MINI-CUBE

USER MANUAL

Rev. 1.11

Automatic instrument for ESR determination
with modified Westergren method

Software version 1.xx

FOR IN VITRO DIAGNOSTIC USE ONLY

DIESSE

CE

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MINI-CUBE models:

This manual is applicable to the following MINI-CUBE instrument models:

Catalog number	Description
10392	MINI-CUBE (Streck reference number 240401)

MINI-CUBE Accessories:

Catalog number	Description
10293	TEST DEVICE NEXT 500 (500 tests) (Streck reference number 240403)
10294	TEST DEVICE NEXT 1K (1000 tests) (Streck reference number 240404)
21430440	Bluetooth MINI-CUBE printer (Streck reference number 240402)
20550510	External barcode reader (Streck reference number 240405)

Manual revisions list:

MANUAL revisions	Description of changes
0 of 01/06/2016	Original
1 of 01/10/2016	Chapter 3 composition of the instrument
1.1 of 25/01/2017	Modification of the list of manual revisions and drafting of the document software revisions available at: http://www.diesse.it/_files/files_prodotti/File/minicube/MINICUBE_Firmware_History.pdf
1.2 of 22/02/2018	Edit description “Test Device NEXT”
1.3 of 14/01/2019	Addition of Rx symbol; insertion of Intended Use and Performances sections
1.4 of 18/02/2019	“Capillary blood” phrasing removed from Intended Use, added “semiquantitative” in Intended Use
1.5 of 19/02/2019	Corrected an error in Intended Use section
1.6 of 31/01/2020	Addition of management of pediatric tubes called Microtainer ® MAP
1.7 of 25/05/2020	Addition of performance data for Microtainer ® MAP tubes
1.8 of 31/07/2020	Revision of the Procedure and performances for BD Microtainer® MAP tubes, update of WEEE and RAE normative references
1.9 of 07/2022	Update of the manual with new logo and new graphic design with updated brand colors Update of the manual following the latest FW release (V. 1.26). Update of the screen with the new heading. Adding of APPENDIX MINI-CUBE PRINTER TOOL II – MPT II INSTALLATION GUIDE
1.10 of 11/2023	General update of the manual
1.11 of 03/2024	Update of the paragraphs 2.1, 4.2, 4.3 and 4.7.3

Manufacturer

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If any serious incident in relation to this device has occurred in the European Union market territory, please report without delay to the manufacturer and competent authority of your Member State.

For technical assistance please contact your distributor: **Streck LLC**

Technical Services 800.843.0912 x7510 or technicalservices@streck.com

STRECK

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SYMBOLS

Key of graphic symbols	
CE	The instrument meets the requirements of the European Directive on in vitro diagnostic medical devices (98/79/EC).
IVD	In vitro diagnostic medical device
	Date of manufacture
SN	Serial number
	Manufacturer
Key of electric and safety symbols	
	Earth (ground) terminal
	WEEE: Waste from Electrical and Electronic Equipment - Obligation of separate waste collection according to 2012/19/EU Directive
	Warning, read the manual, observe the safety symbols.
	Caution: risk of electric shock
Key of graphic symbols used in this document	
	WARNING: potential risk of personal injury; all the conditions indicated in the relative text must be read and understood before proceeding.
	CAUTION: potential risk of damage to the instrument; all the conditions indicated in the relative text must be read and understood before proceeding.
	Important Information.
	BIOHAZARD: risk of contamination with potentially infected substances.
MET	Complies with MET standards for the Canadian and US markets

LIMITATIONS AND WARNINGS

Before installation and use of the instrument, **for proper and safe use**, it is advisable to **carefully read** the warnings and instructions in this user manual. It is important that this user manual be kept together with the instrument for future reference.
In the event of sale or transfer, make sure that this manual accompanies the instrument to allow new users to be informed about the instrument's functions and the related warnings.
It is recommended to allow only **qualified and skilled laboratory personnel** to use the instrument.

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.

BIO-CONTAMINATION HAZARDS

	When an analysis system like the MINI-CUBE is used, all precautions must be taken regarding biological risks. The samples do not require preparation. The samples must be disposed of in accordance with laboratory instructions and with local laws. Observe personal and group safety measures foreseen for the operator and appropriate for the work environment. Comply with directives on safety and with applicable laws.
	In the case of leakage of biological material during the working cycle, clean external surfaces of the instrument using appropriate personal protective equipment and observe regulations on sanitization. Contact Technical Services at 800.843.0912 or technicalservices@streck.com for further instruction and assistance.
	All supplied materials must be disposed of in accordance with local laws.

Content

1 INTRODUCTION

INTENDED USE

1.1. Intended purpose

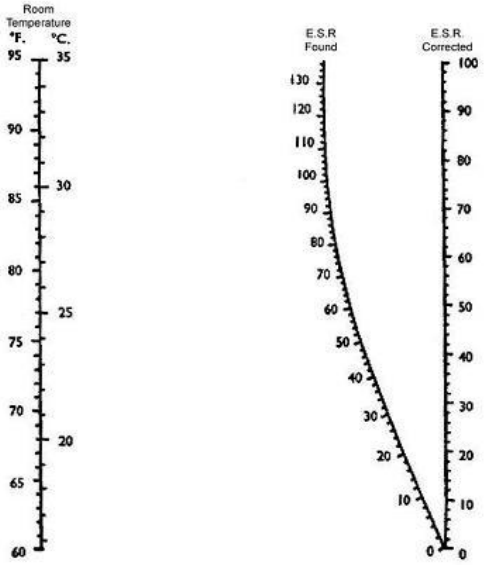
The MINI-CUBE is an automated instrument for the Erythrocyte Sedimentation Rate (ESR) determination with the modified Westergren method using venous and capillary whole blood anticoagulated with K2EDTA or K3EDTA.

1.2 Presentation of the instrument

The MINI-CUBE (Fig 1.0) is an automated instrument designed to measure the erythrocyte sedimentation rate (ESR) of blood samples anti-coagulated with EDTA, directly from the EDTA tube. The instrument analyzes four blood samples simultaneously on a random access and continual loading basis. The color touch screen allows the user to select various instrument functions which are described in more detail in the following sections. ESR results obtained in only 20 minutes show excellent correlation to the Westergren Reference method at one hour (ref. 1-10).

Fig. 1.0

The instrument is designed with the temperature correction always activated and relates the results to a temperature of 18°C according to Manley's Normogram (graph 1.0).



Graph 1.0 Manley's Normogram

1.3 Clinical significance of ESR

The erythrocyte sedimentation rate measures the distance travelled by red blood cells in autologous plasma for a certain period of time. In normal conditions, red blood cells tend to reciprocally move apart due to the presence of negative electric loads from the numerous residues of sialic acid present at a membrane glycoprotein level. When the protein composition of plasma changes with the production of "acute phase proteins" at hepatic level, following an inflammatory process or tissue damage, the bond of these proteins (fibrinogen, immunoglobulins) with the surface of the red blood cells, changes the membrane potential negative load (Z) and the red blood cells can bind, forming a rouleaux formation. These rouleauxed cells aggregate to form microspheres of a uniform radius which sediment as their density exceeds that of plasma. The ESR value increases in all conditions with increased acute phase proteins, particularly fibrinogen which is considered to account for 70% of the sedimentation phenomenon, and increased immunoglobulins observed with oncological/haematological diseases and acute infections. The ESR is therefore a non-specific measurement of an inflammatory state; the rate is high in numerous, different pathological conditions such as inflammatory diseases (infections, rheumatic diseases), a relative/absolute increase in globulins (nephrotic syndrome, myeloma), tissue necrosis (myocardial infarction, tumours). Literature suggests the ESR is useful in diagnosing some diseases, such as polymyalgia rheumatica, temporal arteritis,

rheumatoid arthritis and Hodgkin's disease, and is useful as an effective marker of pharmacological treatment in some diseases including rheumatoid arthritis, vasculitis, collagenosis, and septic arthritis. The ESR in usually higher in females compared to males and increases in pregnancy and tends to rise with age in both genders.

1.4 Normal ESR values (Westergren citrated)

With the Westergren reference method, the test is performed on blood diluted in citrate; with four parts blood to one part anti-coagulant. The diluted blood is then aspirated in a special, graduated, 2.5 mm diameter pipette which is kept upright. The erythrocyte sedimentation level is recorded after one hour, measuring the distance between the plasma meniscus to the top layer of sedimented red blood cells.

Guidelines for ESR Reference Values for the Westergren
ESR Method* are as follows:

Normal 0-20mm/hr

* Follow CLSI *Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard. CLSI document H02.*
Reference values should be established locally in accordance with the individual laboratory's accrediting agencies. Refer to CLSI document H02 for age and gender-specific reference values.

1.5 Materials required for use of the instrument

Exclusively use the materials of the MINI-CUBE line manufactured by DIESSE DIAGNOSTICA SENESE S.p.A. (Always read the instructions for use that accompany each product before operating); any other part or accessory used in the instrument may cause damage or incorrect results. The manufacturer therefore declines all responsibility for damages deriving from inappropriate use.

1.6 Precautions

The MINI-CUBE system offers a closed tube system which provides less exposure to potentially infectious samples; however, all necessary precautions and personal protective equipment for handling biological material apply. Waste material should be disposed of in accordance with your local waste requirements.

1.7 Maintenance procedure

The MINI-CUBE is designed to require minimal maintenance.

Weekly:

Note:

It is advisable not to leave the instrument turned on all the time but to switch it off and on at least once a week.

It is advisable turn the instrument off when it is not in use (e.g. at the end of the day).

For any type of maintenance activity:

- Switch-off the instrument and disconnect from the power source.
- Use all appropriate personal protective equipment (gloves) during operation.

In the event of biological material leakage, wipe the outer surfaces of the instrument with 70% isopropyl alcohol and immediately contact Technical Services at 800.843.0912 or technicalservices@streck.com for further instruction.

1.8 External cleaning of the instrument

External cleaning is required for safety reasons.

Decontamination procedure:

1. With the instrument turned off, clean with liquid sanitizing used in the laboratory and leave to dry.
2. Repeat the operation with 70% isopropyl alcohol.
3. Leave the instrument turned off for at least 1 hour before starting a new operating cycle or carrying out any other operation on the instrument.

Do not attempt to remove any of the screws or open the instrument and/or clean the interior. Please contact Technical Services for further instruction.

2 TECHNICAL DATA

2.1 Technical description

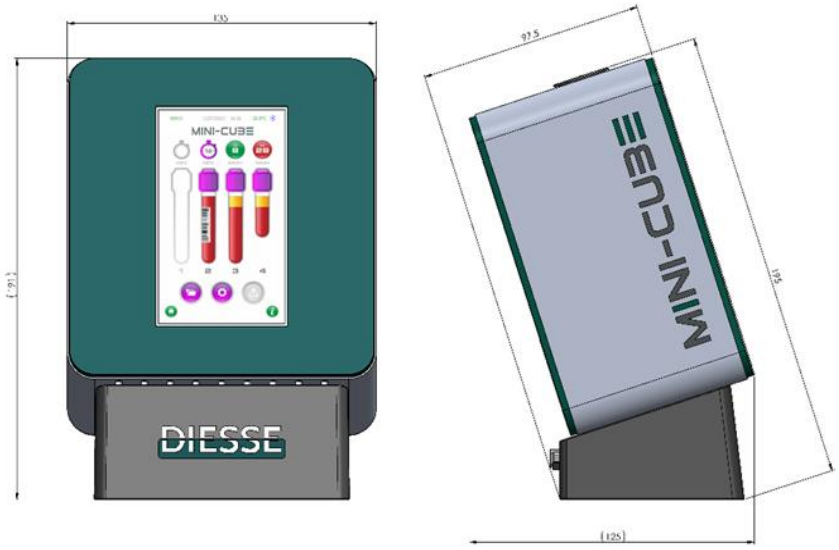


Fig. 2.0

The MINI-CUBE module consists of a single body containing all the operating functions necessary for analyzing the sample.

Reading unit

The motor lifts the reading unit which utilizes four optical sensors (one per position) to verify the suitability of the sample and detect the sample level at baseline and level after 20 minutes of sedimentation.

Detection of the sample

The optical sensor of each position scans the inserted test tube, checking that it contains an adequate volume of blood and identifying the type of tube (13x75 mm EDTA tube, BD Microtainer® or BD Microtainer® MAP tubes).

Alarm

The function of the alarm is to alert the operator during various stages of the operating cycle or in the event of errors.

Identification of the sample

The sample is identified by an external bar code reader (optional accessory). The patient ID code can also be manually entered using a stylus on the keypad display.

2.2 External connections of the instrument

(A) USB cable

(B) USB stick

The MINI-CUBE has a Bluetooth 4.0 connection for an external printer (optional accessory).

The power supply, serial/USB ports for connection to a computer (A), a USB port for connection to the USB mass storage device (B) that can be used to update software or export files and a port for the external bar code reader are positioned at the rear of the instrument. The functional units of the module are described below.

Fig 2.1

Fig. 2.2

2.3 Updating software

Updating software is a simple, direct procedure:

- Save the new software (i.e. *mcfw.bin* file and *System* folder) into a USB mass storage device
- With the instrument switched off, insert the USB device into the appropriate port (Fig. 2.2)

Power on the instrument and wait for a few seconds. The instrument will update automatically.

Software revisions history is available on DIESSE's website:

https://www.diesse.it/en/download/id:21651/

2.2 Technical features

USE	Internal use
POWER SUPPLY	Input: 100-240 Vac, 50-60Hz, 0.5A Output: 9Vdc@2A marked UL LPS, DC output shall be provided a reinforced insulation between primary and secondary circuits
DIMENSIONS (mm)	135 x 191 x 125
WEIGHT	1.5 kg (3.31 lbs)
ROOM TEMPERATURE	Operating temperature From +15° to +35°C Storage temperature From +5° to +45°C
RELATIVE HUMIDITY (RH)	20%-80% without condensation
ALTITUDE	maximum 2000 meters (6562 ft)
NOISE LEVEL	below 80 decibels
LEVEL OF POLLUTION	2 pollution degrees
MEASUREMENT RANGE	4 ml Tube: 1 - 140 mm/hr Pediatric Tube: 1 - 100 mm/hr
CENTRAL UNIT	ARM Cortex-M4 180 MHz Microprocessor
DISPLAY	480x272 TFT 16.7 Million colors + Resistive Touch Panel
OPTICAL UNIT	4 pairs of optical elements (photodiode + phototransistor)
INTERFACES	USB
CLASS OF DEVICE	I

SAFETY STANDARDS	CEI EN 61010-1; CAN/CSA-C22.2 No. 61010-1-12; ANS/UL 61010-1-2012
EMC	CEI EN61326
INSTALLATION CATEGORY	II

2.5 Unit of measure

The units of measure are expressed according to the INTERNATIONAL MEASURING SYSTEM as indicated in the technical standard CEI EN ISO 80000-1:2013.

3 INSTALLATION

The MINI-CUBE is a precision instrument and must be handled with appropriate care and precautions. Inappropriate operations may damage the internal optoelectronic components and cause mechanical damage. Follow the instructions in this chapter in order to ensure proper operation of the instrument and safety of the operator.

3.1 Transport and handling

The instrument must be transported and handled in its original packaging. Do not leave the packed instrument in a damp environment or allow the boxed package to get wet. If the instrument has been subjected to temperature conditions below 10°C for more than 24 hours, allow the instrument to sit at room temperature for one hour prior to installing/powering on.

3.2 Packaging characteristics

Save the original packaging including the internal parts.

The instrument is packed in:

1. An external cardboard box
2. Molded housing in CFC and HCFC-free expanded, closed cell polyethylene.

Box Dimensions	
33 x 23 x 15	cm
1.5	Kg

3.3 Materials provided

The MINI-CUBE is supplied with the following materials:

- User Manual
- USB mass storage with multi-lingual manual
- Non-capacitive touch stylus

- DC power Supply (see characteristics in *Technical Features* section)
- One power cable for each module according to IEC International Standards (Female Plug IEC 320 C-13; Male Plug Schuko EEC 7-VII; Rating: 10A / 250V AC)
- USB cable

Fig. 3.0

3.4 Unpacking the instrument

1. Open the box from the top and remove the User Manual, Quick Reference Guide and accessories.

Fig. 3.1

2. Remove the instrument and power supply unit from the box
3. Remove the expanded polyethylene blocks containing the instrument and power supply unit

Fig. 3.2

4. Remove the protective pack from the instrument
5. Verify the materials supplied against the packing list

3.5 Setup

For normal safety requirements and given the type of examination it performs, the instrument must be positioned away from heat sources, in areas unreachable by liquids and in a dust-free environment. Position the instrument on a solid, perfectly level bench, not subject to shaking or vibrations. The 15 cm or 6" perimeter distance as indicated in figure 3.3 must be observed as a safety precaution.

Fig. 3.3

It is advisable to position the instrument to 1 meter away from devices that generate electromagnetic waves (e.g. laboratory fridges, centrifuges) and instruments that do not have CE marking.

The safety of the instrument and operator is not guaranteed if one or more of the following conditions are violated.

- The main power source must be compatible with the voltage and current specifications indicated on the back of the instrument.
- Contact Streck Technical Services for compatibility prior to attempting to connect any non-Diesse external accessories (i.e. barcode reader, printer, USB drive).

3.6 Installation procedure

Only use the power supply unit provided

1. Position the instrument on a solid surface.
2. After checking that the power switch is in the “OFF” position, connect the power supply unit plug provided with the instrument.
3. Connect the power supply unit cable to the main power source.
4. Optional - connect the barcode scanner and Bluetooth printer. Once the MINI-CUBE is powered on, a series of beeps will be heard indicating that the system recognized the scanner. Follow the printer installation steps in chapter 4 to enable the printer.

3.7 Limitations and warnings

IN CASE OF FIRE OR GENERAL DANGER, TURN OFF THE INSTRUMENT AND UNPLUG THE POWER CABLE.

3.8 Composition of the instrument

The instrument is made up of the following materials, expressed in percentages:

Material	%
IRON	10
COPPER	3
ALUMINIUM	60
PLASTIC MATERIALS (PVC, ABS...)	20
SILICON	2
Gold	0,1
Tantalum	0,2
Cadmium	0,2
Others (No Latex)	4,5

3.9 Disposal

The MINI-CUBE instrument relies on the use of an electrical power source and therefore, in compliance with the European Directive 2012/19/EU and later amendments by the European parliament, it is classified as Electrical-Electronic Equipment. Disposal of the instrument at the end of its life cycle, must be executed in accordance with local waste disposal regulations.

In order not to incur the sanctions envisaged by the law, it is absolutely forbidden the disposal of the instrument in the municipal solid waste.

4 USE

4.1 Instructions for the operator

Before reading this section of the Manual, it is important to read the previous chapters in order to avoid problems with the operation of the instrument.

4.2 Compatible test tubes

- Standard 13 x 75 mm EDTA Tubes with Hemogard™ or Conventional stoppers
- EDTA Microtainer® TUBES (BD)
- Microtainer® MAP TUBES (BD)

4.3 Sample requirements

The following sample requirements are critical for accurate results:

- The sample volume must be 2.0 mL to 4.0 mL in the standard 13 x 75 mm EDTA tube or 500 µL in the Microtainer® and Microtainer® MAP tube
- The test must be performed within 4 hours of collection with the sample at room temperature (18 – 25 °C).
- The test may be performed on blood samples adequately stored at 2 - 8°C for a maximum period of 24 hours. Ensure that the sample is at room temperature for at least 15 minutes and well-mixed prior to inserting into the instrument and performing the test.

4.4 Preparation of the sample

Before starting a test, the samples must be **manually** mixed as follows:

Gently and completely invert the test tube for 10 - 12 times immediately before starting the analysis. Do not shake or agitate the sample vigorously, as this could cause bubbling or hemolysis.

WARNING: Make sure the test tube is hermetically sealed. **Always mix pediatric samples thoroughly before starting the test!**

4.5 Test tube labelling

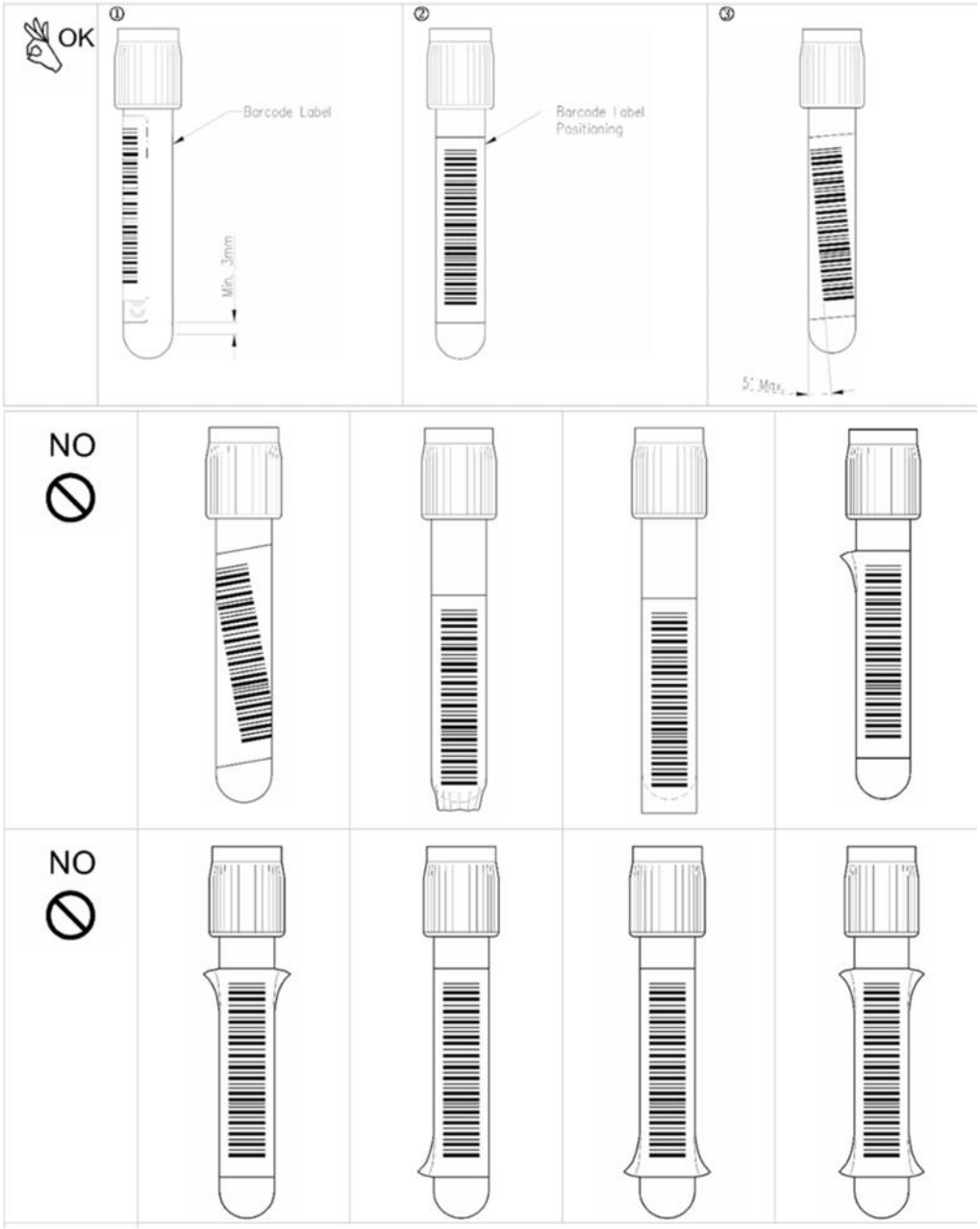


Fig 4.0

The MINI-CUBE can accept sample tubes with a maximum of 1 secondary label adhered as close to the lavender EDTA

cap as possible and with a label-free gap on one side. Pay attention to the excessive thickness of the two labels and any ripples that may be created, as these can increase the external diameter of the tube and results in the instrument getting stuck. The secondary labels must be positioned completely adhering to the surface of the tube to prevent any fragments of label or adhesive from accumulating in the instrument, hindering the analysis of the sample. The secondary label must be also applied in the same position as the label already present. As the samples are loaded, it is important to align the label-free gap with the dot on the insertion ring so the label-free gap is towards the right of the analyzer (fig. 4.1).

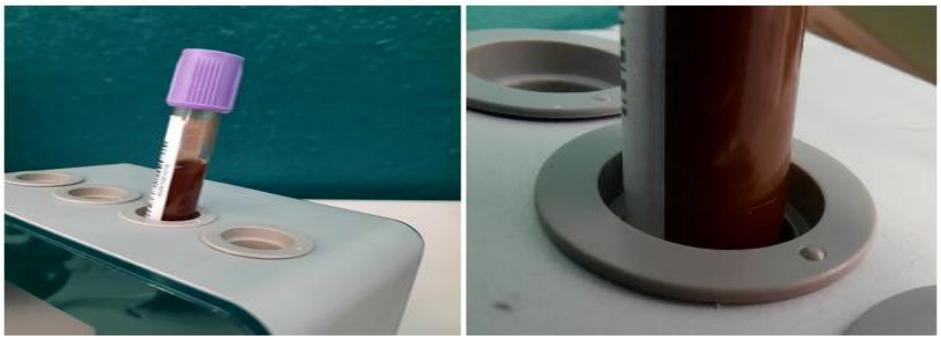


Fig 4.1

4.6 MAP test tube labeling

The secondary label must be applied below the bottom of the internal micro-tube (Fig. 4.2)

This allows a completely free view of the blood level and of the sedimentation in the tube.

Fig 4.2

4.7 Description of the MINI-CUBE menu

Slide the power switch on the back of the instrument to turn on the MINI-CUBE.

4.7.1 Home

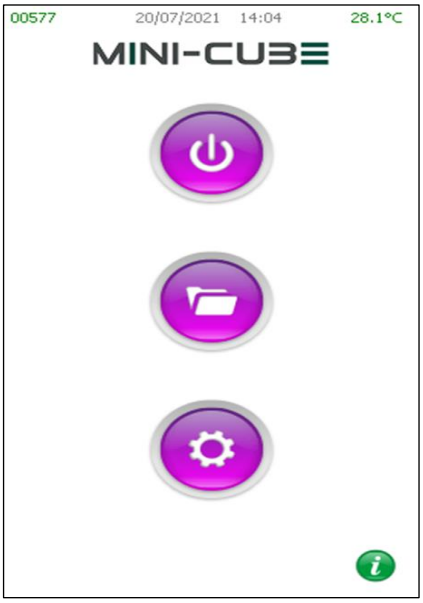


Fig. 4.3

It is recommended to use a stylus on the touch screen display. Once powered on, the Home page (Fig. 4.3) is displayed to access the following functions:

START: Tap this icon to go to the Analysis screen and run a sample

ARCHIVE: Tap this icon to view the data archive.

SETTING: Tap this icon to view/change instrument settings.

4.7.2 Performing an analysis

Click START; the instrument initializes with a system and motor checks and the LEDs are powered on.

A prompt will display to indicate “INITIALIZATION” is in progress

Fig. 4.4

The instrument is ready to run a sample once the “INITIALIZATION” prompt disappears.

The counter in the top left hand corner of the screen shows the number of tests remaining in the MINI-CUBE. For each result produced, the instrument decreases the number of tests available by one. The counter font color will change depending on the number of tests remaining; green font indicates that more than 50 tests are available, red font indicates less than 50 tests are available. When the test number is zero, new analyses cannot be performed. Load a new TEST DEVICE NEXT (also called Check Device Transponder) to perform further testing.

Date/Time: Indicates the current date and time.

Bluetooth: This symbol indicates that the Bluetooth connection is enabled and the system is ready to communicate with accessories (e.g. a printer).

Temperature: Indicates the internal temperature of the instrument in °C or °F. Green indicates that temperature correction is enabled. Red indicates that temperature correction is disabled.

Timer: Indicates the minutes remaining until completion of the test.

Position: Sample position number.

Export: Allows data export to printer .

Refer to Appendix “MINI-CUBE PRINTER TOOL II – MPT II INSTALLATION GUIDE”, for instructions on how to connect printer via Bluetooth.

OFF: Powers off the LEDs and returns to the main screen. If a cycle has started, a warning window will appear to confirm the end of the test.

Information: Select to open an interactive guide on instrument operation.

4.7.3 Inserting the test tubes

It is good laboratory practice to enter SAMPLE ID prior to inserting test tube

If connected, use the barcode reader to scan the ID code of the patient sample. A window will be displayed with the acquired code in the “Sample ID” field and a “Cancel” button. A separate patient code may be scanned in the “Patient ID” field, by touching the “Patient ID” field and scanning a separate barcode with that information. Pressing "Cancel" eliminates the whole operation (the acquired codes are ignored and the window closes). Upon inserting the test tube in a position, the window closes and the screen displays the sample tube with a barcode label (Fig. 4.5.).

Fig. 4.5

To enter the “Sample ID” and “Patient ID” manually before inserting a test tube, touch any empty position on the display (Fig. 4.6) to open the “New Sample” window.

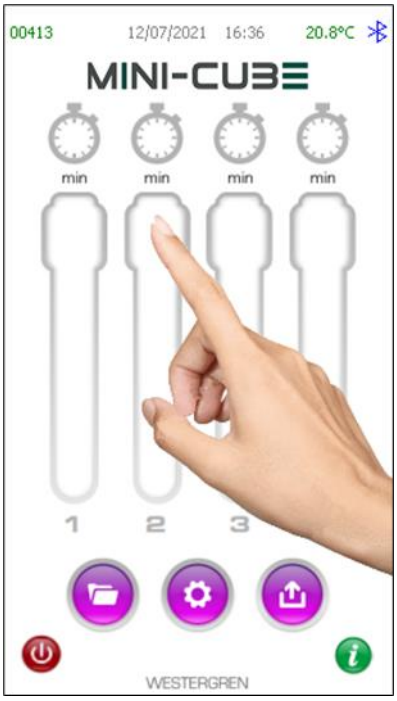


Fig. 4.6

Touch the desired“Sample ID” field to display a keyboard and enter the sample and/or patient codes and then insert the tube. In this step, it is also possible to insert the sample code using the external barcode reader.

It is also possible to associate to the sample a Patient ID already present in the archive; just click on the Archive icon and search for the desired patient. Once the code has been entered, it can no longer be edited on this screen.

Procedure for BD Microtainer® MAP tubes

If most of the test tubes in use are BD Microtainer® MAP tubes, select ON in the dedicated MICROTUBE MAP parameter in the settings menu.

When this setting is enabled, ALL tubes will be identified as MAP tubes. When inserting MAP tube in any empty tube position, it will be displayed as a short (pediatric) tube with the letter M on the cap for MAP.

(For the information regarding sample ID entry or add statement, refer to section below Fig. 4.6.)

Note: for correct recognition of the BD Microtainer® MAP, make sure that the tube has been inserted all the way in position, by pressing lightly on the cap.

To run a standard 13 x 75 mm EDTA tube or a short BD Microtainer® tube when the MAP setting is enabled, touch any empty tube position on the screen to open the NEW SAMPLE window. Select "Microtube MAP (N)" and insert the tube in any empty position. Standard 13 x 75 mm ETDA tube will be displayed as a full-length tube while short Microtainer® tube will be displayed as a short (pediatric) tube without the letter M on the cap.
(For the information regarding sample ID entry or add statement, refer to section below Fig. 4.6)

If most of the test tubes in use are not BD Microtainer® MAP tubes, select OFF in the dedicated MICROTUBE MAP parameter in the settings menu. To run a MAP tube when the MAP setting is disabled, touch any empty position on the screen, select "Microtube MAP (Y)" in the NEW SAMPLE window and insert the MAP tube in any empty position.
(For the information regarding sample ID entry or add statement, refer to section below Fig. 4.6)

NOTE: In V1.24 software and higher, the test time for standard 13 x 75 mm EDTA tubes is 20 minutes while and the test time for all Microtainer®, BD Microtainer® MAP, is 14 minutes.

4.7.4 Starting the analysis cycle

Once a sample is inserted, the instrument scans the tube to determine the blood level at the sedimentation baseline. During the first scan, a pop-up window opens with the “TUBE DETECTION” message and the display shows the type of test tube (normal or pediatric) and the blood level detected. The countdown begins at this point.

During the analysis cycle, the user can access the Archive and Settings menus although access to edit some instrument settings will be reduced while a sample is running.

At the conclusion of the test, the instrument will alarm to alert the user that the analysis is complete and the result will be displayed above each position.

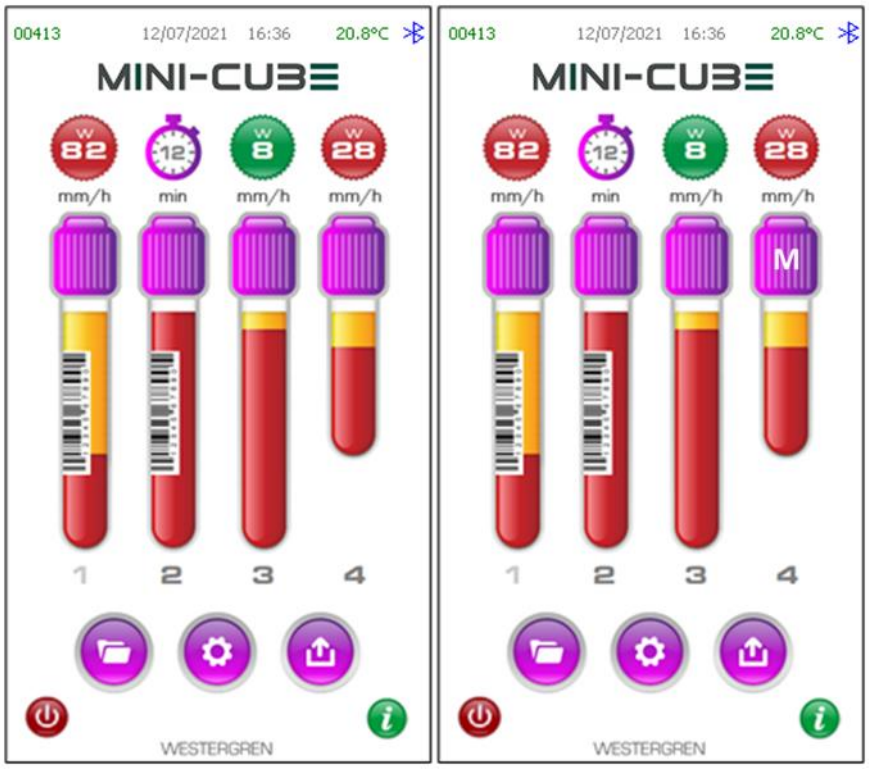


Fig. 4.7

To cancel a run, either remove the tube and an immediate “ERR” message will display or press the OFF icon and a prompt will read, “There are X sample(s) in process. Are you sure you want to stop the analysis?” Proceed accordingly.

Results: Green indicates an ESR in the normal range (which can be set or edited in the Settings menu as the “threshold value” parameter). Red indicates an ESR that has exceeded the set threshold value. The results are reported in mm/hr according to the Westergren method (default setting).

4.7.5 Archive

Click the Archive button 

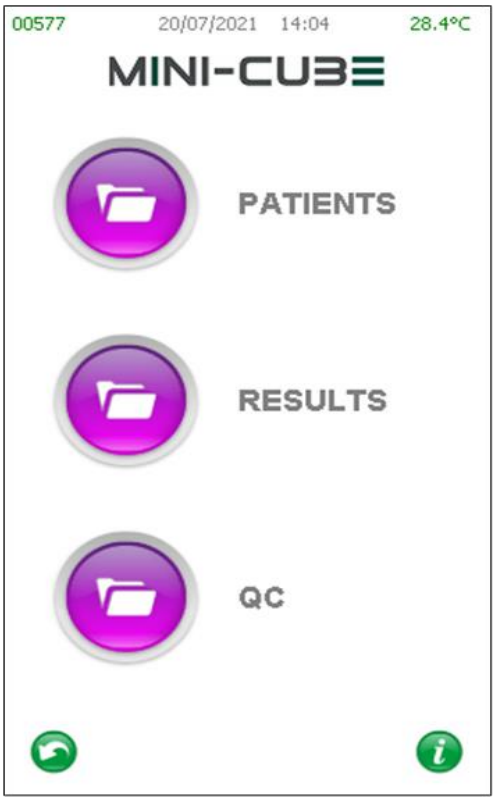


Fig. 4.8

From the Archive Menu it is possible to search for the data relating to all the analyzed samples.

The archive consists of the Patients Archive, Results Archive and QC Archive. Each archive can contain up to 5000 records.

NAME

SURNAME

ID PAT.

In the **Patients Archive**, you can search for a patient by name, surname and patient ID, clicking on the relative key in succession, entering the first letters or the complete name in the specific search bar.

Click on the export icon to print the entire a list of patients or to create a new list. By clicking on the export icon after selecting only specific patients it for selected is possible to patients, or edit, delete, or print them or send them to host. Test results will only appear in the Patient Archive if a patient name is manually associated with a sample.

In the **Results Archive,** samples can be sorted by date (default), by name or by code (based on the selection made in the item ORGANIZE, in the Settings menu).

Fig. 4.9

Each sample in the archive is characterized by: time and date of the analysis cycle, the position occupied, SAMPLE ID (or PATIENT ID or name/surname) and the ESR value. Click on the export icon to send to host the list of results, to print the list or filter the database by name, patient ID, sample ID or date.

If a sample has been recognized as a Pediatric tube, a “P” in subscript will be displayed immediately to the right of the ESR value on the screen and the “PEDIATRIC” item will be indicated on the sample printout. If Hematocrit correction is enabled, an “H” will be displayed in superscript immediately to the right of the result.
The Hematocrit result can be entered in the individual Patient results that are found in the Results Archive.

"Note: once the Hematocrit value is entered, the Hematocrit corrected ESR result will override the original ESR result. Finally, if an error occurred during the analysis cycle, the entry "ERR" is reported in correspondence with the ESR value.

Several samples can be selected from the Archive menu and, by clicking on the export button, it is possible to print them, permanently delete them or send them to host. To enter a patient’s record (Fig. 4.10), press and hold the string containing the patient’s name.

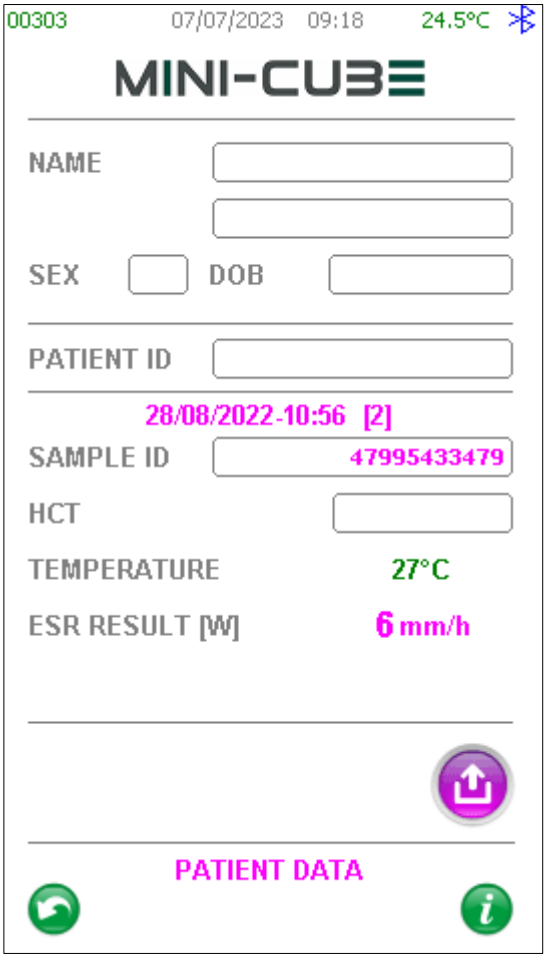


Fig. 4.10

NAME: Displays the patient's Name and Surname

SEX: Patient's gender.

DOB: Patient's Date of Birth

PATIENT ID: To insert the patient code in the "Patient ID" field, the barcode on the card needs to be scanned or edited manually. If a code is not entered, the instrument will generate one automatically.

SAMPLE ID: This is a unique code that identifies a specific sample analyzed.

HCT: Option to enter the patient's hematocrit value (Hct correction is limited to values < 40%).

TEMPERATURE: The instrument's internal working temperature. The temperature is displayed in green if the test is performed with temperature correction enabled. If temperature correction is disabled, the temperature is displayed in red.

ESR RESULT: Result of the ESR test and relative reference scale. This fields also contains any error entry (ERR) with the relative identification code. For the detailed error message table see Chapter 6 Troubleshooting

EXPORT: Prints the patient record.

From any screen, press the Arrow Back icon on the bottom left side of the display to return to the previous page.

Finally, by accessing the **QC Archive**, it is possible to display all the controls performed, based on the instrument's positions. For all the details relating to the controls settings and the QC Archive. (See chapter 5).

It is always possible to print the results via the Bluetooth printer (accessory). It will first be necessary to connect the printer to the instrument from the Settings menu (see APPENDIX: MINI-CUBE PRINTER TOOL II – MPT II INSTALLATION GUIDE). Once connected, pressing the EXPORT key will allow to print the results

Fig. 4.11

4.7.6 Settings

Click Settings.

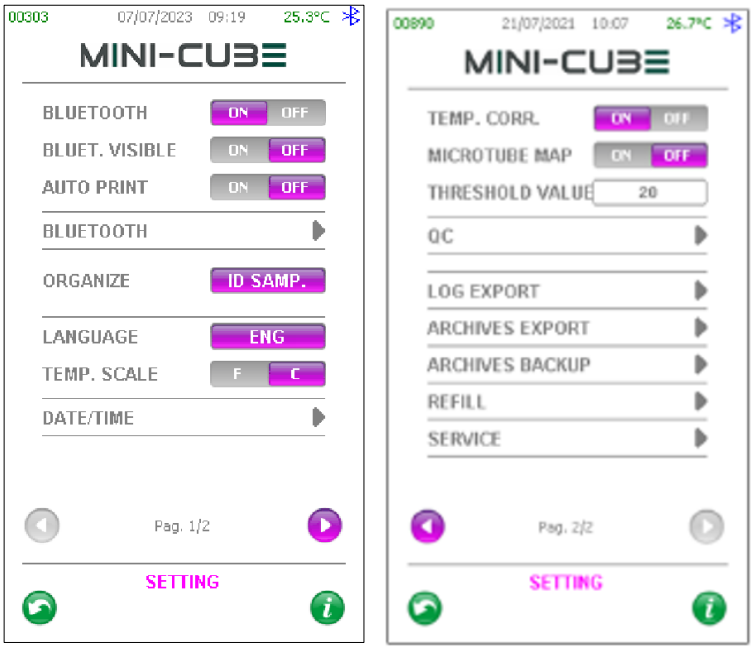


Fig. 4.12

From the Settings menu, the user can customize various functions:

BLUETOOTH: Enable or disable the Bluetooth connection with other devices.

BLUET.VISIBLE: Enables external visibility for Bluetooth connections such as a printer.

AUTO PRINT: Set to "ON" for automatic printing of results at the conclusion of each analysis cycle.

BLUETOOTH : ▶ Allows to search for all Bluetooth devices to which connection is possible (printers).

ORGANIZE: Edit how data will be saved and displayed in the archive (by name, surname, sample ID, patient ID).

LANGUAGE: Allows to select the language among those available (i.e. English, Italian, Dutch, Spanish or French).

TEMP. SCALE: Allows to select the temperature scale in degrees Celsius or Fahrenheit.

DATE/TIME: Set the date and time format. Military time is an option and the following date formats are available:
DD/MM/YYYY
MM/DD/YYYY
YYYY/DD/MM

Note:
Please consider GG=DD.

TEMP. CORR.: Enable or disable Temperature Correction. See chapter 1 for explanation of temperature correction. The default setting is ON.

MICROTUBE MAP: Enable or disable the automatic recognition of the MAP test tube. See paragraph 4.7.3, for the use of BD Microtainer® MAP.

THRESHOLD VALUE: Set a threshold value for the normal ESR reference range limit; when this value is exceeded the instrument will display the result in red to alert the operator that the sample exceeds the normal range (Default is 20 mm/h).

QC: View the QC menu and configure quality control settings.

LOG EXPORT: Allows data export to USB drive (files .LOG).

ARCHIVES EXPORT: Allows the user to choose to export between the Sample, Patient or QC archives to a USB drive. Archives are exported in Excel format as .CSV files.

ARCHIVES BACKUP: Allows to Backup or restore all the archives. Archives are backed up in .ARC files, which is the only file format that can be imported in the instrument for restoring them.

REFILL: Allows to load a certain number of executable tests in the memory using the TEST DEVICE NEXT (Check Device Transponder) (Streck part numbers 240403, 240404) (Fig 4.13).

Fig. 4.13

In this sub-menu, the user can load more tests by inserting the transponder in the slot at the base of the instrument, and following the instructions displayed on the screen (Fig.4.14).

Fig. 4.14

SERVICE: Service menu that can only be accessed by personnel authorized by DIESSE Diagnostica Senese S.p.A.

5 QUALITY CONTROL

From the settings menu, under QC, the user can register a new lot of control (Fig. 5.0). Depending on whether the control is Normal (NORM) or Abnormal (ABN), the user can select the dedicated card through the "TYPE" setting and enter the specific data. If the QC barcode is scanned (ESR-Chex Plus), the name, barcode, lot number, expiration date and control limits are automatically programmed.

The name may be manually entered into each level of QC if desired

After the NORM and ABN registration, when using arrow to return to Setting menu, a prompt will as you "QC Settings modified, confirm new settings? Select Yes to save QC data.

If another type of commercial control for ESR is used, labels with dedicated bar codes should be created and the data should be entered manually.

During daily operation, when the barcode of an expired QC is scanned, upon confirmation of the QC sample, a message will appear on the screen requesting user confirmation to continue with the insertion of the expired QC. ((This occurs in analysis screen NOT QC Settings menu)). (Fig. 5.0). The label "QC EXPIRED" will be also present in the print report of the expired QC at the end of the analysis.

If the ESR result is within the control limits of the QC, "PASS" will be reported on the print report corresponding with the QC RESULT. if the ESR result is out of the control limits, the print report will report "FAIL".

Note: it is possible to register only one Normal and one Abnormal QC lot at a time

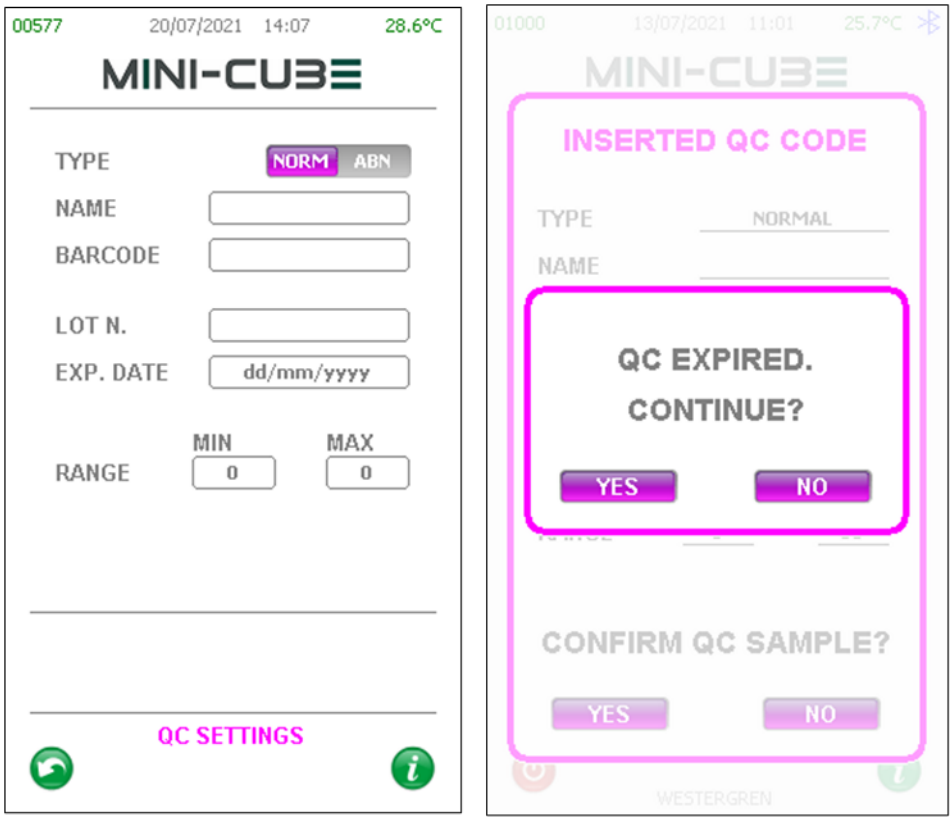


Fig. 5.0

It is recommended to run two levels of control (Normal and Abnormal) each day of patient testing with the Diesse MINI-CUBE. In the QC archive, the user can view the historical QC data. Results are stored by the position in the instrument and can be organized by date or by barcode. Like other archives, the date, barcode, type of control and result are displayed on this screen.

Click on the Download icon to print the QC list or filter it by barcode or date. If some QC have been individually selected, by clicking the Download icon it also possible to send them to host. Click and hold down a control string to enter the record displaying the individual details: type of control, name, barcode, lot number, expiration date, expected results ranges, date and time of the test, position occupied and ESR result. All these information can be printed by clicking on the Download icon present in the record page.

From this record, or the main list, press on the Chart icon to view the QC data in a Levey-Jennings chart (Fig. 5.1).

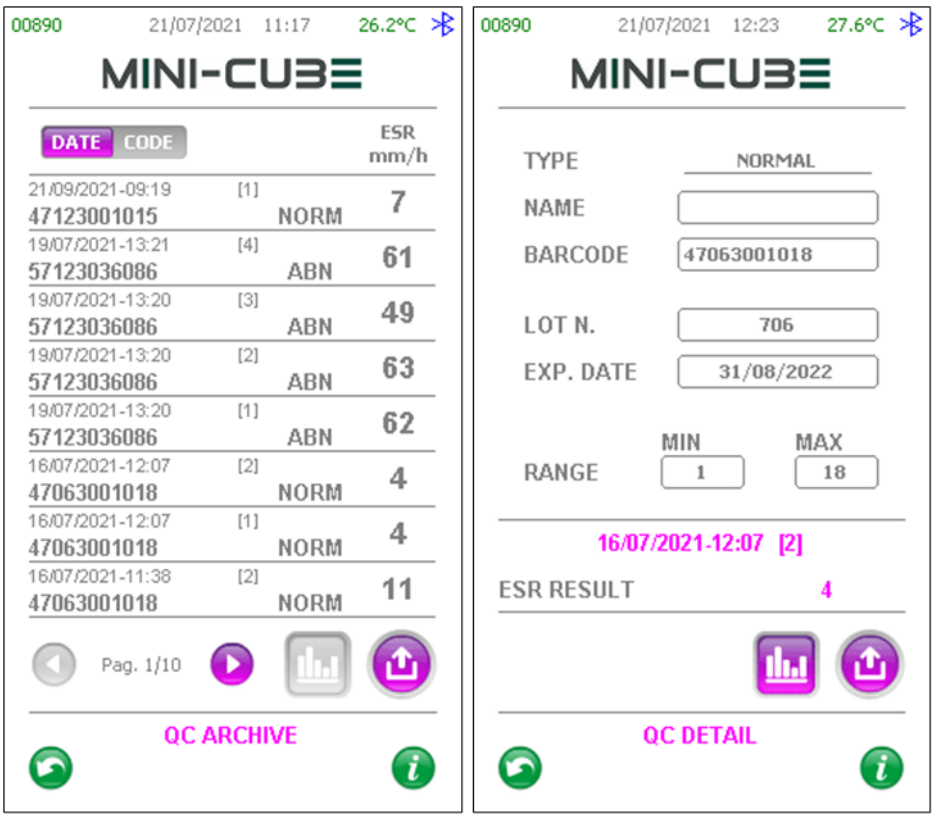


Fig. 5.1

This screen displays the QC information including the number of measurements performed, the average, standard deviation, and the CV%. The Levey-Jennings chart displays the control data points on the x-axis, and the mean and standard deviations (+/- 1SD, +/- 2SD) are shown on the y-axis.

WESTGARD statistical rules are commonly used by laboratories to evaluate their data set and identify systematic and random errors that might lead to a failure to comply with established objectives of accuracy and precision.

The following Westgard rules are used in the control chart:

- 1_{2S}: A control value exceeds the mean of two standard deviations.
- 1_{3S}: A control value exceeds the mean of three standard deviations.

- 2_{2S}: Two consecutive values exceed the mean of two standard deviations on the same side of the mean.

- R_{4S}: The difference between two consecutive values exceeds the four standard deviations.

- 4_{1S}: Four consecutive values exceed the mean of a standard deviation on the same side.

- 10_{X}: Ten consecutive values fall on the same side compared to the mean.

Upon conclusion of the test, in addition to being printed on the receipt, the result will be displayed on screen using a colour code, as explained in the table below.

Colour code	Meaning
	The processed QC has met the acceptability range
	The processed QC did not meet the acceptability criteria; therefore, it is out of range.
	The processed QC did not comply with the accuracy and precision rules of Westgard, as previously described.

Fig. 5.2

Press the Export icon to print the list of data for the selected control or to search and filter by lot.

5.1 Performing QC analysis

Control materials are processed in the same manner as patient blood samples (See chapter 4). To run a QC sample, scan the QC barcode (previously registered in the settings menu), and then load the tube in any free position. The MINI-CUBE will recognize a QC tube by the registered lot number, and will display an image on the screen with a barcode label, whether the QC sample is manually entered or barcoded, as shown in Fig. 5.2. The tube with a white cap indicates a

Normal level control while the tube with a black cap indicates an Abnormal level control.

Fig. 5.3

Since the instrument can register only one Normal and one Abnormal QC lot at a time, during the analysis it is possible to process only one Normal and one Abnormal control material that will be automatically recognized as QC . If other QC with barcodes or lot numbers different from the registered are processed, they will be recognized as normal patient blood sample (with a purple cap).

6 TROUBLESHOOTING

If any problem persists, contact Streck Technical Services at 800.843.0912 x7510.

ERROR MESSAGES	CAUSE/REMEDY
Remove all test tubes	The system is attempting to initialize but test tubes were detected. Remove the test tubes and start the cycle again.
Err	A test tube has been removed from its position before the end of the analysis, or the system is having trouble detecting the sample.
Low	The blood level is below the allowed minimum

High	The sample blood level is too high or there could be an issue with the secondary label (number of labels or thickness). Refer to Chapter 4 for the ideal label placement.
Exam not available. Need refill	No tests remaining. Refer to Chapter 4 to load a new transponder.
Printer error... Retry?	The printer could be OFF. Turn ON or repeat the installation printer procedure.
USB pendrive not found	Remove and reinsert USB drive and try again
CHECK DEVICE already used	The transponder does not have any tests remaining. Please load a new transponder.
Warning! Remain n tests	The number of tests remaining is low. Load a new transponder soon.

Tab. 6.0

6.1 Measuring abnormal samples

The clinical significance of an ESR result obtained from an abnormal sample, including but not limited to icteric, lipemic, cold agglutinins, anemic conditions, low hemoglobin concentrations, hemolysis, or any pathological condition that interferes or prevents a clear red blood cell to plasma interface, should be determined by the clinician ordering the test. Manual and automated ESR measurements in samples without a clear interface are subject to a high degree of variability. In the MINI-CUBE, the sample may go undetected or yield variable results. Visually inspect the sample at the conclusion of the test to confirm the presence of a clear interface.

7. CONNECTION TO A HOST COMPUTER

Foreword: Hardware data

The Communication between the MINI-CUBE and an external PC may be done in two possible ways:

1- Using the Direct **USB Connection**:

In this case connect a standard USB Cable A-B between the PC Host USB Port (Rectangular Type A Connector) and the Mini Cube Client USB Port (Square Type B Connector).

In this case a ***software Driver (STM32_SW)*** for MS Windows has to be installed on the PC (downloadable from the website www.diesse.it) in order to set the communication with the MINI-CUBE through a virtual COM port over USB.

On the MINI CUBE the parameter "**HOST BY USBH**" has to be set **OFF** in the Service Menu. Since the Service Menu can only be accessed by authorized personnel, please contact our Technical Support.

2- Using a serial **RS232 COM** port on the PC:

In this case the" **MINI CUBE USB-to-Serial adapter**" (code: R30006190) has to be used.

Connect a standard RS232 straight Cable between the PC RS232 COM port and the Adapter's Serial Connector.

Then connect a standard USB cable A-B between the MINI Cube Host USB Port (Rectangular Type A connector) and the Adapter's Clinet USB Port (Square Type B Connector).

On the MINI CUBE the parameter "**HOST BY USBH**" has to be set **ON** in the Service Menu. Since the Service Menu can only be accessed by authorized personnel, please contact our Technical Support.

The electrical levels of the signals are of the standard RS232C type.

- The default transmission speed is 9600 bit/s, the data format is of the 8 data bit type, 1 stop bit and no parity bits
- The DB9 Male “RS232C” connector reflects the following pin-out:

PIN	SIGNAL
2	Rx of data from Host
3	Tx of data towards Host
5	GND

Detailed specifics of the communication protocol are available for consultation on the web site at the following address: www.diesse.it/

MINI-CUBE SPECIFICATION PROTOCOL

8. PERFORMANCES

MINI-CUBE Precision

Test Protocol: Eight vials of ESR-Chex control (4 vials of level 1 and 4 vials of level 2) were used in this study. The level 1 vials were inserted in each well of the instrument and tubes were analyzed according to the parameters of each study. Each study was repeated with level 2 vials. The mean, standard deviation and coefficient of variation (CV%) were calculated for intra-assay precision (repeatability and within-lab), and inter-instrument precision.

Quality Control Material:

ESR-Chex Level 1 (Normal)	Lot 5159	Exp. Date 2016-06
ESR-Chex Level 2 (Abnormal)	Lot 5159	Exp. Date 2016-06

Instruments:

MINI-CUBE – Instrument A	Serial 1039200026	Software Version 0.64
MINI-CUBE – Instrument B	Serial 1039200027	Software Version 0.64
MINI-CUBE – Instrument C	Serial 1039200029	Software Version 0.64

Results:

Acceptance criteria, CV% ≤ 15%

Intra-assay precision (Repeatability):

Means of 4 replicates of each QC blood sample tested on one instrument by a single operator during 1 working day.

	ESR Value (mm/h) Streck ESR-Chex	
Replicate	Normal	Abnormal
1	11	52
2	11	47
3	11	50
4	11	64

Mean	11	53
SD	0.00	7.46
CV%	-	14.1

Intra-assay precision (Within-lab):

Means of 20 replicates of each QC blood sample tested on one instrument by a single operator during 5 working days.

	ESR Value (mm/h) Streck ESR-Chex				
Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
1	11	11	12	11	13
2	11	11	11	11	13
3	11	11	11	11	13
4	11	10	10	10	14

Mean	11
SD	1.09
CV%	9.9

	ESR Value (mm/h) Streck ESR-Chex				
Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
1	52	51	53	50	51
2	47	47	49	47	50
3	50	65	65	63	67
4	64	50	53	48	52

Mean	54
SD	6.84
CV%	12.7

Inter-instrument precision:

Means of 60 replicates of each QC blood sample tested on 3 instruments by a single operator during 5 working days.

		ESR Value (mm/h) Streck ESR-Chex				
Instrument	Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
Instrument A	1	11	11	12	11	13
	2	11	11	11	11	13
	3	11	11	11	11	13
	4	11	10	10	10	14
Instrument B	1	10	11	10	10	10
	2	10	11	11	11	11
	3	10	10	11	11	10
	4	9	11	11	9	11
Instrument C	1	10	11	10	11	11
	2	10	10	11	11	11
	3	11	10	11	11	11
	4	10	11	11	11	10

Mean	11
SD	0.88
CV%	8.0

		ESR Value (mm/h) Streck ESR-Chex				
Instrument	Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
Instrument A	1	52	51	53	50	51
	2	47	47	49	47	50
	3	50	65	65	63	67
	4	64	50	53	48	52
Instrument B	1	50	52	51	49	49
	2	47	49	48	46	46
	3	65	65	65	48	62
	4	50	50	52	63	48
Instrument C	1	55	53	56	54	50
	2	50	50	53	52	48
	3	66	65	72	68	63
	4	51	50	55	54	49

Mean	54
SD	6.93
CV%	12.8

All the values obtained during the precision evaluation experiment fell within the expected range and confirmed the precision and repeatability of the MINI-CUBE instrument.

MINI-CUBE Correlation

Overview: This study was conducted to verify correlation of the automated Diesse MINI-CUBE system with different sample volumes (4.0 mL, 3.0 mL, 2.0 mL and 500 µL) to the Modified Westergren benchmark method. 500 µL samples were prepared in both BD Microtainer® blood collection tubes and BD Microtainer® MAP microtubes. Four MINI-CUBE systems were evaluated against the manual Fisherbrand™ Dispette™ 2.

Sample Preparation for Modified Westergren:

Blood samples collected in standard 10.0 mL K2EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion. Using a transfer pipet, aliquots of 1.0 mL of blood were added to the fill line of a Dispette 2 reservoir, capped and mixed by manual inversion eight times allowing the air bubble to reach the end of the tube with each inversion. Following manufacturer instructions carefully, the Dispette 2 tubes were grasped at the 180 mm region and inserted through the cap membrane of the filling reservoir. After penetrating the reservoir, the pipet was gently pushed to the bottom of the reservoir and tubes were gently transferred and placed on a level stand at room temperature. ESR levels were recorded in mm/hr at exactly 60 minutes.

Sample Preparation for Diesse MINI-CUBE:

4.0 mL sample volume: Blood samples collected in standard 13 x 75 mm, 4.0 mL draw volume K2EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion.

2.0 mL and 3.0 mL sample volume: Blood samples collected in standard 10.0 mL draw volume K2EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion. Using a pipet, aliquots of 2.0 mL or 3 mL of blood were added to standard 13 x 75 mm K2EDTA tubes, capped and mixed by manual inversion eight times allowing the air bubble to reach the end of the tube with each inversion.

500 µL sample volume: Blood samples collected in standard 13 x 75 mm, 4.0 mL draw volume K2EDTA tubes were inverted six to eight times allowing the air bubble to reach the end of the tube with each inversion. Using a pipet, aliquots of 500 µL of blood were added to BD Microtainer® K2EDTA tubes and BD Microtainer® MAP K2EDTA tubes, capped and mixed by manual inversion eight times allowing the air bubble to reach the end of the tube with each inversion.

Care was taken during sample mixing to avoid the formation of bubbles, which could interfere with sample results. Identification numbers assigned to each donor were entered into the MINI-CUBE systems. When prompted, the tubes were inserted into a free position in the MINI-CUBE to initiate testing. Results in mm/hr automatically printed at the conclusion of the measurement.

Results:

In summary, the data collected indicates the MINI-CUBE system maintains excellent correlation to the Modified Westergren method.

		Study 1		Study 2*		Study 3*	
Method 1	Method 2	Correlation		Correlation		Correlation	
Diesse MINI-CUBE (4.0 ml) BD 13 x 75 mm K_2EDTA	Dispette 2	96.7%	n = 50	91.6%	n = 50	93.8%	n = 48
Diesse MINI-CUBE (3.0 ml) BD 13 x 75 mm K_2EDTA	Dispette 2	-	-	-	-	94.8%	n = 48
Diesse MINI-CUBE (2.0 ml) BD 13 x 75 mm K_2EDTA	Dispette 2	93.5%	n = 20	-	-	92.3%	n = 48
Diesse MINI-CUBE (500 µl) BD Microtainer® K_2EDTA	Dispette 2	82.2%	n = 50	89.5%	n = 50	84.3%	n = 48
Diesse MINI-CUBE (500 µl) BD Microtainer® MAP K_2EDTA	Dispette 2	n/a	n/a	80.1%	n = 50	79.5%	n = 48

*Study 2 and Study 3 contain software updates to improve the BD Microtainer® correlation and add BD Microtainer® MAP tube compatibility.

9. BIBLIOGRAPHY

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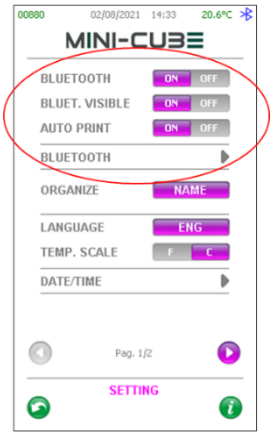
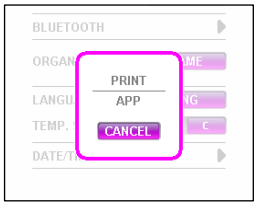
APPENDIX: MINI-CUBE PRINTER TOOL II – MPT II INSTALLATION GUIDE

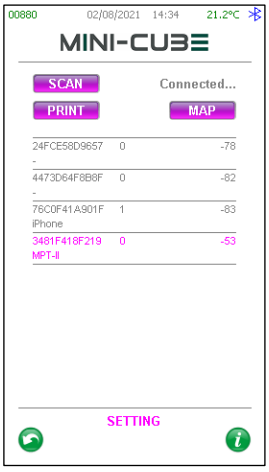
1. Turn the MINI-CUBE Instrument ON
2. Choose SETTING 
3. The BLUETOOTH option must be “ON” 
4. The BLUET. VISIBLE option must be “ON”
5. The AUTOPRINT option must be ON if you want that the instrument automatically prints the results



6. Choose BLUETOOTH menu, then select PRINT
7. Turn ON the MINI-CUBE Printer Tool – (MPT-II)



8. The instrument will search for Bluetooth devices. In this menu, the name of the MINI-CUBE Printer Tool – (MPT-II) must be shown
9. SELECT the name of the printer and TAP ON it
10. When the message “Connected …” appears, the printer is online and ready to print



11. Try to test with the “PRINT” command

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