Clini5

USER MANUAL

This manual is in compliance with the requirements of the Regulation (EU) 2017/746

for In vitro diagnostic-medical devices

callegari

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Review history

Review	Date	Changes
Review 001	05/05/2022	First issuing for professional use
Review 002	22/05/2024	- General review - Graphics review - Changes to paragraphs: 3.2. – addition of detail about intended use 4.3. – addition of information about device disposal in Italy 7.5.2.3.2. – addition of detail about cuvette orientation Annex II – addition of information about serious incidents

GRAPHIC CONVENTIONS

➢	Indicates the operations which the operator must perform
1. 2.	Perform the operations in the described order
⧫	Press this icon on the display to perform the described operation

SYMBOLS

	In vitro diagnostic-medical device
	Catalogue number (item code)
	Serial number
	CE marking
	Manufacturer
	Date of manufacture
	DC current
	Refer to the User Manual
	Attention
	Biological Risk
	Temperature Limit
	Electrical Risk
	Warning symbol
	Keep away from sunlight

	Recyclable
	Do not release into the environment after use
	Dispose of the instrument separately from household waste (Dir. 2012/19/EU – RAEE)
	Keep dry
	Handle with care
	Fragile, handle with care
	This side up
	Do not use if package is damaged
	Barcode
	Data Matrix

1 WARNINGS AND PRECAUTIONS

1.1 USE REQUIREMENTS

Maintenance of the device must be guaranteed by its owner and requires training regarding advanced functions and quality control of the device, as well as use and preservation of reagents.

Before using the device, read the instructions for use, labels and any other information provided with the device carefully. Familiarise yourself with the device.

In order to ensure correct functioning of the device and to avoid inaccurate results, use the Callegari original reagents only.

1.2 SAFETY-RELATED INFORMATION

1.2.1 PERSONAL HARM

Damage to health caused by toxic chemicals

Refer to the safety data sheets of the reagents and follow protective standards.

Safety-related risks caused by the ingress of liquids

Liquids which come into contact with the power supply or with the device can jeopardise its safety. Work with reagents, cleaning solutions and other liquids away from the device and the power supply.

Safety-related risks caused by the use of unsuitable accessories, auxiliary items or spare parts

Any spare parts not recommended by Callegari S.r.l. jeopardise the safety, operation and precision of the device.

Safety-related hazard caused by contamination of the device, of accessories or of auxiliary items

Decontaminate the device, the accessories and the auxiliary items after use or before sending it for servicing (see. 8.1 CLEANING AND DISINFECTION CLEANING AND DISINFECTION).

Risk of injury caused by accidental dropping of the device

Move the device with both hands, making sure to firmly grip the device and the lid.

1.2.2 DAMAGE TO THE DEVICE

Damage caused by the ingress of liquids

Before cleaning or disinfecting the device, switch it off and unplug it. Do not allow liquids to enter the reading cells. Do not spray the device to clean or disinfect it. Plug the device back in only after it and the power supply have completely dried.

Damage caused by aggressive chemicals

Do not clean the device, accessories and auxiliary items with aggressive chemicals, such as acids and bases, acetone, formaldehyde, halogenated hydrocarbons or phenols.

Clean the device only by using cotton cloths lightly moistened with diluted water-alcohol solutions.

	**Damage to the device caused by using an unsuitable power supply** Use the power supply provided with the device only; using a different power supply jeopardises the safety and the functioning of the device. Callegari S.r.l. will not be held liable for damages caused by use of non-original spare parts.
	**Compromised function due to mechanical damage** If the device has undergone mechanical damage, run a check to make sure the device is working before use.
	**Damage caused by non-compliant packaging** Callegari will not be held liable for damages caused by using inappropriate packaging. Transport the device using the original packaging only.
	**Damage caused by inappropriate cleaning of the reading cells** Clean the reading cells with a lightly moistened cotton swab only.

1.3 NOTES ON THE LIABILITY OF THE PRODUCT

Callegari S.r.l. will not be held liable for personal harm or property damage if:

a) The device is not used in compliance with the instructions for use.
b) The device is used differently than according to its intended use.
c) The device is used with accessories, auxiliary items or consumables other than those recommended by Callegari S.r.l.
d) Maintenance or repairs of the device are carried out by personnel not authorised by Callegari S.r.l.
e) The user makes unauthorised changes on the device.

The manufacturer disclaims any type of liability regarding the collection, processing and safety, of personal data registered and used by the user/buyer.

2 RECOMMENDATIONS FOR USE

2.1 USE OF THE USER MANUAL

- Read the user manual before putting the device into use.
- Read the reagent's instructions for use carefully before performing the tests.
- These instructions for use are a part of the product and must be stored with it.
- Always include the user manual when transferring the device to third parties.
- In case you lose the User Manual, request a copy from the manufacturer.

Note: the images in this manual have been inserted for illustrative purposes only and its content does not necessarily reflect the actual values, images or the language of the manual in use.

2.2 PRECAUTIONARY MEASURES DURING USE

- Avoid any external contamination of the device while handling blood.
- Always use the supplied/appropriate cables and power supplies.
- Do not use radio systems or household appliances (e.g., pacemaker, TV, etc.) close to the device.
- Do not use the device in the immediate vicinity of heat sources, open flames or flammable gases.
- Do not place liquids near the device or the power supply.
- Do not move the device when performing an analysis.
- Use the device within the temperature and humidity range indicated in this manual.
- Do not look straight into the reading cells during the autotest phase.
- Use the device with adequate brightness conditions:
  a. Do not expose it to intense light sources such as sunlight or spotlights
  b. Provide sufficient lighting to perform the analysis operations.

2.3 PRECAUTIONARY MEASURES FOR STORAGE AFTER USE

- Store the device on a flat surface protected against blows and vibrations as specified in this manual.
- Store it at a temperature ranging from 8 to 38°C.
- Keep the device protected against dust and humidity.
- Use the specific lids supplied with the device, paying particular attention to the lid protecting the reading cells.
- Do not place any objects on top of the device.

	The surfaces might be contaminated with potentially pathogenic agents or viruses which cause infectious diseases. Clean thoroughly, at least daily, with appropriate disinfectants (see. 8.1.2).

3 DESCRIPTION

3.1 IDENTIFICATION OF THE IVD DEVICE

The present manual refers to the Clini5 IVD device (article code 126181P).

3.2 INTENDED USE

CLINI5 is an automated photometer designed for quantitative determination of main clinical chemistry parameters in whole blood samples.

CLINI5 is an in vitro diagnostic medical device intended for professional use and is used exclusively in combination with specific reagents for monitoring the physiological state of said parameters.

CLINI5 is designed for use by healthcare professionals such as physicians, dentists, pharmacists, biologists and nurses. The system is designed to be used in medical and/or dental offices, pharmacies and any location where healthcare professionals are expected to practice.

For the intended use of every assay refer to its instructions for use.

3.2.1 USE LIMITATIONS AND CONTRAINDICATIONS

Only the analysis of parameters listed in this manual is possible with the Clini5 device.

The tests performed with the Clini5 system are tests for monitoring of the physiological state and as such cannot be considered sufficient to perform a diagnosis or establish a therapeutic regime if not followed by a further, necessary, in-depth diagnostic investigation.

The interpretation of the results is an exclusive responsibility of the physician.

⚠	Do not use to diagnose diabetes. Do not use the device to monitor glycaemia in the household treatment of diabetes mellitus.

The manufacturer will not be held liable for the interpretation of the obtained results and for any damage caused by the use of products and treatments, of any type or nature, chosen, recommended or prescribed on the basis of the data processed by the device.

3.2.2 PRECAUTIONARY MEASURES

The device is intended for professional use.

⚠	The assays which can be determined with Clini5 have been developed in such a way as to reduce the manual operations of the user and the direct contact with the reagents to a minimum. In all cases, the precautions normally taken when handling reagents, chemicals and other potentially harmful substances, shown on the safety data sheets of the reagents (provided on request), are recommended. ▪ Carefully close the tubes containing the biological samples during and after execution of the test. ▪ Work on a waterproof surface and clean it thoroughly at the end of each tests. ▪ Do not eat, drink or smoke while performing the tests. ▪ Never pipette by mouth. ▪ Dispose of the reagents in compliance with applicable local regulations.

It is recommended not to:

- Place your fingers inside of the reading cells
- Place foreign objects inside of the reading cells

3.3 MEASUREMENT PRINCIPLE

The Clini5 device is a photometer with five completely independent reading cells with different fixed wavelengths (505, 340, 610 nm). The device is temperature-controlled at 39°C to guarantee the utmost accuracy and uniformity of the results.

The device employs specific wet chemistry reagents which are pre-dosed in cuvettes (see 3.4.3 PARAMETERS).

3.4 FEATURES

- ❖ Clini5 is a photometer with 5 reading cells. Each cell executes the reading at a fixed wavelength.
- ❖ The device is supplied with a 7” TFT display with capacitive touch screen.
- ❖ An optional printer allows users to print out results from the device.
- ❖ Clini5 can be connected via Ethernet, Wi-Fi*.
- ❖ The body of the machine has a housing for the storage of accessories and auxiliary items required to perform the tests.
- ❖ Clini5 is fitted with a multipurpose lid which becomes a workstation when using the device and protects against dust.
- ❖ There is an additional lid to protect the 5 reading cells against dust and dirt.

*** Wi-Fi functions may be unavailable in some areas.**

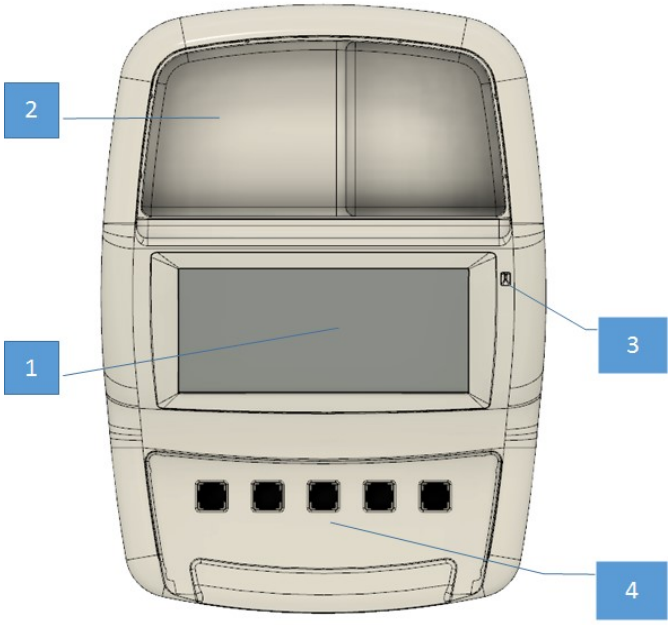
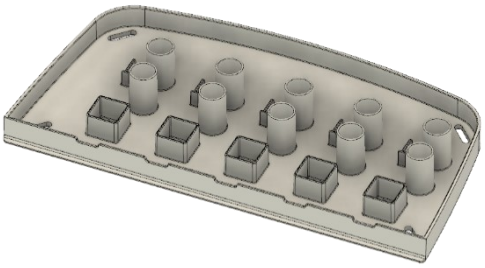
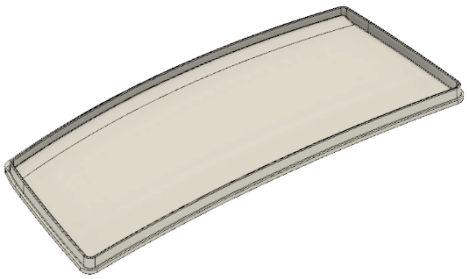


Figure 1

(1) Display
(2) Storage housing
(3) Gesture sensor
(4) Reading cells

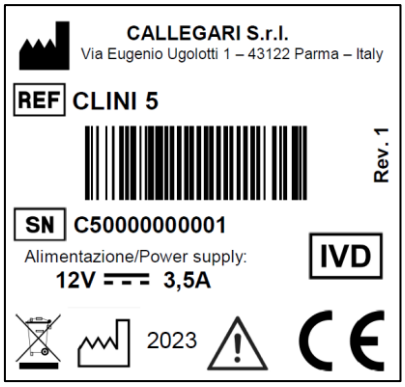
Work station lid	
Reading cells lid	

3.4.1 TECHNICAL FEATURES

Measurement principle	Absorbance (Lambert-Beer law)
Number of Reading Cells	5
Dimensions of Reading Cells	Approximately 13x13 mm
Temperature of Reading Cells	39±0.2°C
Light Source	LED, Light Emitting Diode
Wavelength (nm)	505 - 610 - 340
Optical path	1 cm
Analytical performance	Refer to the instructions for use of single reagents
Display	7” TFT with capacitive touch screen
Connectivity	Ethernet, Wi-Fi
Interface	3xUSB
Weight	2.7 Kg approx.
Dimensions	240 (w) x 330 (d) x 155 (h) mm
Power supply	12 V DC – 3.5 A
Energy absorption	max. 45 Watts
Work Conditions	15-30°C (Rh 90% max without condensate)
Storage conditions	08-38°C (Rh 95% max.)
Safe Work conditions	15-40°C
Conformity	CE Marking

3.4.2 SERIAL NUMBER LABEL

Clini5 has an identification label affixed on the bottom, bearing: name of the manufacturer, serial number and power supply specifications.



3.4.3 PARAMETERS

WAVELENGTH (nm)	PARAMETER	SAMPLE
505	Uric acid	*Whole blood*
505	Total cholesterol	*Whole blood*
610	HDL cholesterol	*Whole blood*
---	LDL cholesterol	*Calculated (Friedewald formula)*[1]
505	Haematocrit	*Whole blood*
505	Haemoglobin	*Whole blood*
610	HbA1c	*Whole blood*
505	Erythrocytes	*Whole blood*
505	FORT	*Whole blood*
505	FORD	*Whole blood*
---	REDOX index	*Calculated* [2]
505	Glycaemia	*Whole blood*
505	Triglycerides	*Whole blood*
505	CHOL - GLU	*Whole blood*
---	CHD risk	*Calculated (Framingham)*[3]
340	ALT/GPT	*Whole blood*
340	AST/GOT	*Whole blood*
---	AST/ALT ratio	*Calculated* [4]

3.5 RESULTS

The test results are viewed on the display and can be printed with the optional thermal printer.

Results are also delivered to a smartphone via 2D code, which can be scanned, specifically generated by the device.

The results are automatically saved in an anonymous form and listed in chronological order which can be accessed to at the end of testing. Results may otherwise be saved by associating the result to a client ID. To do so, access the database protected by a PIN code which may be changed by the user.

3.6 DEVICE AUTOTEST

When switched on, the device runs an autotest which checks the general functions of the device.

[1] The instrument automatically calculates the LDL cholesterol value whenever the multiple “LDL” test is conducted (see.0).

[2] The instrument automatically calculates the oxido-reductive index whenever a multiple “Redox Index” test is conducted.

[3] The instrument automatically calculates the CHD risk whenever a multiple “CHD Risk” or “LDL” test is conducted.

[4] The instrument automatically calculates the AST/ALT ratio whenever a multiple “AST/ALT” test is conducted.

A second autotest is performed automatically for each reading cell following the selection of the test to perform. Any malfunctions are viewed on the display. In case of malfunction, please see **ANNEX II - CLINI5 TROUBLESHOOTING** and/or **ANNEX III - CLINI5 – ERROR MESSAGES.**

If the problem persists, contact the Callegari S.r.l. assistance service.

4 TRANSPORT, STORAGE AND WASTE DISPOSAL

4.1 TRASPORT

The device must only be transported in its original packaging, making sure that the following environmental conditions are met:

Temperature	Relative humidity	Atmospheric pressure
-10°C–+50°C	Max. 95%	30kPa-106kPa

If the device is transported after being used, it must undergo a cleaning and disinfection cycle (see 8.1)

4.2 STORAGE

Temperature	Relative humidity	Atmospheric pressure
8-38°C	Max. 95%	70kPa-106kPa

Place the device away from direct light and protected against dust, sand or chemicals.

Do not expose it to high or low temperatures or to air draughts.

Clini5 should be used at a proper distance (at least 1.5 metres) from other devices or household appliances, such as TVs, mobile phones, compact disc readers, etc.

4.3 WASTE DISPOSAL

Disposal of the device.

Refer to local laws when disposing of the device.

	The Clini5 system and its components must be treated like potentially hazardous biological waste. Before reusing, recycling or disposing of the system and its components, they must be decontaminated (by performing a cleaning/disinfection cycle see 8.1).

Within the European Community, the waste disposal of devices is regulated by Directive **2012/19/EU** regarding waste electric and electronic equipment (WEEE) which prohibits these devices from being disposed of together with common household waste.

In Italy from the entry into force of the decree 49/2014, which transposes the WEEE decree Callegari Srl as manufacturer, collects and disposes of the electronic equipment of its production.

Any waste may otherwise be discarded of by taking it to authorised recycling sites.

5 INSTALLATION OF THE DEVICE

No specialised personnel is required to install Clini5.

5.1 CHECKING THE PACKAGING/SUPPLIED MATERIAL

Before opening the package, make sure that the device has not been damaged and that the seals and internal anchoring elements are intact.

Do not use sharp or pointed tools to open the packaging to prevent damaging the contents.

Check the contents of the box referencing the delivery document and/or the list of material and accessories supplied, as shown below:

1 Clini5 Photometer
1 Power supply
1 Bag containing 50ul Pipette and 5 crocodile clips for capillary handling
1 Quick start guide
1 Envelope containing Callegari Quality Control certificate

Attention. *The warranty period is established by the law in force. Keep the original packaging of the product for that period and use it to send the device back to the manufacturer for extraordinary maintenance*.

5.1.1 AUXILIARY ITEMS SUPPLIED WITH THE DEVICE

- Power supply kit 12V (cod. 600169)
- 50 µl fixed-volume pipette (cod. AD-10259).

5.1.2 ACCESSORIES, AUXILIARY ITEMS AND REAGENTS PURCHASED SEPARATELY

- Reagents for Clini5 series
- If foreseen: Wi-Fi dongle
- Centrifuga 6000 (cod. 126136)
- Thermal printer (if foreseen – cod. 114107).

5.2 MODELS AND TESTS

The Clini5 series performs a comprehensive range of biochemical-clinical assays as described in the table below:

ANALYTE	SAMPLE	Wavelength (nm)
Uric acid	*Whole blood*	505
Total cholesterol	*Whole blood*	505
HDL cholesterol	*Whole blood*	610
LDL cholesterol	*Calculated (formula of Friedewald)*	-
Haematocrit	*Whole blood*	505
Haemoglobin	*Whole blood*	505
Erythrocytes	*Whole blood*	505
FORT	*Whole blood*	505
FORD	*Whole blood*	505
Glycaemia	*Whole blood*	505
Triglycerides	*Whole blood*	505
CHOL-GLU	*Whole blood*	505
HbA1c	*Whole blood*	610
ALT	*Whole blood*	340
AST	*Whole blood*	340
CHD risk	*Calculated (Framingham)*	-
Redox Index	*Whole blood*	-
AST/ALT ratio	*Whole blood*	-

The reading cells are arranged as pictured below.

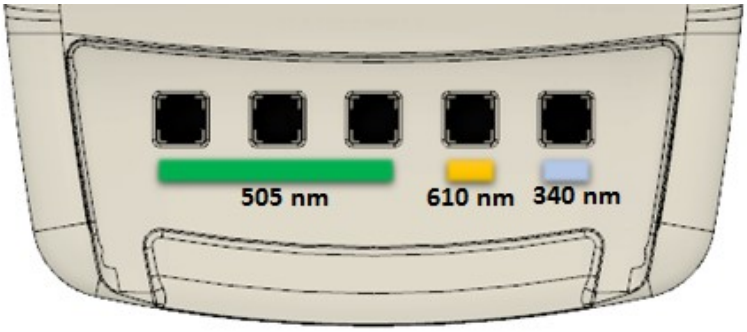


Figure 2

5.3 WHERE TO PLACE THE DEVICE

To work correctly, the Clini5 device must be placed appropriately taking the following precautions:

⚠	Do not use outdoors, but in closed environments and at a controlled temperature
	Handle the device with both hands
	The electric system must comply with regulations in force
	Use a flat, stable and waterproof support surface at least 60x60cm with the device placed at least 10 cm from the edges (100x100 if used in combination with the Callegari Centrifuga 6000)
	Room temperature between 15-30°C
	Absence of air draughts or exposure to direct sunlight/artificial light
	Do not use the device with heat sources, open flames or flammable gases in the immediate vicinity
	Make sure there are no liquids in the immediate vicinity of the device
	Use the device in an environment with lighting sufficient to perform the intended operations
	Do not use radio systems or household and electronic appliances in general (pacemakers, TV etc.) in the immediate vicinity of the device
	It is recommended to place the device in a sufficiently isolated area in order to prevent the user and any other persons from coming into contact with blood during the analysis.

5.4 REAR PANEL

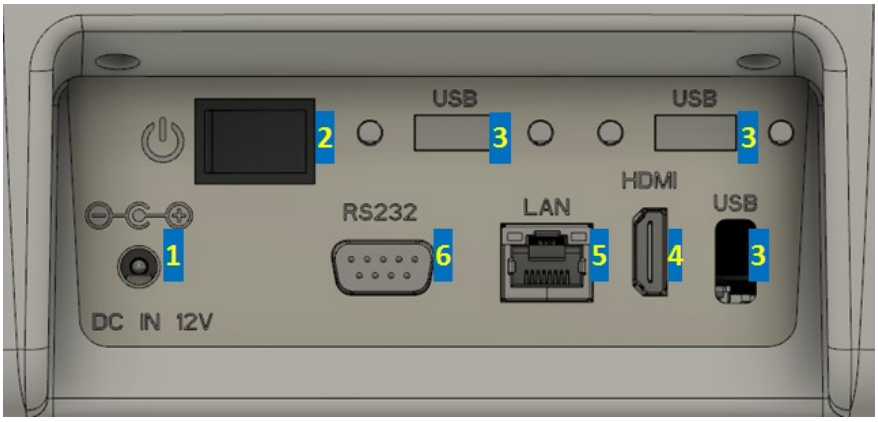


Figure 3

(1) Power supply socket
(2) ON/OFF switch
(3) USB ports
(4) HDMI socket
(5) Ethernet socket (RJ45)
(6) RS232 socket

5.5 CONNECTING THE DEVICE TO THE POWER NETWORK

	Electric system compliant with regulations in force
	Use only the provided power supply. If it is not available, contact the assistance service
	Before connecting the power supply to the power network, always check the integrity of the cables.

ATTENTION. Do not use accessories, power supplies and cables other than those provided and/or appropriate; this might increase emissions and reduce the necessary protections. When following the specific warnings, Clini5 operates in compliance with the safety regulations in force; make sure that the electrical system is equipped with protective conductor (earth). Although Clini5 is equipped with devices for filtering interference on the power line, there are cases, albeit infrequent, in which the noise and malfunctioning of the network (for example frequent outages) may result in problems. In these cases, the device should be powered with a UPS. Clini5 has undergone strict electromagnetic compatibility tests (EMC), resistance to external electrical interference, resistance to electrostatic discharges etc. according to the standards in force. **Conformity with technical standards.** The device complies with directives 2014/35/EU, 2014/30/EU as amended in reference to normative standards applied EN 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use - and EN 61326-1 - Electrical equipment for measurement, control and laboratory use – EMC requirements. Clini5 must not be installed on top of other instruments and, vice versa, these must not be placed directly on top of Clini5. If stacking is required, inspect the Clini5 system to make sure it works properly in the configuration used. Portable communication devices and radio frequencies can interfere with operation of Clini5.

- Connect the power cable to the power supply.
- Insert the power supply jack into the corresponding socket on the back of the device (1) §**Errore. L'origine riferimento non è stata trovata.**
- Plug the device into the wall socket.

6 ANCILLARY OPERATIONS DURING USE OF THE DEVICE

6.1 STORAGE AND SAFETY OF REAGENTS

The Clini5 system can only be used in combination with original Callegari reagents.

- Refer to the instructions for use (IFU) in the packages of the reagents for correct storage.
- The safety data sheets of the reagents are available on request.

Before use:

- Always check the integrity of the packaging.
- Always check the integrity of the cuvettes (absence of scratches, cracks) and of the closing caps.
- Check that there are no traces of liquid on the outer surface of the cuvettes.
- Before conducting a test, check the integrity of the labels on all of the cuvettes (they must not show signs of fading and/or erasure).

Contact the assistance service if you encounter any problems.

6.2 HOW TO TAKE A CAPILLARY BLOOD SAMPLE

It is preferable to conduct testing when the individual is well rested and has fasted for 12 hours.

Before performing a test, carefully read the instructions in the reagent packages and make sure you have all the material required: finger-pricker or sterile lancets (*only use products with CE marking*), disinfectant (*preferably alcohol -do not use hydrogen peroxide*), cotton swab, tubes for reagents, capillaries, pipette and tips when necessary. See ANNEX II - CLINI5 TROUBLESHOOTING of this manual.

Take the sample as follows:

- The individual must remain sat and relaxed for a few minutes.
- Select a point on the side of one of the fingertips of the middle fingers on either hand.
- Gently massage the finger to promote the blood flow to the fingertip.
- Disinfect and let the alcohol evaporate completely.
- Using the specific device, prick the chosen area firmly.
- Gently milk the finger. The individual should be sitting down with the hand pointing downwards to encourage blood flow via gravity.
- Remove this first drop of blood which might contain tissue fluid.
- Press lightly again at the end of the fingertip until a second large drop of blood comes out. Do not force the blood to come out by compressing the finger excessively.
- Collect the desired amount of the sample without drawing air bubbles.
- Eliminate any excess blood.
- Transfer the blood into the test tube and continue according to the specific procedure of the test in progress.

Advice:

- Warm fingers and hands held lower than the heart provide a better blood flow.
- Hold the capillary tube slightly tilted compared to the drop of blood to fill it easily.

⚠	Preferably, use ethyl alcohol to disinfect the finger. **Do not use hydrogen peroxide-based disinfectants or ones which contain glycerol as these will impact results.**

6.3 PRECAUTIONARY MEASURES

The assays which can be determined with Clini5 have been developed in such a way as to reduce the manual operations of the user and the direct contact with the reagents to a minimum. In all cases, the precautions normally taken when handling reagents, chemicals and other potentially harmful substances are recommended.

Work on a waterproof surface and clean it thoroughly at the end of the tests.

6.4 QUALITY CONTROL

Quality control consists of tests carried out in order to ensure the correct functioning of a system and its ability to provide reliable results. This control is carried out as follows:

Internal quality control performed by the manufacturer. This entails a complete series of tests to assess and monitor the functioning of the device and the analytical performance of the reagents in order to guarantee the accuracy of the results. This quality control system eliminates products which do not meet the specifications set out by the Quality Management System in order to minimise the risk of results with significant errors.

Autotest upon switching-on. The device automatically performs an autotest checking the main features every time it is switched on. Any issues encountered are immediately reported.

Periodical inspection of the device, accessories and auxiliary items. To guarantee the reliability of the device over time, Callegari S.r.l. recommends that specialised technicians perform the periodical check of the device on a yearly basis. The thorough inspection of the auxiliary items supplied with the device (power supply and 50 µl fixed-volume pipette) is also recommended.

Control materials (optical prisms and solutions). These are supplied by Callegari S.r.l. on request and are recommended for use with the Clini5 systems. Read the instruction leaflet enclosed in each control package for information regarding use and storage. The results of the checks must be within the ranges indicated by the manufacturer. If the checks do not give the expected results, repeat the tests and contact the Callegari S.r.l. assistance service.

6.5 DISPOSAL OF WASTE RESULTING FROM THE TESTS

	With the aim of environmental protection and to avoid any contact with objects, animals and persons, the waste resulting from use of the Clini5 system must be considered potentially hazardous and must be disposed of according to local regulations in force.
	Sharp objects (tips) must be wrapped up in a sufficient amount of paper towels so that they do not pierce the plastic bag.

7 USE OF THE DEVICE

Clini5 is equipped with a 7” TFT display with *capacitive touch screen* so that the device can be used by simply touching the display.

An accurate graphic menu guides the operator step-by-step by means of videos, messages, sounds, symbols and icons making the device functional and easy-to-use.

	We recommend using a capacitive touch pen (not supplied with the device) and, regardless, avoiding contamination of the touch screen with potentially infectious material.

7.1 LIST OF THE MAIN ICONS

The device’s display has several icons, some acting as buttons and others as indicators.

In general, the buttons are disabled when grey, otherwise they have a different colour.

The buttons normally consist of an icon with an explanatory text.

The status indicators of the reading cells are black when the reading cell is selected, and a different colour when an action is being carried out in the background on a disabled cell.

Icon	Description	B = Button I = Indicator
	Assay panel	B
	Start Test	B
	Reading cell selected in focus: pending action by user	I
	Reading cell selected not in focus: pending action by user	I
	Countdown underway in a cell	I
	Open tutorial video	B
	Test completed	I
	Save	B
	Print on thermal printer	B
	Close screen/interrupt test in progress	B

Icon	Description	B = Button I = Indicator
	Results	B
	Autotest result passed	I
	Autotest result failed	I
	Database	B
	Write/edit	B
	Recover PIN	B
	New Client	B
	Disassociation of result from client (active/inactive)	B
	Search	I
	Delete	B
	Statistics	B
	Go back	B
	Settings	B
	Switch off	B
	Information	B
	2D codes (QR CODE) (active/inactive)	B
	Calculate (active/inactive)	B
	Test/profile booked	I

7.2 DEVICE START-UP

- Press the ON/OFF button on the back of the device (2)
- When starting up the device, select the user language. This selection is stored for subsequent start-ups and will no longer be requested. Further language changes must be carried out from the Settings menu → Language
- When the language has been selected, an EULA will be shown on-screen and must be accepted. After the Eula has been accepted, the device will automatically perform the initial autotest.
- Wait for the autotest to finish
- Set date and time, if necessary.

7.3 AUTOTEST

When switched on, the device automatically performs an autotest checking the main features.

When issues are detected, one or more messages are displayed indicating the type of problem encountered: see the Annex II – Troubleshooting and/or the Annex III - Error Messages section at the end of this manual.

7.4 WARMING UP

When switched on, the device automatically starts the warming up phase of the test cells. When the operating temperature is reached, it remains constant the whole time the device is on.

The temperature is a crucial factor for the execution of certain assays, therefore if the 'Assay panel' option is selected during the warming-up phase, the device will deny access to the Assay panel and it will not be possible to perform any test.

⚠	**It is preferable to turn on the device around 15-20 minutes before using it.**

When the operating temperature is reached, Clini5 is ready to perform the tests at any time.

During the warming up phase, the 'Clients', 'Results' and 'Settings' options are active.

7.5 MAIN MENU

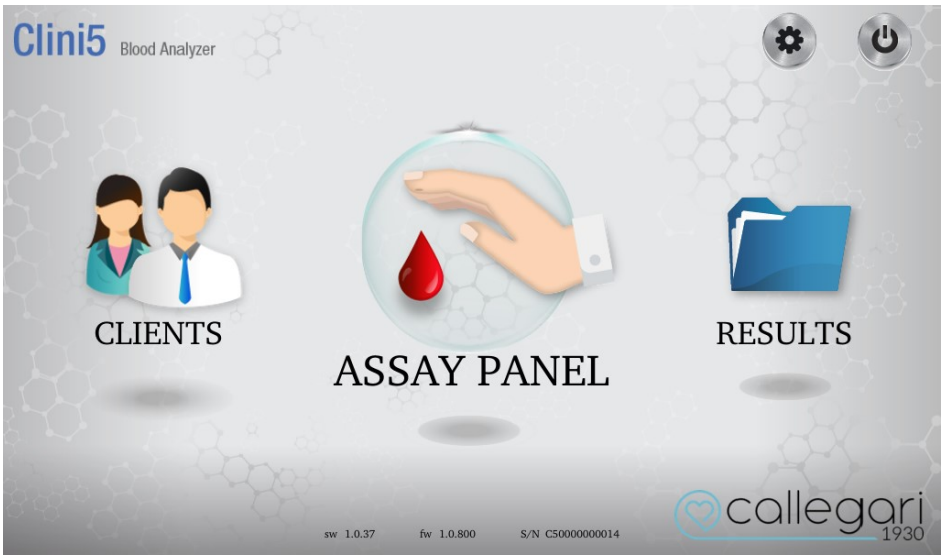


Figure 4

- Select **Assay panel** to perform the tests
- Select **Clients** to view the list of clients and stored data

- Select **Results** for a list of the results in chronological order
- Touch the icon  to access the settings menu
- Touch the icon  to switch off the device.

7.5.1 GESTURE SENSOR

The gesture sensor is found on the top right-hand side of the display. By moving the hand from right to left or left to right in front of the display in a moderate and uniform speed the device enables:

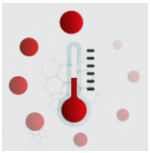
- Selection of Assay panel, Clients or Results from the main menu. To enter the item selected, hover the palm close to the sensor.
- Switching from one screen to the next in the General Statistics section (under Clients, as described in section 7.6).

7.5.2 ANALYSIS

⚠	Before accessing the assay panel, make sure that there are no cuvettes in the cells.

Select the corresponding icon to access the Assay panel menu:

The access is only allowed when the device has reached the operating temperature, otherwise the operator will be warned to wait for the completion of the warming up phase.



When the warming up phase is over, access is granted to the Assay panel:

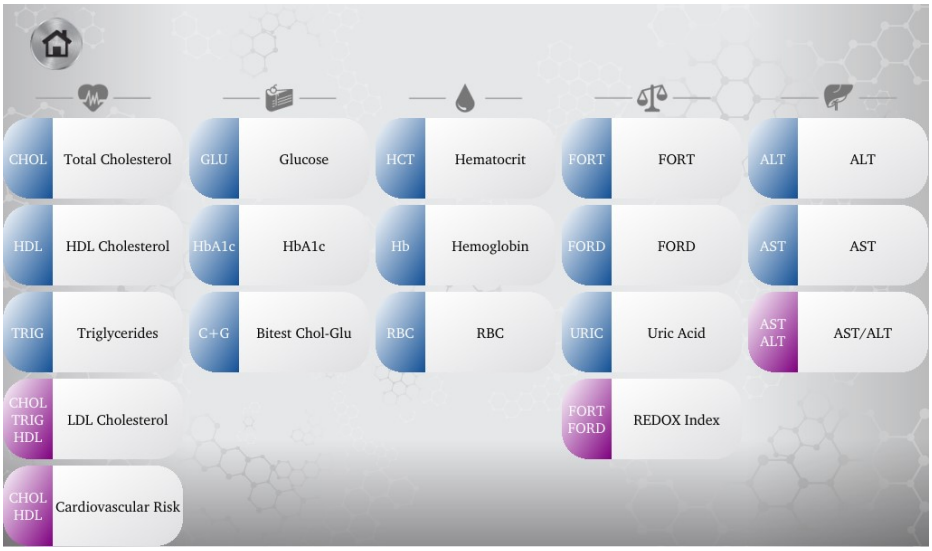


Figure 5

Two different test modes are available, which can be selected from the settings menu (see 7.8.7):

- tutorial mode
- standard mode.

7.5.2.1 Tutorial mode

Tutorial mode is enabled by default when the device is switched on the first time.

When enabled, tutorial mode entails:

- execution of only one test at a time (the 5 reading cells cannot be used simultaneously)
- the user must confirm execution of an action by pressing a button on the screen.

In tutorial mode, each step of the test procedure includes a series of displayed instructions (both texts and videos) which guide the user at every step and is therefore ideal for learning.

When enabled, tutorial mode automatically disables the “Standard” mode.

The tutorial mode can be disabled from the settings menu (see 7.8.7).

7.5.2.2 Standard Mode

The standard mode guides the user step-by-step in the execution of the test, helping them by means of guide messages and videos which can be opened at each step of the test.

Unlike the tutorial mode, the standard mode includes the following points:

- Allows the 5 test cells to be used simultaneously
- The procedure is quicker and does not need to be confirmed by the user (except rare situations)
- The written instructions are more concise and are merged in fewer steps
- Instruction videos are not available by default but can only be opened when necessary
- Option of starting **multiple tests***

This is therefore the ideal mode for the user who has become familiar with the device.

Standard mode, activated from the settings, automatically deactivates tutorial mode.

***Multiple Tests:** it is possible to simultaneously start a panel of correlated tests. Starting one of these specific test panels has the advantage of having instructions aimed at optimising the implementation of several tests simultaneously.*

The table displays the list of multiple tests available and the tests included in the panel.

Test Name	Test to execute
LDL	Total cholesterol, HDL cholesterol, Triglycerides
CHD risk	Total cholesterol, HDL cholesterol
Redox Index	FORT, FORD
AST/ALT	ALT, AST

Attention: multiple tests can only be selected when all of the reading cells are free of cuvettes.

*NOTE: indirect parameters (LDL cholesterol, CHD Risk, Redox Index and AST/ALT ratio) can be calculated by accessing the customer’s file and selecting the results of individual tests obtained in standard mode and/or tutorial mode (see par.**7.6.4.1**)*

7.5.2.3 Perform a test

⚠	Before inserting a cuvette in the reading cell, always make sure that the outside is dry, without scratches or cracks. Check the integrity of the cap before opening it.

7.5.2.3.1 To perform a test

- Touch the button corresponding to the desired test on the monitor.
- If necessary, select several tests (**NOTE:** this is not possible in "Tutorial" mode): if the same test is selected more than once, the counter of the corresponding button increases by one unit.
- Once all the chosen tests have been selected: Press the start button.
- Follow the instructions displayed to obtain the result.

Figure 6

(1) Test ID code
(2) Delete button
(3) Selected test
(4) Counter
(5) Start a test

7.5.2.3.2 Tests with variable calibration coefficients from one lot to another

The ALT, AST, HbA1c and HDL cholesterol tests have different calibration coefficients for each lot.

For this reason, whenever one of these tests is started, the user is prompted to check the correctness of the calibration coefficients and to modify them if necessary.

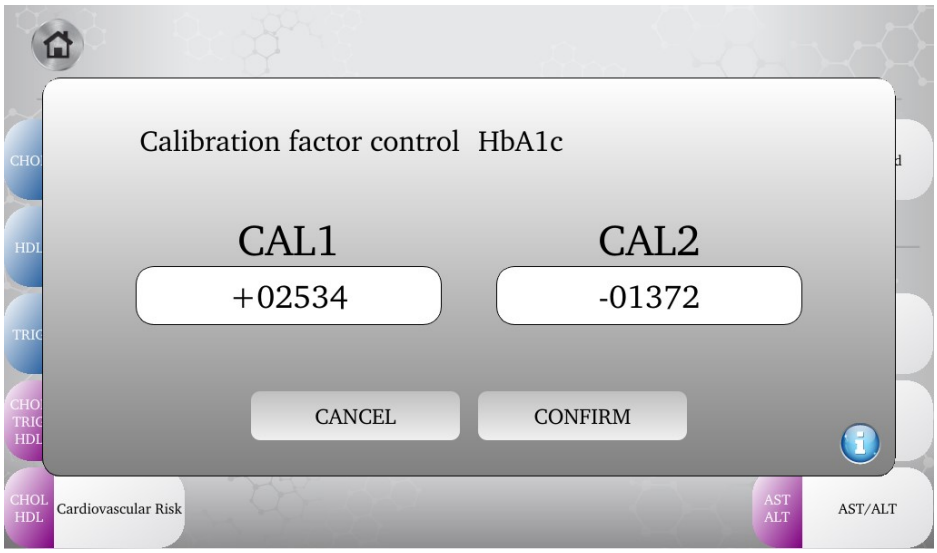


Figure 7

To modify the coefficients:

- Touch the corresponding box (CAL 1 or CAL 2)
- Enter the coefficients of the lot in use with the + or - sign as shown on the reagents label.

⚠	The calibration coefficients for each lot are shown on the reagents' package. Enter the correct coefficients of the lot in use. DO NOT MIX REAGENTS WITH DIFFERENT CALIBRATION DATA. Press  to view position of the calibration coefficients on the label.

7.5.2.3.3 Execution of test: standard mode

The selected tests are assigned gradually when the first reading cell becomes available (see 5.2).

The reading cells are indicated by 5 rectangular boxes at the bottom of the screen (called **"Tabs"**), placed near the cell itself.

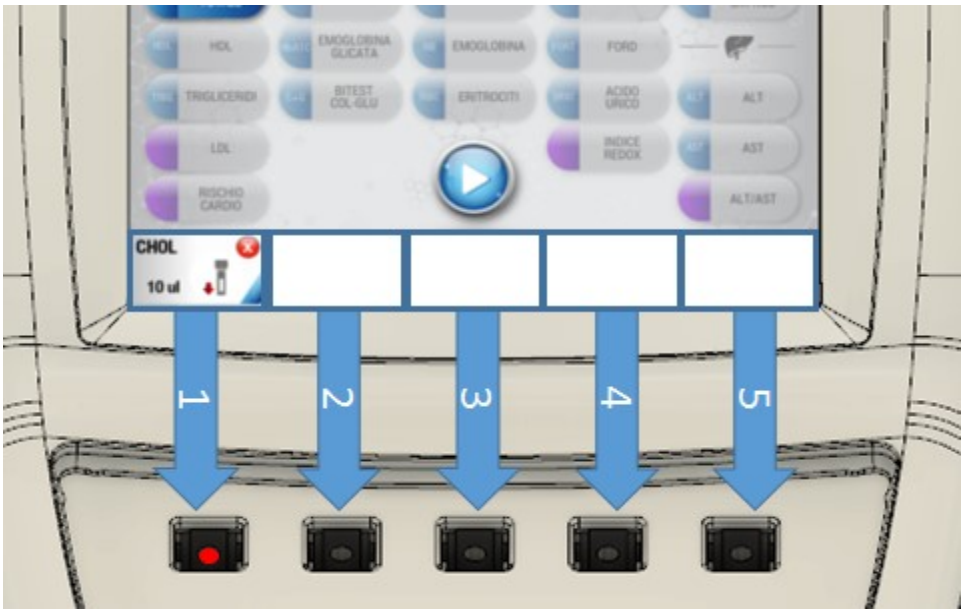
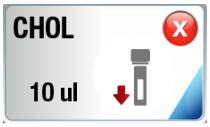


Figure 8

The tabs show concise information regarding the state of the test, the blood volume required to execute it and a delete button.



When the test (or several tests) has been started, the software will prompt to execute a series of actions in order of priority, designed to optimise the time of analysis and to reduce possible manual errors.

The cell where the user is prompted to perform an action is highlighted in solid Blue and brought in the foreground compared to the others (**focused cell**).

NOTE: When several tests are executed simultaneously, it will not be possible to operate on other cells until the required action on the focused cell has been completed.

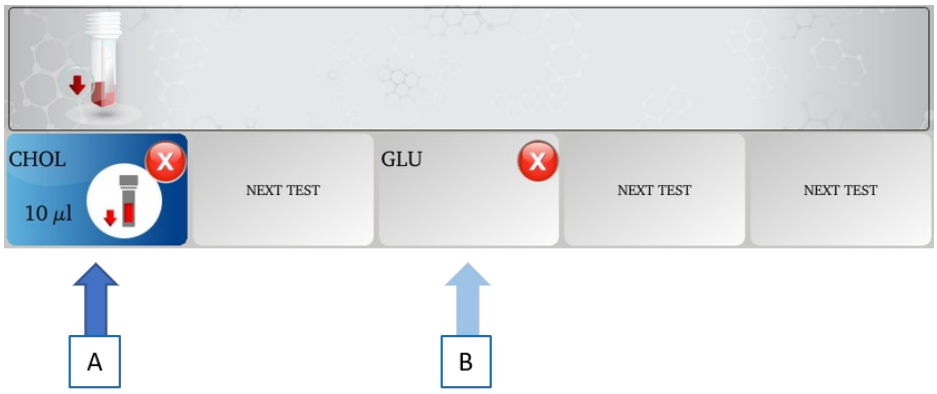


Figure 9

(A) Focused cell: action required

(B) Unfocused cell: pending action

The screen displays the following elements when a cell is focused:

- **Instructions area**: the text instructions are displayed in this area.

- **“Open video instructions” button:** when pressed, a short video clip is displayed showing the action the user is required to perform at that moment.
- **“Action confirmation” button:** when displayed, it allows you to confirm that a certain requested action has been carried out.
- **“Back to test selection menu” button:** while a test is being carried out, you may start a new test to utilise the potential of the 5 reading cells.
- **Icons to cancel the test.**

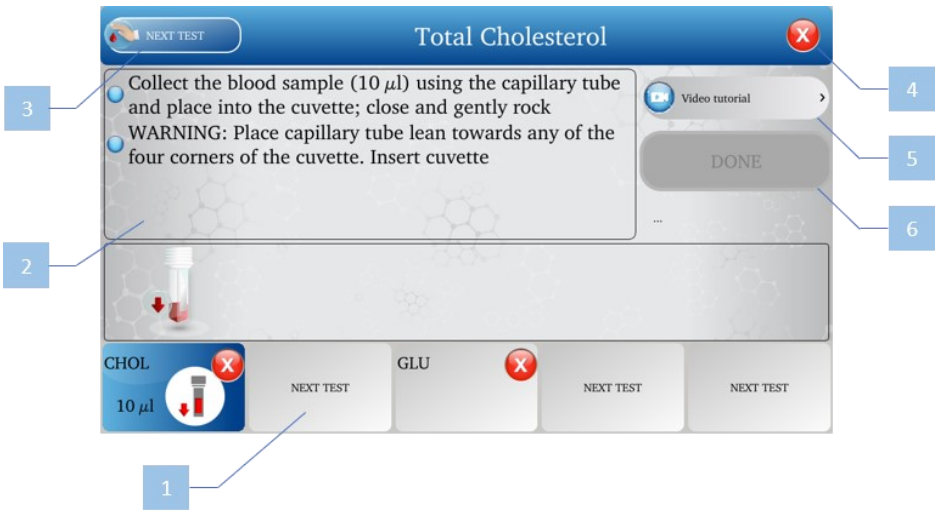


Figure 10

(1) Back to test selection menu (to start a new test)
(2) Instructions area
(3) “Back to test selection menu” button (to start a new test)
(4) “Test deletion” icon
(5) “Open video instructions” button
(6) “Action confirmation” button

When you are prompted to insert the cuvette in the reading cell, **check that the inserted cuvette has the same acronym displayed on screen and that the cuvette label is facing towards the user.**

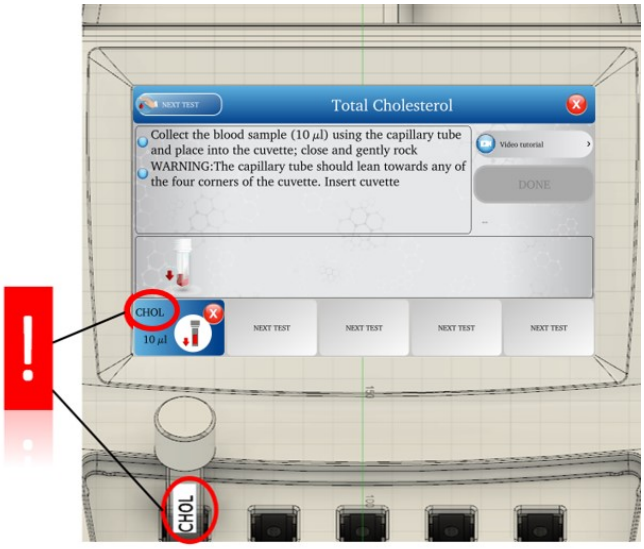


Figure 11

Each test is identified by an acronym on the label of the reagent as well as on the labels on the packaging.

The identifying acronyms of each parameter are listed in the table below:

Trade name of the Test	Parameter analysed	Identifying acronym
CLINI CHOL	Total Cholesterol	CHOL
CLINI GLU	Glycaemia	GLU
CLINI TRIG	Triglycerides	TRIG
CLINI HDL	HDL	HDL
CLINI HbA1c	Glycated haemoglobin	HbA1c
CLINI FORT	Oxidative stress	FORT
CLINI FORD	Antioxidant capacity	FORD
CLINI ALT	Transaminase ALT	ALT
CLINI AST	Transaminase AST	AST
CLINI URIC	Uric Acid	URIC
CLINI C+G	Bitest Cholesterol-Glycaemia	C+G
CLINI Hb	Haemoglobin	Hb
CLINI HCT	Haematocrit	HCT
CLINI RBC	Erythrocytes	RBC

Once a test has started, follow the instructions displayed in order to view the results when the test has been completed (see 7.5.2.7).

***NOTE 1**: You may "shift" from one cell to another by touching the corresponding tab at the bottom of the screen, unless one or more cells are in the "Standby" status: in this case, you must complete all of the requested actions before focusing on another cell.*

***NOTE 2**: some tests might require a centrifugation phase. It is recommended to use the centrifuge supplied by Callegari S.r.l. (cod. 126136) only.*

***NOTE 3**: some tests might require the use of a fixed-volume pipette (50 µl). It is recommended to use the pipette supplied by Callegari S.r.l. only.*

7.5.2.3.4 Execution of test: Multiple tests

In the tests list of the Assay panel, multiple tests are highlighted by purple buttons.

Test Name	Test to excute	Test ID code
LDL	Total cholesterol, HDL cholesterol, Triglycerides	CHOL, HDL, TRIG
CHD risk	Colesterolo Totale, Colesterolo HDL	CHOL, HDL
Redox Index	FORT, FORD	FORT, FORD
AST/ALT	ALT, AST	ALT, AST

Multiple tests, compared to performing the same tests in standard mode, have the advantage of having guided procedures aimed at optimising the execution times.

Once a multiple test has been selected, it engages the required cells and it will not be possible to start any additional test until the multiple test has been completed.

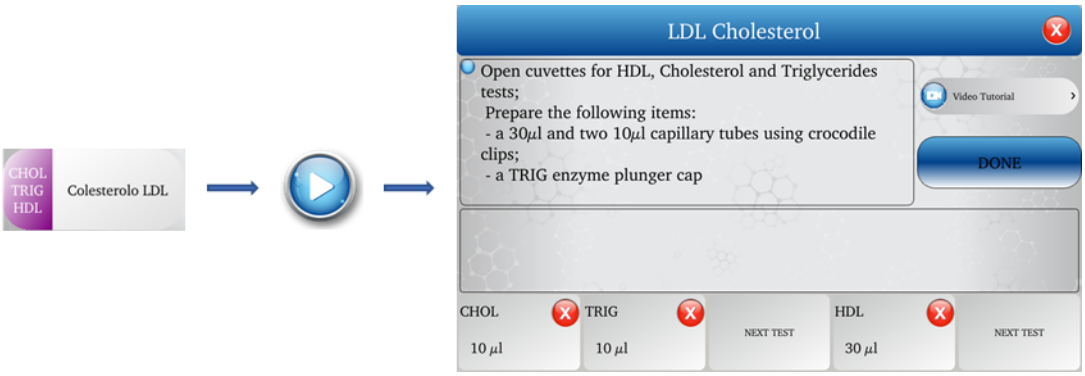


Figure 12

Press  to interrupt a multiple test.

Interrupting one of the tests inside the panel entails interrupting the entire multiple test.

Note: At the end of the LDL and CHD Risk tests, the device will automatically display the questionnaire to determine the CHD risk.

See ANNEX I – ASSESSMENT OF CHD RISK *for further details.*

7.5.2.3.5 Test execution: Tutorial mode

Operation in tutorial mode is the same as already described in the paragraph on the standard mode: select a test and press the start button to execute it.

In this mode, you may only execute one test at a time.

When the test has been started, the focused test screen differs from the standard mode as follows:

- The written instructions might be less concise than in standard mode.
- There is again an area with a video displaying the procedure (reviewed when you want).
- At each step of the test, you are prompted to confirm its execution by pressing the “Done” button (except when you are prompted to insert/extract a cuvette).

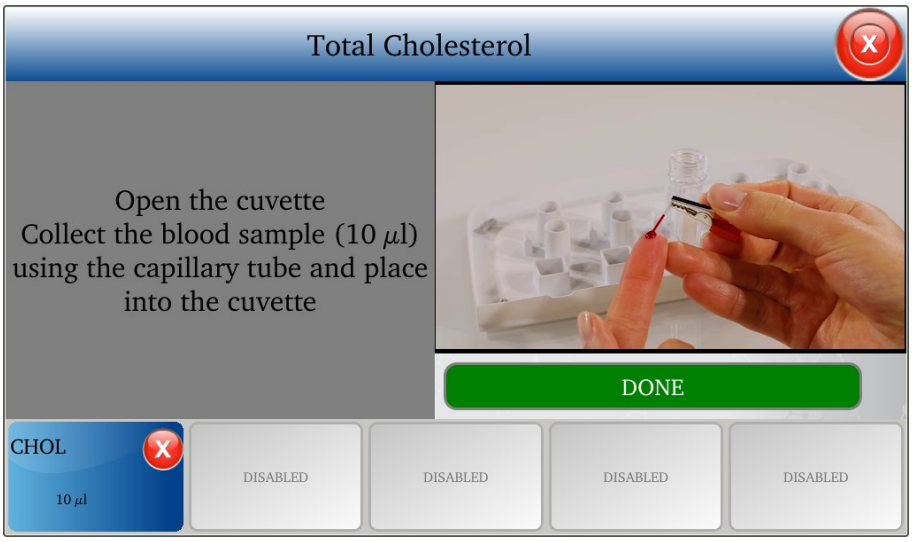


Figure 13

7.5.2.4 Exam execution: test request from the web interface

Once the Clini5 has been connected to a PC (ref. 7.5.2.7 Results: Print - Save – Sharing: to print from PC) access the “Test Request” menu, select the customer and the test/profile to be performed and press “SEND REQUEST”: the icon will appear where the test\profile requested button is, in the Clini5’s Analysis page.

Once the test has been completed, it will be automatically saved in the customer folder chosen during the test request.

7.5.2.5 Use of the workstation (multipurpose lid)

It is advised to always use the workstation included in the upper multipurpose lid to optimise work and to reduce possible procedure errors.

The workstation has 5 functional areas corresponding to the 5 cells.

Position the reagents and other items in an orderly manner to perform the assay(s) selected for the cell(s) in question.

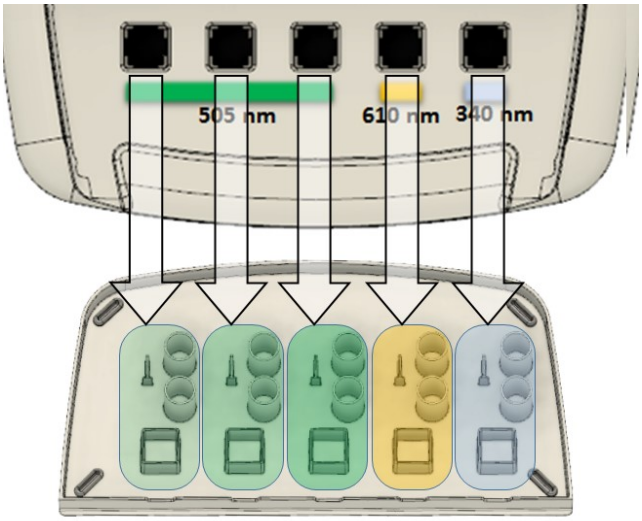


Figure 14

Figure 15

7.5.2.6 Interrupt a test

To interrupt a test, simply extract the cuvette while a reading/countdown phase is in progress.

The cell about to be interrupted turns red: you have 5 seconds to put the cuvette back in before the definitive stop of the test.

As an alternative press

Note 1: we recommend not to interrupt and resume a test more than once: this might affect the accuracy of the results.

Note 2: in case of multiple test, the interruption of one of the tests entails interruption of the entire panel.

7.5.2.7 Results: Print - Save – Share

Figure 16

The results of all the assays conducted are saved automatically and can be viewed in the "Results" section (see 7.7).

At the end of a test, you may:

- Get the result on a smartphone by taking a picture of the 2D code with the specific app.
- Print the result (option only available if there is an optional external printer)
- Save the result and associate it to a client

*ATTENTION: When you extract the cuvette, the result disappears from the screen and can ONLY be retrieved in the "**Results**" section of the main menu* (see 7.7).

Always free the reading cells when results are obtained so that the cells are made available for the next test.

❖ **To get the result on a smartphone:**

Results are delivered to a smartphone by simply taking a picture of the 2D code (QR-code) on the right side of the results screen.

To correctly decode the QR code, a mobile phone which supports this feature on its own is required or an app to read 2D codes (QR CODE) must be downloaded from the specific store of your smartphone (Google Play store for Android, App store for iOS, etc.).

Once you have taken a picture of the code with the specific app, a file is generated showing the result including some details such as:

1. The professional's personalised header (if any)
2. Date and time of the test
3. Name of the client (if the test was already associated to a client – otherwise this field is omitted)
4. Name of the test
5. Results of the analysis with unit of measurement

6. Ranges of reference for male and female (optional)
7. Serial number of the device
8. Miscellaneous

❖ **To save:**

Press the save icon to open the list of clients:

- If the client is already included in the database: select the line corresponding to the client and confirm saving.
- If the client is not in the database, create a new client sheet (see 7.6.2)

When the result has been saved, it can be viewed again by accessing the client area (see 7.6.4)

❖ **To print (optional):**

- **from PC:**

  Connect the Clini5 to LAN/WIFI

  From any device connected to the printer (pc, tablet etc.), open a browser and type in the following address:

  a) http://(IP address) (ex: http://10.0.3.124) (see Figure 19)
  b) http://(serial number Clini5) (ex: http://C50000000014)

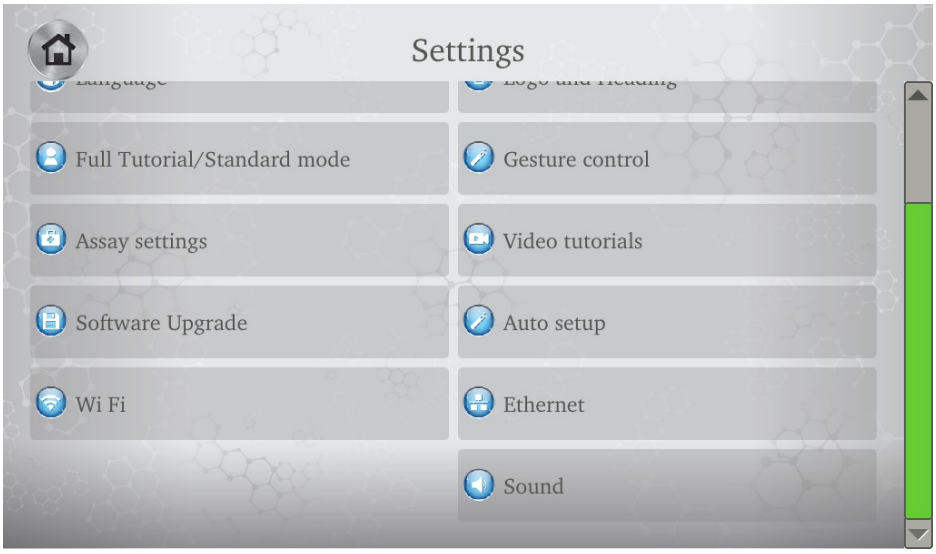


Figure 17

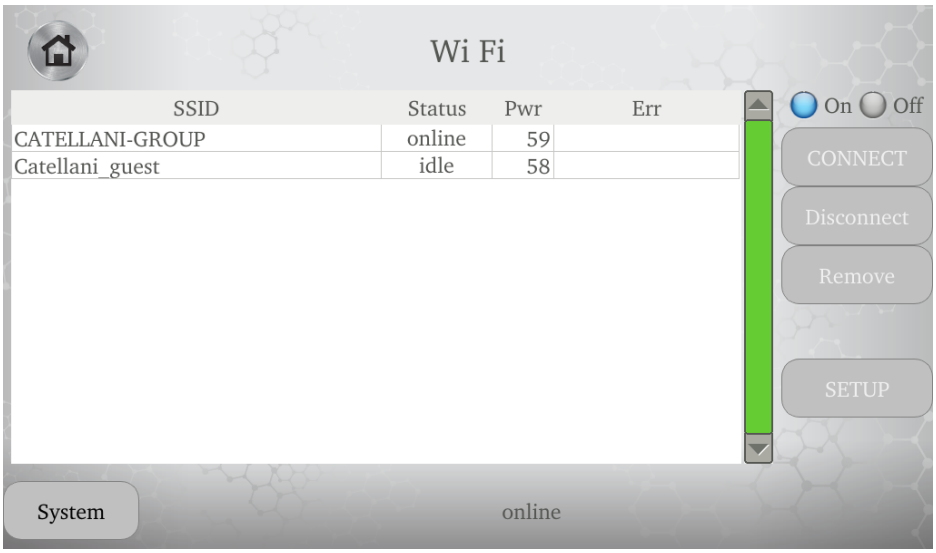


Figure 18

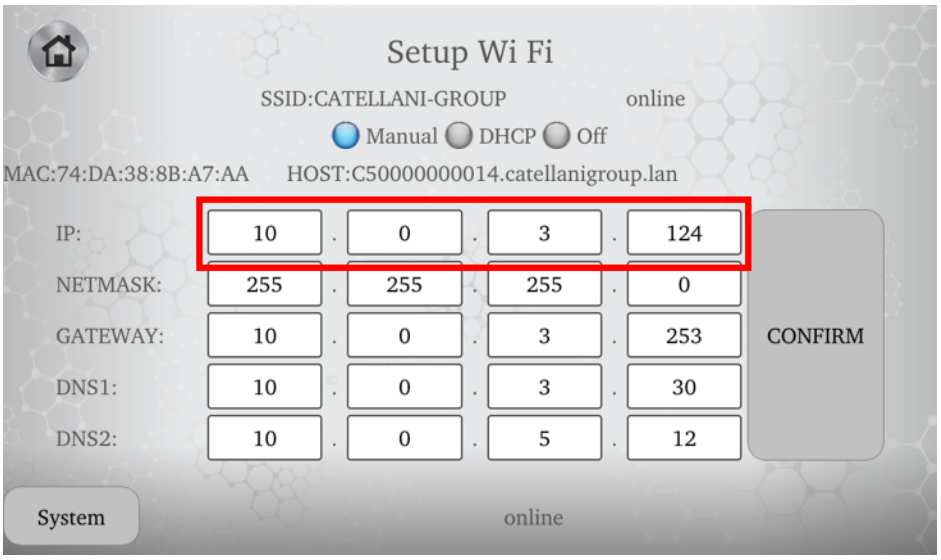


Figure 19

A PIN request screen will open: enter the same PIN assigned to the CLIENTS menu (default 1234): the list of results will open in chronological order, from the most recent to the oldest.

Select the result you want to print.

Press the print button to print the result on the printer online or connected to your device (PC, tablet, etc.).

- **On optional thermal printer:**

If there is an optional printer* you may print the result directly.

**Attention: the optional printer might not be available on all markets.*

The print-out will show the result together with some details such as:

1. The professional's personalised header (if any)
2. Date and time of the test
3. Name of the client (if the test was already associated to a client – otherwise this field is omitted)

4. Name of the test
5. Results of the analysis with unit of measurement
6. Reference ranges for male and female (optional)
7. Miscellaneous.

7.6 CLIENTS

From this menu you may record the obtained results, view them, reprint them and share them as many times as necessary.

You may also view the general statistics.

7.6.1 ACCESS THE CLIENT AREA: PIN

The client menu is protected by PIN to prevent access by unauthorised personnel.

Default PIN: 1234

To modify the PIN: select  and follow the instructions displayed on the screen (enter the new PIN and the previous PIN).

In case of PIN loss: select  and follow the instructions displayed on the screen (to obtain the PIN recovery code, please contact the Callegari customer service or an authorised distributor, providing the information displayed on the screen: S/N of the device and the consecutive number)

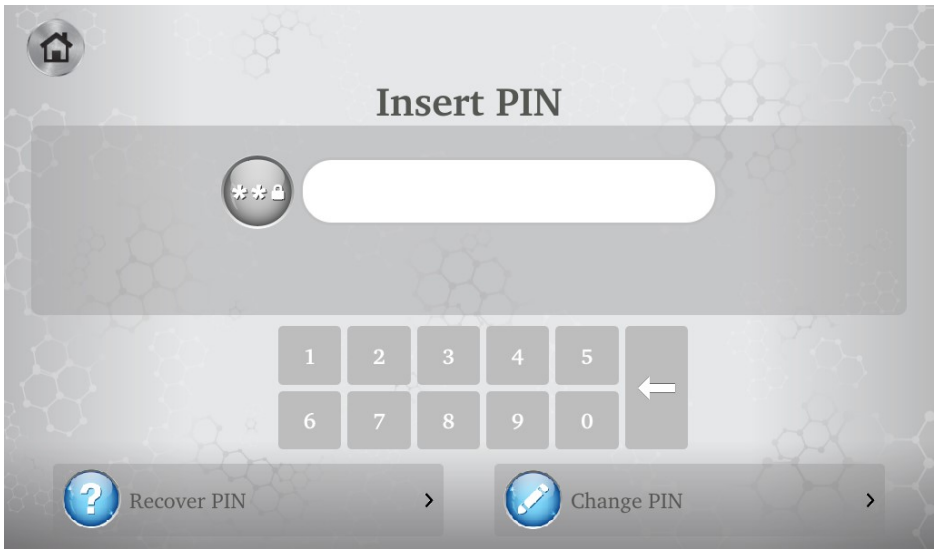


Figure 20

	The manufacturer disclaims any type of liability regarding the collection, processing and safety of the personal data entered and used by the user/buyer

When the correct PIN has been entered, you may access the Client Database.

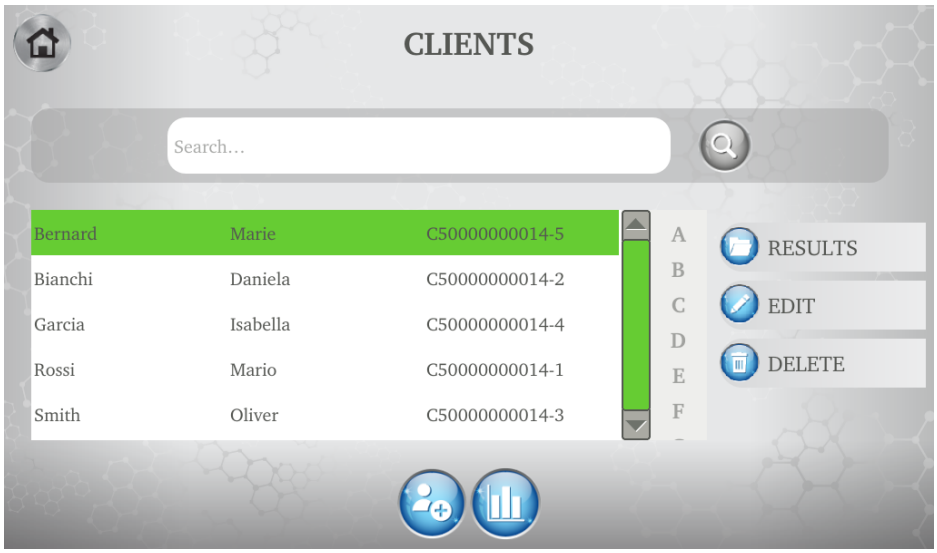


Figure 21

When no client is selected, it is possible to:

- Create a new client
- View the general statistics

To search for a client:

- Enter identification data of the client in the search toolbar (name, surname, etc.). The client will be found if stored in the database.
- Otherwise scroll the client list.

Select a client by touching the corresponding line.

When a client has been selected, it is possible to:

- View the associated results
- Edit the personal data
- Delete the client.

7.6.2 CREATE A NEW CLIENT

Press 

Complete the client information registry*.

**some fields might be mandatory.*

Each client is automatically assigned a unique ID.

To enter details:

➢ touch the desired field (for example “Name”): the keyboard appears automatically on the screen.

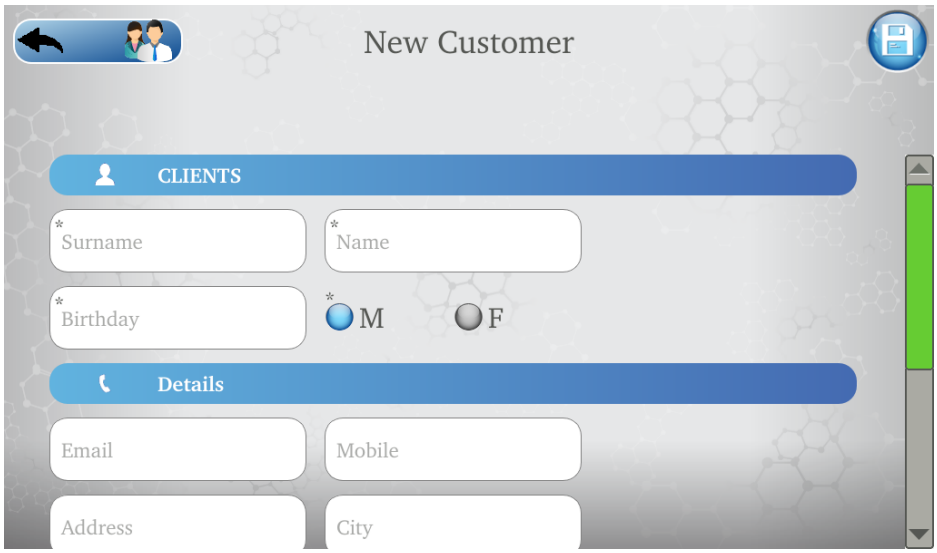


Figure 22

7.6.3 GENERAL STATISTICS

Touch  to display the general statistics of the device (e.g.: number of tests executed during each month of the year, number of registered clients, number of tests executed for each age range, test classification etc.)

7.6.4 VIEW THE RESULTS FOR A CLIENT

Select the client by touching the corresponding line and press the button  .

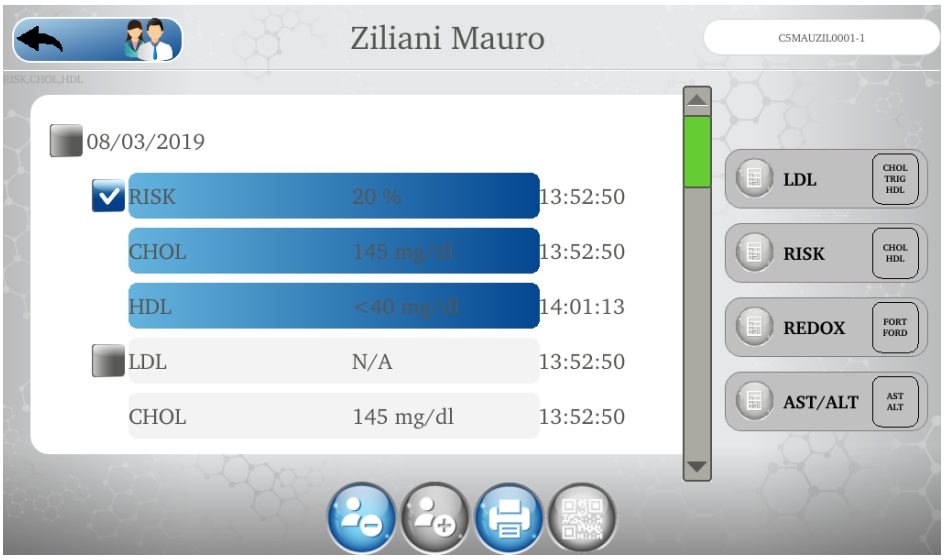


Figure 23

7.6.4.1 Calculation of indirect assays

The indirect assays (LDL cholesterol, CHD Risk, Redox Index and AST/ALT ratio) can be calculated from the customer's file by selecting the results of individual tests obtained in standard mode and/or tutorial mode.

- LDL calculation:
  1. select the CHOL, LDL and TRIG results
  2. press  . The device will automatically suggest the CHD Risk calculation (see ANNEX I – ASSESSMENT OF CHD RISK)
- CHD Risk calculation:
  1. select the CHOL and HDL results
  2. press  (ANNEX I – ASSESSMENT OF CHD RISK)
- Redox Index calculation:
  1. select the FORT and FORD results
  2. press  .
- AST/ALT ratio calculation:
  1. select the AST and ALT results
  2. press  .

The indirect assays can be calculated by selecting results obtained on the same day.

7.6.4.2 Result disassociation

To disassociate/remove the result from the client's file, press  .

7.6.5 EDITING CLIENT PERSONAL DATA

Select the client by touching the corresponding line and press  .

Enter/Edit the personal data of a client.

7.6.6 DELETE A CLIENT

From the list, touch the line corresponding to the client you wish to delete and then press  .

7.7 RESULTS

From the "Results" screen, you may view:

- the results of the last 100 tests performed by the device (Client results);
- the results of the autotests performed by the device (Results of autotest);
- the results of the optical/chemical controls performed by the device (Checks results).

7.7.1 CLIENT RESULTS

The results of the last 100 tests, in chronological order from the most recent to the oldest, are stored automatically and distinguished by date/time, type of test and client ID, if any.

When the maximum number of data that can be stored is reached, the most recent results progressively replace the oldest data.

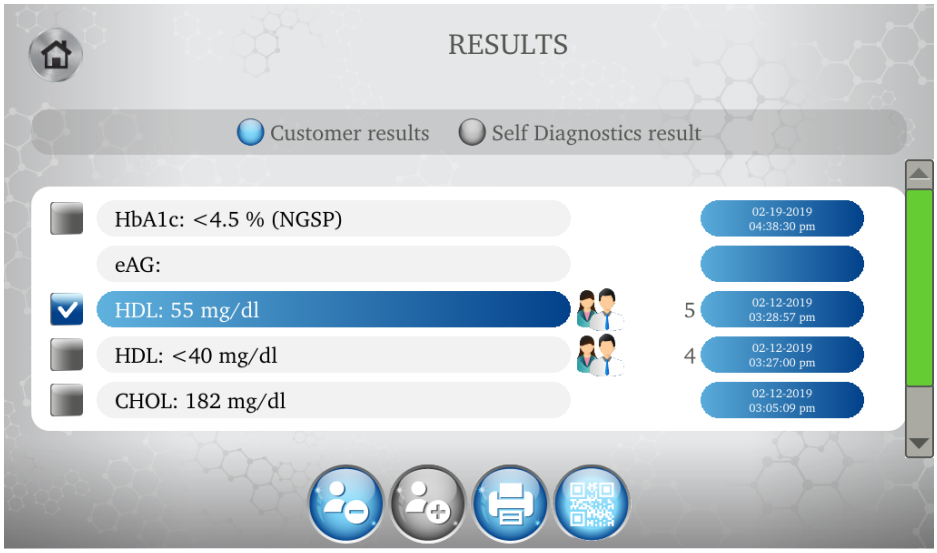


Figure 24

7.7.1.1 Save results

To select one or more results, touch the corresponding tick box.

The selected results can then be saved under a client by pressing .

7.7.1.2 Result disassociation

To disassociate the result that was previously associated with the client, press .

7.7.1.3 Print results (optional)

To select one or more results, touch the corresponding tick box.

The selected results can then be printed by pressing and entering the same PIN to access the Clients area (see 7.6.1). The PIN is required to be entered only for results assigned to clients.

7.7.1.4 How to view the QR code containing results

Select the flagged result. The QR code is displayed by pressing and entering the same PIN to access the Clients area (see 7.6.1). The PIN is required to be entered only for results assigned to clients.

7.7.2 RESULT OF AUTOTEST

The list shows the results of the autotest carried out every time the device is switched on in chronological order from the most recent to the oldest.

The results come with a graphical indicator showing if the test passed or failed (for the icons, refer to the list of main icons described in par. 7.1).

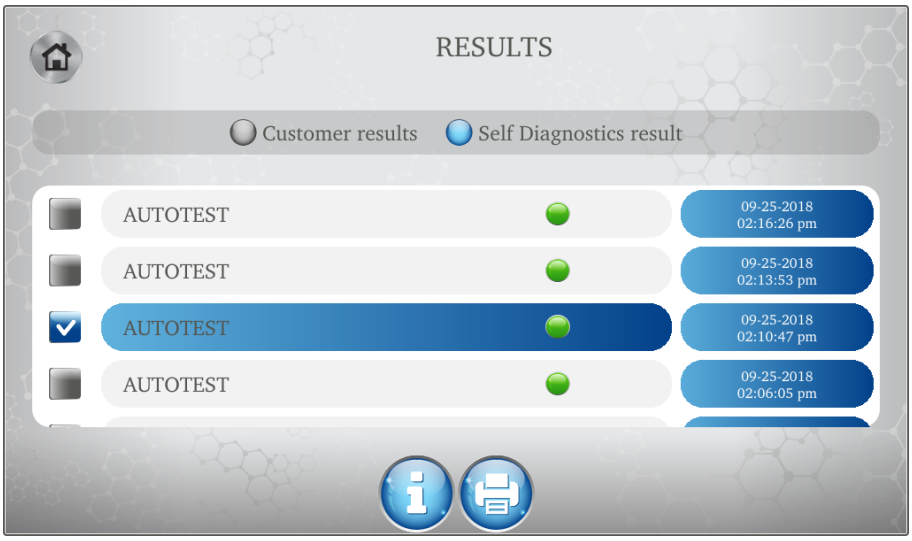


Figure 25

7.7.2.1 View results

In order to select a result, touch the corresponding tick box.

The selected result can be viewed in detail afterwards by pressing  .

7.7.2.2 Print results (optional)

To select one or more results, touch the corresponding tick box.

The selected results can then be printed by pressing  .

- **From PC:**

  Connect the Clini5 to LAN/WIFI
  From any device connected to the printer (pc, tablet etc.), open a browser and type in the following address:

  a) http://(IP address) (ex: http://10.0.3.124) (see Figure 19)

  b) http://(serial number Clini5) (ex: http://C50000000014)

7.7.3 CHECKS RESULTS

The list shows the results of the Checks carried out by the device, in chronological order from the most recent to the oldest. The results come with a graphic indicator showing whether the test was passed or failed (for the icons, refer to the list of main icons described in par.7.1).

7.7.3.1 How to view results

In order to select a result, touch the corresponding tick box.

The details of the result selected can be viewed by pressing  .

7.7.3.2 Print results (optional)

To select one or more results, touch the corresponding tick box.

The selected results can then be printed by pressing  .

- **From PC:**

  Connect the Clini5 to LAN/WIFI

  From any device connected to the printer (pc, tablet etc.) open a browser and type in the following address:

  a) http://(IP address) (ex: http://10.0.3.124) (seeFigure 19)
  b) http://(serial number Clini5) (ex: http://C50000000014)

7.8 SETTINGS

The settings screen contains the following submenus:

- Device Information
- Date/time
- Language
- Logo and heading
- Tutorial/Standard Mode
- Gesture Setting
- Assay Setting
- Video tutorial
- Software upgrade
- Maintenance and Checks
- Wi-Fi (enable/disable)
- Ethernet
- Sound

7.8.1 GENERAL INFORMATION (or DEVICE INFORMATION)

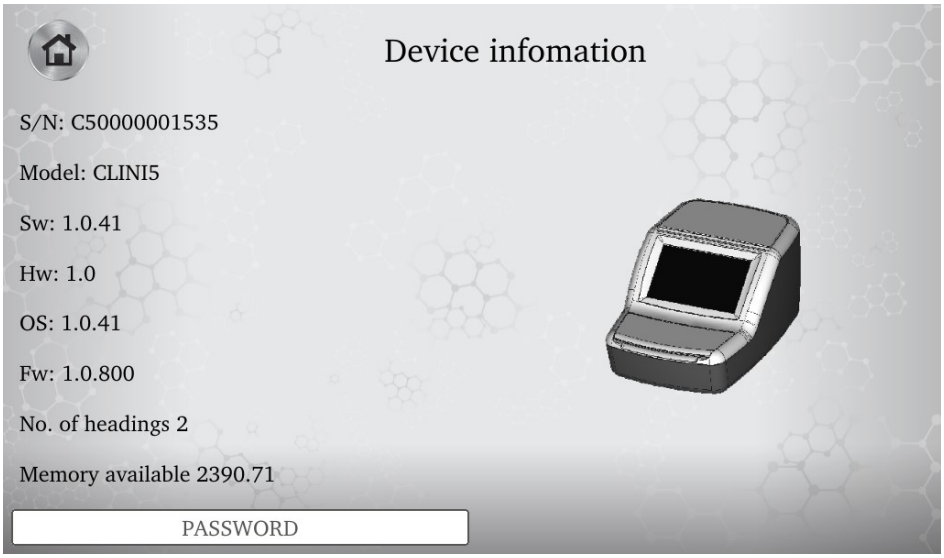


Figure 26

This screen displays:

- Serial number (S/N)
- Model
- Software version (SW)
- Hardware version (HW)
- Operating system version (OS)
- Firmware version (of micro board) (FW)
- Number of headings made
- Storage available

7.8.2 DATE/TIME

Adjust date and time of the device by modifying the contents of dedicated boxes.

7.8.3 LANGUAGE SETTING

To change the operating language, touch the icon corresponding to the desired language.

The device will be restarted.

ATTENTION: changing the language might entail changes to some settings of the device.

7.8.4 LOGO AND HEADING

In this menu, you may set the logo and header which will be used to view and print the results.

⚠	You are free to enter the logo and header the first time. After that, should the header require changing, contact Callegari Srl for the required password.

7.8.4.1 Setting the logo

Insert USB key with the logo (.png format).

Press the 'import' button: the desired logo will be imported.

To remove the logo press the "DELETE" button

7.8.4.2 Setting the header

Touch the text input lines and enter the desired data (Company name, address, phone number etc.)

Press "CONFIRM" to confirm the selections made.

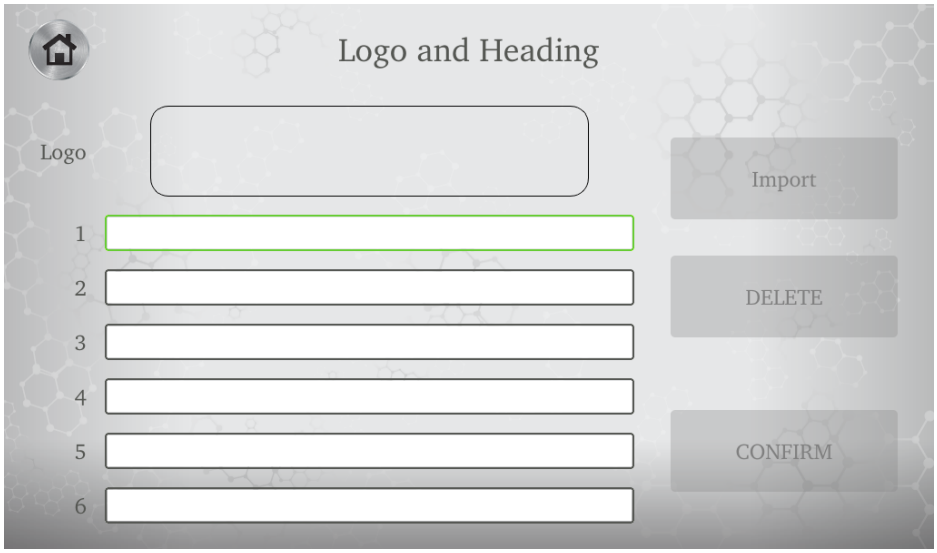


Figure 27

⚠	When the selection is confirmed, the header can only be modified by requesting the specific password from Callegari S.r.l.

7.8.5 Wi -Fi

Activate or deactivate the Wi-Fi.

It is disabled by default.

After activation, the available networks are displayed allowing the user to connect to one of them.

If a network is already saved, it connects automatically.

It is possible, however, to delete a network from the list to eliminate automatic connection.

ATTENTION: the Wi-Fi is optional and supplied via USB dongle

7.8.6 ETHERNET

Sets the parameters for the wired network.

By default it is in DHCP mode.

7.8.7 ACTIVATE/DEACTIVATE TUTORIAL MODE

By selecting this item, it is possible to enable/disable the tutorial mode (see 7.5.2.1).

7.8.8 ASSAY SETTINGS

It allows users to select either measurement units: traditional or international system (SI) (Figure 28_1).

It allows users to select the measurement unit of each single assay: either traditional and/or the international system (SI) (Figure 28_2).

It allows users to enable or disable the normal values for each assay (Figure 28_3).

It allows users to modify the k-factor: the correct k factor for a test is shown on the package of the original Callegari Srl reagents. Make sure that the k-factor matches that shown on the label (Figure 28_4).

It allows users to enable or disable the presence/absence check of a blood sample in the cuvette (Figure 28**Errore. L'origine riferimento non è stata trovata.**_5).

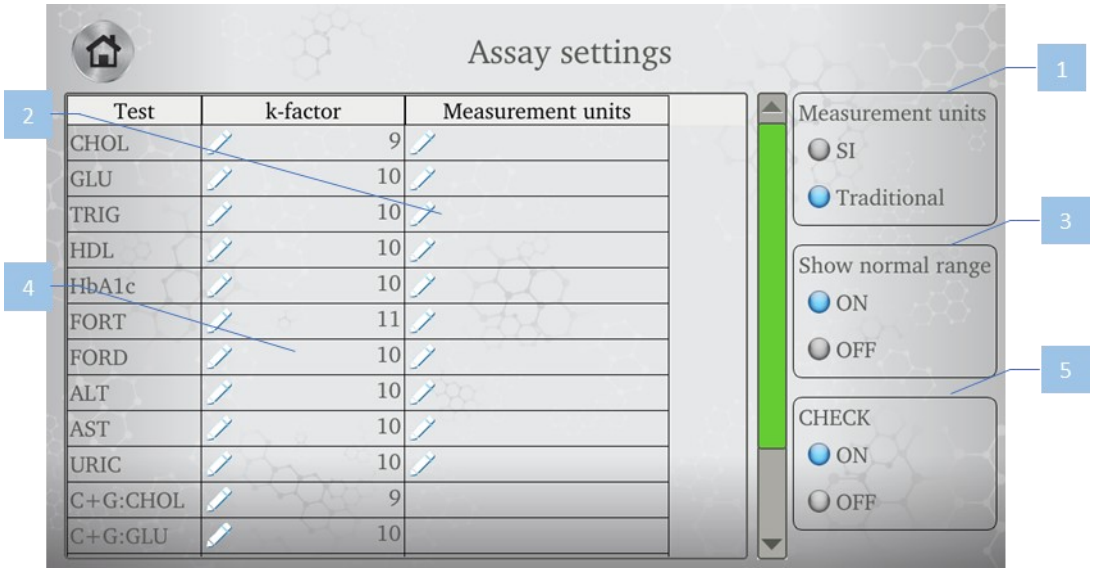


Figure 28

7.8.9 CHECKS

This section allows users to perform controls and settings on the device to ensure the best performance. This section includes:

7.8.9.1 Auto-setup

This function can be selected by the user or prompted by the software and indicated at the end of the autotest.

Free the cells from any cuvettes and cover the cells with the specific lid to prevent external light from entering.

By pressing the “Auto-setup” button the device performs self-adjustments which could take a few minutes.

NOTE: before launching the auto-set, the device must have reached the operating temperature.

7.8.9.2 Optical check

This function allows users to perform a check of the correct optical operation of the device, using the specific Prism Control. After selecting Optical Check:

i. Select the reading cell to be checked
ii. As requested by procedures displayed on the screen, perform the first reading covering the empty reading cells with the provided lid. Next, insert the prism indicated in the procedure of the Clini5 Prism Check
iii. Enter the reference value shown on the label of Clini5 Prism Check

NOTE: To access this section the device must have reached the operating temperature

	*Attention – Before performing the optical check, refer to the Prism package inserts (IFU) and Manual.*

7.8.9.3 Chemical check

It allows users to perform the check of the Clini5 system for determination of the parameters tested on whole blood by using the control solutions provided by Callegari.

After selecting Chemical Check:

i. Select the assays and the reading cell to be checked
ii. Follow the instructions on the screen; use the control solution of the selected test as the sample
iii. Enter the reference value shown on the label of Clini5 Check

NOTE: To access this section the device must have reached the operating temperature

	*Attention – Before performing the optical check, read the Prism Check Manual carefully*

7.8.10 VIDEO TUTORIAL

A video file list opens showing the procedures to carry out for each test on Clini5.

Select the test and start the video.

Video commands:

Touch display to pause/resume; press to exit.

7.8.11 SOFTWARE UPGRADE

Two software update options are available:

a. Manual update

1. Insert the USB stick that contains the update;
2. Press to start the update;
3. Remove the USB stick only after the device has automatically restarted.

b. Automatic update

1. To obtain the activation code, please contact the Callegari customer service or an authorised distributor, providing the information displayed on the screen: S/N of the device and consecutive number;
2. Make sure you have a stable Internet connection (preferably a wired Ethernet connection);
3. Enter the code provided by the Callegari customer service or an authorised distributor;
4. Press to start the update;
5. Wait for the device to restart automatically.

7.8.12 GESTURE SETTING

Enable or disable the gesture sensor.

8 MAINTENANCE

8.1 CLEANING AND DISINFECTION

	**Risk of infection** There is a potential risk of infection. Users must treat any object that came into contact with human blood as a potential source of infection. ▪ Wear gloves. If the gloves tear during cleaning/disinfection, you must remove them and carefully wash your hands with soap and water. ▪ Use proper detergents and disinfectants. ▪ Dispose of cleaning waste correctly. ▪ Do not eat, drink or smoke during cleaning operations.
	**Damage to the device caused by the use of inadequate detergents** ▪ Clean and disinfect with the recommended materials. ▪ Thoroughly dry the device after cleaning. ▪ Do not use abrasive detergents or sharp objects.
	**Damage caused by the ingress of liquids** Before cleaning or disinfecting the device, switch it off and unplug it. ▪ Do not allow liquids to enter the reading cells. ▪ Do not spray liquids directly on the device/do not dip it in any type of liquid. ▪ Thoroughly dry the critical parts that came into contact with liquids (sockets, plugs, power supply etc.). ▪ Do not allow any liquid to enter the internal parts of the instrument.
	**Damage caused by aggressive chemicals** ▪ Do not clean the device and accessories with aggressive chemicals, such as acids and bases, acetone, formaldehyde, halogenated hydrocarbons or phenols or pure ethyl alcohol. ▪ Clean the device with recommended systems only.

➢ Clean the device daily and whenever contaminated by a potentially infectious agent.
➢ Before cleaning or disinfecting the device, switch it off and unplug it.

8.1.1 DISINFECTANTS WHICH CAN BE USED

To disinfect the device, we recommend using commercial virucidal and bactericidal disinfectants specific for medical devices (e.g. chlorhexidine and 2 quaternary ammonium salts in an ethyl and propyl alcohol solution with max alcohol percentage 50%).

Alternatively use a water and alcohol solution (ethyl or isopropyl alcohol) max 50%.

Do not wear gloves with talcum powder during the cleaning operations.

For cleaning: Use soft, dry and lint-free cloths and/or lint-free cotton pads.

8.1.2 CLEANING AND DISINFECTION OF CASING

Switch the device off and unplug it.

Clean the device to eliminate dirt and organic material, before disinfecting it, using a cloth moistened with water.

Then disinfect the device by soaking a soft and a lint-free cloth with an appropriate disinfectant.

8.1.3 CLEANING THE DISPLAY

To clean the display, use isopropyl alcohol solutions only between 70 and 99% in concentration or plain water.

- Switch the device off and unplug it.
- Then disinfect the device by soaking a soft and lint-free cloth with disinfectant.
- Immediately dry with a dry cloth.

8.1.4 CLEANING THE READING CELLS

Switch the device off and unplug it.

- Clean the reading cells with a cotton swab slightly moistened with a disinfectant.
- Do not pour or spray any solution directly into the reading cells or on the display.
- Do not place sharp objects or your fingers in the reading cells while cleaning.
- Plug the device back in only after completely drying it.

To prevent dust from depositing in the reading cells, cover the cells using the lid supplied when testing is over.

8.1.5 CLEANING THE WORK STATION LID

- For the work station lid: thoroughly clean the cuvette and Eppendorf pipette support elements with a cotton swab moistened in water and alcohol.
- Always keep the device, especially the reading cells, protected against dust by using the specific lid supplied.

8.1.6 CLEANING THE CROCODILE CLIPS FOR CAPILLARY HANDLING

- Clean the crocodile clips for capillary handling with paper towel moistened in a virucidal and bactericidal disinfectant.
- Always keep the device, especially the reading cells, protected against dust by using the specific lids supplied.

8.1.7 CLEANING AND DISINFECTING THE WORK SURFACE

- After each use, clean and disinfect the work area surrounding the device with a specific virucidal and bactericidal disinfectant.

8.2 PIPETTE

Callegari S.r.l. recommends using the 50µl fixed-volume pipette supplied with the device only.

It is recommended to replace the pipette in case:

1. The pipette was dropped/has been damaged
2. The pipette plunger does not move smoothly but it jolts

	If liquid was suctioned without using the specific disposable tip, the pipette must be discarded off and replaced immediately.

8.3 BALANCES FOR THE CENTRIFUGE

Callegari S.r.l. recommends using Centrifuga 6000 (cod. AD-126136) only.

We recommend checking the balancing cuvettes supplied with the centrifuge or included in the package of the device every two months (refer to the User manual of the centrifuge).

If you notice that liquid in the balancing cuvette has evaporated, excessive noise or an increase in vibrations during centrifugation, contact the assistance service.

9 BIOCHEMISTRY AND PROCEDURES

Detailed biochemistry information and instructions are found in the package inserts of each reagent.

ANNEX I – ASSESSMENT OF CHD RISK

The software scores the percentage risk of a cardiovascular event (e.g heart attack or stroke) happening within the next ten years based on the values of total cholesterol and HDL and the following risk factors:

- Gender (M/F)
- Age (20-79)
- Smoking habit (Yes/No)[5].
- Systolic diastolic blood pressure, PAS, mmHg (<120, 120-129, 130-139, 140-159, >160)
- Current treatment with antihypertensive drugs, PAS treated (Yes/No).

The risk assessment is not applicable in case of:

- Individuals aged <20 and >79 years
- Coronary heart disease and/or diabetes
- Pregnancy.

The risk is estimated by calculating the individual scoring according to the model of the Framingham study approved by the Public Health Department of the United States (NIH, National Institutes of Health, Publication No. 02-5215, September 2002 – Final report of the Third Report of the National Cholesterol Education Program (NCEP) -Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Adult Treatment Panel III).

Execution of risk assessment with Clini5:

- Execute the tests in standard mode by selecting the CHD risk or LDL test (from the Assay panel).

When the tests are completed, the following screen is displayed when the print command is given:

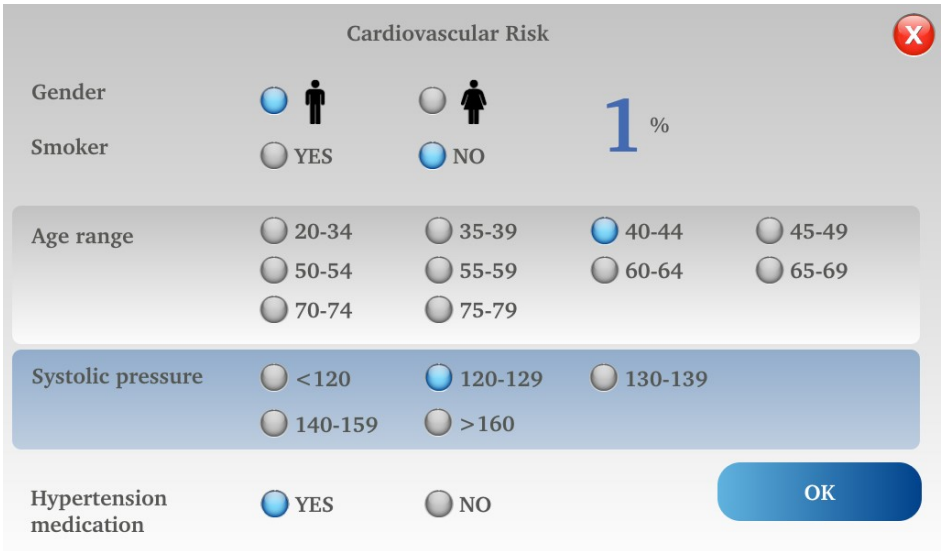


Figure 29

N. B.: By selecting in LDL test, the CHD Risk assessment will not be executed.

Enter the individual's information. The percentage of risk displayed is updated in real time by selecting/changing the options.

[5] Only individuals who have not smoked even one cigarette in over one month are considered ex-smokers.

ANNEX II - CLINI5 TROUBLESHOOTING

In case of a serious incident, as defined in Article 2(68) of the Regulation (EU) 2017/746, contact Callegari Assistance centre immediately.

PROBLEM/ERROR DISPLAYED	*CAUSE*	SOLUTION
Autotest failed	*Power supply problems*	Check that the cables are connected properly. Switch off Clini5. Unplug the device and plug it back in. If the message persists, contact the Assistance Centre.
	Cuvette inserted in one or more cells	Switch off Clini5. Free the cells from any cuvettes still inserted. Check that there are no foreign objects inside the cells or excessive dust and dirt. Switch the device back on. If the message persists, contact the Assistance Centre.
	LED not working/presence of foreign bodies or dirt inside reading cells	Switch off Clini5. Check that there are no foreign objects inside the cells or excessive dust and dirt. Switch the device back on. If the message persists, contact the Assistance Centre.
One or more reading cells do not work	*Cell deactivated automatically by the system after failure of the autotest*	Power cycle the device. If the cell is still shown as not working when the device is restarted, contact the Assistance Centre.
	Cuvette presence sensor not working	Contact the Callegari Assistance Centre or your local distributor.
	Dirt/foreign objects inside the reading cell	Remove the foreign object/dirt if possible. Contact the Callegari Assistance Centre or an authorized distributor.
The device does not switch on	*Power failure*	Check that the supplied power supply is connected to the socket and that the jack is inserted in the power socket of Clini5. Check that the green light on the power supply unit is on.
		Press the ON/OFF button at the back of the device. If the problem persists, contact the Callegari Assistance Centre or an authorized distributor.
The display does not switch on	*Power failure /faulty display*	Check that the device is plugged in as described above. Switch the device on by pressing the ON/OFF button at the back of the device. Wait a few seconds and check whether a red light can be seen inside the reading cells. If a red light is seen, contact the assistance service and report the defect on the display.

PROBLEM/ERROR DISPLAYED	*CAUSE*	SOLUTION
Unexpected values (incorrectly too high or too low)	*The wrong type of disinfectant was used*	Use only the disinfectants recommended (Refer to the information leaflets of the reagents). Allow the skin to dry before taking the sample. E.g., disinfectants containing glycerol and/or H_2O_2 interfere with the reaction of some parameters, including cholesterol, triglycerides, FORT and FORD thus reducing the accuracy of the results.
	The blood sample was not taken correctly	Do not provoke haemolysis; do not apply excessive pressure on finger. Remove the first blood drop. Capillary blood must be analysed immediately after blood sampling. Venous blood drawn in the presence of appropriate anticoagulants can be preserved at 2-8°C for 4-6 hours (Refer to the assay package insert of the reagents). When performing parameters entailing use of the centrifuge, check that the supernatant obtained by centrifugal force is transparent.
	The volume of the sample is not correct	Do not allow air bubbles to form while collecting the blood (this causes lower readings). Make sure that the capillary or the tip of the pipette with which the sample is taken fills correctly (the results will be lower if not completely filled). If taking the sample with a pipette, make sure the tip is placed into the liquid. Eliminate any excess blood on the outer surface of the capillary or of the tip (this causes higher values), by wiping on the fingertip only.
		Completely empty the capillary or tip (if not emptied, the results will be incorrectly low). The solution inside the capillary and test tube must have the same colour, indicating a uniform dilution of the sample.
	Presence of chelating agents, iron and/or antioxidants in the sample	Substances such as EDTA, desferal, D-penicillamine, citric acid and its salts, BHT, BHA, ascorbic acid (vitamin C), etc. interfere with the reaction of some parameters giving rise to unreliable values (Refer to the information leaflets of the reagents).
	Position of the capillary in the cuvette	When present, the capillary must be placed in a corner so that it does not interfere with the light beam. If necessary, move the capillary by lightly tapping the cuvette, held in slightly tilted position.
	Condition of the cuvette	Remove any streaks and/or fingerprints with a soft dry cloth. Check that the walls of the cuvette are undamaged.

PROBLEM/ERROR DISPLAYED	*CAUSE*	SOLUTION
Unexpected values (incorrectly too high or too low)	*Wrong procedure*	Conduct the tests according to the provided instructions. Ensure the correct amount of enzyme has been used and that it has been added at the right step of the procedure.
	Anomalous haematocrit values	Haematocrit values between 37% and 48% do not influence results.
	Condition of reagents	Store reagents at the right temperature as indicated in the package inserts and labelling. Enzyme reagents and kits for glycated haemoglobin, HDL, ALT/GPT and AST/GOT must be stored at + 2 to + 8°C.
Warming-up system not working	*Temperature sensors not working*	Contact the Callegari Assistance Centre or an authorised distributor.
Access denied to Assay panel	*Warming up not completed*	Wait 15-20 minutes until warming up is completed.
		Check that the room temperature is between 15°C and 30°C. If not, move the device to premises where the temperature is within that range.
	Warming up not completed	Check that the room temperature is within the range indicated. If the temperature returns to that range, wait at least one hour and try to access the Assay panel again. If the problem persists, contact the Callegari Assistance Centre or an authorised distributor.
Indication of very high temperature	*Clini5 is in premises with higher temperatures than the recommended work conditions*	Check the temperature range indicated in the manual. Switch the instrument off and move it to appropriate premises. Clini5 will resume regular operation when it returns to the indicated temperature values.

ANNEX III - CLINI5 – ERROR MESSAGES

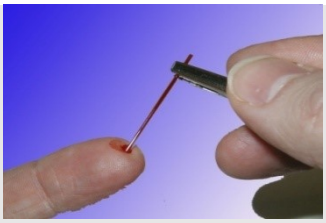
Message code	Description of the problem	Message
MSG01	Signal check failure	WARNING: reading cell x signal check failure. Reading cell disabled.
MSG02	Blanking performed without blood (incorrect)	WARNING: Ensure blanking is performed with blood sample
MSG03	Blanking performed with blood (incorrect)	WARNING: Incorrect blanking. Ensure blanking is performed without blood sample
MSG04	No reading cell available	WARNING! No reading cell available
MSG05	Blanking values too high	WARNING: Blanking error I. Check: capillary tube volume/capillary tube has been emptied/ haematocrit range of sample
MSG06	Blanking values too low	WARNING: Blanking error II. Check: capillary tube volume/capillary tube positioning/ haematocrit range of sample
MSG07	Presence sensor reading below the critical threshold (reading cell occupied)	WARNING: Ensure reading cell x is empty
MSG08	Insufficient signal	WARNING: Ensure reading cell x is empty
MSG09	Temperature sensor 1 damage	Temperature sensor error. Contact customer service
MSG10	Temperature sensor 2 damage	Temperature sensor error. Contact customer service
MSG11	No USB stick detected	No USB stick detected
MSG12	Invalid data	Invalid data
MSG13	Presence sensor fault	WARNING: reading cell x presence sensor fault. Reading cell disabled
MSG14	Photodiode signal lower than the minimum allowed threshold	WARNING: reading cell x Signal error. Reading cell disabled.

Message code	Description of the problem	Message
MSG15	Temperature measured by temperature sensors too different	Temperature sensor malfunction. Contact customer service
MSG16	Wrong Password	Invalid Password
MSG17	Auto-set of reading cell x not possible: it's occupied	WARNING: reading cell x Cannot auto-set. Reading cell is occupied
MSG18	Auto-set of reading cell x not possible: signal incorrect within the allowed threshold	WARNING: reading cell x incorrect signal. Reading cell disabled
MSG19	Auto-set not possible. Warming in progress	WARNING: Warming in progress.
MSG20	Incorrect PIN	INCORRECT PIN
MSG22	Software update not available/ no USB stick	WARNING: No update available. Check that the USB stick has been inserted and or update available (directory root)
MSG23	Update failed	WARNING: Update failed
MSG24	Result saving failed	Insufficient memory. Saving failed. Perform backup to free up space
MSG25	No internet connection	No connection
MSG26	System error	SYSTEM ERROR

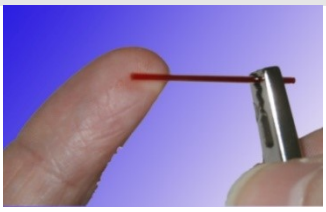
ANNEX IV: HOW TO TAKE A CAPILLARY BLOOD SAMPLE

1. Prepare the finger-pricker (use only products with CE marking), disinfectant, cotton, reagent tubes, clips, capillaries. The individual needs to remain seated and relaxed for a few minutes before taking the sample.
2. Milk the fingertip
3. Disinfect and let it dry well
4. Prick firmly
5. Remove the first drop of blood

6. Have a second large drop flow out
7. Collect the desired volume keeping the capillary tube slightly tilted downwards



8. Wipe away any excess sample on the outer walls of the capillary on the finger



9. Transfer the sample into the cuvette of the test to be executed

ANNEX V: REFERENCE VALUES[6]

Parameter	*Traditional System*	*International System*	*Conversion Factor*[7]
HAEMATOCRIT	Men: 42-52% Women: 37-47%		
HAEMOGLOBIN	Men: 14.0-17.4 g/dl Women: 12.0-16.0 g/dl	140-174 g/l 120-160 g/l	0.1
ERYTHROCYTES	Men: 4.20-5.40 million/mmc Women: 3.60-5.00 million/mmc		
TOT. CHOLESTEROL	<190 mg/dl	<5.00 mmol/l	38.6
HDL CHOLESTEROL	>40 mg/dl	>1.04 mmol/l	38.6
LDL CHOLESTEROL	<115 mg/dl	<2.98 mmol/l	38.6
TRIGLYCERIDES	<150 mg/dl	<1.69 mmol/l	88.5
GLYCAEMIA	<100 mg/dl	<5.55 mmol/l	18.02
URIC ACID	Men: 3.4-7.0 mg/dl Women: 2.4-6.0 mg/dl	0.20-0.42 mmol/l 0.14-0.36 mmol/l	16.7
ALT/GPT	Men: < 43U/l Women: < 36U/l		
AST/GOT	Men: < 38U/l Women: < 31U/l		
FORT	< 310 units FORT	< 2.36 mmol/l H_2O_2 eq.	131.6
FORD	1.07-1.53 mmol/l Trolox eq.		
HbA1c[8]	***NGSP*** Non diabetic <6%	***IFCC*** Non diabetic <42mmol/mol	IFCC= (NGSP*10.93)–23.5

[6] The reference ranges of each parameter are similar to those obtained by analysing serum or plasma with standard laboratory methods (details and bibliography are provided in the instruction leaflets of the reagents). The reference ranges shown by the device are used as a guide to understand results. In the event results are outside of the normal ranges, always consult a qualified medical professional before taking any action.

Since the reference values can vary based on demographic factors such as age, gender and genetics, as well as geographic origin, **it is recommended to refer to the normal ranges for the population taking the test.**

[7] To convert a result from the Traditional System (mg/dl) to the International system (mmol/l), divide the value in mg/dl by the corresponding conversion factor. Clini5 automatically switches from one System to another (see Settings Menu→ Unit of Measurement).

[8] The values are consistent with those recommended by the Diabetes Control and Complications Trial (DCCT) and included in NGSP (National Glycohemoglobin Standardization Program) format standardization method acknowledged in all Countries. Operators can convert NGSP/DCCT values into IFCC (International Federation of Clinical Chemistry) values. Clini5 automatically switches from one system to another (see Settings Menu→ Unit of Measurement → HbA1c).