INSTRUCTIONS MANUAL

Software Release N°3.19
Rev. 2.4 issued on March 2018

“Automatic instrument for ESR determination
with modified Westergren method”
(Patented)

For In Vitro Diagnostic use only
Standard applied in this document:

- 98/79/EEC “directive relevant to the In Vitro Medical-Diagnostic Devices (IVD)”
- EN 61010-1 (CEI 66-5) “Safety requirements for electrical equipment for measurement, control laboratory use – Part 1: General requirements”. The instrument is classified in Class I
- EN 61010-2-081 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.
- EN 61010-2-101 “Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for In Vitro Diagnostic (IVD) medical equipment”.
- EN 61326-1 “Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements-Part 1: General requirements”
- EN 61326-2-6 “Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements-Part 2-6: In Vitro Diagnostic (IVD) medical equipment”
- 2014/35/EU “Low Voltage Directive”
- 2014/30/EU “Electromagnetic Compatibility Directive”
- 2011/65/EU “Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive – RoHS2”
- NCCLS H02-A5 Procedures for ESR; approved standard – fifth edition

**LIST OF MANUAL REVISIONS**

<table>
<thead>
<tr>
<th>MANUAL REVISIONS</th>
<th>VERSION SW VES-MATIC CUBE 80</th>
<th>DESCRIPTION OF MODIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00 of 05/07</td>
<td>2.23 of 05/07</td>
<td>Initial revision</td>
</tr>
<tr>
<td>2.03 of 02/10</td>
<td>2.23 of 05/07</td>
<td>Section 7.2 – The sentence in which we explained that ACK and answer have to be sent in one frame has been deleted.</td>
</tr>
<tr>
<td>2.04 of 07/10</td>
<td>2.23 of 05/07</td>
<td>Changed the customer care address with those of the technical support</td>
</tr>
<tr>
<td>2.05 of 02/11</td>
<td>2.24 of 09/10</td>
<td>The Annex about warranty is deleted</td>
</tr>
<tr>
<td>2.06 of 05/11</td>
<td>2.24 of 09/10</td>
<td>Inserting of the correct catalogue number of rack: R30003720</td>
</tr>
<tr>
<td>2.07 of 01/12</td>
<td>2.28 of 11/11</td>
<td>Changed the EC Declaration and deleted the CC references</td>
</tr>
<tr>
<td>2.1 of 04/15</td>
<td>2.31 of 09/13</td>
<td>Complete restyling</td>
</tr>
<tr>
<td>2.2 of 07/17</td>
<td>3.18 of 2016</td>
<td>New features</td>
</tr>
<tr>
<td>2.3 of 12/17</td>
<td>3.19 of 2017</td>
<td>Section 1.6 – A typing error (265 VA) present in the table has been corrected</td>
</tr>
<tr>
<td>2.4 of 03/18</td>
<td>3.19 of 2017</td>
<td>Edit Description of “Test Device”</td>
</tr>
</tbody>
</table>
APPLICATION OF THE MANUAL

This manual applies to the following models of the VES-MATIC CUBE 80:

<table>
<thead>
<tr>
<th>DIESSE Code</th>
<th>Model description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10380</td>
<td>VES-MATIC CUBE 80</td>
</tr>
</tbody>
</table>
## SYMBOLS

### Legend of graphic symbols used on the instrument.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![IVD]</td>
<td>In Vitro Diagnostic medical device.</td>
</tr>
<tr>
<td>![DATE]</td>
<td>Date of manufacturing of the unit.</td>
</tr>
<tr>
<td>![SN]</td>
<td>Serial number of the unit.</td>
</tr>
<tr>
<td>![MAN]</td>
<td>Manufacturer.</td>
</tr>
</tbody>
</table>

### Legend of Electrical and Safety symbols used on the instrument.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![PROTECTIVE]</td>
<td>Protective conductor terminal.</td>
</tr>
<tr>
<td>![WASTE]</td>
<td>Obligation of separate waste collection according to 2012/19/EU directive.</td>
</tr>
<tr>
<td>![WARNING]</td>
<td>Warning, read the Manual and pay attention to the safety symbols.</td>
</tr>
<tr>
<td>![WARNING][2]</td>
<td>Warning, risk of electric shock.</td>
</tr>
</tbody>
</table>

### Legend of symbols used in this document.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ATTENTION]</td>
<td>ATTENTION, potential hazard of personal injuries, all conditions indicated in the text have to be read and understood before proceeding.</td>
</tr>
<tr>
<td>![CAUTION]</td>
<td>CAUTION, potential danger of damage to the machine, all conditions indicated in the text have to be read and understood before proceeding.</td>
</tr>
<tr>
<td>![NOTE]</td>
<td>NOTE, important information</td>
</tr>
<tr>
<td>![BIOHAZARD]</td>
<td>BIOHAZARD, danger of contamination with possibly infected materials.</td>
</tr>
<tr>
<td>![CSA]</td>
<td>Instrument satisfying CSA standards for the Canadian and U.S.A. market.</td>
</tr>
</tbody>
</table>
WARNINGS AND LIMITS

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

In the event of sale or transfer, make sure that this manual accompanies the VES-MATIC CUBE 80 to allow new users to be informed about the instrument’s functions and the related warnings.

Use of this instrument is recommended by qualified and skilled personnel only. The installation must be carried out by an authorised DIESSE Diagnostica Senese S.p.A. technician who will create an Installation Report supplied separately with the Installation Check Guide.

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

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

<table>
<thead>
<tr>
<th>BIOHAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially infected material is treated.</td>
</tr>
<tr>
<td>When an analysis system like the VES-MATIC CUBE 80 is used, all precautions must be taken regarding biological risks. The samples do not require preparation. The samples must be disposed off in accordance with the laboratory instructions and with local laws.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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)</td>
</tr>
<tr>
<td>All supplied materials must be disposed off in accordance with the local laws.</td>
</tr>
</tbody>
</table>
CONTENTS

CHAPTER 1 ........................................................................................................................................ 9
  1.1 INTENDED USE OF THE INSTRUMENT .............................................................................. 9
  1.2 PRESENTATION OF THE INSTRUMENT ........................................................................... 9
  1.3 GENERAL DESCRIPTION OF THE INSTRUMENT .......................................................... 11
     1.3.1 COMPATIBILITY WITH TEST TUBES USED FOR THE CBC TEST .................. 12
  1.4 MATERIAL SUPPLIED WITH THE INSTRUMENT ............................................................ 14
  1.5 LIST OF MATERIAL REQUIRED BUT NOT PROVIDED ....................................................... 15
  1.6 TECHNICAL SPECIFICATIONS ............................................................................................ 16
  1.7 TECHNICAL DESCRIPTION OF THE INSTRUMENT ......................................................... 17
  1.8 INFORMATION ABOUT DISPOSAL ....................................................................................... 19

CHAPTER 2 .................................................................................................................................... 20
  2.1 PREPARATION AND CHECKS BEFORE INSTALLATION ...................................................... 20
  2.2 PLACEMENT .......................................................................................................................... 20
  2.3 LIMITATIONS AND WARNINGS ............................................................................................ 23

CHAPTER 3 .................................................................................................................................... 25
  3.1 SWITCHING ON THE INSTRUMENT ................................................................................... 25
  3.2 DESCRIPTION OF THE SOFTWARE .................................................................................... 25
     3.2.1 Main menu ...................................................................................................................... 25
     3.2.2 Settings Menu .................................................................................................................. 39
  3.3 CHECK DEVICE .................................................................................................................... 44
  3.4 READING OF THE RESULTS PRINTOUT ............................................................................ 46

CHAPTER 4 .................................................................................................................................... 53
  4.1 GENERIC DESCRIPTION OF AN ESR ANALYTIC CYCLE IN THE VES-MATIC CUBE 80 ............................................................................................................................... 53
  4.2 DETAILED DESCRIPTION ...................................................................................................... 53
     4.2.1 Initial power up ................................................................................................................... 53
     4.2.2 Preparation of the sample .................................................................................................. 54
     4.2.3 Warnings and limitations .................................................................................................. 57
     4.2.4 Preparation sequence for a test ....................................................................................... 58
     4.2.5 Conclusion of the analytical cycle .................................................................................... 58
     4.2.6 Conclusion of the daily analytic activity ......................................................................... 58

CHAPTER 5 .................................................................................................................................... 59
  5.1 GENERAL RECOMMENDATIONS ........................................................................................ 59
  5.2 CLEANING/DISINFECTION OF THE INSTRUMENT .......................................................... 59
  5.3 REPLACEMENT OF PRINTER PAPER ................................................................................. 59
  5.4 REPLACEMENT OF THE FUSES .......................................................................................... 61

CHAPTER 6 .................................................................................................................................... 63
  6.1 TROUBLESHOOTING ............................................................................................................ 63
  6.2 INDEPENDENT MANAGEMENT OF SOME PROBLEMS ...................................................... 64
     6.2.1 Procedure for access to the Classifier Module ............................................................... 64
     6.2.2 List of some error messages and their solution ............................................................... 65
CHAPTER 7 .................................................................................................................................................... 66
  7.1 EXTERNAL BARCODE READER ............................................................................................................. 66
  7.2 CONNECTION TO THE HOST COMPUTER ............................................................................................. 66

BIBLIOGRAPHY .............................................................................................................................................. 67

APPENDIX A: EC DECLARATION OF COMPLIANCE .................................................................................. 68

APPENDIX B: ACCESSORIES, SPARE PARTS AND CONSUMABLES ......................................................... 68

APPENDIX C: QUICK-START INSTRUCTIONS ............................................................................................. 69
CHAPTER 1

1.1 INTENDED USE OF THE INSTRUMENT
Automatic instrument for the determination of erythrocyte sedimentation rate (ESR).

1.2 PRESENTATION OF THE INSTRUMENT
The VES-MATIC CUBE 80 is an automatic bench top instrument designed and programmed to determine the Erythrocyte Sedimentation Rate (ESR) on whole blood samples anti-coagulated with EDTA with continuous and random loading of samples. It can analyse up to a maximum of 90 samples per hour.

The instrument carries out the ESR analysis directly from the test tubes being used on the blood cell counter in the laboratory. The instrument is managed by an on-board, touch screen PC.

The main innovation of the system is that the sedimentation of red cells in autologous plasma is read directly in the original EDTA tubes used for the full blood count, by means of a specially designed optical system. Due to this feature, no part of the system comes in contact with or consume any of the blood samples during its operation. As a result, there is no transfer of blood from the original tube into any part of the analyzer and no production of waste fluids. The system is therefore designed to maximize the operator safety and protection. The VES-MATIC CUBE 80 is environmentally friendly since it eliminates the possibility of biological contamination of the environment via biological waste and reduces the amount of plastic tubes that have to be disposed of thus decreasing the laboratory costs.

The analysis is carried out completely automatically (mixing of the samples and reading of the results) and the results, obtained in only 20 minutes, are comparable to those obtained with the Westergren method in 1 hour (60 minute sedimentation performed at 18°C using dedicated glass pipettes of 200 mm, with an internal bore with a diameter of 2.5 mm).

The instrument is designed with the temperature correction always activated, relates the results to a temperature of 18°C according to Manley’s Nomogram\(^{10}\) (Graphic 1.1). However, it is possible to de-select the temperature correction for individual laboratory needs.

Graphic 1.1 Manley’s Nomogram\(^{10}\)
**Clinical concept of the ESR**

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

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

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

In the classical formulation of Westergren the test is performed on blood anti-coagulated with citrate, in the proportion of 4 parts blood to one part of anticoagulant. The diluted blood is then aspirated inside a special graduated pipette with inner diameter of 2.5 mm held vertically in a stand; the level of sedimentation of the erythrocytes is recorded after one hour, measuring the distance between the lower face of the meniscus of the plasma and the upper face of the layer of sedimented red blood cells.

**General functioning of the instrument:**

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

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

The analytical results are obtained from the internal processing of the readings; the values obtained are correlated with the Westergren reference method. The instrument is designed to express the results of the ESR measurement in Westergren.
Normal ESR values

Normally ESR values are between 1 and 10 mm/hr for males and between 1 and 15 mm/hr for females; in pathological conditions results can increase to values of up to 100 mm/hr and higher.

Indicative normal range of the VES-MATIC CUBE 80 instrument (values expressed in Westergren).

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MALES</td>
<td>up to 10 mm/hr</td>
</tr>
<tr>
<td>FEMALES</td>
<td>up to 15 mm/hr</td>
</tr>
</tbody>
</table>

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

1.3 GENERAL DESCRIPTION OF THE INSTRUMENT

![Diagram of the instrument]

Fig. 1.3.1 Front view closed

1. Instrument control unit with display equipped with Touch Screen ‘Tablet PC’
2. Printer
3. Rack introduction compartment

![Diagram of the instrument with components labeled]

Fig. 1.3.2 Front view open

1. Sample rack introduction compartment
2. Mixer
3. Test tube withdrawal clamp
1.3.1 COMPATIBILITY WITH TEST TUBES USED FOR THE CBC TEST

<table>
<thead>
<tr>
<th>VACUETTE™ (GREINER BIO-ONE) AND SIMILAR</th>
<th>VACUTAINER® (BD) VACUTEST® KIMA, VENOSAFE® TERUMO VACUTRUST, ETC.</th>
<th>‘RUBBER’ RUBBER CAP, BD, TERUMO</th>
<th>‘SARSTEDT®’</th>
</tr>
</thead>
</table>

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

- ① Switch « I » [ON]/ « O » [OFF]
- ② Filtered outlet with fuse holder lodging
The VES-MATIC CUBE 80 is designed to work with the same test coming from the blood cell counter present in the laboratory.

The test tube models described in the table above are substantially different in height, diameter, shape and dimensions of the cap.

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.
1.4 MATERIAL SUPPLIED WITH THE INSTRUMENT

The VES-MATIC CUBE 80 is supplied with the following materials:

<table>
<thead>
<tr>
<th>Q.ty</th>
<th>Description</th>
<th>Code</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Operating Manual (hard copy)</td>
<td>R30600541</td>
<td>-------</td>
</tr>
<tr>
<td>2</td>
<td>Lifting handles</td>
<td>R10340531</td>
<td>-------</td>
</tr>
<tr>
<td>2</td>
<td>Sample holder racks</td>
<td>R30003650</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Rack input extensions</td>
<td>R10338870</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Microswitch keys V.2</td>
<td>R10345960</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Roll of thermal paper H.mm L=57 D=50</td>
<td>R12300000</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Delayed 5x20 mm UL fuse blocks 5A</td>
<td>R20400070</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Power cable 3x0.75 L=2m SCHUKO 90°-C13</td>
<td>R21890040</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Power cable SVT PLUG USA/OUTLET VDE 2MT UL</td>
<td>R21890370</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>BARCODE READER Z-3010 + CABLE 171-10R435-200 (VES-CUBE)</td>
<td>R20550510</td>
<td></td>
</tr>
</tbody>
</table>

**Consumables:**

- Test Device 1K (1000 tests) [Ref: 10292]
- Test Device 5K (5000 tests) [Ref: 10291]
- Test Device 10K (10000 tests) [Ref: 10290]
- ESR Control Cube 4x9ml (2 Normal vials + 2 Abnormal vials) [Ref: 10435]
- ESR Control Cube 2x9ml (1 Normal vial + 1 Abnormal vial) [Ref: 10436]
- Thermal paper for printer (1 pack) [Ref: 10403]
- Calibrator (TEST TUBE READER) [Ref.: 19900900]
The safety and performance requirements of the instrument can no longer be guaranteed when the instrument is powered using a different cable from the one supplied, compatible with the power supply of the country of installation.

The safety and performance requirements of the instrument are not guaranteed whenever the instrument is used with different materials from the ones supplied (External barcode reader, moulded sample holder rack, delayed 5A fuses (5x20 mm) UL, internal barcode reader programming guide).

1.5 LIST OF MATERIAL REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Cleaning paper
- Solutions for cleaning the instrument
## 1.6 TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Power supply</strong></td>
<td>Europe: 230Vac@50Hz&lt;br&gt;USA/Canada: 110-120Vac@60Hz</td>
</tr>
<tr>
<td><strong>Absorbed electric power</strong></td>
<td>165VA</td>
</tr>
<tr>
<td><strong>Fuses</strong></td>
<td>2 x 5.0 AT (Delayed) (5x20 mm) UL</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>650 x 580 x 690 mm (l x h x d)</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>45 Kg</td>
</tr>
<tr>
<td><strong>Room temperature</strong></td>
<td>Operational: from +15 to +35°C&lt;br&gt;Storage: from +5°C to +45°C</td>
</tr>
<tr>
<td><strong>Relative humidity threshold</strong></td>
<td>from 20% to 80% without condensation</td>
</tr>
<tr>
<td><strong>Central unit</strong></td>
<td>Free scale i.MX31 ARM11 Microprocessor;&lt;br&gt;Flash 128MB NAND&lt;br&gt;128 MB DDR RAM</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>TFT 800x 600 colour with Touch Screen</td>
</tr>
<tr>
<td><strong>Control unit peripherals</strong></td>
<td>Microprocessor card on owner bus</td>
</tr>
<tr>
<td><strong>Internal analytic section</strong></td>
<td>89 positions chain for the appropriate test tube</td>
</tr>
<tr>
<td><strong>Step progress chain</strong></td>
<td>19 seconds in the normal functioning</td>
</tr>
<tr>
<td><strong>Analysed samples collection section</strong></td>
<td>8x14 position sample holder rack (4x14 samples to be analysed and 4x14 analysed)</td>
</tr>
<tr>
<td><strong>Optical units</strong></td>
<td>Two couples of optic-electronic elements (Led &amp; analogical sensor)</td>
</tr>
<tr>
<td><strong>Printer</strong></td>
<td>Alphanumeric with thermal paper 58 mm wide, 36 characters per line, speed 20 mm/sec.</td>
</tr>
<tr>
<td><strong>Interface</strong></td>
<td>2 x RS232C, 2 USB Host, 1 USB Client, 1 Slot Compact Flash</td>
</tr>
<tr>
<td><strong>Protection category</strong></td>
<td>CLASS I</td>
</tr>
<tr>
<td><strong>Safety standards</strong></td>
<td>CEI EN 61010-1 (Ed.2001-11); CAN/CSA-C22.2 Nr.61010-1-04 (Ed.2004-07); UL61010-1 (Ed.2004-07)</td>
</tr>
<tr>
<td><strong>EMC</strong></td>
<td>2014/35/EU “Electromagnetic Compatibility Directive”</td>
</tr>
<tr>
<td><strong>Installation category</strong></td>
<td>II</td>
</tr>
</tbody>
</table>
1.7 TECHNICAL DESCRIPTION OF THE INSTRUMENT

The "Selection Module" consists of:

- **TABLET PC'- CENTRAL UNIT**
  Herein resides the application software that controls, manages and receives data, via serial connection from the single peripheral microprocessor cards where the EEPROM resides and all parameters of the instrument are memorised.
  It is fitted with:
  - **DISPLAY**
    Display (Fig. 1.7.1) that allows the visualization and the interaction (by means of a touch screen) with all the software functions.

  ![Fig. 1.7.1](image1)

- **KEYBOARD**
  The keyboard functions are executed both using the display's touch screen (Fig. 1.7.1) which allows interaction with all the software control functions, and with the 7 buttons (Fig. 1.7.2) located on the frame of PC Tablet:

  ![Fig. 1.7.2](image2)

  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”

- **ACUSTIC ALARM**
  This functions as an alert for the operator during specific phases of the work cycle: whenever the instrument is switched on, it emits a special signal; each time 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 out the information regarding the processed test tubes (sample code, ESR result) contained in the sample holder rack and all useful information regarding the working cycle (date, hour, temperature). For a detailed description see paragraph 3.4.

**The “Preparatory Module” consists of:**

- **SAMPLE PRESENCE DETECTION UNIT**
  The unit comprises a group of sensors to detect the samples in the rack

- **BARCODE READING UNIT**
  This unit executes the barcode reading of each sample so that the instrument can execute a Host Query to differentiate the test tubes that require an ESR and thus must be inserted in the test tube holder chain. The samples which do not require ESR evaluation are left in the rack which is subsequently removed together with them.

- **CLAMP UNIT**
  This unit moves the test tubes from the rack to analysis module and once tested back to the rack.

- **RACK PULLING UNIT**
  This unit allows the rack to be moved during the analysis. The sample holder racks ejected from the instrument must be refrigerated. Locating of a specific sample is easy. The sample and location coordinates are provided for each sample in the sample holder rack, which itself is identified by a specific identifier.

**The “Analysis module” consists of:**

- **POWER SUPPLY UNIT**
  Mainly comprising 3 switching power suppliers; it supplies the electricity to the various modules following a criterion for the allocation of load.

- **TEST TUBE HOLDER CHAIN**
  The test tube holder chain consists of 89 links in which the test tubes are inserted; with the help of two traction wheels, the chain rotates clockwise inside the analysis module, transferring the test tubes to the mixing unit and subsequently 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 final reading is carried out.

- **MIXING UNIT**
  Unit in charge of the execution of complete rotation by 180° of the sample holder chain for a track of 5 test tubes, to guarantee the homogenous mixing of the red blood cells.
- **READING GROUP 1 & 2**
  In each group a motor lifts the reading unit that, with 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 chain of the Analysis Module and the transfer to the sample holder rack.

**The Classifier Module consists of:**
At the end of the analytical procedure, the clamp removes the test tube from the chain by pushing it up, and inserts it into the tube of the transfer test tube group, specifically positioned above the chain.

**1.8 INFORMATION ABOUT DISPOSAL**
The VES-MATIC CUBE 80 instrument is operated by mains voltage, therefore has been classified as Electrical-Electronic Equipment according to the European Directive 2012/19/UE dated July 04 2012, and subsequent amendments.
At the end of its life cycle, the instrument must be treated as separate collection, potentially infected waste and eliminated according to law.
CHAPTER 2

2.1 PREPARATION AND CHECKS BEFORE INSTALLATION

The following conditions must be ensured 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 on the back of the instrument; it is advisable 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 connecting with external instruments (host, PC, external Barcode Reader), always remember to 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.

- 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 paragraph 5.2) has to be always available.

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

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

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

Decommissioning and shipment of the system have to be performed by personnel authorized by DIESSE Diagnostica Senese S.p.A.

2.2 PLACEMENT

The environment intended for this instrument is the analysis laboratory. For normal safety requirements and in view of the type of examination to be performed, the instrument must be positioned away from heat sources, in areas that cannot be reached by liquids, in dust-free environments, on perfectly clean, level surfaces that are not subjected to shocks or vibrations.
The VES-MATIC CUBE 80 has been manufactured to conform to the electromagnetic emissions directives, however it is nevertheless advised that, whenever possible, the VES-MATIC CUBE 80 is placed far from possible generators of electromagnetic waves (for example fridges, laboratory centrifuges) and from instrumentation without CE labelling as they could occasionally interfere with the functioning of the instrument.

It is advisable that a bench that can support the weight of the instrument is used. The bench top should not exceed 90 cm in height, to guarantee an ergonomically correct position for the operator during the input of the commands on the Tablet PC and the loading and unloading of the sample holder racks in the sample module.

The bench top where the instrument will be placed, should allow enough space, about 40 cm, on each side of the instrument for the operator to easily load and unload the sample holder rack in the sample module (Fig. 2.2.1, Fig. 2.2.2 and Fig. 2.2.3)

To be able to reach the connectors on the back side of the instrument and 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, objects or containers on the instrument.

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**Fig. 2.2.1 Frontal view with the extensions for rack input**

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**Fig. 2.2.2. left side of the VES-MATIC CUBE 80 (sample holder rack exiting)**

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**Fig. 2.2.3. right side of the VES-MATIC CUBE 80 (sample holder rack entering)**
Choose a position close to an undisturbed electric socket free from electrical fluctuations.

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

To move the instrument, always apply the supplied handles, 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 analyser avoid blows and excessive inclination that could cause damage.

Commissioning the system:
1. Assure that the power switch is in the OFF “0” position before continuing.
2. Plug connections with external instruments (see paragraph 2.1).
3. Install the rack insert extension as shown 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 plug on the right side of the general power switch on the instrument itself (as shown in Fig. 2.2.5). Connect the plug of the power cable to the power source.

![Fig. 2.2.5](image)

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. 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 advisable to contact technical assistance to verify the good functioning.

8. Test cycle: Insert a rack with at least 5 labelled test tubes and start the analytical procedure. Check that: the instrument executes the initial “reset” in a correct manner, that the procedure finishes correctly without interruptions, that the barcodes attached to the processed test tubes have been correctly acquired by the instrument (the print concerning the conducted analytical cycle facilitates this verification operation).

! Remember that the test tubes to be analysed must be inserted into the red part of the rack as the green part is used by the instrument to unload the samples already analysed.

2.3 LIMITATIONS AND WARNINGS

- **IN CASE OF FIRE OR HAZARDS IN GENERAL, TURN OFF THE INSTRUMENT AND UNPLUG THE POWER CABLE**

- **DISCONNECT** the machine from the power source, before any technical intervention or in the case of malfunctioning of the instrument.

- **It is forbidden to OPERATE** on the machine while parts are moving (it is only allowed to key in commands on the touch screen and/or introduce and remove racks).

- **Limitations regarding the Check Device (consumable to be purchased for the use of the instrument):** Test Device (called also “Check Device Transponder RF”) destined to refill the “test counter” (“Check Device”) of the instrument (see paragraph 3.3).
The supplied Check Device test tubes can be used only once and can’t be used again. The Check Device test tubes are electronic devices and when exhausted have to be disposed of according to the laws in force.

- **Reagents and consumables**

  Any materials and/or accessories supplied for the VES-MATIC CUBE 80 are specially designed and cannot be replaced with other types of materials or supplies. Using other types of materials can seriously jeopardize the performance of the instrument. DIESSE Diagnostica Senese S.p.A. declines every responsibility for the performance of the product if original reagents and materials are not used.

**Potentially infected material is treated**

When the VES-MATIC CUBE 80 is used all precautions regarding the biological risk must be applied.

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

*Observe personal and group safety measures foreseen for the operator and appropriate for the work environment. Comply with the instructions in security matter and with the laws in force.*

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

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

*Samples that are not treated correctly cannot guarantee a good end result.*
CHAPTER 3

3.1 SWITCHING ON THE INSTRUMENT

Switching on
After verification of the installation of the instrument as described in Chapter 2, move the power switch, situated on the left of the power cable on the back of the instrument, to the On position “I” (Fig. 2.2.5)

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

During the initial check 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
From the Main Menu (Fig. 3.2.a), using the function buttons, it is possible to:
- Start the analysis with the VES-MATIC CUBE 80
- Access the service menu
- Modify the display mode (for example: Analysis Mod. View, Loader Mod. View, Data View)
- Unload samples that remain in the analytical chain of the Analysis Module
- Unload the sample holder rack
- Access the archives of the instrument
- Open the cover
Description of the commands and information common to the 3 modalities:

**Start:** starts the analysis cycle.
The Start-up command allows the initialisation of the instrument for the analytical procedures. Once Start is selected it executes a Reset of the instrument after which it is 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 of all analysed 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 the removal of any samples still present in the classifier module and to memorise the analysis in the archive (see paragraph 3.2.2).
If the Stop button is pressed during the analytical 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.b). This avoids unwanted interruptions of the analytical cycle.
At the end of a work cycle, remember to press the stop button before turning off the instrument, otherwise the data regarding the last analysis cycle will not be saved to the archives.

Fig. 3.2 b

Fig. 3.2 c
Moreover, the confirmation of the “YES” button automatically activates a counter of the stop time (decreasing second counter, with the duration of 90 seconds). This maximum interruption time allows the operator rapid interventions with minimal influence on the final ESR value recorded by the instrument. The time passed in “STOP” appears in the “Next result” window which will be renamed “STOP Time”. At the end of the intervention, that has to take less than 90 seconds, it is enough to push the “START” button and the instrument will resume its analytical activity.

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

**Archive:** allows access to the database of the instrument

**Settings:** allows access to the configuration menu of the instrument (see paragraph “Setup Menu”)

**Find:** allows the search for a sample within the instrument

**Analysis Mod. View:** allows the graphical display of the processes inside the VES-MATIC CUBE 80 regarding the Analysis Module

**Loader Mod. View:** allows the graphical display of the loading/unloading module processes in the rack (preparer module).

**Data view:** allows the display of the data of the samples present in the cycle of analysis

**Alarm OFF:** deactivates the sound alarms of the instrument

**Classificator ID:** indicates the identification number (bar code) of the used sample holder rack

**Classificator residual 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 colour of the window indicates that more than 1000 tests are available, orange indicates availability of between 500 and 1000 executable tests, yellow indicates that 0 to 500 tests remain available, while red indicates that the number of available tests is exhausted. This leads to the automatic block of the transfer of the samples from the preparer module to the analysis module. The samples already in the analysis module are nevertheless read and the relative ESR results are displayed. With the test counter at “0” the instrument is blocked. To be able to execute other tests it is necessary to recharge the analyser with a Check Device

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

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

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

**Counter of the total number of samples transferred from preparer module to analysis module**

indicates the total number of samples transferred from the preparer module to the analysis module. To display the total number of tests conducted by the instrument during its lifespan it is necessary to contact a technician authorised 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.

**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 above, 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.

![Image of sample status colors]

- **= new (new sample to be analysed)**
- **= mixed (sample being mixed)**
- **= sedimentation (sample in sedimentation)**
- **= completed (sample analysed)**
- **= Low/High/Error (sample for which a problem was encountered: blood level too low, to high or an error, for further explanations see paragraph 3.4)**

**Fig. 3.2 d**

**Open the cover:** allows the upper door to be opened to check for any irregularities or problems. This button is only available when the cycle has not been started, otherwise the button is disabled.

**Download samples:** Once a cycle has ended (pressing stop), this key allows a scan to be made of the analytical chain and the unloading of test tubes to be detected. If the instrument is turned off and on, this button will be deactivated: to activate it, it will be necessary to press the start button and the stop button at the end of reset.

**Downl Classific.:** ejects the sample holder rack.

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

**Sequence of operations in case of forced interruption of analytical cycle**
1. Press the START button
2. At the end of the reset insert a sample holder rack in the dedicated zone (Fig. 2.2.3)
3. Press the STOP button
4. Press the UNLOAD SAMPLES button and wait for the end of the procedure.

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

**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); for example to recover an urgent sample or in the case of an instrument block due to a forced interruption of the analytical cycle.
Sequence of operations

1. Press the STOP button
2. Press the “DOWNL 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 above, 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

- = sample tube waiting to be processed
○ = empty position or not yet verified by the sensor
● = analysed sample
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 above, it is possible to have information about the samples being analysed. This window displays (Fig. 3.2 f):

**POS:** position of the sample in the chain

**ID:** Identification code of the sample

**READ1:** Reading no. 1 corresponding to the level of the entire column of blood after mixing. This data can only be seen after typing the specific access code. (Access to this function is only allowed to personnel authorised by DIESSE Diagnostica Senese S.p.A.).

**READ2:** Reading no. 2 corresponding to the level of the erythrocyte column after mixing. This data can only be seen after typing the specific access code. (Access to this function is only allowed to personnel authorised by DIESSE Diagnostica Senese S.p.A.).

**ESR:** ESR result

**Find function**

The find button allows the detection of a sample inside the VES-MATIC CUBE 80 and its possible recovery by insertion of its bar code number (Fig. 3.2 g) using the keyboard and pressing the OK button.
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).

![Image of input panel](image)

**Fig. 3.2 g**

**Removal of the sample**
Pressing the “**YES**” button will start the sample recovery procedure.

⚠️ **ATTENTION**
The sample recovery procedure will interrupt the analysis cycle.

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

- **DB Historical**: allows access to the Historical Archive of the samples present in the database.
- **DB Pending**: allows access to the archive of the pending samples present in the database. The pending samples are those that are not yet sent by the Host nor saved in the Historical Archive.
- **DB Quality Check**: allows access to the Historical Archive of the Quality Control samples present in the database.
- **Back**: returns to the Main Menu.
Fig. 3.2 h

There are 3 archives (Fig. 3.2 h):

The **Historical archive** (Fig. 3.2 j) stores up to a maximum of 10,000 samples managed in a scrolling mode. Only samples for which the host computer or the operator has authorised the analysis are saved in this archive. Only for these samples it is possible to see, print and send the results to the host. Also only for these results the check device counter is reduced. Samples sent to the host are highlighted on the display page of this database with an asterisk.

The **Pending archive** (Fig. 3.2k) stores:

1) The samples already processed that have not yet received authorisation from the host to execute their analysis. The results of these samples cannot be displayed. The presence of a sample in this database is limited to 72 hours (the date/time field of the sample itself is considered as the beginning), after which all information about the sample will be removed. The instrument, during the stand-by period, will try to communicate with the host to know which pending samples should be saved and rendered available to the operator and which should be removed. The operator can manually force the authorisation for one or more samples: select the sample/s and push “Send to host”. This forcing manoeuvre determines the passing of the data regarding the sample to the host, their transfer them from the Pending Archive to the Historical Archive and the decrease of the test counter of the check device (see paragraph 3.3)

2) Samples with the unreadable bar codes are also stored in this archive. In this case, the operator must open the Pending Archive to manually insert missing codes (this can be done with the external bar code reader or with the virtual Windows CE keyboard). Afterwards the instrument can ask authorisation to the host also for these samples.

If the instrument works without a host connection only samples with the unreadable bar codes will be present in this archive. Upon opening the Pending Archive, the position of the sample in holder rack and the result of the ESR will be displayed. The relative missing codes must be manually inserted by the operator using the external barcode reader or with the virtual Windows CE keyboard, as indicated in the paragraph “Description of the commands and the information in the Pending Archive mode”.

The **Quality Check Archive** (Fig. 3.2 i) contains the historic data regarding the results of the “ESR Control” samples; this database has an autonomic management regarding the other archives.
Description of the commands and information in Historical Archive mode

**Fig. 3.2**

**Show All (List all):** all samples present in the Historical Archive of the database are listed.

**FIND:** search function of samples based on barcode 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 sample(s), selected by means of the checkbox, to the host

**Delete:** eliminates the selected sample(s)

**HCT Corr:** If you select a sample, you can insert the Hematocrit correction entering the HCT value on the keyboard and pushing the ENTER button

Hematocrit influences the ESR value. The relationship is described by Fabry’s formula:

\[ F = \frac{(WG*15)}{(55-HCT)} \]

This function has been implemented to correct the ESR Value according to the HCT value of patient.

The function can be activated manually or by interfacing schedule to LIS using ASTM protocol (this feature can be enable by the personnel of Diesse Diagnostica Senese SpA).

The ESR values, corrected with this function are indicated, both in the printed report and in the Historical archive with the letter "H".
Example of printed report

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

Create TXT file: Creates a text file containing all the data present in the current database

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

Back: returns to the main menu

In addition to the buttons described above, the following information is also available:

Records num. in archive: total number of samples present in the Quality Archive of the database

Records num. in list: total number of samples present in the list that is displayed.

List errors: interpretation of the letters indicated in an error code.

The following data 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 has been already sent to the host.

Date: date of the analysis

Time: time of the analysis
ESR: VES result (if it is set to 0 it means that the sample data has not been analysed on the host's request, but availability is active).

Errors: error code

ID Rack: identification of the sample holder rack.

Pos Rack: position in the sample holder rack (identified by an alphanumeric code)

**Description of the commands and the information in Pending Archive mode**

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

**ATTENTION:**

1. As a reminder, if the instrument is connected to a host, a PENDING sample does not display the ESR results

2. Every time the VES-MATIC CUBE 80 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 k**

**Show All (List all):** lists all samples present in the Pending Archive of the database

**FIND:** search function of samples based on barcode or date

**Select all:** immediate selection of all present samples.

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

**Refresh code:** allows the manual input of a barcode using the Windows CE keyboard if it was not read automatically by the instrument. The keyboard will appear automatically inserting the desired bar code into the field above this command.
Acquire Barcode: allows the input of a bar code by means of the external bar code reader if it was not read automatically by the instrument
Move Historical DB: sends the sample(s), selected by means of the checkbox, to the Historical database and to the host
Delete: eliminates selected sample(s)
Arrow Up: executes multiple selections of samples by scrolling up the list
Arrow Down: executes multiple selection of samples by scrolling down the list
Back: returns to the main menu

In addition to the buttons described above, the following information is shown:

Records num. in archive: total number of samples present in the Pending Archive of the database
Records num. in list: total number of samples present in the list that is displayed.

The following data is also visible on the display screen:

Code: barcode of the sample
Date: date of analysis
Time: time of analysis
ID Rack: identification of the sample holder rack.
Pos Rack: position in the sample holder rack (identified by an alphanumeric code)

Description of the commands and information in Quality Check Archive mode

ATTENTION:
As a reminder, a QUALITY control sample is managed in a different manner

Show All (List all): lists all samples present in the database of the Quality Check Archive
FIND: search function of samples based on barcode 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
Delete: eliminates the sample(s) selected
Print: prints the list of the samples that are selected by means of the check box
Create TXT file: allows export of the Database of the QC archive in text format
Arrow Up: executes multiple selections of samples by scrolling up the list
Arrow Down: executes multiple selection of samples by scrolling down the list
Back: returns to the main menu

In addition to the buttons described above, the following information is presented:
Records num. in archive: total number of samples present in the Quality Check Archive of the database
Records num. in list: total number of samples present in the list that is displayed.
List errors: interpretation of the letters indicated in an error code.

The following data is also visible on the display screen:
Code: barcode of the sample
Host: if an [*] is present near the alphanumeric identification code of the sample, this means the sample has been already sent to the host.
Date: date of analysis
Time: time of analysis
ESR: ESR result
Errors: error code
ID Rack: identification of the sample holder rack.
Pos Rack: position of sample in the sample holder rack (identified by an alphanumeric code)
Batch num: the lot number of the QC sample.
Exp date: expiry date of the QC sample
Min Val: the minimum value obtainable with the QC sample
Max Val: the maximum value obtainable with the QC sample
3.2.2 Settings Menu

Description of the commands and information of the Settings menu

This function allows access to the following update and service procedures (Fig. 3.2 l):
Language, Qc Setting, Date/time, Temperature Corr., User Setup, Service, Export Files

**Language**
Allows the selection of the language. If pressed, the window “Select language” (Fig. 3.2 m) appears. To choose the language setting of the instrument, press the corresponding button on the display.
**QC Settings**

The quality control settings window (Fig. 3.2 n) allows the set-up of all parameters for the QC samples so that they can be properly recognised by the VES-MATIC CUBE 80 and stored separate from the normal samples.

![Quality Control Settings](image)

**Fig. 3.2 n**

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

**Explanation of each section**

**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**

- **Barcode**: insert barcode present on the test tube(s) of the QC sample(s)
- **Lot num.**: insert the batch number of the QC sample (written on the package)
- **Expiration Date**: insert expiry date of the QC sample (written on the package)
- **Val. Min**: insert the minimum value obtainable with the QC sample (written in the Certificate of Analysis of a given lot)
- **Val. Max**: insert the maximum value obtainable with the QC sample (written in the Certificate of Analysis of a given lot)

**Commands in the Quality Control setup window**

- **Confirm**: saves the inserted and/or modified data
- **Back**: returns to the Settings menu.
**Date/Time**

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

![Set Date/Time window](image)

**Fig. 3.2 o**

**Explanation of each section:**

**Date:**

Set-up of the date format

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

To complete the selection of the date format, press “Confirm” button, return to “Analysis Mod. View”, switch off and then switch on the instrument. After this operation, the date will be displayed in the selected format.

**Set-up of the Date**

- DD: sets the day number, using the buttons + and –
- MM: sets the month number, using the buttons + and –
- YYYY: sets the year number using the buttons + and –

**Time:**

Set-up of the time

- HH: sets the hour using the buttons + and –
- MM: sets the minutes using the buttons + and –
- SS: sets the seconds using the buttons + and –

**Commands of the Setup Date/Time window**

- **Confirm:** saves the inserted or modified data
- **Back:** returns to the main menu (SETTINGS)

**Temperature corr.**

This button allows the activation/deactivation of the automatic temperature correction of the results (when the automatic correction of the temperature is activated the relative window is coloured green...
and displays the writing ‘ENABLED, when it is deactivated, the window is red and shows the writing ‘DISABLED’

**User Settings**

**Description of the fields**

**ESR MAX VAL:** This field allows the user, basing on specific needs, to set up the ESR value above which the sample will be retested. All samples with ESR results higher than the inserted value will be automatically re-analysed.

**MAX NUM RETRY:** This field allows setting the number of repetitions of the analytic cycle of samples with ESR results higher than the set value; the maximum number of sample repetitions is three.

![User Settings](image)

**Description of the commands**

**Touch screen calib.:** 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 and will be lost after the next turning off of the instrument.

**Positioner step:** this command (which should be used by expert operators only) allows rapid retrieval of a test tube from the analytical chain. After opening the front panel of the instrument and inserting the appropriate micro switch key to avoid a complete stop, it is possible to determine, by pressing the button several times, the advancement of the desired test tube up to the point in which manual access for the removal of it is possible.

**CheckDev Procedure:** This button starts the procedure of recharging of the check device (see section 3.3)

**ESR Correction:** This button allows to enter the historical database and search samples. Once selected a number of samples with ESR value in the acceptability range, it’s possible to use the ESR correction clicking on the relative button and entering manually the correct value.

Although the International Reference test method (reference to ICSH 2011) is used for the alignment of all the instruments, this function may be used to guarantee the correlation with the Reference test. The function can be enabled by Diesse (Technical assistance).

Then, pressing INTERPOLATE button, the system creates a conformity matrix for all the samples in the database. Return to the previous menu pressing to the BACK button (Fig. 3.2 q).
If this function is activated "CUSTOM MATRIX ENABLED" will be printed in the report. **Back:** returns to the Settings menu.

**Fig. 3.2 q**

**Export Files**
pressing this button allows copying of the following files on an external memory support (SD card): COUNTERS (INI.File), ERRORLOG (TXT.File), EVENTS (TXT.File), LOG (TXT.File), Vescube (DB.File), Vescube (INI.File).

**Procedure**
Insert the SD card in the relative slot, as shown in the Fig 3.2 r, the button “Export Files” will activate illuminating the command in white.
Press the button and wait for the end of the operation before removing the SD card.
Service: allows the access, by means of a password, to the service menu of the instrument

Only personnel authorised by DIESSE Diagnostica Senese S.p.A. is allowed to access this function.

Back: allows return to the MAIN MENU (Settings).

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

To top-up the number of available tests it is necessary to open the instrument cover. This will allow access to the Check Device Reloading device, placed on the left side of the mixing unit (see Fig. 3.3 b).
Insert the “Check Device Transponder RF” inside the device (see Fig. 3.3 c).
After placing the “Check Device Transponder RF” test tube in the slot, choose the **CheckDev Procedure** in the User Settings menu (Fig 3.2 p). After a delay of a few seconds a message will appear in the dialog bar: “Refill check device executed” if the outcome of the recharge is positive, “Error in refill check device” in the case of a negative result (in this case it is advisable that the operator retrieves the “Check Device Transponder RF” test tube and repeats the operation from the beginning).

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

**Functioning of the check device:**

1. When the result of a sample is saved on the historical database, and possibly printed, the counter of the check device is decreased.
2. In case the instrument works **without a Host connection** all results are saved on the historical database, printed, displayed and for each one the counter of the check device is decreased. The results regarding samples with a not readable bar code are saved in the Pending Archive (see paragraph 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 the others samples will not be analyzed.
4. In case of **a temporary absence of a Host connection**, the instruments proceeds as follows
   a. The test tubes will be processed and the data saved temporarily (72 hours) in the Pending Archive. The data of these test tubes are all displayed, except the analytic result.
   b. At the moment of the positioning of the tube in the sample holder rack only the bar code and the position of the tube in the sample holder rack will be printed, the result of the analysis will not be printed.
c. At the end of the analytical cycle the instrument, with regular intervals and for a maximum of 72 hours, will continue to interview the Host to establish which pending samples (already analysed) were actually requested.

d. The results regarding the tubes requested by the Host are transferred and saved in the Historical Archive and sent to the Host. The counter of the Check Device will be decreased in consequence. The results of the samples not requested by the Host will be removed from the Pending Archive.

e. If it is not possible to re-activate the connection with the Host, the operator can enter in the Pending Archive and manually force the acceptance of one or more samples. The data must be printed right away, sent to the Host (if possible) and saved in the Historical Archive. The check device test counter will be decreased.

f. After a period of 72 hours in the Pending archive the data of the test tubes will be removed.

g. If, because of the lack of connection to the host, the instrument is unable to send the results of the accepted test tubes, they are copied and memorised in the Historical Archive. The instrument will try periodically for 72 hours to send them to the host, after which the data is only available in the Historical Archive.

h. The operator can re-send to the Host the data of one or more samples present in the Historical Archive. In this case the instrument will try periodically to send them to the Host for a maximum of 72 hours.

5. In case the number of executable tests finishes during the analytical activity, the instrument will save for 72 hours in a virtual archive all data regarding the analysed samples (up to a maximum of 3,000 items). The obtained results will not be displayed until the test counter is reloaded.

This temporary saving (72 hours) allows analysis to be completed, the data on analysed samples not to be lost and therefore to avoid repeating the analysis and provide the laboratory with enough time to obtain a new Check Device Transponder RF to top-up the test counter.

The number of the tests still available in the instrument is indicated in the dedicated window (Fig. 3.2.1 b); its colour informs the user of the remaining available tests; green indicates the possibility of analysing more than 1000 tests, orange indicates that the number of available tests is between 500 and 1000, yellow indicates that the tests available are less than 500, while the red indicates the number of executable tests is exhausted.

3.4 READING OF THE RESULTS PRINTOUT

The VES-MATIC CUBE 80 prints the results of each sample in real time.

The complete printout with header of the results regarding the samples in a sample holder rack (classifier) is obtained in three cases:

1) When the sample holder rack (classifier) is complete. In this case the instrument will automatically slide the sample holder rack up to the exit positioned at the lower left side of the instrument (Fig. 2.2.2). From this position it is possible to extract the sample holder rack completely. At the same time the printer will complete the printout of the results of the samples in that sample rack holder that will appear as shown in Fig. 3.4.

2) When the day of the analytical routine is completed and after having pressed the “Stop” button. In this case the sequence of operations is the following: pressing the “Stop” button, activation and pressing the “Unload sample holder” which allows the sample holder rack to slide to the
exit, printout of the results regarding the samples contained in that sample holder rack, which will appear as described in Fig. 3.4.

3) When the samples to be analysed in the sample holder rack (classifier) have been completed and there is a new rack queuing up. In this case, the conveyor belt will move the sample holder to the exit of the VES-CUBE and the printer will end the data printout on the classifier rack, as shown in Fig. 3.4.

The printed out report contains:
- name of manufacturer : DIESSE,
- name of the instrument,
- software release (V. X.xx),
- serial number of the instrument (SN),
- temperature detected inside the instrument (°C – °F),
- correction of the temperature (active = ‘ON’, not active = ‘OFF’),
- date DD/MM/YYYY or MM/DD/YYYY of analysis time (HH/MM/SS) of analysis,
- barcodes (ID BarCode),
- corresponding ESR value (WEST 1H) (if the ESR value does not appear on the printout this means that the sample has not been analysed or that it is in the Pending Archive)
- position of the sample in the sample holder rack (classifier) identified by an alphanumeric code (POS NUM).

At the end of the list of samples and their related data, the barcode of the sample holder rack (CLASSIFICATOR CODE) will appear.

When a control sample is analysed the results printout shows the following:

**QC PASS xx/xx,**

N. Lot xxxx,

Expiration date DD/MM/YY,

xxxxxx (QC barcode)

ESR value reading for that control sample

Position in the sample holder rack

To evaluate the obtained result, refer to the technical instructions supplied with the control sample.
When a sequence of points appears in “ID BarCode” column, this means that the internal barcode reader did not read that barcode. However the sample, whose the position is indicated in the respective sample holder rack, has been analyzed anyway and the relative data are stored in the Pending Archive. At this point the operator can continue as described in the paragraph 3.2.2 (Historic DB and Pending DB).
ATTENTION - NEW FEATURE

Among the print functions, now there are 4 new possibilities:

1. Traditional printing with classical error codes (ERR) (Fig. 3.4)
2. Printing with the new error codes. As reported in the example below the printing can show new error codes (Fig. 3.4 a).

---

**Fig. 3.4 a**

3. Print the results in agreement with Westregren method (Fig. 3.4 and 3.4 a)
4. Print the results in agreement with Pachenkov method.

The results of the ESR according Pachenkov (very widespread method in Eastern Europe) is linked to the traditional Westergren method by the following formula:
y = Pachenkov (ESR)  
x = Westergren (ESR)  

\[ y = -0.0017x^2 + 0.86161x + 1.6524 \]

According to the formula it is possible to calculate the Pachenkov ESR value, starting from the Westergren one.

Both the values are reported in the final printing: the first result is Westergren ESR while the second is Pachenkov ESR (Fig 3.4 b)

This feature can be enabled by personnel authorized by DIESSE Diagnostica Senese S.p.A.

**ATTENTION**

“1#”: If the result is equal to 1 the # symbol appears.  
It is advisable to visually check the sample to investigate if the result is due to problems.
of label (L), problem of clotting (C), mixing (M), problems or leakage of blood along the walls, due to the type of test tube, etc.

The following messages may be shown in the “WEST 1H” column:
- ERR: means that the instrument has not been able to reveal any “characteristic point” useful for the readings, thus it is advisable to check the sample and, after excluding labelling problems, clots, etc. to repeat the analysis.
- LOW: means that the quantity of blood in the tube is insufficient (≤ 1.5 ml). Verify the blood level in the tube. If the volume is lower than 1.5 ml, repeat the blood drawing.
- HIGH: means that the quantity of blood in the tube is excessive (> 4 ml). Verify that an air space exists between the bottom end of the cap and the sample level. If the blood level in the test tube is excessive, remove, after mixing, about 500 μl of blood and repeat the test.
- xx*: value of ESR with an asterisk (for example “43*” as in Fig. 3.4) means that the instrument has read a value, but advises the operator that the state of the sample does not correspond to that specified in paragraph 4.2.2 (Fig. 4.2.2 a, 4.2.2 b, 4.2.2 c). The operator is advised to check the sample to exclude labelling problems, clots, etc., and decide whether to validate the obtained result or to repeat the analysis.

<table>
<thead>
<tr>
<th>HIGH</th>
<th>LOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Tube with sample level HIGH: exceeds 4 ml.</td>
<td>Sample test tube with sample level LOW: less than 1.5 ml.</td>
</tr>
<tr>
<td>Verify that an air space exists between the bottom end of the cap and the level of the sample. If the level in the test tube is excessive, remove, after mixing, about 500 μl of blood and repeat the test.</td>
<td>Verify the blood level in the tube. If the volume is lower than 1.5 ml, repeat the blood drawing.</td>
</tr>
</tbody>
</table>

**ATTENTION - NEW FEATURE**
This software release contains a set of new error codes.

This feature can be enabled by personnel authorized by DIESSE Diagnostica Senese S.p.A.

It could be present 2 types of situations.
1. Presence of error codes without result
2. Presence of error codes with result

**Presence of error codes without result**
In this case the sample must be checked. If appropriate, it has to be analyzed again

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 advisable to check the sample and, after excluding labelling problems, clots, etc. to repeat the analysis.
- !CREP: means that the instrument has not been able to reveal any “characteristic point” useful for the readings after the sedimentation time; thus it is advised to observe the sample and, after excluding problems like clotting (C) etc. to repeat the analysis.
- !CBLM: 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 (L), clotting (C), mixing (M) or leakage of blood along the walls, due to the type of test tube (or so on) to repeat the analysis.
- !CLBI: 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 (L), interference (I), clotting (C) etc. to repeat the analysis.

Presence of error codes with result

In the column “WEST 1H” the following messages can be present:
- !LBI: 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 (L), interference (I), etc. to repeat the analysis.
- !BLM: 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 (L), mixing (M) problems or leakage of blood along the walls, due to the type of test tube, etc. to repeat the analysis.
- L: means that the quantity of the blood to test is not sufficient (≤ 1.5 ml). Verify the level of the sample, in case this is lower than 1.5 ml, repeat the blood drawing.

“1#”: If the result is equal to 1 the # symbol appears.
It is advisable to visually check the sample to investigate if the result is due to problems of label (L), problem of clotting (C), mixing (M), problems or leakage of blood along the walls, due to the type of test tube, etc.
CHAPTER 4

4.1 GENERIC DESCRIPTION OF AN ESR ANALYTIC CYCLE IN THE VES-MATIC CUBE 80

ESR Erythrocyte Sedimentation Rate 1h.
Gives the results in accordance with the Westergren citrate method with a reading after one hour; the overall duration of the analysis for the first sample is 24 minutes then the results come out every 38 seconds.

**Description of the test cycle:**
- At the beginning of the analysis, the instrument queries the sensor positioned underneath the rack pulling unit to check if a sample holder is present on board. If not present, a request for the sample holder insertion will appear on the information bar. Once inserted, the rack is pulled first under the sensors that will check the presence and location of the first samples and then to the optimum position for allowing the pincers to draw out the test tubes.
- At this point, the samples are withdrawn by the pincers and placed in front of the barcode reader, the samples will be turned around until the barcode can be read by the reader.
- After the barcode reading a host query for each sample is conducted (if there is a connection with a host), to recognise if the identified sample requires an ESR analysis.
- After recognising the sample, the samples for which an ESR analysis has been requested will be introduced into the chain, otherwise they will be placed back on the rack.
- The samples for ESR are inserted one by one in the underlying chain of the analysis module and moved, with a step time of 19 secs, to the mixing zone. On entering the mixing zone, every sample is rotated by 180°, 3 times every step, so after 5 steps inside the mixing zone every sample has been mixed 15 times.
- At the exit from the mixing zone, the instrument will execute the first reading for the determination of the total blood level in the sample.
- Every test tube is then moved with a step time of 19 secs to the second sensor (overall time of 20 mins)
- 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 ESR results are reported in Westergren units.
- The analysed test tubes are removed one by one from the chain, by means of an ejection system and positioned in the green area of the sample holder rack in positions identified by alphanumeric co-ordinates.

4.2 DETAILED DESCRIPTION

4.2.1 Initial power up
After the installation of the instrument as indicated in Chapter 2, move the power switch, situated on the left of the power cable on the back of the instrument, to the On position "I" (Fig. 2.2.5).

At the first power up, to verify the status of the instrument and the efficiency of the Optical Reading Group, the following is advised.
Introduce the ESR Control Cube (REF 10435-10436) Normal and Abnormal levels in two test tubes that are normally used in the laboratory, position them in
the rack and start an analytic cycle. At the end of the test verify that the results obtained correspond to the expected values (refer to the Certificate of Analysis (CoA) supplied with the product).

**Quality Control Test**

The performance of the VES-MATIC CUBE 80 instrument is verifiable at any moment using ESR Control Cube (REF 10435-10436). It constitutes a stable material that allows the determination of the precision of the instrument in the measurement of the Erythrocyte Sedimentation Rate.

The expected values are reported in the lot-specific CoA present in the product package (see paragraph 1.3).

For the conservation, the preparation and use of ESR Control Cube refer to the relative Instructions of Use.

### 4.2.2 Preparation of the sample

No special preparation of the test tubes is required, since the VES-MATIC CUBE 80 uses the test tubes from the haematology analyser (CBC examination).

**Suitability of the sample**

The sample can be considered suitable when:

- the test is executed within 4 hours of the drawing (NCCLS H02-A5 Procedures for ESR; approved standard – fifth edition, Point 4.2)
- the test is executed on the blood sample conserved at 4° for a maximum period of 24 hours. In this case assure that the sample is reported to room temperature before inserting it into the instrument for the analytic cycle.
- always invert the tube before inserting it into the instrument (ATTENTION: during this operation no clots should be found).

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

**Filling of the test tube**

For a correct execution of the ESR exam by the VES-MATIC CUBE 80 instrument, the level of blood in the test tube is fundamental. The instrument itself will verify the correct filling of the test tube, measuring the level and comparing it with the pre-set tolerance values of maximum and minimum level.

**ATTENTION:** In the case of excessive (over 4.0 ml) or insufficient filling (below 1.5 ml) the instrument will print an error message. If the filling is excessive, it signals “HIGH”, if the filling is insufficient it signals “LOW”. In both cases the analysis must be repeated with the correct quantity of blood. The same message will appear on the results printout.
Check of test tube labelling

Sample labelling method and compatibility with the number of labels
VES-MATIC CUBE 80 models are designed to work with a maximum of two labels, not overlapping, attached to the same test tube to be analysed. (Fig. 4.2.2 a).

The internal barcode reader, inside the preparer module, is mechanically regulated to work with labels applied to the sample at least 3 mm above the rounded bottom of the test tube Fig. 4.2.2 a①; it is also programmed to read barcodes placed at 90° from the reading band, i.e., with the code perpendicular to the longitudinal axis of the test tube Fig. 4.2.2 a②. The reader nevertheless can correctly read sloping barcodes (corrected) by + 5° (Fig. 4.2.2 a③).

![Correct height of application of the label on the test tube](image)

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

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

![Maximum number of label layers attached to test tube and accepted by the VES-MATIC CUBE 80.](image)

Fig. 4.2.2 b Maximum number of label layers attached to test tube and accepted by the VES-MATIC CUBE 80.
It is important to verify, before loading the instrument, that the labels adhere perfectly to the test tubes: the adhesive parts, if detached, can cause frictions during the mechanical movements of the groups (inserter, ejector and sorter), creating inserting and ejecting problems in the analytical chain and possible blocks of the reading sensors.

In Fig. 4.2.2 c some “INCORRECT” labelling examples are displayed, which are potential causes of mechanical blocks and/or reading problems on the Optic-Electronic Sensors.

Fig.4.2.2 c INCORRECT sample labelling modes
4.2.3 Warnings and limitations

Insert the samples to be analysed in the red area only of the sample holder rack and insert the rack in the right side of the VES-CUBE, along the extension (see photo)

![Fig. 4.2.3 a](image)

**Fig. 4.2.3 a**

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

**Fig. 4.2.3 b left side**

**Fig. 4.2.3 c right side**

**ATTENTION**

Do not switch off the instrument during the working phases or during the Reset procedure. To safeguard the database it is advisable that the instrument is turned off **ONLY after pushing the STOP button** on the display and awaiting the completion of the movement.
4.2.4 Preparation sequence for a test

**Loading procedure of the samples**
1. Press the START button, waiting the Reset will be completed.
2. Insert the rack in its housing (Fig. 4.2.4).
3. Insert the rack’s (Classifier’s) barcode (using the external barcode reader or the virtual Windows CE keyboard after pressing the grey button “Classifier ID”)

![Image of sample rack](image)

Fig. 4.2.4

4.2.5 Conclusion of the analytical cycle
An analytic sample cycle 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 relative result print report

Every time the analysis of the samples present on a single holder rack is complete, the instrument will print out the results regarding all the test tubes. The printout contains also the code of the sample holder rack, date, time and the temperature of the analytical cycle, installed software version and the serial number of the instrument (see paragraph 3.4).

4.2.6 Conclusion of the daily analytic activity
At the end of the daily analytical activity and every time one desires to access the archive, it is necessary to press the ‘STOP’ button. This operation allows the ‘ARCHIVE’ button to become active (“illuminated”) and at the same time to save all data obtained until that moment.

Before turning off the instrument’s main switch, it is advisable ALWAYS press “STOP” button (see paragraph 3.2.1). Otherwise the data saving in the archive will be compromised.
CHAPTER 5

5.1 GENERAL RECOMMENDATIONS
The VES-MATIC CUBE 80 is designed and constructed to require only a minimum amount of maintenance.

For any intervention:
- disconnect the power from the instrument.
- use the personal protective equipment, required while operating the instrument.
- do not remove barriers and do not elude the security devices.

In case of leakage of biological material inside the instrument or contamination of its external or internal surfaces accessible to the operator, use the suitable solutions for the sanitisation following the procedure described in paragraph 5.2.

5.2 CLEANING/DISINFECTION OF THE INSTRUMENT

The external cleaning is required for safety reasons. Use a bland, non-aggressive detergent solution.
Do not use solvents, diluents, acids, acetone or similar materials in order to avoid damaging the outer casing.

SANITISING Procedure (for the internal parts in contact with the operator)
1. The instrument must be switched off; any residues or leakage have to be cleaned with a liquid detergent and then left to dry.
2. Use a ready-to-use isopropyl alcohol spray cans available on the market.
3. Spray well inside the instrument and on top of the sample-holder plate.
4. Close the lid of the instrument and leave switched off at least for one hour before beginning a new work cycle or any other type of operation in the instrument.

For the internal cleaning of non-accessible parts the operator must contact Technical Assistance.

5.3 REPLACEMENT OF PRINTER PAPER

Procedure:
- Switch-off the instrument and disconnect from the power source.
- Lift the printer window.
- Remove the paper pin.
- Substitute the old paper roll 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 opening of the paper guide, taking care to level it precisely with a pair of scissors and respecting the paper rotation direction.
• Connect the instrument to the power source and switch-on
• Push the paper until self-loading begins (Fig. 5.3 c). It is possible to use a toothed roll as indicated by “B” (Fig. 5.3 a and b) to facilitate loading

• Lower the print head lever.
• Let the paper move forward until extending from the front (Fig. 5.3 d, e).

• Pull the paper through, close the window and extract the paper that extends from the front (Fig. 5.3 f).
5.4 REPLACEMENT OF THE FUSES

Operate as follows to replace the fuses:

1. Turn off the instrument and disconnect it from the mains.

2. Remove the fuse box using a flathead screwdriver.

3. Replace the blown fuses with the new ones provided.
4. Refit the fuse box and reconnect the instrument to the mains.

5. Turn the instrument back on.

If the fuses blow again when turning on, contact Technical Service.
CHAPTER 6

6.1 TROUBLESHOOTING

The PC Tablet, besides performing command operations and control of the peripherals, constantly checks the most important parts of the instrument. When an anomaly is encountered, the process in progress is automatically interrupted and a sound signal is sent; at the same time, the type of breakdown or problem encountered is displayed on the screen.

The possible messages are the following:

<table>
<thead>
<tr>
<th>MESSAGE AND FAULT</th>
<th>CAUSE AND SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Error 0x01 (Positioner)</td>
<td>Error of the chain movement. Besides possible electric defects, it can be verified mechanical obstructions that have to be removed (see paragraph Independent Management of some problems). If the problem persists, contact Technical Service.</td>
</tr>
<tr>
<td>Device Error 0x04 (Mixing device)</td>
<td>Error in mixer device of the test tube in the analysis module. Besides possible electric defects, it can be verified mechanical obstructions that have to be removed (see paragraph Independent Management of some problems). If the problem persists, contact Technical Service.</td>
</tr>
<tr>
<td>Device Error 0x05 and 0x06 (Reader 1 or 2)</td>
<td>Errors in the reader devices of the optical sensors. Besides possible electric defects, it can be verified mechanical obstructions that have to be removed (see paragraph Independent Management of some problems). If the problem persists, contact Technical Service.</td>
</tr>
<tr>
<td>Device Error 0x08 (Sample holder)</td>
<td>Error in the movement of the sample holder rack. Press the STOP button to interrupt the analysis cycle and let the rack exit by selecting “Unload sample holder rack”. If the problem persists, contact Technical Service.</td>
</tr>
<tr>
<td>Device Error 0x10 (CLAMP H)</td>
<td>Movement error along horizontal axis on pincers unit. Besides possible electric defects, it can be verified mechanical obstructions that have to be removed (see paragraph Independent Management of some problems). If the problem persists, contact Technical Service.</td>
</tr>
<tr>
<td>Device Error 0x11 (CLAMP V)</td>
<td>Movement error along vertical axis on pincers unit. Besides possible electric defects, it can be verified mechanical obstructions that have to be removed (see paragraph Independent Management of some problems). If the problem persists, contact Technical Service.</td>
</tr>
<tr>
<td>Device Error 0x13 (Rack Detect)</td>
<td>Error in the system that identifies the rack during the loading of the VES-MATC CUBE 80. Besides possible electric defects, it can be verified mechanical obstructions that have to be removed (see paragraph Independent Management of some problems). If the problem persists, contact Technical Service.</td>
</tr>
<tr>
<td>Device Error 0x20 (Transponder)</td>
<td>Error of the Check Device Transponder RF refill device. Contact Technical Service.</td>
</tr>
<tr>
<td>Error test tube absent (Ph Chain)</td>
<td>The system does not detect an expected test tube in the chain. Besides possible electric defects, it can be verified mechanical obstructions that have to be removed (see paragraph Independent Management of some problems). If the problem persists, contact Technical Service.</td>
</tr>
<tr>
<td>Check Device exausting</td>
<td>The test counter is running out, the instrument has no more than 500 hits available (box is yellow). Recharge the instrument. If the problem persists at the end of the recharging, contact Technical Service.</td>
</tr>
<tr>
<td>Check Device exausted</td>
<td>The test count has run out (box is RED). Recharge the instrument. If the problem persists at the end of the recharging, contact Technical Service.</td>
</tr>
</tbody>
</table>
### Check-Device Recharge Error
Problems in the recharge of the test counter.

Insert a different device in the instrument.
If the problem persists at the end of the recharging, contact Technical Service.

### Check the left frontal switch
Error in right micro-switch of the front panel.

Verify the correct positioning of the front container on the indicated side of the micro-switch.
If the problem persists, contact Technical Service.

### Check the right micro-switch
Errors in right micro switch on the front panel.

Verify the correct positioning of the front container on the indicated side of the micro-switch.
If the problem persists, contact Technical Service.

### Host Timeout
Error of connection line to host computer.

Verify the correct connection of the cable on the back side of the VES-MATIC CUBE 80.
Verify the correct functioning of the IT network of the laboratory.

### Printer: paper end
Printer paper ran out.

Insert a new roll of paper in the printer (see paragraph 5.3)
If the problem persists, contact Technical Service.

### Printer head up
The printer head is lifted.

Lift the lid of the printer and lower the head, using the black lever on the right side of the head.
If the problem persists, contact Technical Service.

### Printer: communication error
Communication error between printer and PC Tablet.

Verify the presence of the paper and the position of the printer’s head.
If the problem persists, contact Technical Service.

---

After any ERROR signal it is advisable to repeat the whole operation at least once, to ensure that the error isn’t caused by external factors, like the momentary interruption or variation of electricity.

Switch the instrument off and wait a few 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 systems.)

### 6.2 INDEPENDENT MANAGEMENT OF SOME PROBLEMS

**ATTENTION:** The procedures described below must be carried out only while the instrument is switched off. Before reactivating the instrument it is necessary to restore all safety covers

### 6.2.1 Procedure for access to the Classifier Module
1. Remove the two Insertion Extension Racks by sliding them upwards by about 1 cm and moving them to the outside to free them from the holding buttons (Fig. 6.2.1 a)

Push the Insertion Extension Racks upwards, then move them outwards, following the order of the arrows
2. Open the Preparer Module door and lift the front cover vertically about 1 cm, pushing from the bottom, so that it slides upwards.

3. Completely remove the front cover.
   Verify if there are any test tubes causing a block and remove them.
4. For reassembly follow the reverse procedure to the one described until the upper part of the cover is aligned with the lateral panels.

6.2.2 List of some error messages and their solution
When the instrument is in the “View Analysis Module” or “View Preparer Module” mode it can indicate error messages on the screen in the “information bar” (see Fig. 3.2 b). Some error messages and the operating instructions for their solution by the operator are shown below.

Verify front left micro-switch: in this case it is advisable to verify the correct application of the front cover, without necessarily switching off the instrument.

Device Error 0x04 (Mixing device): the normal movement of the mixer is blocked.
It is advisable to access the Analysis Module following the procedure described in paragraphs 6.2.1 and 6.2.2 with the instrument turned off. 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 correctly.

Error Test Tube absent (Ph. Chain): this error may occur if the sample remains blocked in the rack caused by adherence generated by the incorrect labelling of the test tube (see paragraph 4.2.2) In this case, it is sufficient to restart the analysis to move on to the next sample.
CHAPTER 7

7.1 EXTERNAL BARCODE READER

The recording of the identification number of the sample holder rack can be performed means of the external BAR CODE READER supplied with the instrument.

GENERAL SPECIFICATIONS FOR CONNECTION:

Before connecting the external Barcode Reader verify that:

a. it is fitted with a cable with a female DB9 connector in DTE configuration with a current of 5Vdc on 9 pins (refer to the Barcode Reader instruction manual).

b. the signals on the DB9 female connector are compatible with the connector placed on the back of the instrument to which it is connected:

<table>
<thead>
<tr>
<th>PIN</th>
<th>SIGNAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Tx data to reader (not used)</td>
</tr>
<tr>
<td>3</td>
<td>Rx data from reader</td>
</tr>
<tr>
<td>5</td>
<td>GND</td>
</tr>
<tr>
<td>9</td>
<td>+ 5 V</td>
</tr>
</tbody>
</table>

TECHNICAL INFORMATION

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

**The reader must be connected, WHILE THE INSTRUMENT IS TURNED OFF**, to the appropriate DB9 male placed on the back of the Window Group. On turning on the instrument, if it is 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

Host connection is allowed by two procedures, mono and bidirectional communications, performed using RS232C communication port.

Moreover it is also available the International protocol ASTM 1394-97. For technical details, refer to Service Manual or contact your local Technical Assistance.
BIBLIOGRAPHY

1. How to Define and Determine Reference Intervals in the Clinical Laboratory: Approved Guideline*EA-ASSE-2000-NCCLS


APPENDIX A: EC DECLARATION OF COMPLIANCE

The current EC Declaration of Conformity is available for the download from DIESSE’s website www.diesse.it

APPENDIX B: ACCESSORIES, SPARE PARTS AND CONSUMABLES

- 2 Sample holder racks [Ref: R30003720]
- 2 Micro-switch keys [Ref: R10343131]
- 1 Roll of thermal paper h.mm l=57 D=50 [Ref: R12300000]
- 2 5x20mm UL 5A delayed fuse blocks [Ref: R20400070]
- 1 3x0.75 L =2m SCHUKO 90°-C1 Power cable [Ref: R21890040]
- 1 SVT PLUG USA/OUTLET VDE 2MT UL Power cable [Ref: R21890370]
- 1 Z-3080+Cable CAB50607-R9 Barcode reader [Ref: R20550510]

Consumables

- Test device 1K (1000 tests) [Ref: 10292]
- Test device 5K (5000 tests) [Ref: 10291]
- Test device 10K (10000 tests) [Ref: 10290]
- ESR Control Cube 4x9ml (2 normal vials + 2 abnormal vials) [Ref: 10435]
- ESR Control Cube 2x9ml (1 normal vial + 1 abnormal vial) [Ref: 10436]
- Thermal paper for printer (4packets) [Ref: 10403]
- Calibrator (TEST TUBE READER) [Ref: 19900900]
APPENDIX C: QUICK-START INSTRUCTIONS

Excerpt from this Instructions Manual

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

- Turn the instrument on using the main switch, situated to the left of the power cable on the back of the instrument, turning it to position “I” (Fig. 2.2.5).
- Press the START button, wait for the Reset to be completed.
- Check that the labels adhere perfectly to the test tubes: the adhesive parts, if detached, could cause friction during the mechanical movement systems (inserter, ejector, and sorter), creating inserting and ejecting problems in the analytical chain and possible blocks of the reading sensors.
- Blood sample level: the minimum acceptable level is ≥1.5 ml; maximum acceptable level is < 4.0 ml.
- No special preparation of the test tubes is required, since the VES-MATIC CUBE 80 uses the ones coming from another analytical system (CBC examination).
- Insert the rack in its housing (see Fig 4.2.3 c). Remember that the rack loading positions are only the ones with a red interior (see Fig 4.2.4). The remaining positions are used by the machine to unload the analysed samples.
- Once the rack has been inserted, type the relative barcode.
- Press the STOP button to interrupt the analysis.
- ATTENTION! Do not switch off the instrument during the working phases or during the Reset procedure. To safeguard the database it is advisable that the machine is switched off ONLY after pushing the STOP button on the display, awaiting completion of the movements.
- At the end of the daily analytical activity and every time access to the archive is required it is necessary to press the ‘STOP’ button. This activates (‘illuminates’) the ‘ARCHIVE’ button and at the same time saves all data obtained until that moment.
- It is advisable to press the ‘STOP’ button ALWAYS before switching off the instrument (see paragraph 3.2.1, description of the “Stop” button function).