

# **SQA-VISION**

## **USER GUIDE**

Release Date : July 2023

**V e r s i o n   1 0 4 . 1 7 . 6**

**Table of  
Contents**

<b>SECTION 1: System Specifications and Requirements.....</b>	<b>4</b>
<b>SECTION 2: System Overview .....</b>	<b>6</b>
Testing Capillary .....	7
Slide Adaptor.....	7
Semen Parameters Reported by the SQA-VISION .....	8
Table of Reportable Ranges of the SQA-VISION .....	8
<b>SECTION 3: Technology .....</b>	<b>9</b>
Concentration:.....	9
Motility: .....	9
<b>SECTION 4: Getting Started .....</b>	<b>9</b>
System Installation .....	9
Auto-Calibration and Self-Test .....	10
Device Communication Screen .....	10
Service Menu .....	10
Add Test Credit (TC) Codes .....	11
SQA-VISION Navigation.....	11
Service Data .....	13
SQA-VISION Settings .....	15
TEST PATIENT .....	21
<b>SECTION 5: Test Patient .....</b>	<b>21</b>
CLINICAL TESTING .....	21
Entering Patient / Sample Data.....	21
Testing Semen Samples.....	21
Full Volume and 1:2 (1+1) Diluted Samples Test Results.....	25
10 µl Sample Test Results .....	26
Low Quality Test Results .....	27
Low Quality Counter .....	27
Counter for Manual Semen Analysis.....	28
Vitality Counting Screen.....	29
DNA Frag Counting Screens .....	30
Debris / Round Cells Scan .....	32
Longevity .....	33
ART PREP Mode.....	34

Post Vasectomy Testing .....	36
CRYO Dosing Process.....	40
CRYO TESTING .....	39
PRE-FREEZE Sample Testing .....	42
POST-THAW Sample Testing .....	42
<b>SECTION 6: QC / Proficiency .....</b>	<b>42</b>
Control Sample Testing .....	44
Proficiency Sample Testing .....	46
Internal QC .....	47
<b>SECTION 7: Visualization .....</b>	<b>48</b>
Standard Slide Preparation .....	49
Visualizing the Sample .....	49
Counting Spermatozoa.....	50
Manual Morphology .....	51
Vitality and DNA Frag.....	54
10-microliter Counter .....	56
Manual Morphology and Vitality Data Entry .....	56
Capturing Images .....	56
<b>SECTION 8: Archive.....</b>	<b>57</b>
<b>SECTION 9: Error and Warning Messages.....</b>	<b>61</b>
<b>APPENDIX 1: Filling the SQA-VISION Capillary with a Full Volume Sample .....</b>	<b>64</b>
<b>APPENDIX 2: Filling the SQA-VISION Capillary with a Low Volume Sample .....</b>	<b>66</b>
<b>APPENDIX 3: Preparing Slides for the SQA-Vision Visualization System .....</b>	<b>67</b>
<b>APPENDIX 4: Using the SQA-VISION Visualization System .....</b>	<b>68</b>
<b>APPENDIX 5: Cleaning the Capillary Compartment.....</b>	<b>69</b>
<b>APPENDIX 6: Reference Values of Semen Parameters .....</b>	<b>70</b>
<b>APPENDIX 7: Measuring WBC's in Semen .....</b>	<b>71</b>
<b>APPENDIX 8: Concentration Standard: Counting Chambers.....</b>	<b>72</b>
<b>APPENDIX 9: Globozoospermic Sample Assessment.....</b>	<b>73</b>
<b>APPENDIX 10: SQA-Vision Visualization Counters .....</b>	<b>74</b>
<b>APPENDIX 11: Post Vasectomy Analysis .....</b>	<b>75</b>
<b>APPENDIX 12: Assessing Debris/Round Cells In Semen Samples .....</b>	<b>76</b>
<b>APPENDIX 13: Product Performance Data .....</b>	<b>78</b>

## Specifications

**SECTION 1: System Specifications and Requirements**

Dimensions: 32 X 30 X 24 cm

Weight: 7 Kg

AC power supply: 100-240 VAC, 50-60 Hz, 20 VA

Noise level: 20-23 [dBA]

SQA-Vision device power consumption: 34.12 [BTU/hour] = 10 [Watt]

**Front Panel**

- Displays: LCD display
- Testing: Measurement and Visualization compartments
- Other: Multi-button keypad, Focus knob, Field of View Stage knob

**Keypad**

- **Operational keys:** I-Button, Service, Enter, Esc, Delete, four cursor buttons and ten numeric buttons (0-9).
- **Video control key:** Zoom In/Out

**Measurement Compartment**

- **Sources of radiant energy** - two LEDs for motility and concentration channels
- **Detector system** - two photo detectors - Motility and Optical Density

**Operating System**

- **Analysis Time:** Normal Test – 75 seconds; Low Quality – 2 additional minutes; Postvasectomy (automated) – 5 minutes
- **Software:** Resides on flash memory. System can be upgraded from a PC CD-ROM
- **Motility channel input signal:** Analog, up to 5V.
- **Concentration channel input signal:** Modulated (kHz) analog, up to 5V.

**Rear Panel**

- Power connector w/fuse-holder (fuse 250V,1A), 2 connectors for USB 2.0 A Male to B Male Connection Cables.

**Left Side Panel**

- On/Off power switch

**Visualization Compartment**

- White LED illumination system with luminous intensity 35000 mcd.
- Digital CCD, resolution: at least 1280 x 1024 pixels, high resolution of "live" and "frozen" images provided by capturing a high # of frames per sec.
- Objective: Standard, x40, chromatic aberration correction.
- Zoom system for smooth magnification transition between x1188 and x1725
- Focus regulator
- Field of View Stage knob



## Requirements

## Maintenance Schedule

- **Daily:** Clean measurement compartment daily when running samples and after every 10-15 tests and/or for ANY spillage. Follow manufacturer's cleaning instructions using manufacturer cleaning kit (Refer to the appendix section "Cleaning the Capillary Compartment" in this User Guide). **ONLY use the Manufacturer's cleaning kit and cleaning brush or damage will occur to the SQA-VISION device and the system will not operate!**

## Manufacturer Recommendations

- Operate the SQA-VISION away from devices that may cause electronic noise or other devices causing vibrations such as centrifuges.
- Turn system **OFF** when not in use for extended period of time.
- When running Post-vasectomy tests do not interrupt test cycle nor interfere with system or testing capillary in any way – this test is highly sensitive to any motion and requires complete stability of the system during the 5-minute testing cycle.
- Variations in ambient temperature can affect semen sample parameters. **It is essential that semen samples are not heated** for testing. The SQA-VISION is calibrated to conduct tests at room temperature: 20-25°C (68-77°F).
- **Semen is considered a biologically hazardous material and is subject to individual laboratory protocols for handling such materials and at a minimum:**
  - Laboratory coat, mask and gloves for operating personnel protection.
  - Sample handling and waste disposal in specially marked hazardous waste containers.
  - Sample handling should only be performed by trained personnel.

## Operating Temperature and Humidity

- Maximum operational humidity is up to 80% for temperatures of up to 31°C with decreasing linearly to 50% at > 38°C.
- Operates in a wide range of ambient temperatures (15-38°C) however the system is calibrated to accurately assess semen samples at room temperature: 20-25°C (68-77°F). Note: Extreme ambient temperature may impact the accuracy of test results.

## Operational Environmental conditions:

- System is intended for indoor use at a maximum altitude of 2000m, mains supply fluctuations  $\pm 10\%$ , Overvoltage Category II, Pollution Degree II.

## PC / Hardware

- **PC and device:** "All in One" computer with SQA-Vision device and related software.

## Quality Control

- **Internal:** Electronic Self-Test and Auto-Calibration. Runs automatically upon start-up. In addition, reference values are verified prior to each test.
- **External:** Runs QC samples per laboratory protocol.
- Runs assayed latex bead control: **QwikCheck™ Beads** (supplied by Medical Electronic Systems) for concentration and negative control for motility/concentration OR non-assayed: Latex beads or stabilized sperm CAP or NEQAS for concentration.

## Sample Testing

- **Sample Testing Temperature:** Calibrated for room temperature only. Motility results will be impacted by heating the specimen (not recommended).
- **System calibrated to test Human semen and specified Control samples only.**
- **SQA-VISION measurement capillary:** Disposable, plastic, testing capillary. Requires 500  $\mu\text{l}$  of sample for full volume testing, 10  $\mu\text{l}$  for low volume testing, 300  $\mu\text{l}$  for diluted mode. Use only manufacturers' certified testing capillaries in the automated system.

## Overview

- **Field of View Stage:** This stage is an integral part of the SQA-VISION visualization compartment. Either VISION™ fixed coverslip slides (when manual sperm counting is required) or standard slides (for assessing debris/round cells/morphology, DNA Fragmentation and capturing images) can be used.

## SECTION 2: System Overview

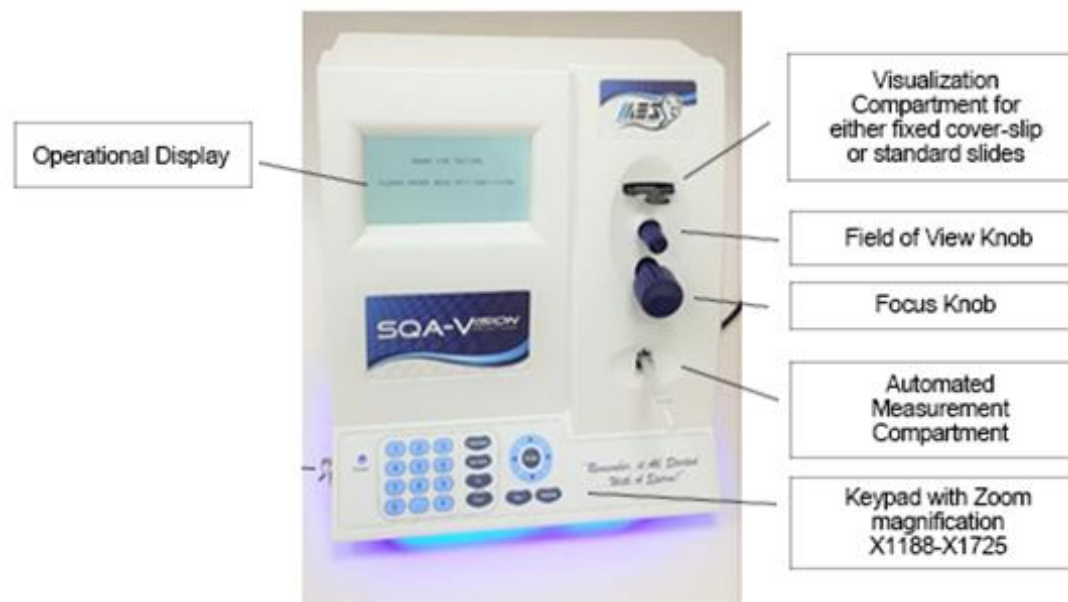
The SQA-VISION is a high performance analytical medical device that combines technology in optoelectronics, computer algorithms and video microscopy. The SQA-VISION and a fully integrated computer (TOUCH-SCREEN option) work together to provide user friendly semen analysis testing. Samples are run in the SQA-VISION and all data entry and user interface is computer based.

**FRESH, POSTVASECTOMY, WASHED, ART PREP, SWIM-UP, DENSITY GRADIENT, LONGEVITY and FROZEN** semen samples are run automatically. **VITALITY, DIFFERENTIAL MORPHOLOGY**, and **DNA FRAGMENTATION** can be assessed using a variety of CLICK/MARK counters and the high resolution vision visualization screen. The CRYO testing flow feature is designed for Sperm Banking and includes donor tracking and semen testing, dosing by a variety of parameters (motile, progressively motile or number of sperm) and pre/post thaw QC testing.

When results fall below the automated dynamic range of the system, a LOW QUALITY COUNTER opens automatically for manual sperm counting. Debris and round cell assessment can be performed using the DEBRIS/ROUND CELLS SCANNER. Oligozoospermic and low-quality IVF samples can be viewed and assessed using the SQA-VISION high resolution visualization feature and user-friendly click counters as well. Morphology differential counts can be assessed manually using the Morphology Counter and the visualization system. The automated semen analysis time: Normal quality samples ~ 75 seconds, Post-vasectomy ~ 5 minutes.

The system automatically performs self-verification. Two compartments: **automated testing** and **visualization** allow the user the flexibility to analyze all types of semen samples.

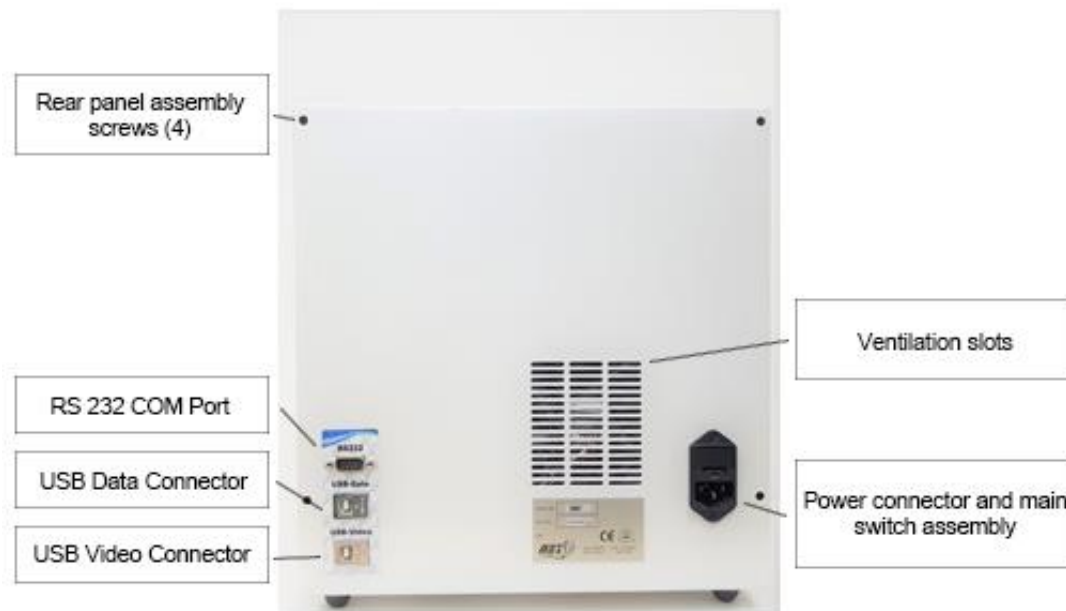
### Front Panel



### Keypad Navigation

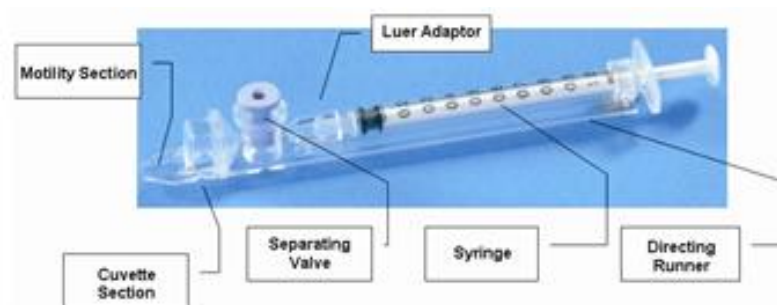
- **Numeric, Enter, Esc, Delete** and **Arrow** keys are used by the service personnel only.
- Press **Service** key to open the Service Menu (please refer to the corresponding section of the User Guide).
- Use **Zoom In / Out** for changing the video magnification.

## Back Panel



## SQA-VISION Components

### Testing Capillary



- Disposable, designed to collect and test samples in a biologically safe manner.
- Motility is measured in the 0.3 mm (thin) "Capillary Section". This section requires 10 microliters of semen.
- Concentration is measured in the 10 mm (tall) "Cuvette Section". This section requires 450 microliters of semen.
- The capillary is inserted into the measurement chamber of the SQA-VISION. Refer to the Appendix section of this guide for instructions on how to fill the SQA-VISION testing capillary with normal and low volume samples.

### Slide Adaptor



- Accommodates an SQA-Vision™ fixed coverslip slide or a standard slide (20-micron depth)
- Refer to Appendix section for full instructions on how to use the slide adaptor.

**Test Results****Semen Parameters Reported by the SQA-VISION**

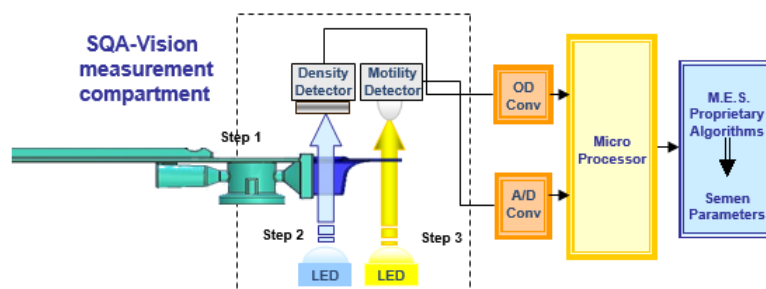
<b>Automated Test Results: WHO 6<sup>th</sup> Criteria</b>			
Sperm Concentration	M/ml	Motile Sperm Concentration (MSC)	M/ml
Total Motility	%	Rapid Progressively Motile Sperm Concentration (RPMSC)	M/ml
Rapidly Progressive	%	Slow Progressively Motile Sperm Concentration (SPMSC)	M/ml
Slowly Progressive	%	Functional Sperm Concentration (FSC) (Prog motile sperm with normal morphology)	M/ml
Non-Progressive	%	Velocity	mic/sec
Immotile	%	Sperm Motility Index (SMI)	#
Normal forms (WHO 5 <sup>th</sup> )	%		
<b>TOTALS PER SEMEN VOLUME</b>			
Sperm #	M/ejac	Functional Sperm	M/ejac
Motile Sperm	M/ejac	Morphologically Normal Sperm	M/ejac
Progressively Motile Sperm	M/ejac		
<b>POSTVASECTOMY</b>			
Motile, Immotile and Total Sperm	M/ml	# Motile, # Immotile and # Total Sperm/sem volume	M

**Reportable Range****Table of Reportable Ranges of the SQA-VISION**

<b>SQA-Vision Reportable Range (Automated Results)</b>						
Sample Type	Sperm Conc. M/ml	Motility %	Normal Morph %	MSC M/ml	PMSC M/ml	Motile/Immotile/ Total Sperm M/ml
Fresh	<2 - 400	0 - 100	2 - 30	<0.2 - 400	0 - 400	-
Washed	<2 - 200+	0 - 100	2 - 30	<0.2 - 200+	0 - 200+	-
Swim-up, Density Gradient and Frozen	-	-	-	<0.2 - 200+	0 - 200+	-
Post-Vasectomy	-	-	-	-	-	0 - 400

## Technology

## SECTION 3: Technology



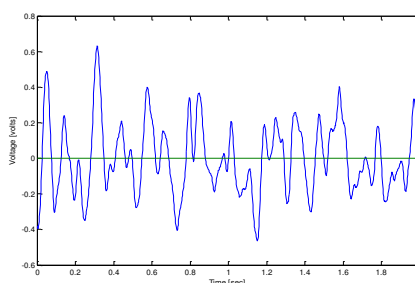
**Step 1: The capillary is inserted into the measurement compartment.**

**Step 2: Concentration:**

- Millions of sperm cells are analyzed: A very specific wavelength of light is absorbed by the sperm cells in the concentration chamber of the SQA-VISION testing capillary.
- An optical density detector measures the amount of light absorbed by the sperm cells and converts it to optical density (OD).
- The "OD" reading is translated into sperm concentration by a microprocessor based on proprietary MES algorithms.

**Step 3: Motility:**

- Tens of thousands of sperm cells are analyzed in the thin section of the SQA-VISION capillary as they move through a light beam in the SQA-VISION: The movement of motile sperm cells causes light disturbances.
- These light disturbances are converted into electronic signals with "peaks and valleys."
- The electronic signal peaks are analyzed by microprocessor software based on a proprietary MES algorithm and translated into motility parameters.



**Electronic Signal of Motile Sperm**

## SECTION 4: Getting Started

## System Installation

- Attach the supplied electrical cable to the outlet on the device's back panel.
- Plug cable into a grounded electrical source.
- Plug 2 cables into the data transfer and video output connectors on the rear panel of the device and to the USB connectors of a PC.
- Turn on the SQA-VISION by pressing the main switch located on the left side. The **Power** indicator will illuminate, and the following screens will be displayed on the device:

**Getting  
Started with  
the TESTING  
SYSTEM**

**NOTE:**

Do not touch the device during the stabilization process.

**Auto-Calibration and Self-Test**

SQA-VISION VERSION X.XX.XX  
PLEASE WAIT  
SYSTEM STABILIZATION AND  
AUTOCALIBRATION

- This process takes 5-7 minutes.
- When the system stabilization and auto-calibration processes are complete, a series of tests will be run:

**Self-Test**

SYSTEM SELF-TEST:

- Do not insert a capillary/slide into the device or use the keypad.
- The **device communication** screen will appear when the Self-Test process is complete. The SQA-VISION is now ready:

READY FOR TESTING  
PLEASE ENTER DATA  
INTO SQA-VISION

- Press: The **Service** key of the VISION to open the **SERVICE MENU**:

SERVICE MENU

SERVICE DATA  
SERVICE PERSONNEL  
ADD TESTS TO COUNTER

- Select **SERVICE DATA** and press **Enter**. The screen below will display coded service data:

SERVICE DATA		
1. 18	8. 112	15. 1.3
2. 5	9. 10	16. 110
3. 150	10. 6	17. 2
4. 28	11. 89	18. 1000
5. 70.65	12. 31	19. 100
6. 512	13. 100	20. 100
7. 0.000	14. 100	

- Press **Enter** to open two more Self-Test screens. **The same data is displayed on the SQA-VISION computer screen (see the SERVICE DATA section below).**
- **SERVICE PERSONNEL** is a password protected support screen.

**Device  
Communication  
Screen**

**Service Menu**

## Add Test Credit (TC) Codes

## SQA-VISION OVERVIEW

- For users implementing the new TC-Code internal feature, please reference the TC-Code Quick Start Guide found in the accessory kit or visit [www.testcreditcode.com](http://www.testcreditcode.com) for instructions on how to load Test Credits onto your device.

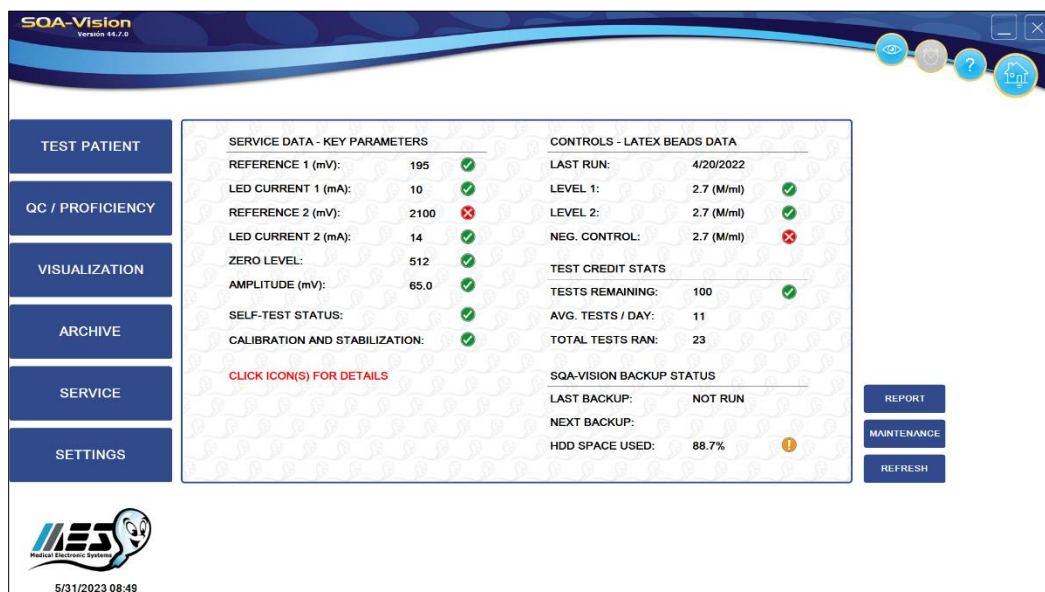
### The SQA-Vision app

- Double click the SQA-Vision icon on the PC desktop to open the screen below:



- Enter the User Name: **administrator**
- Enter the password: **fertility** and press **ENTER** to display the **HOME SCREEN**

## Home Screen



## SQA-VISION Navigation

### SQA-VISION APP: Touch-Screen Navigation

The SQA-Vision user interface is mouse click or touch-screen interactive. Six Main Menu navigation buttons are displayed on the left side of the screen:

- TEST PATIENT**
- QC/PROFICIENCY**
- VISUALIZATION**
- ARCHIVE**
- SERVICE**
- SETTINGS**

The following icons are displayed in the upper right-hand corner of the screen:



**Minimize:** Drops the screen to the PC taskbar**Longevity Timer:** Activated when running a Longevity Test**Help:** Opens Help menus**Exit:** Shuts down the Vision software**HOME:** Opens the Vision Service Data, Controls, Test Credits and Back-up status.**Video Preview:** Provides a view of the sample prior to initiating a test

Click the **HOME** screen button for the following information: **Service Data - Key Parameters, Controls - Latex Beads Data, Test Credit Status** and **SQA-Vision Back-up Status**.

- Parameters that pass the requirements are shown in green and checked (✓).
- Problematic service parameters are marked with a yellow exclamation mark.
- All parameters that have failed are displayed in red on the home screen:

**HOME SCREEN**

SERVICE DATA - KEY PARAMETERS			CONTROLS - LATEX BEADS DATA		
REFERENCE 1 (mV):	195	✓	LAST RUN:	4/20/2022	
LED CURRENT 1 (mA):	10	✓	LEVEL 1:	2.7 (M/ml)	✓
REFERENCE 2 (mV):	2100	✗	LEVEL 2:	2.7 (M/ml)	✓
LED CURRENT 2 (mA):	14	✓	NEG. CONTROL:	2.7 (M/ml)	✗
ZERO LEVEL:	512	✓	<b>TEST CREDIT STATS</b>		
AMPLITUDE (mV):	65.0	✓	TESTS REMAINING:	100	✓
SELF-TEST STATUS:		✓	AVG. TESTS / DAY:	11	
CALIBRATION AND STABILIZATION:		✓	TOTAL TESTS RAN:	23	
<b>CLICK ICON(S) FOR DETAILS</b>			<b>SQA-VISION BACKUP STATUS</b>		
			LAST BACKUP:	NOT RUN	
			NEXT BACKUP:		
			HDD SPACE USED:	88.7%	!



5/31/2023 08:49

- Click the or icon to read an explanation of the problem.
- Click **TROUBLESHOOT** to see the corrective action details.



## Service Report

## Service Data


- Open the **SERVICE REPORT** by pressing the **REPORT** button in the lower right-hand corner of the **Home** screen or from the **Service** screen (see below).

Page 1 of 1

**SQA-VISION SERVICE REPORT**

**M.E.S. Medical Electronic Systems**  
5757 W. Century Blvd. Suite 805  
Los Angeles, CA. 90045

PHONE: 866-557-9064  
FAX: 310-670-9069  
E-MAIL: [service@mes-sr.com](mailto:service@mes-sr.com)  
WEB: [www.mes-sr.com](http://www.mes-sr.com)




---

**SYSTEM INFORMATION**

SERIAL NUMBER:	2345	SOFTWARE VERSION:	4.23.44
DEVICE VERSION:	4.23.44	REPORT DATE / TIME:	07/31/2013 13:19

---

SELF-TEST DATA	RESULTS	UNITS	PASS CRITERIA	STATUS
REFERENCE 1	210	mV	150 - 300	
LED CURRENT 1	8	mA	5 - 20	
REFERENCE 2	2920	mV	2,600 - 3,400	
LED CURRENT 2	15	mA	10 - 32	
AMPLITUDE	88.11	mV	50 - 100	
ZERO LEVEL	499	BITS	500 - 525	
OD1	0.090		0 - 0.01	
OD2	1.125		0.8 - 1.2	
OD3	2.077		1.8 - 2.2	

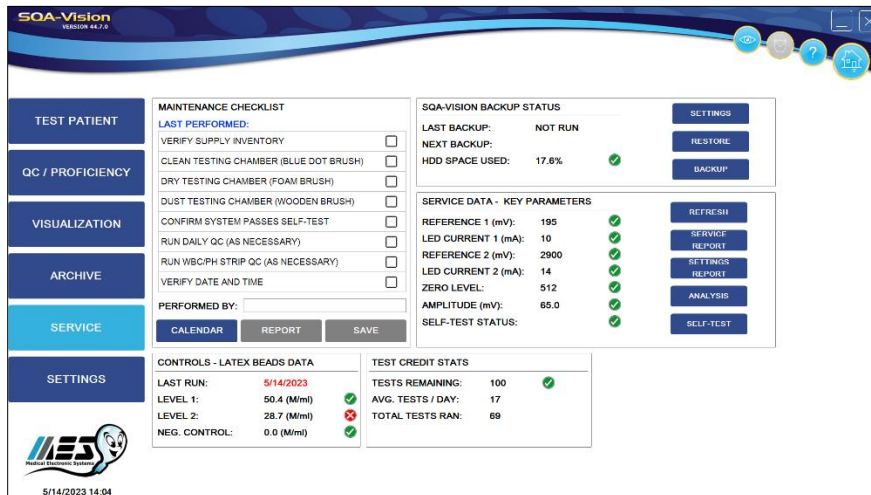
---

CALIBRATION DATA	RESULTS	SYSTEM VALUES	RESULTS
CONTROL REF. 1	15	TEST NOISE	1
MISC AMPLIFICATION	100	AVERAGE	88.11
SMI THRESHOLD	28	AVERAGE WIDTH	953
MIN. SP. HEIGHT	5	SPIKES	15
MAX. SP. WIDTH	150	COUNT	28
MIN. SP. WIDTH	10	TRANSMITTANCE	100
NOISE THRESHOLD	5	OD	0.000
CONTROL Z.I.	102		
OD AMPLIFICATION	100.0		
OD VALUE	1.700		
OD CORRECTION	100.0		
LB OD AMP	100.0		
AMP. CORRECTION	100.0		
AMPLITUDE AMP.	100.0		

PRINTED FROM SQA-VISION SERIAL #2345 AT 13:20 ON 07/31/2014 | [LES US] | CONC 2

## Service Screen

Click/Tap: **MAINTENANCE** button from the **Home** screen (or the **Main Menu**). To open the **SERVICE** screen displayed below:



**SQA-Vision**  
VERSION 4.23.44

**TEST PATIENT**

**QC / PROFICIENCY**

**VISUALIZATION**

**ARCHIVE**

**SERVICE**

**SETTINGS**

**MAINTENANCE CHECKLIST**

LAST PERFORMED:

VERIFY SUPPLY INVENTORY ☐

CLEAN TESTING CHAMBER (BLUE DOT BRUSH) ☐

DRY TESTING CHAMBER (FOAM BRUSH) ☐

DUST TESTING CHAMBER (WOODEN BRUSH) ☐

CONFIRM SYSTEM PASSES SELF-TEST ☐

RUN DAILY QC (AS NECESSARY) ☐

RUN WBCPH STRIP QC (AS NECESSARY) ☐

VERIFY DATE AND TIME ☐

PERFORMED BY: \_\_\_\_\_

CALENDAR REPORT SAVE

**SQA-VISION BACKUP STATUS**

LAST BACKUP: NOT RUN

NEXT BACKUP: \_\_\_\_\_

HDD SPACE USED: 17.6% ☒

SETTINGS RESTORE BACKUP

**SERVICE DATA - KEY PARAMETERS**

REFERENCE 1 (mV): 195 ☒

LED CURRENT 1 (mA): 10 ☒

REFERENCE 2 (mV): 2900 ☒

LED CURRENT 2 (mA): 14 ☒

ZERO LEVEL: 512 ☒

AMPLITUDE (mV): 65.0 ☒

SELF-TEST STATUS: ☒

REFRESH SERVICE REPORT SETTINGS REPORT ANALYSIS SELF-TEST

**CONTROLS - LATEX BEADS DATA**

LAST RUN: 5/14/2023

LEVEL 1: 50.4 (M/ml) ☒

LEVEL 2: 28.7 (M/ml) ☒

NEG. CONTROL: 0.0 (M/ml) ☒

**TEST CREDIT STATS**

TESTS REMAINING: 100 ☒

AVG. TESTS / DAY: 17

TOTAL TESTS RAN: 69

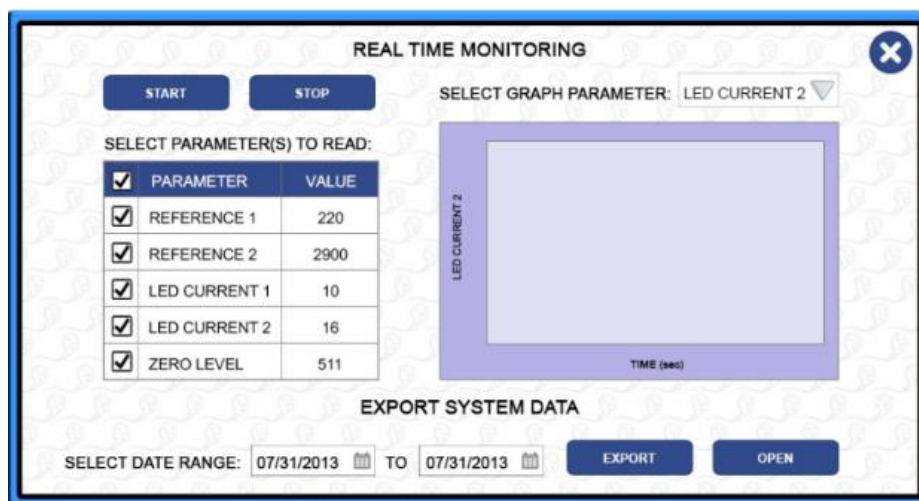
5/14/2023 14:04

- Daily Maintenance Checklist** documents the daily servicing of the SQA-Vision.
- Controls - Latex Beads Data** shows the latest QC test results.
- SQA-Vision Backup Status** displays the last and next scheduled backup date based on the user settings and the HDD (computer) space used.
- Service Data - Key Parameters** displays the status of the most critical service parameters.
- Test Credit Status** displays the: Number of tests remaining, average tests run per day and total # of tests run.

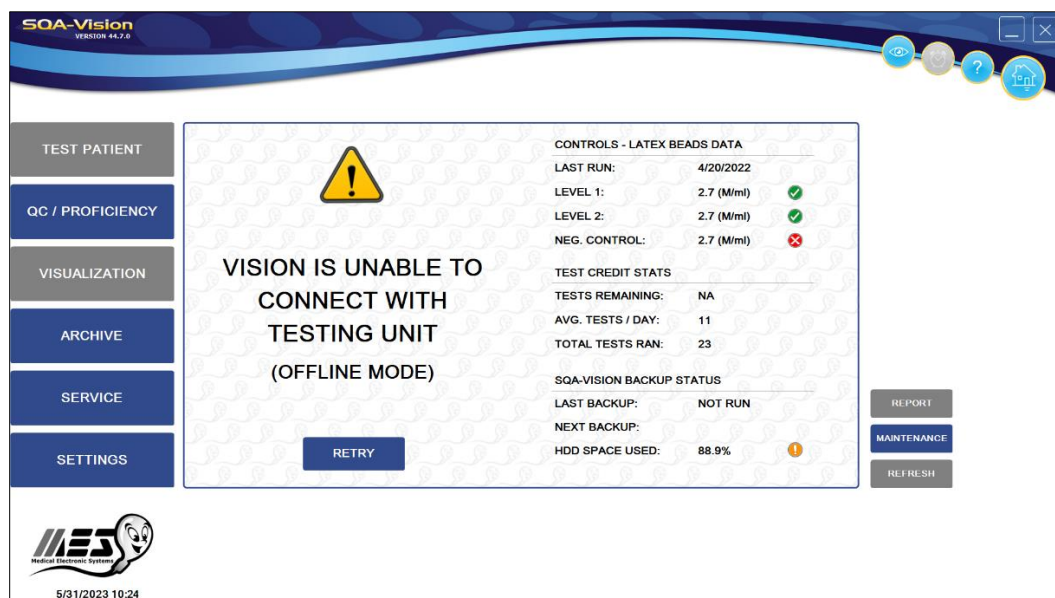
Parameters that are critical to the device function are displayed with a status icon.

- Click on the yellow or red warning icons to display information/corrective action.
- From the **SERVICE** screen, click (press) the appropriate buttons:
  - **SETTINGS**: opens a screen which displays all of the VISION settings
  - **RESTORE**: restores the backup data
  - **BACKUP**: initiates the backup process
  - **REFRESH**: runs a re-test of the Service Data
  - **SERVICE REPORT**: obtain a Service Report
  - **SETTINGS REPORT**: obtain a Settings Report
  - **ANALYSIS**: monitors critical service parameters. Select parameters from the dropdown menu provided.
  - **SELF-TEST**: initiates a check of the self-testing parameters

Click the **ANALYSIS** button to display the screen below which monitors service parameters in real time and may be used for troubleshooting/service support.



If there is a problem connecting the Vision to the PC, the message below will appear.



## Settings

## SQA-VISION Settings

Open **Settings** from the **Service** or **Main Menu** screen to set-up system and testing defaults. Seven buttons will be displayed at the top of the screen: **Controls**, **Proficiency**, **Test Patient**, **Visualization**, **System**, **Service** and **Lab Interface**.

## Controls Settings

## Please note:

All Set-up fields must have data. Enter the Control information from the QwikCheck™ or other assayed control kits.

If CONTROL settings are not known, enter "0" for LOT #, TARGET and RANGE and enter the current date for the EXP. DATE field.

## Please note:

To run 10 replicates: After each completed test, remove the capillary and initiate the CONTROL test again using the same capillary.

The screen to set-up **Controls** is shown above. Two QC materials, latex beads or stabilized sperm, can be set manually. QwikCheck™ beads assayed control information can be set-up manually or by using a barcode reader (scan the barcode shown under "Latex Beads Set-up" and then scan the barcode on the QwikCheck Beads box).

The information below will automatically be updated:

- **Lot #, Expiry Date, Target, Range**

Set the preferred **Graph Color** for each level of beads by clicking the colored circle. Press: **Clear** to delete the settings or **Save** to keep the settings.

Print the **Settings Report** using the **Report button** when the settings are completed.

### Set-Up: Non-Assayed Material to Establish the target value and +/- range:

**Step 1:** Enter the following information from the product labeling:

- **LOT#** - number identifying the control media lot
- **EXP. DATE** - control media expiration date (MM=month, YY=year)

**Step 2:** Enter the **TARGET VALUE** and **+/- RANGE**:

- Enter 0 for the target value
- Enter 0.0 for the +/- range

**Step 3:** Save settings

**Step 4:** Establish the target value and +/- range for each level:

- Fill a testing capillary and run 10 replicates in the **QC/PROFICIENCY** mode following the onscreen instructions
- Calculate the mean target value. Based on laboratory protocols determine the +/- range (Example: 2SD)
- Open Controls Settings again and update the **TARGET VALUE** and **+/- RANGE** for the control

If the settings have been entered incorrectly, a message will be shown: "DATA INPUT ERROR / RE-ENTER THE VALUE".

## Proficiency Settings

For laboratories who participate in peer reviewed **Proficiency Challenge Schemes** (such as CAP), manually enter the: **Sample #, Date** and **Notes** for up to four levels of samples when received from the supplier. Request protocols from your distributor for running samples other than CAP on the SQA-VISION.

## Test Patient Settings

Go to: **Test Patient Settings** to set-up default preferences for semen testing.

**Test Patient** Setting options/definitions:

- **CONCENTRATION STANDARD:** Select "1" for 10-20-micron counting chambers that do not require sample dilution; Select "2" for hemacytometers (please see the appendix section for a comprehensive list of counting chambers).
- **10 MICROLITER COUNTER (motility estimation):** Select to automatically open the visualization screen. Estimate motility for low volume (10 microliter) tests in order to provide a complete report (excluding morphology parameters).
- **LOW QUALITY COUNTER:** Select to automatically open a visualization screen for manual counting when test results fall below the dynamic range of the VISION.
- **WHO COUNTER:** Check this box to count Total Cells and Immotile Cells instead of Immotile Cells and Motile Cells when visual assessment is needed (per WHO recommendations).
- **DEBRIS/ROUND CELL SCAN CUTOFF:** Select to assess samples that may contain a concentration of debris/round cells that could impact automated results. The VISION provides criteria for identifying these samples and automatically activating the Debris Scanner. An option is also provided to assess ALL sample by selecting "scan for debris on all samples".

- **AUTO VITALITY TEST:** Select to activate Vitality Test right after completion of automated semen assessment. Vitality results will be obtained automatically and incorporated in the Semen Analysis Report.
- **MANUAL MORPHOLOGY DATA ENTRY:** Select **Manual Morphology Data Entry** in the **Test Patient Settings** to automatically display a grid to enter manually assessed Morphology when the morphology button is clicked. The results will be displayed in the patient report. If this option is set, all other SQA-Vision morphology counters will be disabled.
- **MANUAL VITALITY DATA ENTRY:** Select **Manual Vitality Data Entry** in the **Test Patient Settings** to automatically display a grid to enter manually assessed Vitality results when the Vitality button is clicked. The results will be displayed in the patient report. If this option is set, all other SQA-Vision Vitality counters will be disabled.
- **POST VAS FIELD BY FIELD COUNT:** Leave this box unchecked to assess 50 fields of view per slide without clicking 'next' for each new field of view. Count 50 fields of view per slide.
- **TESTING CRITERIA:** Either WHO 3rd, 4<sup>th</sup>, 5<sup>th</sup> or 6<sup>th</sup> criteria can be set.
- **MORPHOLOGY RANGE:** Set Morphology Upper Range Limit as an integer number from 10% through 30% based on the lab morphology assessment data. The default limit is 20%.
- **LES:** Set by the factory based on region.
- **DEFAULT TEST TYPE:** Select **NO DEFAULT** to select a test type (Fresh, Washed, Frozen, etc.) each time a test is run. Alternatively, an individual test type can be set up as a default. Then, when TEST PATIENT is selected, the relevant testing input screen will be presented.
- **LIST OF PARAMETERS:** Select the semen parameters to include in the test report. Reference Values are pre-set based on WHO criteria but can be modified by overwriting them. Use the convenience buttons 'Select All' or 'Clear All' if desired.
- **PATIENT DATA ENTRY - PATIENT AGE ONLY (NO BIRTH DATE):** Check this box to enter only the patient age, not the exact birth date.
- **VOLUME WEIGHT:** Select to calculate volume from weight (Gram/Ounce).
- **MANUAL DATA ENTRY - OPTIONAL FIELDS:** Enter any labeling desired in any one of these fields. They will appear as labeled on the test report and on the data entry/patient testing screen.
- **LONGEVITY INTERVAL:** Set the time interval defaults for longevity testing.



## Visualization Settings

**Visualization Settings:** Use the screen above to set and define options:

- **Video Settings:** set by the factory.
- **Vitality Settings:** Select either **Click Count** (no cell marking) or **Mark Count** (a circle will mark the cell) to assess live/dead sperm cells.
- **Morphology Settings:** **Normal vs. Abnormal** to only differentiate between the % of normal or abnormal forms or **Full Differential** to conduct a full morphology differential

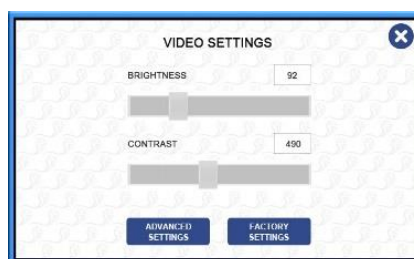


complete with color coded circles marking the various spermatozoa abnormalities (**Mark Count**) or without marking (**Click Count**).

- **DNA Fragmentation settings:** Select the default colors of **HALO/NO HALO** or **HALO GRADING** mark counts; Select count type: **Click or Mark Count**.
- **Grid Size / Color:** Define the desired grid settings for the VISION video screen.
- **Circle Size:** Define the circle size for marking cells in the Morphology / Vitality counters.

The following buttons are located at the bottom of the video screen:

- **Refresh:** Re-balance the camera background
- **Grid On/Off:** Click **Grid On** to activate the grid; Click **Grid Off** to remove.
- **Freeze/Real Time:** Click **Freeze** to stop the video; Click **Real Time** reactivate.
- **Full Screen:** Select to open a full screen; press Esc on the PC keyboard to close.
- **Settings:** Adjust the video parameters shown below:



Use **Advanced Settings** for fine tuning and **Factory Settings** to restore video defaults using the three buttons in the lower right-hand corner:

- **Defaults:** To restore default settings
- **Report:** To generate the Settings Report
- **Save:** To save the new settings

Open the **System Settings** to set up:

## System Settings

- **Facility Information:** Enter facility information and insert a logo which will be displayed on the Semen Analysis Test Report.
- **Language File Upload:** Change the language to suit the user.
- **Sound Type:** Select an alert to signal the completion of test/data transfer.
- **User and Password Setup:** Select a user name and password.
- **Test Report Settings:** Select the parameters to be displayed in the test report.
- **Enable CRYO Bank mode:** Select to work in the CRYO Bank flow for sample dosing, freezing and QC.
- **Test initiated from host:** Select to pull the testing plan from the host system and initiate testing based on the plan.
- **Show mode selector:** Switch between Clinical LAB and CRYO mode without the need to go to SETTINGS.
- **MLF/PMLF setting (for CRYO mode only):** Set the criteria for dosing cryo samples by a motility or progressive motility loss factor.
  - **Average of last:** Select to set the period of time for averaging and determining the motility or progressive motility loss factor.

- **Processing Lost:** Prevent sample over-dilution by adding a factor to compensate for motility lost in the procedure itself (e.g. dilution, centrifugation, etc.). the target value defined for dosing will be increased. Example: The target value is 50M/ml progressively motile cells but the Processing loss factor is 20%. The system will calculate the target as  $(50 \times 1.2 = 60)$ .
- **2 Media Dilution Ratio:** Allows for a two-step dilution. The freezing media will be calculated as a ratio from the total volume (normally 1:3) and the rest of the dilution will be washed media (excluding the semen volume).
- **Extending Steps: Two types of dosing: Sperm Target Dosing or Volume Dosing**
  - **Target dosing:** Meeting the required target # of cells in each dose.
  - **Volume dosing:** The system will calculate the amount of freezing media to be added to meet a pre-defined ratio of sample to media.

## Service Settings

Open the **Service Settings** to set up:

- **Maintenance Activities:** Accept/overwrite the activities listed.
- **Backup Frequency:** Set the back-up schedule for the VISION. A system back-up reminder will pop up based on the schedule.
- **Service Data (save to database):** Save service data for troubleshooting.
- **QC Frequency:** Set-up how often to perform control testing.
- **Maintenance is obligatory:** If selected, the system will not permit testing until all maintenance tasks are completed.

## Lab Interface Settings


Lab Interface works with the facility LIS to provide SQA-VISION test results and patient data transfer to the facility mainframe. The screen below displays set-up/data transfer options/criteria.

FIELD NAME	FORMAT
# IMMOTILE SPERM/VOL. (PV)	0.00
# MOTILE SPERM/VOL. (PV)	0.00
# Sperm Counted	0
# TOTAL SPERM/VOL. (PV)	0.00
ABNORMAL	0.0
ABNORMAL 1	0.0
ABNORMAL 2	0.0
ABNORMAL 3	0.0

Click the **Report** button to generate a settings report (1<sup>st</sup> page is shown below).



## Settings Report

PHONE: 310-670-9066 FAX: 310-670-9069 E-MAIL: <a href="mailto:sales@mes-llc.com">sales@mes-llc.com</a> WEB: <a href="http://www.mes-global.com">www.mes-global.com</a>		M.E.S Medical Electronic Systems 5757 W. Century Blvd 805 Los Angeles, CA. 90045				Page 1 of 2
SQA-VISION SETTINGS REPORT						
<b>SYSTEM INFORMATION</b>						
SERIAL NUMBER:	5368	SOFTWARE VERSION:	44.7.0.19			
DEVICE VERSION:	03.00.073	REPORT DATE / TIME:	5/14/2023 02:10			
<b>SETTINGS</b>						
LANGUAGE FILE:	English (United States)	VIDEO COMPRESSION:				
DEFAULT TEST TYPE:	NO DEFAULT	VIDEO DEVICE:	ICube			
CONC. STANDARD:	CONC. STANDARD 2	VIDEO SUBTYPE:	default			
TESTING CRITERIA:	WHO 6TH	SOUND TYPE:	Windows Background.wav			
MORPH. UPPER LIMIT RANGE:	20	DO NOT SHOW FACILITY INFO ON REPORT:	NO			
DEBRIS SCAN CUTOFF:	SCAN FOR DEBRIS ON ALL SAMPLES	UPPER MARGIN:	35			
WHO COUNTER:	NO	SHOW SAMPLE INFORMATION ON THE FIRST PAGE ONLY:	NO			
LOW QUALITY COUNTER:	YES	HIDE PAGE NUMBER ON THE FIRST PAGE:	NO			
10 MICROLITER COUNTER (MOTILITY ESTIMATION):	YES	REPORT TYPE:	STANDARD			
MANUAL MORPHOLOGY DATA ENTRY:	NO	NUMBER OF IMAGES PER TEST REPORT PAGE:	4			
MANUAL VITALITY DATA ENTRY:	NO	MORPH. TEST TYPE:	NORMAL / ABNORMAL			
POST VAS. FOV-CLICK:	NO	MORPH. COUNT TYPE:	MARK COUNT (CIRCLE)			
PATIENT AGE ONLY (NO BIRTH DATE):	NO	MORPH. COUNT 1:	NORMAL			
SHOW PARAMETERS RANGES:	YES	MORPH. COUNT 2:	ABNORMAL			
AUTO-EXPORT ENABLE:	NO	VITALITY COUNT TYPE:	MARK COUNT (CIRCLE)			
AUTO-EXPORT INCLUDE IMAGES:	YES	VITALITY COUNT 1:	LIVE			
LES:	ROW	VITALITY COUNT 2:	DEAD			
PATIENT DATA OPTIONAL INPUT 1:	OPTIONAL 1	DNA FRAG. COUNT TYPE:	MARK COUNT (CIRCLE)			
PATIENT DATA OPTIONAL INPUT 2:	OPTIONAL 2	DNA FRAG. TEST TYPE:	HALO / NO HALO			
MANUAL OPTIONAL INPUT 1:	OPTIONAL MANUAL 1	DNA FRAG. COUNT 1:	HALO			
MANUAL OPTIONAL INPUT 2:	OPTIONAL MANUAL 2	DNA FRAG. COUNT 2:	NO HALO			
MANUAL OPTIONAL INPUT 3:	OPTIONAL MANUAL 3	CIRCLE RADIUS:	20			
MANUAL OPTIONAL INPUT 4:	OPTIONAL MANUAL 4	CIRCLE PIXEL SIZE:	3			
PRINTED FROM SQA-VISION SERIAL # 5368 AT 02:10 ON 5/14/2023						

## SECTION 5: Test Patient

### TEST PATIENT

CLINICAL ☒ CRYOBANK

The button above is used to select either CLINICAL or CRYO testing as described below.

### CLINICAL TESTING

#### Entering Patient / Sample Data

Enter information about the patient and the sample prior to initiating the testing process. To accurately "classify" the semen sample by type and volume and to understand the testing options, refer to the information below:

#### Sample Data

Select: **SAMPLE / TEST TYPE** based on the following sample definitions/options:

- **FRESH** – Sample is not enriched, diluted or treated and is within 1 hour of collection. Required testing volume is  $\geq 0.5$  ml (the entire testing capillary needs to be filled) or, if less sample is available, the sample can be diluted 1:2 [1+1] for a full report of all semen parameters. A 10-microliter sample can be loaded into just the thin capillary section for a limited report of just motility parameters.
- **POSTVASECTOMY (POST VAS)** – Fresh sample designated as post-vasectomy and tested within an hour of collection will report Motile, Immotile and Total Sperm in M/ml and per ejaculate. Samples analyzed for Qualitative Results (Present or Absence of sperm) can be analyzed within 24 hours of collection using the Manual option only on the Vision.

- **ART PREP** – Semen sample prepared for intrauterine injection (IUI) or in-vitro fertilization (IVF).
- **WASHED** – Sample is enriched or prepared for artificial insemination by centrifugation using a washing media to replace the seminal plasma. Frozen samples containing egg yolk buffer are excluded from this mode. Testing volume required is  $\geq 0.5$  ml or less (please see the comments for Fresh semen).
- **SWIM-UP** – Sample is prepared for artificial insemination using a "swim-up" procedure. Only motility-related parameters will be reported (MSC, PMSC, SMI and VELOCITY). Testing volume required is  $\geq 10$   $\mu$ l.
- **DENSITY GRADIENT (GRADIENT)** – Sample is prepared for artificial insemination using a density gradient enrichment procedure. Only motility-related parameters will be reported (MSC, PMSC, SMI and VELOCITY). Testing volume required is  $\geq 10$   $\mu$ l.
- **FROZEN** – Samples which were frozen and recently thawed. Only motility-related parameters will be reported (MSC, PMSC, SMI and VELOCITY) in order to quantify the impact of the freezing/thawing process on motility. Testing volume required is  $\geq 10$   $\mu$ l.
- **LONGEVITY** – Fresh samples tested over a predetermined time sequence to assess the sample stability over time. Testing volume required is  $\geq 0.5$  ml. One testing capillary is required per each sequential test.
- **MANUAL (3 options – refer to Appendix 10):**
  - **Semen Analysis** – Any sample tested manually using the visualization compartment.
  - **Vitality** – % Live spermatozoa assessed using Vitality kit stain.
  - **DNA Fragmentation** – DNA Fragmentation Index (DFI, %) calculated by assessing sperm with HALO/NO HALO or by HALO GRADING (per WHO 6<sup>th</sup> criteria). Samples must be prepared using a DNA Fragmentation kit and can be assessed easily using the DNA Fragmentation counter.

Select: **TEST PATIENT** from the **Main Menu** to display the screen below with 9 types of sample testing options: **Fresh, Post-vasectomy, Art Prep, Washed, Swim-up, Density Gradient, Frozen, Longevity** and **Manual**. Select **FRESH** to display the screen below:

If only one type of sample is run constantly, set the TEST TYPE default in the SETTINGS section of the VISION. The appropriate test type will then open automatically (the user can still select another test type from the displayed test options).

The screenshot displays the SQA-VISION software interface. At the top, there's a header with the logo and version number. Below the header is a navigation bar with buttons for different test types: FRESH, POST VAS, ART PREP, WASHED, SWIM UP, GRADIENT, FROZEN, LONGEVITY, and MANUAL. The 'TEST PATIENT' button is highlighted. On the left side, there's a vertical menu with buttons for QC / PROFICIENCY, VISUALIZATION, ARCHIVE, SERVICE, and SETTINGS. The main area contains several input fields: PATIENT ID (dropdown), FIRST NAME, LAST NAME, SAMPLE ID, BIRTH DATE, ABSTINENCE (days), COLLECTED DATE, COLLECTED TIME, RECEIVED DATE, RECEIVED TIME, VOLUME (ml), WBC CONC. (M/ml), pH, APPEARANCE (dropdown), VISCOSITY (dropdown), LIQUEFACTION (dropdown), OPTIONAL 1, and OPTIONAL 2. At the bottom, there's a COMMENTS field and three buttons: 1+1 DILUTION, 10 MICRO, and TEST NOW. The bottom status bar shows the date and time: 4/24/2023 08:09.

Enter the requested patient/sample information using the SQA-VISION keyboard:

- **PATIENT ID** (mandatory entry) – Unique patient ID/number (Maximum of 20 characters). Select PENDING if the patient ID is unknown (and enter it later).

## Patient Information

## Sample Information

### PLEASE NOTE:

Refer to the appendix section of this user guide for information on how to measure semen WBC's and pH and how to handle viscous samples.

- **FIRST NAME** – First name identifying the patient (PENDING is accepted).
- **LAST NAME** – Last name identifying the patient (PENDING is accepted).
- **SAMPLE ID** (mandatory for Longevity and ART PREP testing) - Unique sample ID/number (Maximum of 20 characters).
- **BIRTH DATE** – Birth date of the patient (PENDING is accepted).
- **ABSTINENCE** - Number of days since the patient's last ejaculation.
- **DATE/TIME COLLECTED** – Date and time the sample was collected.
- **DATE/TIME RECEIVED** – Date and time the sample was received.
- **VOLUME** (mandatory entry for Post Vas) – Enter the volume of the **whole** ejaculate (Fresh, Post Vas and Longevity test) or of the sample (other types of tests) in milliliters. Do not enter '0' for the volume. Enter >0 or leave empty. If Calculate Volume From Weight feature is set, the CUP WEIGHT and FINAL WEIGHT results should be entered in the patient data entry screen, and the software will calculate an ejaculate volume per WHO 6<sup>th</sup> manual guidelines:

CUP WT. (G):  FINAL WT. (G):

- **INITIAL and FINAL SAMPLE VOLUME (ml)** - Mandatory parameters for the CENTRIFUGED Post-vasectomy sample (initial volume must be > final volume).
- **WBC CONC.** – select < 1 M/ml (normal) OR >= 1 M/ml (abnormal) leukocytes (Mandatory parameter for Fresh, Washed and Longevity tests).
- **pH** – pH of the semen sample (QwickCheck Test Strips recommended).
- **APPEARANCE** – Categories one of which should be selected from the drop-down menu below based on visual assessment of the specimen:

APPEARANCE:

OPTIONAL 1:

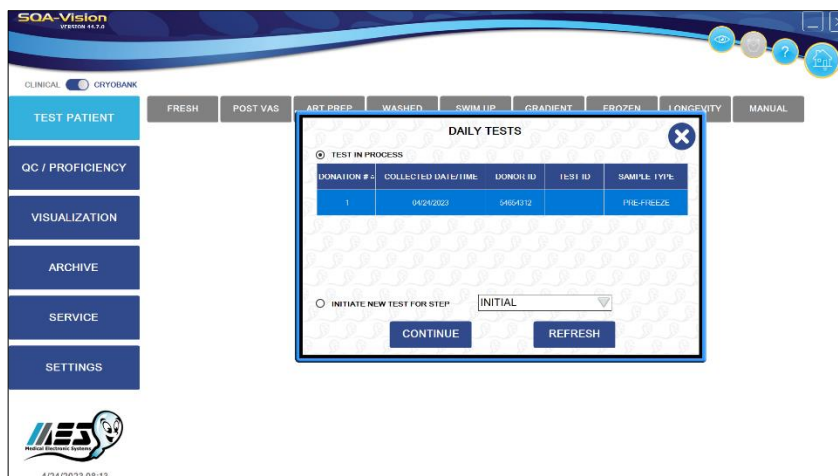
COMMENTS:

- **VISCOSITY** – Normal/Abnormal (NORMAL viscosity is defined as semen leaving the pipette in small discrete drops or forming a thread <2 cm long). The "Decreased Viscosity" option can be selected for Fresh and Longevity tests if the seminal plasma is very thin and watery.
- **LIQUEFACTION** – Liquefaction time interval can be selected from the drop-down menu below:

LIQUEFACTION:

- **COMMENTS** – Enter comments if required.
- **OPTIONAL** – Enter optional fields if desired.

Daily Testing Table screen:



- When tests are initiated from the HOST system, select the required test from the table and then continue to the testing screen. It is also possible to initiate the test locally from this table by selecting the step from the dropdown menu at the bottom of the screen.

## Testing Mode

### PLEASE NOTE:

See the appendix section of this guide for information about dilution medias.

## Testing Semen Samples

In the lower righthand corner of the Test Patient screen, there are three options for testing semen:

- 1:2 (1+1) DILUTION** – For testing low volume semen samples of 0.3 to 0.5 ml. Dilute sample 1:2 (1+1) using the QwikCheck™ Dilution kit. **If the LOW VOLUME sample is viscous, first treat it with the QwikCheck™ Liquefaction kit and then dilute the sample.** The SQA-VISION algorithm compensates for the sample dilution as long as the sample has been diluted accurately (For example, if the total sample volume is 0.4 ml then 0.4 ml of dilution media must be added).
- 10 MICRO** – Recommended if only 10 µl of semen can be used for testing. Only motility-related parameters will be reported (MSC, PMSC, SMI and VELOCITY).
- TEST NOW** – Select to begin testing **FULL volume (≥ 0.5 ml) sample** if the **DILUTION** and **10 MICRO** buttons are not selected. A complete semen analysis report will be generated. If one of the two options above is selected, TEST NOW will initiate the testing process according to a highlighted option.

Click **TEST NOW** and wait for the SQA-Vision to self-calibrate. During this time do not use the keypad or insert a testing capillary/slide. Prepare a sample for testing when the screen below is displayed:



- Low Volume Sample:** Aspirate 10 µl of sample into only the thin motility section of the testing capillary. Follow onscreen instructions (above) and refer to "Filling the SQA-VISION Capillary with a Low Volume Sample" in the appendix.
- Non-Diluted & Diluted 1:2 (1+1) Sample Instructions:** Fill the entire testing capillary (not the syringe) following the online instructions (below) and "Filling the SQA-VISION Capillary with a full Volume Sample" in the appendix.

### PLEASE NOTE:

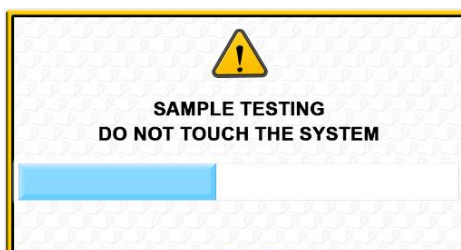
Prior to running each test, the system will perform auto-calibration (do not insert a capillary until the screen instructs you to do so).

**PLEASE NOTE:**

The SQA-VISION will automatically begin testing when a capillary is placed into the testing chamber.



- **Insert Testing Capillary** screen will appear when the VISION is ready to test. Insert the testing capillary as instructed and testing will begin automatically:



- When the testing capillary is inserted, a **Sample Testing** progress bar will be displayed. Do not touch or use the VISION until the progress bar finishes and the screen indicates **"Importing Test Results"** (approximately 75 seconds).
- A **SYSTEM IS BUSY** message will be displayed if any button is clicked during the testing process.

**SQA-Vision**  
VERSION 44.7.0

PATIENT ID: 1236565659 | PATIENT NAME: Michael Johnson | BIRTH DATE / AGE: 1/12/1987 36

TEST PATIENT	PARAMETER	RESULT	REF. VALUE	STATUS
QC / PROFICIENCY	VOLUME (ml):	3.0	>= 1.4	
	pH:	7.0		
	WBC CONC. (Mml):	<1	< 1	
	CONCENTRATION (Mml):	157.9	>= 18	
	MOTILITY (%):	38	>= 42	↓
	PROGRESSIVE (%):	24	>= 30	↓
	RAPIDLY PROGRESSIVE (%):	1		
	SLOWLY PROGRESSIVE (%):	23		
	NON-PROGRESSIVE (%):	14	<= 1	↑
	IMMOTILE (%):	62	<= 20	↑
VISUALIZATION	MORPH. NORMAL FORMS (%):	4	>= 4	
	MOTILE SPERM CONC. (Mml):	59.5		
	PROG. MOTILE SPERM CONC. (Mml):	37.3		
	RAPID PR MOTILE SPERM CONC. (Mml):	1.3		
	SLOW PR MOTILE SPERM CONC. (Mml):	36.0		
	FUNCTIONAL SPERM CONC. (Mml):	3.8		
	VELOCITY (mic/sec):	25		
	SPERM MOTILITY INDEX:	71		
	SPERM # (Micjac):	473.7	>= 39	
	ARCHIVE	DEBRIS		
MORPH.				
VITALITY				
DNA FRAG.				
CAPTURE				
GRAPHS				
ADDITIONAL				
RETEST				
AUTHORIZE				
REPORT				
SERVICE	SAMPLE INFORMATION			
	TEST TYPE:	FRESH		
	SAMPLE ID:	47878666		
	COLLECTED DATE / TIME:	5/16/2023 09:29		
	RECEIVED DATE / TIME:	5/16/2023 09:29		
	TEST DATE / TIME:	5/16/2023 09:30		
	CRITERIA:	WHO 6TH		
	SAMPLE TESTED:	FULL VOLUME		
	ABSTINENCE (days):	8		
	APPEARANCE:	Clear/White/Gray		
SETTINGS	VISCOSITY:	NORMAL		
	LIQUEFACTION:	0-30 Minutes		
	COMMENTS:			
	VISUAL ASSESSMENTS:			
	RETEST			
	AUTHORIZE			
	REPORT			
	SAVE			
	5/16/2023 09:32			

**Full Volume  
and 1:2 (1+1)  
Diluted**

- The table above will be displayed after testing **FRESH** and **WASHED** semen samples with full testing volume or diluted 1:2 (1+1).
- The results are saved automatically (**Save** button will be disabled).
- Click **PENDING** to enter patient data that was not entered previously. A data box will open. Enter the data and click: **SAVE** (see screen below).



## Samples Test Results

The screenshot shows the SQA-Vision software interface. On the left is a sidebar with buttons: TEST PATIENT, QC / PROFICIENCY, VISUALIZATION, ARCHIVE, SERVICE, and SETTINGS. The main area displays patient information: PATIENT ID: PENDING, PATIENT NAME: PENDING, BIRTH DATE / AGE: PENDING. Below this is a list of parameters and their results. A modal window titled 'ENTER PATIENT DATA' is open, containing fields for PATIENT ID, FIRST NAME, LAST NAME, and BIRTH DATE, with a SAVE button. At the bottom of the main area are buttons for DEBRIS, MORPH, VITALITY, DNA FLAG, CAPTURE, GRAPHS, and ADDITIONAL. On the right side, there is a section for 'FRESH' and 'FROZEN' samples with their respective dates and times.

- Click to open the **Debris Scanner** (if not set to open automatically), assess **Morphology**, **Vitality** or **DNA Fragmentation** manually, **Capture** video images and/or pictures, generate **Graphs**, enter **Additional Parameters** or **Retest** the sample.

## Test Report

The **Semen Analysis Test Report** can be opened by clicking the **REPORT** button. It can be exported, printed, zoomed-in and closed using the taskbar.

- When testing a 10 µl sample only motility-related parameters will be reported. The same type of report will be generated for Swim-up, Density Gradient and Frozen tests or any type of test that uses only 10 µl of semen. See the results below:

## 10 µl Sample Test Results

PATIENT ID: 54547876   PATIENT NAME: Mike Smith   BIRTH DATE / AGE:		
PARAMETER	RESULT	SAMPLE INFORMATION
VOLUME (ml):	3.0	TEST TYPE: FROZEN
MOTILE SPERM CONC. (M/ml):	8.3	SAMPLE ID: 44545646
PROG. MOTILE SPERM CONC. (M/ml):	5.5	COLLECTED DATE / TIME: 5/2/2023 07:50
RAPID PR MOTILE SPERM CONC. (M/ml):	1.3	TEST DATE / TIME: 5/2/2023 07:50
SLOW PR MOTILE SPERM CONC. (M/ml):	4.2	CRITERIA: WHO 6TH
VELOCITY (mic/sec):	28	SAMPLE TESTED: 10 MICROLITERS
SPERM MOTILITY INDEX:	27	
MOTILE SPERM (M/volume):	24.9	
PROG. MOTILE SPERM (M/volume):	16.5	

- If the 10 Microliter Counter (motility estimation) option is activated in the Test Patient Settings, estimate the motility using the visualization counter to obtain a complete report (excluding morphology parameters) – refer to Appendix 10.

PATIENT ID: 54547876   PATIENT NAME: Mike Smith   BIRTH DATE / AGE:		
PARAMETER	RESULT	SAMPLE INFORMATION
VOLUME (ml):	3.0	TEST TYPE: FROZEN
CONCENTRATION (M/ml):	41.7	SAMPLE ID: 44545646
MOTILITY (%):	20	COLLECTED DATE / TIME: 5/2/2023 07:50
PROGRESSIVE (%):	13	TEST DATE / TIME: 5/2/2023 07:50
RAPIDLY PROGRESSIVE (%):	3	CRITERIA: WHO 6TH
SLOWLY PROGRESSIVE (%):	10	SAMPLE TESTED: 10 MICROLITERS
NON-PROGRESSIVE (%):	7	
IMMOTILE (%):	80	
MOTILE SPERM CONC. (M/ml):	8.3	
PROG. MOTILE SPERM CONC. (M/ml):	5.5	
RAPID PR MOTILE SPERM CONC. (M/ml):	1.3	
SLOW PR MOTILE SPERM CONC. (M/ml):	4.2	
VELOCITY (mic/sec):	28	
SPERM MOTILITY INDEX:	27	
SPERM # (M/volume):	125.1	
MOTILE SPERM (M/volume):	24.9	
PROG. MOTILE SPERM (M/volume):	16.5	

## Low Quality Test Results

- Low quality test results may be reported as < (less than) or > (greater than) when one or more of the parameters fall below the SQA-VISION dynamic range and the Low Quality Counter is not used. Only Sperm Concentration, Total Motile, Motile Sperm Concentration and SMI values will be reported automatically due to the limited number of sperm cells, very low motility and/or poor morphology. To obtain more precise values and a full report, use the **Low Quality Counter** (see section below) to enter manual results.
- An example of automated low quality results is displayed in the screen (next page).

Set-up the **Low Quality Counter** in **Test Patient Settings** to automatically open the visualization screen when test results fall below the SQA-VISION dynamic range. The instructions below will automatically be displayed in this situation – refer to Appendix 10 for the slide type:

## Low Quality Counter

- When **Low Quality (LQ) Counter** is marked in **Test Patient Settings**, the counter will automatically activate when a low quality sample is run: Using a Vision Fixed Coverslip Slide (See Appendix 10), assess the number of **Total, Immotile, Slowly-Progressive** and **Non-Progressively Motile** spermatozoa in the field of view and enter the number into the specified entry boxes as displayed below.
- Click: **NEXT FIELD** and turn the Visualization Field of View Stage knob to move to new fields of view to assess additional sperm cells.

- Activate **GRID ON, FULL SCREEN** and **FREEZE** functions for easier counting.
- During the process of counting, the Number of **FIELDS COUNTED** and **TOTAL SPERM COUNTED** will be shown on the screen.
- Use the **FREEZE** option to accurately assess the total number of sperm cells.
- Only the last or ALL of the counting results can be **CLEARED** by clicking the appropriate buttons.
- Click **NO SPERM SEEN** if no spermatozoa were found in all fields of view. The following warning message will be shown in this case:



- Click the **RESULTS** button to finalize the manual assessment.
- The test results will be displayed as shown below:

## Counter for Manual Semen Analysis

Manual Semen Analysis can be performed using the **Manual Counter** which can be opened by selecting **TEST PATIENT > MANUAL** from the Main Menu:

Enter the patient and sample data and click: **Semen Analysis** and the Manual Counter screen (next page) will be displayed.

- Specify the sample dilution using the drop-down menu.



- Using a Vision Fixed Coverslip Slide (see Appendix 10), assess the number of **Total, Immotile, Slowly-Progressive** and **Non-Progressively Motile** spermatozoa in the field of view and enter the number into the specified data entry boxes as displayed below.
- Click: **NEXT FIELD** and turn the Visualization Field of View Stage knob to move to a new field of view to assess additional sperm cells.
- When the **WHO COUNTER** is NOT activated in **Test Patient Settings**: Assess the number of **Motile, Immotile, Slowly-Progressive** and **Non-Progressive** spermatozoa in multiple fields of view and enter the number into the specified data entry boxes as displayed below.
- Click **NEXT FIELD** and turn the Visualization Field of View Stage knob to move to a new field of view to assess additional sperm cells.

**SQA-Vision**  
VERSION 44.2.0

CLINICAL ☒ CRYOBANK

**TEST PATIENT**

QC / PROFICIENCY

VISUALIZATION

ARCHIVE

SERVICE

SETTINGS

**MANUAL COUNTER**  
ZOOM OUT TO VISUALIZE

PATIENT ID: 5645486216 BIRTH DATE / AGE: 8/7/1977 45  
 PATIENT NAME: M. Johnson TEST TYPE: MANUAL  
 SAMPLE ID: 12355659 CRITERIA: WHO 6TH  
 TEST DATE / TIME: 5/17/2023 15:48 SAMPLE TESTED: FULL VOLUME

MOTILE: [ ] IMMOTILE: [ ] NEXT FIELD  
 RAPID PR: [ ] SLOW PR: [ ] CLEAR LAST  
 CLEAR ALL  
 SAMPLE DILUTION: NONE

FIELDS COUNTED: 0 | TOTAL SPERM COUNTED: 0

NO SPERM SEEN: ☐

RESULTS

5/17/2023 15:46

REFRESH GRID ON FULL SCREEN FREEZE SETTINGS

- The Number of **FIELDS COUNTED** and **TOTAL SPERM COUNTED** will be shown on the screen when counting sperm cells.
- Buttons are provided to clear the last or all of the counted results.
- Click **NO SPERM SEEN** if no spermatozoa were found in all fields of view.
- Click the **RESULTS** button to finalize the manual assessment.
- The test results will be displayed as shown below:

**SQA-Vision**  
VERSION 44.2.0

CLINICAL ☒ CRYOBANK

**TEST PATIENT**

QC / PROFICIENCY

VISUALIZATION

ARCHIVE

SERVICE

SETTINGS

PATIENT ID: 5645486216 | PATIENT NAME: Michael Johnson | BIRTH DATE / AGE: 8/7/1977 45

PARAMETER	RESULT
VOLUME (ul)	2.0
WBC CONC. (M/mL)	<1
CONCENTRATION (M/mL)	61.1
MOTILITY (%)	47
PROGRESSIVE (%)	37
RAPIDLY PROGRESSIVE (%)	32
SLOWLY PROGRESSIVE (%)	5
NON PROGRESSIVE (%)	10
IMMOTILE (%)	53
MORPH. NORMAL FORMS (%)	NA
MOTILE SPERM CONC. (M/mL)	29.0
PROG. MOTILE SPERM CONC. (M/mL)	22.7
RAPID PR MOTILE SPERM CONC. (M/mL)	19.6
SLOW PR MOTILE SPERM CONC. (M/mL)	3.1
FUNCTIONAL SPERM CONC. (M/mL)	NA
VELOCITY (mic/sec)	NA
SPERM MOTILITY INDEX	NA
SPERM # (M/volume)	122.2
MOTILE SPERM (M/volume)	106.0

DEBIS MORPH VITALITY DNA FRAG. CAPTURE GRAPHS ADDITIONAL

5/17/2023 15:48

**SAMPLE INFORMATION**

TEST TYPE: MANUAL  
 SAMPLE ID: 12355659  
 COLLECTED DATE / TIME: 5/17/2023 15:45  
 HQ-OR-HQ-DILUTE / TIME: 5/17/2023 15:45  
 TEST DATE / TIME: 5/17/2023 15:47  
 CRITERIA: WHO 6TH  
 SAMPLE: 18-519-0  
 APPEARANCE: Clear/White/Grey  
 VISCOSITY: NORMAL  
 LIQUID FRACTION: 0.30 Minutes

COMMENTS:

VISUAL ASSESSMENTS:

RETEST REPORT SAVE

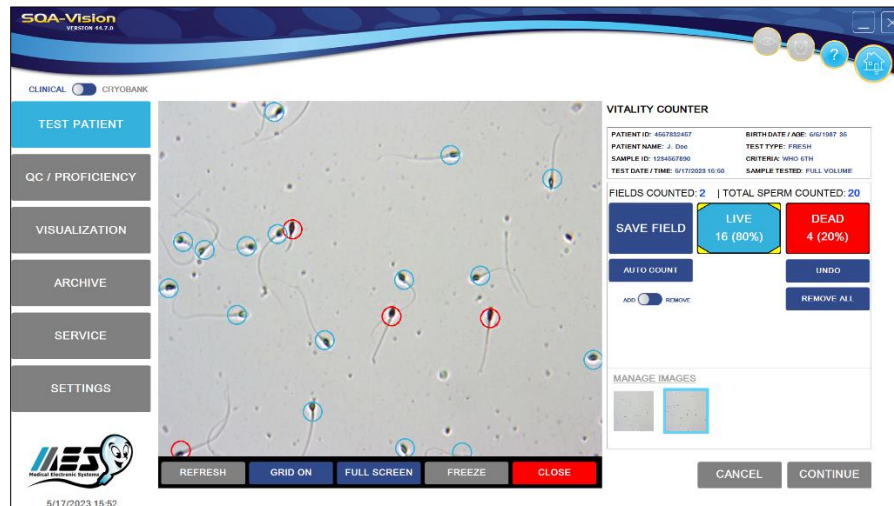
## Vitality Counting Screen

Both the Vitality and DNA Fragmentation analysis can be performed with a standard 1" by 3" slide and 22x22 coverslip (see Appendix 10 for complete instructions)

**Vitality:** To include Vitality test results in the semen analysis report, perform Vitality testing right after automated semen analysis. To run a separate Vitality report, click MANUAL. Enter the Patient/Sample Data, then click VITALITY to open the assessment screen and instructions.

Select AUTO VITALITY TEST in the Patient Settings screen to activate Vitality mode automatically right after completion of automated semen assessment. Capturing screen or clicking AUTO COUNT

will activate automated Vitality assessment. Save each assessed field and capture the next one until sufficient number of sperm is assessed.

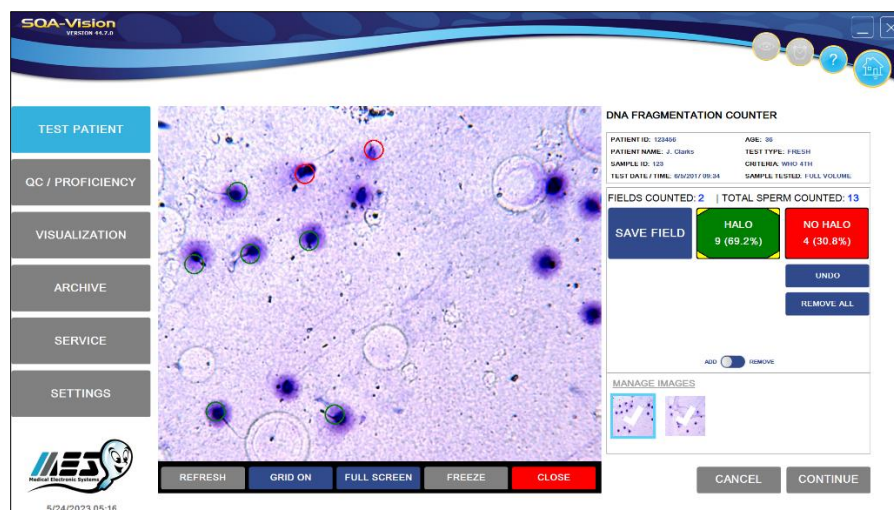


## DNA Frag Counting Screens

**DNA Fragmentation:** To include DNA test results in the semen analysis report, perform DNA testing right after automated semen analysis by clicking the DNA FRAG. button at the bottom of the screen. To run a separate DNA report, click MANUAL. Enter the Patient/Sample Data, then click DNA FRAGMENTATION to open the screen below. Prepare the sample following the DNA fragmentation kit instructions and follow the onscreen instructions for assessment.

Two DNA FRAGMENTATION assessment options are available: **HALO/NO HALO** or **HALO GRADING**

Select: **HALO/NO HALO** and the screen below will open.



Use the counter to capture a minimum of 200 sperm cells:

### NON-FRAGMENTED DNA

- **HALO:** NON-FRAGMENTED DNA (large/medium size HALO  $>1/3$  of the minor diameter of the core)

### FRAGMENTED DNA

- **NO HALO:** FRAGMENTED DNA (small/NO HALO/NO HALO and degraded  $\leq 1/3$  of the minor diameter of the core)

Click **RESULTS:** DFI % will be generated automatically.

Select: **HALO GRADING** to assess 5 categories (WHO 6<sup>th</sup> Criteria) of DNA fragmentation using the counting screen shown below.

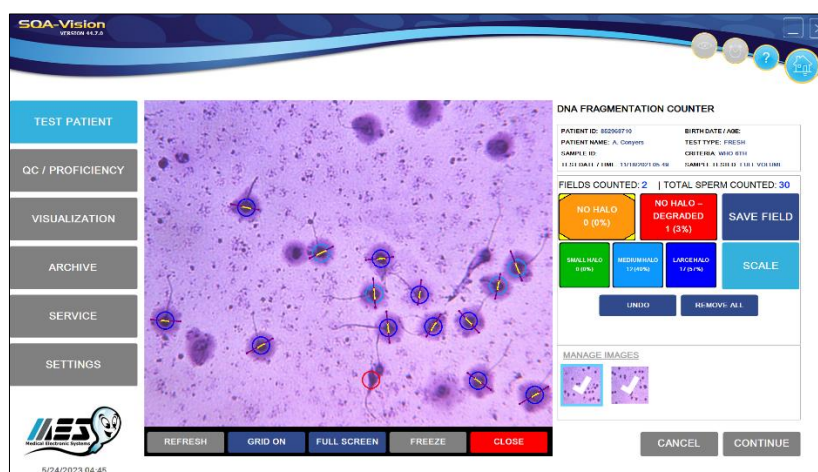
#### NON-FRAGMENTED DNA

- **LARGE HALO**: Halo width is similar to or larger than the minor diameter of the core.
- **MEDIUM HALO**: Halo size is between large and small halo criteria.

#### FRAGMENTED DNA

- **SMALL HALO**: Halo width is similar to or smaller than 1/3 of the minor diameter of the core
- **NO HALO**: No halo exists
- **NO HALO-degraded**: No halo exists AND the core is irregularly or minimally stained.

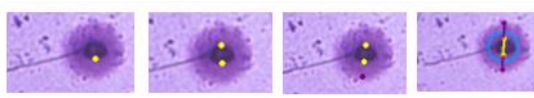
Click **RESULTS**: DFI % will be generated automatically.



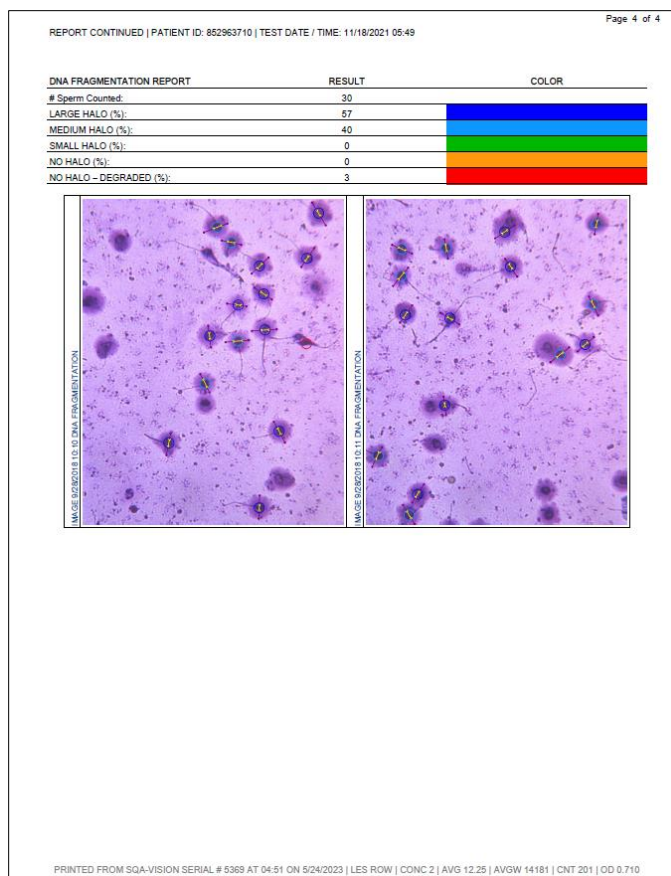
A scaling (measurement) tool can be used to easily define the minor diameter of the core first then the halo width:

Click the **SCALE** button, then follow these instructions, in the sequence below:

- First, select (by clicking), the Minor Core Diameter by placing one dot on each opposing side of the sperm head or CORE. A line will automatically be generated (this will establish the Minor Core Diameter).
- Following the same line (axis) established for the Minor Core Diameter, place one dot on each of the distal ends of the halo that extend from the two ends of the core axis.
- These dots will be connected by a line generated by SW.
- The HALO ratio (R) will now be assigned automatically by the SQA-Vision based on this calculated formula:  $R = ((\text{Distance of two external HALO dots} - \text{distance of two external CORE dots}) / 2) / \text{Distance of two external CORE dots}$ .



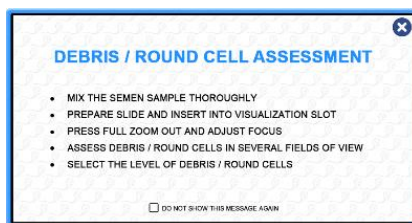
Click **RESULTS**: DFI % will be generated automatically. Click **REPORT**: for a DFI report.



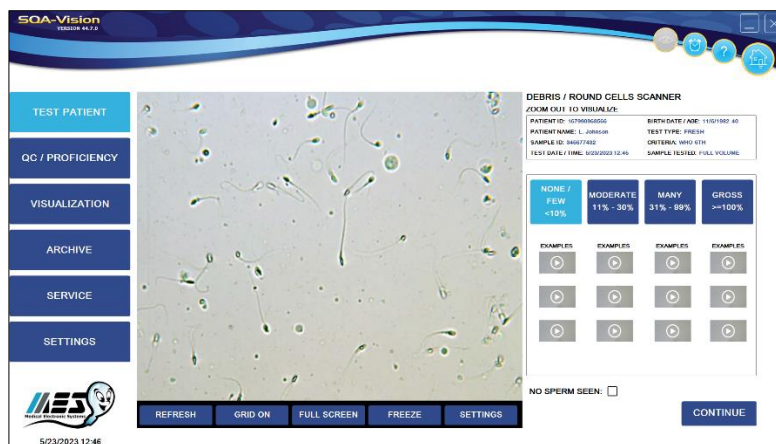
## Debris / Round Cells Scan

If the automated test results fall below the pre-set **Debris/Round Cell Scan** cutoffs established in **SETTINGS** or this feature is activated for all samples, the **Debris/Round Cell Scanner** will automatically open during the testing cycle.

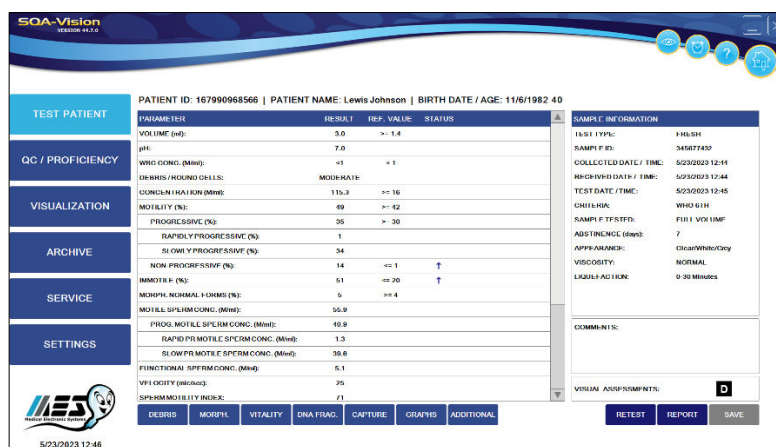
- The **Debris/Round Cell Scanning** can always be opened at the end of a test.
- The SQA will automatically compensate for the level of debris/round cells based on selecting **NONE/FEW; MODERATE; MANY or GROSS** level.
- Using a Vision Fixed Coverslip Slide or and standard slide 1" x 3" with a 22X22 mm coverslip (see Appendix 10 for details), estimate the debris/round cells as a % compared to the amount of spermatozoa:
  - NONE/FEW: <10% (for every 10 sperm 1 or less piece of non-sperm debris)
  - MODERATE: 10-30% (for every 10 sperm there are 1-3 non-sperm debris)
  - MANY: 30-99% (for every 10 sperm there are 3-9 non-sperm debris)
  - GROSS: >100% (for every 10 sperm there are 10 or more non-sperm debris)
- The sample preparation instruction screen below will be displayed prior to activating the **Debris/Round Cell Scanning** screen.





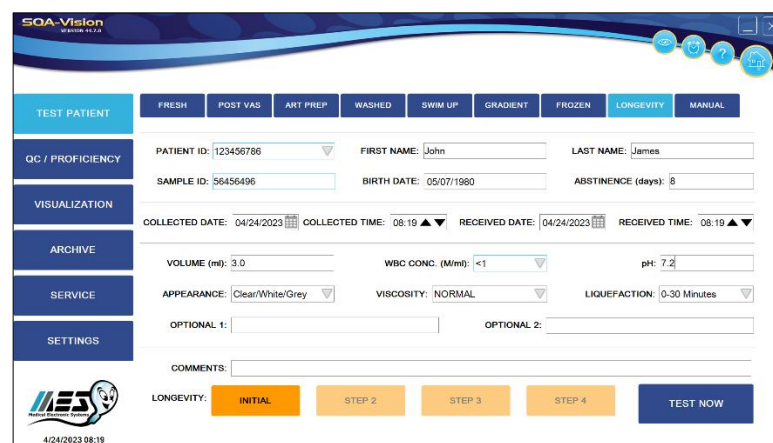


- Click: **CONTINUE** to open the results screen:



## Longevity

Select **LONGEVITY** to assess a **FRESH** sample over established time intervals. The time intervals can be pre-set in the SQA-Vision (please refer to the **SETTINGS** section):



### PLEASE NOTE:

Storing the semen in the capillary between testing intervals is not recommended as motility will be affected.

- Click the **TIMER** icon in the upper right-hand corner of the screen to activate the Longevity timer and to view the selected testing intervals.
- One testing capillary per test is required.
- After each testing sequence, raise the blue valve of the testing capillary and expel the semen until the next testing cycle (this will preserve motility).
- After the first test sequence is completed, no changes can be made to the time settings or patient/sample data screen.

- Longevity testing for four intervals is shown below:

- Click: **REPORT** to view the Longevity Test report.

## ART PREP Mode

From the Main Menu, select **TEST PATIENT>ART PREP**. Two modes for testing **ART PREP** samples are available: pre-preparation and post-preparation (**PRE-PREP** and **POST-PREP**):

Selecting FRESH or WASHED or FROZEN sample type is provided for running **PRE-PREP** mode. Selecting WASHED or SWIM-UP or GRADIENT sample type is provided for running **POST-PREP** mode. Only LOW VOLUME (10-microliter) samples can be run in these modes. The results of these modes will look like this:

**SQA-VISION**  
VERSION 104.17.6

PATIENT ID: 56599965 | PATIENT NAME: James John | BIRTH DATE / AGE: 2/1/1998 25

**TEST PATIENT**

**QC / PROFICIENCY**

**VISUALIZATION**

**ARCHIVE**

**SERVICE**

**SETTINGS**

**PARAMETER** | **PRE-PRP** | **POST-PRP**

TEST TIME:	17:20
VOLUME (ml):	3.0
pH:	7.0
WBC CONC. (M/ml):	<1
MOTILE SPERM CONC. (M/ml):	57.2
PROG. MOTILE SPERM CONC. (M/ml):	35.8
RAPID PR MOTILE SPERM CONC. (M/ml):	1.3
SLOW PR MOTILE SPERM CONC. (M/ml):	34.5
VELOCITY (mic/sec):	25
SPERM MOTILITY INDEX:	71
MOTILE SPERM (M/volume):	171.6
PROG. MOTILE SPERM (M/volume):	107.4
SAMPLE EVALUATION:	NA

**SAMPLE INFORMATION**

TEST TYPE: ART PREP

SAMPLE ID: 68995656

COLLECTED DATE / TIME: 4/24/2023 17:19

RECEIVED DATE / TIME: 4/24/2023 17:19

TEST DATE / TIME: 4/24/2023 17:20

CRITERIA: WHO 6TH

STEP TEST TYPE: FRESH

SAMPLE TESTED: 10 MICROLITERS

ABSTINENCE (days): 8

APPEARANCE: Clear/White/Grey

VISCOSITY: NORMAL

LIQUEFACTION: 0-30 Minutes

COMMENTS:

VISUAL ASSESSMENTS:

MOTILITY MORPH. VITALITY DNA FRAG. CAPTURE GRAPHIS ADDITIONAL POST PREP

RETEST REPORT SAVE

4/24/2023 17:21

If 10-MICROLITER COUNTER (MOTILITY ESTIMATION) feature is set, and motility is assessed by visual estimation upon completion of automated sample testing, report containing more parameters than in the low volume mode will be generated. Upon completion of both PRE-PREP and POST-PREP tests, Semen Analysis Report as shown below will be displayed:

Page 1 of 1

**SEMEN ANALYSIS TEST REPORT**

M.E.S Medical Electronic Systems  
5757 W. Century Blvd 805  
Los Angeles, CA. 90045

PHONE: 310-670-9066  
FAX: 310-670-9069  
E-MAIL: [sales@mes-ic.com](mailto:sales@mes-ic.com)  
WEB: [www.mes-global.com](http://www.mes-global.com)

**PATIENT INFORMATION**

FIRST NAME: James LAST NAME: John

PATIENT ID: 56599965 BIRTH DATE / AGE: 2/1/1998 25

**SAMPLE INFORMATION**

SAMPLE ID: 68995656 TEST RUN BY: Administrator

TEST TYPE: ART PREP APPEARANCE: Clear/White/Grey

COLLECTED DATE / TIME: 4/24/2023 17:19 VISCOSITY: NORMAL

RECEIVED DATE / TIME: 4/24/2023 17:19 LIQUEFACTION: 0-30 Minutes

TEST DATE / TIME: 4/24/2023 17:20 CRITERIA: WHO 6TH

ABSTINENCE (days): 8 SAMPLE TESTED: 10 MICROLITERS

OPTIONAL 1: NA OPTIONAL 2: NA

STEP TEST TYPE: FRESH / WASHED

PARAMETER	PRE-PREP RESULTS	POST-PREP RESULTS
TEST TIME:	17:20	17:24
VOLUME (ml):	3.0	3.0
pH:	7.0	NA
WBC CONC. (M/ml):	<1	<1
MOTILE SPERM CONC. (M/ml):	57.2	50.2
PROG. MOTILE SPERM CONC. (M/ml):	35.8	31.5
RAPID PR MOTILE SPERM CONC. (M/ml):	1.3	1.3
SLOW PR MOTILE SPERM CONC. (M/ml):	34.5	30.2
VELOCITY (mic/sec):	25	25
SPERM MOTILITY INDEX:	71	71
MOTILE SPERM (M/volume):	171.6	160.6
PROG. MOTILE SPERM (M/volume):	107.4	94.5
SAMPLE EVALUATION:	NA	NA

COMMENTS:

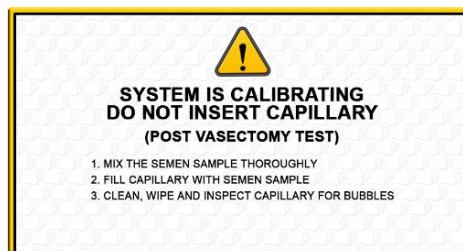
PRINTED FROM SQA-VISION SERIAL # 1234 AT 17:25 ON 4/24/2023 | LES ROW | CONC 2 | AVG 30.00 | AVGW 12000 | CNT 200 | OD 1.100

## Post Vasectomy Testing

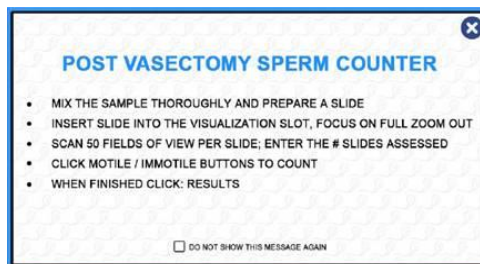
From the Main Menu, select **TEST PATIENT > POST VAS**. WHO 5th ed. recommends running a non-centrifuged semen sample first to search for motile and non-motile spermatozoa. If no sperm cells are found, the sample should be centrifuged and re-tested. Refer to Appendix 11 for guidance. Two modes for testing **POST VAS** samples are available: **SEMI-AUTO** and **MANUAL**.

- Enter patient/sample information into the **POST VAS** data entry screen (below).
- Select **RAW SAMPLE** or **CENTRIFUGED** button to specify the sample type.
- If **CENTRIFUGED** is selected: Enter **Initial Volume** (before centrifugation) and **Final Volume** (after centrifugation). A warning will be shown if the Initial Volume used for centrifugation exceeds the ejaculate Volume or if the Final Volume exceeds Initial Volume.
- Click the **SEMI-AUTO** or **MANUAL** button in the lower right hand corner of the **POST VAS** screen:

If the **Semi-automated** mode is selected, the following instructions are displayed:



- Fill the testing capillary and when: **Insert Testing Capillary** is displayed, insert the testing capillary to begin the five-minute Post Vas test, which detects the presence of motile cells.
- At the end of automated test, the **POST-VAS Counter** with sample preparation instructions will open. The number of motile sperm detected will be displayed.
- If the **POST VAS FOV-CLICK** setting is not checked (default), instructions will be displayed (no need to check NEXT FIELD when changing to a new field of view) - refer to Appendix 10 for the slide type to be used:



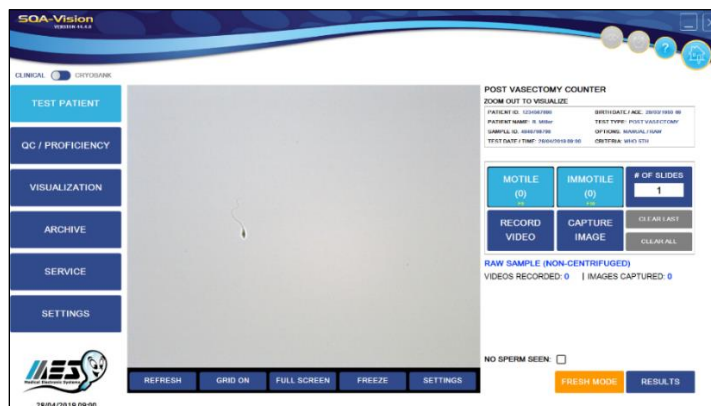
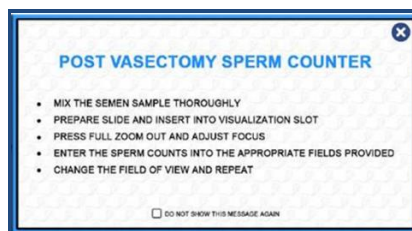
- If the **POS VAS FOV-CLICK** setting is checked, select NEXT FIELD to visualize a new field of view. Instructions will be displayed - refer to Appendix 10 for the slide type to be used:

## Semi-automated POST VAS

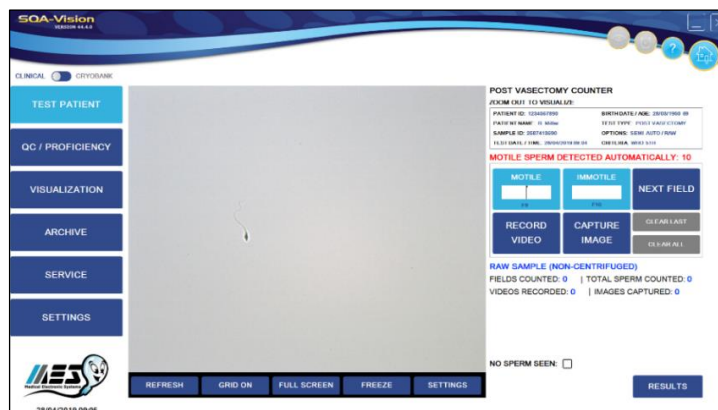
### Please note:

The automated POSTVASECTOMY test takes approximately 5 minutes to run and is highly sensitive to motion. Please do not disturb the SQA-VISION or the testing capillary during the testing cycle or the results may be impacted.





- Count spermatozoa in the entire fixed coverslip slide by turning the Field of View knob and clicking the Motile/Immotile buttons (one click per each cell).
- Enter # of slides counted (several slides can be counted in one testing round).
- Select "No Sperm Seen" if no sperm cells were found.
- Click FRESH MODE if many sperm cells are seen and a normal test can be run.
- If **POS VAS FOV-CLICK** setting was checked, the following screen will open:



- Count the number of MOTILE and IMMOTILE sperm cells seen in multiple fields of view and enter the results in the **MOTILE** and **IMMOTILE** boxes of the **Post-vasectomy Counter**.
- Click **NEXT FIELD** when changed.
- Capture **Images** and/or **Video** clips if desired.
- Select: **RESULTS** in the **Post-vasectomy Counter** when manual counting is completed. The test results displayed will be based on both automated and manual assessment.
- If no manual data is entered and the **RESULTS** button is clicked, only automated results will be reported.

**SQA-VISION**  
VERSION 104.17.6

PATIENT ID: 1215655964 | PATIENT NAME: Michael Johnson | BIRTH DATE / AGE: 1/8/1987 36

TEST PATIENT	PARAMETER	RESULT
QC / PROFICIENCY	VOLUME (ml):	3.8
	pH:	7.8
VISUALIZATION	WBC CONC. (M/ml):	<1
	MOTILE SPERM (M/ml):	0.02
	IMMOTILE SPERM (M/ml):	0.02
	TOTAL SPERM (M/ml):	0.04
	# MOTILE SPERM/VOL. (M):	0.05
	# IMMOTILE SPERM/VOL. (M):	0.05
ARCHIVE	# TOTAL SPERM/VOL. (M):	0.12
SERVICE		
SETTINGS		

5/2/2023 09:28

DEBBS MICROPL VITALITY DNA / RAS CAPTURE GRAPH ADDITIONAL

REPORT DATA

**SAMPLE INFORMATION**

TEST TYPE: POST VASECTOMY  
 SAMPLE ID: 526559696  
 COLLECTED DATE / TIME: 5/2/2023 09:27  
 RECEIVED DATE / TIME: 5/2/2023 09:27  
 TEST DATE / TIME: 5/2/2023 09:27  
 CRITERIA: WHO 6TH  
 OPTIONS: MANUAL / CENTRIF.  
 ABSTINENCE (days): 7  
 APPEARANCE: Clear/White/Grey  
 VISCOSITY: NORMAL  
 LIQUEFACTION: 0-30 Minutes

COMMENTS:

VISUAL ASSESSMENT:

- Images and video clips can be captured while using the Post Vasectomy Counter or from the RESULTS screen once the testing cycle is completed by selecting **CAPTURE** (at the bottom of the screen).
- Select **Graphs** and/or **Additional** to enter more data.
- To generate a Post Vasectomy Test Report, click: **REPORT** (please see below).

## Manual POST VAS


**NOTE:** The **MANUAL** Post Vas mode can also be used to report a Qualitative Result of "Present or Absent" sperm cells within 24 hours of collection. A note should be made that Motility was not assessed in this case.

Page 1 of 1

SEMEN ANALYSIS TEST REPORT

M.E.S Medical Electronic Systems  
5757 W. Century Blvd 805  
Los Angeles, CA 90045

PHONE: 310-670-9066  
 FAX: 310-670-9069  
 E-MAIL: [sales@mes-llc.com](mailto:sales@mes-llc.com)  
 WEB: [www.mes-global.com](http://www.mes-global.com)



**PATIENT INFORMATION**

FIRST NAME: Mike LAST NAME: Smith  
 PATIENT ID: 1234567890 BIRTH DATE / AGE: 2/27/1986 37

**SAMPLE INFORMATION**

SAMPLE ID: 5464998996 TEST RUN BY: Administrator  
 TEST TYPE: POST VASECTOMY APPEARANCE: Clear/White/Grey  
 COLLECTED DATE / TIME: 4/30/2023 21:41 VISCOSITY: NORMAL  
 RECEIVED DATE / TIME: 4/30/2023 21:41 LIQUEFACTION: 0-30 Minutes  
 TEST DATE / TIME: 4/30/2023 21:43 CRITERIA: WHO 6TH  
 OPTIONS: MANUAL / CENTRIF. ABSTINENCE (days): 8  
 OPTIONAL 1: NA OPTIONAL 2: NA

PARAMETER	RESULT
VOLUME (ml):	3.0
pH:	3.0
WBC CONC. (M/ml):	<1
MOTILE SPERM (M/ml):	0.02
IMMOTILE SPERM (M/ml):	0.03
TOTAL SPERM (M/ml):	0.05
# MOTILE SPERM/VOL. (M):	0.06
# IMMOTILE SPERM/VOL. (M):	0.09
# TOTAL SPERM/VOL. (M):	0.15

COMMENTS:

PRINTED FROM SQA-VISION SERIAL # 1234 AT 21:43 ON 4/30/2023 | LES ROW | CONC 2 | AVG NA | AVGW NA | CNT NA | OD NA

## Donor Information

### CRYO TESTING

Enter the Donor/Sample data in the Donor Information Screen

- **DONOR ID** (mandatory entry)- unique donor ID for each donor
- **Donation #** (mandatory entry)- unique donation # for each newly ejaculated sample from the donor
- **Test ID**- Unique test ID/number
- **ABSTINENCE** - Number of days since the patient's last ejaculation
- **DATE/TIME COLLECTED** – Date and time the sample was collected.
- **DATE/TIME RECEIVED** – Date and time the sample was received.
- **VOLUME** (mandatory entry) – Enter the volume of the **whole** ejaculate (Fresh, Post Vas and Longevity test) or of the sample (other types of tests) in milliliters. Do not enter '0' for the volume. Enter >0 or leave empty. If Calculate Volume From Weight feature is set, the CUP WEIGHT and FINAL WEIGHT results should be entered in the patient data entry screen, and the software will calculate an ejaculate volume per WHO 6<sup>th</sup> manual guidelines:

CUP WT. (G):  FINAL WT. (G):

- **WBC CONC.** (mandatory entry) Select WBC <1 M/ml (normal) OR ≥1 M/ml (abnormal)
- **pH** – pH of the semen sample (QwickCheck™ Test Strips recommended for pH and WBC).
- **APPEARANCE** – Categories one of which should be selected from the drop-down menu below based on visual assessment of the specimen:

- **VISCOSITY** – Normal/Abnormal (WHO 5<sup>th</sup> defines NORMAL viscosity as semen leaving the pipette in small discrete drops or forming a thread <2 cm long). Select: "Decreased Viscosity" if the seminal plasma is very thin and watery.
- **LIQUEFACTION** – Liquefaction time interval can be selected from the drop-down menu below:

- **COMMENTS** – Enter comments if required.
- **OPTIONAL** – Enter optional fields if desired.

Test Results Screen:

## CRYO Dosing Process

### Dosing SET-UP

Donor cryo doses can be set up after testing based on Volume or Sperm target/dose.

#### Volume Dosing

- **DOSE VOLUME:** Define the dose volume.
- **MEDIA RATIO:** The dilution media volume (freezing media) will be calculated as a ratio (normally 1:3) from the semen volume
- **QC SAMPLE VOLUME (ml):** Input the volume for post thaw QC samples.
- **# OF QC VIALS:** Enter how many QC vials will be reserved for post thaw QC.

#### Sperm Target Dosing

- **DOSING METHOD:** define the target parameter for the dosing calculation.
- **TARGET #SPERM/DOSE (M):** Define the target value for dosing.
- **DOSE VOLUME:** Define the dose volume.
- **2 MEDIA DILUTION RATIO:** The system allows two modes of dilution in the dosing process. When using one media only, all the dilution will be related to one media (which is normally the freezing media). If 2 media dilution is selected, then normally freezing and

washing media will be used to dilute the sample. The freezing media volume will be calculated as a ratio from the total volume (normally 1:3) and the rest of the dilution will be washed media (excluding the semen volume)

- **MLF/PMLF (%)** (Motility or Progressive Motility Loss Factor): The loss factor is automatically calculated based on setting definitions and test results history when available. If previous tests are unavailable, the MLF/PMLF is either 50% (factory default) or can be set-up manually by pressing the 3 Dot button and entering a timeframe for sample history and an estimate of the Initial Factor loss (see screen below). When the factor is set to 1, it will not impact the dosing target.
- **AVERAGE OF LAST:** Enter the desired period of time test results will be used to calculate the MLF/PMLF.
- **PROCESSING LOSS:** Set an initial factor as a margin of safety to compensate for loss of motility due to various procedures such as dilution and centrifugation. The set target value will be multiplied by the initial factor to allow a margin of safety and avoid over dilution. When the factor is set to 1, it will not impact the target.
- **QC SAMPLE VOLUME (ml):** Input the volume for post thaw QC samples.
- **# OF QC VIALS:** Enter how many QC vials will be reserved for post thaw QC.

**PRESS: CALCULATE** to automatically display dosing instructions:

- **ADD FREEZING/ WASHING MEDIA (ml):** Volume of media needed to obtain the desired target values and doses from the sample.
- **TOTAL VOLUME:** The volume of the sample after adding media.
- **# OF DOSES:** Total number of doses possible, based on the target value and loss factor.
- **SAMPLE EVALUATION:** PASS/FAIL the dosing criteria based on the displayed instructions.
- **REPORT:** Generate a printable PDF file of the results and dosing instructions.
- **SAVE & CLOSE:** Information will be saved and the dosing screen closed.
- **SEND:** When all is completed and approved, press the SEND (to host) button (displayed in the lower right hand corner) and proceed to the next step.

**MANUAL** MLF/PMLF SET-UP Screen (after tapping the 3-Dot button)

## PRE-FREEZE Sample Testing

- Access from the **DAILY TESTING TABLE** or, alternatively, open the **TESTING SCREEN** and enter the required Donor/Sample information.
- PLEASE NOTE:** It is possible to modify/update dosing instructions by opening the dosing screen (bottom of the screen) and pressing **CALCULATE** after adjusting the dosing.

**TEST PATIENT**

DONOR ID: 2325655964 | DONATION #: 345234788

PARAMETER	INITIAL	PRE-FREEZE	POST-THAW	REF. VALUE	STATUS
STEP TIME:	12:29	12:31	12:33		
VOLUME (ml):	3.0	3.0	3.0	>= 1.4	
pH:	7.0	NA	NA		
WBC CONC. (M/ml):	<1	NA	NA	< 1	
CONCENTRATION (M/ml):	157.9	251.2	251.2	>= 16	
MOTILITY (%):	38	20	20	>= 42	↓
PROGRESSIVE (%):	24	13	13	>= 30	↓
RAPIDLY PROGRESSIVE (%):	1	1	1		
SLOWLY PROGRESSIVE (%):	23	12	12		
NON-PROGRESSIVE (%):	14	7	7	<= 1	↑
IMMOTILE (%):	62	80	80	<= 20	↑
MORPH. NORMAL FORMS (%):	4	NA	NA	>= 4	
MOTILE SPERM CONC. (M/ml):	59.5	50.2	50.2		
PROG. MOTILE SPERM CONC. (M/ml):	37.3	31.5	31.5		
RAPID PR MOTILE SPERM CONC. (M/ml):	1.3	1.3	1.3		
SLOW PR MOTILE SPERM CONC. (M/ml):	36.0	30.2	30.2		
FUNCTIONAL SPERM CONC. (M/ml):	3.8	NA	NA		
VELOCITY (mic/sec):	25	25	25		
SPERM MOTILITY INDEX:	71	71	71		

**SPERM TARGET DOSING SETUP**

DOSING METHOD: ☐ MOTILE SPERM ☒ 2 MEDIA DILUTION RATIO

TARGET SPERM COUNT (M): 5

DOSING VOLUME (ml): 0.5

M:F (%): 50

QC SAMPLE VOLUME (ml): 0.2

FOR QC ONLY: 2

ADD FREEZING MEDIA (ml): 1.5

ADD WASHING MEDIA (ml): 2.5

TOTAL VOLUME (ml): 7.5

# OF DOSES: 14

SAMPLE VOLUME: 14

REPORT:  SAVE & CLOSE:

**TESTING SCREEN**

TEST TYPE: CRYOBANK (FRESH)

COLLECTED DATE / TIME: 5/23/2023 12:27

TEST DATE / TIME: 5/23/2023 12:31

CRITERIA: WHO 6TH

INITIAL SAMPLE TESTED: FULL VOLUME

APPEARANCE: Clear/White/Creamy

VISCOSITY: NORMAL

LIQUEFACTION: 0-30 Minutes

COMMENTS:

VISUAL ASSESSMENTS:

RETEST:  SEND:  REPORT:  SAVE:

## POST-THAW Sample Testing

- Access from the **DAILY TESTING TABLE** or open the **TESTING SCREEN** and enter the required Donor/Sample information.

**TEST PATIENT**

DONOR ID: 2325655964 | DONATION #: 345234788

PARAMETER	INITIAL	PRE-FREEZE	POST-THAW	REF. VALUE	STATUS
STEP TIME:	12:29	12:31	12:33		
VOLUME (ml):	3.0	3.0	3.0	>= 1.4	
pH:	7.0	NA	NA		
WBC CONC. (M/ml):	<1	NA	NA	< 1	
CONCENTRATION (M/ml):	157.9	251.2	251.2	>= 16	
MOTILITY (%):	38	20	20	>= 42	↓
PROGRESSIVE (%):	24	13	13	>= 30	↓
RAPIDLY PROGRESSIVE (%):	1	1	1		
SLOWLY PROGRESSIVE (%):	23	12	12		
NON-PROGRESSIVE (%):	14	7	7	<= 1	↑
IMMOTILE (%):	62	80	80	<= 20	↑
MORPH. NORMAL FORMS (%):	4	NA	NA	>= 4	
MOTILE SPERM CONC. (M/ml):	59.5	50.2	50.2		
PROG. MOTILE SPERM CONC. (M/ml):	37.3	31.5	31.5		
RAPID PR MOTILE SPERM CONC. (M/ml):	1.3	1.3	1.3		
SLOW PR MOTILE SPERM CONC. (M/ml):	36.0	30.2	30.2		
FUNCTIONAL SPERM CONC. (M/ml):	3.8	NA	NA		
VELOCITY (mic/sec):	25	25	25		
SPERM MOTILITY INDEX:	71	71	71		

**SAMPLE INFORMATION**

INITIAL TEST TYPE: CRYOBANK (FRESH)

TEST ID: 345234788

COLLECTED DATE / TIME: 5/23/2023 12:27

TEST DATE / TIME: 5/23/2023 12:33

CRITERIA: WHO 6TH

INITIAL SAMPLE TESTED: FULL VOLUME

APPEARANCE: Clear/White/Creamy

VISCOSITY: NORMAL

LIQUEFACTION: 0-30 Minutes

COMMENTS:

VISUAL ASSESSMENTS:

RETEST:  SEND:  REPORT:  SAVE:

## SECTION 6: QC / Proficiency

- Select: **QC/PROFICIENCY** to run system quality control and proficiency challenge samples that have been set-up in the **Settings** (refer to this section for instructions). Three options will be displayed:
- LATEX BEADS**
- STAB. SPERM**
- PROFICIENCY**
- QC MARK COUNT**

**LATEX BEADS** and **STABILIZED SPERM** have a maximum of three pre-set levels for testing (all setting fields must be filled with setting data for testing to be performed):

- LEVEL 1 / LEVEL 2 and NEGATIVE CONTROL**



## Latex Beads

### Please note:

When a new control lot is used, the control default settings must be changed prior to initiating a test.

Refer to **Controls Settings** section.

**SQA-Vision**  
VERSION 104.17.6

CLINICAL ☒ CITYORANK

TEST PATIENT LATEX BEADS STAB. SPERM PROFICIENCY MARK COUNT

QC / PROFICIENCY VISUALIZATION ARCHIVE SERVICE SETTINGS

**LEVEL 1**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 44.1  
STATUS: PASS

SAMPLE INFORMATION  
LOT #: 211018001  
EXP. DATE: 01/2020  
TARGET (M/ml): 49  
RANGE (V): 8.9  
PASS RANGE: 42.1 - 55.9  
LAST RUN: 28/04/2019 09:29

**LEVEL 2**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 9.0  
STATUS: FAIL

SAMPLE INFORMATION  
LOT #: 211018002  
EXP. DATE: 01/2020  
TARGET (M/ml): 25  
RANGE (V): 5.0  
PASS RANGE: 20.0 - 30.0  
LAST RUN: 28/04/2019 09:30

CORRECTIVE ACTION

**NEGATIVE CONTROL**

TEST NOW

TEST RESULTS  
CONC. (M/ml): PENDING  
MSC (M/ml): PENDING  
STATUS: PENDING

SAMPLE INFORMATION  
LOT #: 211018003  
EXP. DATE: 01/2020  
TARGET (M/ml): 0.0  
RANGE (V): 0.0  
PASS RANGE: 0.0  
LAST RUN: PENDING

SETUP QC ARCHIVE REPORT

28/04/2019 09:30

## Stabilized Sperm

**SQA-Vision**  
VERSION 104.17.6

CLINICAL ☒ CITYORANK

TEST PATIENT LATEX BEADS STAB. SPERM PROFICIENCY MARK COUNT

QC / PROFICIENCY VISUALIZATION ARCHIVE SERVICE SETTINGS

**LEVEL 1**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 275.8  
STATUS: FAIL

SAMPLE INFORMATION  
LOT #: 250618001  
EXP. DATE: 06/2019  
TARGET (M/ml): 48  
RANGE (V): 12.8  
PASS RANGE: 36.0 - 60.0  
LAST RUN: 28/04/2019 10:14

CORRECTIVE ACTION

**LEVEL 2**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 30.7  
STATUS: PASS

SAMPLE INFORMATION  
LOT #: 250618002  
EXP. DATE: 06/2019  
TARGET (M/ml): 26  
RANGE (V): 6.5  
PASS RANGE: 19.5 - 32.5  
LAST RUN: 28/04/2019 10:13

**LEVEL 3**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 30.7  
STATUS: FAIL

SAMPLE INFORMATION  
LOT #: 250618003  
EXP. DATE: 06/2019  
TARGET (M/ml): 15  
RANGE (V): 1.5  
PASS RANGE: 13.5 - 16.5  
LAST RUN: 28/04/2019 10:16

CORRECTIVE ACTION

SETUP QC ARCHIVE REPORT

28/04/2019 10:16

## Proficiency Testing

PROFICIENCY testing has a maximum of 4 levels for testing:

**SQA-Vision**  
VERSION 104.17.6

CLINICAL ☒ CITYORANK

TEST PATIENT LATEX BEADS STAB. SPERM PROFICIENCY MARK COUNT

QC / PROFICIENCY VISUALIZATION ARCHIVE SERVICE SETTINGS

**PROFICIENCY # 1**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 30.7

SAMPLE INFORMATION  
SAMPLE ID: 280419001  
ISSUE DATE: 28/04/2020  
NOTE:  
LAST RUN: 28/04/2019 10:18

**PROFICIENCY # 2**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 275.8

SAMPLE INFORMATION  
SAMPLE ID: 280419002  
ISSUE DATE: 28/04/2020  
NOTE:  
LAST RUN: 28/04/2019 10:19

**PROFICIENCY # 3**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 98.7

SAMPLE INFORMATION  
SAMPLE ID: 280419003  
ISSUE DATE: 28/04/2020  
NOTE:  
LAST RUN: 28/04/2019 10:24

**PROFICIENCY # 4**

TEST NOW

TEST RESULTS  
CONC. (M/ml): 98.7

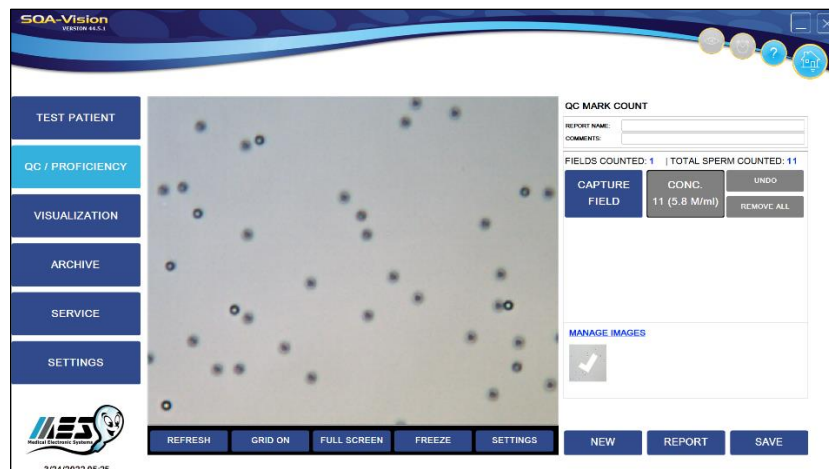
SAMPLE INFORMATION  
SAMPLE ID: 280419004  
ISSUE DATE: 28/04/2020  
NOTE:  
LAST RUN: 28/04/2019 10:25

SETUP QC ARCHIVE REPORT

28/04/2019 10:25

**Visualization QC** mark count is used to verify the concentration of QwikCheck Beads vs. the automated results or labeled target values. It is recommended (Appendix 10) to use a Vision Fixed Coverslip Slide for assessment.

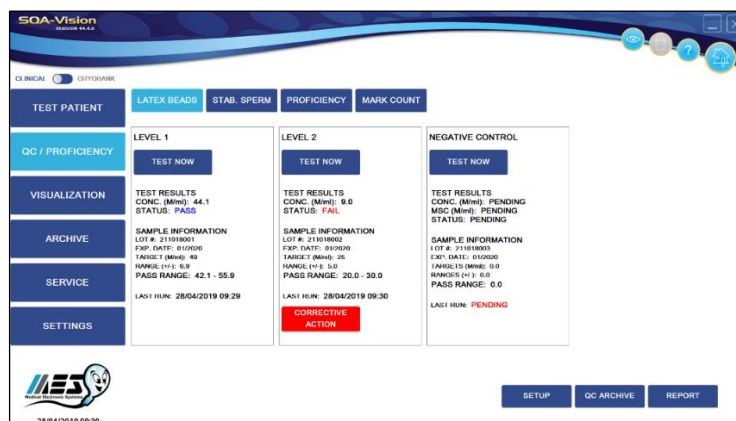
## Control Sample Testing



- At the bottom of each **QC/PROFICIENCY** testing screen, a **SETUP**, **QC ARCHIVE** and **REPORT** button is available.
- **QwikCheck™** beads produced by Medical Electronic Systems are assayed for SQA-VISION quality control and can be ordered through MES distributors.
- Commercially available latex beads or Stabilized Sperm CAP or NEQAS can be run as **non-assayed** controls.
- Daily or per laboratory protocol control testing is recommended.
- Controls and proficiency defaults must be set prior to testing (Please refer to the Settings section). Results **PENDING** will be displayed if the pre-set testing schedule is not met or if a new lot of beads is set-up but not yet tested. If testing is attempted without setting up the defaults, an alert message will be displayed.

## CONTROL Testing

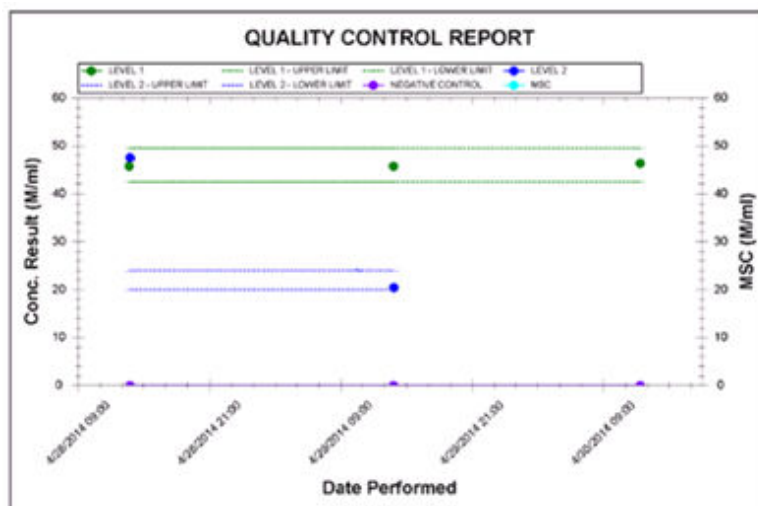
- Click: **TEST NOW** on the desired Level of LATEX BEADS or STABILIZED SPERM to be tested to open the sample preparation instructions screen displayed below.
- Follow the onscreen instructions for filling the testing capillary or refer to the Appendix section of this guide: "Filling the SQA-VISION Capillary with a Full Volume Sample."
- Insert the testing capillary into the VISION when prompted and testing will begin automatically.
- The test results screen below will be displayed when the testing is completed.



- The **PASS/FAIL** results will be displayed based on the test results vs. the target value and +/- range (Non-assayed controls target range is set to "0").
- A **CORRECTIVE ACTION** button is displayed for all **FAILED** results. Click to open the table seen below which provides a list of corrective actions:

PROBLEM DESCRIPTION	CORRECTIVE ACTION
SYSTEM REQUIRES CLEANING	CLEAN SYSTEM - RE-TEST
CONTROL MATERIAL EXPIRED	RUN NEW BATCH OF CONTROLS
SAMPLE HANDLING / MIXING	HOMOGENEOUSLY MIX - RE-TEST
TARGET VALUE / RANGE SETUP	CORRECT SETUP AND RE-TEST
CONTROL IMPROPERLY STORED	RUN NEW BATCH
WRONG LEVEL TESTED	RUN CORRECT LEVEL
NON-ASSAYED RUN AS ASSAYED CONTROL	RE-TEST AS NON-ASSAYED CONTROL
USER DEFINED	

- Select the problem associated with the test failure and press **SAVE**. It will then be recorded in the **QC ARCHIVE** with the corrective action noted.
- To add new reasons/corrective actions use the **USER DEFINED** field.
- Implement the corrective action and re-run the test.
- Click: **REPORT** to view and print the test results graph/report seen below:




Page 1 of 2

QUALITY CONTROL REPORT – LATEX BEADS

M.E.S Medical Electronic Systems

5757 W. Century Blvd. Suite 805  
Los Angeles, CA. 90045

PHONE: 866-557-9064  
FAX: 310-670-9069  
E-MAIL: [services@mes-llc.com](mailto:services@mes-llc.com)  
WEB: [www.mes-global.com](http://www.mes-global.com)



QUALITY CONTROL INFORMATION

QC TYPE: LATEX BEADS

REPORT DATE / TIME: 07/31/2013 13:15

DATES: 04/28/2014 – 04/30/2014

DATE / TIME	LEVEL	LOT #	EXP. DATE	TARGETS (M/ml)	PASS RANGES	RESULTS (M/ml)	STATUS	CORRECTIVE ACTION
04/28/2014 09:21	1	345345345	04/2014	45	35.0 – 55.0	66.6	↑	RE-TEST AS NON-ASSAYED CONTROL
04/28/2014 09:34	2	345632456	04/2014	22	19.0 – 24.4	22.2		
04/28/2014 09:55	NEG.CONTROL	324523454	04/2014	0.0 (CONC./ MSC)	0.0 – 0.0 (CONC./ MSC)	0.0 / 0.0		
04/29/2014 09:00	1	345345345	04/2014	45	35.0 – 55.0	41.2		
04/29/2014 09:07	2	345632456	04/2014	22	19.0 – 24.4	21.7		
04/29/2014 09:15	NEG.CONTROL	324523454	04/2014	0.0 (CONC./ MSC)	0.0 – 0.0 (CONC./ MSC)	0.0 / 0.0		
04/30/2014 10:10	1	345345345	04/2014	45	35.0 – 55.0	39.0		
04/30/2014 10:51	NEG.CONTROL	324523454	04/2014	0.0 (CONC./ MSC)	0.0 – 0.0 (CONC./ MSC)	0.0 / 0.0		

PRINTED FROM SQA-VISION SERIAL #234 AT 13:20 ON 07/31/2014

Proficiency Sample Testing

**PROFICIENCY** tests are run the same way as a QC/CONTROLS (CAP) or by following a protocol provided by MES for each Proficiency distribution (NEQAS and QuaDeGa). The results are submitted and compared to a peer group by the proficiency test provider and the lab is provided with PASS/FAIL results.

SQA-Vision  
Version 104.17.6

CLINICAL ☒ CRYODIAGN

LATEX BEADS STAB. SPERM **PROFICIENCY** MARK COUNT

TEST PATIENT

QC / PROFICIENCY

VISUALIZATION

ARCHIVE

SERVICE

SETTINGS

PROFICIENCY # 1

TEST NOW

TEST RESULTS  
CONC. (M/ml): 30.7

SAMPLE INFORMATION  
SAMPLE ID: 280419001  
ISSUE DATE: 28/04/2020  
N011C  
LAST RUN: 28/04/2019 10:18

PROFICIENCY # 2

TEST NOW

TEST RESULTS  
CONC. (M/ml): 275.8

SAMPLE INFORMATION  
SAMPLE ID: 280419002  
ISSUE DATE: 28/04/2020  
N011C  
LAST RUN: 28/04/2019 10:19

PROFICIENCY # 3

TEST NOW

TEST RESULTS  
CONC. (M/ml): 98.7


SAMPLE INFORMATION  
SAMPLE ID: 280419003  
ISSUE DATE: 28/04/2020  
N011C  
LAST RUN: 28/04/2019 10:24

PROFICIENCY # 4

TEST NOW

TEST RESULTS  
CONC. (M/ml): 98.7

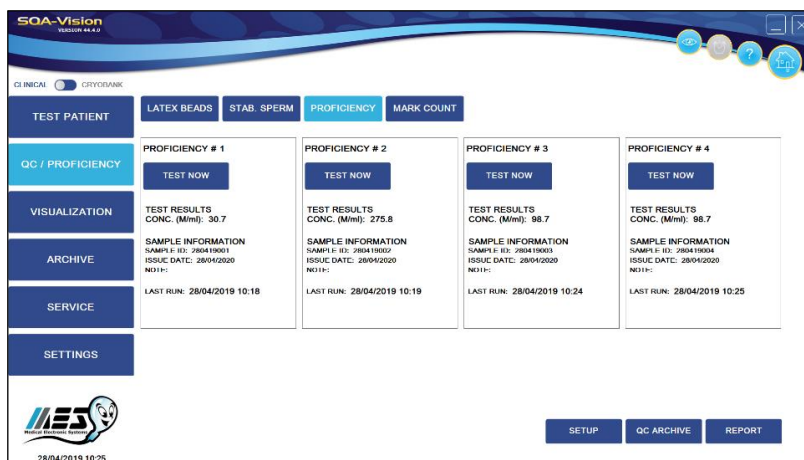
SAMPLE INFORMATION  
SAMPLE ID: 280419004  
ISSUE DATE: 28/04/2020  
N011C  
LAST RUN: 28/04/2019 10:25



28/04/2019 10:25

SETUP QC ARCHIVE REPORT

**PROFICIENCY (CAP)** tests are run the same way as a QC/CONTROLS. The results will not be compared to target ranges, as they are not available (the results are compared to a peer group mean value by CAP):



- Request protocols from your distributor to running proficiency schemes (except CAP)
- All **QC** and **PROFICIENCY** results are saved automatically in the **QC ARCHIVE**.

## Internal QC

### Electronic Self-Test and Auto Calibration

The SQA-VISION automatically runs a series of tests when the system is initially turned on and prior to sample testing to check calibration settings.

#### Start-up:

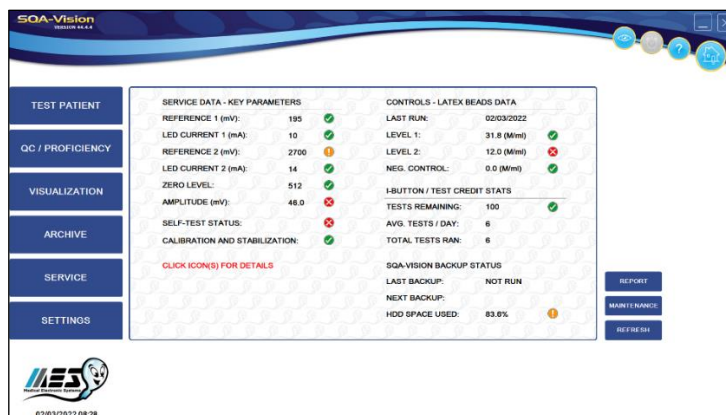
- **Stabilization and autocalibration:** Checks system stability and reference parameters to insure they are within acceptable ranges. A warning message will advise if there is a failure.
- **System noise:** Measures the electronic noise level of the system to insure effective measurement of electronic signals.
- **Self-test:** The system produces electronic signals that simulate motility and concentration measurements to check device performance and verify that the calibration settings are consistent with factory specifications. The SQA-VISION reports Self-Test failure if the system is not within acceptable Self-Test ranges.

#### Prior to testing a sample:

- **Autocalibration verification:** Reference parameters of the concentration and motility channels are measured again (without a testing capillary).
- **System noise:** Measures electronic noise level of the system to insure effective measurement of electronic signals. Prior to running a test, the SQA-VISION will automatically adjust the noise level threshold to insure accurate readings.
- **Electronic spikes:** Checks for measurement points that are out of range electronically and displays a warning message if out of range.

#### How to print a SERVICE PARAMETER report to prepare for technical support:

- If a Self-Test failure occurs, the status icon in the HOME screen will turn red:



- Click: **SELF-TEST STATUS** icon to open a warning message with instruction on how to resolve the problem:



- Click: **REPORT** from the **HOME** or **SERVICE** screen to generate a **SERVICE REPORT**. This may be required for troubleshooting and technical support (please refer to the SERVICE DATA section).

## Visualization System

### SECTION 7: Visualization

The SQA-VISION Visualization System is used to view and count sperm cells, capture static and dynamic images, scan for debris and round cells, and perform manual morphology and vitality assessment. The system displays real time videos or pictures of the semen sample on a PC monitor. Refer to Appendix 10 for guidance on slides and zoom settings.

The visualization system:

- Accommodates a QwikCheck Coverslip Slide for SQA-Vision or a standard slide (both 20-micron depth) – refer to Appendix 10 for the slide type used for specific assessments.
- Provides the visualization settings and video control adjustment in the SQA-VISION PC software (refer to this user guide for detailed instructions).
- Allows smooth magnification transition from x1188 to x1725 (use Zoom In/Out).

#### Fixed Coverslip Preparation

- Mix the semen sample thoroughly and pipette ~5 µl of semen.
- Load sample in the fixed coverslip where instructed by the arrows (there are two wells on each slide for duplicate counts). After filling, 'drop' the slide into the slide-holder as shown below:



## Operating Instructions Fixed Coverslip



Insert the slide-holder into the VISION visualization compartment:



### Standard Slide Preparation

#### Standard Slide Preparation

- Load 10 µl of semen onto the **distal** end of a standard slide and cover with a 22 mm x 22 mm cover-slip (to insure 20-micron depth).
- Insert the prepared standard slide into the SQA-VISION slide holder and insert into the visualization compartment of the VISION as shown above.

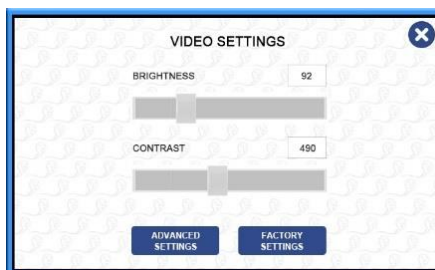
### Visualizing the Sample

#### Visualization Process

- The video screen is opened automatically during the testing process when (refer to Appendix 10 for the slide type used for specific assessments):
  - **LOW QUALITY** sample results fall below the dynamic range of the SQA-VISION. In these cases, the manual counting results will be used to report final test results (requires a fixed coverslip slide).
  - **DEBRIS/ROUND CELL** scanning is initiated (a standard slide or fixed coverslip can be used).
- The video screen is also used to assess **MORPHOLOGY, VITALITY, DNA FRAGMENTATION** and to **CAPTURE** screen images/videos from an open or archived test record.
- To assess **MORPHOLOGY** and **VITALITY** use stained smears or stained wet preparations; DNA Fragmentation is assessed using a special BASO kit. Screen images/videos can be **CAPTURED** using standard slides or fixed coverslips.
- When using the **MARK COUNTING** option (marking each cell counted), the **MORPHOLOGY, VITALITY** and **DNA Fragmentation** images will be saved in the archive along with the associated (open) patient test record.
- Final manual **MORPHOLOGY, VITALITY** and **DNA Fragmentation** results will be displayed in the semen analysis report. The **CAPTURED** images will be saved with the associated (open) patient record.
- Images/videos saved offline will not be attached to any patient record.
- Select **VISUALIZATION** in the **Main Menu** to open the video screen and view a sample which is not connected to any test record saved in the archive.
- **To VIEW cells:** Press **ZOOM IN** to the maximum magnification (x1725).
- **To COUNT cells:** Press **ZOOM OUT** to the minimum magnification (x1188).

## Counting Spermatozoa

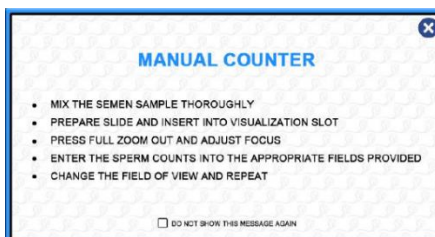
- Insert the prepared slide into the visualization chamber. (Refer to Appendix 10 for slide type).
- Click the **SETTINGS** button at the bottom of the video screen to adjust **CONTRAST** and **BRIGHTNESS** (see below).



- Bring the image to optimal focus using the device **FOCUS** knob (for more details, please refer to the VISUALIZATION SETTINGS section of this manual).

### Counting Spermatozoa Using the Visualization Screen

- Spermatozoa can be manually counted in low quality samples when results fall below the automated dynamic range of the SQA-VISION and for ANY sample if the **MANUAL** mode is selected as described above.
- Set-up the visualization compartment defaults in advance (Refer to the **VISUALIZATION SETTINGS** section of this manual). Advanced Settings defaults are pre-set by the manufacturer for the best resolution.
- Select **MANUAL** test in the **Main Menu** and enter the patient/sample data.
  - Click: **TEST NOW** and the instructions below will be displayed (refer to Appendix 10 for the slide type to be used):



- Follow the onscreen and the WHO 5th edition instructions for semen sample collection and preparation.
- Adjust the **FOCUS** knob to bring the image into optimal focus: Turn clockwise all the way. Then turn counterclockwise until a clear image appears on the screen.
- Click: **GRID ON** at the bottom of the screen. The screen of the SQA-VISION is divided into a grid containing 20-distinct squares (see below):

- Count a **minimum of 200 sperm cells** (according to WHO recommendations) in as many fields as required by turning the knob of the Field of View Stage to advance to the **NEXT FIELD**.
- In the **MANUAL COUNTER**, enter the number of **TOTAL, IMMOTILE, SLOW PROG** and **NON PROG** sperm counted in the entire field of view.
- Click: **NEXT FIELD** and select a new field of view. Count the sperm cells.
- Repeat until 200 cells are counted per WHO recommendations (the display keeps track of the **TOTAL SPERM COUNTED** automatically).
- Select **RESULTS** when counting is completed. The software will calculate and report final semen parameters.

## Manual Morphology

### Manual Morphology Assessment

- Manual Morphology assessment can be performed in a variety of ways based on the user designated setting (to set up defaults go to: **Settings>Visualization>Morphology**). It is recommended to use QwikCheck Pre-Stained slides (refer to Appendix 10 for details).

#### MORPHOLOGY SETTINGS

CRITERIA: WHO 5TH

TEST TYPE

NORMAL / ABNORMAL ☒

FULL DIFFERENTIAL ☐

COUNT TYPE

CLICK COUNT (KEY) ☒

MARK COUNT (CIRCLE) ☐

#### MORPHOLOGY SETTINGS

CRITERIA: WHO 5TH

TEST TYPE

NORMAL / ABNORMAL ☒

FULL DIFFERENTIAL ☐

COUNT TYPE

CLICK COUNT (KEY) ☐

MARK COUNT (CIRCLE) ☒

#### MORPHOLOGY SETTINGS

CRITERIA: WHO 5TH

TEST TYPE

NORMAL / ABNORMAL ☐

FULL DIFFERENTIAL ☒

COUNT TYPE

CLICK COUNT (KEY) ☐

MARK COUNT (CIRCLE) ☒

#### MORPHOLOGY SETTINGS

CRITERIA: WHO 5TH

TEST TYPE

NORMAL / ABNORMAL ☐

FULL DIFFERENTIAL ☒

COUNT TYPE

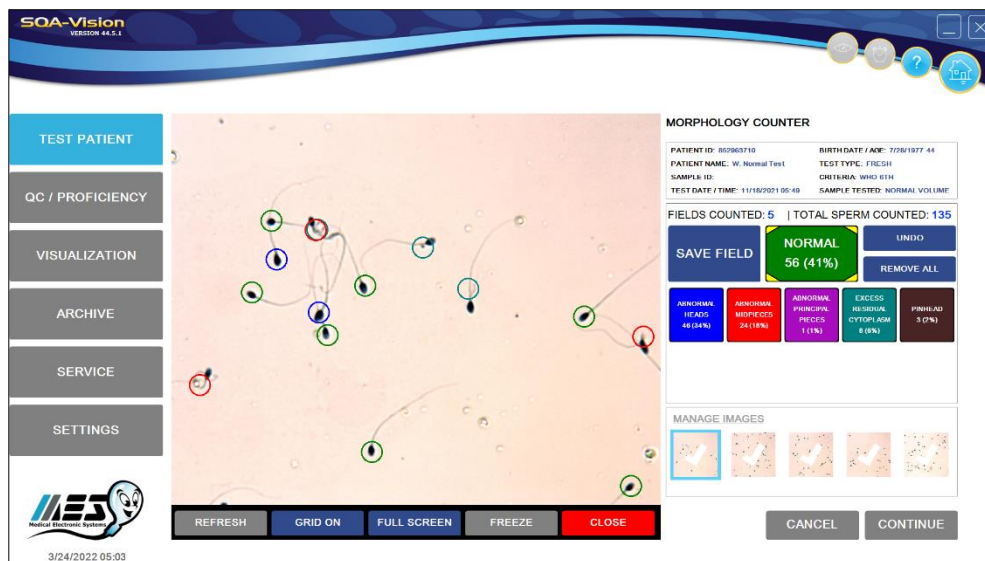
CLICK COUNT (KEY) ☒

MARK COUNT (CIRCLE) ☐

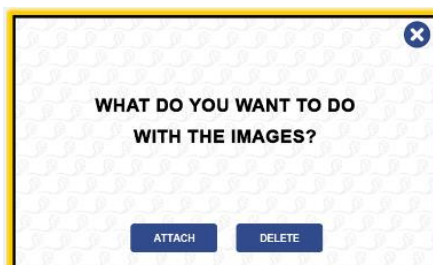
- A **Normal/Abnormal** or **Full Differential** morphology count can be performed using the **COUNTER** default options and procedure described in the table below.

Click Count (Key)	Normal / Abnormal	Full Differential
<p>1. Select: <b>Normal / Abnormal</b> or <b>Full Differential</b> to count and classify sperm cells in the <b>Settings</b>.</p> <p>2. Each click of the button will add another cell to the category corresponding to the button labeling.</p> <p>F (function) keys on the PC keyboard can be used for counting as well (see the F key noted on the buttons).</p> <p>3. Continue to assess the sample by moving to new fields of view by turning the Field of View knob on the device.</p> <p>4. Click: <b>Continue</b> when the appropriate # of sperm have been assessed.</p> <p>5. The <b>TOTAL SPERM COUNTED</b> are displayed automatically.</p>	<p><b>MORPHOLOGY COUNTER</b></p> <p>PATIENT ID: 1234567890098 BIRTH DATE / AGE: 12/12/2001 21  PATIENT NAME: M. Smith TEST TYPE: FRESH  SAMPLE ID: 5465888974 CRITERIA: WHO 6TH  TEST DATE / TIME: 6/23/2023 11:00 SAMPLE TESTED: FULL VOLUME</p> <p>TOTAL SPERM COUNTED: 15</p> <p><b>NORMAL</b> 11 (73%) <b>ABNORMAL</b> 4 (27%) UNDO REMOVE ALL</p> <p>CANCEL CONTINUE</p>	<p><b>MORPHOLOGY COUNTER</b></p> <p>PATIENT ID: 1234567890098 BIRTH DATE / AGE: 12/12/2001 21  PATIENT NAME: M. Smith TEST TYPE: FRESH  SAMPLE ID: 5465888974 CRITERIA: WHO 6TH  TEST DATE / TIME: 6/23/2023 11:11 SAMPLE TESTED: FULL VOLUME</p> <p>TOTAL SPERM COUNTED: 26</p> <p><b>NORMAL</b> 16 (60%) UNDO REMOVE ALL</p> <p><b>ABNORMAL HEADS</b> 3 (12%) <b>ABNORMAL MIDPIECES</b> 1 (4%) <b>ABNORMAL PRINCIPAL PIECES</b> 3 (12%) <b>EXCESS RESIDUAL CYTOPLASM</b> 3 (12%) <b>PINHEAD</b> 2 (7%)</p> <p>CANCEL CONTINUE</p>
<p><b>Mark Count (circle)</b></p> <p>1. Select: <b>Capture Field</b> (the button will change to <b>Save Field</b>).</p> <p>2. The <b>Normal / Abnormal</b> or <b>Full Differential</b> buttons will be activated.</p> <p>3. Click: <b>Normal</b> and then click each normal sperm in the field of view (the spermatozoa will be marked with a colored circle according to the settings).</p> <p>4. Click: <b>Abnormal</b> or select a specified abnormality and click on each sperm with this abnormality (or all abnormal).</p> <p>5. The number of fields and sperm cells counted (totally and in each category) and their relative percent of the total will be displayed.</p> <p>6. When all sperm cells are counted, click <b>Save Field</b> button.</p> <p>7. Repeat the same procedure in each new field of view obtained by turning the Field of View knob.</p> <p>8. Click: <b>Continue</b> when the assessment is completed.</p>	<p><b>MORPHOLOGY COUNTER</b></p> <p>PATIENT ID: 1234567890098 BIRTH DATE / AGE: 12/12/2001 21  PATIENT NAME: M. Smith TEST TYPE: FRESH  SAMPLE ID: 5465888974 CRITERIA: WHO 6TH  TEST DATE / TIME: 6/23/2023 11:11 SAMPLE TESTED: FULL VOLUME</p> <p>FIELDS COUNTED: 5   TOTAL SPERM COUNTED: 15</p> <p><b>CAPTURE FIELD</b> <b>NORMAL</b> 10 (67%) <b>ABNORMAL</b> 5 (33%) UNDO REMOVE ALL</p> <p><b>MANAGE IMAGES</b></p> <p>CANCEL CONTINUE</p>	<p><b>MORPHOLOGY COUNTER</b></p> <p>PATIENT ID: 1234567890098 BIRTH DATE / AGE: 12/12/2001 21  PATIENT NAME: M. Smith TEST TYPE: FRESH  SAMPLE ID: 5465888974 CRITERIA: WHO 6TH  TEST DATE / TIME: 6/23/2023 11:11 SAMPLE TESTED: FULL VOLUME</p> <p>FIELDS COUNTED: 5   TOTAL SPERM COUNTED: 27</p> <p><b>CAPTURE FIELD</b> <b>NORMAL</b> 16 (60%) UNDO REMOVE ALL</p> <p><b>ABNORMAL HEADS</b> 2 (7%) <b>ABNORMAL MIDPIECES</b> 5 (19%) <b>ABNORMAL PRINCIPAL PIECES</b> 2 (7%) <b>EXCESS RESIDUAL CYTOPLASM</b> 2 (7%) <b>PINHEAD</b> 2 (7%)</p> <p><b>MANAGE IMAGES</b></p> <p>CANCEL CONTINUE</p>

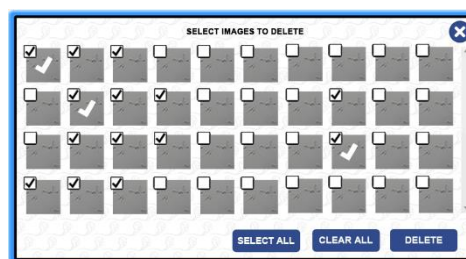
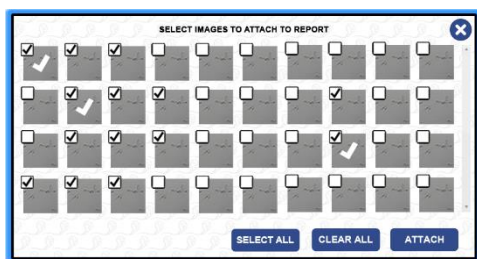
- The screen below shows **Morphology Differential** with **Marked Cells** (the **active** button is marked with yellow angles):



- All images that have been saved by pressing **SAVE FIELD** are shown as small icons and can be attached to a record or deleted by clicking **MANAGE IMAGES**.




- Click **ATTACH** or **DELETE** and one of the following boxes will appear:



- Select the desired images and click **ATTACH** or **DELETE**.
- The selected images will be attached to the **Semen Analysis Report** or deleted.
- The same procedure is used for managing **Vitality** and other captured semen images.
- If the Morphology assessment is opened from the Test Results screen (after a test is run) or opened from a patient record selected from the Archive, the manual morphology results will be included in the final semen analysis report.
- Morphology results will not be attached to a patient record if morphology is performed offline.
- The **Morphology Report** can be opened from the archive (please see the Archive section):

PHONE: 310-670-9066  
FAX: 310-670-9069  
E-MAIL: [sales@mes-lic.com](mailto:sales@mes-lic.com)  
WEB: [www.mes-global.com](http://www.mes-global.com)

M.E.S. Medical Electronic System  
5757 W. Century Blvd 805  
Los Angeles, CA. 90045

 Page 1 of 1

**MORPHOLOGY REPORT**

**REPORT INFORMATION**

REPORT NAME:	MORPH. TEST TYPE:	FULL DIFFERENTIAL
CRITERIA: WHO 6TH	MORPH. COUNT TYPE:	MARK COUNT (CIRCLE)
REPORT DATE / TIME: 5/31/2023 10:37		

PARAMETER	RESULT	REF. VALUE	STATUS	COLOR
NORMAL (%):	50	>= 4		
HEAD DEFECTS (%):	10			
NECK AND MIDPIECE DEFECTS (%):	30			
TAIL DEFECTS (%):	0			
CYTOPLASMIC DROPLETS (%):	10			
PINHEAD (%):	0			

PRINTED FROM SQA-VISION SERIAL # 1234 AT 10:39 ON 5/31/2023

## Vitality and DNA Frag

- **Select Vitality or DNA Fragmentation (DNA FRAG.)** from the Test Results screen or from a patient record in the SQA-Vision archive to perform a manual assessment using the **VITALITY** or **DNA Fragmentation COUNTER**.
- **Live** and **Dead** sperm cells for **Vitality** and **HALO / NO HALO** or **HALO GRADING** for **DNA FRAG.** can be counted by selecting the **Click Count (Key)** or the **Mark Count (Circle)** options in the Vitality or DNA Fragmentation settings (Go to: **Settings > Visualization > Vitality or DNA Fragmentation**).
- It is recommended to use a standard 1" X 3" slide with a 22X22 fixed coverslip for assessment (Refer to Appendix 10 for details).

**VITALITY SETTINGS**

**COUNT TYPE**

☐ CLICK COUNT (KEY) ●

☒ MARK COUNT (CIRCLE) ●

**DNA FRAGMENTATION SETTINGS**

**COUNT TYPE**

☐ CLICK COUNT (KEY) ●

☒ MARK COUNT (CIRCLE) ●

**TEST TYPE**

☒ HALO / NO HALO

☐ HALO GRADING

**DNA FRAGMENTATION SETTINGS**

**COUNT TYPE**

☐ CLICK COUNT (KEY) ●

☒ MARK COUNT (CIRCLE) ●

☐ SMALL HALO

**TEST TYPE**

☐ HALO / NO HALO

☒ HALO GRADING

●

●



- The table below shows how to use the two **COUNT TYPE** options:

### Click Count (key)

1. Select the **Live / Dead** or **Halo / No Halo** buttons to count sperm cells for each category
2. Each click will add another cell to the selected category (Live / Dead or Halo / No Halo).
3. Turn the Field of View knob to move to a new field of view and repeat the clicking procedure above until the desired number of sperm cells have been assessed.
4. The number of sperm cells assessed in all fields of view will automatically be displayed in the **TOTAL SPERM COUNTED** field.
5. Click: **Continue** when the counting is completed.

**VITALITY COUNTER**

PATIENT ID: 123456789008 BIRTHDATE / AGE: 12/12/2001 21  
 PATIENT NAME: M. Smith TEST TYPE: FRESH  
 SAMPLE ID: 6667999976 CRITERIA: WHO 6TH  
 TEST DATE / TIME: 6/23/2023 10:41 SAMPLE TESTED: FULL VOLUME

TOTAL SPERM COUNTED: 9

LIVE 6 (67%)	DEAD 3 (33%)	UNDO
		REMOVE ALL

CANCEL CONTINUE

**DNA FRAGMENTATION COUNTER**

PATIENT ID: 123456789008 BIRTHDATE / AGE: 12/12/2001 21  
 PATIENT NAME: M. Smith TEST TYPE: FRESH  
 SAMPLE ID: 6667999976 CRITERIA: WHO 6TH  
 TEST DATE / TIME: 6/23/2023 10:44 SAMPLE TESTED: FULL VOLUME

TOTAL SPERM COUNTED: 8

HALO 6 (75%)	NO HALO 2 (25%)	UNDO
		REMOVE ALL

### Mark Count (circle)

1. Press: **Capture Field** (will change to **Save Field**)
2. The **Live/Dead** or **Halo/No Halo** buttons will be activated
3. Select: **LIVE**, then click on each live (not stained) sperm in the field of view to mark it with a circle of a pre-set color).
4. Select: **DEAD**, then click/mark each dead sperm (stained)
5. Select: **HALO**, then click/mark each sperm with halo
6. Select: **NO HALO**, then click/mark each sperm without halo
7. Select: **HALO GRADING** to assess 5 DNA FRAG categories, using the scaling tool provided.
8. The number of fields and cells counted in each category and their relative percent of the total will be shown.
9. Click: **Save Field** when all sperm cells in the field of view are counted.
10. Press: **Capture Field** and move to a new field of view by turning the Field of View knob. Repeat the procedure above.
11. Click: **Continue** when the counting is completed.

**VITALITY COUNTER**

PATIENT ID: 123456789008 BIRTHDATE / AGE: 12/12/2001 21  
 PATIENT NAME: M. Smith TEST TYPE: FRESH  
 SAMPLE ID: 7545459997 CRITERIA: WHO 6TH  
 TEST DATE / TIME: 6/23/2023 10:49 SAMPLE TESTED: FULL VOLUME

FIELDS COUNTED: 5 | TOTAL SPERM COUNTED: 123

CAPTURE FIELD	LIVE 83 (67%)	DEAD 40 (33%)
AUTO COUNT	UNDO	
REMOVE ALL		

MANAGE IMAGES

✓	✓	✓	✓	✓
---	---	---	---	---

CANCEL CONTINUE

**DNA FRAGMENTATION COUNTER**

PATIENT ID: 123456789008 BIRTHDATE / AGE: 12/12/2001 21  
 PATIENT NAME: M. Smith TEST TYPE: FRESH  
 SAMPLE ID: 7545459997 CRITERIA: WHO 6TH  
 TEST DATE / TIME: 6/23/2023 10:49 SAMPLE TESTED: FULL VOLUME

FIELDS COUNTED: 1 | TOTAL SPERM COUNTED: 8

CAPTURE FIELD	HALO 6 (75%)	NO HALO 2 (25%)
		UNDO
REMOVE ALL		

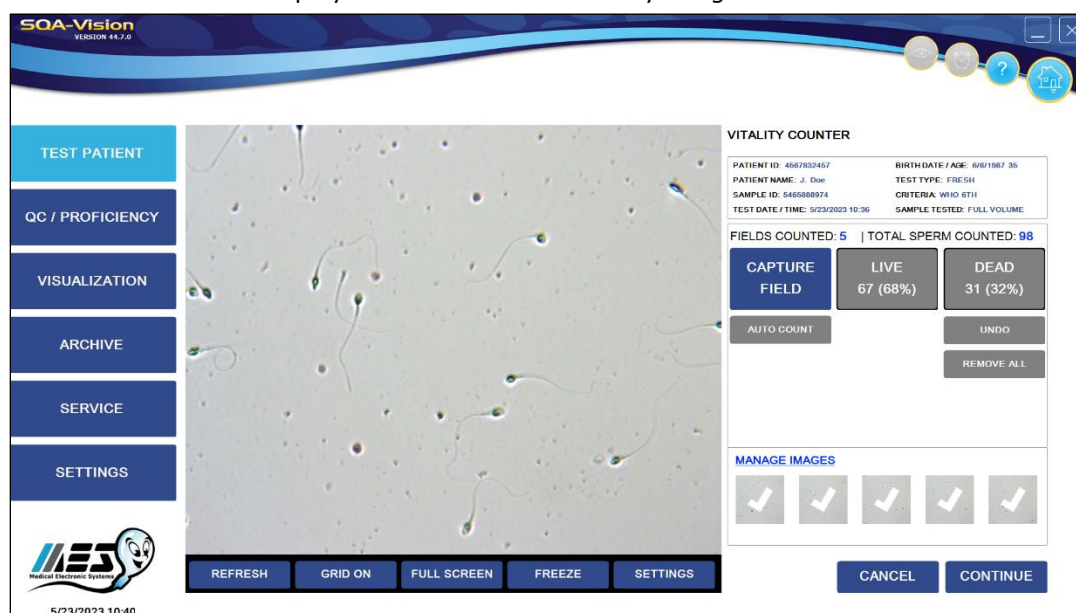
**DNA FRAGMENTATION COUNTER**

PATIENT ID: 123456789008 BIRTHDATE / AGE: 12/12/2001 21  
 PATIENT NAME: M. Smith TEST TYPE: FRESH  
 SAMPLE ID: 7545459997 CRITERIA: WHO 6TH  
 TEST DATE / TIME: 6/23/2023 10:52 SAMPLE TESTED: FULL VOLUME

FIELDS COUNTED: 1 | TOTAL SPERM COUNTED: 37

NO HALO 7 (19%)	NO HALO - DEGRADED 2 (5%)	CAPTURE FIELD
SMALL HALO 3 (8%)	MEDIUM HALO 14 (38%)	LARGE HALO 12 (32%)
		SCALE
UNDO REMOVE ALL		

- The screen below displays an eosin-stained Vitality image:



- If the Vitality or DNA Fragmentation assessment is performed from the Test Results screen (after a test is run) or from a patient record opened in the Archive, the Vitality or DNA Fragmentation results will be included in the final semen analysis report.
- All Vitality or DNA Fragmentation images that have been saved by pressing **SAVE FIELD** (counting by marking) are shown as small icons and can be managed by clicking the **MANAGE IMAGES** link (please refer to the managing images description above).
- Results will not be attached to a patient record if Vitality or DNA Fragmentation is performed from the MANUAL mode as individual test or offline.

## 10-microliter Counter (Motility Estimation)

### 10-microliter Counter

The 10-microliter Counter is used for estimating motility in order to obtain a full test results report. It is recommended to use a Vision Fixed Coverslip Slide for assessment (refer to Appendix 10 for details). Perform the motility estimation using the visualization screen which can be set to open automatically when completing an automated low volume test. Morphology parameters will not be reported.

## Manual Morphology and Vitality Data Entry

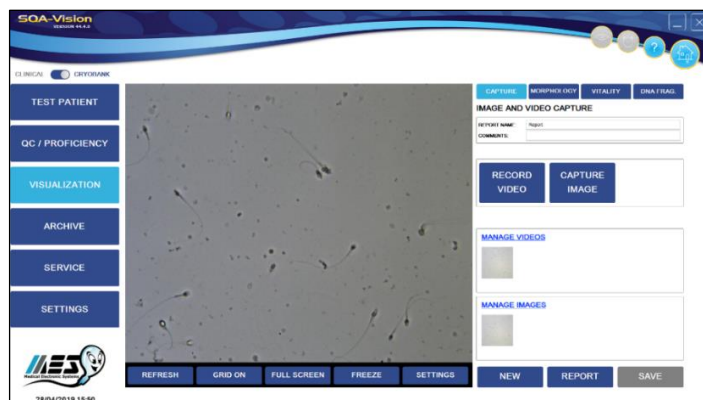
### Manual Morphology and Vitality Data Entry

- To enter Morphology and/or Vitality results obtained using the microscope, set the Manual **Morphology** and **Vitality Data Entry** defaults in the Test Patient Settings.
- A Morphology and/or Vitality Data Entry screen will open automatically when clicking the Morphology or Vitality button.
- Either % Normal Forms or a Morphology differential can be entered based on the settings in the Visualization Settings Morphology section.
- When the Manual Morphology and/or Vitality Data Entry is activated other SQA-Vision visualization counter(s) are disabled.

## Capturing Images

### Capturing Images

- Select: **CAPTURE** from the TEST RESULTS screen or from a test opened in the Archive or from the Visualization screen (offline) - refer to Appendix 10 for the slide type to be used.
- Click: **RECORD VIDEO** or **CAPTURE IMAGE** from the screen seen below:



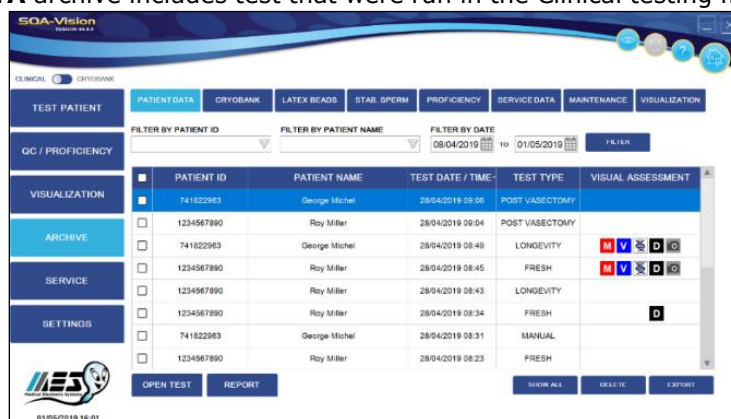
- Click: **Stop Capturing** to end the video recording.
- The captured videos and images will be saved in the database and shown as small icons in the corresponding sections above.
- If videos/images are captured from the Test Results screen or from records in the Archive, the videos and images will be attached to the patient record.
- All images that have been saved can be managed by clicking **MANAGE IMAGES**.
- Saved images can be viewed by pressing **REPORT**.
- If videos are captured offline from the Visualization screen the videos and images will not be attached to any patient record.

## Archive

### SECTION 8: Archive

The **SQA-VISION ARCHIVE** stores PATIENT and CRYO DATA, QC results (LATEX BEADS and STABILIZED SPERM), PROFICIENCY, VISUALIZATION, MAINTENANCE and SERVICE records.

The **PATIENT DATA** archive includes test that were run in the Clinical testing flow as shown below:



- **PATIENT DATA** records can be selected by searching by: Patient NAME, ID or DATE RANGE.
- Click on the buttons at the bottom of the screen:
  - **OPEN TEST** – Displays the test results for the selected record
  - **REPORT** – Opens the Semen Analysis Report of the selected record
  - **SHOW ALL** – All records will be displayed
  - **DELETE** - The selected record(s) will be deleted
  - **EXPORT** – Records can be sent to the PC in CSV format. If the export fails an error message will be displayed.
- **Test Date/Time** column displays the date and time tests were run for the selected patient.
- The test results records can be sorted by PATIENT ID, NAME, TEST DATE/TIME and TEST TYPE by clicking the desired sort in the header of the patient records.

The **CRYOBANK** archive contains DONOR ID, DONATION #, TEST DATES, STAGING of the testing process and VISUAL ASSESSMENT records as shown below:

**SQA-Vision** VERSION 44.4.0

CLINICAL ☐ CRYOBANK

TEST PATIENT | PATIENT DATA | **CRYOBANK** | LATEX BEADS | STAB. SPERM | PROFICIENCY | SERVICE DATA | MAINTENANCE | VISUALIZATION

QC / PROFICIENCY

FILTER BY DONOR ID:  FILTER BY DONATION #:  FILTER BY DATE: 08/04/2019 TO 01/05/2019

	DONOR ID	DONATION #	TEST DATE / TIME	STAGE NAME	VISUAL ASSESSMENT
<input checked="" type="checkbox"/>	123456	6	15/04/2019 15:30	POST THAW	
<input type="checkbox"/>	123456	5	14/04/2019 11:28	INITIAL (FRESH)	M V O
<input type="checkbox"/>	123456	1	14/04/2019 09:22	POST THAW	
<input type="checkbox"/>	123456	6	11/04/2019 15:16	PRE FREEZE	
<input type="checkbox"/>	123456	6	11/04/2019 14:48	INITIAL (FRESH)	
<input type="checkbox"/>	123456	1	11/04/2019 11:58	PRE FREEZE	
<input type="checkbox"/>	123456	1	11/04/2019 11:48	INITIAL (FRESH)	
<input type="checkbox"/>	12345	4	11/04/2019 09:49	POST THAW	

OPEN TEST | REPORT | SHOW ALL | DELETE | EXPORT

**MES** Medical Electronic Systems

01/05/2019 15:48

The LATEX BEADS and STABILIZED SPERM archive groups test results by date. The Level, Lot #, Expiration Date, Target, Range, Concentration, MSC, Status (Pass/Fail) and Corrective Action data provide comprehensive QC information:

**SQA-Vision** VERSION 44.4.0

CLINICAL ☐ CRYOBANK

TEST PATIENT | PATIENT DATA | CRYOBANK | **LATEX BEADS** | STAB. SPERM | PROFICIENCY | SERVICE DATA | MAINTENANCE | VISUALIZATION

QC / PROFICIENCY

FILTER BY LEVEL:  FILTER BY STATUS:  FILTER BY DATE: 28/04/2019 TO 01/05/2019

	DATE / TIME	LEVEL	LOT #	EXP. DATE	TARGETS (M/ml)	PASS RANGES	CONC. (M/ml)	MSC (M/ml)	STATUS	CORRECTIVE ACTION
<input type="checkbox"/>	01/05/2019 14:31	2	21101800	05/2019	25.0	19.0 - 31.0	49.2	NA	FAIL	CORRECT SETUP AND RE-TEST
<input checked="" type="checkbox"/>	01/05/2019 14:30	1	21101800	10/2019	49.0	42.1 - 55.9	49.2	NA	PASS	
<input type="checkbox"/>	28/04/2019 09:30	2	21101800	01/2020	25.0	20.0 - 30.0	9.0	NA	FAIL	
<input type="checkbox"/>	28/04/2019 09:29	1	21101800	01/2020	49.0	42.1 - 55.9	44.1	NA	PASS	
<input type="checkbox"/>	28/04/2019 09:28	1	21101800	01/2020	49.0	42.1 - 55.9	9.0	NA	FAIL	

REPORT | SHOW ALL | DELETE | EXPORT

**MES** Medical Electronic Systems

01/05/2019 16:06

- Records are displayed in the **QC** archive by DATE RANGE.
- The status column displays when QC tests passed or failed (red).
- Use the buttons at the bottom of the screen to manage archive data or to open a report.

The **PROFICIENCY** archive groups test results by date. The PROFICIENCY #, SAMPLE ID, ISSUE DATE, CONCENTRATION and NOTES provide comprehensive information:

DATE / TIME	PROFICIENCY #	SAMPLE ID	ISSUE DATE	CONC. (M/ml)	NOTE
28/04/2019 10:25	4	280419004	28/04/2020	98.7	
28/04/2019 10:24	3	280419003	28/04/2020	98.7	
28/04/2019 10:19	2	280419002	28/04/2020	275.8	
28/04/2019 10:18	1	280419001	28/04/2020	30.7	

- Records are displayed in the **PROFICIENCY** archive by DATE RANGE.
- The DATE/TIME column displays the dates when the **PROFICIENCY** tests were performed.
- Use the buttons at the bottom of the screen to manage archive data or to open a report.

The **MAINTENANCE** archive tracks and displays by operator name that all steps were completed.

PERFORMED BY	DATE / TIME	ALL STEPS PERFORMED?
Lab technician 157	3/5/2020 17:08	YES

- Records are displayed in the MAINTENANCE archive by the DATE RANGE.
- The DATE/TIME column shows the dates when the maintenance was performed.
- Use the buttons at the bottom of the screen to manage archive data or to open a report.



The **SERVICE DATA** archive displays information by TEST DATE/TIME and STATUS confirmation (**PASS/FAIL**) if ALL PARAMETERS are IN RANGE:

SERVICE DATA DATE / TIME	TYPE	STATUS
01/05/2019 15:45	SELF-TEST	PASS
01/05/2019 15:39	SELF-TEST	PASS
01/05/2019 14:45	SELF-TEST	FAIL
01/05/2019 14:40	SELF-TEST	FAIL
01/05/2019 12:08	INTERNAL	PASS
01/05/2019 10:55	INTERNAL	PASS
28/04/2019 16:25	SELF-TEST	PASS
28/04/2019 16:13	SELF-TEST	PASS

- Records are displayed in the **SERVICE DATA** archive by the DATE RANGE.
- The SELF-TEST DATE/TIME column displays the dates when the SERVICE DATA parameter(s) were collected.
- The STATUS column shows when the Self-Test passed or failed.
- Use the buttons at the bottom of the screen to manage archive data or to open a report.

The **VISUALIZATION** archive displays information by MEDIA FILE NAME, DATE/TIME and the MEDIA TYPE of stored image:

REPORT NAME	DATE / TIME	TYPE
QC Report	01/05/2019 12:52	VISUAL QC
Report	28/04/2019 15:52	VISUAL QC
Report	28/04/2019 15:50	CAPTURE
Vitality Report	28/04/2019 15:48	VITALITY
Testing 28.04.2019	28/04/2019 12:55	VISUAL QC

- Records are displayed in the **VISUALIZATION ARCHIVE** by DATE RANGE.
- The DATE/TIME column displays information by the date the information was stored.
- Use the buttons at the bottom of the screen to manage archive data or to open a report.



## Error and Warning Messages

### SECTION 9: Error and Warning Messages

#### General Warning

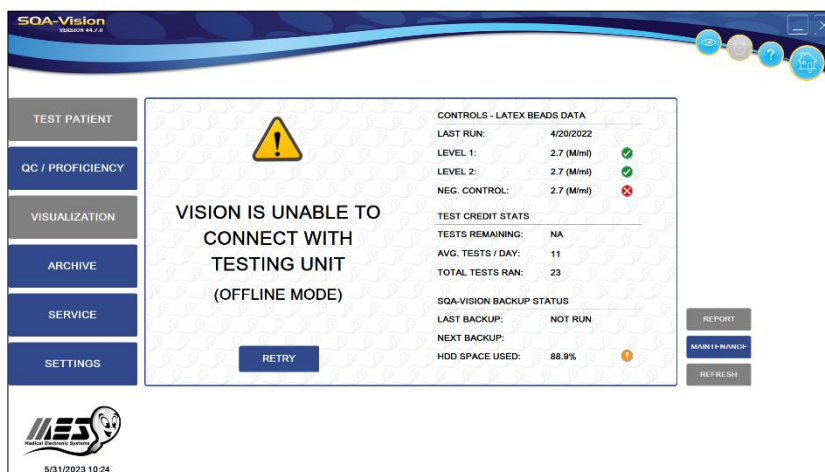
- The SQA-VISION must be operated properly, according to the manufacturer's specifications to insure that the equipment's built-in protection for both the operator and the environment is operational.
- **CAUTION:** There is a risk of electrical shorting if the SQA-VISION battery is replaced by an incorrect type. Replacement batteries **MUST** be the same type and manufacturer. Dispose of used batteries in accordance with the manufacturer's instructions.
- Environmental conditions for storage and transport: It is recommended to store the SQA-VISION at temperatures between +20°C and +30°C.
- Following the manufacturer's recommended use, the expected life span of the SQA-V is a minimum of 5 years. The life span can be extended when utilizing the manufacturer's annual preventative maintenance plan.

#### Stabilization and Self-Test Failure

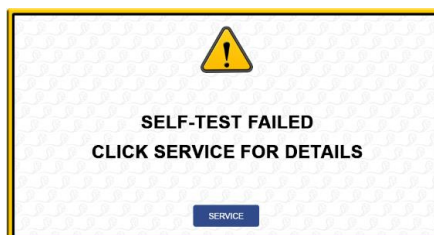
##### Device Messages:

<p>STABILIZATION FAILED TURN OFF MAIN SWITCH ON REAR PANEL REACTIVATE UNIT</p> <p>IF PROBLEM PERSISTS, CALL FOR TECHNICAL SUPPORT</p>	<p>FAILED SELF-TEST TURN OFF MAIN SWITCH ON REAR PANEL CLEAN OPTICAL CHAMBER REACTIVATE UNIT IF PROBLEM PERSISTS, CALL FOR TECHNICAL SUPPORT</p>
---------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------

##### PC Messages:

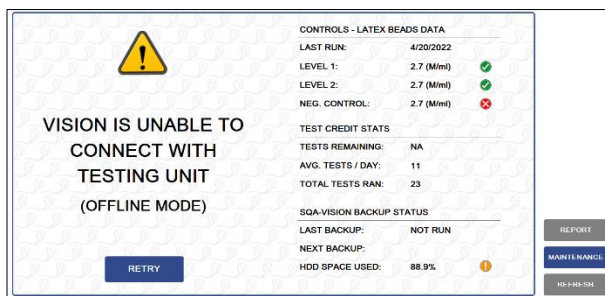


- Click: Self-Test Status icon to open a warning/instruction message:



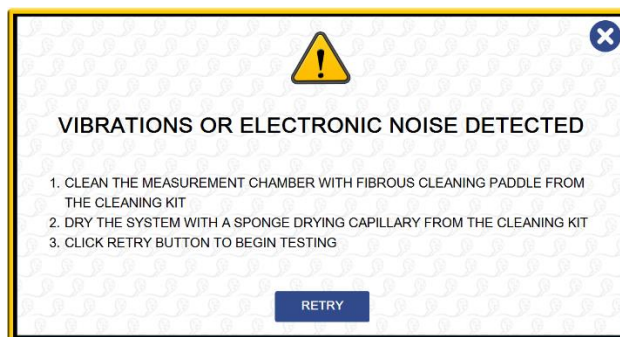
- Ensure there is no testing capillary in the measurement compartment.
- Remove the SQA-VISION from sources of electronic noise and vibrations.
- Clean the measurement compartment (refer to Appendix).
- Reboot the SQA-VISION without a testing capillary in the chamber:
  - Turn the system **OFF** then back **ON** at the main switch.
- Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the SQA-VISION **SERVICE DATA**:
  - In the PC: **Click SERVICE > SERVICE REPORT > PRINT**

### Communication Failure



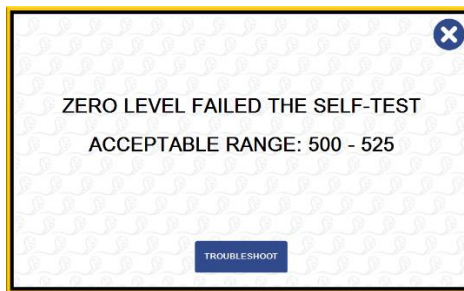
- Click the RETRY button to re-establish a connection.
- Check communication cables connection between the device and PC.
- Reboot both device and PC.
- Work offline if the problem recurs and call for technical support.

### Electronic Noise



- Ensure there is no testing capillary in the measurement compartment.
- Remove the SQA-VISION from sources of electronic noise and vibrations (centrifuge).
- Clean the measurement compartment (refer to Appendix) and after cleaning:
  - Turn the system **OFF** then back **ON** at the main switch.
- From the PC main menu: Select **TEST PATIENT** and rerun the test.
- Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the SQA-VISION **SERVICE DATA**:
  - In the PC: **Click SERVICE > SERVICE REPORT > PRINT**

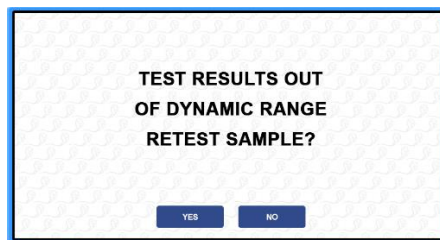
## Zero Level



## Auto-calibration

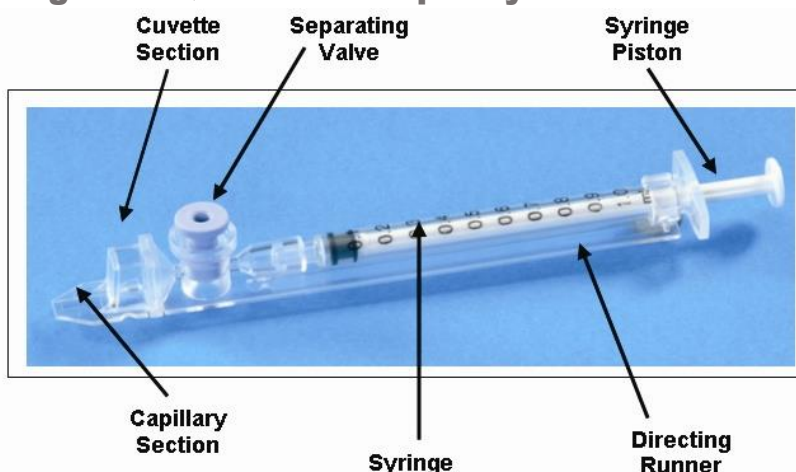


## Out of Dynamic Range



- A message will appear indicating that the test results for Sperm Concentration and/or MSC are beyond the upper limits of the dynamic range established by the manufacturer for testing. This message will appear if the SQA-VISION reads:
  - CONCENTRATION > 500 M/ml or MSC > 450 M/ml
- Review sample handling technique (Appendix "Filling the SQA-VISION Capillary").
- Re-test the sample using a new SQA-VISION capillary. If the message appears again, reboot the system.
- Call for technical assistance if problem persists.

## APPENDIX 1: Filling the SQA-VISION Capillary with a Full Volume Sample



### Sample size, collection container and preparation:

1. Sample volume should be **at least .5 ml**. If sample volume is less than .5 ml see Appendix 2.
2. Sample container should be **wide-necked and deep enough** to facilitate inserting the capillary into the sample at the bottom of the container.
3. The semen sample must be **completely liquefied and well mixed prior to aspiration**. Gently rotate container to fully mix liquefied specimen.

**WARNING:** Do not shake nor use a pipette to aspirate and dispense specimen in order to mix, otherwise air bubbles will form.



**Figure 1**

4. **Carefully check that 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, thus ensuring that no air bubbles will be aspirated into the capillary.

### Filling the capillary:

1. **Push the syringe piston in fully**. 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 piston head **pull the piston 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**

**NOTE:** Transferring the sample to a standard "tissue culture dish" (3 cm in diameter/1 cm deep) will allow better visual control when filling the capillary as an intermediate step (see Figure 2).

3. Holding the capillary in a vertical position (Figure 3), **visually confirm that the sample has completely filled** the thin section (without a meniscus) and the cuvette section and appears in the Luer adaptor. **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.
4. **Quickly (to avoid wicking) and thoroughly 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 prevent the SQA-VISION optical chamber from becoming clogged. 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 3 Inspect for bubbles



Figure 4 Wipe the tip

5. Slowly and carefully **push-in the separating valve** until it is level with the plastic (Figure 5). The capillary is now ready to be inserted into the SQA-VISION measurement compartment for testing.

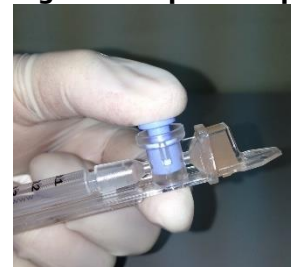


Figure 5 Push-in the piston

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





## APPENDIX 2: Filling the SQA-VISION Capillary with a Low Volume Sample

### Sample size, collection container 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 (Figure 1).
2. The semen sample must be **completely liquefied and well mixed prior to aspiration**. Gently rotate the container to fully mix the liquefied specimen. ***WARNING: Do not shake nor use a pipette to aspirate and dispense specimen in order to mix, otherwise air bubbles will form.***
3. **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, thus ensuring that no air bubbles will be aspirated into the capillary.
4. **It is recommended that the sample be withdrawn from a standard "tissue culture dish"** (3 cm in diameter/1 cm deep) to allow for better visual control when filling the capillary.



Figure 2

x

### 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). The exact quantity aspirated can be determined by the gradations on the 1 ml syringe. Aspirate the sample until it just appears in the cuvette part while keeping the tip of the capillary well below the sample level and well below the level of any bubbles covering the liquid. Withdraw the capillary tip from the semen sample and visually inspect the capillary to ensure that the sample has completely filled the thin section (no meniscus).
3. Quickly (to avoid wicking) and **thoroughly 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 prevent the SQA-VISION optical chamber from becoming clogged. 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.
4. The separating valve must now be removed. Detach the entire syringe from the hub (Figure 2) and 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-VISION.
5. **PLEASE NOTE: Test Low Volume samples as soon as the sample is aspirated into the capillary.**



Figure 1



Figure 3



Figure 4



## APPENDIX 3: Preparing Slides for the SQA-Vision Visualization System

The SQA-VISION Visualization System is used to view and count sperm cells, capture static and dynamic images, scan for debris and round cells, and perform manual morphology and vitality assessment.

The visualization system:

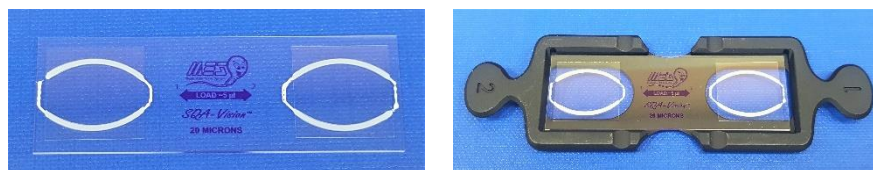
- Accommodates a QwikCheck Fixed Coverslip slide for the SQA-Vision or a standard slide (both 20-micron depth) - refer to Appendix 10 for the slide types used for variety of assessments.
- Provides the visualization settings and video control adjustment in the SQA-VISION PC software (refer to this user guide for detailed instructions).
- Allows smooth magnification transition from x1188 to x1725 (use Zoom In/Out).

### User Instructions:

- The Field of View Stage is designed for SQA-VISION fixed coverslip and standard laboratory slides that are 76 mm long and 25.6 mm wide.
- QwikCheck Fixed Coverslip slide are made for the SQA-Vision and are available from the distributor. The slides are dual chamber, 20µm depth with wells placed for optimal visualization in the SQA-Vision.

### QwikCheck Fixed Coverslip Slide for SQA-V VISION Preparation

- Mix the semen sample thoroughly and pipette ~5 µl of semen.
- Load sample in the fixed coverslip where instructed by the arrows (there are two wells on each slide for duplicate counts). After filling, 'drop' the slide into the slide-holder as shown below:



- Insert the slide-holder into the VISION visualization compartment as show below. Reverse the slide insertion direction to view the second well (the slide and slide-holder is marked with a #1 and #2).
- Optimize the video image using the focus knob. Change fields by turning the Field of View knob.

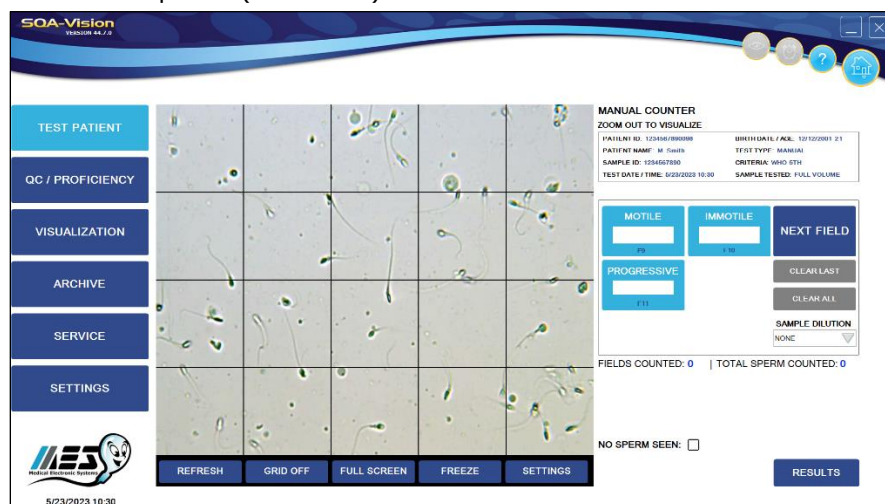


### Standard Slide Preparation

- Load 10 µl of semen onto the distal end of a standard slide approximately 12 mm from the edge of the slide and cover with a 22 mm x 22 mm cover-slip (to insure 20-micron depth).
- The droplet of semen should be evenly spread across the entire surface area of the cover-slip automatically, without any additional pressure applied to the cover-slip.
- Place the prepared standard slide into the SQA-VISION slide holder and insert into the visualization compartment of the VISION as shown above.
- Optimize the video image using the focus knob. Change fields by turning the Field of View knob.

## APPENDIX 4: Using the SQA-VISION Visualization System

1. Follow the instructions in the WHO 5th ed. laboratory manual for the examination and processing of human semen. Thoroughly mix the sample before step #2.
2. Load a fixed coverslip with ~5 µl of semen sample (recommended). Prepare a new slide if air bubbles or liquid spillage occurs.
3. Insert the slide into the Visualization Field of View Stage (Refer to the SQA-VISION User Guide APPENDIX 3: Using Slides in the Visualization System for details).
4. Press the ZOOM-OUT button on the SQA-VISION keypad all the way.
5. Adjust the **FOCUS** knob to bring the image to the best focusing: Turn clockwise all the way. Then turn counterclockwise until a clear image appears on the screen.
6. Click **GRID ON** button at the bottom of the screen. The screen of the SQA-VISION is divided into a grid containing 20-distinct squares (see below):



1. To count a minimum of 200 sperm cells (according to WHO manual recommendations), turn the knob of the Field of View Stage and a new field of view will be displayed in the grid.
2. When **WHO counter** is marked in **Test Patient Settings**: Assess the number of **Total**, **Immotile**, **Slowly-Progressive** and **Non-Progressively Motile** spermatozoa counted in the entire field of view.
3. When **WHO counter** is NOT marked in **Test Patient Settings**: Enter the number of **Motile**, **Immotile**, **Slowly-Progressive**, and **Non-Progressive** cells in the sample. **spermatozoa** counted in the entire field of view.
4. Click **NEXT FIELD** button at the right-hand side of the screen and count the sperm in the next field.
5. Click **RESULTS** button upon completion of counting and the software will calculate the final semen parameters.
6. Refer to the **Test Patient** and **Visualization** sections of this manual for Morphology, Vitality assessment, capturing images and scanning debris.

## APPENDIX 5: Cleaning the Capillary Compartment

### When to clean: **DAILY (step 1)**, **WEEKLY (step 2)**

- 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)

**PLEASE NOTE: Cleaning and drying Paddles are for ONE TIME use only!**

### CLEANING: **STEP 1 (DAILY)**

- Insert the long brush (bristle side down) into the upper portion of the lower chamber of the SQA in the same manner as a testing capillary (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)
- **Monitor the system's "REF. 2" parameter. It should be between 2800 and 3200 mV if possible.**

### CLEANING: **STEP 2 (WEEKLY)**

1. Use a **Fibrous material** cleaning paddle (fig 4)
  - Moisten with only **ONE** drop of cleaning fluid.
  - Shake off excess fluid.
  - Insert into the measurement compartment fibrous material facing **DOWN ONLY** (fig 5)
  - Move the cleaning capillary in and out three times.
2. Use a sponge-tipped drying paddle into the testing chamber and leave it for 10 – 15 seconds (fig 6).

**NOTE: Do not move this drying paddle in and out**



Figure 1 Long cleaning brush



Figure 2 Cleaning lower chamber



Figure 3 "Dusting off"



Figure 4 FIBROUS cleaning paddle



Figure 5 Insert **Fibrous material face DOWN**



Figure 6 Insertion of **drying paddle**

**APPENDIX 6: Reference Values of Semen Parameters**

<b>SEMEN PARAMETER</b>	<b>REFERENCE VALUE*</b>	<b>SOURCE</b>
Concentration	≥16 M/ml	WHO 6 <sup>th</sup> manual
Motility	≥42 %	WHO 6 <sup>th</sup> manual
Progressive (Rapidly + Slowly)	≥30 %	WHO 6 <sup>th</sup> manual
Non-progressive	≤1%	WHO 6 <sup>th</sup> manual
Immotile	≤20%	WHO 6 <sup>th</sup> manual
Vitality	≥54 %	WHO 6 <sup>th</sup> manual
Normal Forms (morphology)	≥4%	WHO 6 <sup>th</sup> manual
Motile Sperm Concentration (MSC)	≥6 M/ml	MES
Progressively Motile Sperm Concentration (PMSC)	≥5 M/ml	MES
Functional Sperm Concentration (FSC)	-	-
Velocity (Curvilinear velocity – VCL)	≥5 mic./sec.	MES
Sperm Motility Index (SMI)	≥80	MES
Sperm #	≥39 M	WHO 6 <sup>th</sup> manual
Motile Sperm	≥16 M	MES
Progressively Motile Sperm	≥12 M	MES
Functional Sperm	-	-
Morphologically Normal Sperm	≥2 M	MES

\* The reference values established above are based on WHO 6th edition manual data or MES (for proprietary semen parameters).

## APPENDIX 7: Measuring WBC's in Semen

### SQA-VISION Visualization System

Prepare a fixed coverslip slide with 3µl or a standard slide with 10 µl of semen and refer to the "Using the Visualization System" section of this guide. At ZOOM OUT assess up to 10 fields by turning the Field of View knob. Count leukocytes (WBC) in all fields of view. Divide total # of leukocytes by # fields of view counted to obtain the WBC concentration in M/ml. If WBC  $\geq$  1M/ml are found, select WBC  $\geq$  1M/ml in the PATIENT/SAMPLE DATA entry screen. Alternatively select WBC < 1M/ml.

### QwikCheck™ Test Strips for Semen (recommended) Please refer to the product insert for the latest updated information.

Place one drop of semen on the test patch for WBC's (leukocytes) and follow the instructions on the TEST STRIP label/insert. Compare the patch to the color scale for WBC on the container to determine if the WBC is < 1m/ml or  $\geq$  1m/ml. *NOTE:* Test strips are also supported for pH testing of semen.

#### Clinical Trial

The WBC patch of the test strip changes color due to a chemical reaction caused by the presence of esterase in granulocytes. Esterase cleaves to the indoxyl ester, liberating the indoxyl which then reacts with diazonium salt to produce a violet dye. This chemical reaction is not affected by bacteria, trichomonads or erythrocytes present in the specimen.

QwikCheck™ test strips were evaluated by Medical Electronic Systems (MES) for use as a qualitative indicator (WBC's  $\geq$  1M/ml) of WBC's in human semen. To test this application, WBC's were isolated from blood and re-suspended in seminal plasma. Varying concentrations of WBC's in seminal plasma were tested using the test strips. Test results were analyzed visually and by spectrophotometer readings.

#### Results and Conclusion

When the WBC concentration in semen is  $\geq$  1 Million/ml the Leukocytes patch of the QwikCheck™ test strips reacts, and reaches or exceeds the darkest color on the color chart. This is considered abnormal according to WHO 2010, 5<sup>th</sup> edition, Pg. 107). Any color LIGHTER than the Leukocytes  $\geq$  1M patch on the label is considered Leukocytes < 1 Million/ml which is considered normal.

#### References

WHO laboratory manual for the examination and processing of human semen, 5th edition, 2010, Pg. 16 (pH) and 107 (Leukocytes), WHO Press.

## APPENDIX 8: Concentration Standard: Counting Chambers

A number of commercially available counting chambers are used in laboratories for manually counting sperm cells. These chambers vary by depth and one type requires a diluted sample. It has been clinically established that counts vary by approximately 30% depending on the chamber used.

The SQA-VISION permits the user to select the type of chamber the laboratory has implemented as a standard for manual semen analysis. Once the concentration standard (CONC. STANDARD) has been selected the SQA-VISION will automatically run semen samples based on that standard.

### SQA-VISION Set-Up:

- Select SETTINGS > TEST PATIENT.
- Select a **CONC. (concentration) STANDARD** based on aligning the system with the options shown in the table below:
  - **CONC. STANDARD 1**
  - **CONC. STANDARD 2**
- Commercially available counting chambers are divided into two unique groups:
- **Standard 1:** 10-20-micron depth and do not require sample dilution.
- **Standard 2:** 100-micron depth (haemocytometers) that require sample dilution.

The table below classifies some commercially available chambers:

CHAMBER STANDARD 1	CHAMBER STANDARD 2
Makler	Beurker-Tuek
Micro-Cell	Buerker
Fixed Cover slip disposable chambers	Fuchs-Rosenthal
	Fuchs-Rosenthal (modified)
	Improved Neubauer
	Neubauer
	Malassez
	Thoma
	Thoma Modified



## APPENDIX 9: Globozoospermic Sample Assessment

### ASSESSING GLOBOZOOSPERMIC SAMPLES ON THE SQA-VISION

**BACKGROUND:** The absence of an acrosome in the head of the sperm cell (globozoospermia) cannot be assessed automatically by the morphology test of the SQA-VISION. This technical bulletin describes the incidence of this disorder and demonstrates how to identify these samples prior to running the automated SQA-VISION semen analysis.

**WHAT IS THE INCIDENCE OF GLOBOZOOSPERMIA?** An article in Human Reproduction (January/February 2007) 13 (1): 63-75 **GLOBOZOOSPERMIA REVISITED** best describes this condition and incidence:

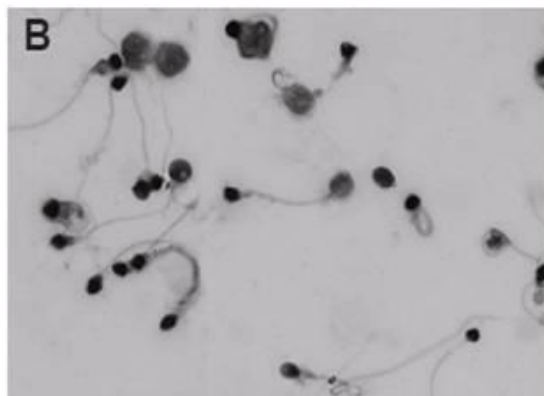
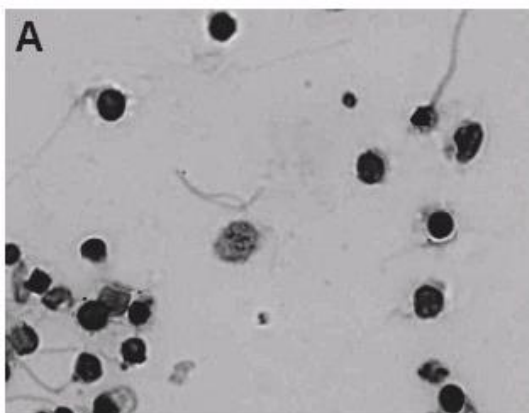
#### Abstract

Globozoospermia is a rare (incidence <0.1%) but severe disorder in male infertility. Total globozoospermia is diagnosed by the presence of 100% round-headed spermatozoa lacking an acrosome. It is still unclear whether patients whose ejaculate contains both normal and globozoospermic cells (partial globozoospermia) suffer from a variation of the same syndrome. Apart from the fact that affected males suffer from reduced fertility or even infertility, no other physical characteristics can be associated with the syndrome. ICSI is a treatment option for these patients, although low fertilization rates after ICSI show a reduced ability to activate the oocyte. In globozoospermic cells, the use of acrosome markers has demonstrated an absent or severely malformed acrosome.... The pathogenesis of globozoospermia most probably originates in spermiogenesis, more specifically in acrosome formation and sperm head elongation...More research is needed to elucidate the pathogenesis of human globozoospermia to further understand globozoospermia as well as (abnormalities in) spermiogenesis and spermatogenesis in general. Globozoospermia is normally diagnosed by the detection of round-headed sperm heads during routine light microscopic examination of a semen sample.

For the full article please go to: <http://humupd.oxfordjournals.org/content/13/1/63.full>

#### **SCREENING FOR GLOBOZOOSPERMIA when using the SQA-VISION:**

"Globozoospermia is normally diagnosed by the detection of round-headed sperm heads during routine light microscopic examination of a semen sample." Before running samples, prepare a standard slide and view it in the visualization system to screen for globozoospermia. Some examples of globozoospermia are demonstrated below.



## APPENDIX 10: SQA-Vision Visualization Counters

### SQA-Vision Visualization Counters: Features and Use Table

Use the table below to guide you through how to use the various Vision Visualization screens for the most accurate counting results.

Visualization Screen	ZOOM SETTING*		Type of Slide (Standard/Pre-Stained/Fixed Coverslip)	Use
	Zoom In	Zoom Out		
<b>Debris Scanner</b>	√	√	MES Fixed Coverslip Slides or 1" x 3" slide + 22 x 22 mm coverslip	Assess % Debris/Round Cell presence in the sample (Low, Moderate, Many, Gross).
<b>Morphology</b>	√	√	QwikCheck Pre-Stained Slides + 22 x 22 mm coverslip	Assess Sperm Morphology: Normal vs. Abnormal or Full Differential based on user defined parameters.
<b>Vitality</b>	√	√	1" x 3" slide + 22 x 22 mm coverslip	Assess Live vs. Dead sperm. Reported as % Live (also known as Viability).
<b>DNA Fragmentation</b>	√	√	1" x 3" slide + 22 x 22 mm coverslip	Assess sperm Halo for genetic factors. Reported as % Halo vs. % No Halo or Halo Grading.
<b>Low Quality Counter</b>		√	MES Fixed Coverslip Slides	Assess samples below the dynamic range of the SQA system (Concentration < 2, or Motile Sperm Concentration < 0.2).
<b>Manual Counter</b>		√	MES Fixed Coverslip Slides	For manual counting of sperm parameters: Concentration, Motility, and Progressive Motility.
<b>Post VAS Counter</b>		√	MES Fixed Coverslip Slides	For manual counting of Post Vas samples. Reporting of motile, immotile and total sperm cells in limited quantities.
<b>QC Mark Counter</b>		√	MES Fixed Coverslip Slides	For manually counting the number of Beads per field for QC of visualization screen and comparison to manual results.

#### Assessment Notes:

- Low-Quality Counter: Count at least ten fields of view.
- Manual Counter / QC Counter: Count at least ten fields of view but not less than 200 SPERM if available.
- Post Vas Counter: Count 50 fields of view (lock to lock on the stage adjustment knob).

## APPENDIX 11: Post Vasectomy Analysis

### Post Vasectomy Analysis on the SQA-V Gold and SQA-Vision: AUA Guidelines

**Overview:** The SQA-Vision Post Vas analysis methodology and standards are based on the American Urological Association (AUA) recommendations. Please note that AUA guidelines may be updated from time to time.

#### American Urological Association (AUA) Guideline for Post Vas semen analysis (PVSA):

- To evaluate sperm motility, a fresh, uncentrifuged semen sample should be examined within two hours after ejaculation.
- Patients may stop using other methods of contraception when examination of one well-mixed, uncentrifuged, fresh post-vasectomy semen specimen shows azoospermia or only rare non-motile sperm (RNMS or  $\leq 100,000$  non-motile sperm/mL).
- Eight to sixteen weeks after vasectomy is the appropriate time range for the first PVSA. The choice of time to do the first PVSA should be left to the judgement of the surgeon.
- Vasectomy should be considered a failure if any motile sperm are seen on PVSA at six months after vasectomy, in which case repeat vasectomy should be considered.
- If  $> 100,000$  non-motile sperm/mL persist beyond six months after vasectomy, then trends of serial PVSAs and clinical judgment should be used to decide whether the vasectomy is a failure and whether repeat vasectomy should be considered.

#### SQA-Vision Post Vas Analysis:

"Sperm per Scan" is not used as a reporting method on the SQA-Vision. The SQA-Vision reports a quantitative number of Motile and Immotile sperm in both *M/mL* and *Sperm per ejaculate Volume* with an infinitely low reportable range depending on the number of fields of view analyzed.

The SQA-Vision performs an automated scan to assess *Motile Sperm*. In addition, the manufacturer's recommendation is to perform a manual count using the SQA-Vision Post Vas Counter at 'Zoom Out'. A minimum of 50 fields of view should be assessed "lock to lock" using an MES Fixed Coverslip Slide and utilizing at least 1 well of the MES Fixed Coverslip Slide or standard wet preparation. Each sperm seen at "Zoom Out" on the SQA-Vision's field of view represents 1 M/mL, resulting in a sensitivity of 20,000 sperm/ml (0.02 M/mL) if only one slide well is scanned. The system supports the assessment of multiple slide wells resulting in even higher sensitivity.

Motile, Immotile and Total Sperm parameters are reported in M/mL, Sperm per Ejaculate Volume, or interpreted as "Sperm Present" and "Motile Sperm Present" based on the laboratories' standard operating procedure. The SQA-Vision follows current AUA guidelines and recommendations with much greater sensitivity than the SQA-V Gold.

**NOTE:** When reporting a Qualitative Result of "Sperm Seen or No Sperm Seen", only the Manual Counter of the SQA-Vision should be utilized on samples delivered within 24 hours and the results should include a note that Motility was not assessed.

## APPENDIX 12: Assessing Debris/Round Cells In Semen Samples

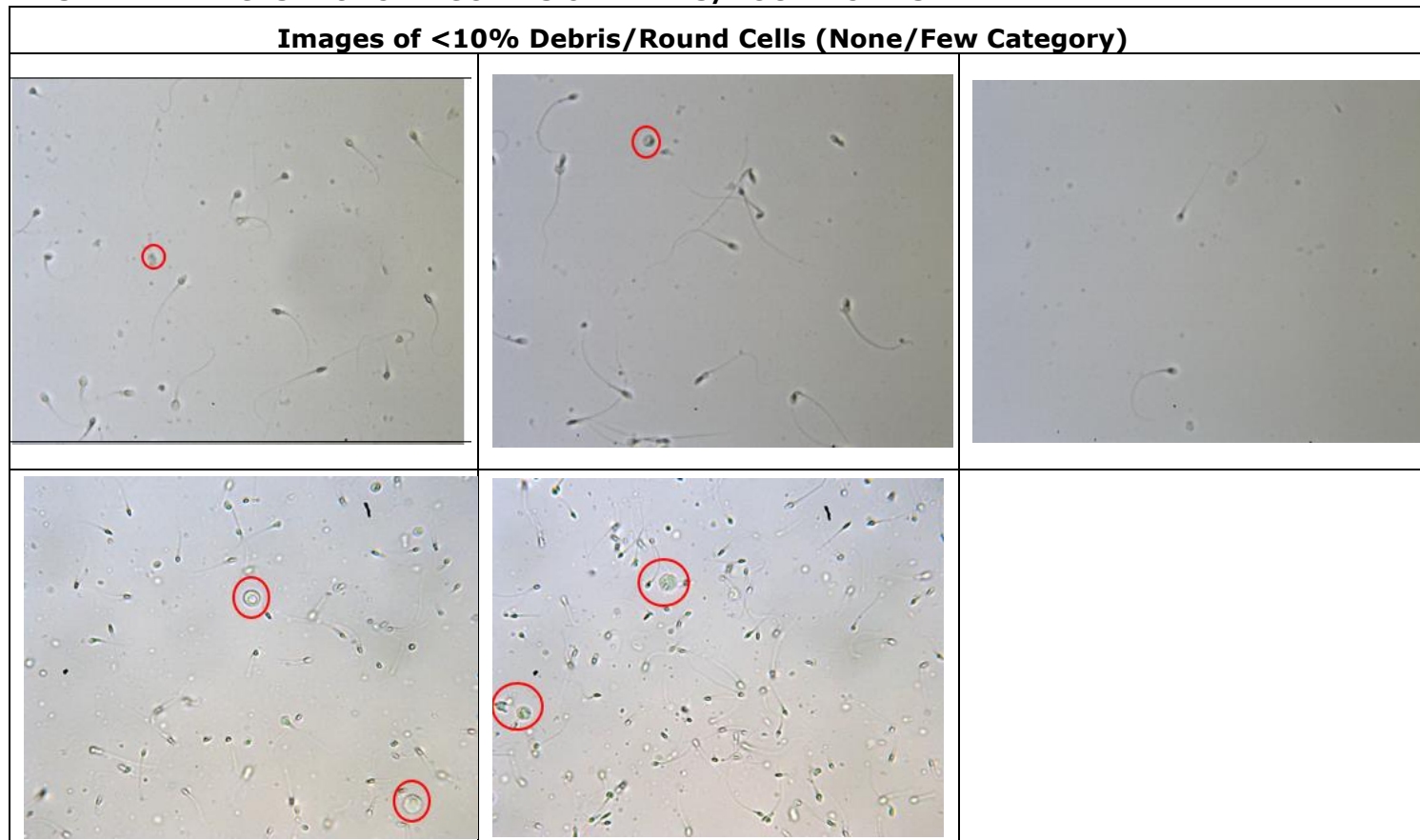
**OVERVIEW:** Grading the degree of debris/round cells in semen samples run on the SQA is important because these components (that are the size of sperm heads or larger) can influence the accuracy of reporting automated concentration. This technical bulletin provides guidance for assessing/grading the % of sample debris/round cells by category.

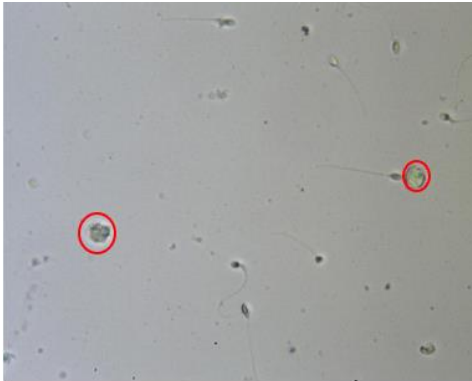
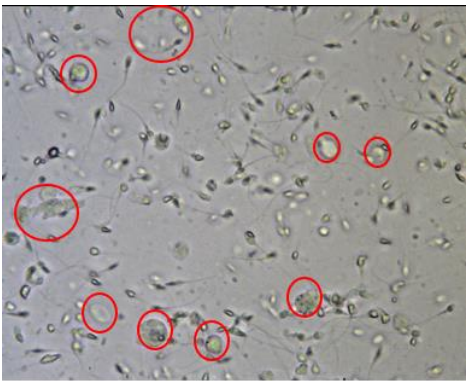
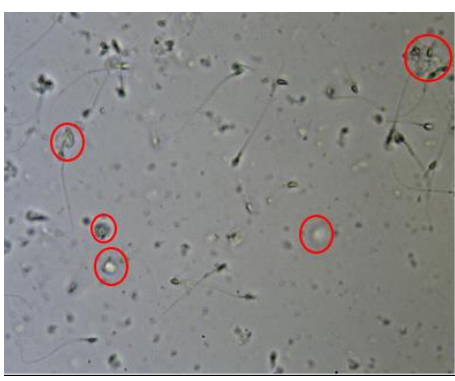

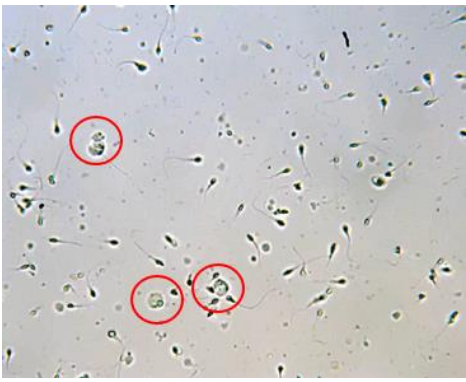
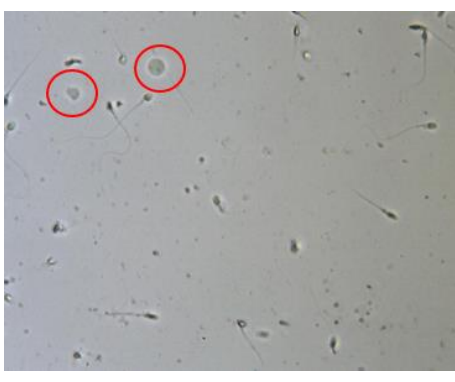
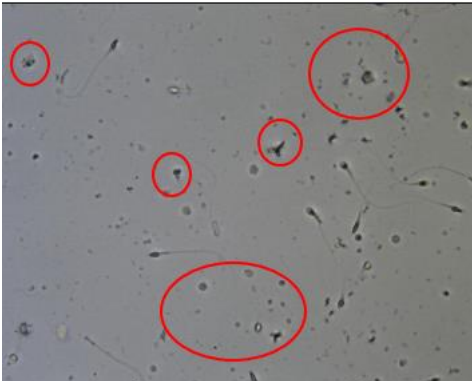

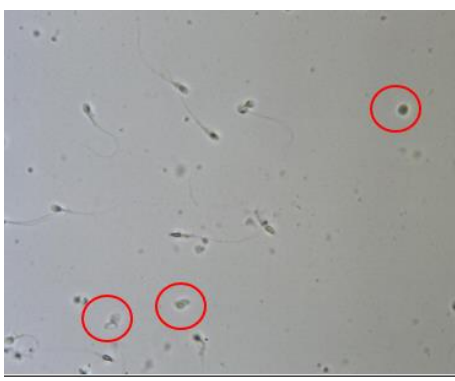
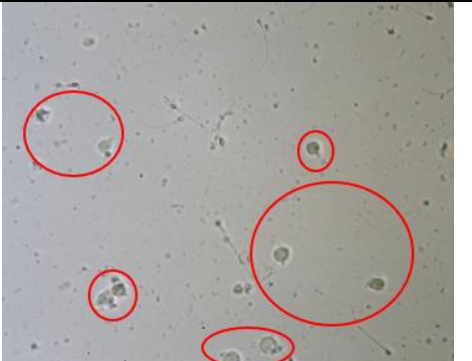


### ASSESSMENT TECHNIQUE:

1. Debris/round cells are graded as a percentage in proportion to the number of sperm cells
2. Only particles without tails that are **the size of sperm heads or larger** should be counted as debris/round cells
3. Several fields may be required to estimate the % range of debris/round cells in the sample
4. The absolute number of debris/round cells is only important for determining the **percentage range of these components vs. sperm** and to properly select how to classify them by **category** (refer to table below)

#	% Range of Debris/Round Cells vs Sperm	Example	Debris Category in SQA
1	Less than 10%	# Sperm 50 and # Debris 1 = 2%	None/Few < 10%
2	10 to 30%	# Sperm 50 and # Debris 10 = 20%	Moderate 10%-30%
3	31 to 99%	# Sperm 50 and # Debris 30 = 60%	Many 31%-99%
4	≥ 100%	# Sperm 50 and # Debris 60 = 120%	Gross ≥ 100%

### SAMPLE IMAGES with CATEGORIES of DEBRIS/ROUND CELLS



Images of 10-30% Debris/Round Cells (Moderate Category)		
		
		
Images of 31-99% Debris/Round Cells (Many)		
		
Images of >= 100% Debris/Round Cells (Gross)		
		



## APPENDIX 13: Product Performance Data

### Abbreviations:

TSC: Sperm Concentration (Count)  
 PMSC: Progressive Motile Sperm Concentration  
 OD: Optical Density

MSC: Motile Sperm Concentration  
 Morph Norm Forms: Morphologically Normal Forms  
 MV: Millivolt

### Performance Data Summary

The performance the SQA-VISION is summarized in the text, tables and graphs below. All values concerning sperm concentration measurements are expressed as  $\times 10^6$  sperm cells per milliliter (M/ml). Motility and Morphology values are expressed as a percent (%). All testing was performed using human patient and donor semen samples using the SQA-V for the comparison equivalent to the SQA-Vision system.

### Calibration:

Each SQA-VISION is biologically calibrated against two reference systems at Medical Electronic System's laboratory.

### Reportable Range:

Reportable range of the SQA-Vision automated results						
Sample Type	Sperm Conc. M/ml	Motility %	Morph %	MSC M/ml	PMSC M/ml	Motile / Immotile / Total Sperm M/ml
Fresh	<2 - 400	0 - 100	2 - 30	<0.2 - 400	0 - 400	-
Washed	<2 - 200+	0 - 100	2 - 30	<0.2 - 200+	0 - 200+	-
Swim-up, Density Gradient, Frozen	-	-	-	<0.2 - 200+	0 - 200+	-
Post-Vasectomy	-	-	-	-	-	0 - 400

## Precision and accuracy established in clinical trials using human semen samples

### Clinical claims:

#### Specificity

- Concentration: 85%
- Motility: 80%
- Progressive Motility: 80%
- Morph. Norm Forms (WHO 3<sup>rd</sup>): 65%
- Morph. Norm Forms (WHO 4<sup>th</sup>): 60%
- Morph. Norm Forms (WHO 5<sup>th</sup>): 90%
- Postvasectomy: 90% of motile cells detected

#### Sensitivity

- Concentration: 90%
- Motility: 85%
- Progressive Motility: 85%
- Vitality: 90%
- Morph. Norm Forms (WHO 3<sup>rd</sup>): 85%
- Morph. Norm Forms (WHO 4<sup>th</sup>): 65%
- Morph. Norm Forms (WHO 5<sup>th</sup>): 80%

#### Correlation to Manual Method

- Concentration: 0.9
- Motility: 0.8
- Progressive Motility: 0.8
- Vitality: 0.9
- Morph. Norm Forms (WHO 3<sup>rd</sup>): 0.65
- Morph. Norm Forms (WHO 4<sup>th</sup>): 0.45
- SQA-Vision Visualization: 0.9

#### Linearity

Linear Sperm Concentration throughout the SQA-V reportable range of 0 M/ml to 400 M/ml

- Squared regression coefficient of Dilution Curve  $R^2 \geq 0.9$ .
- Averaged coefficient of variation CV of measured vs. expected sperm concentration  $\leq 20\%$ .

Table 1: Sensitivity/Specificity		
SQA-V vs. Microscope	Sensitivity	Specificity
<b>Trial #1: WHO 3rd</b>		
Concentration	100%	95%
Motility	97%	85%
Morph Norm Forms	94%	75%
<b>Trial #2: WHO 4th</b>		
Concentration	94%	90%
Motility	87%	90%
Morph Norm Forms	69%	70%
<b>Trial #3: High Sensitivity/Postvasectomy</b>		
Motile Sperm Cells	95%	95%
Immotile Sperm Cells	99%	100%
<b>Trial #4: WHO 5th (ART laboratory, University Hospital of Nantes, France and MES)</b>		
Concentration	98%	100%
Motility	92%	91%
Progressive Motility	93%	94%
Morph Norm Forms	82%	94%

**Table #2: Correlation to Manual Method**

Parameters	Correlation Coefficients		
	Trial #1: (WHO 3 <sup>rd</sup> )	Trial #2: (WHO 4 <sup>th</sup> )	Trial #4: (WHO 5 <sup>th</sup> )
Sperm Concentration	0.93	0.94	0.97
Motility	0.86	0.87	0.88
Morph. Normal Forms	0.66	0.49*	NA*

Note: Claims are less than actual correlations noted (see tables 1 and 2).

**Background:** The automated concentration, motility and morphology readings were compared to standard microscopic results based on WHO 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> standards and MES protocols. Four independent sites clinical trials were conducted. A total of >750 human semen samples were analyzed as described below with approximately 350 samples of low quality and tested in the Postvasectomy mode.

#Samples	Fresh	Washed	Frozen	High Sensitivity
>750	>300	42	30	>350

#### Analytical Specificity:

- To achieve analytical specificity a specific wave length of light which is maximally absorbed by sperm cells and minimally absorbed by other cells and seminal plasma is used.
- Low noise and high electronic resolution hardware components and compensation circuits ensure that analytical specificity is optimized.

#### Limitations of clinical specificity:

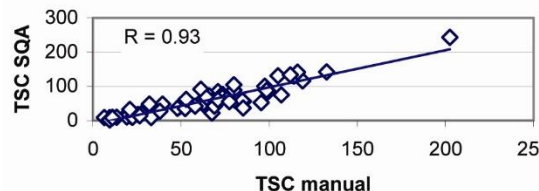
- Highly viscous samples can only be read accurately with liquefaction (QwikCheck™ Liquefaction Kit used).
- Sample size must be  $\geq 0.5$ ml for fully automated tests ( $\geq 0.25$ ml for dilution mode).
- % Normal Morphology is a parameter derived from the electronic signals of the system by a proprietary algorithm. This is not a direct assessment of the stained smears.
- Results obtained from the use of the SQA-Vision visualization system may be affected by the subjectivity of the operator.
- Dynamic range limitation as stated above.

#### Method comparison:

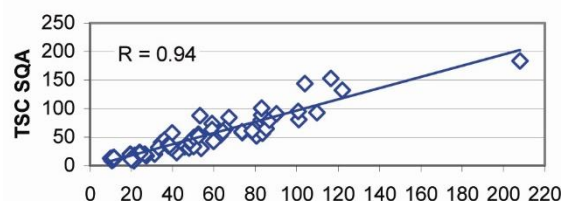
- SQA-V and SQA-Vision were compared to the microscope based on WHO 3<sup>rd</sup> (Trial #1), 4<sup>th</sup> (Trial #2) and WHO 5<sup>th</sup> (Trial #4) guidelines.
- Sensitivity and Specificity** were calculated using ROC curves with the cutoffs based on the reference values of WHO 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> guidelines (see Table #1).
- Correlation** coefficients of the SQA-V results to the manual method are presented in the Table #2.
- Precision:** Inter-device (Tables #3) and intra-device (Table #4) variations were compared to inter- and intra-operator variability using Coefficients of Variation (CV, %). Duplicate samples were assessed by two methods. The CVs

\* Correlation is low or NA due to narrow dynamic range of this parameter per strict criteria and manual analysis subjectivity.

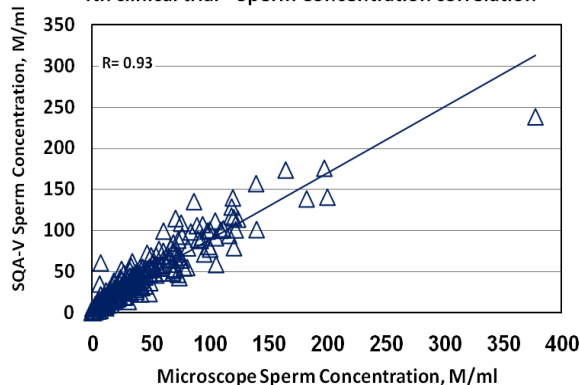
1st clinical trial - TSC correlation



2nd clinical trial- TSC correlation



4th clinical trial - Sperm Concentration correlation



characterizing precision were calculated for multiple semen parameters.

- The **POSTVASECTOMY** test (Trial #3) compared two assessment methods:
  - Microscope (standard slide: X400; 10 fields of view)
  - SQA-V visualization system (see table #5).
- Motile and Immotile sperm cells were analyzed by use of the SQA-V visualization system and microscope.
- 218 semen specimens contained motile cells and were used as the basis for the Post Vas visualization method comparison (Table #5).

**Table #3: Precision: Trial #1 and #2 (n=154)**

Parameter	Range	Method	
		SQA-V CV%	SQA-V CV%
Sperm Concentration	Entire Range	3.1	6.1
	5-40	5.2	5.9
	41-80	2.1	5.5
	>80	2.5	3.2
Motility	Entire Range	5.1	7.2
	10-50	7.6	10.3
	51-55	1.5	3.4
	>55	6.0	4.1

**Table #4: Mean Values and Precision: Trial #4 (n=246)**

Semen Parameter	Mean		CV, %		
	Op1	Op2	SQA-V	Manual	SQA-V
Sperm Concentration	41.0	40.2	41.4	11.5	3.4
Total Motility	54.7	56.9	54.9	10.7	5.0
PR Motility	37.9	39.0	36.6	13.3	7.5
NP Motility	16.8	17.9	18.4	27.3	6.8
Morphology	7.6	7.6	11.5	27.4	6.5

Note: Op1 - operator 1; Op2 - operator 2

**Table #5: Percentage Motile Cells Detected: Trial #3 Postvasectomy mode**

Method Comparison of 218 Samples with Motile Cells	# Samples Motile Sperm Detected	% Samples Motile Sperm Detected
Visualization System only	193	89%
Microscope only	161	74%

## SQA-V Linearity

### Clinical claims:

- Linear Sperm Concentration throughout the SQA-V dynamic range of 2M/ml to 400M/ml:
  - Squared regression coefficient of Dilution Curve  $R^2 \geq 0.9$ .
  - Averaged coefficient of variation CV of measured vs. expected sperm concentration  $\leq 20\%$ .

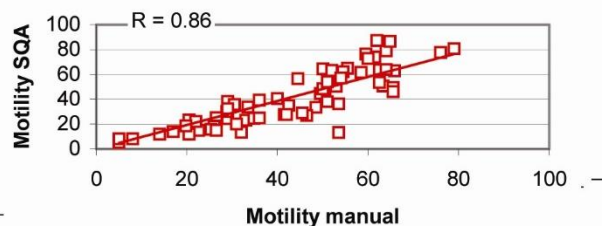
Goal: To demonstrate the ability of the SQA-V to accurately report sperm concentration along the dynamic range of the system using sequentially diluted human semen samples.

**Methodology:** 4 fresh human semen samples were pooled, divided into two aliquots and centrifuged at 600g for 15 minutes. The seminal plasma was decanted and the pellets were re-suspended in washing media: DPBS & HepesHTF. Sequential dilutions were run in 4 SQA-V systems.

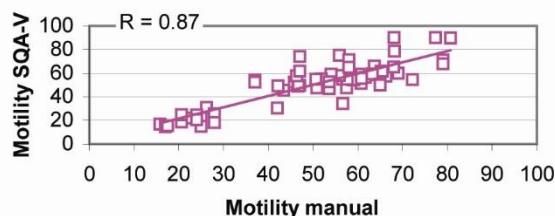
### Limitations of method:

- Dilution errors contribute to the accuracy of the linearity test results.
- Sample handling errors such as the introduction of bubbles into the testing capillary can cause inaccurate readings.

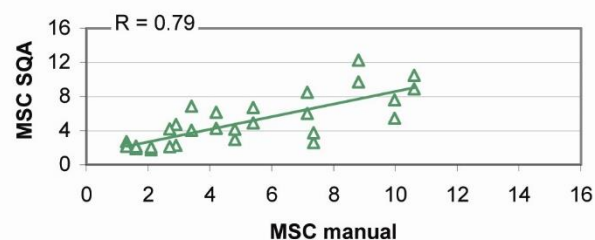
### 1st clinical trial- Motility correlation



### 2nd clinical trial - Motility correlation



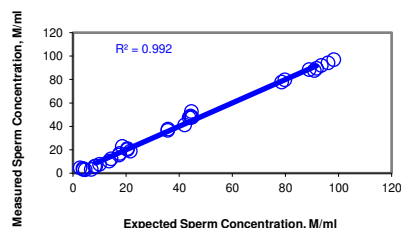
### 2nd clinical trial - MSC correlation



### Limitations of method:

Samples were assessed by different operators using a microscope and the SQA-V. Inter-operator subjectivity may have affected the results of the study.

**SQA-V DILUTION CURVE USING SEMEN DILUTED WITH DPBS & HEPES SOLUTION**



### Results:

- Squared regression coefficient  $R^2$  of Dilution Curve (trend line) was found to be 0.992 (note: graph displaying results of four SQA-V's and DPBS and Hepes dilution media).
- Averaged coefficient of variation CV of measured vs. expected sperm concentration was 10%.