With Ves-Matic Cube 200 model 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]

Sample holder Rack

Microswitch keys V.2

Barcode reader Z-3080+Cable CAB50607

Delayed 5x20 mm UL Fuse block 5A

Power cable 3x0.75 L=2m SCHUKO 90°- C13

Rack input extensions

Roll of thermal paper H.mm L=57 D=50

Power cable SVT PLUG USA/OUTLET VDE 2MT UL

Consumables

▪	Check device test tube 1K for Ves-Matic Cube 200 (1000 hits)	[Ref.: 10292]
▪	Check device test tube 5K for Ves-Matic Cube 200 (5000 hits)	[Ref.: 10291]
▪	Check device test tube 10K for Ves-Matic Cube 200 (10000 hits)	[Ref.: 10290]
▪	ESR Control 9ml (2 Bottles Normal + 2 Bottles Abnormal)	[Ref.: 10430]
▪	ESR Control 9 ml (1 Bottle Normal + 1 Bottle Abnormal)	[Ref.: 10434]

The safety and performance requirements of the instrument can not 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.

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

Current	Europe: 230Vac@50Hz;Usa/Canada: 110-120Vac@60Hz	
Absorbed electric power	265VA	
Fuse block	2 x 5,0 AT (Delayed) (5 x 20 mm) UL	
Dimensions	650 x 680 x 690 mm (l x h x d)	
Weight	70 Kg	
Room temperature	In exercise	from +15 to +35°C
	warehouse	from + 5°C to + 45°C
Allowable relative humidity	from 20% to 80% without condensation	
Central unit	Microprocessor Intel XScale PXA 255 32 MB; FLASH 64MB SDRAM	
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	
Optic groups	Two couples of optic-electronic elements (Led & analogical sensor)	
Printer	Alphanumeric with thermal paper wide 58mm, 36 characters per line, speed 20mm/sec.	
Interface	2 x RS232C, 2 USB Host, 1 USB Client, 1 Slot Compact Flash	
Protection category	CLASS I	
Security of the device	EN61010-1	
EMC	EN61326-1	
Installation category	II	

1.5 BLOCK SCHEMATIC

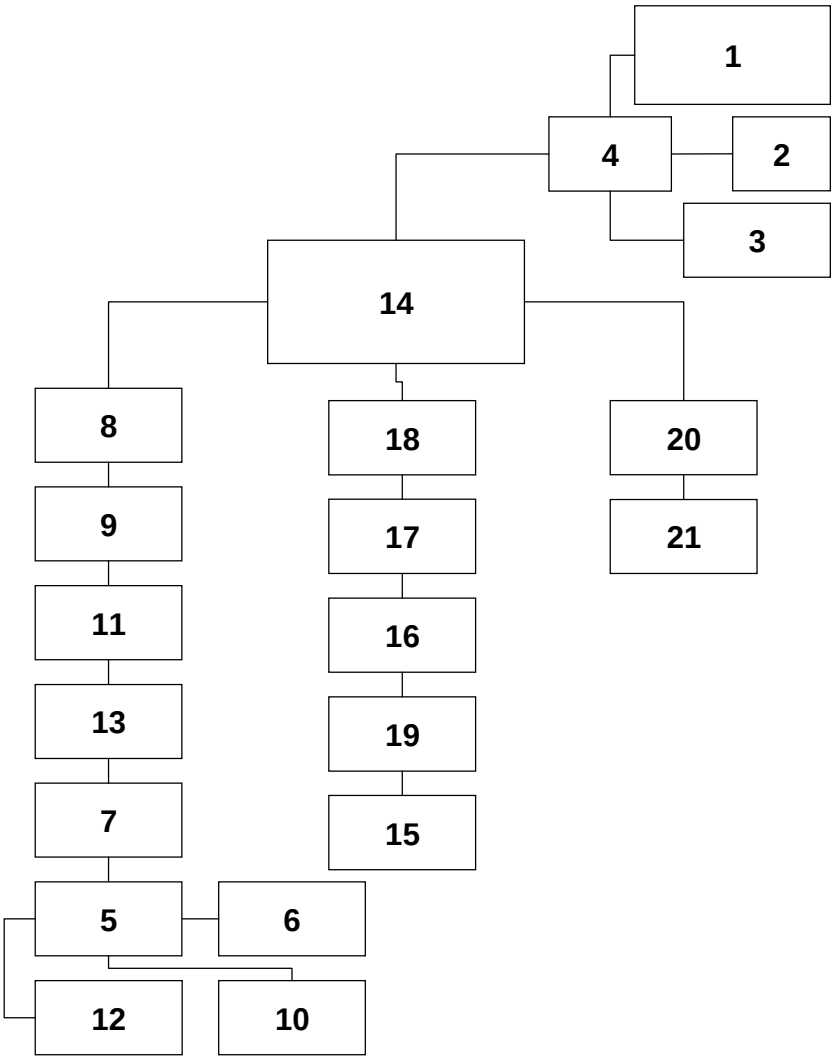


Fig. 1-5 Block Schematic – Ves-Matic Cube 200

(More detailed schemas are contained in the Service Manual)

LEGEND:

1- Tablet PC (with Display and keyboard)
2- Printer
3- Interface external connections
4- Serial Interface 232/485
5- Rack detection card
6- Internal barcode reader
7- Front Transferer
8- Back Transferer
9- Test Tube Extracter (only model Advia Bayer® and Beckman Coulter)
10- Right Translator
11- Left Translator
12- Clamp group
13- Automatic test tube inserter
14- Feeder
15- Motor chain group
16- Mixing group
17- Reading group 1
18- Reading group 2
19- Expulsion group
20- Test Tube Transferer
21- Sample holder rack puller

1.6 TECHNICAL DESCRIPTION OF THE INSTRUMENT

The "Window group constitutes of :

- 'TABLET PC'- Central unit

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

  It is out-fitted with:

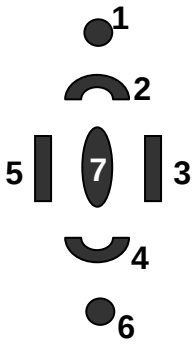
  - DISPLAY

    Allows the display and interaction (by means of a touch screen) with all the software functions.

fig. 2.1

  - KEYBOARD

    The keyboard functions are carried out by both the touch screen system (fig. 2.1) which allows interaction with all the control software functions, as well as the 7 buttons (fig2.2), 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

- ACOUSTIC SIGNAL SYSTEM

  Functions as an alert to call the attention of the operator during specific phases of the work cycle: each time the instrument is switched on, it emits a special signal to notify that it is on, each time that a button on the keyboard is pressed it emits a characteristic “beep“, and additionally, to signal a problem it emits a specific alarm sound.

- PRINTER

  Prints the information regarding the processed test tubes (date, time, temperature, sample code, ESR) contained in the sample holder rack and all useful information regarding the working cycle (date, hour, temperature).

- RACK MOVEMENT GROUP

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

  By means of a combined movement of two *trasferers* and of 2 *traslators* the racks rotate anti-clockwise inside the module to be transferred to the bar code obtaining position and to the position where the test tube is withdrawn from the *preparator*.

- RACK PRESENCE DETECTION GROUP

An 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 READING GROUP

This group executes the barcode reading of each sample so that the instrument can execute a Host Query to differentiate the test tubes that have to be processed for ESR and that have to be inserted in the underlining test tube holder chain.

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

- CLAMP GROUP

Sustained by 2 motors that provide for the vertical and horizontal movement of the clamp, this unit provides for the withdrawal of the test tube from the haematology rack and for the transfer of it to the inserter tube.

- INSERTER GROUP

Connection unit between preparer module and analysis module which guides the test tubes to be processed from one destination to the other..

"Analysis module constitutes of:

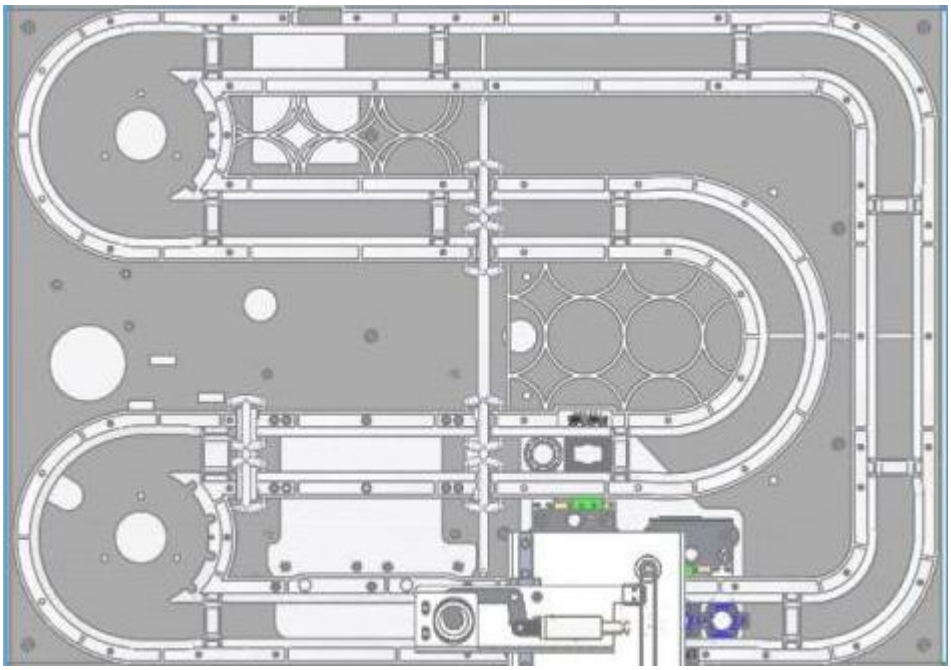
- POWER SUPPLY GROUP

  Composed of 3 switching power suppliers; supplies the electrical current tensions to the various modules following a criterion for the allocation of charges.

- 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 mixing 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.



- MIXING GROUP

  Unit in charge of the execution of the inclination and rotation by 120° 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

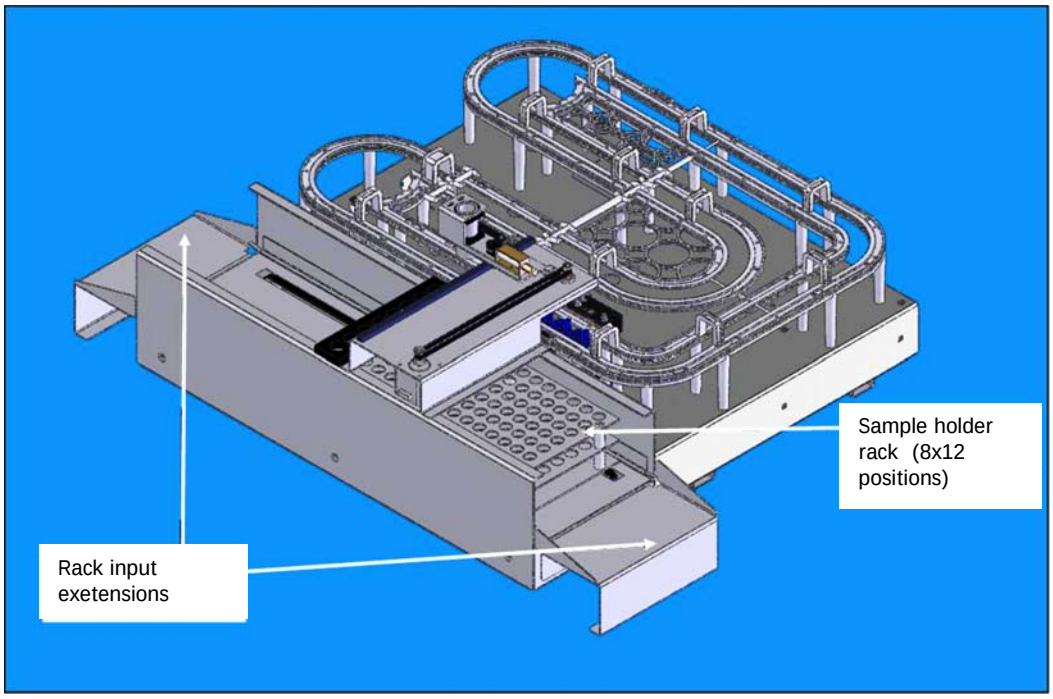
  Measures the temperature inside the instrument and is positioned in the analysis module. The value of the temperature is visible in the 'temperature window' on the display.

- EJECTOR GROUP

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

The "Classifier module":

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



- 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 (8x14 positions per rack).

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

1.7 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

Therefore:
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

2 CHAPTER 2

2.1 PREPARATION AND CHECKS BEFORE INSTALLATION
2.2 PLACEMENT
2.3 LIMITATIONS AND WARNINGS

Installation must be carried out by a technical installer authorized by Diesse Diagnostica Senese SpA with a resulting installation report. Refer to the Installation guide.

The disconnection and expedition fo the instrument had to be done by a technician authorized by DIESSE Diagnostica Senese S.p.A.

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.

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.
Furthermore it is advised that the Ves-Matic Cube 200 be placed far from possible generators of Electro magnetic waves (for example fridges, laboratory centrifuges) and from instrumentation without the CE mark, since they could affect the proper 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 80cm 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 40cm, 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.
Choose a position close to an undisturbed outlet free from electrical fluctuations.

fig. 2.2.2. <u>left side</u> of the Ves-Matic Cube 200 (exiting sample holder rack)

fig. 2.2.3.<u>right side</u> of the Ves-Matic Cube 200 (entering sample holder rack)

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 be disconnected from the power source and covered.

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)

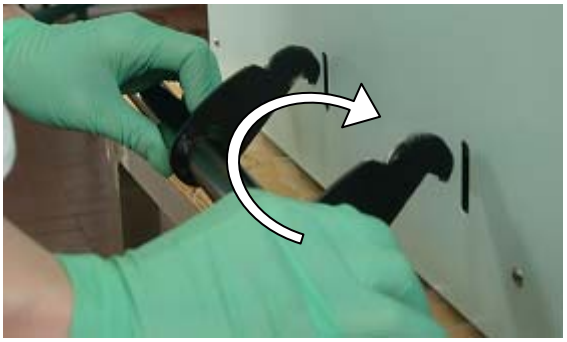


fig.2.2.4 a

fig.2.2.4 b

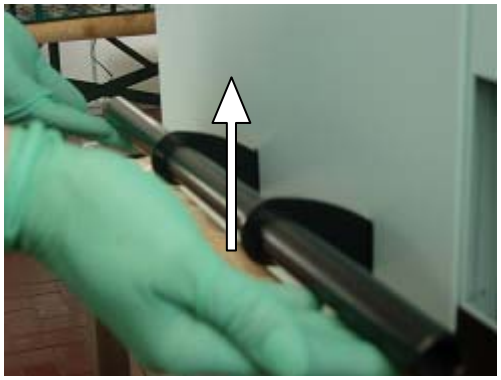
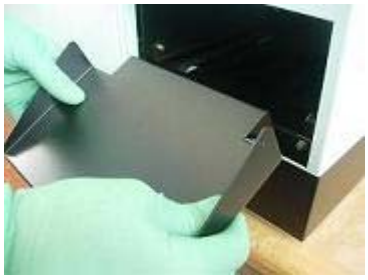


fig.2.2.4 c

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

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 power switch on the instrument itself (as shown in fig. 2.2.5) Connect the plug of the power cable to the power network.

Figura 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).

Limitations regarding the Check Device (consumable buyable for the use of the instrument): **the instrument is provided with special 'Ves Check Device test tubes" destined to refill the "test counter" of the instrument; these are inserted as normal test tubes in the sample holder rack; the refill of the test counter is automatic and the used check device will be removed for the instrument as a normal sample. (see paragraph 3.3).**

Using other material types can seriously jeopardize the performance of the instrument.
DIESSE SpA declines every responsibility on the performance of the instrument if the materials used are different from those indicated in this manual.

All Ves Check Device test tubes supplied can be used only once and can't be used again.
All empty Ves Check Device test tubes have to be disposed of according to the laws in force.

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.

3 CHAPTER 3

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 <<1>> (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

Below is a depiction of the main menu screen.

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 (for example Rack ADVIA BAYER and test tube VACUTAINER BD) fig. 3.2.a)

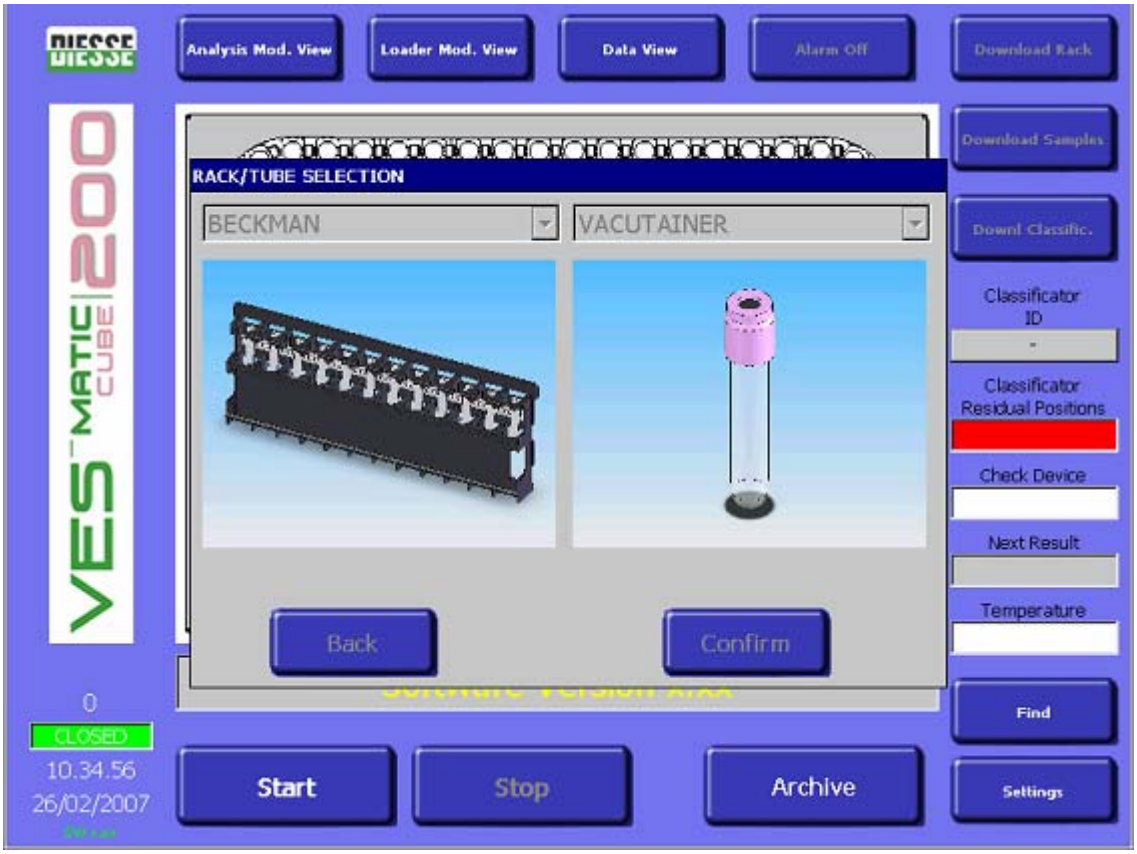


fig. 3.2.a

From the Main Menu, 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: “Analyses Mod view””, “Prearat. Mod Vew”, “Data View”)
- . Unload samples that remained in the sample holder chain
- . Unload the sample holder racks
- . Unload the loading racks, of present, form the Preparer Module
- . Access the database of the instrument

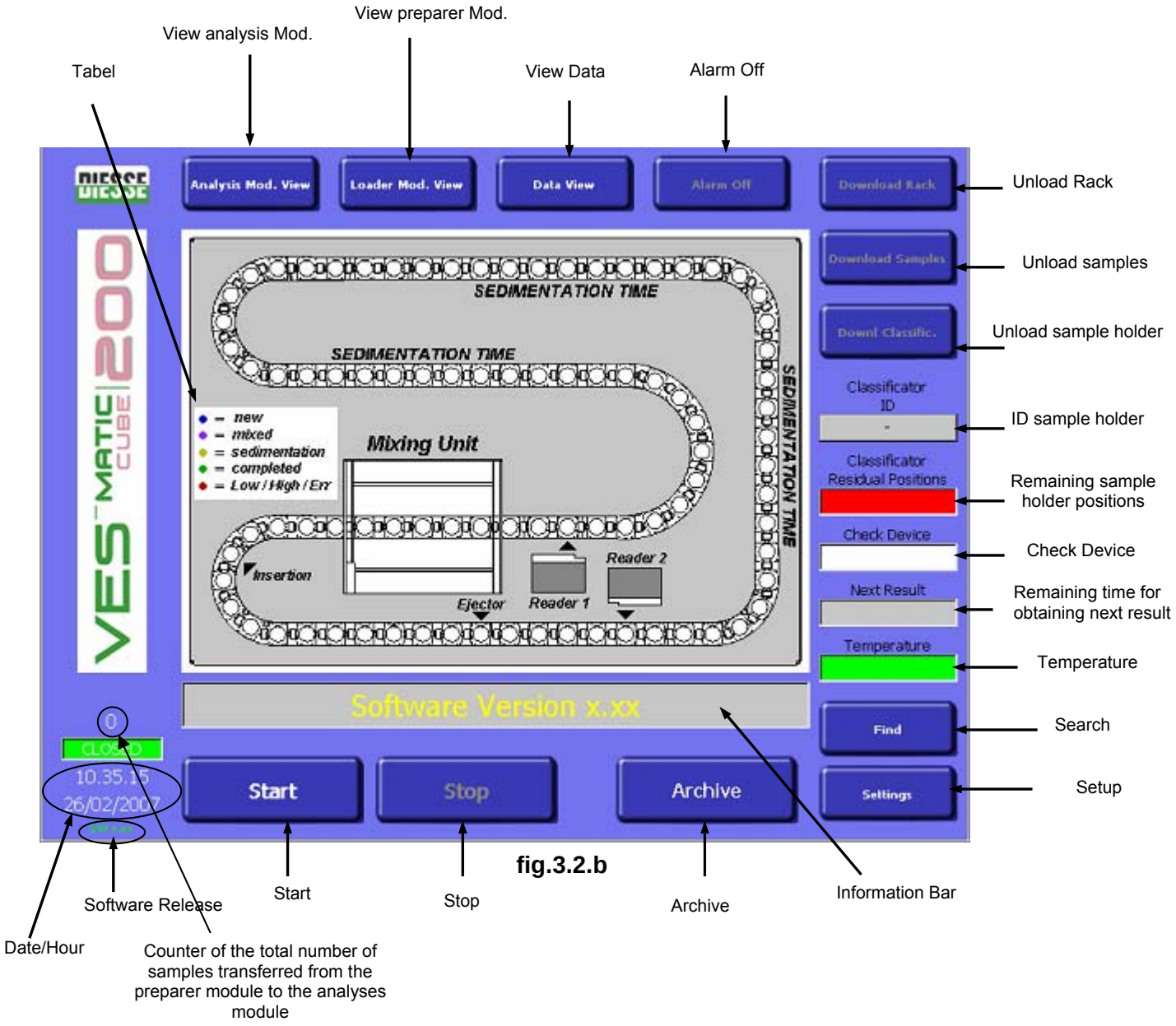


fig.3.2.b

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 off 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.

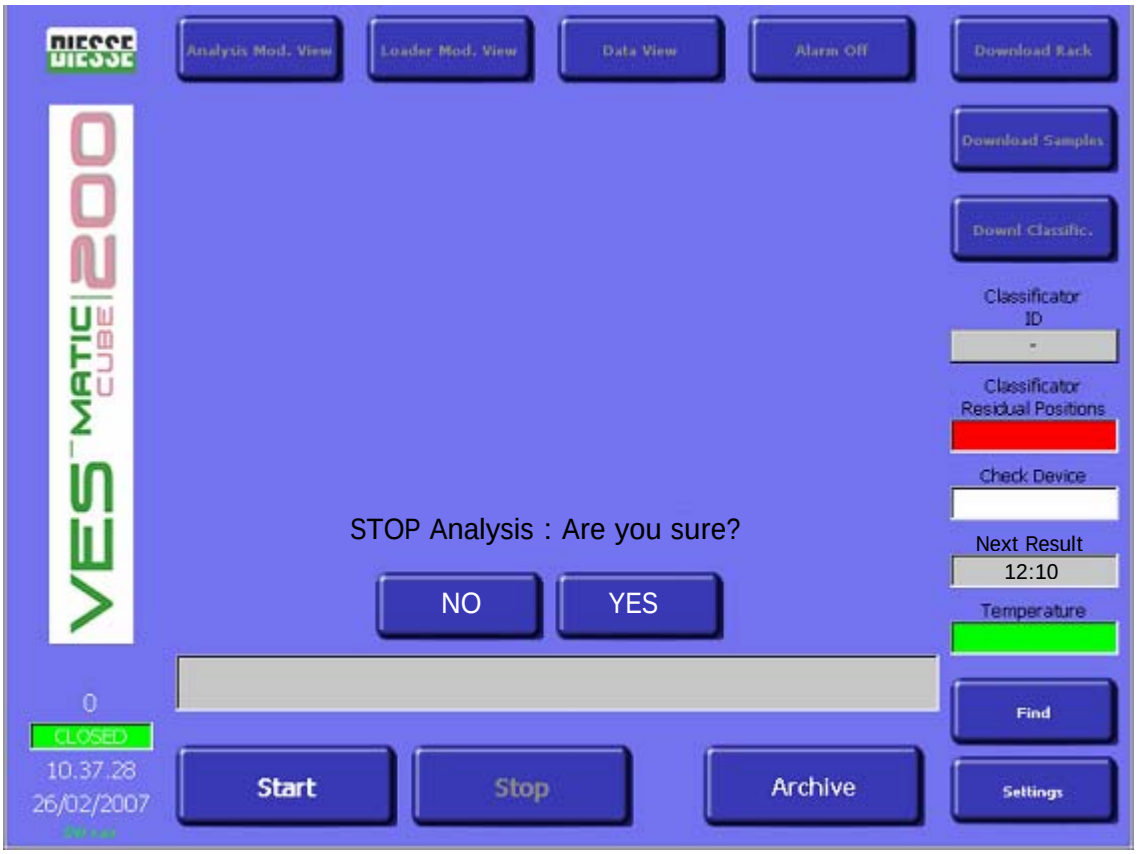


fig. 3.2.c

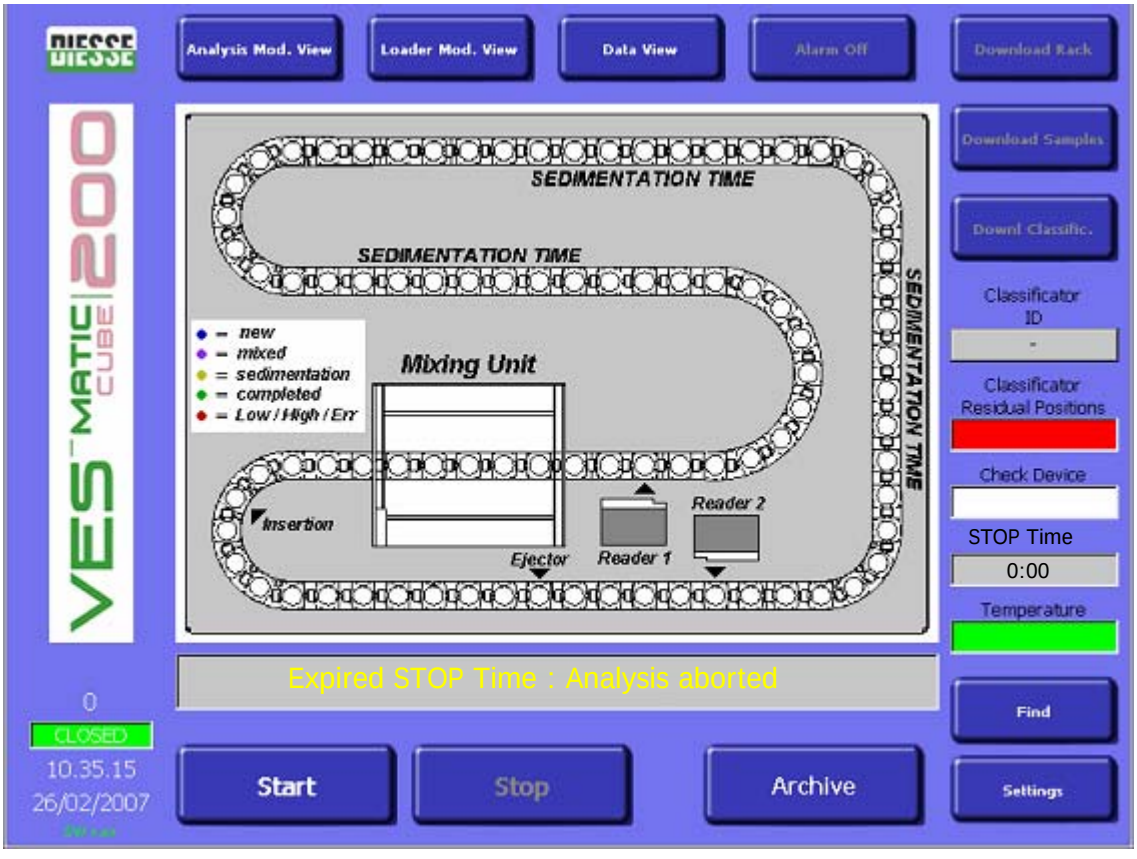


fig. 3.2.d

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 without changing the sedimentation. 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 analyses cycle is re-started within 90 seconds, the instrument will resume the analyses of the samples present in the analytical chain and will complete the reading of the relative ESR; the data of the test tubes present in the analytical chain during the "Stop time" are not lost and the link of the barcode of each sample with the relative position in the analytical chain is maintained to guarantee a correct correspondence between the data of the sample (especially the link ID(result).

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 preparer 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

Alarms 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 tests still executable on the instrument. The green color of the window indicates that more than 500 tests are available, the yellow color indicates that from 500 to 250 tests are available, while the red color indicates that remain 250 to 0.

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

Temperature: indicates the temperature on the inside of the instrument

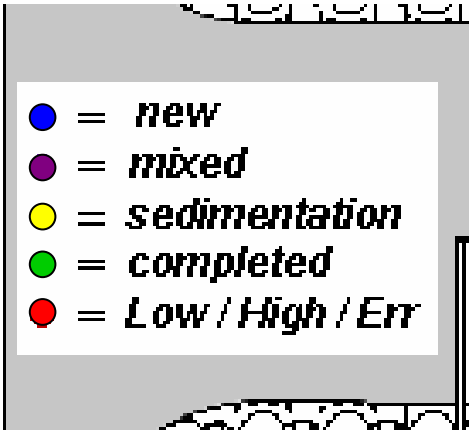
Information bar: shows important information such as the error code (see the table in paragraph 6.1 "Trouble shooting")

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.

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.



Displayed table

- = new (new sample to analyse)
- = mixed (sample being mixed)
- = sedimentation (sample in sedimentation)
- = completed (sample analyzed with success)
- = Low/High/Err (sample for which a problem was enountered, for more explanations see paragraph 3.4)

Unload rack: brings racks 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 an extended blackout.
Unload sample holder: ejects the sample holder rack.

Rack emptying procedure

The rack emptying procedure recovers the racks located at the back of the loading zone; for example recovering an urgent sample or in the case of a shut-off of the instrumental due to a blackout.

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 (preparer module)**
3. **Remove the rack and repeat phase 1 and 2 if necessary**

SEQUENCE OF THE OPERATIONS IN CASE OF A BLACKOUT

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 3. (if necessary insert a sample holder rack)

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 blackout.

SEQUENCE OF THE OPERATIONS

1 Push the STOP button

2 Push the "UNLOAD Classific."button and wait for the end of the procedure.

Description of the commands and information in the View Preparer module mode

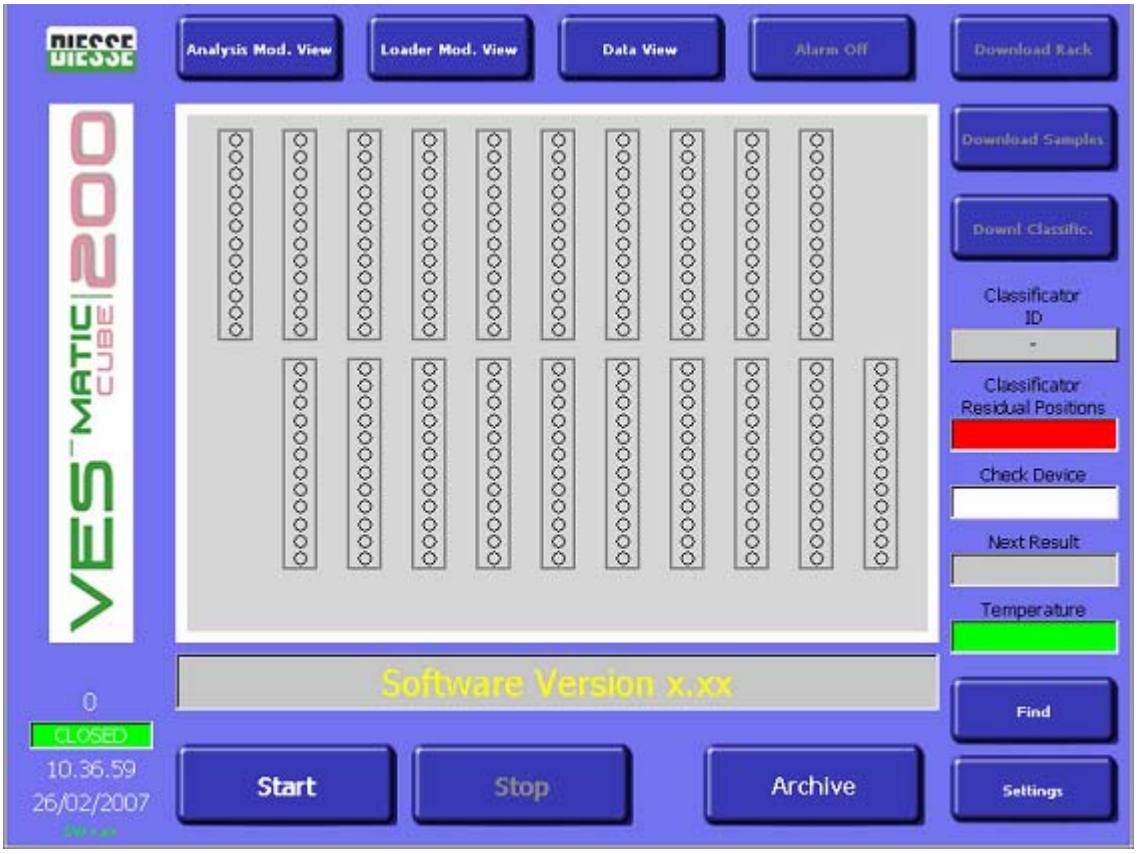
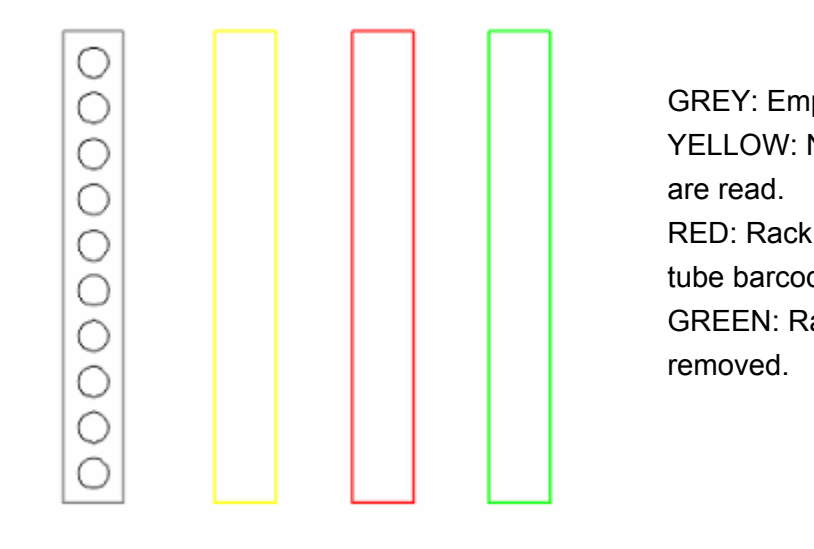


fig. 3.2.e

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)

Colour code of racks in View Preparer 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.

The colour of the corresponding LED supplies a further indication: green; already processed, red; to be processed.

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)

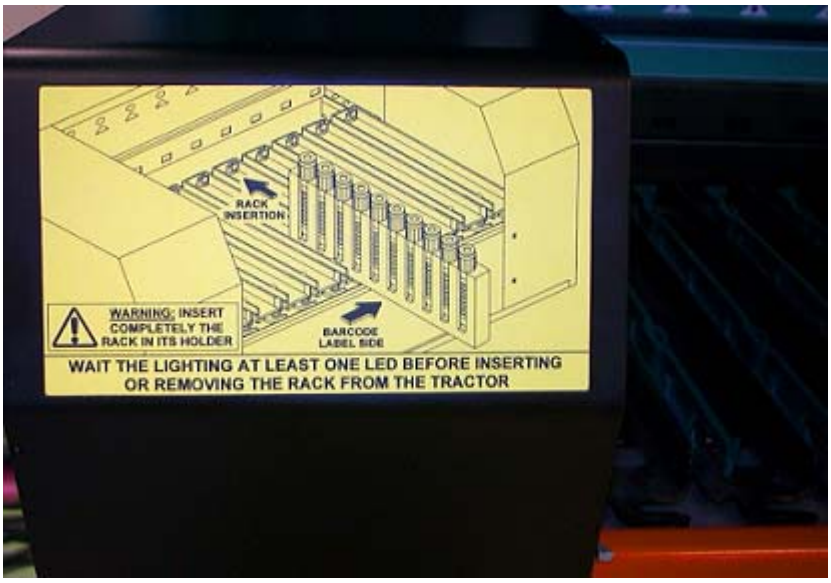
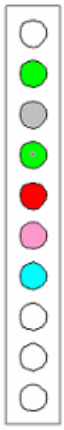


Fig. 3.2. bis

Fig. 3.2. 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

Colour code of positions in the rack in View Preparer mod.ule 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 be cause of mechanical problems.
PINK: Check Device test tube (see paragraph 3.3)
TURQUOISE: test tube found in the rack following the search sample procedure.

Description of the commands and information in View Data mode

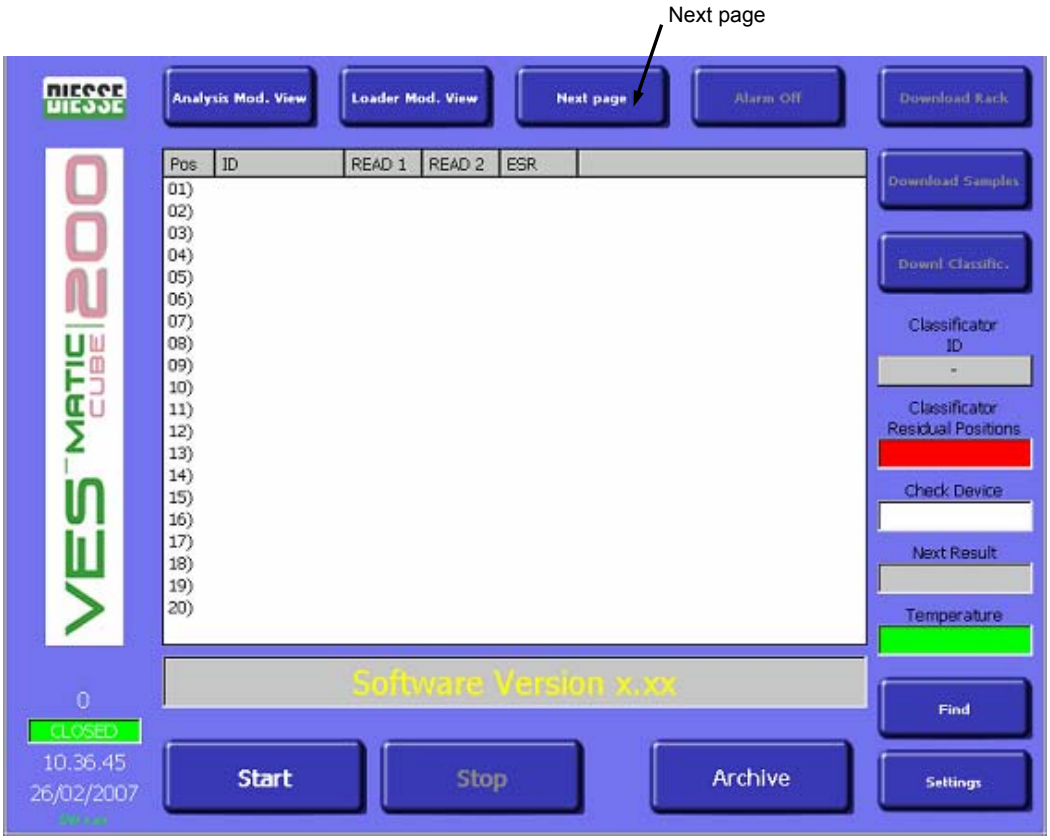


fig. 3.2.f

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, 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.

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) which indicates the position occupied by the test tube and found following the "search sample" procedure.

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.

Preparer 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.

3.2.2 Archive menu

Choosing the **ARCHIVE** command in the main menu, the functions of the ARCHIVE Menu are accessed.

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.

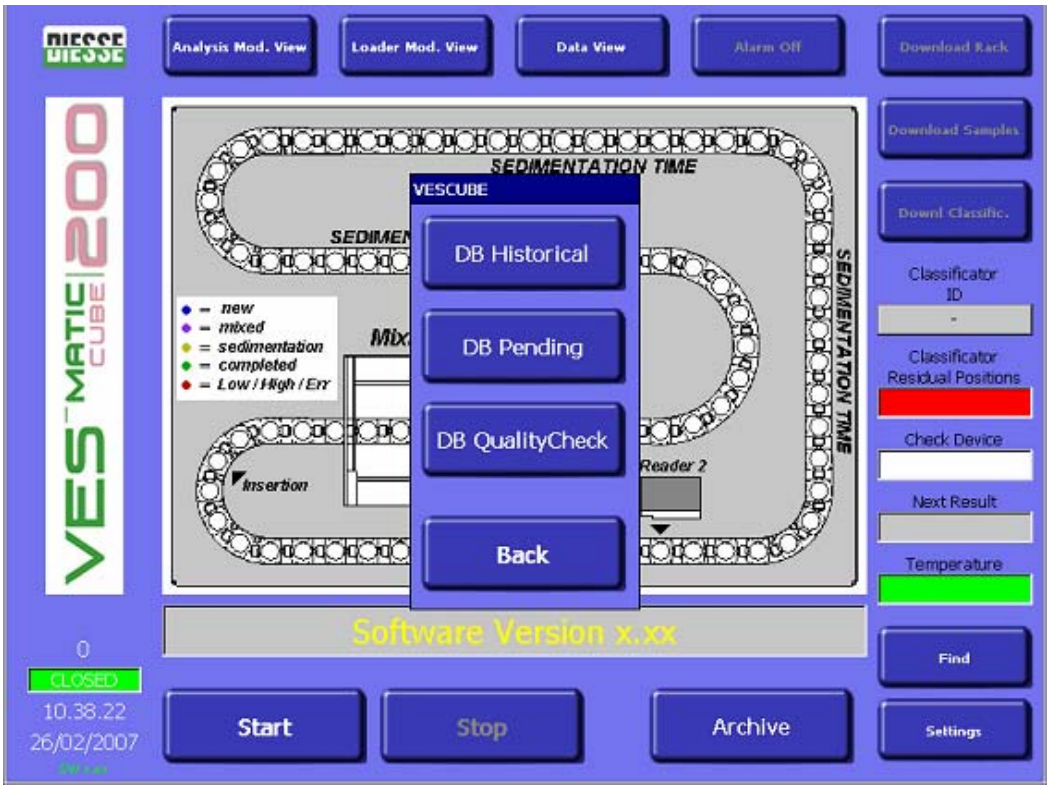


fig. 3.2.h

DATABASE (ARCHIVE)

There are 3 archives (fig. 3.2.h):

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 samples sent to the host will be highlighted with an asterisk.

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. The results of these samples can not 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), after which all information about the sample will be removed. The device, 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.

2 Samples with bar codes 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 bar code reader or manually with the virtual Windows CE keyboard). This way the devices will be able to ask authorization to the host also for these samples.

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 manoeuvre 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. (see paragraph 3.3)

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 windowsCE keyboard

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 relative data.

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.
FIND: equals an “enter”, has the function of sample search based on the date.
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: total number of samples present in the list that is displayed.
Error legend: interpretation of the letters indicated in an error code.

Further more 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
Rack ID: identification of the sample holder rack.
R Pos: position in the sample holder rack (identified by an alphanumeric code)

Description of the commands and 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 Preparer Mod.)

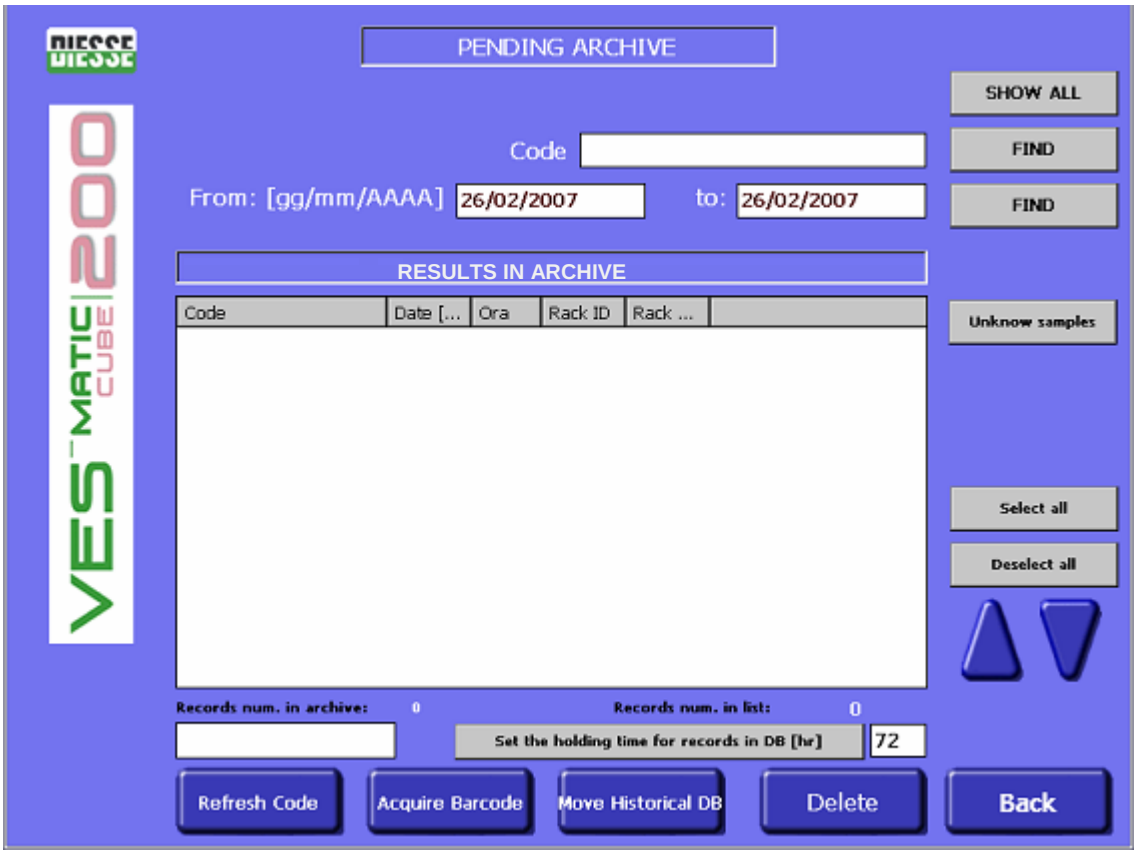


fig. 3.2.j

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 bar code into the field above this command.
Read bar code: allows the input of a bar code by means of the external bar code reader, in case it is not read by the reader inside the instrument

Send to host: sends the selected sample(s) to the host
Eliminate: eliminates the sample(s) selected
Print: prints 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, 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: 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
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)

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 Quality check 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
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
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
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)
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 Description of the commands and information of the Setup menu

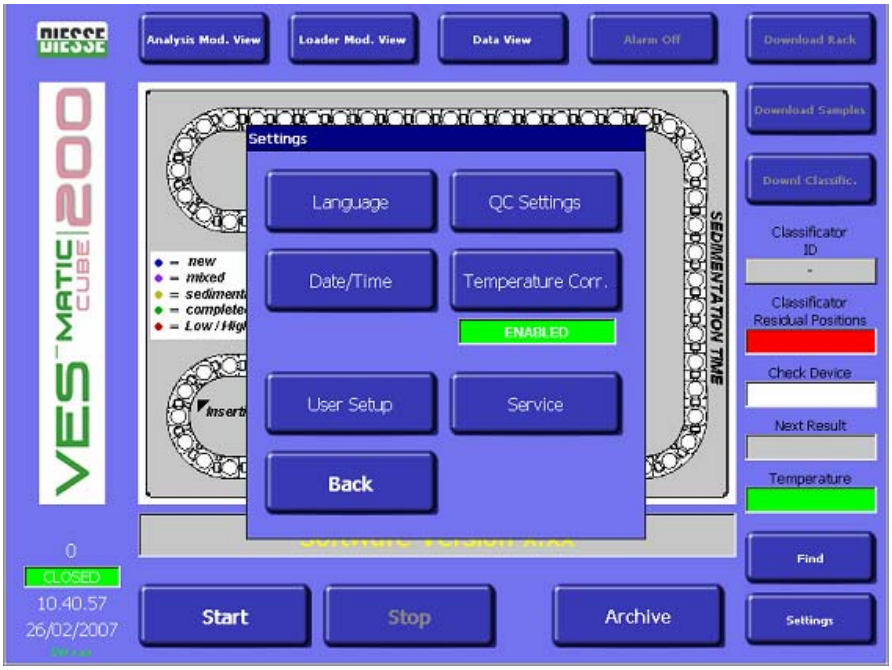


fig. 3.2.I

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.

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

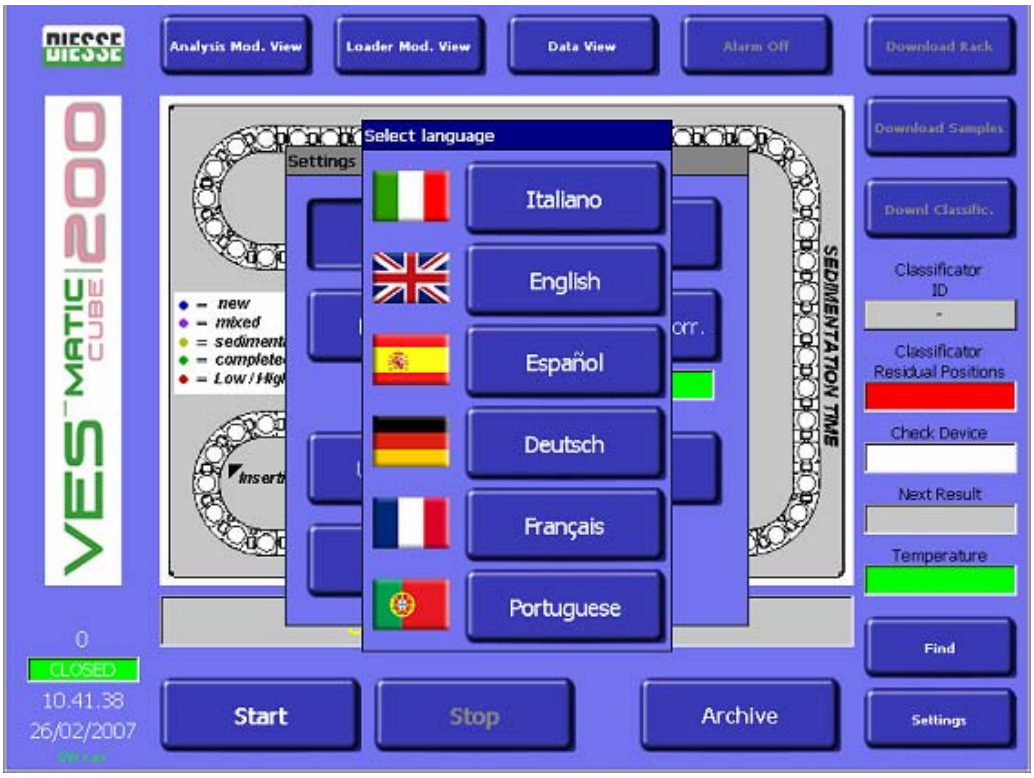


fig. 3.2.m

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 manage them in a different way from the normal samples.

To setup any QC parameter select, by touching it, one of the available white fields (bar code, lot number, expiration date, minimum value, maximum value); immediately the virtual Windows CE keyboard will appear for the input of the values. To cancel possible typing errors simply touch to the right of the character to cancel and to use the BS (back space) button, that allows to cancel a character at the time.

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”)

fig. 3.2.n

To setup any parameter select, one of the available white fields; immediately the virtual WindowsCE keyboard will appear for the input of the values.

Date/time: allows the set up the date and time of the system. Pressing this button the **Set Date/Time** window (fig. 3.2.o) will appear.

EXPLANATION OF EACH SECTION :

Date: Set up date
EXPLANATION OF THE FIELDS:
DD: set up the day, using the buttons + and -
MM: setup the month using the buttons + and –
YY: setup the year using the buttons + and -

Time: setup time
EXPLANATION OF THE FIELDS:
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”)

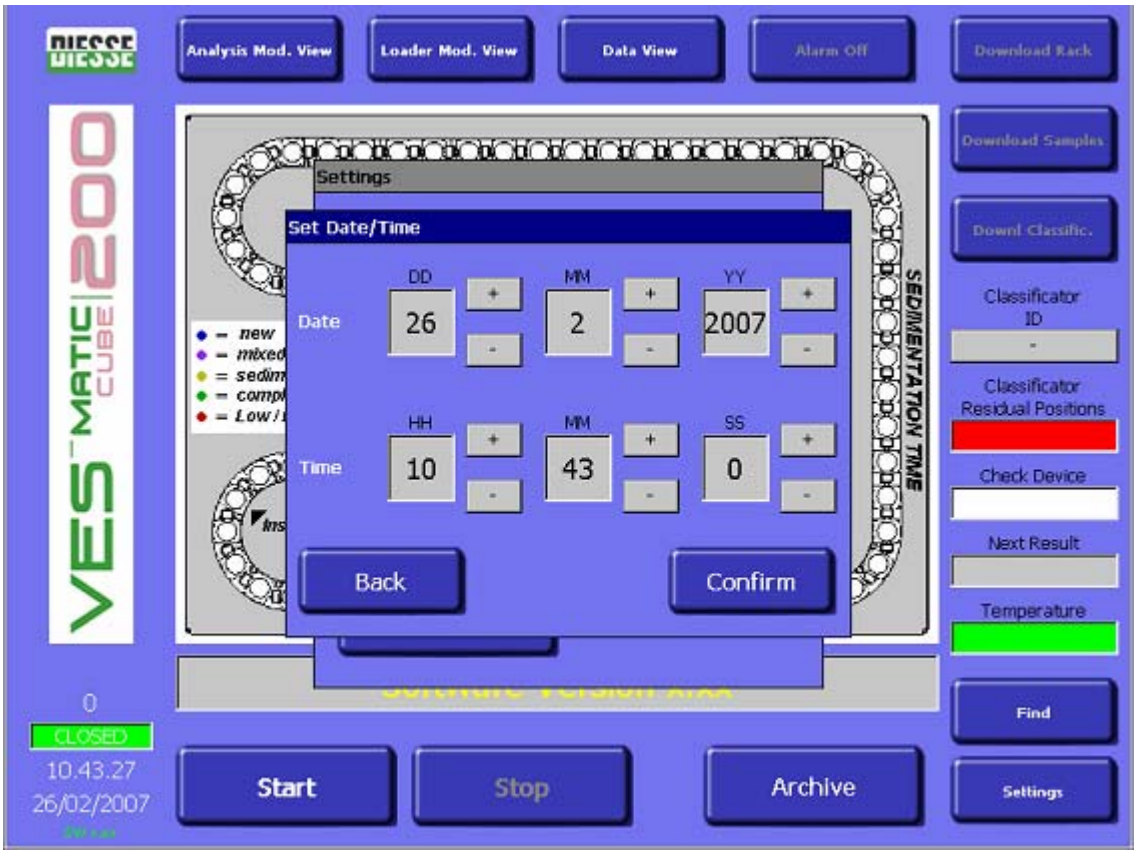


fig. 3.2.o

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’)

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.

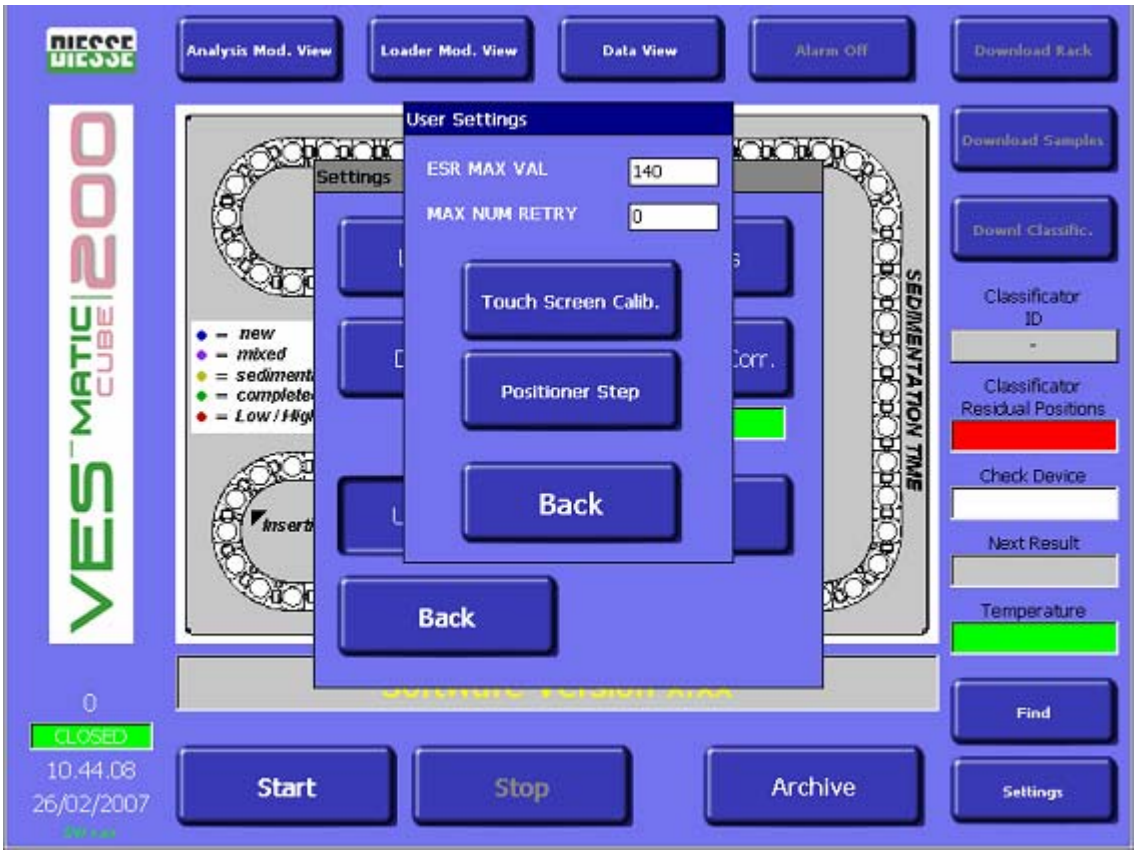


fig.3.2.p

DESCRIPTION OF THE FIELDS

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 of with the general switch.

Positioner step: this command allows to retrieve quickly a test tube from the analytical chain; in fact after opening the front panel of the instrument 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.

This procedure is against the warnings as mentioned in 'LIMITATIONS AND WARNINGS' and should be operated only after consulting technical assistance.

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

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**.**

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 with a "check device test tube" (see fig 3.3 a and paragraph 1.3:"*MATERIAL SUPPLIED WITH THE INSTRUMENT")* The "check device test tube" has the dimensions and appearance of a normal haemocrome test tube and has to be handled as such; to reload the instrument simply insert the "check device test tube" in a rack along with the test tubes containing the samples and start the analytic cycle: the "check device test tube" will automatically transfer the reload to the instrument.
At the end of the operation the "check device test tube" is empty and can not be used again, extract it from the sample holder rack where it's positioned and send it to the disposal following the norms in force. The presence of the "check device test tube" in the instrument is indicated by the special pink colour (color code) that it individuates.

fig. 3.3 a

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 save 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:

1. 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.
2. 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.
3. 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.
4. The results regarding the tubes requested by the host are 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.
5. 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.
6. After a stay of 72 hours in the Pendings archive the data of the test tubes will be removed.
7. 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.
8. 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 is 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 check device to refill the test counter. The number of the tests available in the instrument is indicated by the precise number in the dedicated window, and furthermore its color informs the user of the remaining availability of the tests; in fact the green color indicates the possibility to execute more than 500 tests, the yellow color indicates that the tests available are between 500 and 250, while the color red indicated that less than 250 tests remain available.

3.4 GUIDED READING OF THE RESULTS PRINT

The print of the results regarding the 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, 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.

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 according to this order: the name of DIESSE, the name of the instrument, the release of the software(V. X.xx), the serial number of the instrument (SN), the temperature detected inside the instrument (in C°), the correction of the temperature (active = ‘ON’, not active = ‘OFF’), the date (DD/MM/YYYY) and the time (HH/MM/SS) of the execution of the analyses, the barcodes, the corresponding ESR value and the position of the sampel 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, because that’s the number of spaces available in each sample holder rack. This is case taken into account in point 1 of this paragraph) 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 point2 of this paragraph, only the number of samples contained in the rack and there data will be reported.

* *

DIESSE S. p. A.

* *

VES MATIC CUBE 200 V. 2.20

SN: 2007- 01- 00XX
TEMPERATURE : XX °C
TEMPERATURE CORRECTION : ON
DATE : DD/MM/YYYY
TIME : HH/MM/SS

– –

ID BarCode	WEST 1H	POS NUM
76543328	16	C5
98765499	15	C4
51432109	5	C3
13579111	8	C2
88776655	47	C1
43325544	HIGH	B8
76554888	29	B7
65334567	32	B6
53435661	57	B5
90087006	6	B4
99887788	ERR	B3
65432211	9	B2
……	17	B1
44332255	14	A8
53435543	43*	A7
44326518	52	A6
55467839	24	A5
08975543	18	A4
07869977	LOW	A3
07865234	65	A2
07865432	24	A1

COD SAMPLE HOLDER: 1234

When in the column “ID BarCode” a sequence of points appears this means that the internal barcode reader did not read that code, but 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 Pendings Archive. At this point the operator can continue as described in 3.2.2 “Archive Menu: Historic DB and Pendings 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 (≤ than 1,5 ml). Verify the level of the sample, in case this is lower than 1,5ml, repeat blood draw.
“HIGH”: means that the quantity of blood of the sample is excessive (> 4ml). 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 µl 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 (fig. 4.2.2a,b,c). The operator is advised to verify to exclude problems with labels, coagulates etc. and to decide whether to validate the obtained result or to repeat the analyses.

HIGH	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.
Test tube with sample level to high, above 4,5ml	
LOW	Verify the level of the sample. In case this is under 1,5 ml, repeat the blood draw.
Test tube with sample level low, under 1,5 ml	

4 CHAPTER 4:

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 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 e Advia Bayer, 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 tot 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 o opto-electronic obstructions)

fig. 4.1 a

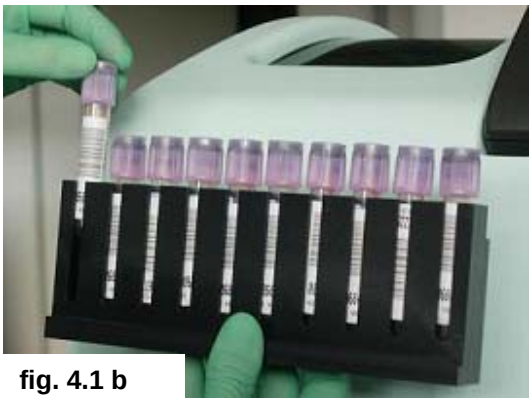


fig. 4.1 b

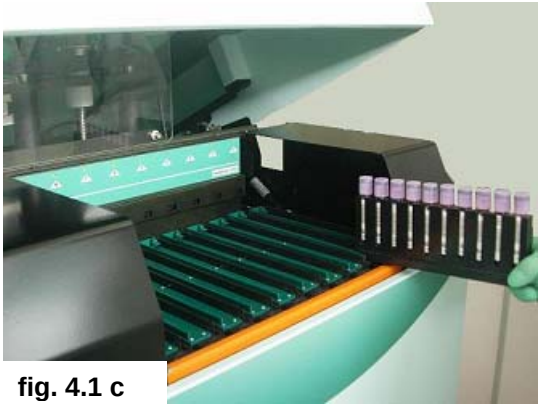


fig. 4.1 c

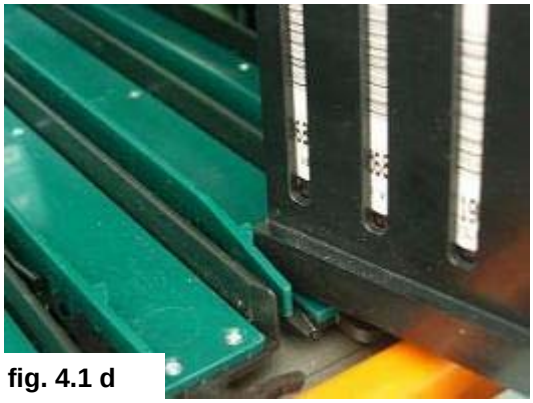


fig. 4.1 d

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 120° for 3 times every step; so after 5 steps inside the mixing zone every samples was mixed for 15 times.
- At the exit from the mixing 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 citrate ESR according to Westergren in mm/h.
- 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 preparator module (3.2, fig. 3.2.bis)

4.2 DETAILED DESCRIPTION

4.2.1 Initial power up

After the installation of the instrument as indicated in chapter 2 (paragraph 2.5), 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 <<1>>

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:

- 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)

Attention: The control blood, contained in both the Normal ESR as well as in the Abnormal ESR, is an artificial control blood with particular characteristics, such as consistent and resistant compression. Thus, to obtain the fluency necessary to execute a correct control test it is necessary to shake the samples for a long time and very thoroughly. Furthermore it is important that the control blood, at the moment of the exam, is of room temperature.

Qualtiy 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 as well as non-vacuum tubes.*
- *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 maneuver 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 the 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.**

Check of test tube labelling

Sample labelling method and compatibility with the number of lables

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 Preparer Module, is mechanically set to read labels attached to the tube at least mm.3 above the 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 + 5" (fig. 4.2.2.a ③).

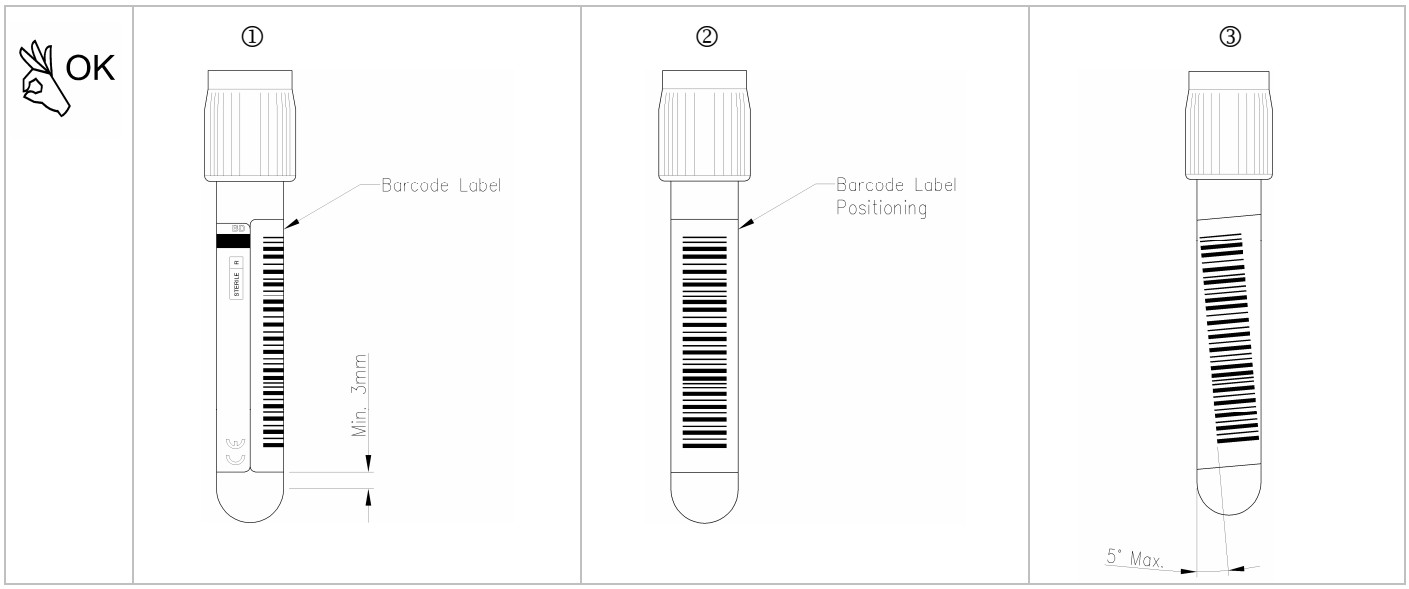


Fig. 4.2.2.a Correct height of application label on test tube

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

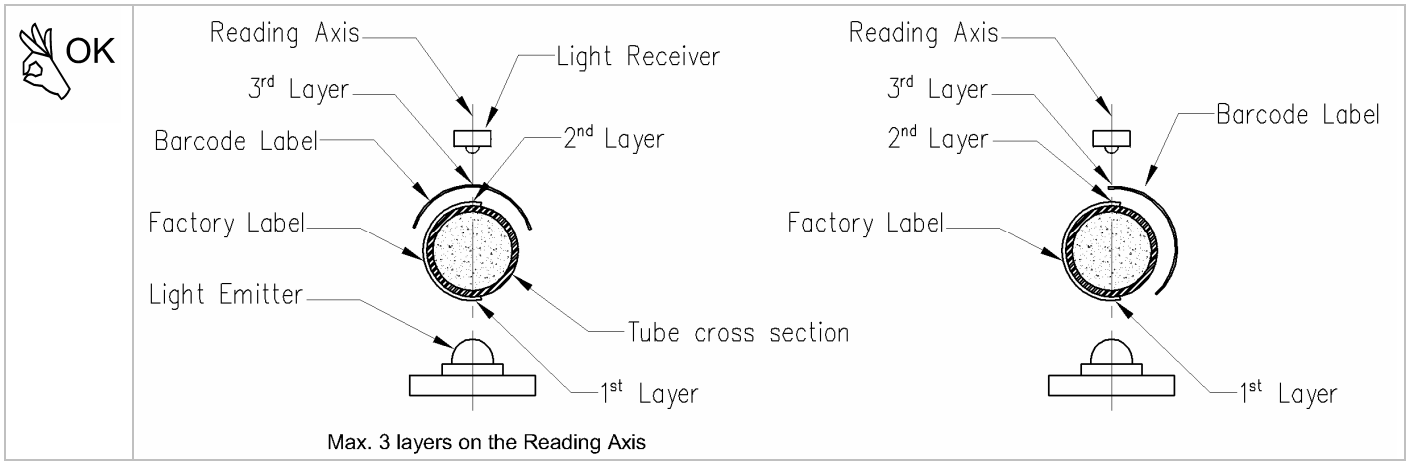


Fig.4.2.2 b Maximum number of label layers attached to test tube and accepted by the Ves Matic Cube 200'

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

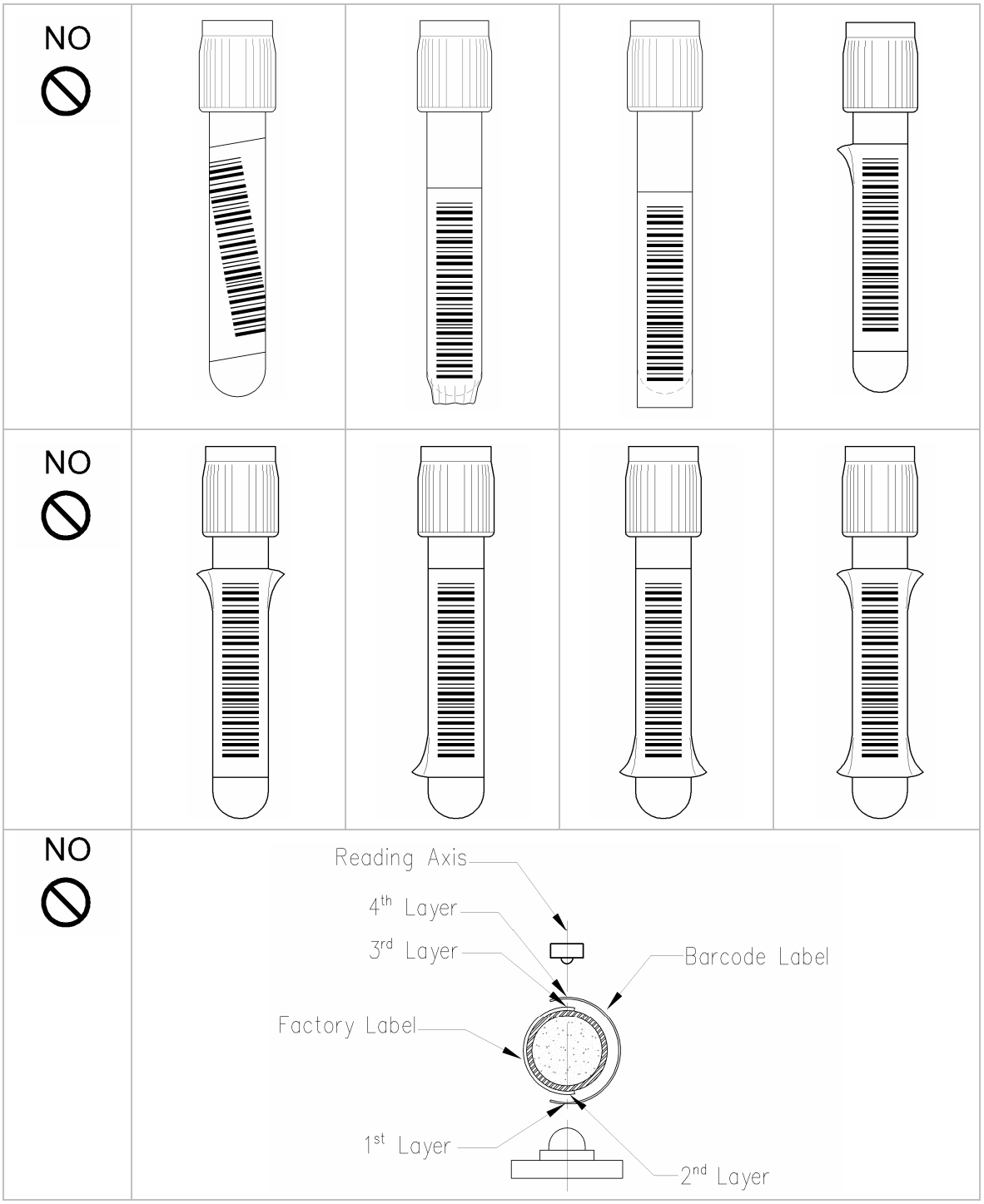


Fig.4.2.2.c Incorrect sample labeling

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 stock 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

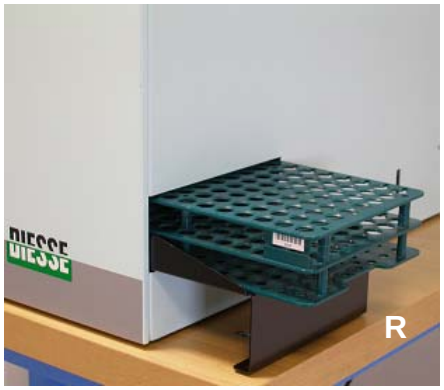


fig.4.2.3.c right side

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 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! 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 rest position.

ATTENTION

	Before starting a analysis procedure make sure that 20 rack holders are inserted correctly in the preparer module (fig. 4.1.a and fig.4.2.d) Insert the sample holder rack (for the storing of the processed test tubes) on the right side of the instrument (fig. 4.2.3.b)
	Do not switch off the instrument during the working phases or during the Reset procedure. For the safeguard of the database it is essential that the **turning off** occurs **EXCLUSIVELY after pushing the STOP button** on the display, waiting the completion of the movements.
	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 not to compromise the automatic movements and 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 hold and in the following way: 1. Free the rack from the retaining hook (fig.4.2.3.e and fig. 4.2.3.f) 2. Slide the rack horizontally in the direction of the operator **without lifting** (fig.4.2.3.g)

fig.4.2.3.d

fig.4.2.3.e

fig.4.2.3.f

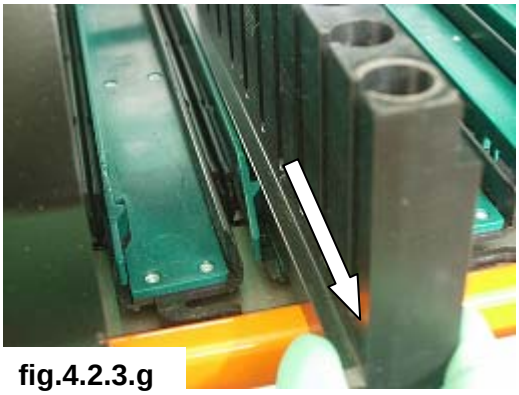


fig.4.2.3.g

4.2.4 Preparation sequence for a test

Loading procedure of the samples:

a. 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 3) lifting it until the upper click.
b. 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
c. 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 print the results of the respective 112 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

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’.

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).

5 CHAPTER 5:

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®n 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 cards.
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 net.
- 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

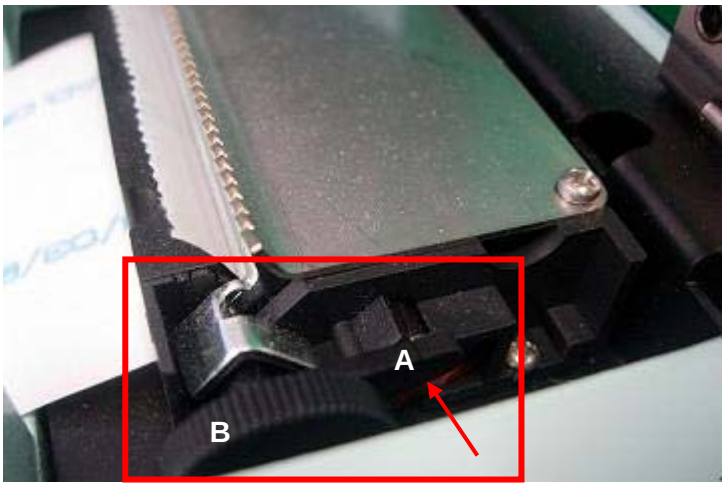


Fig.5.3 a

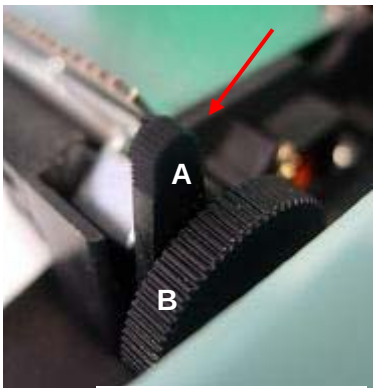


fig.5.3 b

- Connect the instrument to the power net 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)

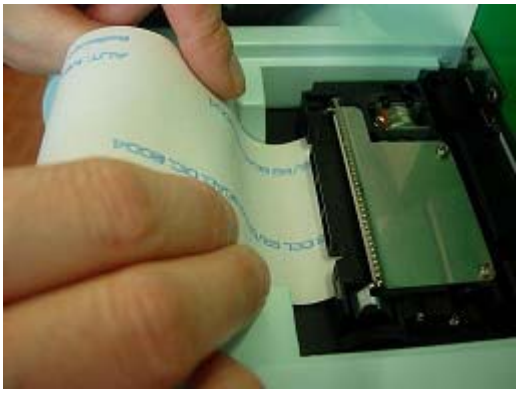


fig.5.3 c

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

fig.5.3 d

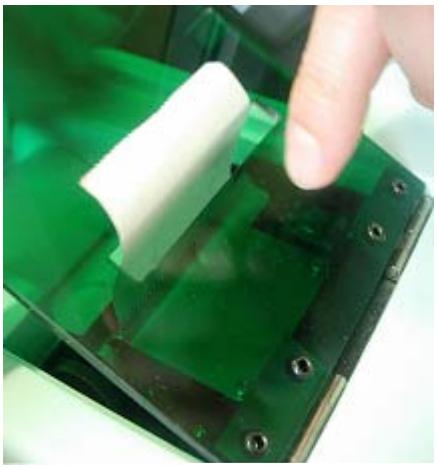


fig.5.3 e

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)

General power supply cable

Filtered outlet with fuse holder lodging

fig. 5.4. a

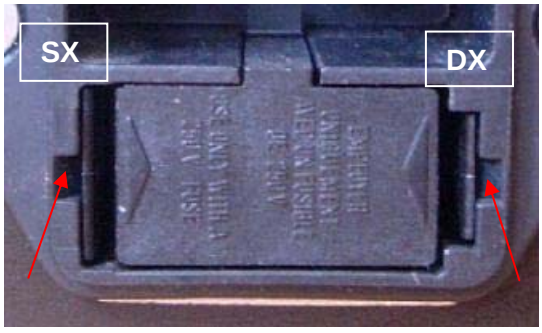


fig. 5.4. b

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.

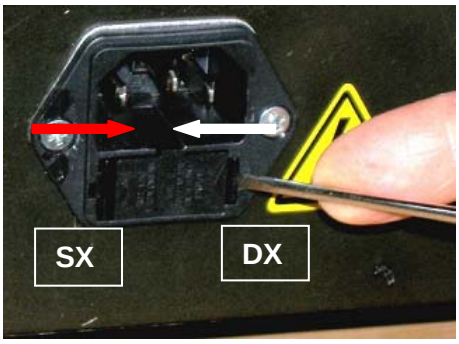


fig. 5.4. c

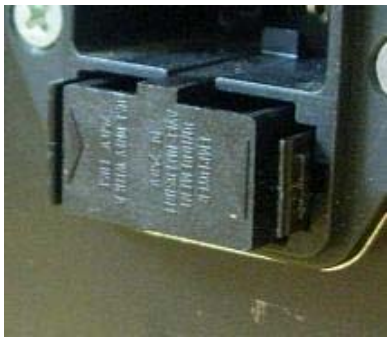


fig. 5.4. d

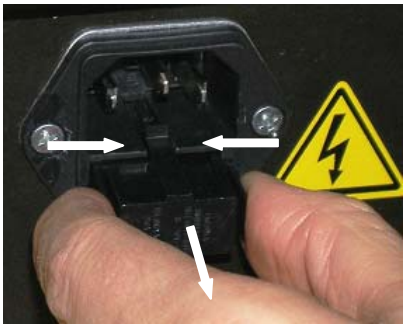


fig. 5.4. d

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.

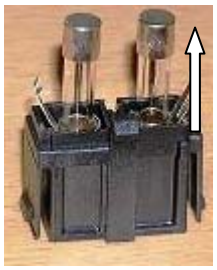


fig. 5.4. e

fig. 5.4. 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.

6 CHAPTER 6

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 an 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 6.2)
Error of the chain movement.	If the problem persists, contact technical service.
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 6.2)
Error in mixer device of the tube in the analysis module.	If the problem persists, contact technical service
Error Device 0x05 e0x06 (Reader 1 o 2)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph 6.2)
Errors in the reader devices of the optical sensors.	If the problem persists, contact technical service.
Error Device 0x07 (Sample holder)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph 6.2)
Error in the device that moves the test tubes from the chain to the sample holder rack	If the problem persists, contact technical service
Error Device 0x07 (Ph Sorter)	Besides possible electric breakdowns, mechanical obstructions can be verified that have to be removed (see paragraph 6.2)
Error caused by a test tube not detected by the removal device from the chain at the end of the cycle.	If the problem persists, contact technical service
Error Device 0x08 (Sample holder)	Press the STOP button to interrupt the analysis cycle and let the rack exit by selecting “Unload sample

Error in the movement of the sample holder rack	holder rack" If the problem persists, contact technical service
Error Device 0x09 (Ejector clamp) ***Only in Bayer models***	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
Malfunctioning of the mechanism that pushes the tube form the rack to allow the clamp to take it (only for Bayer models)	
Error Device 0x10 (Clamp Hor.)	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.
Error in the movement, along the horizontal axis, of the clamp that withdraws the tube (in the upper loading zone, preparer module)	
Error Device 0x11 (Clamp Vert.)	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
Error in the movement, along the vertical axis, of the clamp that withdraws the tube (in the upper loading zone, preparer module)	
Error Device 0x12 (Front Tractor)	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.
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)	
Error Device 0x13 (Detection Racks)	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
Error in the system that identifies the rack during the loading of the Ves-Matic Cube 200.	
Error Device 0x14 (Back Tractor)	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
Error in the movement of the rack movement group at the back side of the preparer module (behind of the rack withdrawal rack group)	
Error Device 0x15 (Left Transferer)	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
Error in the rack transfer system, in the zone behind the front of the loading compartment, preparer module	
Error Device 0x16 (Inserter)	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.
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 6.2) 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 6.2) 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 6.2) If the problem persists, contact technical service.
Page 29 SM	
Check Device running out	Insert a refill in the instrument If the problem persists at the end of the refill, contact technical service.
The test counter is running out, the instrument has no more then 500 hits available (box is yellow)	
Check Device ran out	Insert a refill in the instrument If the problem persists at the end of the refill, contact technical service.
The test count has run out (box is red)	
Error in refill Check Device	Insert a different refill in the instrument. If the problem persists at the end of the refill, contact technical service.
Problems in the refill of the hit counter	
Verify front left microswitch	Verify the correct positioning of the front carter on the indicated side of the micro-switch. If the problem persists, contact technical service.
Error in left microswitch of the front panel.	
Verify front right microswitch	Verify the correct positioning of the front carter on the indicated side of the micro-switch. If the problem persists, contact technical service..
Error in right microswitch of the front panel.	
Timeout Host	Verify the correct connection of the cable on the back side of the Ves-Matic Cube 200. Verify the correct functioning of the IT network of the laboratory.
Error of connection line to host computer.	
Printer: out of paper	Insert a new role of paper in the printer see (paragraph 5.3) If the problem persists, contact technical service.
Printer paper ran out.	
Printer head up	Lift the lid of the printer and lower the head, acting on

The printer head is lifted.	the black lever on the right side of the head. If the problem persists, contact technical service.
Printer: communication error	Verify the presence of paper and the head position. If the problem persists, contact technical service.
Communication error between printer and Tablet PC.	

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 and the Analysis 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. 6.1.a)

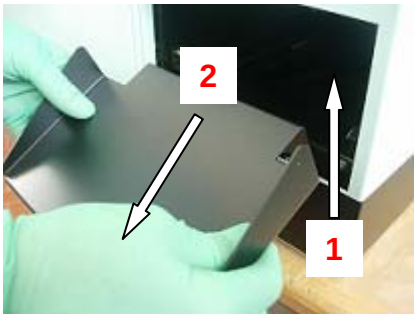


fig. 6.2.1 a

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

2. Open the window of the preparer module and lift the front cover, pushing down in vertical direction for about 1 cm, making it slide from down upwards, freeing it from the four blocking points on the frame as indicated by the 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.

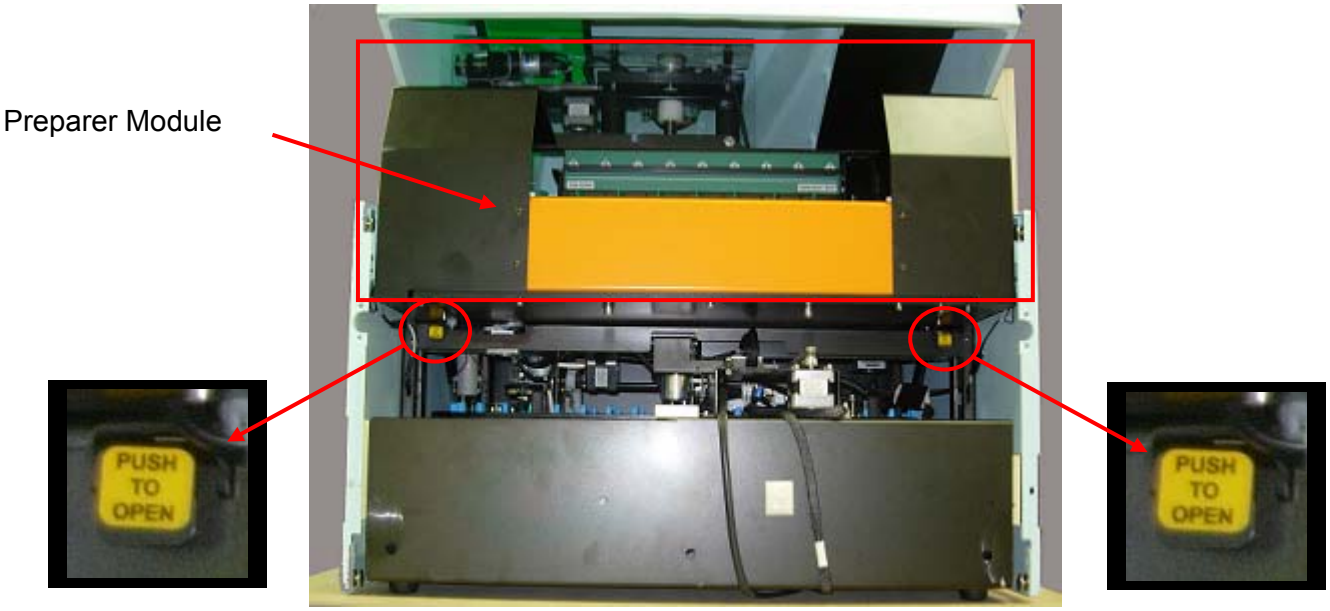


fig 6.2.2.a

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 rectagle 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).

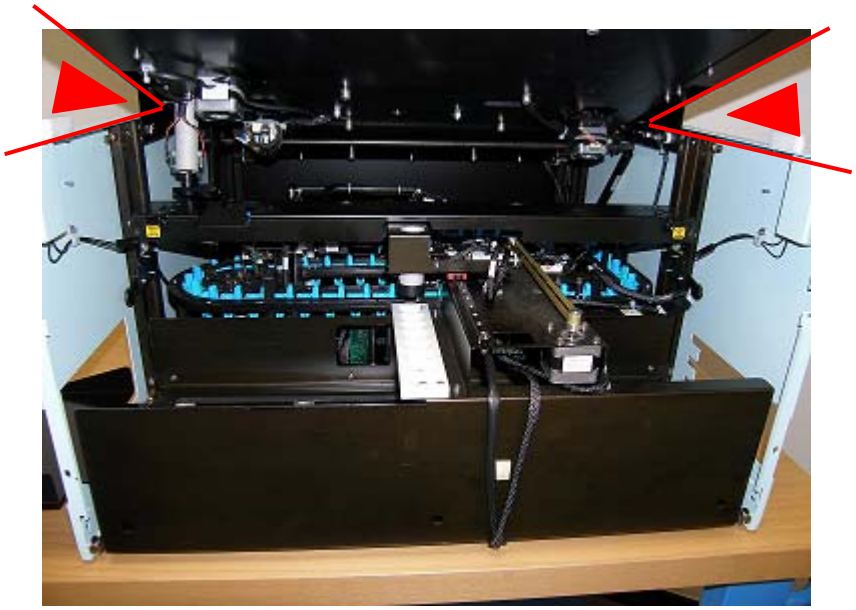


Fig. 6.2.2.b Upwards opening of the Preparer module, the opening angle in respect to the Analyses Module is indicated by the red triangles.

Verify whether or not there are any test tubes that cause a block and remove them.
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 in can indicate error messages on the screen in the "information bar" (see fig. 3.2.b). Following are reported some error messages and the operating instructions for their solution by the operator.
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 when

1. in case of the Sysmex model of the instrument the rack is inserted into the Preparer Module incorrectly. The consequence of the incorrect manuality is the tranfer of the sample to the Analyses module, incusive of "sleeve".
2. the sample remains blocked in the tube caused by frictions generated by an incorrect labling of the test tube (see 4.2.2)

In both cases to remove the block follow, with the instrument turned off, the procedure described in 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 reac in the preparer module.
Error device 0x03(Ejector chain): this error occurs when a sample remains blocked in the mail of the chain. 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.), reposition 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). 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 labelling 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 is 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 ejecter group of the Analysis module. Respecting the direction of introduction of the sample holder rack in the classifier module, as indicated by the yellow arrow (A) in fig. 6.2.3.a, verify the following conditions:

1. the label of the barcode of the sample holder rack has to been 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.

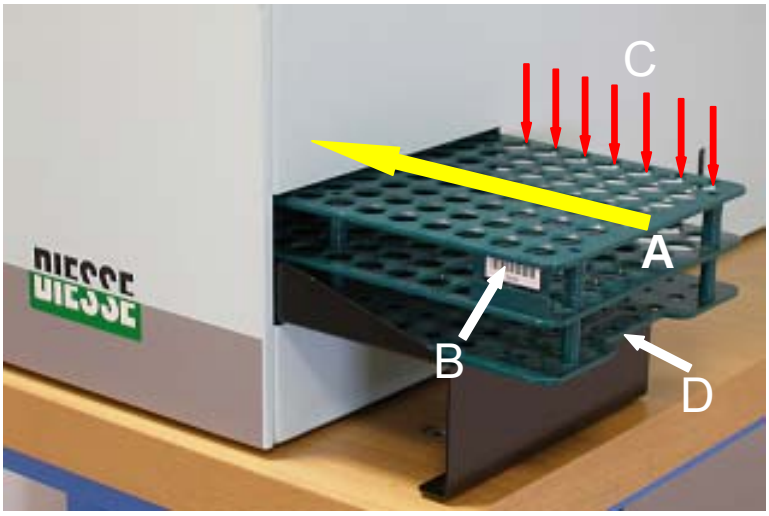
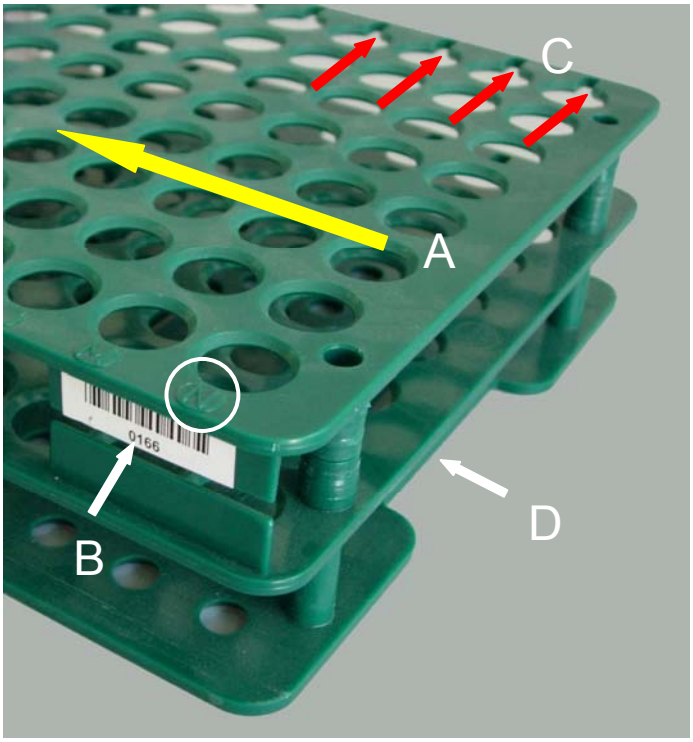


fig 6.2.3.



Detail of fig. 6.2.3.

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

7 CHAPTER 7:

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:

a. 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),
b. 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 Window Group.
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 communicating with the Host Computer

7.2.1 Preface: Technical information

- The electric levels of the signals are of the standard type RS232C.
- The transmission speed is 9600bit/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	**Representation HEX-ASCII**	
Hexadecimal value	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 and send the ACK frame and any reply together in one single frame.

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.

Terminator: 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	Error value campo H-LEN / L-LEN
0x06	0x30	0x36	Data field Length Error

Timeout on NACK Message: 2 Sec.

7.2.5 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. 0x05 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.

7.2.5.1 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

7.2.6 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 Pendings Database.

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 (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:

7.2.6.1.a. *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.

7.2.6.1.b. *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.

7.2.6.1.b.1 Record Tube:

Barcode (ASCII string max 15 characters)	**Terminator** of the string Barcode (0x10)	**ANALYSIS DATE** ASCII string 6 characters	**ANALYSIS TIM** ASCII string 4 characters	**VES** ASCII string 4 characters	**H-FLAGS**	**L-FLAGS**	**RACK ID** ASCII string 4 characters	**POSITION** ASCII string 2 characters

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.

VES: Value of the VES 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:

VES 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

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

7.2.6.1.c. *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.

7.2.6.2 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

7.2.7 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.

7.2.7.1 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:

7.2.7.1.a. *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.

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

QC data	QC Sample Record

7.2.7.1.b.1. *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.

7.2.7.1.b.2. *QC Sample Record:*

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

VES: 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:

VES 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.

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

7.2.7.2 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 7.2.3.1

7.2.8 Example serial protocol

1. Example for the request ESR analysis on two samples (two barcodes, see 7.2.4)

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 AD: 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 BAR CODE + TERMINATOR
SAMPLE 2 BAR CODE + TERMINATOR
ETX: character [0x0D]
H/L CHK: "xor" of all characters from STX to ETX included.

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)

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 AD: 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 BAR CODE + 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 directive EEC 98/79 relevant the Diagnostic Device CE-IVDD

DIESSE DIAGNOSTICA SENESE S.p.A. with main office in Milano, Via San Vittore 96/1 ITALY

Hereby declares

That the design, type of manufacture of the Diagnostic Device CE-IVDD described here below and the version distributed on the market,

is compliant to the

" EEC directive 98/79 relevant the Diagnostic Device CE-IVDD"

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

This declaration shall not be valid if:

- Unauthorised modifications are made to the unit
- The unit is used improperly
- Unauthorised technical operations are made on the unit
- No original spare parts are used.

Product: **Automatic unit for the determination of ESR values**

Type: **Ves-Matic Cube 200**
Version Abbot ; Version Beckman-Coulter
Version Bayer ; Version Sysmex

Technical data: **90-264 Vac (50-60 Hz) Pwr; 265VA**

Is compliant

In whole and in all its parts to the following standards and related amendments:

EN 61010-1 "Safety for electrical equipment for measurement, control, laboratory use– Part 1: General requirement ".

EN 61326-1 "Electrical equipment for measurement, control, laboratory use – EMC requirements – Part 1: General requirement ".

Corresponds to the requirements of the following EEC directive and related amendments:

Low tension Directive (2006/95 EEC)

Electromagnetic compatibility Directive (89/336/EEC) and (93/68/EEC)

Signature: R&D Director

Monteriggioni, 01/09/2005

Dr. Francesco Cocola

Attachment B: WARRANTY CERTIFICATE

WARRANTY CERTIFICATE Ves-Matic Cube 200

Certificate S/N

DIESSE DIAGNOSTICA SENESE S.p.A., subjects all its products to strict quality controls. However should the instrument show signs of malfunctioning despite these controls, you are invited to contact the authorised Technical Assistance Centre indicated to you at the time of delivery of the instrument.

Limits of liability

DIESSE DIAGNOSTICA SENESE S.p.a. assumes all liability for damages arising from manufacturing defects or malfunctioning of the instrument during the **foreseen use** of the same. It declines any other type of liability.

General guarantee regulations:

DIESSE DIAGNOSTICA SENESE S.p.A. guarantees the Ves-Matic Cube 200 for a period of 12 months from the delivery data (the date on the transport document shall be valid) for defects in the materials or manufacturing.

Should the product prove to be defective during the guarantee period the authorised Assistance Centres will repair it and you will only be charged the transport costs.

General Conditions:

1. The materials and manufacture of this product shall not be considered as defective if the instrument has been adapted, modified or adjusted to comply with national or local standards in force in a country where they differ from those for which the product has originally been designed and constructed. This guarantee shall not cover said adaptations, modifications or adjustments or any attempts at the same, irrespective of whether performed correctly or incorrectly, or any damage deriving from the same.
2. This guarantee shall not cover:
   - periodic checks, maintenance and repairs or replacement of parts due to normal wear and tear,
   - transport costs and risks linked directly or indirectly to the guarantee of this product, including the transfer from the assistance centre to the customer's address,
   - damage deriving from incorrect use, negligence, incorrect installation, impact, falls, insufficient voltage connections, use in environments with extreme conditions, damage caused by liquids dropped inside, etc. or deriving from any other accidental cause.
   - malfunctioning of the instrument due to modifications or repairs carried out on the same by unauthorised third parties.
   - damage caused by the assembly of parts or components not approved by the manufacturer.
3. No interventions carried out under guarantee shall interrupt or prolong the duration of the same for any reason whatsoever.

Copy to be filled out and conserved for the warranty period together with the Operating Manual

DIESSE DIAGNOSTICA SENESE S.p.A.
VIA DELLE ROSE 10 • 53035 MONTERIGGIONI • SIENA •ITALIA
Tel. 0577 / 58.71.11
Fax 0577 / 31.86.90

Ves-Matic Cube 200 Warranty Certificate

Certificate S/N

Copy to be FILLED OUT and RETURNED to:

DIESSE DIAGNOSTICA SENESE S.p.A.

Via delle Rose 10 • 53035 Monteriggioni • Siena •Italy

Certificato S/N

INSTRUMENT _____ MODEL _____ SN# 200 □-□□-□□□□

CUSTOMER/COMPANY _____

ADDRESS _____

CITY' _____ ZIP _____ STATE _____

T.D. n° _____ of _____

RESELLER/DISTRIBUTOR DATA	NAME/COMPANY _____ ADDRESS _____
INSTALLER DATA	NAME/COMPANY _____ ADDRESS _____

Remarks:

Attachment C: ASSISTANCE REQUEST FORM

Form Requesting Assistance DATE

Product:		**Client:**	
Serial N°:		**Referee:**	
SW Release:		Address:	
T.D.		Phone:	
Date		Fax:	
Guarantee	YES ☐ NO ☐	E-mail:	

LAST TECHNICAL INTERVETION on the product:
Carried out by: On:

DETAILED DESCRIPTION OF THE PROBLEM

ANY CUSTOMER REMARKS

INTERNAL USE

Tipe of compliant:
☐ Supply
☐ Product
☐ Technical Service

Notice to be forwarded to:
☐ Sales Office
☐ Technical Dpt.
☐ Purchase Office
☐ Quality Ass.
☐ _____

Reply time
☐ BY _____ days
☐ URGENT

Return 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

Pag. 1 di

DIESSE ASSISTANCE SERVICE	**CUSTOMER CARE** Via del Pozzo 5, 53035 Monteriggioni (SI), Italy Tel. ++39 0577 319556 Fax. ++39 0577 319020 e-mail: customercare@diesse.it
LOCAL ASSISTANCE SERVICE	

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

Consumables

▪ Check device test tube 1K for Ves-Matic Cube 200 (1000 hits	[Ref.: 10292]
▪ Check device test tube 5K for Ves-Matic Cube 200 (5000 hits)	[Ref.: 10291]
▪ Check device test tube 10K for Ves-Matic Cube 200 (10000 hits)	[Ref.: 10290]
▪ ESR Control 9ml (2 Bottles Normal + 2 Bottles Abnormal	[Ref.: 10430]

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

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

SERVICE ASSISTANCE DIESSE	*SERVICE ASSISTANCE* **CUSTOMER CARE** Via del Pozzo 5, 53035 Monteriggioni (SI), Italy Tel. ++39 0577 319556 Fax. ++39 0577 319020 e-mail: customercare@diesse.it

Part request form

INSTRUMENT _____ MODEL _____ SN# 200 □ - □□ - □□□□

CLIENT / COMPANY _____

ADDRESS _____

CITY _____ CAP _____ STATE _____

Doc. n° _____ of _____

Note

Code	Description	Conf.	Requested quantity

Date _____ . Signature _____.

Attachment F: 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.

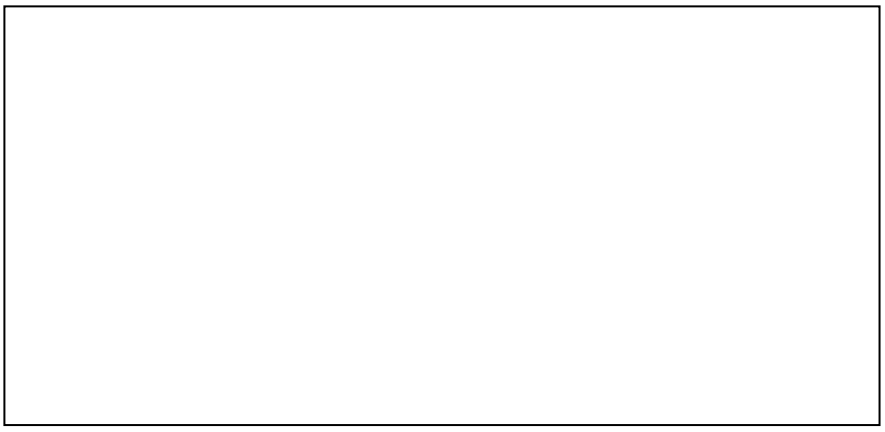
Materials

- 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 haemacrit 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 (±1°) 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 G: QUICK-START INSTRUCTIONS



DIESSE Diagnostica Senese SpA
Via del Pozzo, 5 - Loc. S. Martino • 53035 Monteriggioni (SI) Italy
Tel.: ++39/0577/31.95.60/61/50 • Fax: ++39/0577/31.87.63

http://www.diesse.it e-mail:salesoffice@diesse.it