FRAS 5

USER MANUAL

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Produced and distributed by:

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INDEX

		Pag.
	Declaration of responsibility	3
	Safety precautions	3
	Table of symbols	4
1.	**GENERAL DESCRIPTION**	5
1.1	Preface	5
1.2	Technical characteristics	5
1.3	Device description	6
1.4	Limitations	8
2.	**INSTALLATION AND PRELIMINARY OPERATIONS**	9
2.1	Transport, storage and unpacking	9
2.2	Box contents	9
2.3	Device installation	10
2.4	Device uninstallation	10
3.	**USE OF THE DEVICE**	11
3.1	Switch-on	11
3.2	Main menu	12
3.3	Tests menu	12
3.4	Settings menu	12
3.5	Centrifuge	13
3.6	Printer paper replacement	13
3.7	Functional check	14
3.8	Device storage and maintenance	14
3.9	Fuses replacing	14
4.	**TEST EXECUTION**	17
4.1	REDOX O.B.	17
4.2	OSI REDOX indexes	21
4.3	SAT TEST	22
5.	**MALFUNCTIONS**	25
6.	**MAIN CAUSES OF ERRORS IN TEST EXECUTION**	26
6.1	The most common causes of errors in the pre-analytical phase	26
6.2	The most common causes of errors in the analytical phase	27

DECLARATION OF RESPONSIBILITY

H&D srl disclaims any responsibility deriving from improper use, or from use not in accordance with these IFUs, of this IVD.

H&D srl disclaims any responsibility for damage due to modifications made to the hardware and software by unauthorized people.

H&D srl disclaims any responsibility for damage due to connections to other instruments made by unauthorized people.

If the device is damaged or suspected to be damaged, it must not be switched or repaired by unauthorized personnel, please contact immediately H&D srl (+39 0521-462607 - support@hedsrl.it).

The manufacturer reserves the right to change the information contained in this manual without notice.

Consult this manual before installing and using FRAS5

SAFETY PRECAUTIONS

- ✓ Before switching on the device, ensure that the supply voltage is as required.
- ✓ Device is only suitable for operation with an earthed electrical system.
- ✓ If the instrument is damaged, do not connect it to the electrical grid until it has been repaired by authorized personnel.
- ✓ Disconnect the device if not in use for a long time.
- ✓ Any repair must be carried out by authorized personnel.
- ✓ Do not open the device; there are no user-repairable or replaceable parts inside the instrument.
- ✓ Do not tamper with the device, loosen screws or insert foreign bodies (screwdrivers, bits, etc.) into the existing openings.
- ✓ Take care to avoid the penetration of liquids inside the device; if this should happen by accident, disconnect the device from the electrical grid and do not reconnect it until the instrument has been checked by authorized personnel.
- ✓ In the event of a malfunction of the device, device must not be switched on and please contact H&D srl.

The use of biological samples presents a significant biological risk and must therefore be performed with extreme caution.

TABLE OF SYMBOLS

Number	Symbol	Description
1		Alternating current
2		Earth terminal
3		Gear (power supply)
4		Shutdown (power supply)
5		Warning of risk of electric shock
6		Warning of generic risk
7		Warning of biological risk
8		CE marking
9		Electric fuse
10		In vitro diagnostic medical device
11		Serial number
12		Manufacturer
13		UDI (Unique Device Identifier)

CHAPTER 1

General description

1.1

PREFACE

FRAS 5 is an in vitro diagnostic medical device according to REG 2017/746, class A in compliance with Rule 5 of Annex VIII of REG 2017/746.

FRAS 5 is a POCT photometer (Point Of Care Testing) IVD test used for the analysis of oxidative stress, with the **d-ROMs test**, and of the antioxidant potential, with the **PAT test**, on heparin plasma blood and of the antioxidant potential on saliva, with the **SAT** test.

The tests that can be performed on FRAS 5 are colourimetric; the measurement of the various analytes is proportional to the color of the analysis solution. In order to guarantee a better repeatability and speed of the test, the reading compartment is thermostatically controlled at 37 ° C.

1.2

TECHNICAL CHARACTERISTICS

General characteristics		
Dimensions	40(l) x 26,5(w) x 13 (h) cm	
Weight	2,6 kg	
Distribution	1 fase, neutral to earth	
Power supply	100 ÷ 240 VAC - 50 - 60 Hz	
Consumption	60 W	
IP protection class	IP30	
Interface	3-inch backlit touchscreen	
Integrated accessories	Centrifuge, 1800 G (2 compartments, that can be increased to 4) Thermal paper printer	
Operating conditions:		
Temperature	15 ÷ 32 °C (working) 0 ÷ 50 °C (turned off)	
Relative humidity	20 ÷ 80 % (working) 0 ÷ 90 % (turned off)	
Altitude	< 2000 m (working)	
Sonic pressure	<75 dBA	
Analytical test performance:		
d-ROMs test	Analyte	Blood peroxides
	CV%	<5%
	Unit of measure	U.Carr (0,08 mg/dl H_2O_2)
PAT test	Analyte	Blood iron-reducing power
	CV%	<5,5%
	Unit of measure	U.Cor (1,4 µM VitC)
SAT test	Analyte	Salivary iron-reducing power
	CV%	<5,5%
	Unit of measure	µM VitC

1.3
DEVICE DESCRIPTION

Figure 1 - Overall view of the device

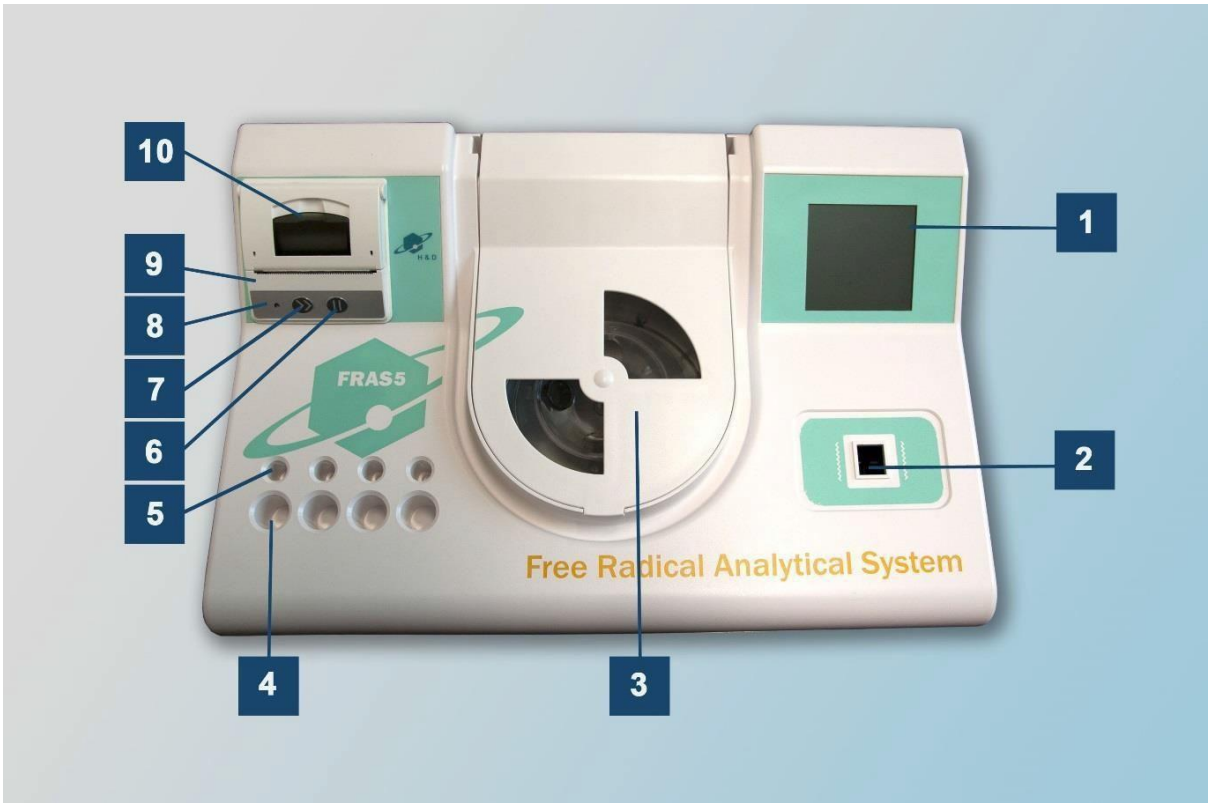


Figure 2 - Front panel with indication of the components

Ref. N.	Name	Notes
1	Display	
2	Reading room	Its temperature is stabilized at 37 ° C
3	Centrifuge door	
4	Cuvettes storage compartments	
5	Microvettes and microtubes storage compartments	
6	Printer pause button	Pressing this button puts the printer in pause; any printing in progress is suspended. Press again to return the printer to the active state.
7	Paper forward button	Pressing this button determines the forward of the paper strip.
8	Printer status LED	
9	Printer	
10	Paper compartment opening lever	Allows the opening of the paper compartment to replace the roll.

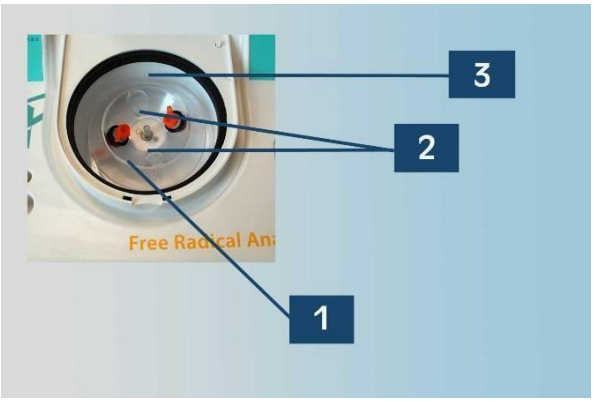


Figure 3 - Detail of the centrifuge compartment with indication of the components

Ref. N.	Name	Notes
1	Rotor	
2	Microvette locations	The microvettes are inserted into the appropriate adapters
3	Capsule	

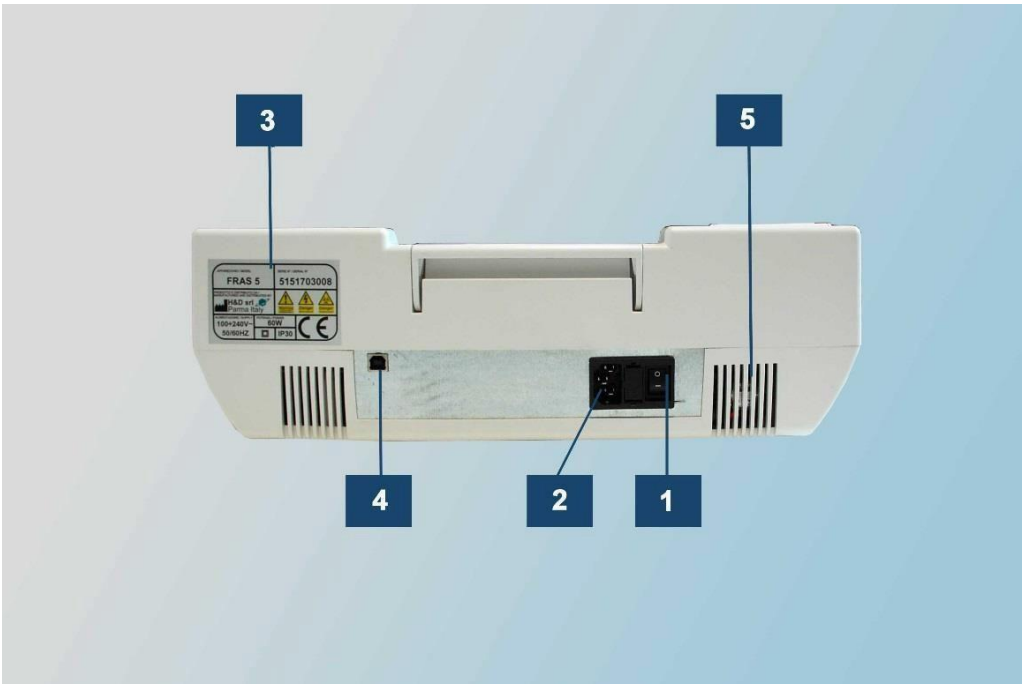


Figure 4 - Rear Panel with Parts Indication

Ref. N.	Name	Notes
1	Switch	Allows the instrument to be switched on. To switch on move the switch to the 'I' position and to the 'O' position to switch off.
2	Power supply socket	For connection to the power grid (with the supplied cable).
3	Identification plate and warning label	Serial number and technical and manufacturer information are stated.
4	USB interface	USB Type B socket for connection to the computer, with a USB cable (accessory), required in cases of device's software updating
5	Fan	

1.3

LIMITATIONS

FRAS 5 is specifically designed to be used only with d-ROMs test, PAT test and SAT test, manufactured and distributed by H&D srl.

FRAS 5 is specifically designed to be used only by healthcare personnel (doctors, nurses, pharmacists, biologists, etc.) and researchers.

CHAPTER 2

Installation and preliminary operations

Before opening the box, check its integrity.

2.1

TRANSPORT, STORAGE AND UNPACKING

TRANSPORT

The packed device has a weight of about 6.00 kg and about 3 kg without the packaging.
The packed device has a dimensions of 51 x 41 x 43.5 (h) cm and 40 x 26.5 x 13 (h) cm without the packaging.
No equipment is required for transport, loading and unloading.
The box must be handled in compliance with the warnings on the outside (TOP/BOTTOM).

STORAGE

The device must be kept in its original packaging, consisting of a box and suitable bumpers, and stored in compliance with the warnings applied on the outside (TOP/BOTTOM).
If during storage or transport the packaging is damaged, it is necessary to check that the instrument has not suffered any evident damage; the integrity of the packaging must therefore be restored before storage.
In case of damage contact the supplier.
The packaging guarantees reliable protection and insulation if the box is stored in a dry and dust-free environment.

UNPACKING

Unpack the instrument carefully. **Do not throw away the packaging and bumpers in case that the instrument has to be returned for assistance**. Move the device carefully, avoid turning it upside down.

2.2

BOX CONTENTS

Quantity	***Description***
2	Balance microvette
1	10 µL micropipette
1	40 µL micropipette
1	Power supply cable
1	USB cable
1	Cover device
2	Thermal paper rolls
1	Stylus
1	User manual
1	Certificate of Conformity

2.3
DEVICE INSTALLATION

FRAS 5 must be placed on a stable and clean surface in an environment with stable and controlled temperature and humidity, away from heat sources and magnetic fields.

The back of the instrument must be left free for a depth of at least 10 cm to ensure the correct operation of the cooling fan.

FRAS 5 can only be connected to the wall socket with the supplied cable. Once connected to the electrical grid FRAS 5 can be switched on with the button on the back.

FRAS 5 does not require calibration operations. When switched on, the device performs a self-test to check its overall functioning.

2.4
DEVICE UNINSTALLATION

Turn off device and disconnect the power cable from the wall socket.

Chapter 3

Use of the device

3.1 SWITCH-ON

Device can be switched on with a switch located on the left side of the back of the instrument (Figure 4).

When turned on, the following steps are automatically performed.

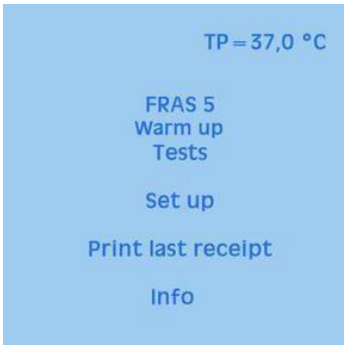
Instrument initialization and self-diagnosis.

The display briefly shows the following message:

Subsequently, the self-test phase begins, at the end of which, if malfunctions have been detected, a warning message is displayed.

HEATING

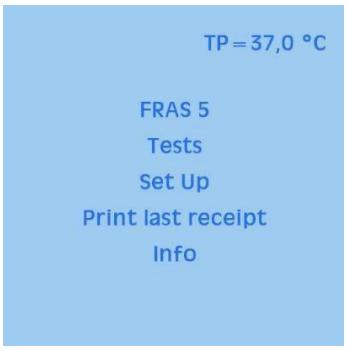
In the event that the heating phase of the reading compartment, which began when the instrument was switched on, has not yet finished, the display shows the words "heating" and the temperature flashing:



During the heating phase, the “Tests” menu is disabled while it is possible to access the “Settings” menu and the “Info” menu.

At the end of the heating phase, the device is placed in the **main menu**.

3.2
MAIN MENU



Select the desired menu.

> Tests: list of tests that can be performed with FRAS 5
> Settings: device settings menu
> Print last receipt: reprint of the last receipt
> Info: shows all the information available on the installed system, the serial number of the instrument and other useful elements to communicate to technical assistance in case of malfunctions

3.3
TESTS MENU

From this menu you can start the tests implemented in the device. Follow the instructions on the display (see chapter 4) and in the package leaflets attached to the tests.

To ensure the device functions correctly and to avoid inaccurate results, only use original H&D srl reagents.

Select the tests and press the → symbol to advance.

> REDOX O.B.: run the d-ROMs test, PAT test in sequence and calculate the OSI REDOX index
> d-ROMs: run the d-ROMs test only
> PAT: run the PAT test only
> SAT: run the SAT test only

3.4
SETTING MENU

Select the required menu and press the → symbol to advance. Within the menus, press √ to confirm the changes made or the ← symbol to exit without saving.

>LCD Contrast: adjust the contrast of the screen using the arrows
>Date and time: set the date and time using the arrows
>Language: select a language among Italian, English, German, Spanish, Portuguese and French
>Printer: disable or enable the printer
>Centrifuge: deactivate or activate the centrifuge
>Receipt header: customize the receipt header following on-screen instructions
>Cuvette sensor calibration: allows you to calibrate the cuvette presence sensor following the on-screen instructions
>Service: menu not accessible by the user

3.5

CENTRIFUGE

- ✓ **Always** use a balancing micro-tube, it can even be an empty micro-tube
- ✓ Place the cuvettes in opposite and non-adjacent holes of the rotor to balance their rotation

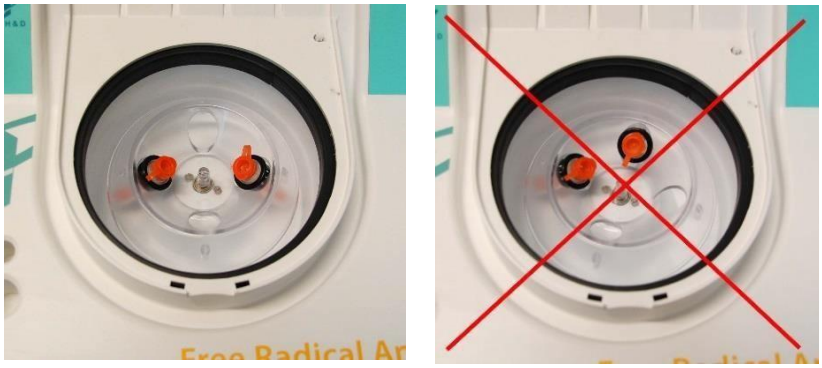


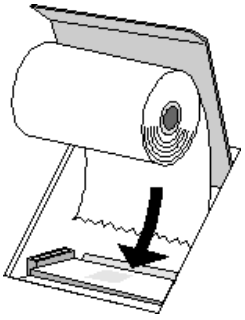
Figure 5 - Correct (left) and incorrect (right) positioning of the microtubes in the centrifuge

- ✓ Make sure the door is closed before starting the centrifuge; if it is not, the display shows a message of error.
- ✓ If the door is opened during centrifugation and kept open for more than 10 seconds, the test is aborted.

3.6

PRINTER PAPER REPLACEMENT

- ✓ Open the door of the paper compartment by lifting the dark tab upwards until a click is heard.
- ✓ Insert the roll into the paper compartment making the initial part of the roll come out.
- ✓ Close the paper compartment.



3.7

FUNCTIONAL CHECK

FRAS 5 does not need to be calibrated before its use but every two years it needs a functional check.
The functional check is performed by analyzing a serum with a known d-ROMs test and PAT Test called “Control Serum for FRAS 5” for the control of the d-ROMs test and the PAT test and a solution called “Calibrator for SAT test” for the control of the SAT test.

The instrument is considered functioning and correctly calibrated if the result of this analysis is consistent with the data reported on the label of the "Control Serum for FRAS 5" or the "Calibrator for SAT test”.

In case of incongruous results, contact H&D srl.

3.8

DEVICE STORAGE AND MAINTENANCE

The maintenance of the device must be guaranteed by the owner of the device itself and requires the following precautions:

- Keep the instrument in a dry and dust-free environment.
- Avoid sudden temperature changes when the device is working or in storage.
- Keep the instrument tidy and clean the shell of the device periodically or when necessary, with a soft and dry cloth; avoid vigorously rubbing the display to avoid damage.
- The inside of the reading compartment or the centrifuge can be gently cleaned with a gauze pad, if visible presence of dust or overflow of liquids.
- Disconnect the instrument from the electrical grid in case of prolonged inactivity, and cover it with the provided cover.

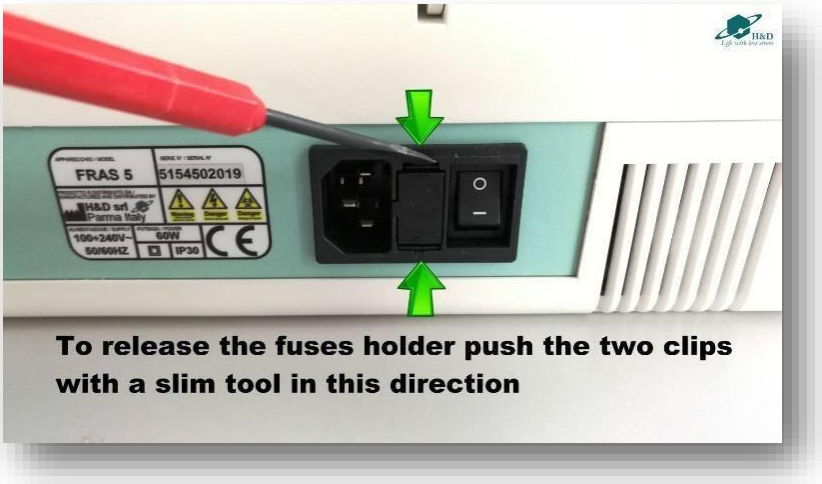
3.9

FUSES REPLACING

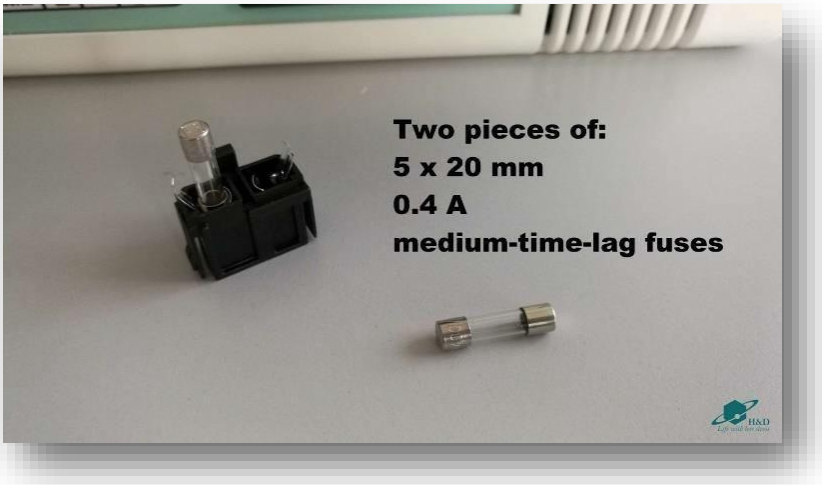
IMPORTANT NOTE: A blown fuse means that an overvoltage or an internal short circuit has occurred!
In the first case the instrument has been correctly protected and it is only necessary to replace the damaged fuse with a new one.
If these should blow again when switched on after replacing the fuse, the instrument is subject to an internal short circuit.
In the event of an internal short circuit, disconnect the instrument from the electrical grid and contact H&D srl (+39 0521-462607 – support@hedsrl.it)

The fuses are located in the back of the device between the switch and the power supply socket.

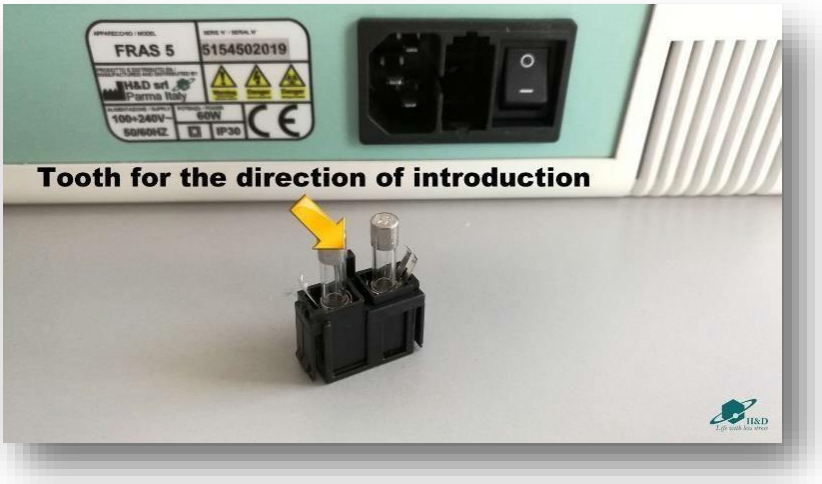
To check and, if necessary, replace the blown fuse(s), unhook the fuse holder.



Fuse technical characteristics: 5x20mm 0,4A medium-time lag



The holder has a tooth which indicates the correct direction of introduction and which must be held on the left side.



Make sure that you have inserted the holder correctly. This happens when it has been pressed until you hear a “click”.

CHAPTER 4

Test execution

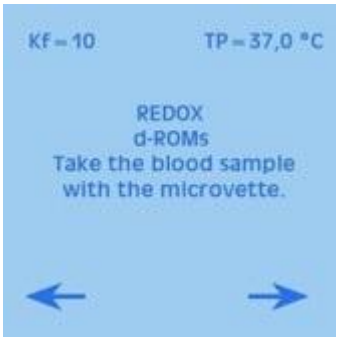
The device provides step-by-step instructions for carrying out the tests. With the → symbol you can go to the next screen, with the **√** confirm and with the ← symbol you can abort the test.

4.1

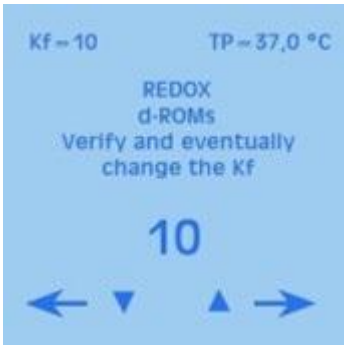
REDOX O.B.

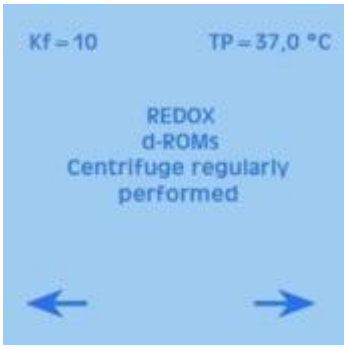
To avoid inaccurate results, only use original H&D srl reagents.

it is advisable to prepare all the material to perform the capillary blood sampling (lancing device and microtube), the reagents necessary for the test and the appropriate pipettes with the disposable tips provided before carrying out the tests.

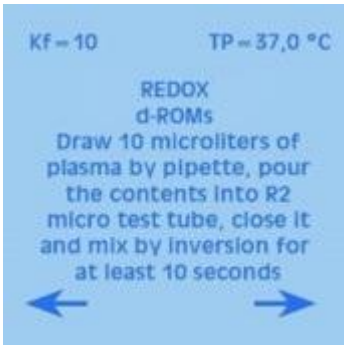


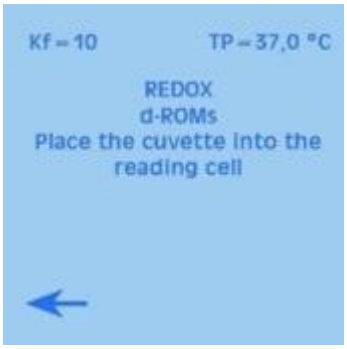
- Gently massage the middle or ring finger, disinfect it using cotton wool soaked in disinfectant and wait until it is dry.
- Take the microtube, remove the inner tube from the outer cylinder and separate the small orange cap from the main cap.
- Using the lancing device, prick the tip of the disinfected finger and immediately press to release the first drop of blood and prevent the immediate closure of the hole.
- Take the inner tube and, keeping it horizontal or slightly inclined, collect the blood by capillarity with the smaller hole filling it for at least two thirds.
- Massage gently from the palm of the hand to the fingertip, to facilitate blood collection, avoiding blood hemolysis due to excessive pressure.
- Close the minor hole with the cap previously removed, only at this point, close the inner tube with the main cap and put the inner tube in the outer cylinder.

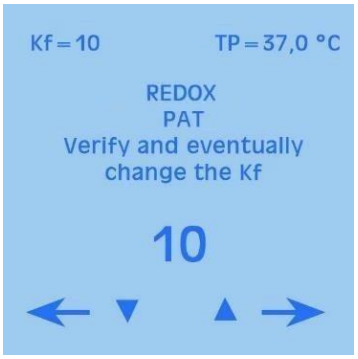




The correct Kf is printed on the label of each reagent and under the box cover of each kit.







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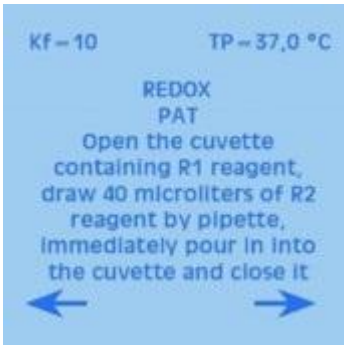
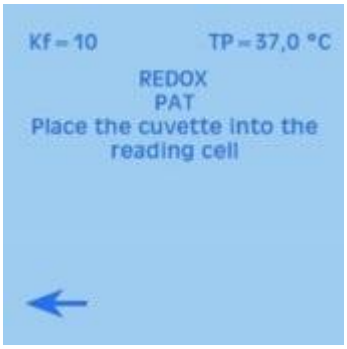
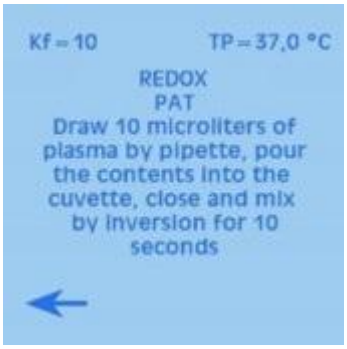

Kf = 10
TP = 37,0 °C
REDOX
PAT
Open the cuvette containing R1 reagent, draw 40 microliters of R2 reagent by pipette, immediately pour in into the cuvette and close it

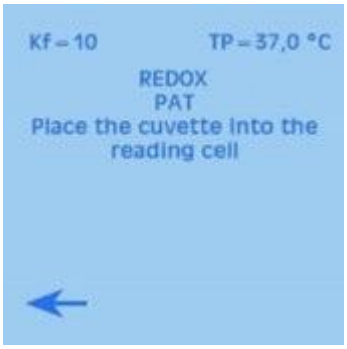
Kf = 10
TP = 37,0 °C
REDOX
Start the timer and mix by inversion for 10 seconds
10s
START

Kf = 10
TP = 37,0 °C
REDOX
PAT
Mix by inversion for 10 seconds
10s


Kf = 10
TP = 37,0 °C
REDOX
PAT
Place the cuvette into the reading cell

Kf = 10
TP = 37,0 °C
REDOX
PAT
Remove the cuvette from the reading cell and open the cuvette





4.2

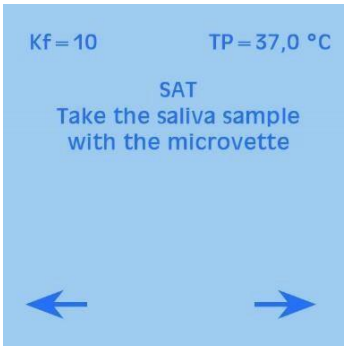
OSI INDEX

OSI REDOX is not a simple arithmetic formula, but a complex logical-mathematical algorithm capable of weighing the information derived from d-ROMs and PAT values, together with the presence or absence of antioxidant supplementation, to quantify in a single value how far the oxidative status is from normal conditions. The higher the OSI index value, the greater the deviation of the redox balance from normal.

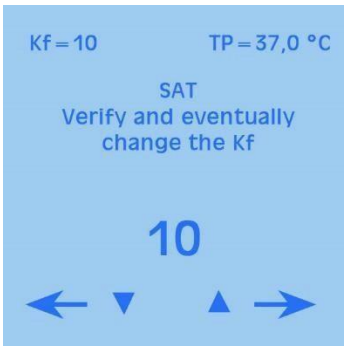
4.3

SAT

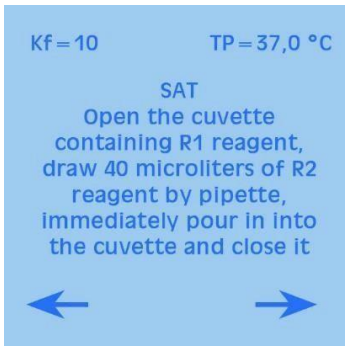
It is advisable to prepare all the material to perform the saliva sampling (cotton and glass), the reagents necessary for the test and the appropriate pipettes with the disposable tips provided before carrying out the tests.



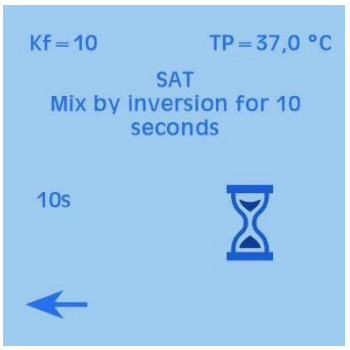
- Fold the cotton swab in 4 parts.
- Swirl the folded tampon in the mouth for one minute simulating chewing without biting it.
- At the end of the minute, collect the saliva in the cup by squeezing the cotton swab.



The correct Kf is printed on the label of each reagent and under the box cover of each kit.

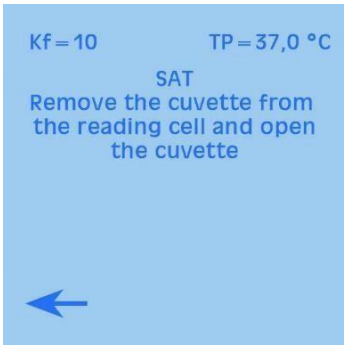


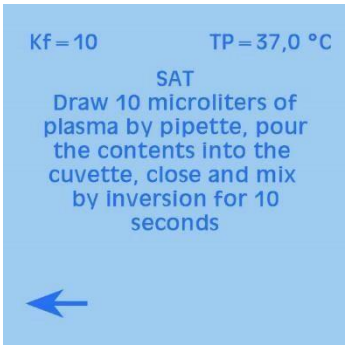
Kf = 10
TP = 37,0 °C
SAT
Start the timer and mix by inversion for 10 seconds
10s
AVVIO

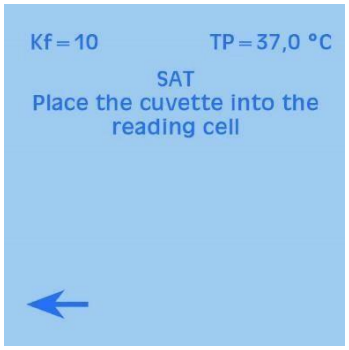

Kf = 10
TP = 37,0 °C
SAT
Mix by inversion for 10 seconds
10s

Kf = 10
TP = 37,0 °C
SAT
Place the cuvette into the reading cell

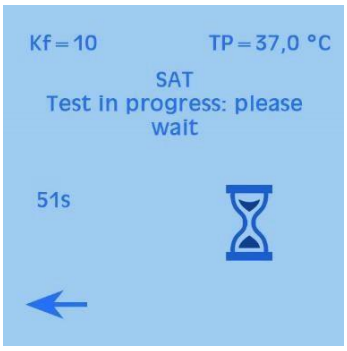
Analytical System

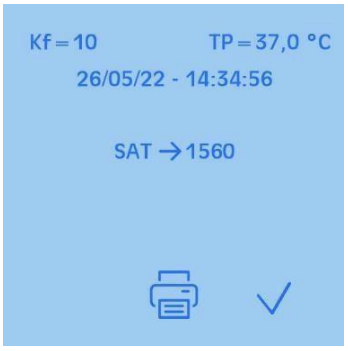

Kf = 10
TP = 37,0 °C
SAT
Remove the cuvette from the reading cell and open the cuvette


Kf = 10
TP = 37,0 °C
SAT
Draw 10 microliters of plasma by pipette, pour the contents into the cuvette, close and mix by inversion for 10 seconds


Kf = 10
TP = 37,0 °C
SAT
Place the cuvette into the reading cell

Radical Analytical System


Kf = 10
TP = 37,0 °C
SAT
Test in progress: please wait
51s


Kf = 10
TP = 37,0 °C
26/05/22 - 14:34:56
SAT → 1560

CHAPTER 5

Malfunctions

Main malfunctions and their solution:

FRAS 5 does not turn on	➢ Check the correct insertion of the power plug on the back of the device. ➢ Check the integrity of the power cable and any accessories (extensions cable, etc.). ➢ Check if the paper roll has run out.
FRAS 5 does not print the receipt at the end of the test	➢ Check if the printer door is perfectly closed. ➢ Check if the paper roll can rotate freely in its seat, and if not, replace it with a suitable roll. ➢ Check if the printer is not disabled in the setup menu.
FRAS 5 vibrates conspicuously during the centrifugation phase	➢ Check if the balancing microtube is in the correct position. ➢ Check that the adapters for the microtubes are perfectly locked in their seat.
FRAS 5 provides apparently incongruous results	➢ See the chapter " Main causes of errors in test execution".

CHAPTER 6

MAIN CAUSES OF ERRORS IN TEST EXECUTION

6.1

THE MOST COMMON CAUSES OF ERRORS IN THE PRE-ANALYTICAL PHASE

FRAS 5			
Critical step	**Error**	**Consequence**	**Solution**
Connection of FRAS 5 to the electrical grid	FRAS 5 is connected to a different electrical grid than the one required by the manufacturer	Possible damage to the electrical system with unpredictable results on the reliability of the tests	Connect the FRAS 5 only to an electrical grid compatible with the technical specifications indicated by the manufacturer
Adjustment of the K-factor	The K-factor of the instrument is set to a different value from that indicated on the kit	Altered test results	Check that the K-factor set corresponds to that indicated on the kit package and if it is different, follow the procedures for the correct adjustment

Kit			
Critical step	**Error**	**Consequence**	**Solution**
Reading of the expiration date of the kits	Use expired kits	Altered test results	Check the expiration date on the package avoiding the use of expired kits
Storage of the kits	Use kits in which one or more components have been exposed to environmental conditions other than those indicated on the label	Altered test results	Follow the manufacturer's specific instructions for correct storage of the kit and avoid using kits stored in inappropriate environmental conditions
	Inadequate closure of the special aluminum package containing the microtubes	Possible evaporation of some components of the kit with consequent tendency of values higher than the real ones	Close the special foil package properly after each measurement
Reagent temperature	Use the reagents at temperatures other than those indicated on the labels	An inadequate temperature interferes with the chemical reactions of the tests with consequent unreliability of the results	Wait until all the test reagents have reached room temperature before use

Patient			
	Error	**Consequence**	**Solution**
	Performing of d-ROMs test immediately after a muscular effort	Altered test results	Carry out d-ROMs test at rest
	Performing of PAT test immediately after a muscular effort	Altered test results	Carry out PAT test at rest
	Performing the tests immediately after a large meal, especially if rich in fat	The plasma after a lunch is temporarily rich in metabolites deriving from the absorption of nutrients and this should be the cause of an incorrect overestimation of the result, furthermore, the plasma enriched with fats could interfere with the photometric reading and this could be responsible for an underestimation of the result	Carry out tests between meals
	Performing SAT test on a non-ing patient	Saliva after eating undergoes a temporary alteration of its composition, this leads to an unpredictable alteration of the test values	Carry out SAT test ing
	Execution of SAT test on a patient who has performed normal hygiene practices less than 30 minutes ago	Saliva after daily oral hygiene undergoes a temporary alteration of its composition, this leads to an unpredictable alteration of the test values	Wait at least 30 minutes before taking SAT test

6.2

THE MOST COMMON CAUSES OF ERRORS IN THE ANALYTICAL PHASE

Common to all tests			
Critical step	**Error**	**Consequence**	**Solution**
Choice of the reagents	Use reagents from different lots or intended for another test	Unreliable values and/or incorrect chemical reactions, impossible to perform analysis	Pay particular attention for the preparation of the analysis and read the labels carefully
Handling of cuvette	Leave “fingerprints” or dirt residues on the smooth surfaces of the cuvette	Possible phenomenon of light diffraction that can cause an alteration of the test values	Handle the cuvette correctly by placing your fingers on the knurled faces. Carefully clean the smooth sides of the cuvette if it is dirty
Extraction of the cuvette at the end of the test	Remove the before the end of the reading	Incorrect optical reading that causes an alteration of the test values	Wait for the end of the beep to remove the cuvette

Blood collection (d-ROMs test e PAT test)			
Critical step	**Error**	**Consequence**	**Solution**
Disinfection of the finger	Use hydrogen peroxide or alkyl ammonium salts	Both disinfectants interfere with the test reaction causing alterations in the test values	Do not use the disinfectants described for the disinfection of the finger
Blood sampling	Trauma during blood sampling	The lysis of erythrocytes and the release of internal components can influence the test values	Avoid any trauma during blood sampling. If trauma, evidenced by red or pink plasma, is suspected, blood sampling should be repeated on another finger
	Use EDTA or citrates as anticoagulants	EDTA and citrates are iron chelators and therefore interfere with the reaction causing alteration of the test values	Use only heparin salts as anticoagulant

Running d-ROMs test			
Critical step	**Error**	**Consequence**	**Solution**
Pipette tip filling	Incomplete or overfilling of the pipette tip	Improper filling of the pipette tip causes the variation of the ratios between the reaction volumes, altering the result	Particular attention is required to extract the pipette tip from the liquid only after having completely released the push button of the pipette
	Erythrocyte sampling	The presence of erythrocytes alters the test values	Particular attention is required in plasma sampling
Sample mixing R2 solution	Too short mixing time	It takes adequate time for R2 to take effect, shorter times can lead to an underestimation of the values	Mix for at least 10 seconds
	Too vigorous mixing with persistent foam formation	The formation of foam alters the absorbance measurement and cause an alteration of the test values	Mix very gently

Running PAT test			
Critical step	**Error**	**Consequence**	**Solution**
Pipette tip filling	Incomplete or overfilling of the pipette tip	Improper filling of the pipette tip causes the variation of the ratios between the reaction volumes, altering the result	Particular attention is required to extract the pipette tip from the liquid only after having completely released the push button of the pipette
	Erythrocyte sampling	The presence of erythrocytes alters the test values	Particular attention is required in plasma sampling
Mixing of reagent R1 with reagent R2	Non-compliant mixing times (prescribed time 10 seconds)	Altered test values.	Strictly adhere to the countdown shown on the display of the device at this point of the analysis

Insert the cuvette containing R1 + R2 + sample for the second reading	Delay the insertion of the cuvette into the device	The PAT test is a kinetic type test so delaying the times beyond those strictly necessary can lead to an alteration of the test values	Do not delay the insertion of the cuvette into the device

Running SAT test			
Critical step	**Error**	**Consequence**	**Solution**
Saliva sampling	Chewing the cotton	Difficulty in soaking the cotton	Accurately describe the method to the patient
	Absence of chewing simulation	Insufficient saliva to soak the cotton and absence of stimulated saliva	Accurately describe the method to the patient
	Leave the cotton in the glass after squeezing	Cotton reabsorbs saliva and becomes difficult sampling the right amount of saliva	Dispose of the cotton immediately after squeezing
Pipette tip filling	Incomplete or overfilling of the pipette tip	Improper filling of the pipette tip causes the variation of the ratios between the reaction volumes, altering the result	Particular attention is required to extract the pipette tip from the liquid only after having completely released the push button of the pipette
Mixing of reagent R1 with reagent R2	Non-compliant mixing times (prescribed time 10 seconds)	Altered test results	Strictly adhere to the countdown shown on the display of the device at this point of the analysis
Insert the cuvette containing R1 + R2 + sample for the second reading	Delay the insertion of the cuvette into the device	The SAT test is a kinetic type test so delaying the times beyond those strictly necessary can lead to an alteration of the test values	Do not delay the insertion of the cuvette into the device

For any doubts do not hesitate to contact

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