SQA-iO
Service Manual

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Table of Contents

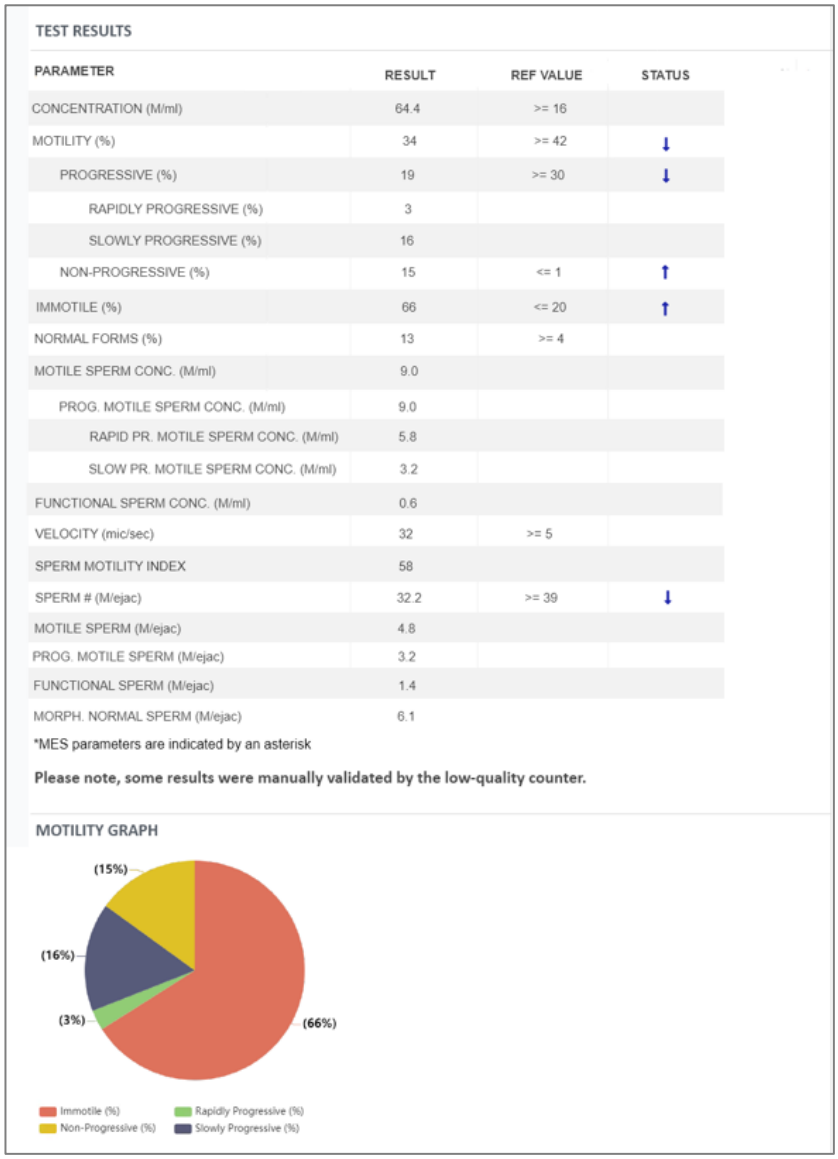
SECTION I: Introduction

The SQA-iO is a high-performance PC-based analytical medical device that tests FRESH semen samples. The device works with a computer application that contains the 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After collection and preparation, a ~1 ml semen sample is withdrawn into an SQA capillary disposable delivery system, inserted into the SQA-iO where key parameters are collected, and sample test results are processed utilizing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



TEST RESULTS

PARAMETER	RESULT	REF VALUE	STATUS
CONCENTRATION (M/ml)	64.4	>= 16	
MOTILITY (%)	34	>= 42	↓
PROGRESSIVE (%)	19	>= 30	↓
RAPIDLY PROGRESSIVE (%)	3		
SLOWLY PROGRESSIVE (%)	16		
NON-PROGRESSIVE (%)	15	<= 1	↑
IMMOTILE (%)	66	<= 20	↑
NORMAL FORMS (%)	13	>= 4	
MOTILE SPERM CONC. (M/ml)	9.0		
PROG. MOTILE SPERM CONC. (M/ml)	9.0		
RAPID PR. MOTILE SPERM CONC. (M/ml)	5.8		
SLOW PR. MOTILE SPERM CONC. (M/ml)	3.2		
FUNCTIONAL SPERM CONC. (M/ml)	0.6		
VELOCITY (mic/sec)	32	>= 5	
SPERM MOTILITY INDEX	58		
SPERM # (M/ejac)	32.2	>= 39	↓
MOTILE SPERM (M/ejac)	4.8		
PROG. MOTILE SPERM (M/ejac)	3.2		
FUNCTIONAL SPERM (M/ejac)	1.4		
MORPH. NORMAL SPERM (M/ejac)	6.1		

*MES parameters are indicated by an asterisk

Please note, some results were manually validated by the low-quality counter.

MOTILITY GRAPH

SQA-iO Reportable Range					
Sample Type	Conc. (M/ml)	Motility (%)	PMSC (M/ml)	Morph Norm Forms (%)	MSC (M/ml)
Fresh	2 - 400	0 - 100	0 - 400	1 - 30	0.2 - 400

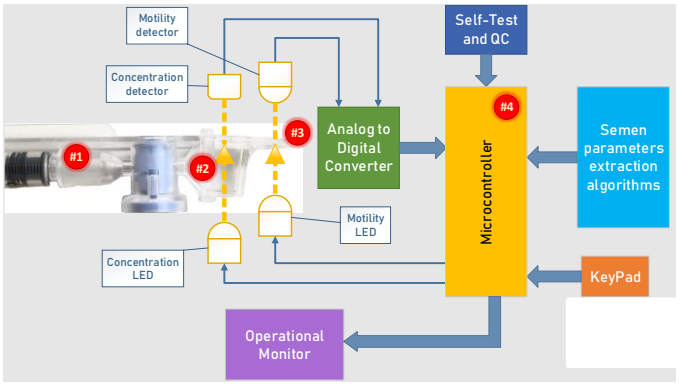
Technology

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 the 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.

SQA-iO Device Overview and System Components

SECTION II: System Specifications and Requirements

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

Measurement Compartment

Front Panel: Measurement Compartment (Capillary insertion for testing)

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 for testing human semen only at room temperature

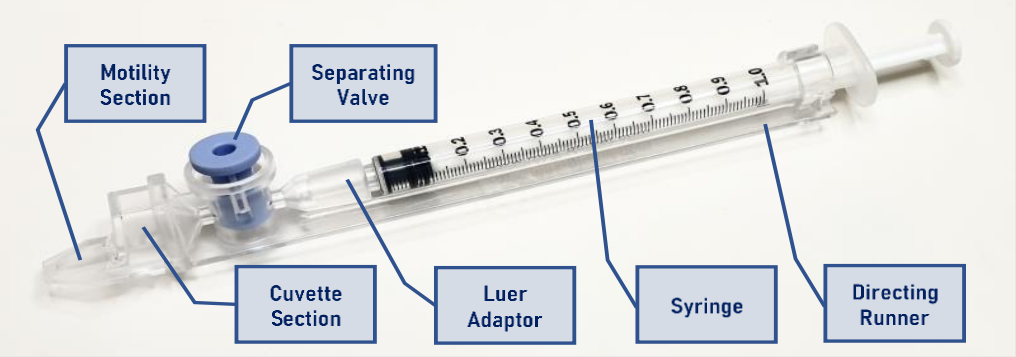
USB Port

Rear Panel: USB connection port

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

Testing Capillary

Testing Capillary: Sample delivery system



Normal sample: Requires approximately 0.5cc of semen
Short samples: Requires approximately 20µl
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 insterting the testing Capillary: Refer to the Appendix section

Maintenance Requirements

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

Testing and Operating 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: 20-25ºC (68-77ºF). 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.

Ambient Condition Restrictions for Operation

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:

- Humidiy exceeing 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

Quality Controls Overview

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.

PASS/FAIL QC Results

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

Controls Run at Start-up

- **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 effective measurement of electronic signals.
- **Self-test:** Electronic signals simulating motility and concentration measurements verify that the calibration settings are consistent with factory specifications.

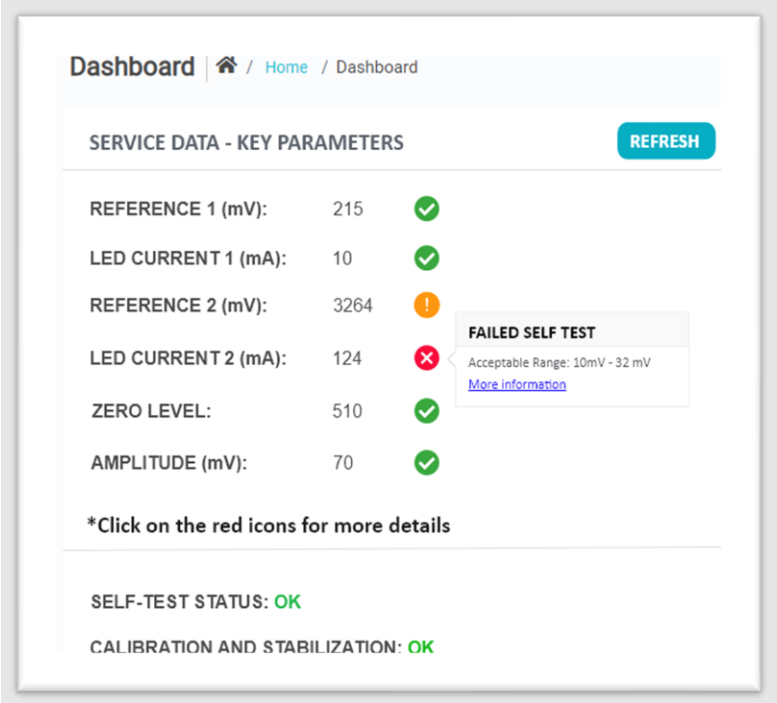
Controls Run Prior to Sample Testing

- **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.

Printing the Service Parameter Report

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

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:



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

Fibrous material cleaning paddles (single use)

Sponge-tipped drying paddles (single use)

Cleaning fluid (single drop dispenser)

Fig.1 Long Cleaning Brush

Fig. 2 Clean the chamber

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)

Fig. 3 "Dust off"

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. 4 Fibrous cleaning paddle

Fig. 5 Insert cleaning paddle down and up

Fig. 6 Dry the testing chamber with sponge

APPENDIX 2: TROUBLESHOOTING GUIDE

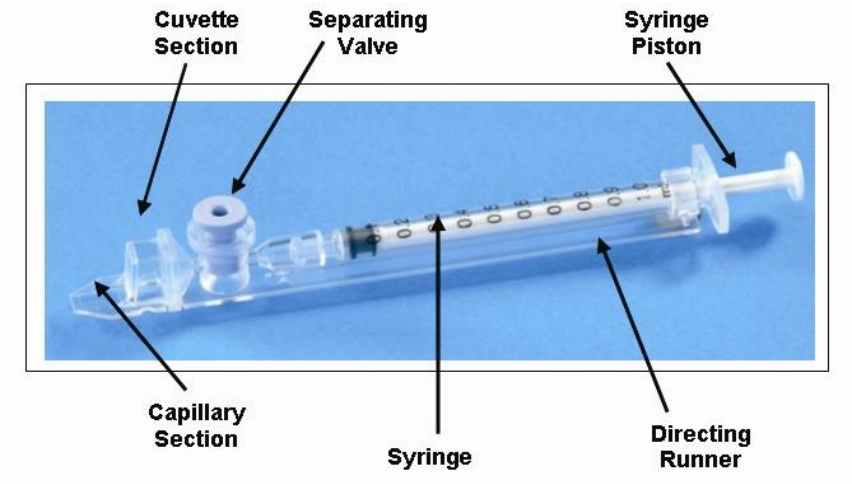
TROUBLESHOOTING OPERATING ERRORS: This table describes what to do when a problem occurs with the SQA-iO app access or when running a test or receiving an error message. It is important to note: **If the SQA-iO case is opened by the user, it is no longer under warranty.**

ISSUE	POSSIBLE FAILURE SOURCE	SOLUTION
Computer connectivity	1. USB connection error indicated on the app header / pop-up warning.	**Remove and reconnect the USB cable** – 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.
Cannot Sign-up	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)
Cannot Login	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?"
Self-test failure	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. 1. Clean the test chamber using ONLY MES cleaning kit. 2. Remove and reconnect USB cable. 3. Reboot the device. If problem persists, refer to MES customer support: https://sqa-io.com/#/support/contact-us
The testing capillary won't go into the SQA-iO	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.
Low Test Credit	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.
Cannot start testing / the START TEST button is disabled	1. No test credits remain	• Add test credit from a new testing kit using the unique code provided. • Order a new test kit by going to SUPPORT
	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).
Internet connection is lost during a test	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. 
Test results are not logical	Test results appear to be out of range.	Go to the Service page and follow the instructions: 1. Clean the test chamber using ONLY MES cleaning kit. 2. Remove and reconnect USB cable and reboot the device. If problem persists, refer to MES customer support: https://sqa-io.com/#/support/contact-us

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
REFERENCE 1 (REF 1)	150 – 350 mV	✓ Reference 1 passed the self-test ✗ Reference 1 failed the self-test
LED CURRENT 1 (LED 1)	5 – 20 mA	✓ LED Current 1 passed the self-test ✗ LED Current 1 failed the self-test Suggestion: Clean the device
AMPLITUDE	50 – 100 mV	✓ Amplitude passed the self-test ✗ Amplitude failed the self-test Suggestion: Clean the device
ZERO LEVEL	500 – 525	✓ Zero Level passed the self-test ✗ Zero Level failed the self-test Suggestion: Clean the SQA-iO. Maintain ambient temperature between 20 – 25°C / 68 – 77°C
REFERENCE 2 (REF 2)	OPTIMAL: 2800 – 3500 PASSED: 2500 – 2800	✓ Reference 2 passed the self-test ! Reference 2 passed the self-test but is not in the optimal range ✗ Reference 2 failed the self-test Suggestion: Clean the device
LED CURRENT 2 (LED 2)	10 – 32 mA	✓ Led Current 2 passed the self-test ✗ Led Current 2 failed the self-test
AUTO-CALIBRATION AND STABILIZATION		✓ Auto-Calibration and Stabilization passed (Zero Level parameter is stable) ✗ Auto-Calibration and Stabilization failed Suggestion: • Remove testing capillary from the measurement compartment • Remove the SQA-iO from sources of vibrations (centrifuge) • Clean the device
SELF-TEST		✓ Self-test passed (The key system parameters are in range) ✗ Self-test failed

APPENDIX 3: Filling the Testing Capillary with a Normal Volume Sample



Sample size, collection and preparation instructions:

1. Sample volume should be **at least .5 ml.** If sample volume is less than .5 ml the sample can be run as a short sample following the instructions in Appendix 2.
2. The sample must be collected without partners, gels or creams and tested within 1 hour of collection for accurate results.
3. Do not heat or refrigerate the sample, maintain an test at room temperature
4. The semen sample must be **completely liquefied and well mixed prior to aspiration:** Gently mix by rotating the sample collection container.

   WARNING: *Do not shake or use a pipette to mix the sample otherwise air bubbles will form and test results will be inaccurate.*

Figure 1

5. **Carefully check that the liquefied, fully mixed specimen is free of air bubbles** (or that there is an adequate amount of sample below the air bubbles) before immersing the capillary into the specimen.

Filling the capillary:

1. **Push the syringe pump fully into the syringe**. Place only thin part of the capillary into the bottom of the sample while angling the sample container at about 45 degrees (Figure 1).
2. Placing two fingers below the syringe pump's head **pull the syringe pump back slowly while keeping the tip of the capillary well below the sample level and below any surface bubbles** (Figure 1). Continue to aspirate the sample until it appears in the Luer adaptor (Figure 2).

Figure 2

3. Check the capillary after filling (Figure 3), **visually confirm that the sample has completely filled** the thin section (without a meniscus) and the cuvette section. A small level of sample should appear in the syringe. **Tap on the syringe to make sure there are no air bubbles** in the sample. If, after tapping, some air bubbles appear below the Luer adaptor, dip the capillary into the semen sample again and aspirate a small quantity of semen to draw the air bubbles into the syringe.

Fig 3 Inspect for bubbles

4. **Quickly (to avoid wicking) wipe the outer surface of the capillary** - both top and bottom (Figure 4) with a delicate wipe (Kimwipes, etc.). It is important to remove all semen from the exterior of the capillary in order to keep the SQA-iO clean. Visually confirm that the capillary chambers are still full following the cleaning process. If some of the sample has been depleted (meniscus formed in the thin part of the capillary) fill the capillary part from the cuvette section by slightly pushing in the piston.

Figure 4 Wipe the tip

5. Slowly and carefully **push-in the blue piston** until it is level with the plastic (Figure 5).

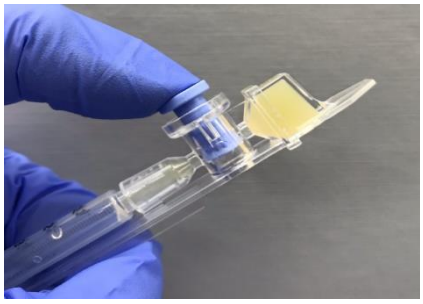


Figure 5: Push in the blue piston

6. The capillary is now ready.

7. **Insert the testing capillary into the measurement compartment with the blue stopper down.** Push it in as far as it will go to ensure that the capillary is properly seated.

APPENDIX 4: Filling the Testing Capillary with a Low Volume Sample

Sample size and preparation:

1. A sample as small as 10 microliters can be tested for motility parameters by filling ONLY the thin section of the testing capillary.
2. The sample must be collected without partners, gels or creams and tested within 1 hour of collection for accurate results.
3. Do not heat or refrigerate the sample, maintain and test at room temperature
4. The semen sample must be **completely liquefied and well mixed prior to aspiration:** Gently mix by rotating the sample collection container.

   WARNING: ***Do not shake or use a pipette to mix the sample otherwise air bubbles will form and test results will be inaccurate.***

Figure 1

Filling the capillary:

1. **Push the syringe piston in fully**. Place only the thin part of the capillary into the bottom of the sample (Figure 1).
2. **Pull the piston back slowly** without withdrawing the capillary from the sample. **Fill only the (thin) capillary chamber** with 10 microliters of semen (Figure 1). Aspirate the sample until it just appears in the cuvette section while keeping the tip of the capillary well below the sample level and well below the level of any bubbles covering the liquid.
3. Withdraw the capillary tip from the semen sample and visually inspect to ensure that the sample has completely filled the thin section (no meniscus).
4. Quickly (to avoid wicking) **wipe the outer surface of the capillary** - both top and bottom with a delicate wipe (Kimwipes, etc.). It is important to remove all semen from the exterior of the capillary in order to keep the SQA-iO clean.
5. Visually confirm that the thin chamber of the capillary is still full of semen after completing the cleaning process. If some of the sample has been depleted push-in the piston slightly until the first drop appears on the capillary tip and then fill the capillary again from the sample container.

Removing the blue piston:

6. The blue piston must now be removed:
   - Detach the entire syringe from the hub (Figure 2)
   - Use the syringe tip to firmly **push-out the separating valve** from the underside of the capillary (Figure 3).
   - Completely detach the separating valve (Figure 4). The capillary is now ready to be inserted into the SQA-iO

Figure 2: Detach the syringe

Figure 3: Push the piston out

Figure 4: Remove the piston

PLEASE NOTE: Test Low Volume samples as soon as the sample is aspirated into the capillary.