

# **SQA-iO<sup>7</sup>**

# **Service Manual**

Version: 187.9.1  
Catalog#: IO-ML-01678-00  
Rev: May 12, 2024



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**SECTION I: Introduction**

The SQA-iO is a high-performance PC-based analytical medical device that tests semen samples. The device works with a computer application that contains device, patient, sample, test results and facility information.

After collection and preparation, a ~1 ml semen sample is withdrawn into an SQA capillary disposable delivery system, inserted into the SQA-iO, and sample test results are processed utilizing proprietary technology and algorithms. The testing process takes approximately 75 seconds.

The system runs an automatic self-test and auto-calibration upon start up and checks device stability before each sample is run.

**Automated  
Test Results  
and  
Reportable  
Range**

PATIENT ID: 4435353   PATIENT NAME: John Doe   BIRTH DATE / AGE: 17/03/1988 32   PHONE NUMBER: 815 5641 425   REFERRING DOCTOR: John Doe															
TEST RESULTS				SAMPLE INFORMATION											
PARAMETER	RESULT	REF VALUE	STATUS	TEST TYPE:	FRESH										
CONCENTRATION (M/ml)	64.4	>= 16		SAMPLE ID:	454548										
MOTILITY (%)	34	>= 42		COLLECTED DATE   TIME:	20/05/2020   10:00										
PROGRESSIVE (%)	19	>= 30		RECEIVED DATE   TIME:	20/05/2020   10:20										
RAPIDLY PROGRESSIVE (%)	3			TEST DATE   TIME:	10/05/2020   11:00										
SLOWLY PROGRESSIVE (%)	16			CRITERIA:	WHO 6 <sup>th</sup>										
NON-PROGRESSIVE (%)	15	<= 1		SAMPLE TESTED:	DILUTED 1+1										
IMMOTILE (%)	66	<= 20		VOLUME (ml):	0.80										
NORMAL FORMS (%)	13	>= 4		WBC CONC. (M/ml):	<1										
MOTILE SPERM CONC. (M/ml)	9.0			pH:	3.0										
PROG. MOTILE SPERM CONC. (M/ml)	9.0			APPEARANCE:	Normal										
RAPID PR. MOTILE SPERM CONC. (M/ml)	5.8			VISCOSITY:	Abnormal										
SLOW PR. MOTILE SPERM CONC. (M/ml)	3.2			LIQUEFACTION:	Normal										
FUNCTIONAL SPERM CONC.* (M/ml)	NA			ABSTINENCE (Days):	3										
VELOCITY* (mic/sec)	NA			OPTIONAL 1:											
SPERM MOTILITY INDEX*	58			OPTIONAL 2:											
SPERM # (M/ejac)	32.2	>= 39	↓	TESTER NAME:	John Doe										
MOTILE SPERM* (M/ejac)	4.8			TITLE (DESIGNATION):	Lab Manager										
PROG. MOTILE SPERM* (M/ejac)	3.2			COMMENTS:											
FUNCTIONAL SPERM* (M/ejac)	NA														
MORPH. NORMAL SPERM* (M/ejac)	6.1														
*MES parameters are indicated by an asterisk															
MOTILITY GRAPH <table border="1"> <caption>Motility Graph Data</caption> <thead> <tr> <th>Motility Category</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Immotile (%)</td> <td>66%</td> </tr> <tr> <td>Non-Progressive (%)</td> <td>15%</td> </tr> <tr> <td>Slowly Progressive (%)</td> <td>16%</td> </tr> <tr> <td>Rapidly Progressive (%)</td> <td>3%</td> </tr> </tbody> </table>				Motility Category	Percentage	Immotile (%)	66%	Non-Progressive (%)	15%	Slowly Progressive (%)	16%	Rapidly Progressive (%)	3%		
Motility Category	Percentage														
Immotile (%)	66%														
Non-Progressive (%)	15%														
Slowly Progressive (%)	16%														
Rapidly Progressive (%)	3%														
					<input type="button" value="SAVE"/>										

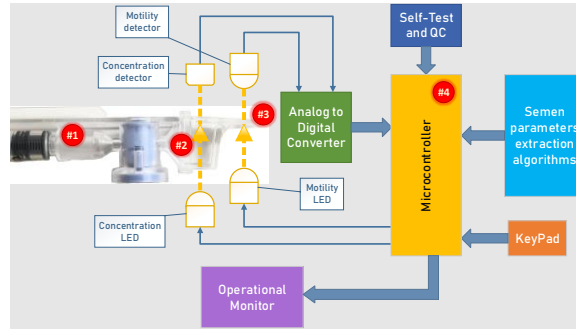
**Technology**

**Motility Channel**

Light disturbances caused by moving sperm cells are converted into **analog signals**. Proprietary algorithms interpret the signals and report motility.

**Concentration Channel**

Based on spectrophotometry analysis of semen samples and application of proprietary algorithms.



1. The capillary is inserted into the measurement compartment.
2. Sample concentration is evaluated in the "tall" 10 mm chamber of the capillary.
3. Motility is detected in the "thin" 0.3 mm section of the capillary.
4. This information is then digitized and routed to the microprocessor that applies algorithms to extract the required clinical semen parameters.

**SECTION II: System Specifications and Requirements**

**SQA-iO Device Overview and System Components**

- Dimensions: 8 X 9.5 X 10.5 cm
- Weight: 0.350 Kg
- Power supply: 5V DC (USB)
- Noise level: 0 [dBA]
- Device power consumption: 1.7 [BTU/hour] = 0.5 [Watts]

Minimum requirements:

- PC: Intel Core i5 M520 2.4GHz or equivalent
- RAM: 4GB
- Monitor Screen: Color, Wide screen – minimum resolution 1024 x 768
- Operating system compatibility: Windows 7 Professional x32 or above
- Communication Ports: one USB port
- Internet Access: 5mb per second

**Front Panel: Measurement Compartment (Capillary insertion for testing)**

**Measurement Compartment**



**Sources of radiant energy:** Two LEDs (motility and concentration channels)

**Detector system:** Two photo detectors (Motility and Optical Density)

**Analysis Time:** 75 seconds

**Software:** Resides on flash memory

**Motility channel input signal:** Analog, up to 5V.

**Concentration channel input signal:** Modulated (kHz) analog, up to 5V

**Calibrated to test human semen only at room temperature** (20-25°C/68-77°F)

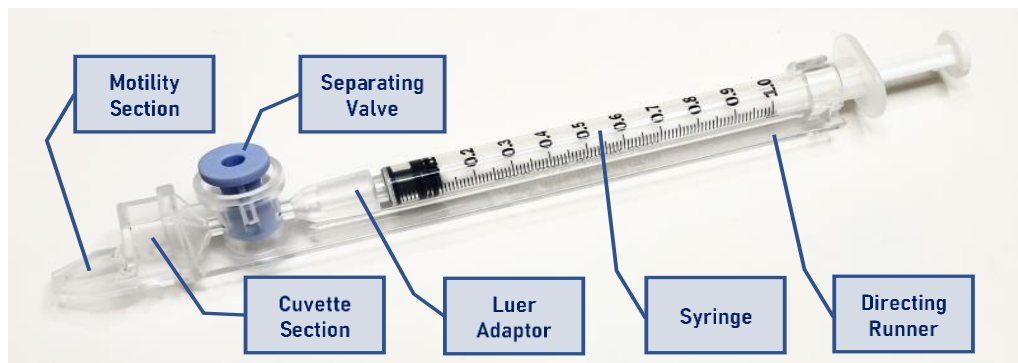
## USB Port Rear Panel: USB connection port

**USB PORT:** 1 connector for USB 2.0B male connection cable



## Testing Capillary

### Testing Capillary: Sample delivery system



**Single-use** design for testing semen in a biologically safe manner

**Motility parameters** are measured in the 0.3 mm (thin) "capillary" section

**Concentration** is measured in the 10 mm (tall) "cuvette" section

**Use only manufacturers' certified testing capillaries for testing**

**Filling and inserting the testing Capillary:** Refer to the Appendix section

### Maintenance Schedule

#### Measurement compartment cleaning:

- When to clean: **WEEKLY**
  - Or if SELF-TEST or any other failure occurs
  - Or if System becomes contaminated with semen
- Use only manufacturer's cleaning kit/supplies to prevent damaging the device
- Refer to the "**Cleaning the Capillary Compartment**" Appendix in this manual for detailed instructions

## Maintenance Requirements

**Manufacturer's Recommendations**

- The SQA-iO is sensitive to vibrations during the testing cycle. Operate away from devices that cause electronic noise or vibrations such as centrifuges.
- Un-plug the device when not in use for an extended period of time.
- Ambient temperature limitations: The SQA-iO is calibrated to conduct tests at room temperature: 20-25°C (68-77°F). This is the recommended range for room temperature maintenance of semen samples prior to testing for up to 1 hour following collection.
- **Sample processing limitations:** The device is calibrated to test semen samples at room temperature. Heating samples in ANY WAY will impact results. Do not heat samples.
- **Semen is considered biologically hazardous material and is subject to individual laboratory protocols for handling such materials. At a minimum, it is recommended to:**
  - Wear laboratory coat, mask and gloves when handling semen
  - Dispose of samples post testing in designated hazardous waste containers
  - Require that only personnel trained to work with biologically hazardous materials test and handle semen samples.

**Operating Temperature, Humidity and Altitude**

- Maximum operational humidity is up to 80% for temperatures of up to 31°C with decreasing linearly to 50% humidity at 38°C.
- Operates in a wide range of ambient temperatures (15-38°C) however the system is calibrated to measure semen samples at room temperature: 20-25°C (68-77°F).
- Intended for indoor use at a maximum altitude of 2000m, mains supply fluctuations ±10%, Overvoltage Category II, Pollution Degree II.

**IMPORTANT NOTES:**

- Humidity exceeding the limitations above may impact test results due to condensation on the optical detectors. Assess ambient humidity and temperature prior to device operation.
- Ambient temperatures exceeding the limitation above may impact the accuracy of semen motility test results because of the known effect of temperature on human semen.

**SECTION III: Quality Control**

**Internal Controls:** A series of tests are automatically run when the SQA-iO is turned on and prior to testing. These internal QC tests check the calibration settings and the internal operating system.

**Internal Controls are run @ SQA-iO Start-up: PASS/FAIL results are reported on the SQA-iO home screen along with troubleshooting information:**

- **Stabilization and autocalibration:** System stability and reference parameters are checked to ensure they are in proper range by analyzing the system sensors. Once stable for 30 seconds the device passes stabilization and autocalibration. A warning message is displayed on the home screen if there is a failure.
- **System noise:** Measures the electronic noise level of the system to insure effectiveness measurement of electronic signals.
- **Self-test:** Electronic signals simulating motility and concentration measurements verify that the calibration settings are consistent with factory specifications.

- **Autocalibration verification:** Reference parameters of the concentration and motility channels are measured again (without a testing capillary).
- **System noise:** Measures the electronic noise level of the system to insure effective measurement of electronic signals. The system automatically adjusts the noise level threshold to insure accurate readings.
- **Electronic spikes:** Checks for measurement points that are out of range.

**Instructions for printing the SQA-iO SERVICE parameters document to prepare for technical support:**

From the SERVICE category, view, download or print the **SERVICE REPORT**, which contains the latest results for system values, self-test and calibration.

AMPLITUDE (mV): 65.01 ✓ 50mV - 100mV

SELF-TEST STATUS: **PASS**

CALIBRATION AND STABILIZATION: **PASS**

SELF-TEST SERVICE REPORT

If a Self-Test failure occurs, the related status icon in the SQA-iO **HOME SCREEN** will turn red. Click on the RED icon to view instructions for how to resolve the problem:

Dashboard / Home / Dashboard

SERVICE DATA - KEY PARAMETERS SELF-TEST

REFERENCE 1 (mV):	215	✓
LED CURRENT 1 (mA):	10	✓
REFERENCE 2 (mV):	3264	!
LED CURRENT 2 (mA):	1245	✗
ZERO LEVEL:	510	✓
AMPLITUDE (mV):	70	✓

\*Click on the icons for more details

SELF-TEST STATUS: **FAIL**

CALIBRATION AND STABILIZATION: **PASS**

**SECTION IV: TROUBLESHOOTING**

The SQA-iO troubleshooting guide is focused on app access and function. The SQA-iO device cannot be opened for service so it is important to follow the cleaning and use instructions for optimal and continued success using the device.

Please refer to the appendix section for a TROUBLESHOOTING GUIDE.

Support is available through your local distributor online. Please contact them directly for questions concerning the device that are not outlined in this service manual.

## Appendix 1: SQA-iO Cleaning Instructions

### APPENDIX 1: Cleaning the SQA-iO

#### When to clean: **WEEKLY**

- Or if SELF-TEST or any other failure occurs
- Or if System becomes contaminated with semen

#### Cleaning kit components:

- Long cleaning brush (provided in the SQA-iO TEST KIT)
- Fibrous material cleaning paddles (single use)
- Sponge-tipped drying paddles (single use)
- Cleaning fluid (single drop dispenser)

#### CLEANING: STEP 1

- Insert the long brush supplied in your TEST KIT (bristle side down) into the chamber of the SQA-iO in the same way a testing capillary would be inserted (Fig 1 and 2).
- Pull the brush out, applying downward pressure to sweep or 'dust off' the optics (you will feel a 'shelf' in the back/top section of the chamber) – (Fig 2 and 3)

#### CLEANING: STEP 2

1. Use a **Fibrous material** cleaning paddle (Fig 4) supplied in your TEST KIT.
  - Moisten with only ONE drop of cleaning fluid.
  - Shake off excess fluid.
  - Insert into the measurement compartment fibrous material facing **down** and move the cleaning paddle in and out 5 times (Fig 5).
  - Then, insert into the measurement compartment fibrous material facing **up** and move the cleaning paddle in and out 5 times (Fig 5).
2. Dry the testing chamber using a sponge-tipped drying paddle that is supplied in your TEST KIT.
  - Insert it into the testing chamber and leave it for 10 – 15 seconds (Fig 6).
  - Leave the drying paddle in place, DO NOT move it in and out.



Fig.1 Long Cleaning Brush



Fig. 2 Clean the chamber



Fig. 3 "Dust off"



Fig. 4 Fibrous cleaning paddle




Fig. 5 Insert cleaning paddle down and up



Fig. 6 Dry the testing chamber with sponge



## APPENDIX 2: TROUBLESHOOTING GUIDE

<b>TROUBLESHOOTING OPERATING ERRORS:</b> This table describes what to do when a problem occurs with the SQA-iO app access or when running a test or receiving an error message. It is important to note: <b>If the SQA-iO case is opened by the user, it is no longer under warranty.</b>		
<b>ISSUE</b>	<b>POSSIBLE FAILURE SOURCE</b>	<b>SOLUTION</b>
<b>Computer connectivity</b>	1. USB connection error indicated on the app header / pop-up warning.	<b>Remove and reconnect the USB cable</b> – follow the pop-up warning instructions that can be activated by clicking the USB icon found in the app header or click the 'Disconnected' button on the app home screen.
	2. USB connection failure after installation	Display of Step 2 of the installation process where the user is asked to connect the USB cable. If it fails, please report using online support by clicking on the link to the troubleshooting page.
	3. Driver error after login/sign-up	Download and reinstall the driver by going to step 2 of the installation process. If it fails, please report using online support.
<b>Cannot Sign-up</b>	1. Missing required information	Fill in the mandatory fields that are missing information. This is indicated by red explanation text when clicking on the 'Register' button.
	2. Did not accept Terms and Conditions	
	3. User already exists	The email entered to "Register" is already in use. Select another email or may require a password reset (see 'Cannot Login' below)
<b>Cannot Login</b>	When clicking on the 'Login' button a warning that user email or password is incorrect/missing	Reset the user password: Request an email with a link to reset the password when receiving message "Forgot email?"
<b>Self-test failure</b>	A failure is indicated by a red warning icon on the HOME page.	Click the red icon indicating a failure. Observe the normal range value. <ol style="list-style-type: none"> <li>Clean the test chamber using ONLY MES cleaning kit.</li> <li>Remove and reconnect USB cable.</li> <li>Reboot the device.</li> </ol> If problem persists, refer to MES customer support: <a href="https://sqa-io.com/#/support/help?tabParam=contactus">https://sqa-io.com/#/support/help?tabParam=contactus</a>
<b>The testing capillary won't go into the SQA-iO</b>	The testing capillary may have been inserted upside down or blue piston is not fully pushed in.	Refer to the Appendix section of this guide for instructions on how to correctly prepare and insert the capillary into the SQA-iO device.
<b>Low Test Credit</b>	A red button is shown when the test credit balance is below 10.	Click the "Tests Remaining" button on the HOME screen to enter a new code for test credits or contact SUPPORT to order a new test kit with a new test credit code. If the credit balance is 0 the "Test Patient" section on the navigation bar is disabled.
<b>Cannot start testing / the START TEST button is disabled</b>	1. No test credits remain	<ul style="list-style-type: none"> <li>Add test credit from a new testing kit using the unique code provided.</li> <li>Order a new test kit by going to SUPPORT</li> </ul>
	2. Information missing in mandatory fields	Fill in all fields that are mandatory as indicated by an asterisk: *
	3. The SQA-iO is not connected	Remove and reconnect the USB cable per the pop-up instructions (and based on the red USB icon shown on the header bar).
<b>Internet connection is lost during a test</b>	Loss of internet connection	The internet connection icon will turn GREY and a pop-up warning will tell the user to reconnect and navigate back to the data entry screen. Start must be pressed again. The patient information is saved and the system will return to the data entry screen. Test credits will not be charged. 
<b>Test results are not logical</b>	Test results appear to be out of range.	Go to the Service page and follow the instructions: <ol style="list-style-type: none"> <li>Clean the test chamber using ONLY MES cleaning kit.</li> <li>Remove and reconnect USB cable and reboot the device.</li> </ol> If problem persists, refer to MES customer support: <a href="https://sqa-io.com/#/support/help?tabParam=contactus">https://sqa-io.com/#/support/help?tabParam=contactus</a>

**TROUBLESHOOTING PARAMETERS OUT OF RANGE:** This table describes what to do when a problem occurs with the service data key parameters. It is a detailed description of the Self-test failure that occurs on the HOME page. To solve the issue, navigate to the SERVICE page, follow the instructions below, and rerun the Self-test. If the problem persists, contact customer support.

PARAMETER	ACCEPTABLE RANGE	DESCRIPTION/SOLUTION
<b>REFERENCE 1 (REF 1)</b>	150 – 350 mV	<p>✓ Reference 1 passed the self-test</p> <p>✗ Reference 1 failed the self-test</p>
<b>LED CURRENT 1 (LED 1)</b>	5 – 20 mA	<p>✓ LED Current 1 passed the self-test</p> <p>✗ LED Current 1 failed the self-test</p> <p>Suggestion: Clean the device</p>
<b>AMPLITUDE</b>	50 – 100 mV	<p>✓ Amplitude passed the self-test</p> <p>✗ Amplitude failed the self-test</p> <p>Suggestion: Clean the device</p>
<b>ZERO LEVEL</b>	500 – 525	<p>✓ Zero Level passed the self-test</p> <p>✗ Zero Level failed the self-test</p> <p>Suggestion: Clean the SQA-iO. Maintain ambient temperature between 20 – 25°C / 68 – 77°C</p>
<b>REFERENCE 2 (REF 2)</b>	OPTIMAL: 2800 – 3500 PASSED: 2500 – 2800	<p>✓ Reference 2 passed the self-test</p> <p>! Reference 2 passed the self-test but is not in the optimal range</p> <p>✗ Reference 2 failed the self-test</p> <p>Suggestion: Clean the device</p>
<b>LED CURRENT 2 (LED 2)</b>	10 – 32 mA	<p>✓ Led Current 2 passed the self-test</p> <p>✗ Led Current 2 failed the self-test</p>
<b>AUTO-CALIBRATION AND STABILIZATION</b>		<p>✓ Auto-Calibration and Stabilization passed (Zero Level parameter is stable)</p> <p>✗ Auto-Calibration and Stabilization failed</p> <p>Suggestion:</p> <ul style="list-style-type: none"> <li>• Remove testing capillary from the measurement compartment</li> <li>• Remove the SQA-iO from sources of vibrations (centrifuge)</li> <li>• Clean the device</li> </ul>
<b>SELF-TEST</b>		<p>✓ Self-test passed (The key system parameters are in range)</p> <p>✗ Self-test failed</p>

### APPENDIX 3: Filling the Testing Capillary with a Semen Sample

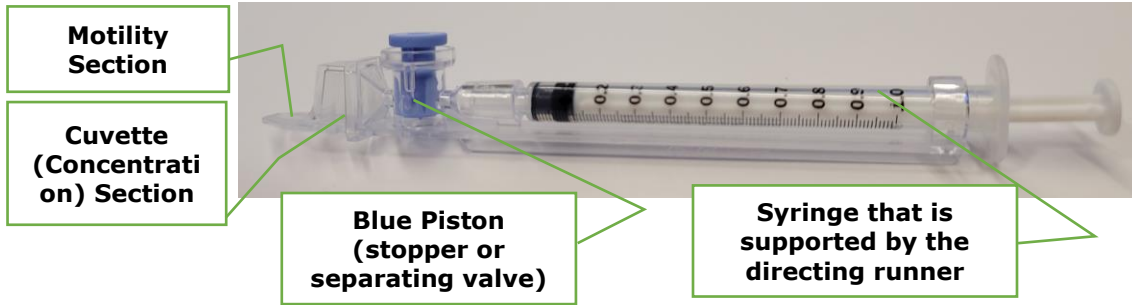
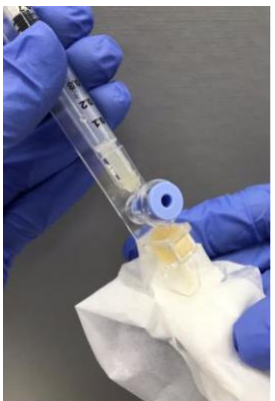


Fig. 1: Filling



Fig. 2: Inspect for bubbles



#### Sample size, collection and preparation instructions:

1. A minimum of .6 ml. of semen is required for the SQA testing capillary.
2. Self-collected the sample without using lubricants/creams or partners.
3. Test the sample after liquefaction and within 1 hour of collection for optimal results.
4. Maintained at room temperature 20-25°C / 68-77°F (do not heat or refrigerate).
5. Measure sample volume according to laboratory protocols.
6. Before filling the capillary, mix the liquefied sample gently by rotating the sample collection container.
7. **WARNING: Do not shake or use a pipette to mix the sample otherwise air bubbles will form and test results will be inaccurate.**
8. Carefully check that the liquefied, fully mixed semen is **free** of air bubbles.

#### Filling the capillary... Ready to test:

1. Push the syringe pump fully into the syringe and then place only thin part of the capillary into the bottom of the sample (Fig 1).
2. Pull the syringe pump back slowly while keeping the tip of the capillary well below the sample level and below any surface bubbles. Continue to aspirate the sample until it appears in the Luer adaptor (Fig. 1 & 2).
3. Check the capillary after filling (Fig. 2), visually confirm that the sample has **completely** filled the cuvette and thin section of the capillary (without a meniscus). Tap on the syringe to make sure there are no air bubbles in the sample. If air bubbles still appear below the Luer adaptor, fill again with a **small** quantity of semen to draw the air bubbles into the syringe.
4. Wipe the tip of the capillary with a **Kimwipe** quickly (to avoid wicking) (Fig. 3). Also wipe the exterior of the capillary if any spillage occurred, in order to keep the SQA-iO clean. Visually **confirm** that the capillary chambers are still full after cleaning. If not, slightly push in the piston of the syringe to re-fill the capillary section.
5. Slowly push in the blue separating valve until it is level with the plastic (Fig. 4).
6. Insert the testing capillary into the SQA-iO **all the way** with the blue valve down (Fig 5)

