



MiOXSYS Analyzer
User Manual



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Made in USA

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MiOXSYS Analyzer

User Manual

FOR EXPORT ONLY. NOT FOR SALE IN USA.

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Description

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

Intended Use

The MiOXSYS Test performed on the MiOXSYS Analyzer is a rapid in vitro diagnostic semen analysis test utilizing an electrochemical technology for the qualitative measurement (millivolts mV) of static Oxidation Reduction Potential (sORP) in human semen.

The MiOXSYS System is intended for professional use in conjunction with standard semen analysis parameters (ejaculate volume, total sperm, sperm concentration, total motility, progressive motility, and morphology) as an aid to assess semen quality. For in vitro diagnostic use only.

The MiOXSYS System is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

The MiOXSYS System is indicated for use in adult males aged 21-45 yrs old who are undergoing semen analysis.

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 MiOXSYS Analyzer is used, knowledge of and attention to these operating instructions is required. Use the Aytu BioScience MiOXSYS Analyzer 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 MiOXSYS 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 MiOXSYS 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 MiOXSYS Analyzer. 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 MiOXSYS Analyzer with the regulatory requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices. Further notes on maintenance can be found in the MiOXSYS 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 MiOXSYS 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

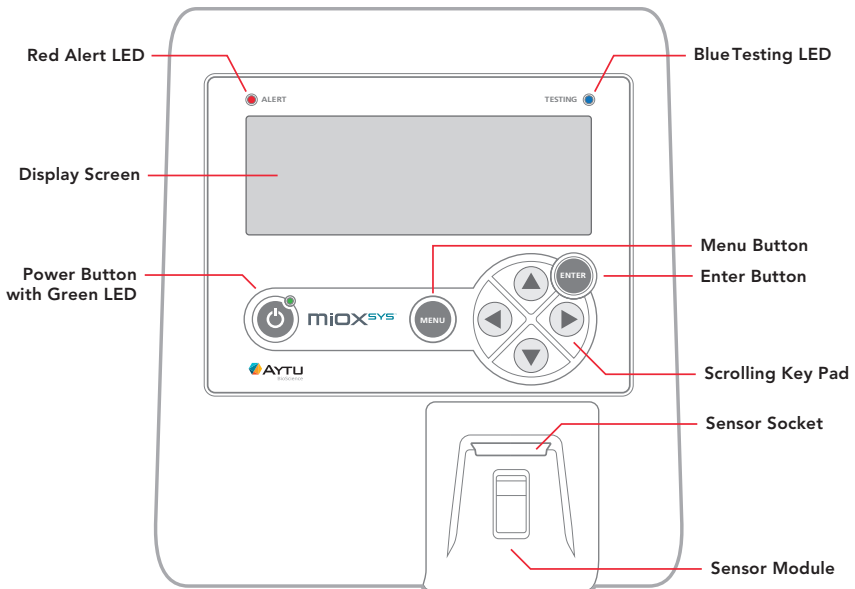
Oxidative stress reflects an imbalance between the systemic manifestation of reactive oxygen species and other oxidants with the biological system's ability to detoxify them or to repair the resulting damage. Disturbances in the normal redox (reduction-oxidation) state of cells can cause toxic effects on cells, including protein oxidation, lipid peroxidation, and DNA fragmentation.

Static oxidation-reduction potential (sORP) has been described as an integrated measure of the balance between total oxidant activity (i.e. reactive oxygen species (ROS), oxidized thiols, superoxide radicals, hydroxyl radicals, hydrogen peroxide, nitric oxide, peroxyxynitrite, transition metal ion, etc) to total reductant activity (i.e. free thiols, ascorbate, α -tocopherol, β -carotene, uric acid, etc).¹ Therefore, the amount of oxidative or reductive stress (redox balance) present in a biological sample, like semen, can be monitored with an sORP sensor using the MiOXSYS System.

The MiOXSYS Test can be used as a complementary measure to standard semen analyses (ie. motility or sperm concentration). The MiOXSYS Test provides a quick and holistic measure of oxidative stress by measuring static oxidation-reduction potential (sORP). Studies to date have demonstrated an inverse relationship between reactive oxygen species (ROS) and sperm concentration, motility, and volume¹⁻³; however, ROS is only one contributor to oxidative stress and can be difficult to measure. Analysis of the seminal plasma proteome suggest that both changes in both antioxidants and oxidants are present.⁴ The advantage of the MiOXSYS Test is that takes into account both oxidant and antioxidant activity, providing a total measure of oxidative stress with no sample preparation.

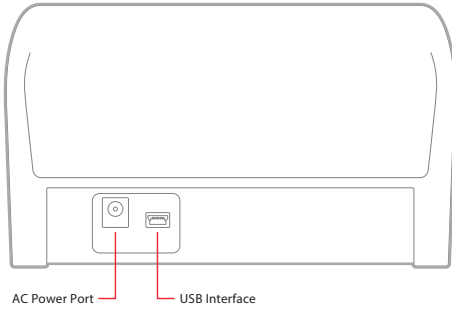
MiOXSYS System

MiOXSYS Analyzer



MiOXSYS System (continued)

Back of MiOXSYS Analyzer



Materials Provided

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

Materials or Equipment Provided Separately

- MiOXSYS Sensors
- MiOXSYS External Control Solutions (low and high solutions)
- USB cable
- USB drive with software for download of data

MiOXSYS Testing Instructions

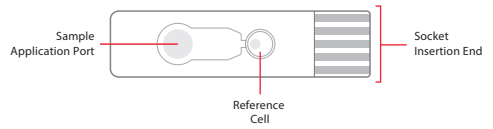
Initial Setup

- Place the MiOXSYS Analyzer on a flat, level surface.

Specimen Collection and Handling

- Semen sample should be collected in accordance with published guidelines for collection and liquefaction for semen analysis. Samples should be tested within one (1) hour of liquefaction.
- Samples that will not be tested within this time should be flash frozen immediately after liquefaction and stored at -80 C until tested. Specimens may be frozen and thawed once.

MiOXSYS Sensor



Other Components

Needed But Not Provided

- Disposable powder-free latex gloves or equivalent
- Sterile sample collection containers, capable of holding >100 μ L of sample
- Vortex mixer
- Micropipette and aerosol resistant pipette tips capable of delivering 30 μ L volume

MiOXSYS Testing Instructions (continued)

Test Procedure

Sample and MiOXSYS Analyzer Setup

- Prior to testing, semen sample should be brought to room temperature 18-30°C (64-86°F)
- Press the power button on the MiOXSYS 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.
- “MiOXSYS” and the date and time will appear on the display screen for 3 seconds.
- When the MiOXSYS Analyzer is ready, “Insert sensor” will appear on the display screen (Figure 1).

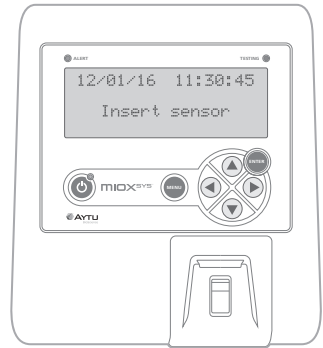


Figure 1

Sensor Insertion

- Unwrap an individual MiOXSYS Sensor.
- Holding sensor at front side edges (Figure 2), insert the MiOXSYS Sensor face-up and with the sensor electrodes facing the MiOXSYS Analyzer. Align the socket insertion end with the sensor socket on the MiOXSYS Analyzer. Make sure the sensor is fully inserted before continuing the test procedure.
- Once the MiOXSYS Sensor is inserted properly, “Waiting for sample” will appear on the display screen, and a 2-minute sample detection countdown timer will begin.

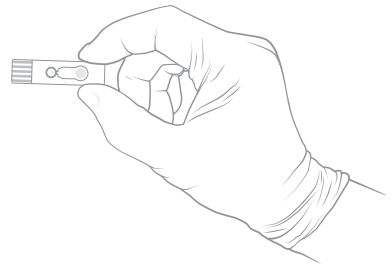


Figure 2

Sample Application

- The sample used for analysis can be either fresh or frozen semen, but should be at room temperature 18-30°C (64-86°F) when tested.
- The sample should be applied using a pipette.
- 30ul is required for each test.
- Apply the sample to the Sample Application Port on the inserted MiOXSYS 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.

MiOXSYS 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 (sORP) in millivolts (mV)

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

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



Discard the MiOXSYS Sensor observing the proper disposal of biological fluids guidelines.

- Once the used MiOXSYS Sensor is removed, "Insert sensor" will appear on the display screen. Repeat the steps in the Sensor Insertion section if performing additional testing.

NOTE: If the MiOXSYS Analyzer is "ON" but inactive, the MiOXSYS 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.

Calculation of Results

- The sORP measurement displayed reflects the average of the final ten (10) seconds (or twenty [20] readings) of the run. The sample analysis is completed in approximately three (3) minutes. sORP values above the normal range indicate a change in the balance between oxidants and antioxidants in favor of the oxidants, and signify the presence of oxidative stress in the specimen.

NOTE: A typical example of calculating and norming sORP values to sperm concentration is illustrated below:

Number	Sample	Date	Time	sORP (mV)
1	Patient A	5/29/2015	10:13 AM	76.8

Sperm Concentration = 62.6×10^6 /mL; Patient sORP = 76.8 mV;
Normed sORP = $76.8/62.6 \times 10^6$ mL = 1.22 mV/ 10^6 sperm mL

MiOXSYS Data Review Instructions

- When testing is not in progress, the previous 50 collected results can be reviewed by pressing the Menu button on the MiOXSYS Analyzer.
- When the MiOXSYS 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 MiOXSYS Analyzer.
- 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.
- Data can also be reviewed on a PC connected with the USB cable by using the included Data Transfer Utility Instructions.

MiOXSYS Identification Instructions

To identify your MiOXSYS Analyzer:

- When the MiOXSYS 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 the MiOXSYS Analyzer
 - D:** serial number of the digital board on the MiOXSYS Analyzer
 - A:** serial number of the analog board on the MiOXSYS Analyzer
 - F:** firmware version number of the MiOXSYS Analyzer

These serial numbers are important if the MiOXSYS Analyzer requires any updates or calibration.

MiOXSYS Analyzer Other Settings

To set the date and time:

- When the MiOXSYS 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 MiOXSYS 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 MiOXSYS Analyzer:

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

- When the MiOXSYS 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 MiOXSYS 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 720.437.6580 or via email at www.info@aytubio.com.
- To exit the “Display test” mode, wait 15 seconds or press any scrolling button.

MiOXSYS Analyzer Other Settings (continued)

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

- When the MiOXSYS 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.

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

- When the MiOXSYS 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.

MiOXSYS Power Supply

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

- The MiOXSYS 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 MiOXSYS unit and an AC power source. Alternatively, the battery will also be charged if connected to a computer with a USB cable.
- The MiOXSYS Analyzer can be operated using battery, USB or AC power.

MiOXSYS Power Off

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

MiOXSYS Maintenance

- All exterior surfaces may be disinfected using an alcohol wipe or swab, as necessary.
- The MiOXSYS Analyzer calibration should be performed by the user at installation and monthly thereafter to ensure accuracy of the results. Please refer to the calibration label on the bottom of the analyzer for its calibration expiration date.

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. MiOXSYS sORP External Control Solutions are supplied separately (cat# 100279). It is recommended that each new lot or shipment of MiOXSYS Sensors be verified upon receipt and before use. External controls tests should be performed thereafter in accordance with appropriate Federal, State, and local guidelines. A separate sensor must be used for each external control test.
3. MiOXSYS System should not be used in patient testing if the external controls do not produce the correct results.

To Check Calibration

Calibration Verification is performed by the user at installation and at monthly intervals thereafter. The Calibration Verification Key (CVK) verifies that the instrument is still within calibration.

1. Press the power button on the MiOXSYS 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.
2. "MiOXSYS" and the date and time will appear on the display screen for 3 seconds.
3. Insert the CVK into the sensor slot with the A-side facing up. The MiOXSYS Analyzer will indicate that a calibration check is being performed on the A-side.
4. When the verification is complete, the results will be displayed in the following order:
 - a. Side A: ORP = 100.3mV • ICell = -100.0 nA

NOTE: Before removing the CVK, record the date, time, results, and check them against the acceptance ranges listed on the Calibration Verification Card.

5. Repeat the procedure for the B-side of the CVK.
6. If the MiOXSYS Analyzer is out of calibration, please discontinue use of the MiOXSYS Analyzer and call Aytu BioScience – 720.292.5449.

MiOXSYS 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

Troubleshooting and Error Codes

Error Message	Description	Troubleshooting
Test Errors		
"Faulty sensor"	The sensor response was too noisy. (Spike detected.)	Repeat test procedure with a new sensor.
"Compliance error"	The measured cell current differs from the acceptable current by more than 5%.	Repeat test procedure with a new sensor.
"Sensor disappeared"	The sensor disappeared during processing.	Repeat test procedure with a new sensor.
"Unknown Sensor" or "Sensor Detect Error" or "Remove Sensor"	The system detected something connected to the sensor socket, but was unable to determine the type of sensor connected. (i.e. the connected sensor is not a MiOXSYS Sensor and is not a CVK.)	Repeat test procedure with a new sensor.
"Socket occupied"	There is something in the socket connector at boot up.	Please turn off power and inspect the socket module for any obstruction and remove. If problem persists, please call Aytu BioScience at 720.292.5449.
"LOW"	Result is below the limit of detection.	Repeat test procedure with a new sensor. If error message persists, repeat test with a new patient sample.
"HI"	Result is above the limit of detection.	Repeat test procedure with a new sensor. If error message persists, repeat test with a new patient sample.
Socket Module Errors		
"Socket module will expire soon Press enter"	The number of sensor insertions has exceeded 9000.	Please contact Aytu BioScience for technical service at 720.292.5449.
"Socket module has expired Power down"	The number of sensor insertions has exceeded 10000.	Please contact Aytu BioScience for technical service at 720.292.5449.
System Errors		
"Self-test error"	An error occurred during self test process	Please discontinue use and contact Aytu BioScience at 720.292.5449.
"Analog Front End** failure"	Insert and sudden removal of sensor prior to test completion.	Power down analyzer completely and repeat test procedure with a new sensor.

MiOXSYS Specifications

Test sample:	Fresh or Frozen Semen
Test result:	Referenced to 1X PBS or ascorbate standard
Sample volume:	30 µL
Measuring range:	.00 to 400mV
Measuring time:	120 seconds/two minutes
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:	64 to 86 (18 to 30 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) – MiOXSYS Analyzer <0.1 oz (0.9 grams) – MiOXSYS sORP Sensor
Sound:	A beep sounds when the measurement is complete and a test result appears on the screen. Fifteen beeps in 15 seconds will sound when the MiOXSYS 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 MiOXSYS System should be transported in the original packaging (including foam and box) or in a designated shipping container supplied by Aytu BioScience.



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

References on File at Aytu BioScience, Inc.

1. Pons-Rejraji, H., et al., [Role of reactive oxygen species (ROS) on human spermatozoa and male infertility]. *Gynecol Obstet Fertil*, 2009. 37(6): p. 529-35.
2. Agarwal, A., et al., Characterizing semen parameters and their association with reactive oxygen species in infertile men. *Reprod Biol Endocrinol*, 2014. 12: p. 33.
3. Du Plessis, S.S., et al., Contemporary evidence on the physiological role of reactive oxygen species in human sperm function. *J Assist Reprod Genet*, 2015. 32(4): p. 509-20.
4. Intasqui, P., et al., Differences in the seminal plasma proteome are associated with oxidative stress levels in men with normal semen parameters. *Fertil Steril*, 2016.

Glossary of Symbols



Manufacturer



Consult Instructions for Use



In Vitro Diagnostic Medical Device



WARNING!

Use Caution



DANGER!

Risk of personal injury or threat to health



CE Mark (product meets the requirements of EC directive 98/79 in vitro diagnostic medical device)



Underwriters Laboratories Certification Mark



Restriction of the Use of Certain Hazardous Substances (RoHS) in Electrical and Electronic Equipment (EEE) Directive (2011/65/ EU)



Catalog Number



Serial Number



Biological Hazard



Authorized Representative in European Community



Do Not Throw In Trash Mark Indicates Compliance with the WEEE (Waste Electrical and Electronic Equipment) Directive



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