RedoxSYS® System
User Manual

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redoxSYS®

RedoxSYS System
User Manual

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Description

The RedoxSYS System uses the Oxidation-Reduction Potential (ORP) Test to measure oxidative stress in a biologic sample.

Intended Use

The RedoxSYS System is intended to be used in the in vitro quantification of oxidative stress using biomarkers of oxidation found in biologic samples. The RedoxSYS System is intended to be used only by trained laboratory professionals.

Warnings and Precautions

It is essential that you read the following warnings and precautions in order to avoid risks to persons and damage to the analyzer and other equipment. Aytu BioScience does not accept responsibility for damage or injury resulting from a lack of observance of the instructions in this manual.

Follow the User Guide!

Each time the RedoxSYS Analyzer is used, knowledge of and attention to these operating instructions is required. Use the Aytu BioScience RedoxSYS System only for the purpose it is intended.

Check that the AC voltage and frequency printed on the AC power adapter label match your electrical socket and whether the shape and configuration of the plug contacts are compatible.

Keep the Analyzer Away From Liquids!

The Aytu BioScience RedoxSYS Analyzer is not waterproof. Fluids entering the instrument could damage the electrical components in the analyzer. Cleaning and disinfecting methods commonly used on laboratory instruments may be used. Please see the notes on care in the RedoxSYS Maintenance section of these instructions.

Allow the Instrument to Reach Room Temperature!

Particularly on moving from a cold into a warm environment (ie, after storage or transport), condensation can form inside and on the outside of the instrument. Wait an appropriate time (approximately 1 hour) before connecting to the main power supply or switching on the instrument.

Use Only the Original Equipment!

Do not attach equipment that is not expressly approved for use with the Aytu BioScience RedoxSYS System. Aytu BioScience does not recommend or guarantee the function of the instrument with other equipment.

Never Open the Analyzer!

There are no serviceable parts inside. Service to any component of this device is to be performed only by Aytu BioScience. Unauthorized repairs or modifications will void the warranty and may violate conformity of the RedoxSYS System with the regulatory requirements of the Medical Device Directive 93/42/EEC. Further notes on maintenance can be found in the RedoxSYS Maintenance section of these instructions.

Be Aware of the Danger of Fatal Electric Shock!

Under no circumstances should you open the AC power adapter. There are no elements inside that require servicing or maintenance.

Never use a mechanically damaged AC power adapter — live connections might be exposed.

The AC power adapter is not waterproof. Therefore, never let liquids come into contact with it. A lightly dampened cloth, however, can be used to clean it when disconnected. Please see the notes on care in the RedoxSYS Maintenance section of these instructions.

Use the AC power adapter only in a socket that has been properly installed.

Do Not Use in Areas Where There is A Risk Of Explosion!

This instrument is not approved for use in areas where there is a risk of explosion.
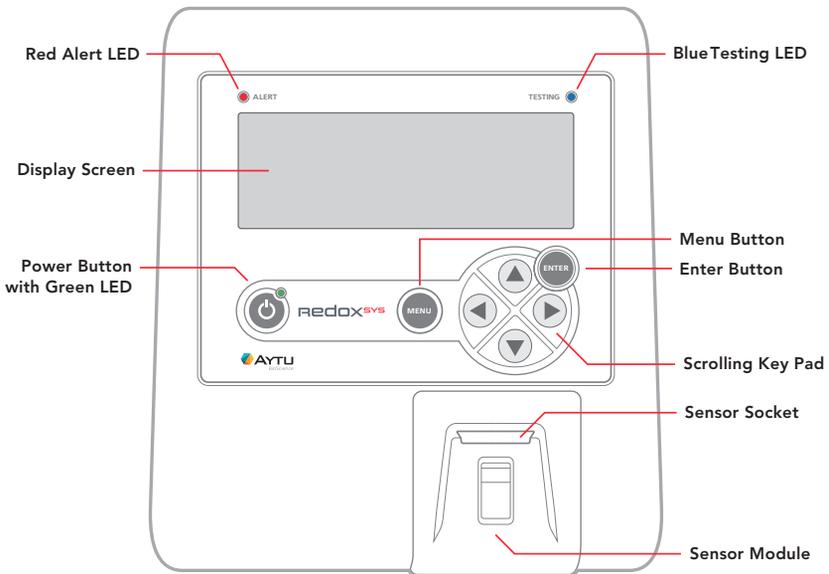
Summary and Explanation

Oxidative stress reflects an imbalance between the systemic manifestation of reactive oxygen species and a biological system's ability to readily detoxify the reactive intermediate species or to repair the resulting damage. Disturbances in the normal redox (reduction-oxidation) state of cells can cause toxic effects through the production of peroxides and free radicals that damage all components of the cell, including proteins, lipids, and DNA. Further, some reactive oxidative species act as cellular messengers in redox signaling.

Oxidation-reduction potential (ORP) in biological systems has been described as an integrated measure of the balance between total oxidants (ie, oxidized thiols, superoxide radicals, hydroxyl radicals, hydrogen peroxide, nitric oxide, peroxynitrite, transition metal ions, etc) and total reductants (ie, free thiols, ascorbate, α-tocopherol, β-carotene, uric acid, etc).[1] Therefore, the amount of oxidative or reductive stress (redox balance) present in plasma can be monitored with an ORP electrode using the RedoxSYS System.

The RedoxSYS System measures the amount of oxidative stress in heparinized mammalian plasma or serum samples by measuring oxidation-reduction potential (reported as "static ORP" on the RedoxSYS display screen). The biologic sample is applied to a RedoxSYS Sensor inserted into a galvanostat-based reader. The test starts when the sample fills the reference electrode, thereby completing the electrochemical circuit. After an initial ORP reading is recorded, the reader applies a small current sweep to the sample, resulting in the exhaustion of important antioxidant species. As a result, the antioxidant capacity of the sample is calculated and reflects the amount of electrons applied to the sample that causes this exhaustion of antioxidants in the sample (reported as "capacity ORP" on the RedoxSYS display screen).
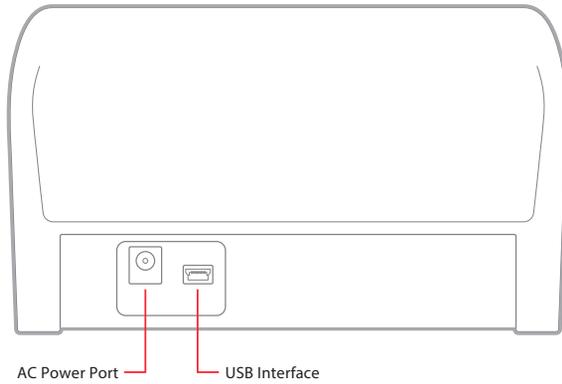
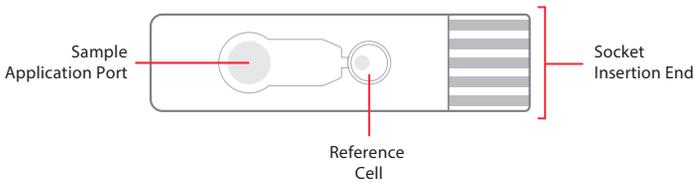## RedoxSYS System
RedoxSYS Analyzer

RedoxSYS System (continued)

Back of RedoxSYS Analyzer

AC Power Port — — USB Interface

RedoxSYS Sensor

Sample Application Port

Socket Insertion End

Reference Cell

Other Components

- AC Power Cord With Plug Adapters
- Instructions for Use
- Calibration Verification Key

Other Components Provided Separately

- RedoxSYS Sensors
- RedoxSYS Control Solution Kit

RedoxSYS Testing Instructions

Initial Setup

- Place the RedoxSYS Analyzer on a flat, level surface.
- The RedoxSYS Analyzer has a permanent rechargeable battery. The battery can be charged by plugging the provided AC power cord into the AC power port of the RedoxSYS unit and an AC power source.
- The RedoxSYS Analyzer can be operated using battery or AC power.

Initial Startup

- Press the power button on the RedoxSYS Analyzer. The green power LED on the power button will illuminate to indicate the unit is on. If using AC power, the display screen will be backlit.
- When the RedoxSYS Analyzer is ready, "Insert sensor" will appear on the display screen.

RedoxSYS Testing Instructions (continued)

Sensor Insertion

- Unwrap an individual RedoxSYS Sensor.
- Holding sensor at front side edges (see **figure 1**), insert the RedoxSYS Sensor face-up and with the sensor electrodes facing the RedoxSYS Analyzer. Align the socket insertion end with the sensor socket on the RedoxSYS Analyzer. Make sure the sensor is fully inserted.
- Once the RedoxSYS Sensor is inserted properly, "Waiting for sample" will appear on the display screen, and a 2-minute sample detection countdown timer will begin.
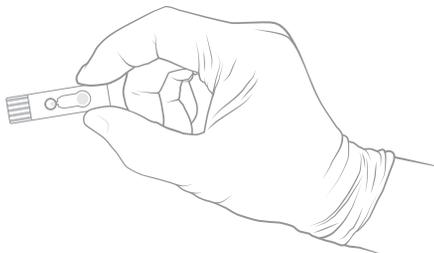
figure 1

Sample Collection

- The sample used for ORP analysis can be either heparinized (sodium or lithium) plasma or serum.
  - **Heparinized plasma collection:** Heparinized plasma can be obtained from whole blood collected in sodium- or lithium-heparinized Vacutainer® blood collection tubes (ie, "green tops") using standard venipuncture methods. The blood collection tubes must be centrifuged at 1,000 Xg for 10 minutes. The top layer (ie, plasma) is suitable for ORP analysis.
  - **Serum collection:** Blood serum can be obtained from whole blood collected in clot activator Vacutainer blood collection tubes (ie,"red tops") using standard venipuncture methods. After blood clotting is achieved (~30 to 60 minutes), the blood collection tubes must be centrifuged at 1,000 Xg for 10 minutes. The unclotted, top blood layer (ie, the serum) is suitable for ORP analysis.

Sample Application

- Heparinized plasma or serum should be applied using a pipette. **Between 20-40μL of sample can be applied. For samples between 20-30μL, it is recommended that the same amount of sample be applied consistently for each test during study.**
- Apply the sample to the sample application port on the inserted RedoxSYS Sensor. Make sure that the entire port is covered.

    Precaution: Please use gloves when handling biological material, as per standard laboratory practice.

Sample Run

- When the sample flow reaches the reference cell of the sensor, the testing automatically begins. Proper execution of the test is also indicated by the blinking of the blue testing LED.
- Once the test is initiated, the display screen will show "Processing sample" and the time remaining.
- Do not press any buttons or remove the sensor while testing is in progress.
- If an error does occur during testing, an error code will appear on the display screen and the red alert LED will illuminate. Please make a note of the error reading for your records. Follow the instructions on the screen to clear the error.

RedoxSYS Testing Instructions (continued)

Test Results

- Audible beeps will indicate the completion of the test.
- On the display screen, the test results will appear in the following order:
  - Date
  - Time
  - Static ORP (in millivolts or mV)
  - Capacity (in microcoulombs or µC)

NOTE: Before removing the sensor, record the date, time, static ORP, and capacity ORP in your records.

- Remove the RedoxSYS Sensor from the sensor socket immediately after the data is recorded.

  Discard the sensor observing the proper disposal of biological fluids guidelines.
- Once the used RedoxSYS Sensor is removed, "Insert sensor" will appear on the display screen. Repeat the steps in these instructions, starting with Sensor Insertion if performing additional testing.

NOTE: If the RedoxSYS Analyzer is "ON" but inactive, the RedoxSYS Analyzer will automatically turn "OFF." A 15-second timeout warning appears on the display screen with a warning beep emitted every second. The timeout clock can be reset by pressing any button.

Specificity, Accuracy, and Interfering Substances

Specificity, accuracy, and interfering substances have not been established.

RedoxSYS Data Review Instructions

- When testing is not in progress, the previous 50 collected results can be reviewed by pressing the Menu button on the RedoxSYS Analyzer.
- When the RedoxSYS Analyzer displays the "Insert sensor" screen, press the Menu button.
- Scroll to "Results (XXX)" using the arrow keys. Press the Enter or right arrow key.
  NOTE: The number after the word "Results" shows how many runs are stored in memory.
- The most recently collected result will be displayed first. All collected results can be reviewed by pressing the up or down arrows on the RedoxSYS unit.
- To return to the "Options" screen, press the Menu or left arrow key.
- To return to the "Insert sensor" screen, press the Menu or left arrow key.

RedoxSYS Identification Instructions

To identify your RedoxSYS Analyzer:

- When the RedoxSYS Analyzer displays the "Insert sensor" screen, press the Menu button.
- Scroll down to the "Serial numbers" option using the down arrow key.
- Press the Enter or right arrow key.
- The following serial numbers will be displayed:
    - **S:** serial number of your RedoxSYS Analyzer
    - **D:** serial number of the digital board on your RedoxSYS Analyzer
    - **A:** serial number of the analog board on your RedoxSYS Analyzer
    - **F:** firmware version number of your RedoxSYS Analyzer

These serial numbers are important if your RedoxSYS Analyzer requires any updates or calibration.

RedoxSYS Analyzer Other Settings

To set the date and time:

- When the RedoxSYS Analyzer displays the "Insert sensor" screen, press the Menu button.
- Scroll down using the arrow buttons to "Set date/time" and press Enter.
- Set date/time by pressing up and down arrows and move the cursor by pressing the left and right arrows.
- Press Enter to save date/time settings.

To set the date format:

- When the RedoxSYS Analyzer displays the "Insert sensor" screen, press the Menu button.
- Scroll down using the arrow buttons to "Set date format" and press Enter.
- Scroll to desired date format using up and down arrow buttons and press Enter.

To clear all data on the RedoxSYS Analyzer:

CLEARING ALL DATA CAN NOT BE UNDONE AND IS NOT RECOMMENDED!!!

- When the RedoxSYS Analyzer displays the "Insert sensor" screen, press the Menu button.
- Scroll down using the arrow buttons to "Clear all data," press Enter.

To check the Display Screen and all LEDs:

- When the RedoxSYS Analyzer displays the "Insert sensor" screen, press the Menu button.
- Using the arrow buttons, scroll to "Display test" and press Enter.
- All lights should illuminate properly. If they do not, contact Aytu BioScience at +1 (720) 437-6580 or via email at info@RedoxSYS.com.
- To exit the "Display test" mode, wait 15 seconds or press any scrolling button.

To determine the total number of sensor insertions (important if your RedoxSYS Analyzer requires any updates or calibration):

- When the RedoxSYS Analyzer displays the "Insert sensor" screen, press the Menu button.
- Using the arrow buttons, scroll to "Socket status" and press Enter.
- The unit's serial number will be displayed as "S/N XXXXX," and the number of sensor insertions will be displayed as "Insertions: XX."
- Press the left arrow cursor or Menu button to go back to the options screen.

RedoxSYS Analyzer Other Settings (continued)

To determine the version of software your RedoxSYS Analyzer is running and the date it was installed (important if your RedoxSYS Analyzer requires any updates or calibration):

- When the RedoxSYS Analyzer displays the "Insert sensor" screen, press the Menu button.
- Using the arrow buttons scroll to "About" and press Enter. The firmware version will be displayed as "F/W Version X.XX.XX," and the date/time of installation will appear below it.
- Press the left arrow key or Menu button to go back to the options screen.

RedoxSYS Power Supply

The RedoxSYS Analyzer should be used only with the supplied universal AC input adapter.

RedoxSYS Power Off

- To properly turn off your RedoxSYS Analyzer, press and hold the power button for 3 seconds.
- The RedoxSYS Analyzer can remain plugged in for proper battery charging if so desired.

RedoxSYS Maintenance

- All exterior surfaces may be disinfected using an alcohol wipe or swab, as necessary.
- The RedoxSYS Analyzer must have regularly scheduled calibrations to ensure accuracy of the results. Please refer to the calibration label on the bottom of the analyzer for its calibration expiration date. Contact Aytu BioScience for instructions for calibration.

Quality Control

1. Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal, state, and local guidelines concerning the running of external controls.
2. RedoxSYS external control solution kit are supplied separately (cat# 100199). It is recommended that each new lot or shipment of RedoxSYS Sensors be verified upon receipt and before use. External controls tests should be performed thereafter in accordance with appropriate Federal, State, and local guidelines.
3. A separate sensor must be used for each external control test.
4. Calibration Verification Key testing should be performed annually **(see CVK table below)**.

RedoxSYS System Calibration Verification Key			
		Acceptance Limits	
		Minimum	Maximum
A-Side	ORP (mV)	99.0	101.0
	ICell (nA)	-101.0	-99.0
B-Side	ORP (mV)	295.8	304.2
	ICell (nA)	-30.4	-29.6

RedoxSYS Specifications

Test sample:	Heparinized mammalian plasma or serum
Test result:	Referenced to 1X PBS or ascorbate standard
Sample volume:	30 µL
Measuring range:	-2000 to +2000 mV
Measuring time:	240 seconds
Memory:	Stores 50 most recent test results
Battery type:	Non-serviceable, 1.8 Ah rechargeable lithium ion battery, 3.0 to 4.2 V
Analyzer/Battery life:	5 years
Operating temperature range:	41° to 113° F (5° to 45° C)
Humidity:	10% to 90% RH
Dimensions:	8.13 in (L) x 7.13 in (W) x 4.13 in (H)
Weight:	33.2 oz (940 grams) – RedoxSYS unit <0.1 oz (0.9 grams) – RedoxSYS sensor
Sound:	A beep sounds when the reading is complete and a test result appears on the screen. Fifteen beeps in 15 seconds will sound when the RedoxSYS Analyzer times out.

NOTE: Electromagnetic emissions are low and are unlikely to interfere with other nearby electronic equipment; nor are emissions from nearby electronic equipment likely to interfere with the analyzer.

Shipping and Handling

The RedoxSYS System should be transported in the original packaging (including foam and box) or in a designated shipping container supplied by Aytu BioScience.

If the RedoxSYS equipment is to be removed from use for repair or disposal, all surfaces should be wiped down with an alcohol wipe or swab.

Explanation of Symbols From the RedoxSYS Analyzer

Manufacturer

Consult Instructions for Use

IVD In Vitro Diagnostic Medical Device

CE Mark (product meets the requirements of the applicable EC directives)

Underwriters Laboratories Certification Mark

REF Catalog Number

SN Serial Number

Biological Hazard

EC REP Authorized Representative

Reference

1. Shapiro HM. Redox balance in the body: an approach to quantitation. *J Surg Res.* 1972;13:138-152.

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