User's Manual

ROS Detector in Sputum Samples

RDSS instruction manual
version V00
2020
Model: G1

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SECTION 1
GENERAL INFORMATION

1 - GENERAL INFORMATION

Content

✱ This instruction manual contains essential information about the ROS detector of sputum samples in-vitro diagnosis functioning.

✱ Before use, this manual should be thoroughly reviewed for the necessary information and prec autions.

✱ Keep this manual in a safe and accessible location (e.g., in its original packaging), away from any substances or liquids which could compromise its perfect legibility.

✱ This manual contains the cleaning methods recommended by Nano Hesgarsazan Salamat Arya for the RDSS device.

✱ If you have any questions or comments about any information in this manual, please contact Nano Hesgarsazan Salamat Arya Co.

1.1 - Aim

This manual aims to supply all the necessary information so that the client will not only attain adequate use of the appliance; he/she will also be capable of using the instrument most autonomously and securely possible. This includes information regarding technical aspects, functioning, maintenance, spare parts, and safety.

1.2 - Symbols used

Symbol Meaning

Symbol	Meaning
	General or specific warning
	See instructions for use
	Serial number
	Indicates the manufacturer's batch code or lot
	Catalogue number
	Instrument isolation class II (only when connected with cigarette lighter cable for models where it is expected)
	Do not reuse
	Do not use if the package is damaged
	Alternating current (where applicable)
	Direct current (where applicable)
	Earth (Ground)
	Store in a cool, dry place
	range of humidity to which the medical device can be safely exposed
	Storage temperature
	should not be disposed of in a landfill
	Do not put Li-Ion battery on trash box
	OFF Power
	ON Power

Symbol	Meaning
	In-vitro diagnosis device
	manufacturer
	Date of manufacture
	Indicates the date after which the medical device is not to be used
	Refer to the instruction manual

1.3 - Signal words

The following signal words are used throughout this manual:

⚠ Warning:

Indicates a potentially hazardous situation which, if not avoided, could result in death or severe injury.

ⓘ Caution:

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

✎ Note:

Indicates additional helpful information.

1.4 - Servicing request

For any information regarding the correct interpretation of the instruction manual, use, maintenance, installation, and restoration of the product, please contact Nano Hesgar Sazan Salamat Arya, Medical Device Technology Incubator, Imam Khomeini Hospital, Chamran Highway, Tehran, Iran.
Tel: +98 21 66907522, Fax: +98 21 66907522
nanohesgar.arya@gmail.com .

In order to facilitate the assistance service, please always indicate the serial number (SN) and Lot number (LOT) shown on the label applied on the box or the device.

1.5 - Demolition

The crossed dustbin symbol applied to the product or on its packaging indicates that the item should be disposed of separately. The correct disposal of the item when use has terminated is defined and organized by the manufacturer.

The end-user, who has to proceed with disposal, must, therefore, contact the manufacturer and follow the system and procedures the manufacturer has organized for the separate collection, treatment, and disposal at end-of-life. The correct separate collection of the out of use device which will permit recycling, treatment, and destruction in an ecologically friendly manner and will contribute to avoiding possible adverse effects on the environment and for health while privileging the reuse and/or recycling of the collected waste components. Please note that the owner will be subject to administrative sanctions in case of unauthorized disposal of the item.

1.6 - Guaranty and Warranty

RDSS products have one year of unconditional warranty and 10 years of after-sales services.

1.7 - Labelling

Each device has got an identifying label, positioned on device itself and/or on the box. This label includes information about the manufacturer, the product, the serial number (SN), or lot number (LOT). It must never be removed or covered.

2 - WARNINGS

2.1 - General warnings

⚠ The product must be used by trained personnel only, having attended specific training for this device and not for similar products.

⚠ Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the procedures to be followed for installation and correct use.

⚠ In the case of any doubts in the correct interpretation of the instructions, please contact Nano Hesgarsazan Salamat Arya Co. for any necessary clarifications.

⚠ Check the appliance regularly, carry out the prescribed maintenance, as indicated by the manufacturer in this user's manual.

⚠ If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.

⚠ Do not alter or modify the appliance in any way; any such interference could cause malfunctions and injury to the patient and/or rescuer.

⚠ The appliance must not be tampered in any way with (modification, adjustment, addition, replacement). In such cases, all responsibility for any malfunctions or injuries caused by the appliance will be denied.

⚠ Register and store with these instructions: lot number, place and date of purchase, the first date of use, date of checks, name of users, any comments.

⚠ ***Attention:*** laboratory testing, post-production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases, the performance of the product could be noticeably different from the results obtained by the date. Instructions are continually being updated and are under tight surveillance of fully

qualified staff with adequate technical formation.

⚠ The best instructions are the continuous use under the supervision of trained and competent personnel.

⚠ Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as a result of contact with blood or body fluids.

⚠ Using device in any way other than described in this manual is forbidden.

⚠ The maximum distant between probe and computer in an operating room should be less than 12 meters and the operator needs to check the results on the computer regularly in order to avoid probe misconnection to the computer.

⚠ Handle with care.

2.2 - Specific warnings

⚠ Training routines must be registered on a particular registry in which the names of those trained, of the trainers, date, and place are indicated. This register, which will certify the eligibility of the operators to use the CDP probe has to be kept for 10 years after the disposal of the device itself. This register will be made available to the competent authorities and/or manufacturer if requested.

⚠ Before using the device, the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could influence the correct functioning and the safety of the device, the patient and or the user are detected, the device must be immediately removed from service and the manufacturer must be contacted.

⚠ Before connecting the appliance, always ensure that the electrical outlet indicated on the device labeling and the type of plug used, correspond to those of the power network to which you want to connect it.

⚠ If the plug supplied with the unit is incompatible with the

electrical outlet, contact a qualified technician to replace the plug with a suitable type. In general, it is unwise to use adapters, multiple sockets and/or extensions. Whenever their use was indispensable, you must use accessories in compliance with safety regulations, although care should be taken not to exceed the maximum power incurred, which are indicated on the adapters and extensions.

⚠ IVD The device can be used for in-vitro diagnosis only.

⚠ When the device is being used, the assistance of qualified staff must be guaranteed.

⚠ The device should not be exposed to or come into contact with any source of combustion or inflammable agents.

⚠ Store in a cool, dry place and do not expose to direct sun.

⚠ Do not store the device underneath any heavy objects which could cause structural damage.

⚠ Store and transport the device in its original packaging.

⚠ Never dismantle the appliance. For any kind of intervention, contact Nano Hesgarsazan Salamat Arya technical service. Any intervention, even minimum, on the device voids the warranty, and in any case does not guarantee the fulfillment of the technical requirements.

⚠ Use only original accessories.

⚠ Do not pull the cable to remove the plug from the socket; to disconnect hold plug with fingers.

⚠ Use and keep the instrument in a safe environment, protected from adverse weather conditions and keep off excessive heating.

⚠ Never immerse the appliance in water.

⚠ Wait for the connection sound after pressing the Connect key. If the RDSS device is on, after about 2 seconds, the sound of the connection is heard. Avoid repeatedly pressing the Connect key.

⚠ This appliance must be used exclusively for which it was designed and as described in this manual. Any other use is considered improper and,

therefore, dangerous, and the manufacturer cannot be held responsible for damage caused by improper, incorrect and/or unreasonable use.

⚠ No electrical and/or mechanical part contained in the RDSS device is designed to be repaired by the customer and/or user. Do not open the device; do not touch the electrical and/or mechanical properties. Always contact Nano Hesgarsazan Salamat Arya technical service.

⚠ Never use the RDSS head probe when the package is open or scratched.

⚠ RDSS probe heads are intended to be in contact with the patient's sputum sample during testing. Make sure the proper contact with the sample in order to avoid any noise due to inappropriate contact.

⚠ As head probes are disposable after testing procedure terminated, they should be removed immediately into the safety box

⚠ RDSS device should be utilized with a specific cover that should be removed immediately into an infectious bag after testing procedure terminated.

⚠ During the time that device reads data from the sputum sample environment, the indicator embedded on it is red. After the reading signal has been completed, the red indicator light is off, and the surgeon can remove the probe from the desired location. It is highly recommended that the probe remains in the environment as long as the indicator light is on; this does not last more than 10 seconds.

⚠ The RDSS head probes are single-used only.

2.3 - Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

2.4 - Environmental conditions

RDSS unit:

 Functioning temperature: from +15 to +60 °C

 Functioning humidity: from 10 to 60%

 Storage temperature: from 0 to +60 °C

Storage humidity: from 0 to 80%

Head probe:

 Functioning temperature: from -10 to +70 °C

 Functioning humidity: from 0 to 80%

 Storage temperature: room temerature

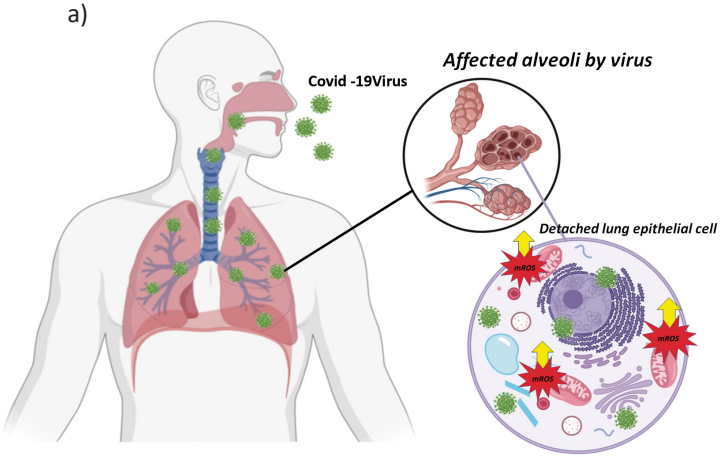
Storage humidity: from 0 to 80 %

3 - PRODUCT DESCRIPTION

3.1 - Intended use

ROS Detector of Sputum Sample (RDSS) system includes a ROS / H_2O_2 electrochemical system (Patent pub. No .: US2018 / 0299401 A1, Pub. Date: Oct. 18, 2018), which is consists of an integrated portable automatic board with an electrochemical reading system and a disposable sensor. Also, the software was designed based on experimental calibration to analyze the data and determine whether the responses to the samples of COVID-19 or respiratory diseases such as asthma and acute pneumonia of any patients were positive or negative. This ROS diagnostic system provides a flexible and straightforward way for physicians to use it quickly and accurately as an in-vitro diagnosis device, and they can use it in laboratories or clinics. For measuring the electrochemical response of patient samples, the device uses voltage potentials in the range of -0.8 to +0.8 volts and a scanning speed of 100 mV / s as standard optimal parameters in biological experiments.

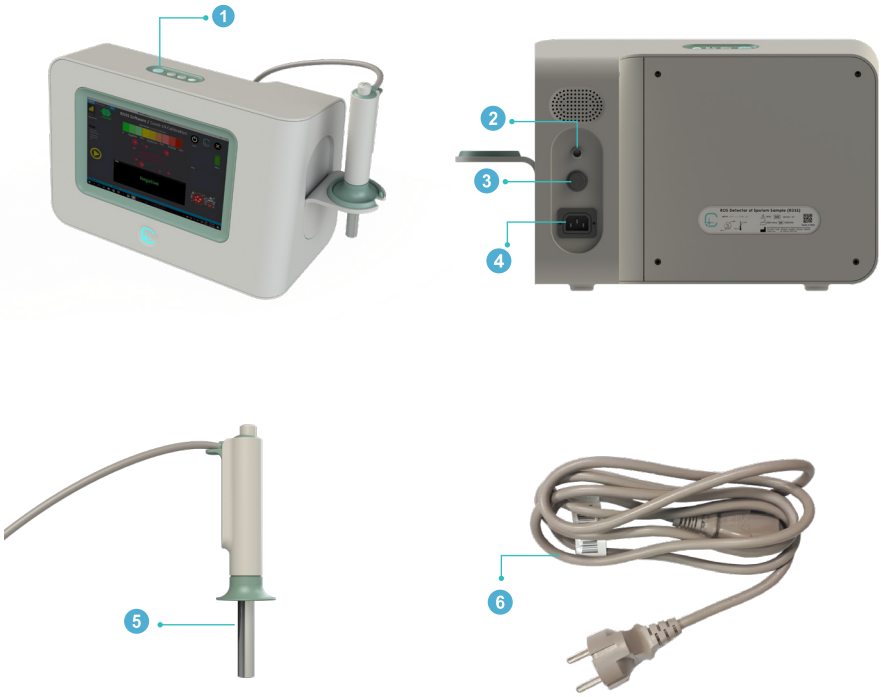
a)


Covid -19Virus
Affected alveoli by virus
Detached lung epithelial cell
mROS
mROS
mROS
mROS

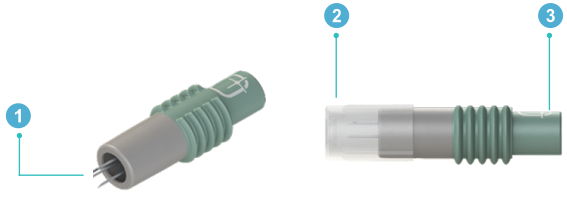
b)


RDSS Software / Covid-19 Calibration
Negative

3.2 - Main components



1	Power LED
2	Input connector
3	Power key
4	Power cable input
5	RDSS probe
6	Adaptor power cable



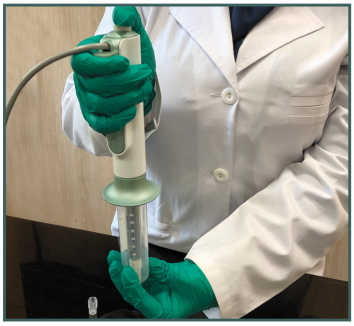
1	Head probe sensing needles
2	Head Prob Cap
3	Head probe connector

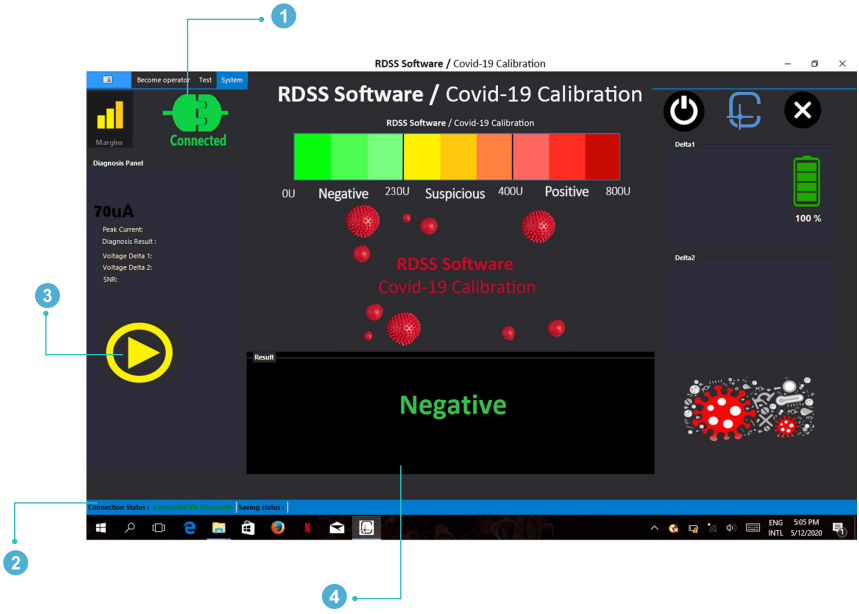
1

2

3

4





1	Connection button on the software
2	Connection status Test key on the software
3	Test key on the software
4	Diagnosis results

3.3 - Model

Model: G1

Nano Hesgarsazan Salamat Arya (NHSA) – ROS Detector of Sputum Samples 12 V, with Bluetooth.

3.4 - Technical information

Specification	SN: R200500
Classification	In-vitro diagnosis device IVD
Medical classification	Class B IVD
Input Power supply	12V ⎓ 5A DC
Power consumption	0.7VA
Maximum current (with Probe connection)	1mA ±5%
Minimum measurable current – resolution (with Probe connection)	1nA ±5%
Isolation class (when used with AC / DC adapter included)	Class II ⧈
Compliance potential	±5V
Readability peak indicator	0uA-300uA
Connection device	HC05-Bluetooth module
Connection specification	Maximum 12m connection length

4 - INSTRUCTIONS

4.1 - Transport and storage

Before transporting the appliance, make sure that it is correctly

packed also assure that there are no risks of shocks, bumps, or falls during transportation.

Keep the original package in case of any further transport and for storage information. Any damage occurred to the appliance during transport and handling is not covered by the guarantee, and the client is responsible for repairs or replacement of the damaged parts. The device must be stored in a dry, cool area away from direct sunlight. It must not be in contact with any substances or chemical agents, which could cause damage and reduce safety characteristics.

4.2 - Preparation

The appliance must be checked before every use to reveal any working abnormalities or damage caused by transport or storage. The RDSS system must contain a measuring unit, a laptop (monitor) and, a connected probe via wire to the unit. The ROS detecting sensors are available in an individual package and should be connected to the head probe connector of the system. The patient's sputum samples should be in a falcone 50 ml. The amount of the sample should be enough for the sensor's needles to be in touch completely with the sputum in the falcon.

⚠ On opening the packaging and before each use, check the integrity of the device, paying particular attention to the presence of damages to the head probe connector, which could make accessible internal parts under tension and cause breakage and/or peeling of power cable. In such cases, do not connect the plug to the power outlet.

4.3 - Importance of cleaning

As this device is designed to detect ROS levels in respiratory diseases, especially in viruses infectious cases, the importance of cleaning the device after each testing procedure must be considered effectively. This device should be cleaned using standard disinfections such as ethyl alcohol 70% based liquids to make sure of the elimination of any probable residue of the patient's sputum on the probe. This device is

designed to test a patient's sputum in a falcon 50 ml tube.

Warning:

Make sure to test the patient's sample in a safe and isolated room in the case of a contagious virus disease.

Each head probe must be eliminated immediately after the testing procedure terminated into an isolated safety box. Otherwise, there is a highly dangerous potential of spreading infections in the environment.

The medical literature reports incidents of cross-contamination resulting from improper cleaning or disinfection. It is strongly recommended that after using RDSS, clean its surface with Alcohol-based rapid disinfectant.

Do not spray disinfectant directly at the connector.

When selecting appropriate methods and conditions for cleaning, disinfection, and sterilization, follow the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices, in addition to the instructions given in this manual.

5 - Alarms Interpretation

The response of the RDSS device was categorized into three main zones include green, yellow, and Red.

In this regard,

- Green zone named "negative."
- Yellow zone named "suspicious."
- Red zone named "positive."

6 - Operating Guideline

✱ Connect the device to the power supply and turn on the main switch (ON/OFF switch on the back of the unit). The LED light of the C+ logo under the monitor will be turned on. The LEDs on the top of the device stay on for a short time and then turn off.

✱ Press and hold the monitor power key on top of the unit for 5 seconds to turn on the main system. After turning on the monitor LED; Take your hand off the key and wait for the device's operating system to boot. After about a minute, the software is automatically displayed on the screen.

✱ Place the head-probe on the RDSS probe, in the manner that the smooth region of head probe become aligned with the signed part of the probe pipe. Then, remove its upper plastic cover.

✱ Touch the Connect icon (on the screen) and wait the connect icon become green.

✱ Give a sputum sample container (a falcon containing 500 microliters of injectable sterile water) and a disposable cover to the candidate.

✱ The sputum sample, in the sampling container, should be well stirred. The time interval between sampling and testing should be less than one minute.

✱ Remove the cap of the head probe, and place it in

the sampling container. Make sure the needles are well inserted into the test solution. Then press the button on the top of the probe to start the test. You can hear short, continuous “beeps” while the rotating Corona logo is displayed on the monitor. Do not move your hand or shake the sample until the end of the test, and announcement of the result.

✱ After about 30 seconds, the test result will appear on the screen.

✱ Test each sample just once and use one head probe at a time. The second test on the same sample is not valid either with the same head probe or a new one.

Do not reuse head probes; head probes are disposable.

⚠ Eliminate the used head probe immediately into an isolated safety box.

Use only the original disposable head probes provided by the manufacturer.

⚠ Make sure to clean the RDSS probe thoroughly with disinfection before using it for the next patient.

ATTACHMENT A – TRAINING REGISTER

⚠ The product must be used only by trained personnel who have attended specific training for the use of this device and just for products with similar characteristics.

⚠ Keep this document at least 10 years after the end of the life of the device.

Operator's name	Training date		Training method (user›s manual, during service, former class, etc.)	Trainer
	Basic Trainig	Advanced Training		

ATTACHMENT B – MAINTENANCE REGISTER

⚠ Perform the required maintenance and to respect the life span of the device, as indicated by the manufacturer in the User's Manual.

Service Date	Kind of service maintenance/ chek/extension of span	Operation made on the Device	Result	Person in change of service (operator/ Authorized centre/ manufacturer)

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