CUBE 30 touch

USER MANUAL

Rev. 1.0 March 2018

Automated instrument for ESR determination
with modified Westergren method

Only for in vitro diagnostic use

diagnostica senese

MANUFACTURER
DIESSE DIAGNOSTICA SENESE S.p.A.
Via delle Rose 10, 53035 Monteriggioni (SI), Italy
Tel. ++39 0577 587111 Fax. ++39 0577 318690
WWW.DIESSE.IT

REGISTERED AND ADMINISTRATIVE OFFICE
Via A. Solari 19, 20144 MILANO,
Tel. ++39 02 4859121 Fax. ++39 02 48008530

For technical assistance please contact your distributor:

CUBE 30 touch accessories

Catalogue code	Description
10293	Test device NEXT 500 (500 tests)
10294	Test device NEXT 1K (1000 tests)
10296	Test device NEXT 5K (5000 tests)
10297	Test device NEXT 10K (10000 tests)
10403	Thermal paper
20550510	External barcode reader

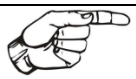
LIST OF MANUAL REVISIONS

REV. USER MANUAL (0448)	DESCRIPTION OF CHANGES
1.0 of 03/2018	Initial revision

Applied directives and regulations:

- Directive 98/79/EC on in vitro diagnostic medical devices
- 2014/35/EC “Low voltage directive”
- 2014/30/EC “Directive on the harmonisation of the laws of the Member States relating to electromagnetic compatibility”
- 2011/65/EU “Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment – RoHS2”
- EN 61010-1 “Safety requirements for electrical equipment for measurement, control laboratory use – Part1: General requirements (CEI 66-5)”.
- EN 61010-2-081 Safety for electrical equipment for measurement, control, laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes (CEI 66-8)”.
- EN 61010-2-101 “Safety for electrical equipment for measurement, control, laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment”.
- EN 61326-1 “Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements – Part 1: General requirements”
- EN 61326-2-6 “Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements - Part 2 – 6: In Vitro Diagnostic (IVD) medical equipment”
- UNI EN ISO 18113-3 Information supplied by the manufacturer (labelling) - Part 3: in vitro diagnostic instruments for professional use
- UNI CEI EN ISO 14971:2012 – Medical devices – Application of risk management to medical devices.
- EN ISO 80000-1:2013 Quantities and Units - Part 1: General

SYMBOLS

Legend of symbols used:	
	The instrument meets the requirements of the European Directive on in vitro diagnostic medical devices (98/79/EC).
	In vitro diagnostic medical device
	Date of manufacture
	Serial number
	Manufacturer
Legend of electrical and safety symbols used.	
	Earthing
	Obligation of separate waste collection according to 2012/19/EU directive
	Attention, read the guide, follow the safety symbols.
	Caution: risk of electric shock
Legend of 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.
	Caution: important information.
	BIOHAZARD: risk of contamination with potentially infected substances.
	Instrument that 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 **read carefully** 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 personnel** to use the instrument.

The safety and performance requirements of the instrument are no longer guaranteed when the instrument is powered using a different cable type from the one supplied, which is compatible with the power supply of the country of installation.

BIO-CONTAMINATION HAZARDS

	Potentially infected material may be handled. When analyzing patient samples, 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 required for the operator and appropriate for the work environment. Comply with directives on safety and with applicable laws in force.
	In the case of leakage of biological material, during the working cycle, use 70% isopropyl alcohol to clean external surfaces of the instrument using appropriate personal protective equipment and observe regulations on sanitization.
	All supplied materials must be disposed of in accordance with local laws.

TABLE OF CONTENTS

Chapter 1

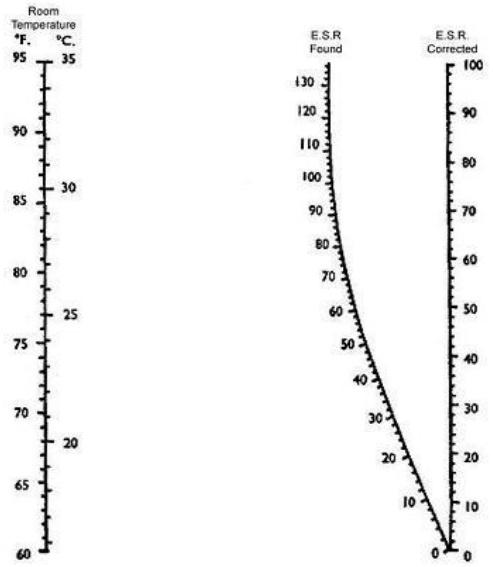
INTRODUCTION

Presentation of the instrument

The CUBE 30 touch (Fig.1) is an instrument designed to measure the erythrocyte sedimentation rate (ESR) of blood samples anticoagulated with EDTA, directly from the EDTA tube in only 20 minutes. The instrument can analyze a load of 30 samples at once or on a random access and continual loading basis. By analysing the sample directly from the EDTA blood collection tube, multiple samples or sample transfers are not necessary. With its colour touch screen, the user can select various instrument functions, which are described in more detail in the following sections. The analysis is fully automated (mixing and reading) and the results provide excellent correlation to the one-hour Westergren reference method.

Fig. 1

The instrument is designed to have temperature correction enabled at all times; it relates the results to a temperature of 18°C according to Manley's Nomogram. However, it is possible to de-select temperature correction according to laboratory needs.



Manley's Nomogram

Clinical significance of ESR

The erythrocyte sedimentation rate test measures the distance travelled by red blood cells in autologous plasma over a certain period of time. In normal conditions, red blood cells tend to move apart reciprocally due to the presence of negative electric charge 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 a hepatic level, following an inflammatory process or tissue damage, the bond of these proteins (fibrinogen, immunoglobulins) with the surface of the red blood cells alters the negative charge of the membrane potential (Z) and the red blood cells can bind, forming a rouleaux pattern. These rouleauxed cells aggregate to form microspheres of a uniform radius, which start to sediment when their density exceeds that of plasma. The ESR value goes up in all cases where there is an increase in acute phase proteins, in particular fibrinogen (which is considered

to account for 70% of the sedimentation phenomenon), and immunoglobulins (which increase in the case of oncological/hematological diseases and acute infections). ESR is therefore a non-specific measurement of an inflammatory state; the rate is high in various pathological conditions such as inflammatory diseases (infections, rheumatic diseases), a relative/absolute increase in globulins (nephrotic syndrome, myeloma), tissue necrosis (myocardial infarction, tumours). ESR is useful for predicting a diagnosis of some diseases, such as polymyalgia rheumatica, temporal arteritis, rheumatoid arthritis and Hodgkin's disease, and is useful as an effective marker for pharmacological treatment in many diseases such as rheumatoid arthritis, vasculitis, collagenosis and septic arthritis. The erythrocyte sedimentation rate is usually higher in women compared to men, increases in pregnancy, and tends to rise with age in both genders.

Normal ESR values (Westergren citrated)

With the Westergren reference method, the test is performed on blood diluted in citrate, with 4 parts blood to one part anti-coagulant. The diluted blood is then aspirated inside a special, graduated, 2.5-mm diameter pipette and kept upright. The erythrocyte sedimentation level is recorded after exactly one hour, measuring the distance between the lower side of the plasma meniscus and the meniscus of the 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.

A doctor must interpret the clinical significance of an ESR value obtained from abnormal samples, including but not limited to icteric or lipemic samples, samples with anemic conditions, low hemoglobin concentrations, hemolysis, or any other pathological condition which can interfere or impede a clear reading of the sedimentation. ESR testing performed on anomalous samples using manual or automated methods are subject to a high degree of variability. In the CUBE 30 touch, these samples may be undetected or they may yield varying results; for this reason, a visual inspection of the sample at the conclusion of the test is recommended, to verify the presence of a clear interface between the plasma and sedimented cells.

Materials required for use of the instrument

To use the instrument, materials must come ***exclusively*** from those manufactured by DIESSE DIAGNOSTICA SENESE S.p.A. (Always read the instructions for use which accompany each product before its use); 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.

WARNINGS

While the CUBE 30 touch system provides a high level of safety in handling biological samples, please take all necessary precautions when handling potentially infected material. Waste material at the end of the cycle must be processed in accordance with the local waste requirements.

DECONTAMINATION PROCEDURE

The CUBE 30 touch has been designed and constructed to require minimal maintenance.

Before any maintenance work:

- Power off the instrument and disconnect it from the power source.

- Use appropriate personal protective equipment during operation.

In the event of biological material leakage during the operating cycle, clean the outer surfaces of the instrument with 70% isopropyl alcohol and contact Technical Services immediately.

External cleaning of the instrument

Periodic external cleaning is recommended.

DECONTAMINATION PROCEDURE:

1. With the instrument switched off, clean the instrument with a liquid disinfectant used in the laboratory and leave it to dry. For the touch screen use a dry microfibre cloth.
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 screws or access the interior of the instrument. For assistance with the interior of the instrument which is not readily accessible to the operator, contact Technical Services.

Chapter 2

TECHNICAL DATA

Technical description

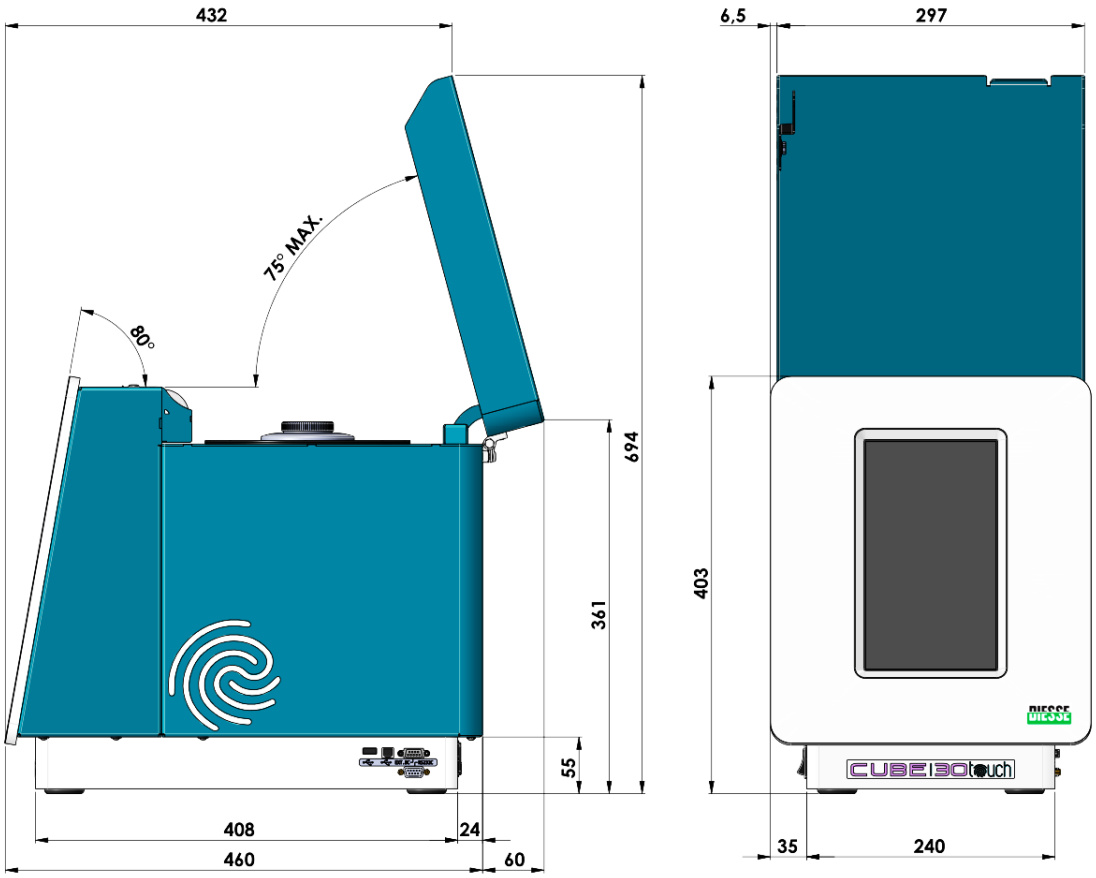


Fig. 2

The CUBE 30 touch consists of a single body containing all the operating functions necessary for analyzing the sample.

Test Tube Carousel

The instrument has 30 positions arranged in two concentric circles of 15 positions each. The test tube carousel is equipped with a plastic adaptor carousel; required for use with EDTA tubes with conventional closure.

Reading Unit

A motor lifts the reading unit, which uses 2 optical sensors to verify the suitability of the sample and detect the level at time zero and at the end of sedimentation.

Sample Detection

Sample detection happens after the cycle has been started, through the optical sensors. The instrument carries out a scan of the test tube inserted in each position, verifying that it contains an adequate volume of blood.

Sample identification

Sample identification is done by an internal barcode reader which reads the barcode when a sample is detected by an optical sensor. The sample ID code may be manually entered with a virtual keyboard or by using an external barcode reader (accessory).

Acoustic Warning

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

Temperature Sensor

This sensor is used to measure the temperature and is fitted in proximity of the test tube carousel.

Printer

The analysis results are printed at the end of each operating cycle or working session.

LIS

Results transmit to the LIS automatically upon completion of the 20-minute test and/or can be viewed in the Tube view.

External connections of the instrument

The power connector is on the back of the instrument (Fig. 3).

Fig.3

Fig.4

The ON/OFF switch is on the left side of the instrument's base (Fig.4).

Fig.5

There are four connection ports on the right side of the instrument's base.

- Two connectors for a Computer/HOST: one is a Serial RS232 (9pin) type; the other is an USB b-standard type.
- A connector for an external barcode reader (EXT. BC).
- A USB a-standard port for connecting to a USB mass storage device (usable for software updates and exporting files) (Fig.5).

Updating software

Fig.6

Updating software is a simple, direct procedure:

- Download the software from the site www.diesse.it
- Save onto a USB mass storage device
- With the instrument switched off, insert the USB device into the appropriate port (Fig.6)
- Power on the instrument and wait for a few seconds. The instrument will update automatically.

Technical features

USE	Internal use
POWER SUPPLY	Europe: 230Vac@50Hz; USA/Canada: 110-120Vac@60Hz Power output: 100VA
DIMENSIONS (mm)	310x470x403 (l x w x h)
WEIGHT	15 kg
TEMPERATURE	15-35°C (operating) 5-45°C (storage)
RELATIVE HUMIDITY (RH)	20%-80% without condensation
ALTITUDE	up to 2000 metres
NOISE LEVEL	below 80 decibel
POLLUTION LEVEL	2 pollution degrees
MEASUREMENT RANGE	0 to >140 mm/hr
CENTRAL UNIT	ARM Cortex-M4 180 MHz Microprocessor
DISPLAY	10.1" vertical, wide
OPTICAL UNIT	2 pairs of optical elements
INTERFACES	USB Host; USB Client; 2x RS232

PROTECTION CLASS	I
SAFETY STANDARDS	IEC 61010-1; IEC 6101-2-081; IEC 61010-2-101 CSA C22.2 No. 61010-1-12 / UL 61010-1:2012
EMC	EN 61326-1/EN 61326-2-6
INSTALLATION CATEGORY	II

Instrument composition

The instrument is composed of the following materials expressed in percentages:

Material in %	CUBE 30 TOUCH
IRON	60
COPPER	3
ALUMINIUM	10
PLASTIC MATERIALS (PVC, ABS...)	20
SILICON	2
Gold	0.1
Tantalum	0.2
Cadmium	0.2
Others (No Latex)	4.5

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.

Chapter 3

INSTALLATION

The CUBE 30 touch is a precision instrument and must handled as such. Inappropriate operations may damage the internal optoelectronic components and cause mechanical damage. Follow the instructions in this chapter in order to ensure the safety of the instrument and of the operator.

Transport and handling

The instrument must be transported and handled in its original packaging. Do not let the instrument or packaging become wet or be exposed to a damp environment. If the packaged instrument has been exposed to storage or transit temperatures below 10°C for more than 24 hours, allow the unit to stand at room temperature for one hour prior to installation.

Packaging characteristics

Keep the original packaging including the materials supplied in Fig 7.

The instrument is packed in:

1. an external cardboard box
2. molded housing in CFC- and HCFC-free, closed-cell polyethylene foam

External packaging dimensions	
600x400x520	mm:
4,0	Kg

Materials provided

The CUBE 30 touch is supplied with the following materials:

- User Manual
- One power cable adherent to IEC International Standards (Female Plug IEC 320 C-13; Male Plug Schuko EEC 7-VII; Rating: 10A / 250V AC).
- One power cable SVT PLUG USA/OUTLET VDE UL 2mt
- Two Delayed 5x20 mm UL fuse blocks 10A
- USB cable
- Plastic Adaptor (A in Fig. 7) for use with conventional stopper EDTA tubes
- Touch screen stylus; “CUBE pen”
- Inspection Certificate
- Packing list

Fig.7

Unpacking the instrument

1. Open the box from the top.

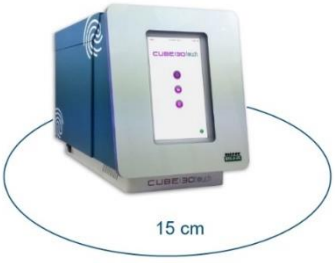
Fig. 8

2. Remove the block of polyethylene foam covering the instrument.
3. Remove the accessories stored inside.
4. Remove the instrument from the box.

Fig. 9

5. Remove the protective bag which wraps the instrument.
6. Verify that the packing list and supplied materials match.

Environment



For normal safety requirements and given the type of testing it performs, the instrument must be positioned in a dust-free environment away from heat sources, and free from any exposure to liquids. Position the instrument on a perfectly level bench, not subject to shaking or vibrations. Observe a 15 cm or 6” perimeter around the instrument as a safety precaution. In addition, it is

advisable to position the instrument a 1meter distance from devices that generate electromagnetic waves (e.g. laboratory refrigerators, centrifuges).

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

- The mains must be compatible with the voltage and current specifications indicated on the metal plate affixed on the rear of the instrument.

- Verify the compatibility of external accessories such as a BC reader or USB devices prior to connecting.

Installation procedure

1 - Position the instrument on a solid surface, as described above.

Fig. 10

2 - Verify that the power switch is in the “OFF” position.

3 - Open the cover, unscrew the central knob, and remove the stabilizing plate used for transport. Insert the plastic adaptor per Fig. 7 (if applicable) and screw the central knob back in place to secure the carousel. QC vials supplied by Diesse and Streck may be run with or without the plastic adaptor.

4 - Connect the power supply cable.

5 - Optional - Before switching on the instrument, connect the external barcode reader (accessory).

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

Disposal

The CUBE 30 touch instrument, to be functional, relies on the use of an electrical power source and therefore, in compliance with the EUROPEAN DIRECTIVE 2012/19/CE of July 04, 2012 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.

Chapter 4

USE

Sample preparation

The following criteria must be met to ensure accurate results:

- The ESR test is performed within 4 hours of collection with samples at ambient temperature (18-25°C), or on blood samples which have been stored at 2-8°C for a maximum of 24 hours since the time of collection. Refrigerated samples should be restored to ambient room temperature prior to analysis.

- The test can be performed if the test tubes contain a volume of blood from 1.5 mL to 4 mL.

- Whether using the CUBE 30 touch system in the batch or random access mode, be sure to mix the samples before starting the test. The sample must be mixed gently by complete inversion of the tube a minimum of 8 times, so that any air bubble move along the entire tube from one end to the other. Do not shake, vortex, or agitate the sample vigorously, as this could cause excessive bubbling or hemolysis.

WARNING: Ensure the test tube is hermetically sealed.

Test tube compatibility

The following 13x75 mm EDTA tubes are compatible with the instrument:

- VACUETTE™ (GREINER BIO-ONE) AND SIMILAR.
- VACUTAINER® (BD) VACUTEST® KIMA, VENOSAFE® TERUMO VACUTRUST,
- RUBBER RUBBER CAP, BD, TERUMO (WITH DESIGNATED ADAPTOR)
- SARSTEDT ®

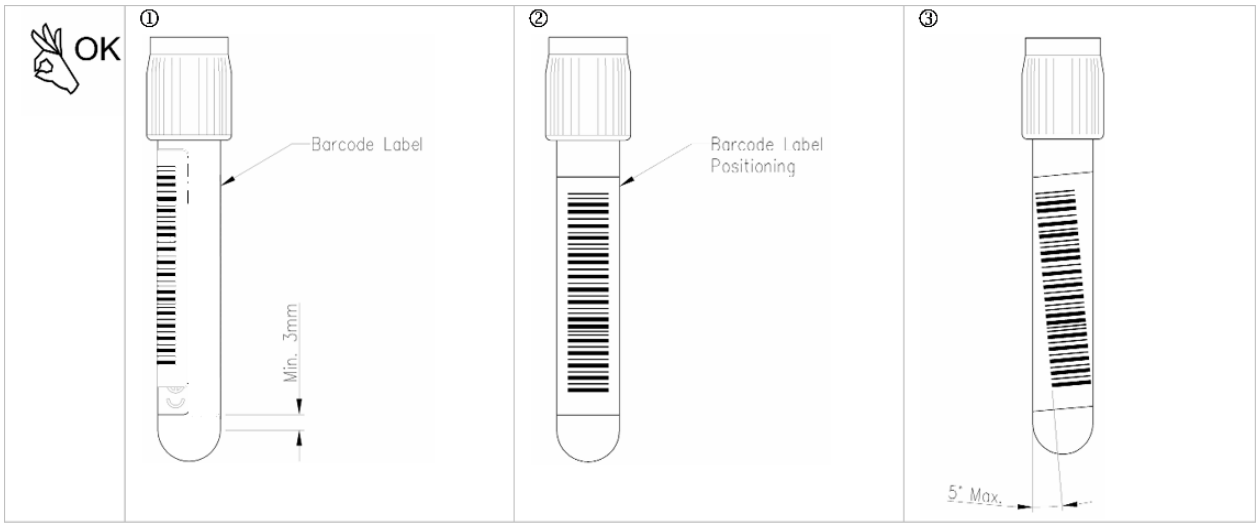
Tubes with hemoguard closures do not require the use of the supplied plastic adaptor, refer to Fig. 7 in Chapter 3.

Test tube labeling

The CUBE 30 touch's optical sensors are able to detect blood sample levels in test tubes with a maximum of **one** secondary label. Secondary labels must be placed directly over the tube manufacturer label, leaving at least 5 mm free space for the optical sensors to detect the blood level in the sample tube.
When placing a label on a tube:

- Ensure the label is flattened smooth against the tube.
- Press the label down securely, including all the edges and corners to ensure that no part of the label is loose.
- Leave a label-free space on the back.

Excessive thickness and possible wrinkles on secondary labels, may increase the test tube's external diameter, increasing the risk of a tube becoming lodged in the instrument. If the operator notes resistance when inserting a test tube, remove the added label before proceeding. Secondary labels must adhere perfectly to the test tube's surface so as to avoid possible label fragments accumulating in the instrument, and thus obstructing analysis of the sample.



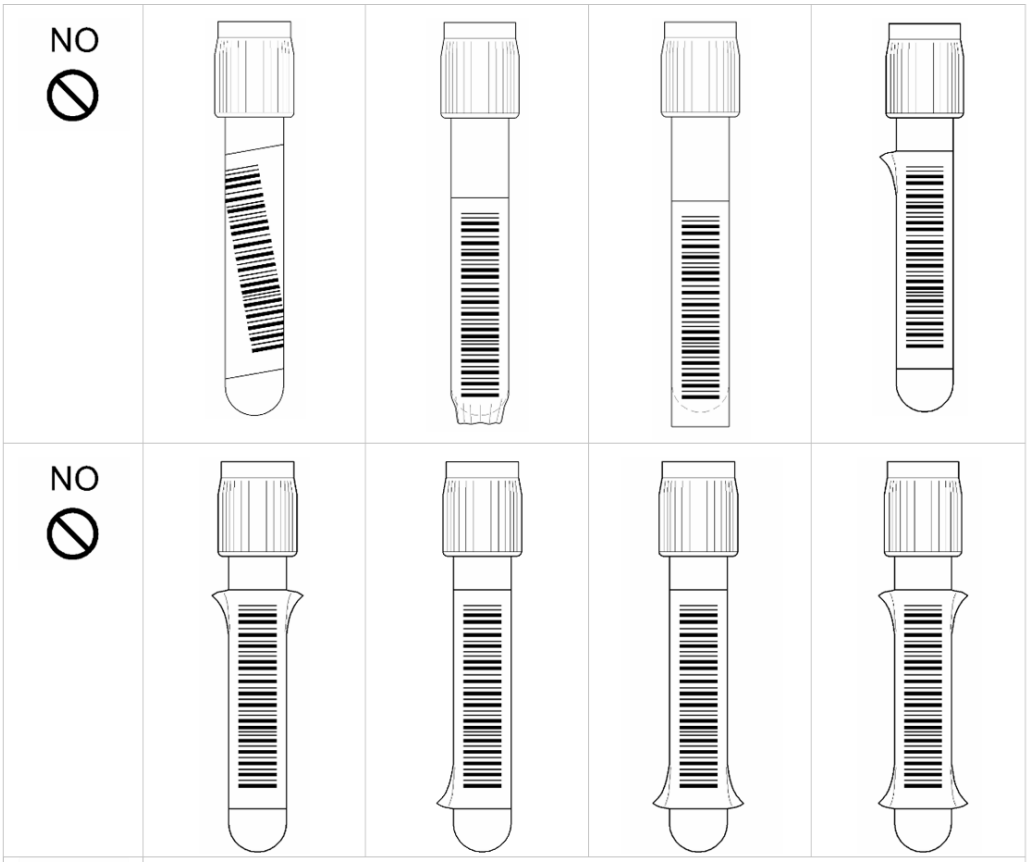


Fig. 11

To ensure barcode readability, tubes must be inserted so that the barcode is positioned toward the mark on the front of each well in the instrument carousel (Fig. 12). If a secondary label is not used, the sample should be inserted so the tube manufacturer's label is facing the mark.

Fig. 12

Menu description

Power on the CUBE 30 touch with the switch on the left side of the instrument. If the USER LOGIN function is active, an ID will be requested for the selected user (see Chapter 6 USER MANAGEMENT). The user can access the home page directly (HOME) when the USER LOGIN function is not active.

HOME

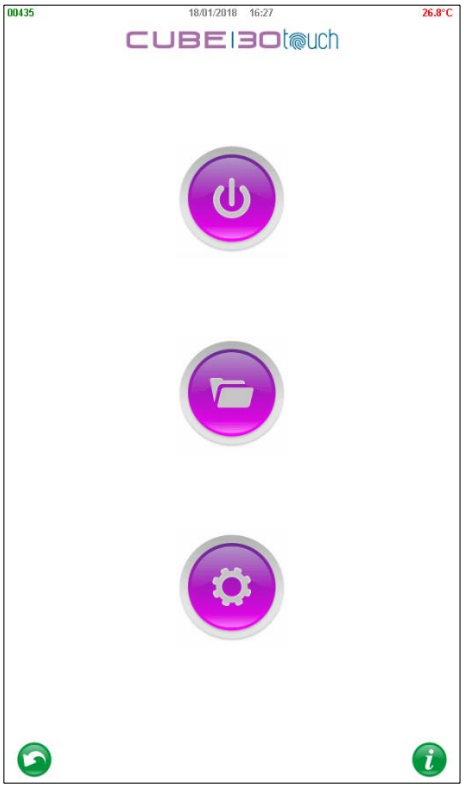


Fig. 13

From the Home screen the user can access three different functions.

START: Access the START cycle screen

ARCHIVE: Access archived data

SETTING: Review / edit system settings

PERFORMING AN ANALYSIS CYCLE

Click START to enter the analysis mode (Carousel view)

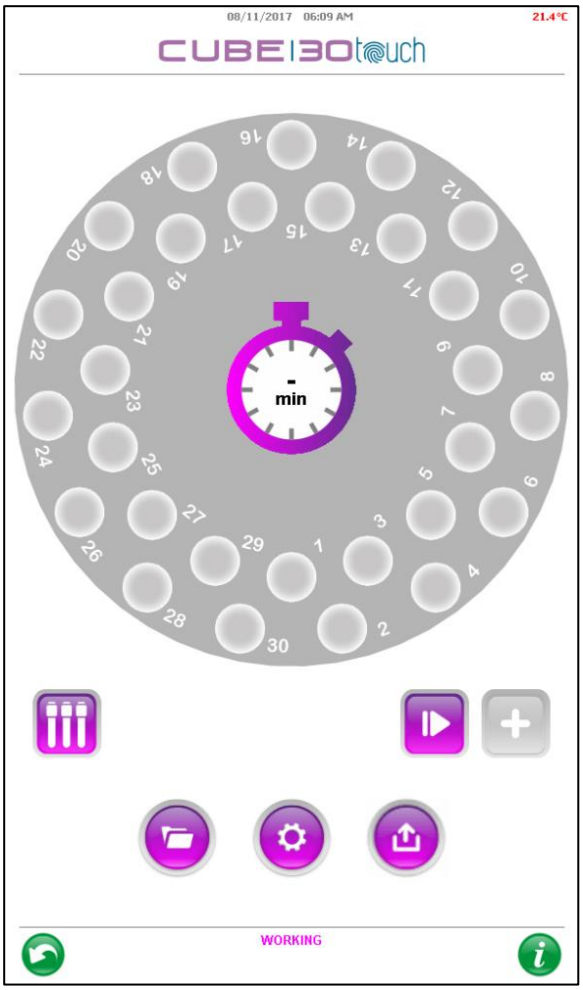


Fig. 14

Description of the information and icons:

00050

The counter in the top left-hand corner of the screen shows the number of tests that can be performed, which decreases with each result produced. The counter turns red to indicate the last 50 executable tests. When the test number is zero, new tests cannot be performed. To carry out further tests, the

counter needs to be reloaded using a new TEST DEVICE (see the paragraph on Settings).

Date/Time: Indicates the current date and time.

Temperature: This indicates the internal temperature of the instrument in °C or °F. Green indicates that temperature correction is enabled (Default Setting). Red indicates that temperature correction is not enabled.

Timer: The timer in the centre of the carousel displays the minutes remaining for all samples started during a cycle in the continuous mode. If samples are inserted in the random-access mode during the cycle, an individual timer will be displayed on the cap of each added sample.

Start Begins the analysis cycle.

Stop: Stops the analysis cycle.

Test tube view: Allows the user to view all the samples at the same time (Tube view). In this mode, the user can see the blood level and the actual sedimentation level for each test tube.

Add: Enables the random-access mode. By pressing this icon, new samples can be inserted when a testing cycle is already in progress.

Export: Allows the user to reprint the results for the last analysis cycle.

BACK: Allows the user to return to the Home screen.

Information: An interactive guide regarding the instrument operation.

Inserting the test tubes

Fig. 15

To start a cycle, open the lid and insert the test tubes in the instrument carousel. Orient the sample so that the barcode faces the mark (❚❚) found at each tube position on the carousel (Fig. 15).

Starting the analysis cycle

Close the lid, and press GO 

The instrument performs a verification on each position to determine the number of samples present. Barcode reading follows. If the barcode reading is not successful, a black dot is shown next to the sample. (Fig. 16) At the end of the barcode reading cycle, a window will display the unread positions (Fig. 17).

Fig. 16

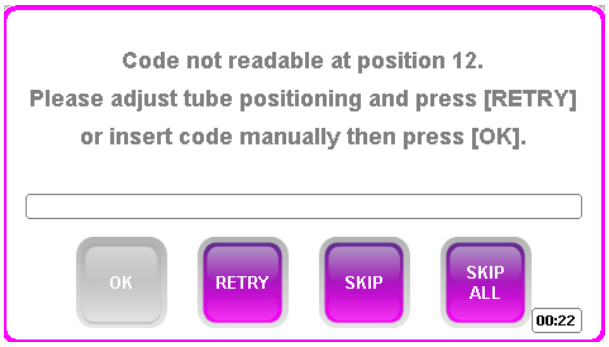


Fig. 17

The user has the following options to select from:

Fig. 18

1. Open the lid, reposition the tube correctly in the carousel, press "**RETRY**" to have the barcode read again/
2. Press the text field and insert the code manually (keyboard will appear on the screen Fig.18) and then press "**OK**".
3. Do not assign an ID for this sample and move on to the next position by pressing "**SKIP**".
4. Do not assign an ID for any of the unidentified samples: press "**SKIP ALL**"

Note: If none of these options are selected within 30 seconds, the "**SKIP ALL**" choice is enabled, and the cycle progresses automatically.

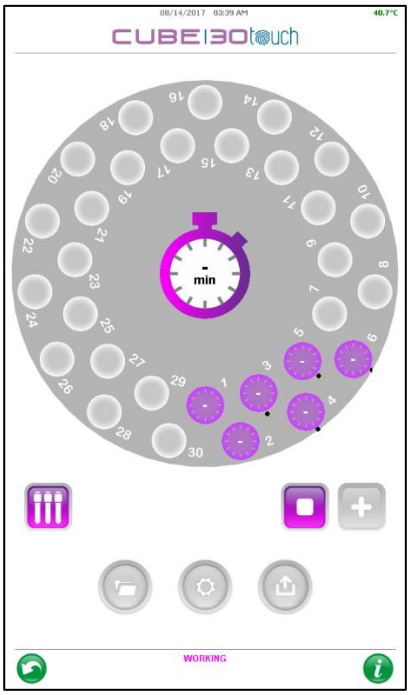


Fig. 19

The instrument then starts the mixing process and a progress bar displays the time remaining. The carousel will make 20 complete rotations (180°) to fully re-suspend the samples.

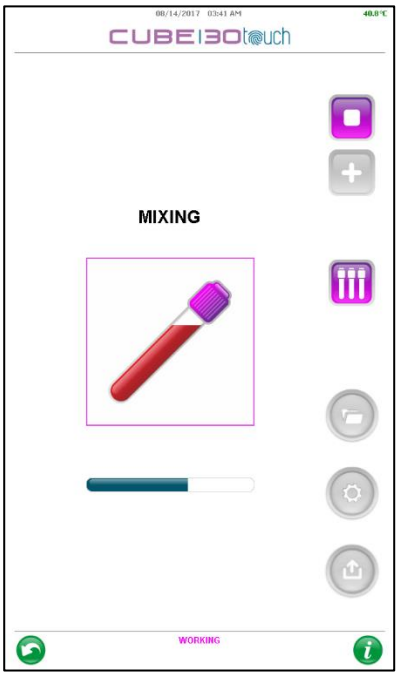
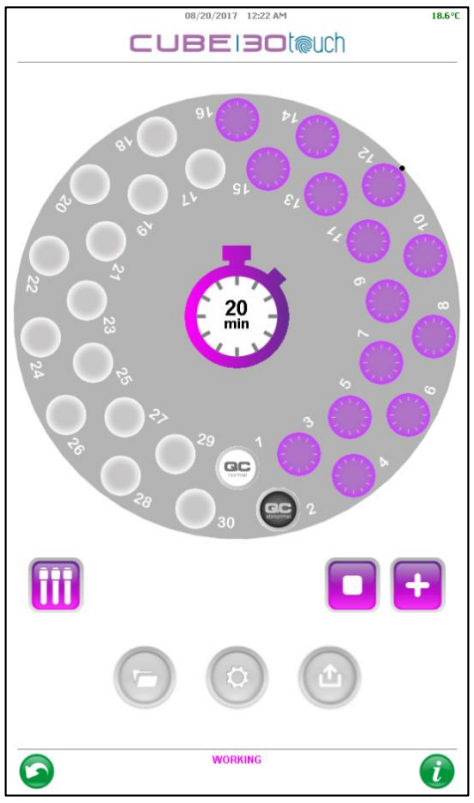


Fig. 20

At the end of the mixing phase, the instrument will perform a scan of each test tube to determine the level of blood at time zero of sedimentation.
A 20-minute countdown begins at this point with the remaining sedimentation timer located in the centre of the carousel.

The user may switch from the “Carousel view” (occupied carousel positions are shown in purple), to the “Tube view” tube blood levels are presented:



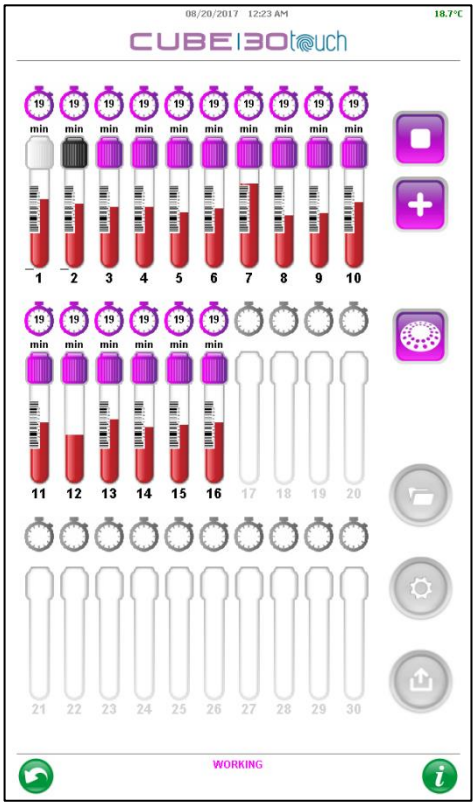


Fig. 21

Inserting a new sample (random access)

During the testing phase, one can insert a new sample by random access at any time.

In this case, it is critical to ensure the sample is carefully and properly mixed prior to inserting. The CUBE 30 touch does not perform mixing for samples which are added in the random access mode.

Random Access procedure:

1. Press the Add button.
2. A prompt to authorize opening the lid will display: “You can open the cover.”
3. Open the lid and insert the tube in the position indicated in the prompt which appears on the screen, example:

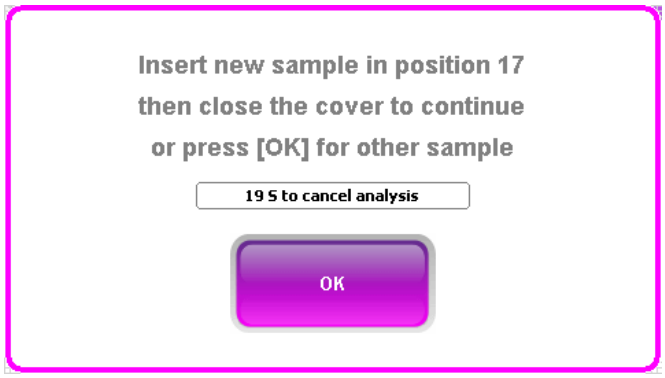


Fig. 22

4. Close the lid.

The user has 30 seconds to complete the operation. Once the sample has been inserted in the correct position, the instrument reads the barcode and begins processing. The remaining test time for this sample will be indicated in an individual timer which corresponds to its position.

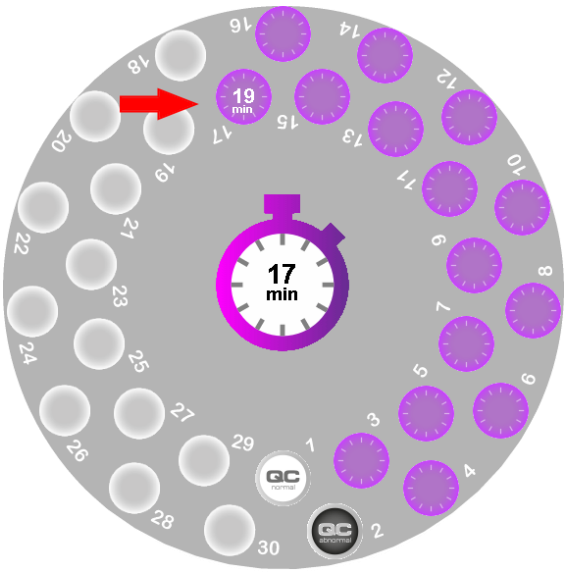


Fig. 23

Note: if samples are not loaded within 30 seconds of opening the cover, as a safety feature, the entire cycle or working session will be aborted. The bottom of the display will show “Cycle #X completed – Ready” and the instrument will not deduct runs from the counter. At the end of the cycle, the instrument allows the user to recover the barcodes which it was not able to scan previously (three short audible alarm warnings) with the same steps described above.

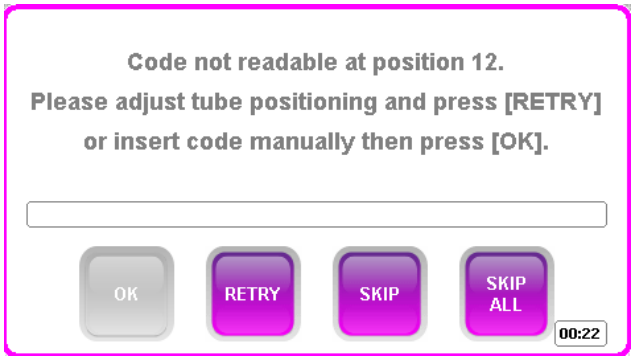


Fig. 24

Results: After the test, the instrument displays the results for each sample in mm/hr, in accordance with the classical Westergren method (W), the default setting. Simultaneously, the instrument provides an automatic printout and sends results to the LIS, if applicable.

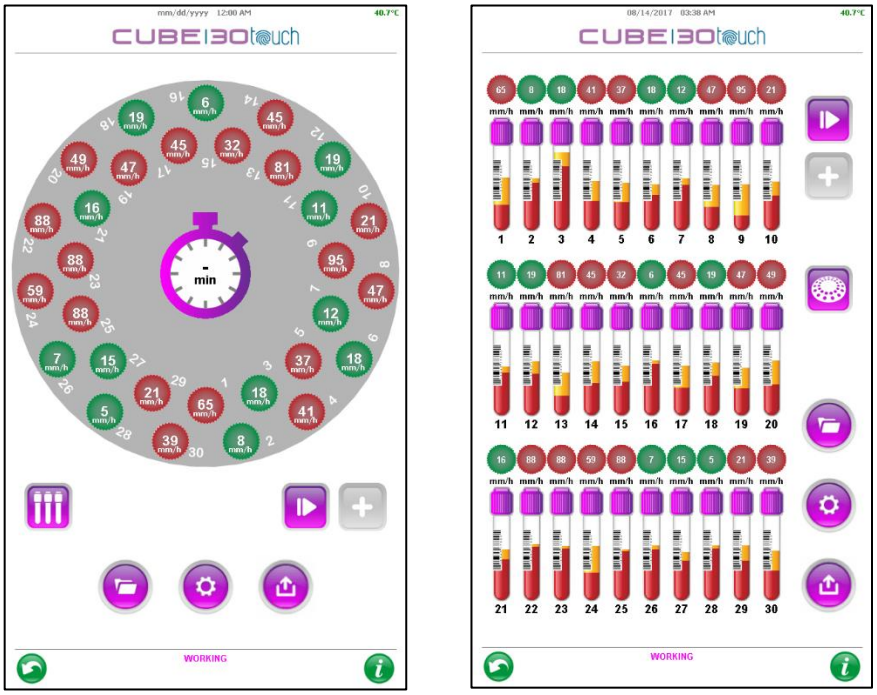


Fig. 25

ESR result is within the normal range, per the “threshold value” established in the Settings menu.

ESR result is beyond the established normal range.

Printing description:

DIESSE
diagnostica senese

CUBE 30 Touch - V 1.00
SN: 0005 - 01- 2018

Date/Time 03/01/2018 10:09
Cycle 1
Temperature 21.5°C ON

POS NUM	ID		WEST (mm/h)
01	1234567890123		22
02	1234567890124		5
03	1234567890125		53
04	1234567890126		16
05	1234567890127		8
06	1234567890128		>140
07	1234567890129		18
08	1234567890133		82
09	.....		44
10	1234567890134		21
11	1234567890135		13
12	1234567890136	§	11
13	1234567890137		5
14+	1234567890138		18
15+	1234567890139		35

Fig. 26

“§”: manual insertion of the sample (barcode not read by the instrument) or exclusion of the barcode reading by the user (“SKIP”, “SKIP ALL”)

“+”: sample inserted by the random access mode (mixing was not performed by the instrument)

ARCHIVE

The Archive menu is searchable and contains up to 5000 records.

Samples may be organized by date or by code (ID), using the appropriate tab.

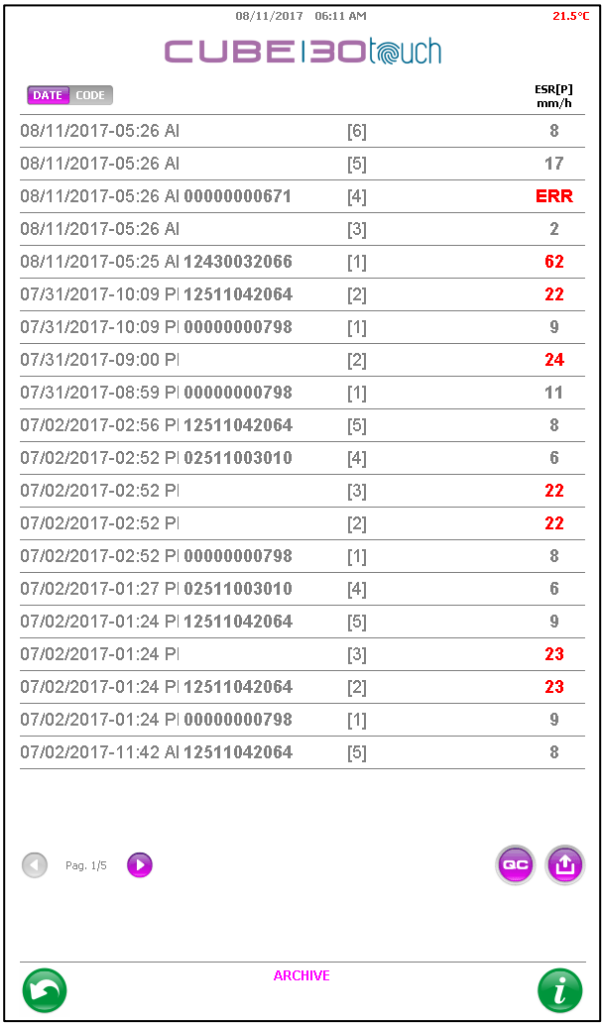


Fig. 27

Each sample in the archive has associated with it:

- Date and time of the analysis cycle
- ID code
- Cycle number for the day
- Position occupied in the carousel
- ESR value (mm/h).

By clicking on the Export icon the user can:

- Send to Host
- Print list
- Filter the archive by sample ID, cycle or date

By pressing and holding a sample result, the user may access and/or enter missing information or add information such as a sample ID or Hematocrit value. If HCT values are entered, the ESR result will be corrected (correction limited to HCT values <40%). Any corrected ESR result will displayed with the letter “H” at the top of the result.

The **Archive QC** function is used to access quality control results (See chapter 5).

SETTINGS

The user can access various functions described on the following pages:

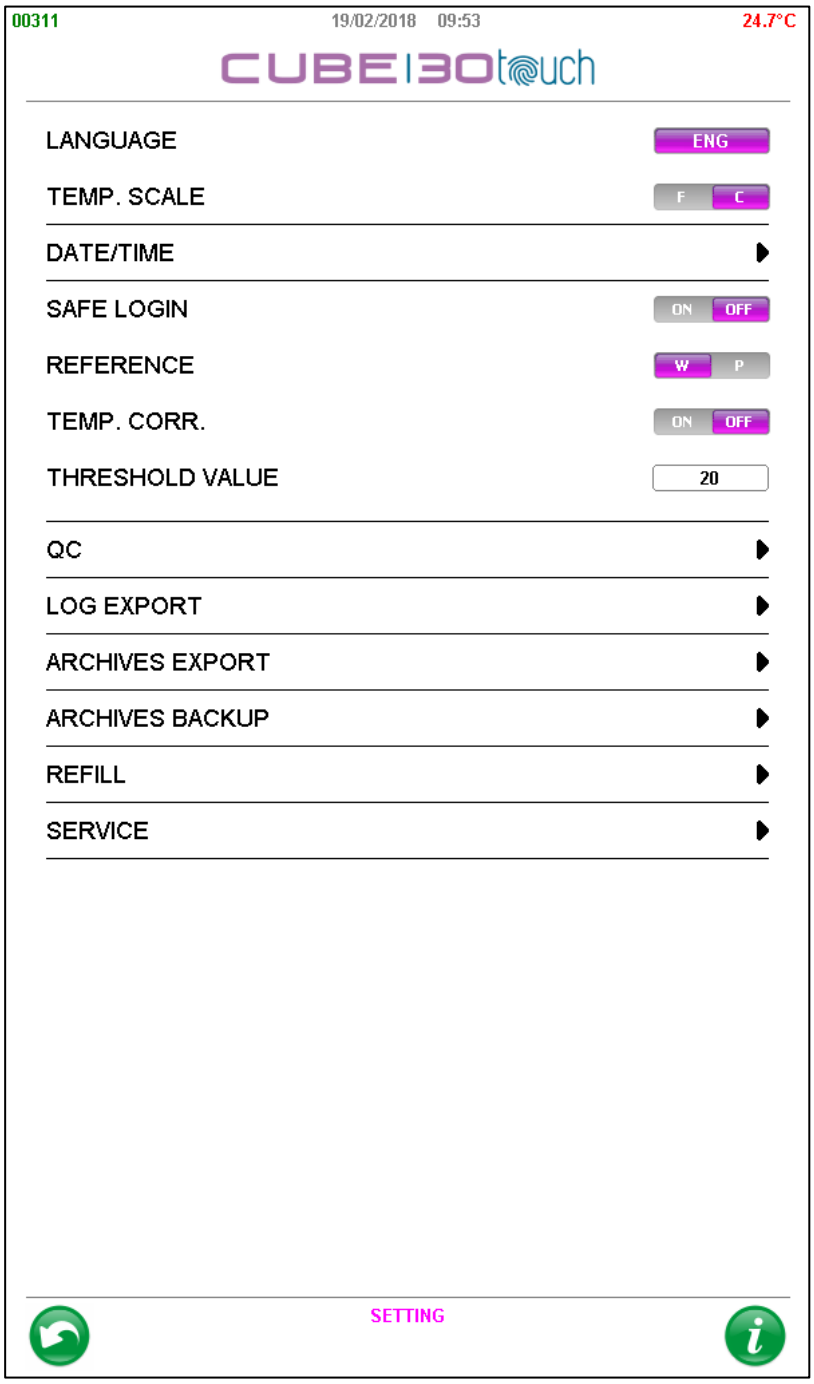


Fig. 28

LANGUAGE: Select the language.

TEMPERATURE SCALE: Set the temperature scale in degrees Celsius or Fahrenheit.

REFERENCE: Select the reference scale for the result (Westergren or Panchenkov).

DATE/TIME: Choose the desired format for date and time.

SAFE LOGIN: Enable or disable access with user ID and password (see chapter 6).

TEMPERATURE CORRECTION: Enable or disable Temperature Correction.

QC: Enter the QC menu to configure quality control settings (See chapter 5).

THRESHOLD VALUE: Set a threshold value; when this value is exceeded the instrument will display the result in red to alert the operator that the result is outside of the normal range. The default value is 20 mm/hr.

ARCHIVES EXPORT: Export the data or QC archive to a USB device, in *.xls format.

LOG EXPORT: Export the instrument's Log file to a USB device, in Log.txt.

ARCHIVES BACK UP: Back up or restore the archives.

REFILL: Load a certain number of executable tests in the memory. Insert the Test Device (Fig. 28) in the relative compartment and follow the instructions which appear on the screen.

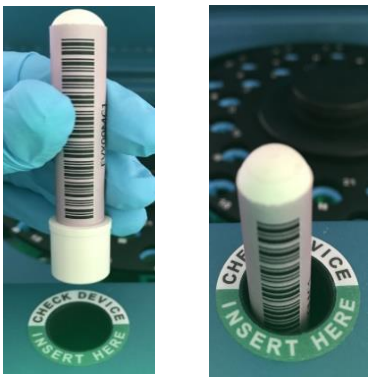


Fig.29

SERVICE: Service menu can only be accessed by personnel authorized by DIESSE Diagnostica Senese SpA.

Chapter 5

QUALITY CONTROL

Quality Control materials supplied by DIESSE Diagnostica Senese and Streck, Inc. are automatically and conveniently identified by the instrument. For this reason, registration of the control material is not necessary. . QC vials supplied by Diesse and Streck may be run with or without the plastic adaptor.

QC registration procedure

To utilize quality control material not supplied by Diesse or Streck:

1. Apply dedicated barcode labels
2. Select the item QC from the Settings menu (Fig. 30)
3. Insert the Normal control in position 1 and press the DETECT icon. The instrument detects the code and displays it in the barcode window
4. Manually insert the relative data for name, lot, expiry, and acceptability limits
5. Remove the Normal QC
6. Insert the Abnormal QC in position 1
7. Repeat the same procedure as at point 3

Following this procedure, the instrument will be able to identify the controls automatically from the barcode.

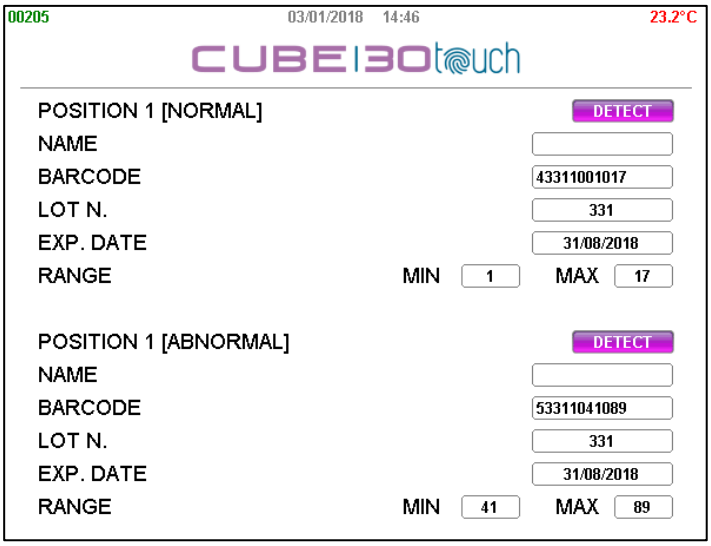


Fig. 30

Performing QC analysis

Control materials are loaded and processed in the same manner as patient samples (See chapter 4). The CUBE 30 touch will recognize the barcoded test tube as a QC sample and display it on the screen as shown in Fig. 31:

- Normal control: white cap
- Abnormal control: black cap

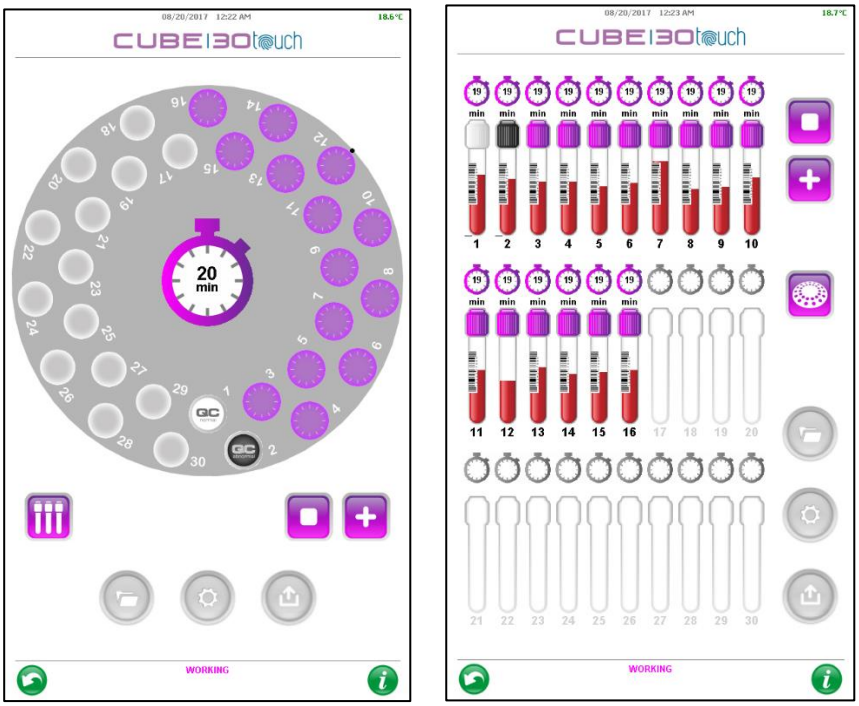


Fig. 31

Fig. 32

Upon conclusion of the test, if QC results are out of range, an orange circle will be displayed and “QC FAIL” will appear on the printout.

QC ARCHIVE

In the QC archive, the user can view historical QC data. Results are stored based on position in the instrument and may be viewed by clicking on the corresponding number. In this screen, like the other archives, the date, code, type of control and result are displayed.

By clicking on the Export icon, the user can send to Host, print the QC list or filter it by barcode or date. By selecting and holding a control record, one can display details (lot, expiration, expected assay ranges).

From this record, or from the QC archive by selecting a control, press on the Chart icon to see results displayed on a Levey-Jennings chart (Fig. 33).

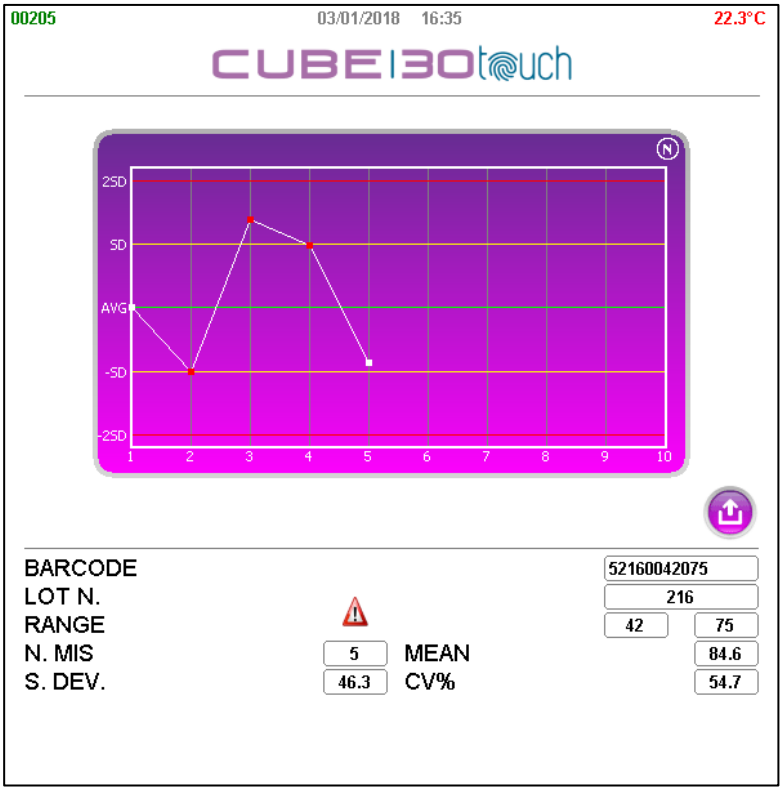


Fig. 33

This view shows the number of measurements taken, the average, standard deviation, and the CV%. In the Levey-Jennings chart, control repetitions are shown on the x-axis, and the mean value and distance from the average measured as standard deviations (±1SD, ±2SD) are shown on the y-axis.

WESTGARD rules are widely established statistical rules which make it possible to identify, on a probability basis, systematic and random errors that can lead to a failure to comply with established objectives of accuracy and precision. The following Westgard rules are commonly used:

- **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
- **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

Press the Export icon to print the list of data related to that QC, or to search and filter by lot.

Chapter 6

USER MANAGEMENT

The instrument allows one to create and manage access with personalized identification. To enable this function, activate “safe login” in the Settings menu.

The first time the feature is enabled, there is a request for information about the first user - the administrator - who will have permissions to add and/or remove up to a maximum of 4 users. To create a user, insert name, surname and 6-digit password. A 4-character user ID will be generated automatically; this ID will identify the user on the instrument’s printouts.

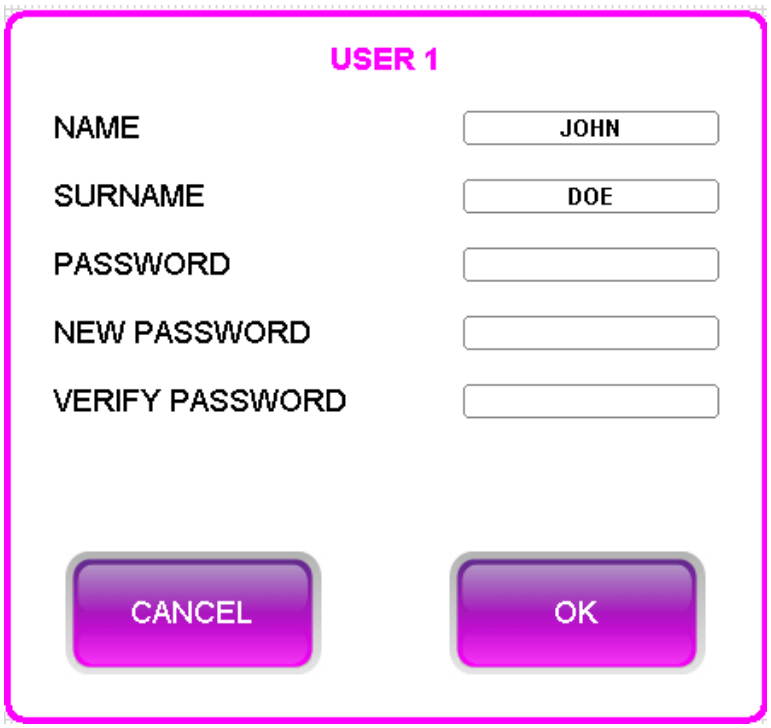


Fig. 34

The ID is comprised of the first letter of the person’s name, the first letter of their last name (If it is missing, the second letter of the name will be used), the position in the user list and a ‘0’.

Fig. 35

Once the 'safe login' function has been enabled and the administrator has been created, the item "User Management" will appear in the Settings menu. When the administrator accesses the instrument, the list of 5 user positions will be available.

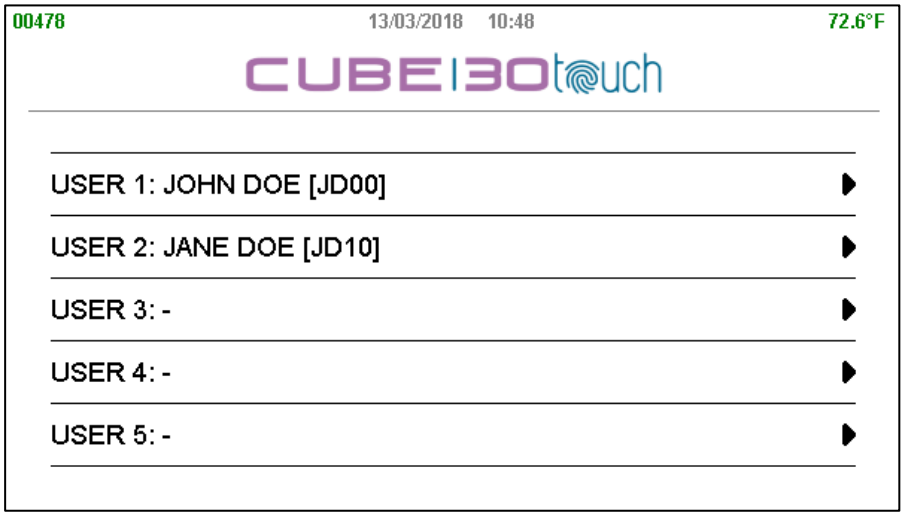


Fig. 36

The administrator has the ability to add a new user, modify user passwords, or to cancel a user. Only the administrator can cancel all of the users, by selecting the item "Reset All Users". Only the administrator can disable the "safe login" function. When it needs to be re-enabled, the administrator and previously registered users will still be stored in the memory.

Note: The only information which can be modified is that of the password. If modification of a name or surname is desired, the user must be cancelled and recreated.

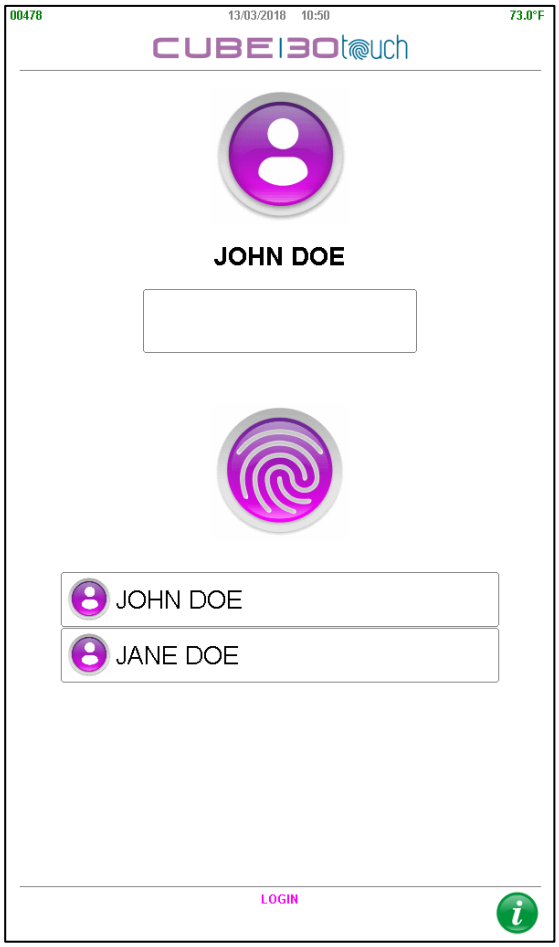


Fig. 37

When a user (and not the administrator) accesses the instrument, and “User Management” is activated in the Settings menu, only the user’s own information is visible, and modification of only his/her password is possible.

Note: When the “safe login” mode is enabled, a user ID is required upon powering the instrument on. The screen shows the list of registered users.

Select a user from the list; that user’s name will appear above the text box where the password can be entered. Once the correct password has been entered, press the fingerprint icon to gain access to the instrument’s main menu.

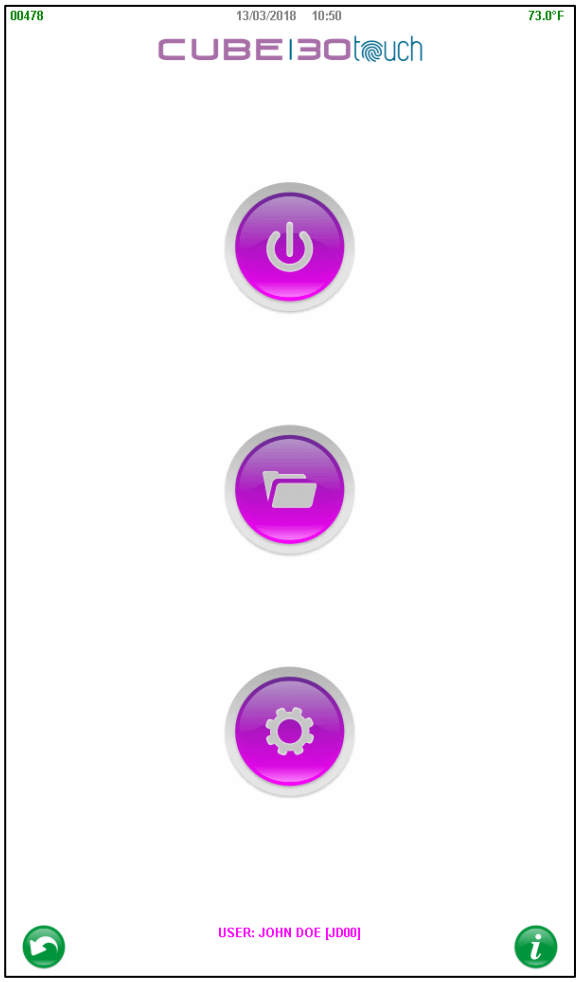


Fig. 38

The “name-surname-ID” of the user who has logged in will appear at the bottom of the screen, and on the bottom left of the screen is a “Back” icon, to be used by the active user to log out.

Chapter 7

TROUBLESHOOTING

ERROR MESSAGES	CAUSE	REMEDY
Low (Lo)	The blood level in the test tube is too low.	If possible, add blood until you reach the required levels.
High (HI)	The blood level inside the test tube is too high.	Try to remove/reposition the label and repeat the test.
	Interference from the label.	If possible, remove blood until you reach the required levels.
Err (2) (3)	The bottom of the test tube was not identified.	Check that the test tube in use is compatible with the instrument and that it has been inserted correctly, as described in chapter 4. Visually inspect the sample for presence of clumps or clots.
Err (6)	The blood level in the test tube was not detected.	
Err (8)	The blood level after the second reading is higher than the initial blood level measured.	
Error Removed tube Err (11)	This appears at the end of the second reading if, during the cycle, the test tube is removed from its position.	Repeat the test for that sample.
Failed control method (13/14)	No confirmation of the control method.	Verify the QC barcode label and position the test tube as explained in chapter 4.

Anomalous test tube **Err (15)**	This may be due to significant sedimentation with a low volume of blood.	Check for the presence of clumps or clots. Try to repeat the test.
Exam not available Reloading required	Zero tests remaining.	Follow the instructions for reloading the instrument with a new test device, as described in chapter 4.
USB device not found	The instrument does not recognize the USB device.	Remove and reinsert the device or replace it.
Caution! "N" tests remain	The number of remaining tests is less than 50.	Be sure to reload the device as soon as possible with a new test device
Used TEST DEVICE	The test Device in use is empty.	Obtain a new test device.

.

Chapter 8

CONNECTION TO HOST COMPUTER

Communication between the CUBE 30 touch and an external computer can be established:

1- Using a USB connection:

Connect a standard A-B USB cable between the computer's USB port (type-A rectangular connector) and the CUBE 30 touch's USB port (type-B rectangular connector). The driver (STM32 SW; download from www.diesse.it) for MS Windows will need to be installed to establish communication with the CUBE 30 touch through a virtual COM port on USB.

On the Cube 30 touch, in the Service menu, the "HOST BY USBD" parameter must be set to ON.

2- Using a serial RS232 COM on the PC.

Connect a straight standard serial cable between the PC's RS232 COM port and the instrument's RS232 (9-pin) serial connector.

On the Cube 30 touch, in the Service menu, the "HOST BY USBD" parameter must be set to OFF.

The electric levels of the signals are all the standard RS232C type.

- The default transmission speed is 9600 bit/s
- the data format is 8-bit,

- 1 stop bit and no parity bit.
- The “RS232C” DB9 male connector reflects the following pin-out:

PIN	SIGNAL
2	Rx of date 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/

CUBE 30 Touch SPECIFICATION PROTOCOL

Chapter 9

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697. (Definition of erythrocyte sedimentation using Micrococapillary tube)

12. NCCLS H02-A5 Procedures for ESR; approved standard – fifth edition, Punto 4.2

Attachment A - CE Declaration of Conformity

The current version of the **CE Declaration of Conformity** may be downloaded from the DIESSE website, www.diesse.it