



OPERATING MANUAL

Release SW 2.xx

[Rev.0.0 of 07/12/2006]

Automatic instrument for determining the erythrocyte sedimentation rate (ESR)

(Patented)

(Diagnostic Device  -IVDD 98/79)



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UNI EN 591 II Edition (November 2001)

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

LIST OF REVISIONS

MANUAL REVISIONS	DESCRIPTION OF MODIFICATION	APPR.
0.0 of 12/2006	-----	

MODELS

This manual applies to the following instrument models:

Diesse Code	Description
10376	VES MATIC EASY

SYMBOLS

Legend of graphic symbols used on the Instrument [Standard applied: EN980:2003].



Instrument satisfying requirements of european directive on in vitro diagnostic medical devices (98/79/EC).



In vitro diagnostic medical device.



Instrument satisfying CSA standards for the Canadian and Usa market



Date of manufacturing of the unit.



Serial number of the unit.



Manufactured by.

Legend of Electrical and Safety symbols used on the instrument:



Attention, read the manual and observe the relative safety symbols.



WEEE: Disposal of Waste Electrical and Electronic Equipment - At the end of its life, this instrument should be disposed of according to separate waste collection provisions [2002/96/EC, 2003/108/EC]

Legend of Symbols used on the document:



WARNING, potential hazard of personal injury, all the conditions indicated in the associated text must be stored and understood before proceeding.



WARNING, potential danger of damaging the instrument all the conditions indicated in the associated text must be known and understood before proceeding.



ATTENTION, important information.



BIOHAZARD, danger of contamination with potentially infected substance.



GENERAL WARNINGS

Before installation and use of the instrument, for ensuring **correct and safe use**, it is recommended **carefully reading** the warnings and instructions contained in this instruction manual.

It is important for this instruction manual always to be stored together with the instrument for future consultation.

In the case of selling or transferring the instrument, make sure that the manual always accompanies the VESMATIC EASY to allow the new owner to be informed about its functioning and relative warnings.

The instrument should be used only by **qualified and competent personnel**.

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CHAPTER 1

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1.1. PRESENTATION OF THE INSTRUMENT

The VESMATIC EASY is a bench instrument designed and programmed to determine the erythrocyte sedimentation rate (ESR) in a maximum of 10 samples of blood (human or animal), contained in dedicated cuvettes, simultaneously or individually in *Random Access* mode [continuous cycle].

The instrument is controlled by a microprocessor, the functioning of which will be described in more detail in the following paragraphs.

The cuvettes containing the blood samples are placed in the instrument after being carefully mixed by slowly, repeatedly turning upside down; the ESR test procedure is then performed automatically and the results are comparable with those obtained with the Westergren method (ref. bibl. 1-10).

Using the 18° slant of the tubes with respect to the vertical axis, the VESMATIC EASY allows for obtaining results equivalent to those of the Westergren method (1 hour) in only 20 minutes, and equivalent to the Westergren method (2 hours) in only 40 minutes.

Clinical meaning of ESR

The instrument provides information about the erythrocyte sedimentation rate (ESR) which reflects the measurement of the rate at which the erythrocytes settle. The ESR value measured at a specific moment is influenced by the concentration of certain proteins, the plasma concentration of which is modified in inflammatory situations, as well as in the presence of various pathologies (for example: neoplasias). It is also affected by certain properties of the erythrocytes and the degree of anemia (Hematocrit).

Very high ESR values are characteristic of multiple myeloma, leukaemia, lymphomas, carcinomas of the breast and lungs, rheumatoid arthritis, SLE, pulmonary infarct. It is high in any type of infection and carcinomas, especially in the presence of hepatic metastases, and in acute and chronic inflammatory diseases.

Normal ESR

During the first hour the ESR value is normally found between 1 and 10 mm in males and between 1 and 15 mm in females; in pathological conditions it increases to values of 100 mm and over.

Normal range for the VES-MATIC EASY

MEN	up to 10 mm	first hour
	up to 20 mm	second hour
WOMEN	up to 15 mm	first hour
	up to 30 mm	second hour

General functioning of the instrument:

The blood collected in the dedicated cuvettes is carefully mixed by the operator and then left to sediment in the ten positions in the instrument. By means of a digital sensor (opto-electronic unit) the instrument automatically determines the sedimentation level of the erythrocytes, following which the data is processed and then either automatically printed or shown on the display.

The analytical results are calculated from the values set on the instruments and obtained via the Westergren reference method.

It is reminded that in the case of samples with a hematocrit value <15% the instrument will print the message "(Sample) EMPTY".

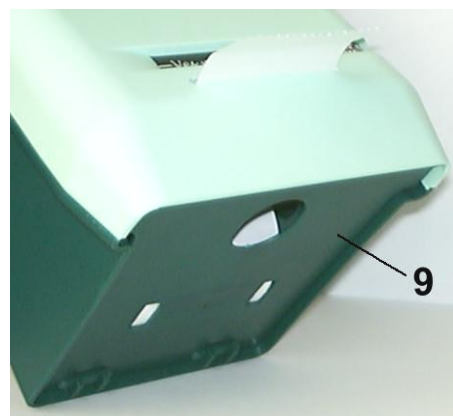
1.2. GENERAL DESCRIPTION OF THE INSTRUMENT



Fig. 1-1

Legend:

- 1) Cuvette-holder with 10 numbered positions
- 2) Display
- 3) Keyboard
- 4) Printout-Paper slit
- 5) EXTERNAL BARCODE connector
(External Barcode Reader)
- 6) USB connector
- 7) ON/OFF switch
- 8) DC IN socket for 9Vdc power supply
- 9) Paper-holder compartment



1.3. MATERIAL SUPPLIED WITH THE INSTRUMENT

The VESMATIC EASY is supplied with the following material:

- 1 Operating Manual [English] [Order Code: P30600650]
- 1 "VESMATIC EASY"CD [Order Code: P30650050]
- 1 Power Supply 9Vdc 2A Mod. ES18A09-P1J [MeanWell] [Order Code: P21440380]
- 1 Power Cord 3x0.75 L=2m Plug SCHUKO 90° - C13 [Order Code: P21890040]
- 1 Power Cord SVT L=2m Male Plug USA / Female Plug VDE 'UL' [Order Code: P21890370]
- 1 USB 1.1 A-B M/M Cable (1.5mt) [Order Code: P21890360]
- 1 Thermal Roller Paper for Printer [Order Code: P12300000]
- 1 Packing-list
- 1 Final Inspection Report
- 1 Guarantee Certificate (for CAN/USA Market)

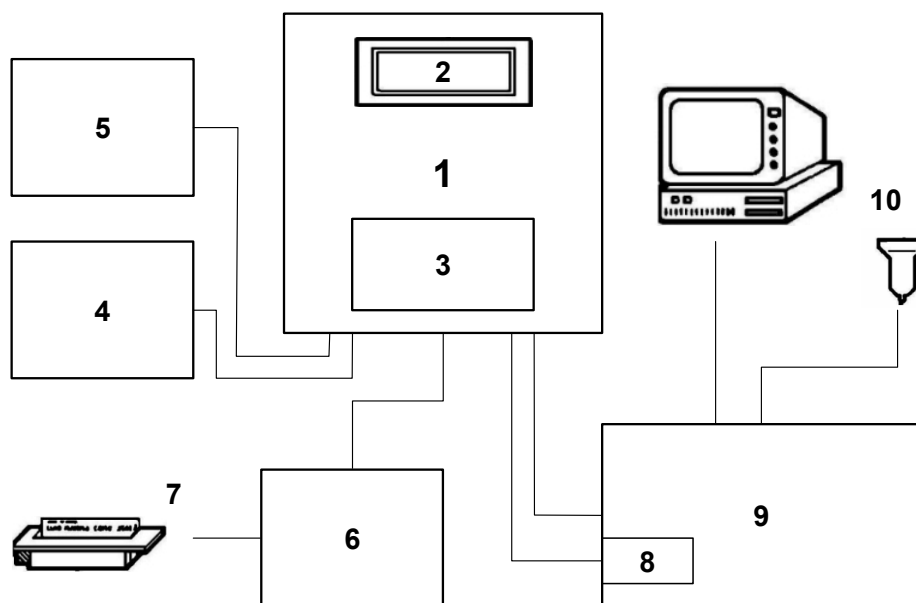
1.4. TECHNICAL SPECIFICATIONS

Power supply	9Vdc@2A	
Dimensions	143 x 218 x146 mm (w x h x d)	
Weigh	1.2 Kg	
Ambient temperature	Operational	from +15 to +35°C
	Storage	from + 5°C to + 45°C
Relative humidity tolerance	from 20 to 80% without condensation	
Central unit	AVR ATMEGA128-16AC microprocessor	
Display	LCD with Backlight, 16 characters x 1 row	
Cuvette-holder	With 10 numbered recesses for the relative cuvettes	
Optical unit	10 pairs of opto-electronic elements in solid state (photodiode + phototransistor).	
Printer	Alphanumeric with thermal paper 58 mm wide, 36 characters per line, speed: 20 mm/sec.	
Interfaces	USB	
Class	II	
Device safety	CEI EN 61010-1 (Ed.2001-11); CAN/CSA-C22.2 Nr.61010-1-04 (Ed.2004-07); UL61010-1 (Ed.2004-07).	
EMC	CEI EN61326 (ED.2004-08)	
Installation category	II	



Safety requirements and functional performances of the instrument are not assured if you use a different power supply from the one supplied in the package.

1.5. BLOCK DIAGRAM



(Detailed diagrams are contained in the Assistance Manual)

Fig.1-3 “Block diagram – VESMATIC EASY”

LEGEND:

- | | |
|------------------------------|-------------------------------------|
| 1- C.P.U. board | 6- Printer interface |
| 2- Display | 7- Printer |
| 3- Keyboard | 8- ON/OFF switch |
| 4- Reading sensors unit | 9- External connections Interface |
| 5- Optical Reader motor unit | 10- External connections [Optional] |

1.6. TECHNICAL DESCRIPTION OF THE INSTRUMENT

CENTRAL UNIT

This controls and processes the data arriving from the sensors and manages the peripherals connected to the same, including the FLASH EPROM containing the programme. It also contains the EEPROM where all the instrument parameters are stored.

OPTICAL READING UNIT

Unit consisting of 10 photodiode + phototransistor couples.

OPTICAL READER MOTOR UNIT

This takes care of lifting the optical reader unit in order to check the cuvettes present or incorrectly inserted, with insufficient or excessive blood, and also detects the sedimentation level.

KEYBOARD

This consists of 4 keys via which the VESMATIC EASY functions are implemented.

CUVETTE-HOLDER

The cuvette-holder consists of ten numbered positions with 18° slant axis for inserting the cuvettes.

ACOUSTIC SIGNAL

This serves the purpose of attracting the operator's attention during specific phases of carrying out the work cycle.

It emits a "beep" after the keys are pressed on the keyboard.

PRINTER

This prints the results of the analyses at the end of each processing cycle.

DISPLAY

This displays all the messages of the instrument.

1.7. INFORMATION REGARDING DISPOSAL

The VESMATIC EASY instrument is operated by mains voltage, therefore it has been classified according to the European Directive 2002/96/EC dated January 27, 2003, and subsequent amendments, as Electrical-Electronic Equipment [Law Decree 25/07/2005 #151 in Italy].

Therefore:

- **DO NOT** dispose of the instrument with urban solid waste, not to incur in fines or penalties.
- At the end of its life, the instrument must be disposed of as **separate collection waste** or sent back to the Manufacturer according to the Manufacturer's disposal recommendations.

For CANADA/U.S.A. Only

Therefore:

- At the end of its life, the instrument must be disposed of as **separate collection waste** or sent back to the Distributor.

CHAPTER 2

TRANSPORTATION AND INSTALLATION OF THE INSTRUMENT 7

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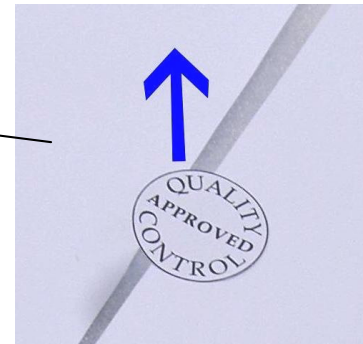
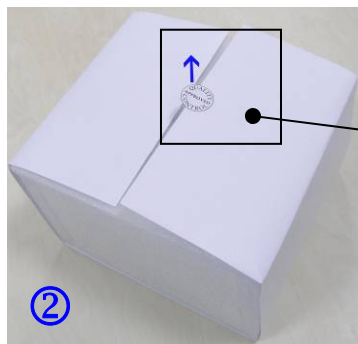
The operator must be trained to be familiar with the procedures, restrictions and warnings indicated in this manual, as well as those pertaining to safety in the work place.

The material for the operator's safety (gloves, containers for disposing of used expendable items, detergent solutions for cleaning the instrument) must always be available.

The positioning of the instrument must comply with the instructions indicated in paragraph 2.5.

2.3. UNPACKING THE INSTRUMENT

1. Open the external box



2. Open the box from the top and remove take out the accessories packed at the sides of the instrument and the side band.



3. Lift the instrument out of the box.



4. Remove the protective bag wrapped around the instrument.
5. Check that the material supplied complies with the packing-list.



In case of damage to instrument and/or accessories during transportation notify the Transport Company.

In case of any shortages notify your distributor.

2.4. GUIDELINES FOR THE INSTALLATION

<u>Sequence</u>	<u>see Paragraph</u>	
1. Unpacking of the instrument	2.3.	<input type="checkbox"/>
2. Installation of the instrument	2.5.	<input type="checkbox"/>
3. Preliminary checks	2.2.	<input type="checkbox"/>
4. Connecting to the power supply and turning on of the instrument	2.6.	<input type="checkbox"/>
5. Running Q.C.Test (in order to check the efficiency of the reading unit)	3.7. / 4.1.	<input type="checkbox"/>
6. Running a cycle of analyses with the test tubes with identification numbers (for checking the functioning of the external barcode, if applicable) [optional]	4.4./4.5.	<input type="checkbox"/>
NOTES & REMARKS		
<hr/>		
<hr/>		
<hr/>		

2.5. POSITIONING

It is expected that the instrument would be used in a diagnostic 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 a clean, level surface that is not subject to shocks or vibration.

It is recommended to place the instrument as far away as possible from any generators of electromagnetic interference (e.g. refrigerators, laboratory centrifuges) as these could compromise the correct operation.

In the event of hazardous, maintain safety distances described in the figure (front panel free; rear, left and right side 15 cm).

“Positioning Ves-matic Easy”



For the same reason it is strictly prohibited to place anything on top of the instrument.
Choose a position near a power point, which is free from interference and voltage surges.



Never move the instrument while it is operating. If necessary to move the instrument it is compulsory to recheck the conditions listed in this paragraph before turning it on again.
Unplug and cover instrument when not in use for long periods.

2.6. INSTALLATION



Use only power supply provided!

1. Place the instrument on a solid surface as described in the previous paragraph.
2. Once the instructions provided in point 2.2 have been fulfilled and the power supply switch has been put in the OFF position, connect the plug of the power supply unit supplied with the unit.



3. Connect the power cord to the power supply and to the AC outlet.



2.7. RESTRICTIONS AND WARNINGS



IN THE CASE OF FIRE OR HAZARDS IN GENERAL, TURN OFF THE INSTRUMENT AND DISCONNECT THE POWER SUPPLY CABLE.

DISCONNECT the instrument from the power supply system before performing any type of technical operation or in the case of malfunctioning of the instrument.

It is only possible to enter the commands with a **light pressure** of the fingers.

Do not carry out OPERATIONS on the instrument while there are parts still in motion! (It is only possible to enter the commands on the keyboard).



Expendable materials [RESTRICTIONS]

The Diesse cuvettes are designed for use with the VESMATIC EASY and cannot be substituted with any other container.

The Diesse cuvettes supplied are disposable and must not be reused.

Cuvettes must be disposed of in compliance with the local regulation.



Treatment of potentially infected material.

All precautions pertaining biological risks must be adopted when using the VESMATIC EASY.

The waste material must be disposed of in compliance with the laboratory regulations and the local laws

Observe all operator safety regulation in line with the working environments.

2.8. SHUTTING DOWN AND SHIPPING



Before shutting down and shipping the instrument it is recommended carrying out the following sanitising procedure:

- A) The instrument must be turned off and cleaned internally of all residues or spillage with a liquid detergent and left to dry.
- B) Use one of the ready-to-use spray cans of isopropyl alcohol available on the market.
- C) Spray well on the sample-holder.
- D) Leave turned off for at least one hour before beginning a new work cycle or any other type of operation on the instrument.



Instrument maybe damaged if dropped.

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3.1. TURNING ON THE INSTRUMENT

Turning on

After having checked the installation of the instrument as indicated in chapter 2, turn the switch, located to rear of the instrument, to the position « ON ».

System start-up

When turned on, the unit will display in a sequence the instrument model and the software version installed on the unit:

SW VERS.2.00

During this phase, the instrument automatically checks the following items of its own system:

- Display
- Clock
- EEPROM data
- Handling motor and home sensor
- Reading sensors
- Printer



In case of malfunctioning, the unit will “beep” and shown an error message on the display. See Chapter 6 - “Self-diagnostics” for help.

SENSOR X KO

If this error message is displayed upon turning on the instrument, do not use the ‘X’ position indicated to process the samples, as the reading sensor associated to that position may be damaged.

Use key ▲ to display a list of damaged sensors and pass to the Main Menu.

Once the initial self-test has been completed, the instrument will “beep” again and show the following words on the display.

SELECT FUNCTION

Now the instrument is ready to perform the functions that will be selected.

3.2. KEYBOARD



The VESMATIC EASY is fitted with a keyboard with 4 bifunctional keys.

The function of each key is only activated when the corresponding key is pressed in and released.

Key functions description



Scrolls up menus, when displayed, and enters numerical values in dedicated menus (e.g. when ID numbers are entered).



Scrolls down menus, when displayed, and enters numerical values in dedicated menus (e.g. when ID numbers are entered).



Pressing this key when branching menus are displayed allows the operator to access the subsequent menu. During alphanumerical characters entry operations and in configuration menus, it enables and confirms, and starts a cycle after selecting a test. If pressed together with key ▲ during the execution of a test, it blocks the instrument functions and aborts the test.



During menu display, it executes the printer's Line Feed. During alphanumerical value entry operations, it has a scrolling or incremental function (10/10).

3.3. MAIN MENU

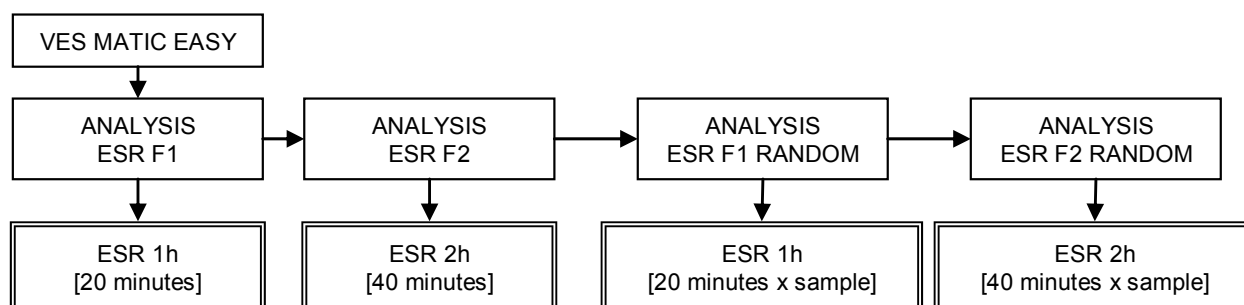
The SELECT FUNCTION menu contains:

- the 4 types of analysis that can be performed by the VESMATIC EASY
 1. ESR I [ANALYSIS]
 2. ESR II [ANALYSIS]
 3. ESR I RANDOM [ANALYSIS]
 4. ESR II RANDOM [ANALYSIS]
- the instrument set-up menu
SETTINGS
- the archive of the results of the last 100 exams completed by the instrument in chronological order
PRINT ARCHIVE (*)
- the menu for the Quality Control of the instrument
QUALITY CONTROL

To scroll the items available, use keys ▲ and ▼ and press **OK** to select an item.

3.4. DESCRIPTION OF THE TESTS

The operator has 2 types of analysis available in the main menu the operator for a total of 4 selectable cycles as described below:





See Operating Instructions before starting a test.

1. ESR F1 (Erythrocyte sedimentation rate 1h) ANALYSIS

ESR I

This gives the results in accordance with the Westergren method with the reading at one hour; the overall duration of the **analysis** is **20 minutes**.

Description of the examination cycle:

- At the beginning of the test, the unit detects the presence of the cuvettes in the sample-holder and performs the first reference reading: the optical reading unit records the initial level of the blood column of each sample. If no cuvette is placed in the unit, the test is interrupted.
- 20 minutes before the end of the test, a second reference reading is taken; the highest value between the two reference readings is validated.
- At the end of the second reference reading, if the cuvettes are either too full [(high sample) HIGH] or too empty [(low sample) LOW], the instrument will beep to warn the operator and, if the printing function had been previously activated, prints a list of the cuvettes filled to inappropriate levels.
- At 0 minutes, the unit takes the last reading and gives results according to the preset mode, corresponding to those obtained with Westergren's method at the first hour.

2. ESR F2 (Erythrocyte sedimentation rate 2h) ANALYSIS

ESR II

This gives the results in accordance with the Westergren method with the reading at one hour and two hours plus the Katz index; the overall duration of the **analysis** is **40 minutes**.

Description of the examination cycle:

- At the beginning of the test, the unit detects the presence of the cuvettes in the sample-holder and performs the first reference reading: the optical reading unit records the initial level of the blood column of each sample. If no cuvette is placed in the unit, the test is interrupted.
- 40 minutes before the end of the test, a second reference reading is taken; the highest value between the two reference readings is validated.
- At the end of the second reference reading, if the cuvettes are either too full [(high sample) HIGH] or too empty [(low sample) LOW], the instrument will beep to warn the operator and, if the printing function had been previously activated, prints a list of the cuvettes filled to inappropriate levels.
- 20 minutes before the end of the test, an additional reference reading is taken.
- At 0 minutes, the unit takes the last reading and gives results according to the preset mode, corresponding to those obtained with Westergren's method at the second hour.

3. ESR F1 RANDOM (Erythrocyte sedimentation rate 1h) ANALYSIS

ESR I RANDOM

This test provides results according to Westergren's method with readings at 1 hour for each sample placed in the sample-holder; this operation is performed independently from the other test tubes introduced. The duration of the **test** is **20 minutes** per sample.

Test cycle description:

- Upon start up, the instrument is ready to receive one or more samples, taking the reading unit at half stroke, and monitors free positions in the sample-holder.
- When the unit detects one or more cuvettes in the sample-holder, the instrument performs the first reference reading. The optical reading unit records the initial level of the blood column of each sample introduced. While the cuvettes introduced are being processed, the instrument keeps monitoring the free positions waiting for new entries.
- 20 minutes before the end of the test, a second reference reading is taken; the highest value between the two reference readings is validated.
- At the end of the second reference reading, if the cuvettes are either too full [(high sample) HIGH] or too empty [(low sample) LOW], the instrument will beep to warn the operator, marks the positions displayed on the screen with the letter W and, if the printing function had been previously activated, print a list of the cuvette filled with inappropriate levels.
- At 0 minutes, the unit takes the last reading on valid existing samples and provides results according to the preset mode, corresponding to those obtained with Westergren's methods at the first hour.
- If, during a test cycle on existing samples, more samples are introduced, the cycle is restarted for the new entries.

4. ESR F2 RANDOM (Erythrocyte sedimentation rate 2h) ANALYSIS

ESR II RANDOM

This test provides results according to Westergren's method with readings at 1 and 2 hours, plus the Katz index for each sample introduced in the sample-holder independently from the other cuvettes introduced. The overall duration of the **test** is **40 minutes** per sample.

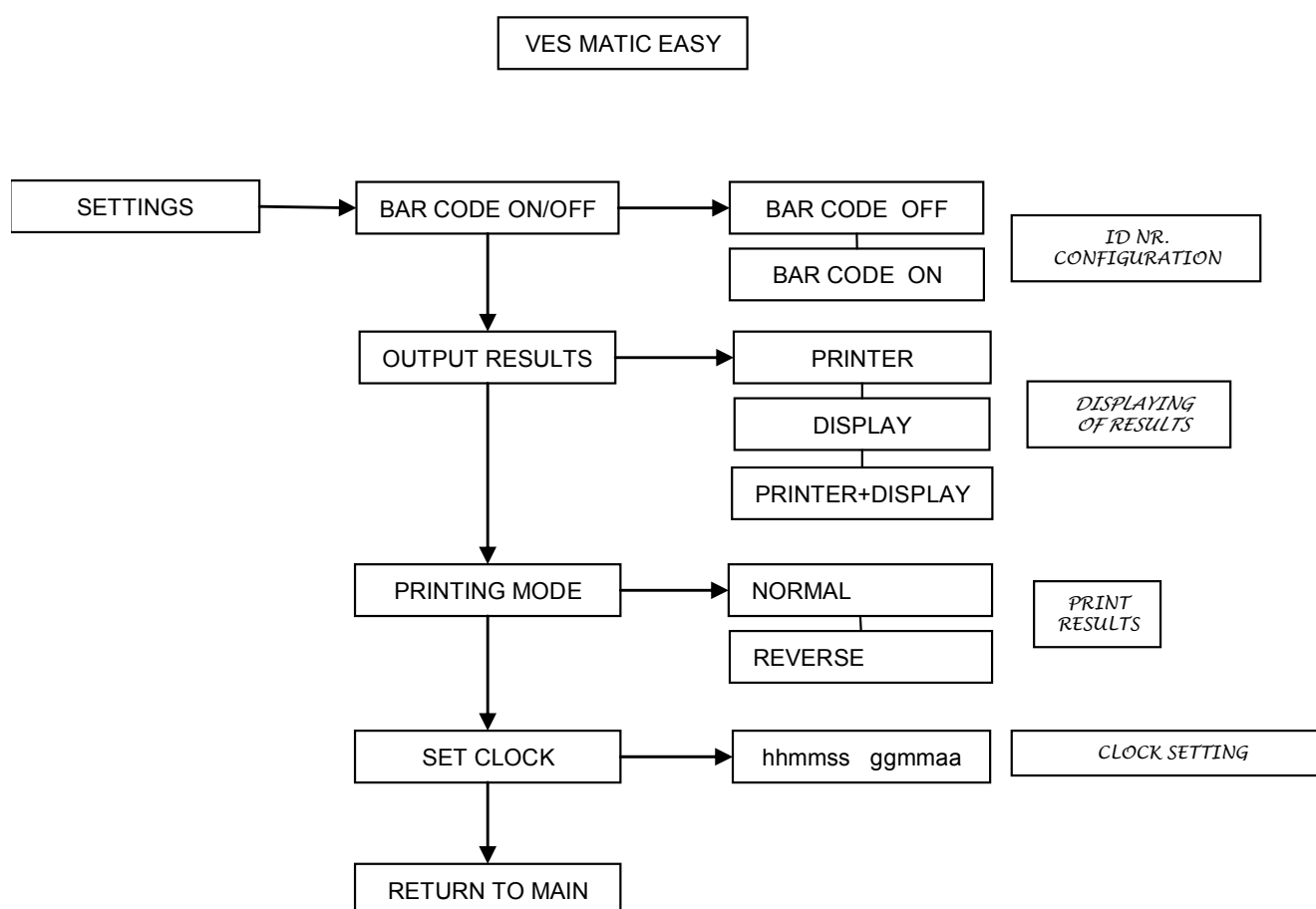
Test cycle description:

- Upon start up, the instrument is ready to receive one or more samples, taking the reading unit at half stroke, and monitors free positions in the sample-holder.
- When the unit detects one or more cuvettes in the sample-holder, the unit performs the first reference reading. The optical reading unit records the initial level of the blood column of each sample introduced. While the cuvettes introduced are being processed, the instrument keeps monitoring the free positions waiting for new entries.
- 40 minutes before the end of the test, a second reference reading is taken; the highest value between the two reference readings is validated.

- At the end of the second reference reading, if the cuvettes are either too full [(high sample) HIGH] or too empty [(low sample) LOW], the instrument will beep to warn the operator, marks the positions displayed on the screen with the letter W and, if the printing function had been previously activated, print a list of the cuvette filled with inappropriate levels.
- 20 minutes before the end of the test, an additional reference reading is taken on the existing samples.
- At 0 minutes, the unit takes the last reading on valid existing samples and provides results according to the preset mode, corresponding to those obtained with Westergren's method at the second hour.
- If, during a test cycle on existing samples, more samples are introduced, the cycle is restarted for the new entries.

3.5. SET-UP MENU - SETTINGS

The SETTINGS menu provides a list of functions (shown below) allowing a number of system operations to be performed. To access these functions, select "SETTINGS" item in the main menu and confirm by pressing **OK**. To exit, select "RETURN TO MAIN" and press **OK**.



3.5.1. DISPLAY AND PRINTER SET-UP

To view and/or print results on the display:

- Select "Settings" from the main menu and confirm with **OK**
- Use ▲/▼ to go to the following wording

OUTPUT RESULTS

- Press **OK** to view the currently configured setting:

PRINTER

- Use ▲ to scroll items in this menu:

DISPLAY

or

PRINTER+DISPLAY

- Press **OK** to store the configuration displayed and return to previous menu.



1. Legend: PRINTER = results print is enabled
DISPLAY = results displaying is enabled
PRINTER+DISPLAY = results print and display are enabled
2. The condition set will remain enabled until a change is entered.

WARNING:



During testing operations in random mode, these display settings are disabled (see section 4.5)

3.5.2. BARCODE READER SET-UP

To enable bar code reading:

- Select "Settings" in the main menu and confirm with **OK**
- Use ▲/▼ to go to the following item:

BAR CODE ON/OFF

- Press **OK** to view the currently configured setting:

BAR CODE OFF

- Use ▲ to enable bar code reading:

BAR CODE ON

- Press **OK** to store the new setting and return to the previous menu.



1. The condition set will remain enabled until a change is entered.
2. When this function is enabled, bar codes can be entered both with an external reader connected to the instrument or manually using function keys.

3.5.3. PRINTING MODE SET-UP

The printing direction of a final report of a test can be set from this menu.

To enable the reverse print function:

- Use ▲/▼ to go to:

PRINTING MODE

- Press **OK** to view the currently configured setting:

NORMAL

- Use ▲ to enable final report reverse print (towards the operator):

REVERSE

- Press **OK** to store the new setting and return to the previous menu.



1. The condition set will remain enabled until a change is entered.
2. Print examples:



Normal



Reverse

3.5.4. UPDATING THE DATE AND TIME

To update Date and Time, go to the settings menu:

- use ▲/▼ to go to:

SET CLOCK

- Press **OK** to view the current date and time on the display in the following format:

hhmmss ggmmaa

[Sequence: Hour/Minutes/Seconds Day/Month/Year]

To enter or change clock parameters:

1. use ▲/▼ to change the flashing number
2. use **Line Feed** to move the cursor rightward by one position
3. press **OK** to store the new time/date and return to the previous menu

The time and date will be stored even if the instrument is turned off.

3.6. PRINTING OF THE RESULTS STORED

The instrument is configured to store and archive (in the PRINT ARCHIVE menu) the last 100 tests (in chronological order), which can be later printed whenever needed.

The archive has a capacity of 100 tests and has a “round” structure: when its maximum capacity is reached, the new test will be overwritten on the oldest record stored in the archive.

When an instrument is new or recently updated (i.e. without stored results), the following message will be displayed: “*ARCHIVE EMPTY*” and, after about 2 seconds, the programme will return to the main menu.

Procedure for printing stored tests:

- Select PRINT ARCHIVE in the main menu and confirm with **OK**;
- The system will ask the user the number of tests to be printed, in reverse chronological order:

LAST RESULTS? 1

Set the number of tests as follows:

- Use ▲/▼ to change flashing numbers;
- Use **Line Feed** to increase the value to be set by 10 points steps;
- To confirm the figure entered and print the list, press **OK**.

When the print is completed, the system will automatically return to the “Select Function” menu.

3.7. QUALITY CONTROL

Using the Quality Control function available on the VESMATIC EASY, ESR Controls can be used. This is a test that monitors the erythrocyte sedimentation rate to verify tests methods.

ESR Controls are stable materials that can be used to determine the accuracy and precision of the Ves-Matic line.

The range of expected values associated with each instrument mode are shown on the ESR Control product insert.



To store, prepare and use controls, please refer to the controls instructions.

QC is performed on all sample-holder positions and provides valid results at the first hour after completing 2 dedicated test cycles.

To configure the instrument, follow this procedure:

- In the “Select Function”, use ▲ / ▼ to go to:

QUALITY CONTROL

- confirm with **OK**;

- you will access the QC control menu:

QC SETUP

- to enable the QC Setup menu, press **OK**;
- to enter the necessary information to perform QC (kit batch number, production date, ESR values of the two sera), pass to the subsequent items listed in the QC setup menu using **▲/▼**:

1. *Production batch number of ESR blood*

INP LOT NUMBER + **OK*** LOT NR 000000

2. *Control production date*

INP DATA + **OK*** DATE = _ _ _ _ _

3. *Min. values of normal Control sample*

INP NORMAL MIN + **OK*** NORMAL MIN 00

4. *Max values of normal Control sample*

INP NORMAL MAX + **OK*** NORMAL MAX 000

5. *Min values of abnormal Control sample*

INP ABNORMAL MIN + **OK*** ABNORMAL MIN 00

6. *Max values of abnormal Control sample*

INP ABNORMAL MAX + **OK*** ABNORMAL MAX 000

- To enter or change the parameters for the Quality Control process:

0. Press **OK*** to change the data to be displayed.

To enter batch number and date

1. Use **▲/▼** to modify the flashing number
2. Use **Line Feed** to move the cursor rightward by one position
3. Press **OK** to save the data entered and return to previous menu

To enter the Normal and Abnormal values:

1. Use **▲/▼** to change the flashing number values
2. Use **Line Feed** to increase the value to be set by 10 points;
3. To confirm the value entered and return to the previous menu, press **OK**.

Use the 'Print settings' function in the Quality Control menu; if the print function has been enabled, a summary of the parameters required for the QC process will be sent to the printer.



1. If the data are not set, QC will be carried out with default values.
2. If the values provided do not correspond to expected values, contact the Technical Support Centre.

To start ESR 1h test cycles devoted to QC (their duration is 20 minutes each):

1. *To carry out QC with Normal Control:*

- Go to the Quality Control menu item:

RUN NORMAL

- Introduce the test tubes containing the Normal Control in the sample-holder;
- Press **OK** to start the test.

2. *To carry out QC with Abnormal Control:*

- Go to the Quality Control menu item:

RUN ABNORMAL

- Introduce the test tubes containing the Abnormal Control in the sample-holder
- Press **OK**.

At the end of the test, the results obtained should be within the data ranges ("OK" in the printed and/or on the display). In case of out of range results, the deviation value will be indicated (+). In this case, contact the Technical Support Centre.

Use ▲/▼ to scroll results on the screen and press **OK** to send results to the printer, if both screen display and print functions are simultaneously enabled (see section 3.5.1.)

To exit and return to the Select Function menu:

- at the end of verifications, go to the Quality Control menu at item:

RETURN TO MAIN

- and press **OK**.

CHAPTER 4

OPERATING INSTRUCTIONS 25

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4.1. TURNING ON FOR THE FIRST TIME

After having installed the instrument as indicated in chapter 2, turn the power supply switch which is located to the left of the power supply cable at the rear of the instrument, onto the position «ON ».



Upon first start-up, perform 2 ESR 1 h tests to verify instrument status and optical reading units efficiency using:

- for the 1st cycle: 10 samples containing ESR Control Normal.
- for the 2nd cycle: 10 samples containing ESR Control Abnormal.

When the test is completed, ensure that the results obtained are included in the acceptable range of values.

As an alternative, if it is necessary to enable the automatic QC, carry out the following procedure:

1. Select the Quality Control item from the Set-up QC menu
2. Set the parameters for performing the QC (see 3.7.)
3. Introduce the test tubes containing ESR Control *Normal* in the sample-holder and launch a Run Normal test from the Quality Control menu (see 3.7.);
4. Introduce the test tubes containing ESR Control *Abnormal* in the sample-holder and launch a Run Abnormal test from the Quality Control menu (see 3.7.);
5. At the end of the analysis, if the Optical Reading Units are calibrated correctly, the results obtained should give a positive result (OK in the printing report or on the display).

If to the contrary, the deviation value (\pm) will be indicated, in this case contact the technical service.

4.2. PREPARING THE SAMPLE

In order to prepare the cuvettes, refer to the package insert and follow the instructions. The most important of which are indicated below:

- *The blood should be collected by means of a withdrawal lasting a maximum of 30 seconds without excessive venous stasis.*
- *The blood can be collected either using the vacuum or via manual technology.*
- *Mix the blood immediately after the withdrawal with at least two complete inversions of the test tube.*

Suitability of the Sample

The sample can be considered as suitable if :

- The exam is carried out within four hours after the withdrawal.
- The exam is carried out on a blood sample stored at 4°C for a maximum period of 12 hours. In this case make sure that the sample is taken up to room temperature before being introduced into the instrument.
- There is no coagulation on tipping up the test tube before being introduced into the instrument
- Check **AIR-TIGHTNESS** of the sealing of the test tube.

Filling the test tube

In order for the VESMATIC EASY instrument to carry out the ESR exam the test tube must be filled to the value within maximum and minimum levels.

In the case of over-filling, the instrument will print a "(sample) HIGH" error message, while in the case of under-filling the instrument will print a "(sample) LOW" error message. In both cases it will be necessary to repeat the filling operation.

4.3. SEQUENCE FOR PREPARING AN EXAM ESR1-ESR2 WITHOUT ID NR. AND VIEWING OF THE RESULTS

Procedure:

1. Mixing the sample

Invert the test tubes slowly and repeatedly (20-30 times) before starting the test to ensure complete blood mixing.

See package insert for further information.

2. Loading the instrument

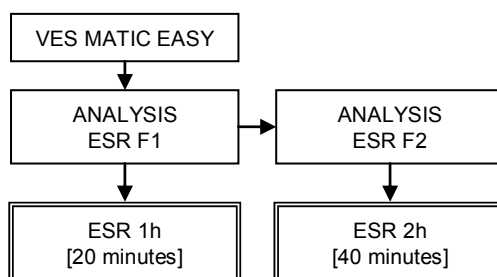
Insert the sample cuvette into one of the open test positions.



During this phase, check that the cuvettes are properly inserted.

3. Programming the device

When the instrument has been loaded, select the type of exam to be carried out following the flow diagram below:



and press **OK** to start the test cycle.



The analysis can be aborted at any time by pressing **▲** and **OK** simultaneously. When the question "ARE YOU SURE?" is displayed on the screen, press **OK** to confirm (press any other key to go back to work cycle).

4. Instrument work cycle

The instrument will automatically carry out the following phases described in point 3.4.

During the performing of the analysis the time left until it is finished will appear on the display.

5. Displaying of results

Once the test has been completed, the results regarding the samples processed are displayed on the screen according to current settings:

- With display on screen enabled (e.g. ESR1):

For each test tube processed, the result is shown matched with sample position (1) and identification number (2)

(1)

N 1 10

 (2)

1 0123456789ABC

Use ▲/▼ to scroll results on the screen.

- With print enabled (e.g. ESR1):

The report is printed in the format shown below:

```
*****
      DIESSE
*****
* VES-MATIC EASY SW VERS 2.00 *
*****

CYCLE                2
SELECT              F1

DATE(dd/mm/yy)       12/12/06
TIME(hh:mm:ss)       16:52:40

1 ..... LOW
3 ..... LOW
4 ..... LOW

-----

POS   ID   WEST
NUM   BarCode  1H

1 ..... LOW
2 ..... 1
3 ..... LOW
4 ..... LOW
5 ..... 1
6 ..... 1
7 ..... 1
8 ..... 1
9 ..... 1
10 ..... 1
```



With enabled display and printer, the unit will first show results on the screen and then wait for operator's confirmation, to be given by pressing **OK**, before sending results to the printer.

Once displaying operations have been completed, the system will automatically go back to the Select Function menu, ready to perform another test.

4.4. SEQUENCE FOR PREPARING AN EXAM ESR1-ESR2 WITH ID NR.

To use the External Bar Code, enable “External Bar Code” in the Settings menu (section 3.5.2.) and connect it to the instrument as shown in section 7.1.

Procedure:

1. select and start up the analysis cycle that the instrument is to perform (without introducing the samples)
2. the operator will be asked to confirm the mode of entering of the identification number and the following message will appear on the display:

MAN=UP LECTOR=OK

3. to start the cycle without entering bar codes (*in this case the operator must have introduced the samples to be processed*), press **OK** twice.

Procedure with external barcode reader:

4. Press OK to enable loading of ID number with an external Barcode reader; the instrument will position reading units at half stroke. During this phase, the following message will be displayed on the screen:

READ BC/INS SAMP

and the instrument emits a beep.

5. The operator will now read the sample identification number with the barcode reader and, after ensuring that the code has been accepted by the system, the following message will be displayed on screen:

ID 0123456789ABC

The operator will now introduce the cuvette into an open position. At this point, the system will produce a prolonged “beep” to confirm that a cuvette has been introduced and the system will automatically associate the identification number acquired to the cuvette introduced

1 0123456789ABC

The system is now ready for another cuvette introduction.

6. If the bar code is not acquired within 10 seconds from reading sensor operation, due to timeout, the system will produce a beep and the following message will be displayed on screen:

EDIT ID?

1. When the bar code is not readable with the barcode reader, press **OK** to enter the bar code manually using the keyboard (see relevant procedure).
2. Press **▲** to set the system back to the condition where it is ready to acquire the ID number with the external barcode reader.



If samples without an ID are used, they can be normally introduced into the instrument. The system will beep to confirm and position itself on the next cuvette housing but displaying a 13-point string on the screen instead of characters.

7. Repeat this procedure for all the remaining samples to be processed.
8. The introduction procedure will be automatically stopped when all the test positions are occupied, but to start a test after introducing one or only a few cuvettes, press **OK** from the keyboard to start the test cycle.
9. When the ID number entering introduction is completed, the system will ask the operator the following question:

PRINT JOBLIST?

the printer is enabled, press **OK** to print a list of ID numbers entered and proceed with the test; otherwise, press **▲** to directly proceed with the test.

Keyboard ID Nr. entering procedure:

4. Press **▲** to enable manual ID number entering; the system will position reading sensors at half stroke. During this phase, the following message will be displayed on screen

ID _____

5. Enter the bar code (max 13 characters):
 - a. Use **▲/▼** to change the selected/flashing number (number or letter)
[accepts alphanumerical characters: numbers, lowercase and uppercase letters]
 - b. Use **Line Feed** to move the cursor of one position rightward (from the 13th figure, go back to the first figure to make corrections)
6. The operator will now introduce the cuvette in the sample-holder. At this point, the system will produce a prolonged “beep” to confirm that a cuvette has been introduced and the system will automatically associate the identification number acquired to the cuvette introduced and will become ready for the next introduction.



If test tubes without an ID are used, they can be normally introduced in the sample-holder: the system will beep to confirm and position itself on the next cuvette housing but displaying a 13-point string on the screen instead of characters.

10. The introduction procedure will be automatically stopped when all the positions in the sample-holder are occupied, but to start a test after introducing one or only a few cuvettes, press **OK** from the keyboard to start the test cycle.
11. When the ID number entering introduction is completed, the system will ask the operator the following question:

PRINT JOBLIST?

the printer is enabled, press **OK** to print a list of ID numbers entered and proceed with the test; otherwise, press **▲** to directly proceed with the test.

4.5. SEQUENCE FOR PREPARING AN EXAM ESR1-ESR2 RANDOM WITHOUT ID NR. AND VIEWING OF THE RESULTS



The Random mode does not include displaying results on the screen, even when the relevant function has been enabled from the Settings menu; but data are always sent to the printer.

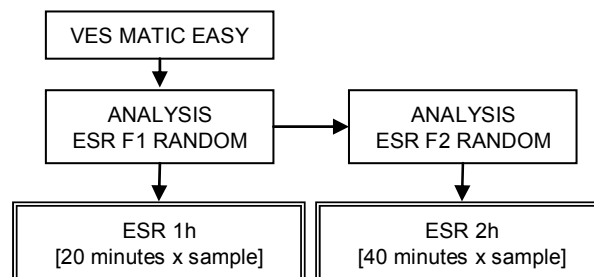
Therefore, we recommend to check that there is enough paper in the printer before starting a Random cycle.

Results are saved by the system. Using the PRINT ARCHIVE function, data can also be printed later (see section 3.6.)

Procedure:

1. Programming the system

Select the type of test to be performed following the Flow Diagram shown below:



press **OK** to start the test cycle.



Upon start-up, the instrument must be empty as the software is ready to retain previously introduced cuvettes as already processed and mark them on the screen display with letter W.

The test can be aborted at any time by pressing **▲** and **OK** simultaneously. When the question “ARE YOU SURE?” is displayed on the screen, press **OK** to confirm (press any other key to go back to work cycle).

2. Mixing the sample

Invert the test tubes slowly and repeatedly (20-30 times) before starting the test to ensure accurate blood mixing.

See package insert for further information.

2. Loading the instrument

Introduce the samples in open positions.

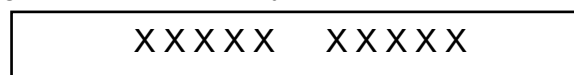


During this phase, check that the cuvettes are properly inserted.

4. System work cycle

The system will automatically carry out the following steps, described in section 3.4.

During the test, the following mask will be displayed on the screen:



Position: 1 2 3 4 5 --- 6 7 8 9 10

Indicating the ongoing status and/or operation for each sample-holder position.

Letter	Meaning	Letter	Meaning
F	Free position	B	Cuvette is in, waiting for second hour reading
1	Cuvette is in, waiting for 1 st reference reading	W	Test completed or interrupted (see print report)
2	Cuvette is in, waiting for 2 nd reference reading	S	KO Sensor
A	Cuvette is in, waiting for first hour reading		



About every 30 seconds, the system will check free positions: if new introductions are detected, a beep is produced and the system status displayed is changed.

5. Results

At the end of the test, the following report will be printed for each sample:

```
DATE 12/12/06 TIME 16:50:41
SELECT F1
10 ..... 1
```

```
DATE 12/12/06 TIME 16:52:40
SELECT F1
1 ..... LOW
```

4.6. SEQUENCE FOR PREPARING AN EXAM ESR1-ESR2 RANDOM WITH ID NR.

To use an External Barcode reader, the “External Barcode reader” item must be set in the ‘Settings’ menu (section 3.5.2.) and the instrument must be connected to the system, as shown in section 7.1.

Procedure:

1. Select and start the test cycle to be performed by the system (without introducing samples).
2. Now read the sample identification number with the external barcode reader.
3. Once the bar code has been acquired, the system will produce a long beep that will not stop until the operator introduces a test tube in the sample-holder, which is detected by the system.



If test tubes without an ID are used, they can be normally introduced in the sample-holder: the system will beep to confirm and then perform the test. A 13-point string will be matched to the print report.

The system performs the test as described in the previous section.

CHAPTER 5

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5.1. GENERAL RECOMMENDATIONS

The VESMATIC EASY has been designed and manufactured in such a way as to require very little maintenance.



For any interventions:

- disconnect the instrument from the power supply,
- use the personal protection devices appropriate during operation,
- do not remove the safety guards and do not ignore the safety warnings.



In the case of any leakage during the work cycle, follow laboratory procedures for biohazardous materials.

5.2. EXTERNAL CLEANING OF THE INSTRUMENT

External cleaning is required for safety reasons. Use a mild, non-aggressive detergent solution.

Do not use solvents, diluents, acids, acetone or similar materials in order to avoid damaging the outer casing.

SANITISING Procedure:

1. The instrument must be turned off, cleaning inside user accessible surfaces of any residues or leakage with a mild liquid detergent and then allow to dry.
2. Use one of the ready-to-use spray cans of isopropyl alcohol available on the market.
3. Spray well into empty sample positions.
4. Leave instrument turned off for at least one hour before beginning a new work cycle or any other type of operation.



For the internal cleaning of non-accessible parts the operator must contact an authorised Assistance Centre.

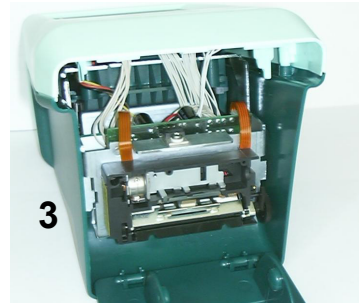
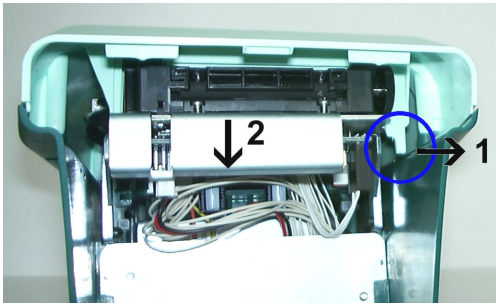
5.3. REPLACING THE PAPER IN THE PRINTER

Procedure:

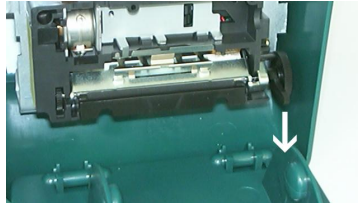
- Disconnect the instrument from the power supply.
- Lay the system on its back side and open the printer compartment.



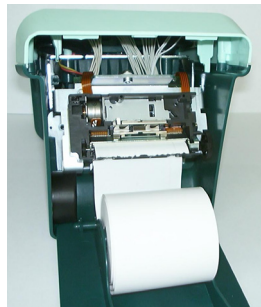
- Lift the lever shown in figure (1) to unhook (2) and invert (3) the printing mechanism.



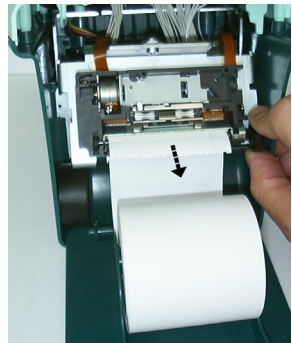
- Raise the head of the printer by lifting up the relative side lever.



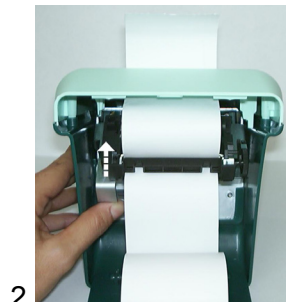
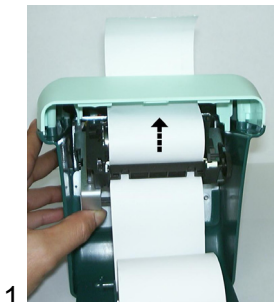
- Replace the old roll with a new one.
- Insert the end of the strip of paper into the slot in the paper guide taking care to cut it off in a straight line with a pair of scissors and following the correct rotation of the paper.



- Lower the lever of the head of the printer again.
- Using the side knob, advance the paper of at least 10 cm.



- Introduce the paper in the printer slot on the front panel (1) and close back the print mechanism (2).



- Close the paper-holder compartment.



- Take the system back in its vertical position and cut off the projecting paper.

5.4. PERIODIC CHECKS

At least once every 6 months, or more frequently, check the Optical Reading Unit's efficiency by performing a QUALITY CONTROL check. See section 3.7 for the procedure.

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6.1. SELF-DIAGNOSIS

Besides carrying out the command and control operations of the peripherals, the C.P.U. (Central Processing Unit) constantly controls the most important parts of the instrument.

Whenever a fault is detected the operation in progress is automatically interrupted with a beep and at the same time a message with the type of fault or trouble detected appears on the display.

The possible messages are as follows:

MESSAGE AND FAULT	CAUSE AND REMEDY

(DISPLAY ERROR) Upon starting up the instrument, no message is displayed on the screen and system produces a prolonged beep.	Contact the technical service.
RTC FAILURE	
(Clock Error) The programme cannot read or update date and time.	This reflects a communication problem between the component that contains the programme and the component that stores the date and time in its memory. Contact the technical service.
UNCALIBRATED	
(Uncalibrated sensors) The system lost the settings for the optoelectronic units.	This may happen when the programme does not find valid values in the EEPROM upon starting up. If no other problem exists, just press OK and these values will be taken to default. <u>However, recalibrate the sensors before using the system again and call the the technical service.</u>
EEPROM FAILURE	
The system lost the test-related information stored in the archive.	This may happen when the programme does not find valid values in the archive saved in the EEPROM. Press OK to reformat the archive (this procedure takes about 20 seconds). If the problem persists contact the technical service.
????	
(Barcode Reading Error) This happens during the acquisition of the ID number with an external barcode reader.	Control the integrity of the bar code label, otherwise replace the label and retry. If the problem persists contact the technical service.

MESSAGE AND FAULT	CAUSE AND REMEDY
<p>ERROR READING</p> <p>This message may be shown when the reading unit movement is not concluded within the established limit or if the home sensor of the reading unit has failed.</p>	<p>Possible electrical faults also check the correct loading of the cuvettes into the sample-holder or mechanical defects which must be removed.</p> <p>In the latter case contact the technical service.</p>
<p>STEP ERROR</p> <p>This message is shown when there is a jam of the reading unit.</p>	<p>Besides any possible electrical faults there may be mechanical defects which must be removed.</p> <p>Contact the technical service.</p>
<p>INSERT PAPER</p> <p>This happens when the printer paper is exhausted.</p>	<p>Replace the paper in the printer (see 5.3.)</p> <p>If the problem persists contact the technical service.</p>
<p>HEAD DOWN</p> <p>This happens when the printer head is up.</p>	<p>Lower the lever of the head of the printer (see 5.3.).</p> <p>If the problem persists contact the technical service.</p>
<p>PRINTER ERROR</p> <p>This happens when there are communication problems between the printer and the CPU Board.</p>	<p><u>With the instrument turned off</u>, open the printer compartment (see section 5.3) and check that the connectors to the printer interface are correctly positioned.</p> <p>Turn on the instrument and check that, pressing the relevant key in Select Function, the printer executes a line-feed (paper is advanced by one row).</p> <p>If the problem persists contact the technical service.</p>
<p>DISABLE PRT?</p> <p>(Disable Printer?) This message is shown after an error is detected in the printer.</p>	<p>If you do not want to interrupt the ongoing test cycle, press OK to confirm and disable the printer after the error message. Once the problem has been solved, print the test results, which will be saved in the EEPROM archive.</p>
<p>SENSOR X KO</p> <p>ALL SENSORS KO</p> <p>(SENSOR ERROR in the print report)</p>	<p>This may be caused by a malfunction of sensors or the motor photoelectric cell limit switch.</p> <p>Contact the technical service.</p>

MESSAGE AND FAULT	CAUSE AND REMEDY
SAMPLE ABSENT	
This message is printed when there is an absence of cuvettes or samples are present with a haematocrit value of < 15%.	
EMPTY	
This message is printed when the instrument identifies empty cuvettes or containing samples with a haematocrit value of < 15%.	
LOW	Correctly fill the cuvette with the same sample of blood following the indications on the cuvette package insert.
This message is printed when the level of the sample is too low or there are samples present with a haematocrit value of < 15%.	
HIGH	Reduce the contents of the cuvette following the indications on the cuvette package insert, close the lid tightly and repeat the exam. If problem is not corrected, contact the technical service.
This message is printed when the level of the sample is too high. This may also occur in the case of a fault in the opto-electronic elements.	
***	Verify the state of the sample inside the cuvette (ex. if there is coagulation). Correctly insert the samples into the specific housings and repeat the exam. If problem is not corrected, contact the technical service.
These symbols are printed when conflicting readings are detected, that is when the ESR 1h value is lower than the reference reading value or when the ESR 2h value is lower than the ESR 1h value. This may also occur in the case of a fault in the opto-electronic elements.	
!! ANALYSIS ABORTED !!	
This message is printed whenever a work cycle has been interrupted or if a test cycle is launched without samples in the cuvette-holder.	



After any type of **ERROR** message it is recommended repeating the entire operation at least once in order to ascertain whether the error is due to external incidental causes, like the momentary interruption or fluctuation of the power supply voltage

Turn off the instrument and wait a few seconds; turn on the instrument again and start the previous program cycle.

CHAPTER 7

SPECIAL FUNCTIONS..... 41



The cables used for the external connections must not exceed 3 metres in length.
Turn off the instrument before making external connections.

7.1.	EXTERNAL BARCODE READER	42
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7.1. EXTERNAL BARCODE READER

VESMATIC EASY is designed to acquire sample identification numbers (ID Nr.) by means of an external barcode reader.

To enable ID Nr. Reading by means of an external barcode reader, see section 3.5.2.

GENERAL CONNECTION SPECIFICATIONS

Before connecting the external barcode reader it is recommended checking that:

- This is fitted with a cable with a DB9 female connector in DTE set-up with a 5Vdc 9-pin power supply (refer to the instruction manual of the barcode reader),
- The signals on the DB9 female connector are compatible with the connector installed on the rear of the instrument to which it is connected:

DB9 Male "EXTERNAL BARCODE" on system rear	
PIN	SIGNAL
2	[Tx] Data transmission towards the reader (not used)
3	[RX] Data received from the reader
5	GND
9	+ 5 V



TECHNICAL INFORMATION:

- The electrical levels of the signals are of the standard RS232 type.
- The communication is one-way from the barcode reader towards the machine.
- The speed of the transmission is 9600 bit/s; the data format is of the type with 8 data bits, 1 stop bit and no parity bit.
- The communication protocol is of the ASCII type; the barcode read must be terminated with the Carriage Return (0x0d).



1. To order the barcode reader refer to the documents attached.
2. The procedures for preparing and conducting an exam with this function enabled are described in paragraph 4.4.

7.2. CONNECTING TO A HOST COMPUTER

It is possible to connect the VESMATIC EASY to a Host Computer via the USB interface, installed on the rear of the instrument.



For connection, use the standard USB cable ['USB 1.1 A-B M/M CABLE' type] supplied with the system. The system is also supplied with a CD-ROM that contains USB drivers for Windows XP and the instructions for installation [Order Code: 22100210] to configure the PC's serial USB port.



WARNING:

In case of any communication problem with the host, check that the COM ID is the same that has been assigned upon installation (sometimes new addresses are assigned to PC ports during subsequent hardware installations).

7.3. SPECIFICATIONS OF THE ASYNCHRONOUS SERIAL COMMUNICATION PROTOCOL

A bi-directional serial communication protocol called "NewProtocol" is installed on the VESMATIC EASY instrument (described in the following section).

7.4. "NEW PROTOCOL" SPECIFICATIONS

The speed of the transmission is 19200 bit/s; the data format is of the type with 8 data bits, 1 stop bit and no parity bit.

Representation of the transit bytes on the serial:

STX	BLK	BLK	LEN	LEN	ADD	ADD	COM	COM	D1	...	Dn	ETX	CHK	CHK
-----	-----	-----	-----	-----	-----	-----	-----	-----	----	-----	----	-----	-----	-----

Each box represents 1 byte that transits on the serial port, while the pair of bytes will be packed in the memory, meaning that they will return to being 1 byte.

STX : ASCII '>' 0x3E character

BLK : Block number, always = '00' unless for multi-block transferrals (see command 03)

LEN : Number of characters from D1 to Dn inclusive

ADD : ID device (00 and FF = Reserved) Range available 01-7F

COM : ID command

If COM=COM+0x80 the end of the block is given by ETX and CHK is not controlled.

D1.Dn : Date relating to the command

ETX : ASCII 'CR' 0x0D Character

CHK : CheckSum (XOR from STX to Dn inclusive)

The response to the protocol must come from the receiving device:

ACK / NAK	ADD	ADD	ETX
-----------	-----	-----	-----

ACK : ASCII 0x06 character

If the command block has been correctly interpreted according to the protocol specifications

NAK : ASCII 0x15 character

If the command block fails to comply with the protocol specifications

ADD : ID device

In the case of the translation of the data making the use of additional blocks necessary these will be numbered in an increasing order starting from 0, moreover, every transmission with additional blocks must finish with the block with a length of nil.

VES EASY SERIAL COMMANDS AND PARAMETER FORMAT

Every command interpreted obtains as a response 'ACK'=[0x06]+ID+CR

In the case of a syntax error or an incorrect command the response will be 'NACK'=[0x15]+ID+CR

0x00: Request for version

VesMatic EASY responds with an ASCII character string containing the firmware version.

Example of version request to the machine with address 0x00 without checksum verification.

Example:

From Host

>00000080+CR+00 The machine with ID '00' is requested to execute command '80' (that is, command '00' without checksum verification)

From VESMATIC EASY

>00100000SW VERS 1.00B +CR+59

0x02: Command requesting machine status

VesMatic EASY responds with a 1-byte message containing machine status information.

If the machine is free, status is 0x00; any other value indicates that the machine is engaged.

Example of machine status request with address 0x00 without checksum verification.

Example:

From Host

>00000082+CR+00 The machine with ID '00' is requested to execute command '0x82' (that is, command '0x02' without checksum verification)

From VESMATIC EASY

>0002000200+CR+33 [FREE]

>00020002FF+CR+33 [ENGAGED]

0x13-P: Request for sending of analyses

As a response to this command, the VesMatic EASY instrument will send a 160-byte record containing the results of 5 tests.

If parameter P is 0x00, the last 5 tests performed will be sent. If parameter P is 0x01, the 5 previous tests will be sent, and so on. If P is 0x13, the first 5 tests stored in the memory will be sent.

If parameter P exceeds the allowed limits (0x00-0x13), a 1-byte syntax error message (0x01) will be sent in response.

Example of a request for the 5 tests before the last 5, to the machine with address 0x00 without checksum verification and with legal parameter P = 0x01.

Example:

From Host

>0002009301+CR+00 The machine with ID '00' is requested to execute command '93' (that is, command '13' without checksum verification) with parameter '01' indicating the tests requested.

From VESMATIC EASY

>00A00013[see description below-160 bytes]+CR+XX

Each 32-byte field containing the results of a test includes the following sub-fields:

E-C-PR-P-T-H-M-S-G-M-A-BC-F1-F2-H1-H2-KI-R1-R2-R3

E (1 byte) Validates the content of the whole field, if its value is zero. If its value differs from zero, the remaining bytes in the field have no meaning.

C (1 byte) Test cycle number.

PR (1 byte) Contains Boolean flags describing test execution methods:

Bit 0 at 0 means normal test, 1 random test.

Bit 1 at 0 means one hour test, 1 two hour test.

If the test is a 1 h test, sub-fields H2 and KI have no meaning.

Bit 2 not used.

	Bit 3 at 0 means barcode off, 1 barcode on.
	Bit 4 at 0 means display off, 1 display on.
	Bit 5 at 0 means printer off, 1 printer on.
	Bit 6 at 0 means normal print, 1 reverse print.
	Bit 7 at 0 means quality control off, 1 quality control on.
P (1 byte)	Position where the tests was performed.
T (1 byte)	Not used.
H (1 byte)	Test time.
M (1 byte)	Test minute.
S (1 byte)	Test second.
G (1 byte)	Test day.
ME (1 byte)	Test month.
A (1 byte)	Test year.
BC (13 byte)	Bar code characters.
F1 (1 byte)	Contains Boolean flags describing test results.
	Bit 0 set means error in one sensor.
	Bit 1 set means no cuvette in.
	Bit 2 set means HIGH sample.
	Bit 3 set means LOW sample.
	Bit 4 set means EMPTY cuvette.
	Bit 5 not used.
	Bit 6 not used.
	Bit 7 set means that one or more previous bits are set.
Note: if one or more bits in sub-field F1 were set, the values shown in fields H1, H2 and KI have no meaning.	
F2 (1 byte)	Contains Boolean flags describing test results.
	Bit 0 set means reading at 2 hours greater than reading at 1 hour (sub-field H1 has no meaning).
	Bit 1 set means reading at 2 hours greater than reference reading (sub-fields H2 and KI have no meaning).
	Bit 2 set means reading at 1 hour greater than reference reading (sub-field H2 and KI have no meaning).
	The other bits are not used.
H1 (1 byte)	ESR results at 1 hour.
H2 (1 byte)	ESR results at 2 hours.
KI (1 byte)	Katz Index result.
R1 (1 byte)	Not used.

R2 (1 byte) Not used.

R3 (1 byte) Not used.

IMPORTANT NOTE:

VESMATIC EASY responds to commands only when it is not in the engaged status.

BEFORE SENDING THIS COMMAND, SEND COMMAND 0x02 TO MAKE SURE THAT THE VESMATIC EASY INSTRUMENT IS IN THE CORRECT CONDITION TO RESPOND.

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Attachment A: CE COMPLIANCE CERTIFICATE (* see page vi)

CE COMPLIANCE CERTIFICATE

In accordance with the directive CE 98/79/CE relating to in vitro medical-diagnostic devices



Diagnostica Senese S.p.A

The company DIESSE DIAGNOSTICA SENESE S.p.A. with its offices in Milan, Via San Vittore 96/1

Certifies

that on the basis of its design and type of manufacturing, the vitro medical-diagnostic device defined hereunder, as well as the version launched on the market,

is compliant

with the

“DIRECTIVE 98/79/CE RELATING TO IN VITRO MEDICAL-DIAGNOSTIC DEVICES (IVD)”

via the fulfilling of Attachment III (with the exclusion of section 6) and the essential requirements as per Attachment I.

This certificate shall lose its specific validity in the event of:

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

Product: **Automatic instrument for determining the ESR**

Type: **VES MATIC EASY**

Technical data: **9VDC@2A**

is compliant

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

EN 61010-1 “ Safety regulations for electrical devices for measuring, controls and laboratory use – Part 1: General regulations”.

EN 61326-1 “Electrical devices for measuring, controls and laboratory use – Electromagnetic compatibility regulations – Part 1: General regulations”.

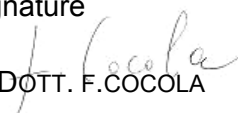
And therefore meets the minimum requirements of the following Community directives and their amendments

EC Low Voltage Directive (2006/95/EEC)

EC Electromagnetic Compatibility Directive (89/336/EEC) and (93/68/EEC)

Siena, 07-12-2006

Signature


DOTT. F. COCOLA

Attachment B: GUARANTEE CONDITIONS (** see page vi)

Ves-Matic Easy Guarantee Conditions

Certificate S/N

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

Limits of liability

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

General guarantee regulations:

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

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

General Conditions:

1. The guarantee shall only be recognised if the guarantee certificate has been returned, together with copies of the transport document, by 30 days after the delivery date.
2. The materials and manufacture of this product shall not be considered as defective if the instrument has been adapted, modified or adjusted to comply with national or local standards in force in a country where they differ from those for which the product has originally been designed and constructed. This guarantee shall not cover said adaptations, modifications or adjustments or any attempts at the same, irrespective of whether performed correctly or incorrectly, or any damage deriving from the same.
3. This guarantee shall not cover:
 - periodic checks, maintenance and repairs or replacement of parts due to normal wear and tear,
 - transport costs and risks linked directly or indirectly to the guarantee of this product, including the transfer from the assistance centre to the customer's address,
 - damage deriving from incorrect use, negligence, incorrect installation, impact, falls, insufficient voltage connections, use in environments with extreme conditions, damage caused by liquids dropped inside, etc. or deriving from any other accidental cause.
 - malfunctioning of the instrument due to modifications or repairs carried out on the same by unauthorised third parties.
 - damage caused by the assembly of parts or components not approved by the manufacturer.
4. No interventions carried out under guarantee shall interrupt or prolong the duration of the same for any reason whatsoever.

Attachment C: FORM REQUESTING ASSISTANCE (** see page vi)

Form Requesting Assistance		DATE
Product: Serial N°: SW Release: T.D. Date Guarantee YES <input type="checkbox"/> NO <input type="checkbox"/>	Client: Referee: Address: Phone: Fax: E-mail: 	
LAST TECHNICAL INTERVENTION on the product: Carried out by: On: 		
DETAILED DESCRIPTION OF THE PROBLEM		
ANY CUSTOMER REMARKS		
INTERNAL USE		
<i>Type of complaint:</i> <i>Notice to be forwarded to:</i> <i>Reply time</i> <i>Return</i> 	<input type="checkbox"/> Supply <input type="checkbox"/> Product <input type="checkbox"/> Technical Service <input type="checkbox"/> Sales Office <input type="checkbox"/> Technical Dpt. <input type="checkbox"/> Purchase Office <input type="checkbox"/> Quality Ass. <input type="checkbox"/> <input type="checkbox"/> BY days <input type="checkbox"/> URGENT	 Fax: E-mail:
NB.: To better understand and troubleshoot the fault reported we recommend: 1. Filling out this form in all its parts 2. Attaching the following to this form (if available): - the documentation supplied by the client (e.g. printing report; photos; etc...) - the documentation supplied by the Service Staff (e.g. printout of the settings; reports; etc...)		
FIRMA 		DATA
Pag. 1 di		

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

Attachment D: FORM REQUESTING ACCESSORIES AND SPARE PARTS

(** see page vi)

Complete and send a legible copy of the following form:

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

Form Requesting Parts			
INSTRUMENT _____	MODEL _____	SN#	200 <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>
CUSTOMER / COMPANY _____			
ADDRESS _____			
CITY _____	ZIP _____	STATE _____	
T.D. no. <input style="width: 100px;" type="text"/> of <input style="width: 100px;" type="text"/>			
Remarks:			
Code	Description	Package	Quantity requested
P12300000	THERMAL ROLLER PAPER H.MM L=57 D=50	4 pz	
P20550510	BARCODE READER Z-3080+ CAB 50607-R9 CABLE	1 pz	
P21440380	POWER SUPPLY MEAN-WELL ES18A09-P1J 9V 2A	1 pz	
P21890040	POWER CORD 3x0.75 L=2m PLUGSCHUKO 90°- EU	1 pz	
P21890360	USB 1.1/ USB 2.0 A-B M/M CABLE	1 pz	
P21890370	POWER CORD 3x0.75 L=2m PLUG USA/CAN 'UL'	1 pz	
10000430	ESR Control 9ml (2 Bottle Normal + 2 Bottle Abnormal)	1 pz	
<div style="display: flex; justify-content: space-between;"> Date _____. Signature _____. </div>			

Attachment E: MANUAL METHOD ACCORDING TO WESTERGREN'S TECHNIQUE

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

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

Materials

- Blood collected not more than three hours earlier with EDTA-K2 (1.5 ± 0.25 mg per mL of blood) or with EDTA-K3 (1.7 ± 0.3 mg per mL of blood). The haematocrit value must be found between 30 and 36% (PCV - packed cell volume 0.33 ± 0.03).
- Anticoagulant/diluent solution consisting of trisodium citrate dihydrate 109 mmol/L (3.28 g dissolved in 100 mL of distilled water).
- Glass sedimentation test tubes with the following dimensions: total length 300 ± 1.5 mm, internal diameter 2.55 ± 0.15 mm with a uniformity of ± 0.05 mm, graded scale 200 ± 0.35 mm long subdivided into 10 mm steps or less with a maximum error tolerance between two consecutive divisions of 0.2 mm; before use the test tubes must be cleaned, dried and free of any residual traces of detergent.
- Supporting rack for holding the test tubes in a perfectly vertical position ($\pm 1^\circ$) and structured so as to be completely stable to prevent any spilling of the blood from the test tubes in.

Procedure

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

Attachment F: QUICK START GUIDE

SUMMARIZED INSTRUCTIONS FOR VES MATIC EASY OPERATION

Excerpt from CHAPTER 4:

- Turn the system on (Section 4.1.).
- When the **SELECT FUNCTION** option is shown on the display, programme the system work cycle (Sections 4.2, 4.4):
 - a. press ▼ once to execute the **ESR I cycle [20 minutes]** for ESR determination (Westergren 1h).
 - b. press ▼ twice to execute the **ESR II cycle [40 minute]** for ESR determination (Westergren 2h).
 - c. press ▼ three times to execute the **ESR I RANDOM cycle [20 minutes per sample]** for ESR determination (Westergren 1h).
 - d. press ▼ four times to execute the **ESR II RANDOM cycle [20 minutes per sample]** for ESR determination (Westergren 1h).
- Introduce previously mixed samples in the 10 sample-holder positions (Section 4.2.), if option a. or b. is selected
- Press **OK** to start the work cycle selected.
- Introduce previously mixed samples in the 10 sample-holder positions (Section 4.4.), if option c. or d. is selected.

Attachment G:PROGRAMMING MANUAL – UPGRADE SOFTWARE

1. INSTALLING THE PROGRAMMING SOTWARE ‘WinBootPrg’

The “VESMATIC EASY” CD [Order Code: P30650050] supplied with the system contains the programming software ‘WinBootPrg’ [Order Code: P22100221] to be used to update the application software.

Connect the instrument to the PC using the USB 1.1 A-B M/M connector [Order Code: P21890360] supplied and install the VCP driver on the PC to configure the USB port (see instructions in the CD-ROM).

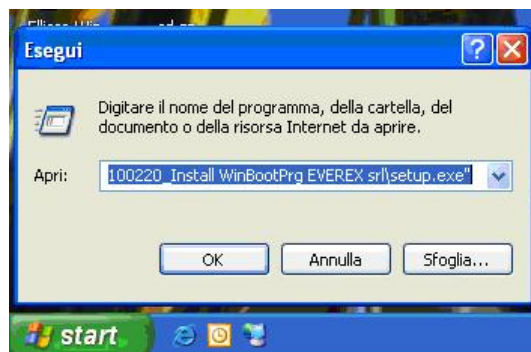
Accessories required:

Programming the instrument requires a Personal Computer (or a notebook) with Windows®XP operating system and a USB port.

Please, carefully follow the instructions below.

Installation of the WinBootPrg software:

1. Double click the **setup.exe** file in the 22100221_Install WinBootPrg EVEREX srl folder in the CD-Rom to launch the program.



2. Press **OK** to start the installation.



3. By default the program is installed in the **c:\Programmi\WinBootPrg** folder (if you want to change its destination, press “Change Directory” and choose the new path); press the Start push-button.



4. Confirm the group of Programs highlighted with **Continue**.



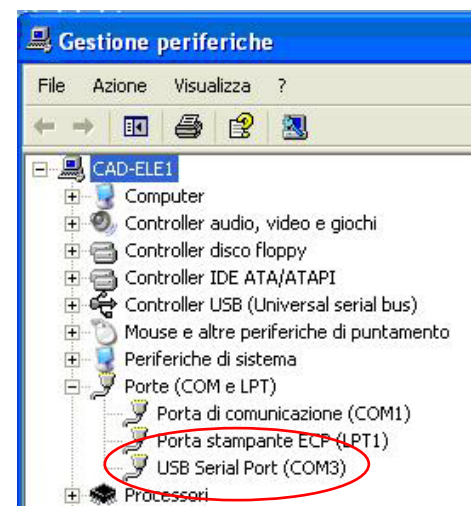
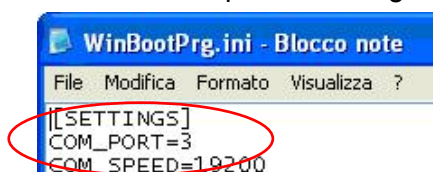
5. When installation is completed, the following message will be displayed '**WinBootPrg installation completed**'; press OK to exit.



2. COPYING THE FILE TO TRANSFER TO THE UNIT

Contact the Support Centre for receiving the update file.

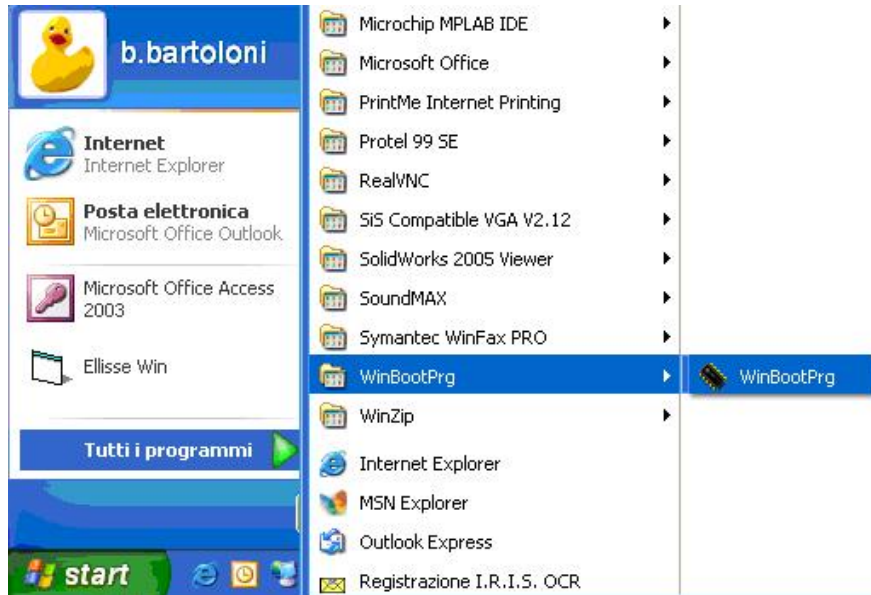
- Copy the application software file (VesMaticEasy_SWXXX.hex) to be transferred to the VesMatic Easy system in the **C:\Programmi\ WinBootPrg** folder.
- Connect the system to the PC and to the power supply mains to ensure that the USB port address [COM_PORT=] in the winbootprg.ini file contained in the WinBootPrg folder corresponds to the USB port address indicated in the system properties [Control panel\System properties\Hardware\Peripheral management].



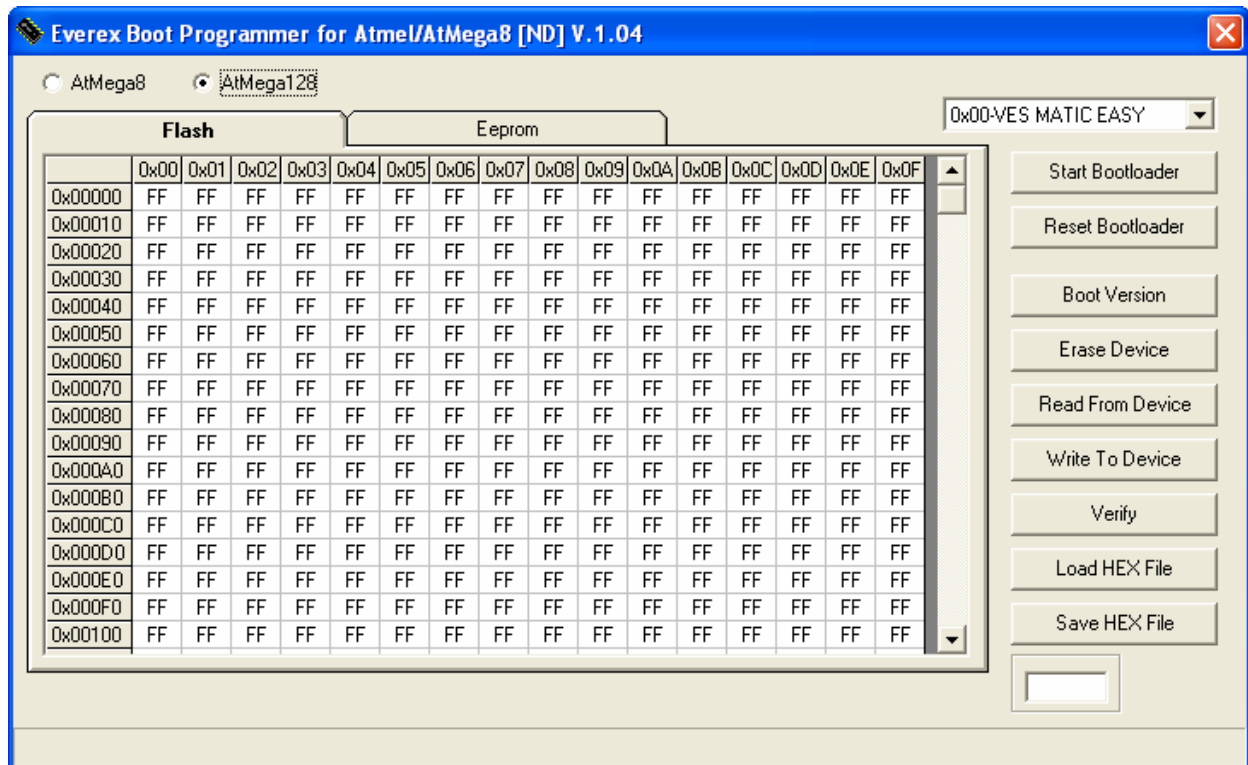
3. If the ports do not corresponds, set the correct port in the winbootprg.ini file and save the new settings.

3. PROGRAMMING PROCEDURE / UPGRADE SOFTWARE

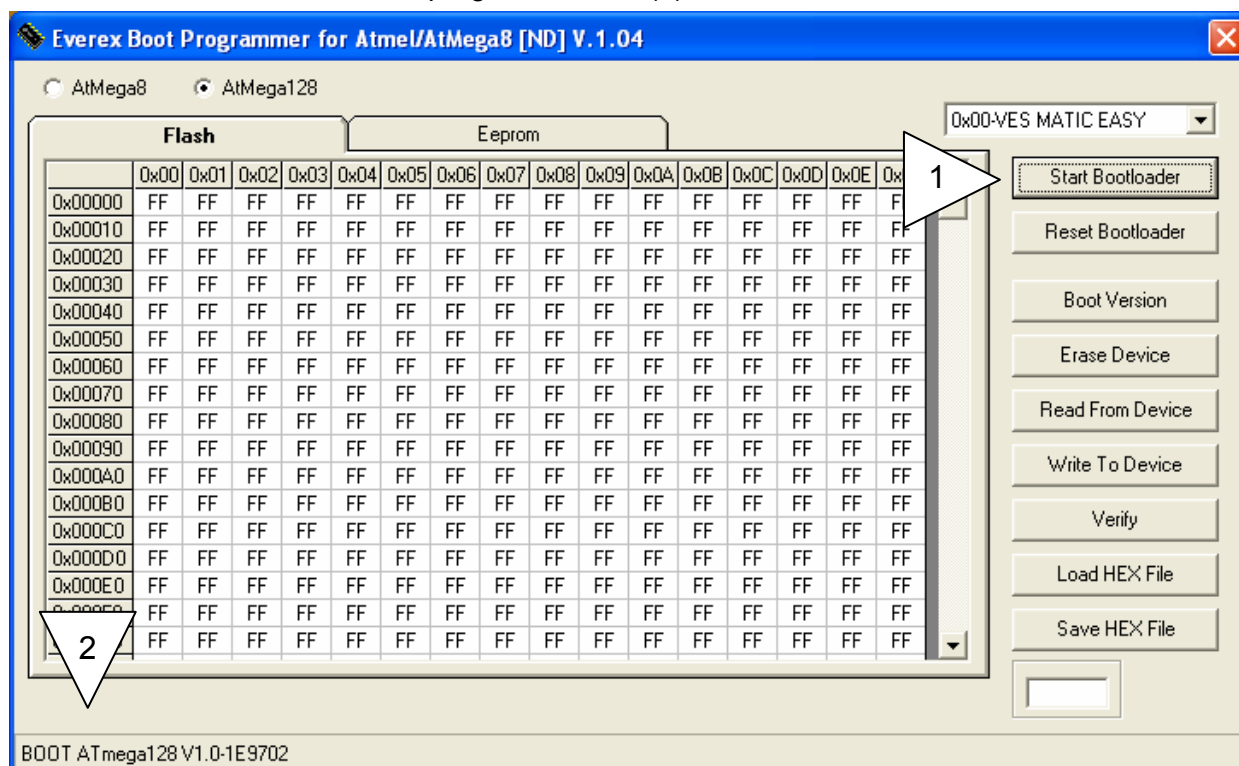
1. Connect the VesMatic Easy to the PC (see section 7.2.) and turn it on.
2. Start the WinBootPrg.exe program from the tool bar on the PC:



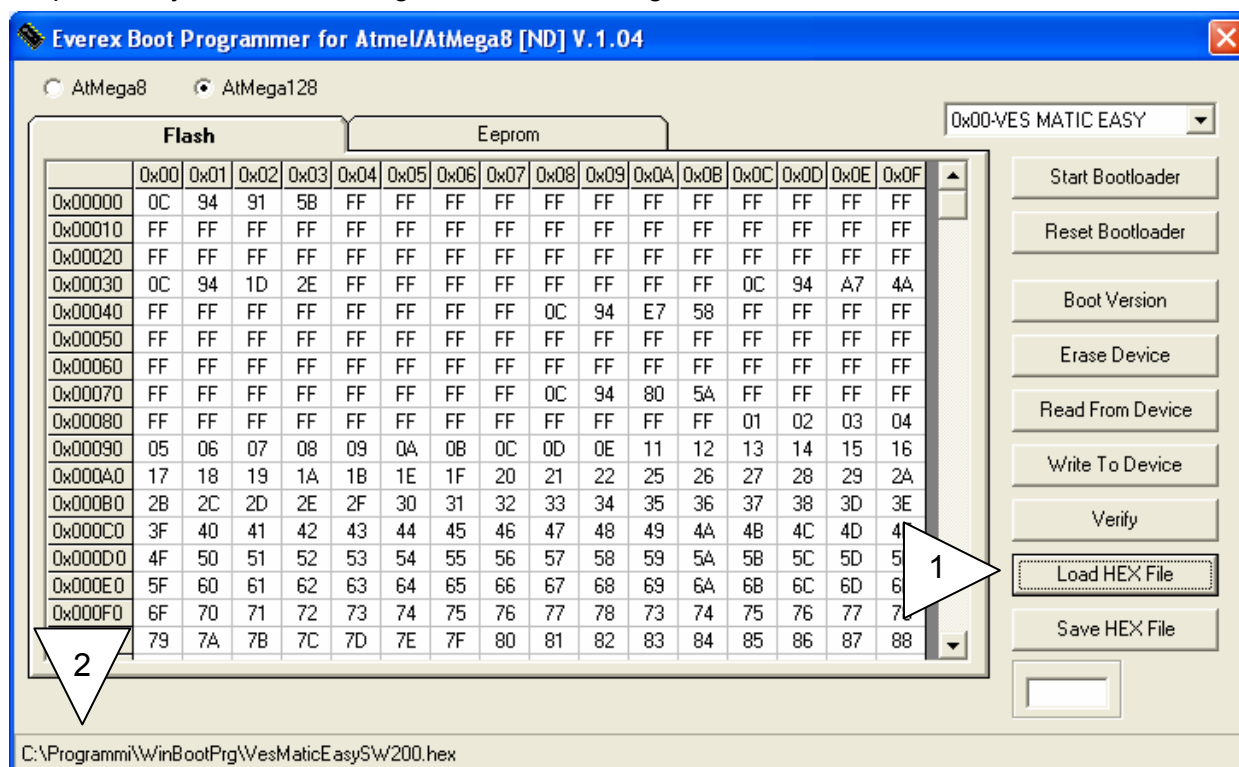
3. During startup, set the program for the microprocessor assembled on the CPU: ATMEGA128.



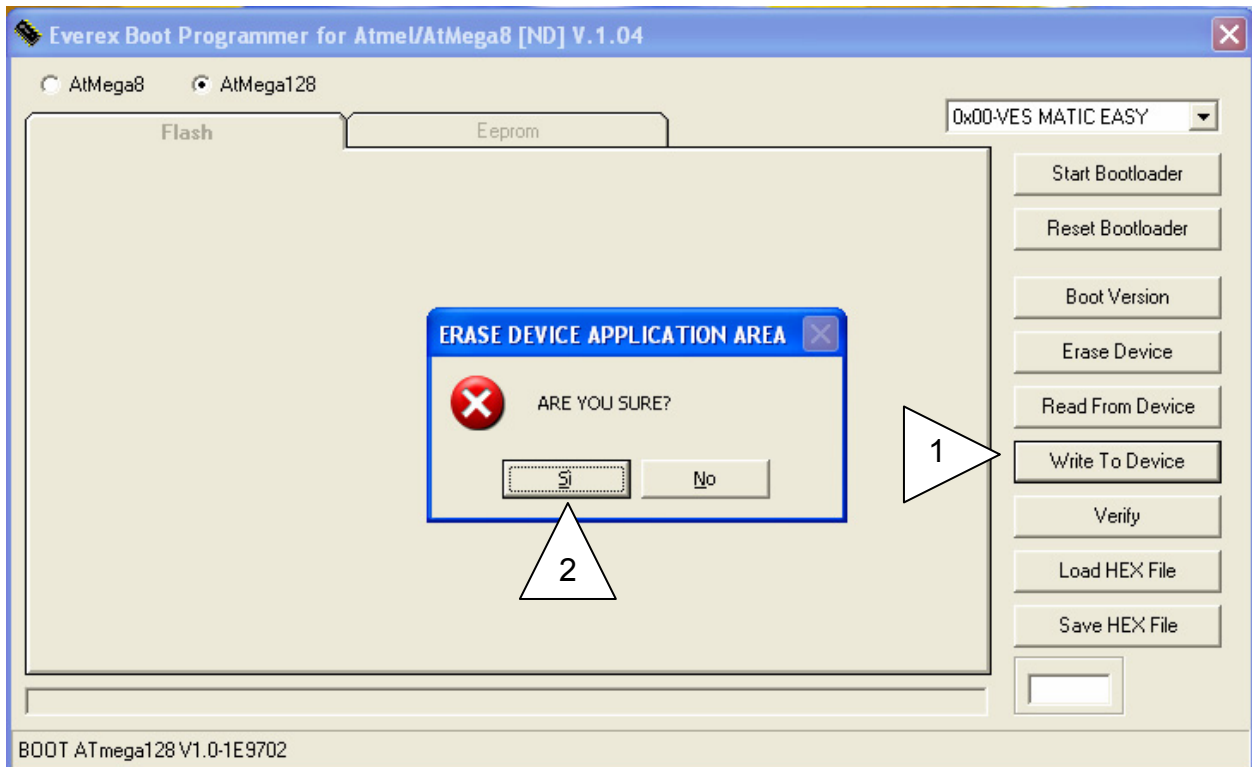
4. Ensure that the instrument is shown in the Select Function menu and launch the program in the instrument CPU to update the application software: select the **Start BootLoader** push-button (1) and ensure that the BootLoader program version (2) is shown in the bar.



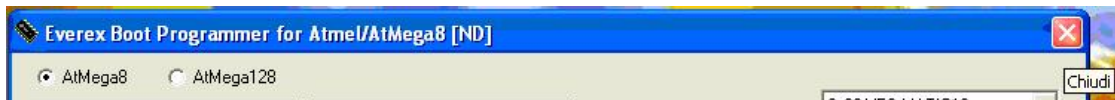
5. Select the application file: press **Load HEX File** (1) and recall the VesMaticEasy_SWXXX.hex (2) file previously saved in C:\Programmi\WinBootPrg.



6. Start programming the system: select **Write To Device** (1) and, when requested, press **YES** (2) to confirm.



7. When programming is completed, turn the instrument off and on again to ensure that the application software version displayed on screen corresponds to the update version.
8. To exit the **WinBootPrg** program, click on the **X (Close)** in the upper right part of the screen.



Remarks:[illegible]

Remarks:[illegible]

