

SQA-Vt

User Guide

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Section 1: Overview

The SQA-Vt is a high performance analytical medical device that combines state-of-the-art technology in electro-optics, computer algorithms and video microscopy. The system can be used to conduct automated or manual testing. The SQA-Vt performs a rapid and reliable automated analysis of neat or diluted turkey semen for: Dosing, Sorting or QC purposes. The video visualization system allows the user the flexibility to view specimens from X300 to X500.

Dosing:

The dosing mode analyzes pooled semen samples. The desired dosing parameters (#Total Cells / #Motile Cells per dose; dose volume) are set by the operator and, after analyzing the sample, the SQA-Vt will automatically display test results and calculate how to optimally allocate doses from pooled semen.

QC:

The QC mode analyzes the quality of Turkey semen prior to insemination after extenders or diluents have been added to the sample.

Sorting:

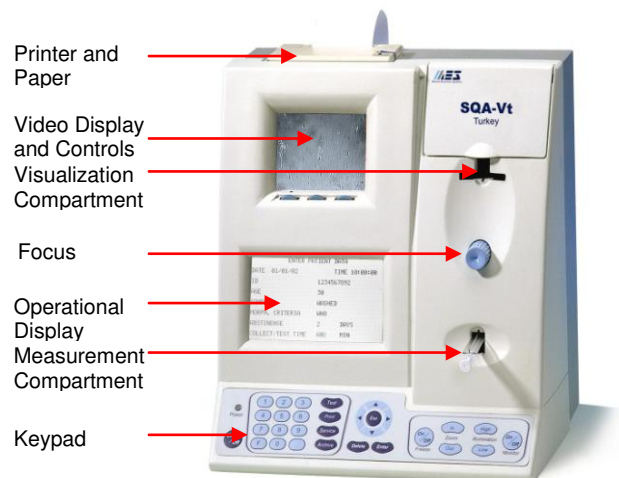
The sorting mode analyzes the semen quality of a single tom in a given flock. A semen analysis report lists the results by Tom# and Flock#.

Test results are archived in the SQA-Vt and then imported into T-Sperm™ software (on a PC) for viewing and analysis.

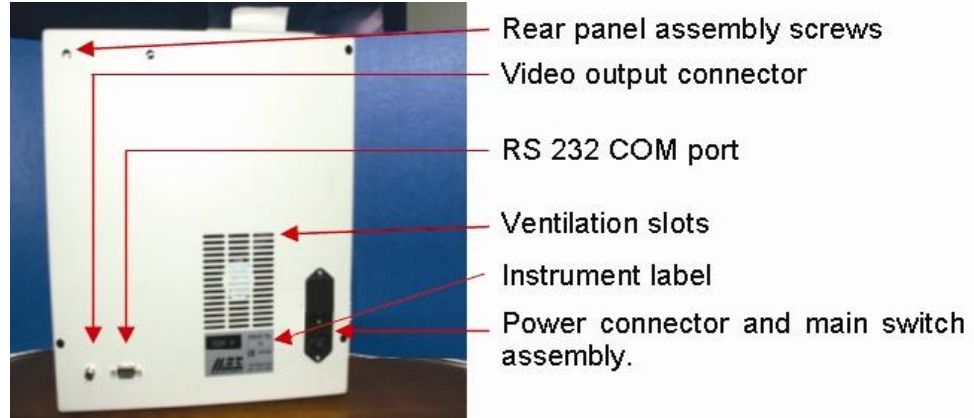
Section 2: System Overview

The Front and Side Panel

NOTE: The focus knob should not be forced to turn beyond the initial stopping point. Turn the knob gently and when resistance is felt it is at the maximum (or minimum) resolution. Forcing this knob beyond the stopping point will cause extensive damage to the SQA-Vt.



The Rear Panel

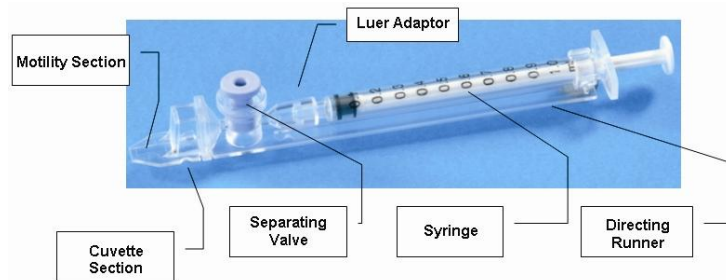


Keypad and Navigation

- Use the ARROW keys to move through the screens.
- Press ENTER to select menu options and to move to the next screen.
- Using ESC will return the user to a previous screen.



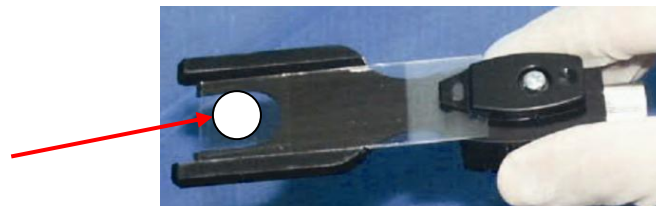
SQA-Vt Testing Capillary



- Plastic, multi-use (animal use only), disposable.
- Can be used in both measurement chambers of the SQA-Vt.
- Refer to the appendix section of this guide for instructions on how to use the capillary and how to clean it.

Slide Adaptor

NOTE: Place the sample approximately 12mm from the end of the slide for proper use (see arrow).



- For use with a standard laboratory slide 76 x 25.6 mm and 22 x 22 mm cover-slip.

Section 3: Operating the SQA-Vt

1. From the rear panel, turn the SQA-Vt power switch on.
2. The Power LED on the front panel will illuminate. Press the **On/Off** key on the keypad.
3. The SQA-Vt will now automatically perform system stabilization, auto-calibration and self-testing.
4. The **MAIN MENU** will be displayed when the system is ready for use. Four options are available from the **MAIN MENU**:

- **NEW TEST**
- **ARCHIVE**
- **SET-UP**
- **SERVICE**

NOTE: Testing cannot proceed without first loading tests from the I-Button. Refer to section 7 SERVICE > ADD TESTS TO COUNTER for instructions.

Section 4: New Test

Three different testing modes can be run from the **NEW TEST** option:

- **DOSING – DOSE PREPARATION**
- **QC – DILUTED SAMPLES**
- **SORTING – INDIVIDUAL TOMS**

Select the desired testing mode and follow the instructions below

Operating the Dosing Mode:

Dosing Set-Up:

After selecting the **DOSING – DOSE PREPARATION** mode the user is required to specify how the dose should be calculated by selecting both:

1. **Cells/dose** and then specify either:
 - Total # Sperm per Dose (total Cells) OR
 - # Motile Sperm per Dose (motile cells only)
2. **Volume/dose (µl)**

Press **ENTER** to begin the testing process. The SQA-Vt will automatically save the last set-up parameters that were specified by the user.

How to run a test:

3. Select **NEW TEST** to run a dosing test in the SQA-Vt.
4. When the **ENTER SAMPLE DATA** screen is displayed, enter the **SAMPLE NUMBER**, **VOLUME** and **Coll. #** (collector number) and **SAMPLE TYPE**:
 - **NEAT:** Undiluted semen or semen diluted up to 20% with semen extenders
 - **DILUTED:** Semen diluted with >20% and <70% extender
5. Press **ENTER**
6. **SAMPLE PREPARATION** instructions will now be displayed.
7. The SQA-Vt will now go through a process of **AUTOCALIBRATION**. During this process – **DO NOT TOUCH UNIT** will be displayed.

NOTE: For sample preparation and the proper use of the testing capillaries, refer to Appendix I and II.

NOTE: Every time the dosing mode is selected the user must specify how to calculate doses and confirm the dosing set-up.

NOTE: Semen diluted more than 70% cannot be tested.

NOTE: The print option is accessible from the 1st test results screen only.

8. When a "beep" and the message **INSERT CAPILLARY INTO CHAMBER** is displayed, insert a testing capillary into the capillary chamber of the SQA-Vt. Testing will begin automatically and take about 40 seconds.
9. A "beep" will indicate that the testing is completed and the test results will be displayed on the screen.
10. Press the **PRINT** button on the SQA-Vt key board to print out a hardcopy test report.
11. Press **ENTER** to view the **DOSING TARGET** and **DOSE PREPARATION**.
12. Press **ENTER** to view the screen for saving data to the SQA-Vt archive.
13. Select **YES/NO** by using the right/left arrows on the keyboard to save/delete the test results.
14. The unit is now ready for the next dosing test.

Operating the QC Mode:

1. Go to **MAIN MENU > SET-UP > DOSING – DOSE** and press **ENTER**.
2. Select **NEW TEST** and press **ENTER**
3. Enter the **SAMPLE#** and press **ENTER**
4. **SAMPLE PREPARATION** instructions will be displayed.
5. The SQA-Vt will now go through a process of **AUTOCALIBRATION**. During this process – **DO NOT TOUCH THE UNIT**.
6. When a "beep" and the message **INSERT CAPILLARY INTO CHAMBER** is displayed, insert a testing capillary into the capillary chamber of the SQA-Vt. Testing will begin automatically and take about 40 seconds.
7. A "beep" will indicate that the testing is completed and the test results will be displayed on the screen.
8. Press the **PRINT** button on the SQA-Vt keyboard to print out a hardcopy test report.
9. Press **ENTER** to view the screen for saving data to the SQA-Vt archive.
10. Select **YES/NO** by using the right/left arrows on the keyboard to save/delete the test results.

The unit is now ready for the next QC test.

Operating the Sorting Mode:

1. Go to **MAIN MENU>SET-UP> SORTING - TOMS** and press **ENTER**.
2. Select **NEW TEST** and press **ENTER**
3. Enter **TOM#** and **FLOCK#** and **SAMPLE TYPE**, then press **ENTER**
4. **SAMPLE PREPARATION** instructions will be displayed.
5. The SQA-Vt will now go through a process of **AUTOCALIBRATION**. During this process – **DO NOT TOUCH THE UNIT**.
6. When a "beep" and the message **INSERT CAPILLARY INTO**

NOTE:
QC Samples contain 200µl of diluted semen and 2ml of testing medium.

NOTE: A warning message will be displayed if the same TOM# is entered twice in the same FLOCK#. Duplicate TOM#'s cannot be stored in the same flock.

CHAMBER is displayed, insert a testing capillary into the capillary chamber of the SQA-Vt testing will begin automatically and take about 40 seconds.

7. A "beep" will indicate that the testing is completed and the test results will be displayed on the screen.
8. Press the **PRINT** button on the SQA-Vt key board to print out a hardcopy test report.
9. Test results will automatically be saved by the SQA-Vt.
10. The unit is now ready for the next Sorting test.

Section 5: Archive

NOTE: To import the SQA-Vt archive to the PC please follow the instructions in the T-Sperm™ User Guide.

NOTE:
 Archive Capacity:
Dosing/QC
 1300 records
Sorting
 2400 records

Select the **ARCHIVE** option to view test results saved in the SQA-Vt Dosing and QC archive*. Highlight the desired sorting function to display information from the three options available in the **ARCHIVE MENU** and press **ENTER**:

- **SAMPLE NUMBER** – Records will be sorted by sample number
- **DATE OF TEST** – Records will be displayed in date order
- **VIEW ALL RECORDS** – View all records in the SQA-Vt archive

The SQA-Vt archives for DOSING/QC and SORTING have a limited storage capacity and must be deleted, overwritten or transferred to T-Sperm when they are full. When the archives are almost full the SQA-Vt will display a warning message and the user can decide whether to delete, overwrite or transfer the archives to T-Sperm at that time.

*The **SORTING** archive can only be viewed from a PC with T-Sperm™ software.

Section 6: SET-UP

Activate the **SET-UP** screen to view/change testing modes: **NEW TEST > DOSING, QC, or SORTING**. The **SET-UP** screen will be displayed automatically each time the system is turned-on. See SECTION 4 "NEW TEST" for details on how to set-up each type of testing mode.

Section 7: SERVICE

Select the **SERVICE MENU** to access one of 5 functions:

- **USER**
- **SERVICE PERSONNEL**
- **SERVICE DATA**
- **ADD TEST TO COUNTER**
- **SETTINGS**

USER:

Select **USER** to obtain **SELF-TEST DATA** (SQA-Vt calibration parameters for QC purposes). Press the PRINT button on the SQA-Vt keypad to print out a hard copy of the SELF TEST DATA.

SERVICE PERSONNEL:

This option is for technical services personnel only and requires a password to access.

SERVICE DATA:

This screen must be activated in order to permit communication between the SQA-Vt and a PC (T-Sperm™ software). In addition, service data required by technical services for troubleshooting can be accessed from this option.

ADD TEST TO COUNTER:

The SQA-Vt requires that tests be "loaded" using an I-Button. To activate a new I-Button to load new tests, select the **ADD TEST TO COUNTER** option and press **ENTER**.

NOTE: If the I-Button is not properly inserted a message:

I-BUTTON NOT PROPERLY ACTIVATED will be displayed. Remove the button, press ESC and try again.

1. The SQA-Vt screen will instruct the user to: **HOLD NEW I-BUTTON AGAINST PORT AND PRESS ENTER**.
2. Make sure the I-Button touches the internal surface of the port. Press the button firmly in the port, moving it left and right to make sure it also touches the edges of the port.
3. The SQA-Vt screen will now display the **#TESTS ADDED** and the cumulative **#TESTS NOW REMAINING** in the SQA-Vt
4. The screen will warn the user if an **EMPTY I-BUTTON** (was) **INSERTED**

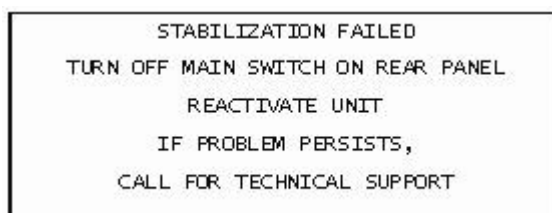
SETTINGS:

Select this option to set the system defaults for:

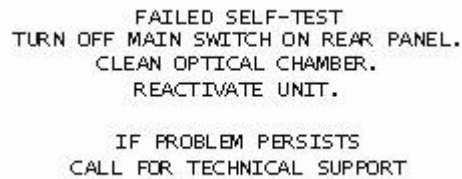
- **Date Format**
- **Temperature**
- **Date/Time Setting**

Follow the on-screen instructions:

1. **DATE:** Select the format **DD/MM/YY** or **MM/DD/YY** using the right/left arrows on the keyboard. Press **ENTER** to confirm.
2. **TEMPERATURE:** Select the temperature format **CELSIUS** or **FAHRENHEIT**. Press **ENTER** to confirm.
3. Set the actual **TIME** and **DATE** and press **ENTER** to confirm

Section 8: Troubleshooting**Stabilization Failed:**

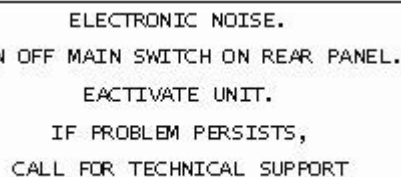
- Check that there is no testing capillary in the measurement compartment.
- Remove the SQA-Vt from sources of electronic noise (cell phones, etc.).
- Clean measurement compartment (refer to Appendix).
- Reboot the SQA-Vt without a testing capillary in the chamber:
 - Turn SQA-Vt **OFF** then **ON** at the main switch on the rear panel.
 - Press the front panel **ON/OFF** key to begin Auto-Calibration/Stabilization.
- Call technical support if failure recurs.

Self-test Failed:


FAILED SELF-TEST
TURN OFF MAIN SWITCH ON REAR PANEL.
CLEAN OPTICAL CHAMBER.
REACTIVATE UNIT.

IF PROBLEM PERSISTS
CALL FOR TECHNICAL SUPPORT

- Check that there is no testing capillary in the measurement compartment.
- Remove the SQA-Vt from sources of electronic noise (cell phones, etc.).
- Clean measurement compartment (refer to Appendix).
- Reboot the SQA-Vt without a testing capillary in the chamber:
 - Turn the system **OFF** then back **ON** at the main switch on the rear panel.
 - Press the front panel **ON/OFF** key to begin Auto-Calibration and Stabilization.
- Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the SQA-Vt internal parameters:
 - Press **SERVICE** key. The SERVICE menu will be displayed.
 - Select **USER** option. Internal parameters will be displayed.
 - Press **PRINT** to generate a record of the internal parameters/service data.

Electronic Noise:


ELECTRONIC NOISE.
TURN OFF MAIN SWITCH ON REAR PANEL.
REACTIVATE UNIT.

IF PROBLEM PERSISTS,
CALL FOR TECHNICAL SUPPORT

- Check that there is no testing capillary in the measurement compartment.
- Remove SQA-Vt from sources of electronic noise (cell phones, etc.).
- Clean measurement compartment (refer to Appendix).
- After cleaning:
 - Press **SERVICE > ESC**. MAIN MENU will be displayed.
 - Select **TEST NEW PATIENT** and re-run test.
- If this message is displayed again, reboot the device:
 - Turn the system **OFF** then back **ON** at the main switch on the rear panel.
 - Press the front panel **ON/OFF** key to begin Auto-Calibration and Stabilization.
 - From MAIN menu: Select TEST NEW PATIENT and rerun.
 - Call technical support if this message returns. Prepare for technical support by printing a copy of the system parameters:
 - Press **SERVICE** key. The SERVICE menu will be displayed.
 - Select **USER** option. Internal parameters will be displayed.
 - Press **PRINT**

Appendix I: Semen Sample Preparation

NOTE: Please contact the manufacturer via email: mes@mes-ltd.com for recommended testing medium. Test results may be impacted by using another medium.

NOTE: To insure that air is not aspirated into the pipette the collected/pooled sample should be at least 200 μ l.

NOTE:

Neat Samples:
Undiluted semen or semen diluted up to 20% with semen extenders

Diluted Samples:
Semen diluted with >20% and <70% semen extenders

EQUIPMENT REQUIRED:

- Testing Medium
- Diluent Dispenser
- 10 ml Plastic Container
- Positive Displacement Pipette
- SQA-Vt capillary

DILUENT PREPARATION:

- Extract 2.0ml of testing medium into a 10ml plastic container using the diluent dispenser.



Figure 1: Diluent Dispenser

SAMPLE PREPARATION:

1. **NEAT SEMEN SAMPLES:**
Extract exactly 100 μ l of semen using the positive displacement pipette. (Go to Step #3)
2. **DILUTED SAMPLES:**
Extract exactly 200 μ l of semen using the positive displacement pipette (Figure 2).
3. Wipe the tip of the pipette to remove any excess semen.
4. Add the semen from the pipette to the 2.0ml of diluent in the 10ml plastic container (Figure 3).
5. Close the plastic container and gently but thoroughly mix the sample for 10-20 seconds (Figure 4).
6. Visually inspect the sample to insure that it is uniform and there are no semen aggregates.
7. The sample is now ready for testing. Fill the SQA-Vt testing capillary following the instructions in the appendix section of this guide.



Figure 2: Sample Preparation



Figure 3: Add semen to the diluent

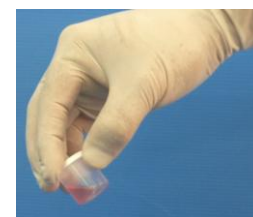
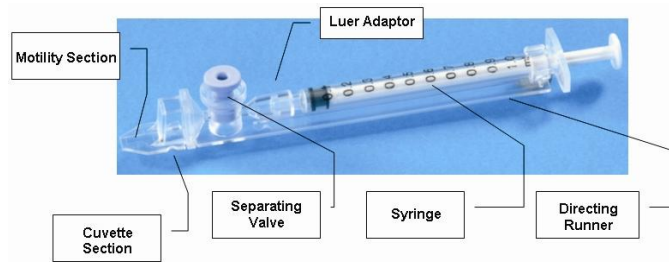


Figure 4: Mixing the sample

**SQA-Vt
Testing
Capillary**

Appendix II: Capillary Filling Instructions



1. Push the syringe piston in fully. Place only the thin part of the capillary into the bottom of the diluted sample - 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).
3. Hold the capillary in a vertical position and visually confirm that the sample has completely filled the thin section and the cuvette section and appears in the Luer adaptor (Figure 2).
4. Tap on the syringe to make sure there are no air bubbles in the sample.
5. Quickly and thoroughly wipe both the top and bottom of the outer surface of the capillary with a tissue such as Kimwipes, etc. (Figure 3). Visually confirm that the capillary chambers are still full after wiping. If some of the sample has been depleted, a meniscus will be visible in the thin section of the capillary. If this is evident, push very slightly on the piston to re-fill the thin capillary section.
6. Slowly and carefully push-in the separating valve until it is level with the plastic. The capillary is now ready for testing (Figure 4)
7. Insert the capillary into the SQA-Vt (below) with the blue stopper facing down.



Figure 1



Figure 2



Figure 3



Figure 4



NOTE: If air bubbles are still present in the capillary after tapping on the syringe, dip the capillary into the semen sample again and aspirate a small quantity of semen to draw air bubbles into the syringe.

NOTE: It is important to remove all semen from the exterior of the capillary in order to prevent the SQA-Vt optical chamber from becoming clogged.

Appendix III: SQA-Vt Cleaning Instructions

When to clean:

- Daily or after every 25 tests
- If the system fails **SELF TEST**

CLEANING: STEP 1

1. **TURN OFF** SQA-Vt and unplug it at main electrical outlet.
2. Select a **BLUE DOT** fibrous material capillary.
 - Moisten with **ONE** drop of cleaning fluid, shaking off excess fluid.
 - Insert into the measurement compartment - fibrous material facing up, and move back and forth a few times in the directional runner.
 - Turn the cleaning capillary over – fibrous material facing down and move back and forth a few times in the directional runner.
3. Select a sponge material capillary and insert it in the same compartment in order to dry the chamber.

CLEANING: STEP II

If the SQA-Vt still does not pass self-test, the channel that measures concentration may need cleaning. Use the cleaning brush:

1. Insert the brush (bristle-side down) fully into the upper portion of the lower chamber of the SQA-Vt in same manner as a testing capillary.
2. Pull the brush out of the chamber while sweeping or "dusting off" the lens (you will feel a step or shelf at the back and top of the chamber – this is the top of the lens).
3. Switch SQA-Vt unit **ON** and observe self-test results. The SQA-Vt should now PASS the self-test. If not, repeat cleaning procedure with the brush.

CLEANING THE VISUALIZATION COMPARTMENT:

Open the visualization compartment door (upper slot) and swing the cover above the lens to the left. Wipe the lens with 98% alcohol (not provided).

Please use manufacturer recommended cleaning kits only. Cleaning kits can be ordered from the SQA-Vt distributor.



Appendix IV: Capillary Washing/Drying Instructions



Testing Capillary



Repositioning the blue valve with the jig



Removing the plunger



Reassembled capillary

Washing 10 ml sample collection cups

(For animal applications ONLY!)

Both testing capillaries and 10ml sample collection cups can be washed and re-used up to 5 times by following this EASY procedure:

Step 1 After running a test:

- Use the white capillary jig to re-position the blue capillary valve
- Expel semen by pumping the plunger a couple of times
- Soak the testing capillary in tap water until ready to wash

Step 2 Set-up: Fill with 1 liter/2 quarts of solution as follows:

- Bowl #1: Tap water (marked "TAP WATER")
- Bowl #2: Distilled water (marked "DISTILLED WATER")
- Bowl #3: Isopropyl Alcohol 70% - 100%

Step 3: Remove all liquid from the testing capillary:

- Pump the syringe plunger a couple of times to remove liquids.

Step 4: Capillary Washing – Follow this order:

- Bowl #1 Tap Water: Completely fill each capillary with tap water. Expel the solution into a hazardous waste container. **Repeat 2 times** then go to Bowl 2.
- Bowl #2 Distilled Water: Completely fill each capillary with distilled water. Expel the solution into a hazardous waste container. **Repeat 2 times** then go to Bowl 3.
- Bowl #3 Isopropyl Alcohol: Completely fill each capillary with isopropyl alcohol and expel the solution into a hazardous waste container. **Repeat 2 times.**
- Remove the plunger from the syringe.

Step 5: Capillary Drying Options:

- Place the capillaries:
 - On a flat surface and dry overnight.
 - In a commercial desiccator - follow manufacturer instructions.
 - In an oven on low heat for a few hours.

Step 6: Final Preparation/Inspection:

- Replace the plunger into the syringe and inspect the capillary.
- Discard capillaries with debris, cracks or broken parts.
- Make a dot on the capillary with a water proof marker after each washing cycle.

Capillary re-assembly

- Place the syringe plunger back into the SQA-Vb capillary.
- Confirm (using the jig) that the blue stopper to the correct position.
- Inspect the capillary for cracks, broken parts or remaining semen. Discard capillaries that are not acceptable. Check syringe by aspirating air in and out twice.
- Mark a dot on the capillary after washing to indicate the # washings.

Washing 10 ml sample collection cups

Refer to Step 4 and Step 5 of the Capillary Washing Procedure above - follow the same process for washing in solution bowls #1; #2 and #3. Turn upside down on absorbent paper to dry overnight or place in a commercial warming oven for a few hours.

Appendix V: The Visualization System

The SQA-Vt Visualization System permits the user to analyze/view semen samples using either a standard slide or the SQA-Vt testing capillary. Additionally, the visualization system is a critical "link" to T-Sperm III which allows the user to view samples on a PC monitor. The visualization system:

- Accommodates either an SQA-Vt testing capillary or a standard slide.
- Operates via control knobs to set focus, brightness, contrast and color, and via the keypad zoom, illumination, and on/off functions.
- Has a magnification range: x300 to x500.

Operating Instructions:

Slide Preparation:

1. Use 10 µl of semen (20 micron sample depth).
2. Use only a standard slide with a 22mm x 22mm cover-slip.
3. Place the sample approximately 12 mm from the distal end of the slide
4. Load the prepared slide into the SQA-Vt slide adaptor and insert into the visualization compartment of the SQA-Vt.

Testing Capillary Preparation:

1. Fill the SQA-Vt testing capillary following the instructions in the appendix section of this guide.
2. Insert the capillary into the visualization compartment of the SQA-Vt.

Testing Process:

1. The video display will automatically illuminate when the SQA-Vt is turned on.
2. Use the monitor **ON/OFF** key on the keypad to independently operate the video display.
3. To ensure that the visualization system is working properly prior to use:
 - Press the **HIGH ILLUMINATION** key multiple times to ensure a maximum level setting.
 - Turn **BRIGHTNESS, CONTRAST** and **COLOR** buttons all the way counterclockwise.
 - Turn **FOCUS** knob fully clockwise.
4. Use **ZOOM IN** for maximum magnification (x500) and **ZOOM OUT** for minimum magnification (x300).
5. Insert the semen sample into the visualization chamber.
6. Turn the **BRIGHTNESS** knob clockwise until the video screen just begins to lighten-up.
7. Turn the **FOCUS** knob counter-clockwise until the image is in focus.
8. Adjust **CONTRAST, COLOR, BRIGHTNESS, FOCUS** and object **ILLUMINATION** controls for optimal image quality.

NOTE: The focus knob should not be forced to turn beyond the initial stopping point. Turn the knob gently and when resistance is felt it is at the maximum (or minimum) resolution. Forcing this knob beyond the stopping point will cause extensive damage to the SQA-Vt.

Appendix VI: Glossary of Terms

	SQA-Vt Terms	Definition
Menu	SN	Serial Number of the SQA-Vt
	DATE/TIME	The date and time the test was performed
	TEMP	The room temperature measured just prior to testing
	SAMPLE #	Dosing Mode: The number assigned to the pooled sample
	SAMPLE #	QC Mode: The number assigned to the QC semen sample
	TOM #	Sorting Mode: The identifying (wing) number of the tom being tested
	FLOCK #	Sorting Mode: The identifying number of the entire flock being tested
Test Results	TSC	Total spermatozoa concentration(count)in Billions/ml
	MSC	Motile spermatozoa concentration in Billions/ml
	MOTILITY %	Motile cell concentration divided by Total cell concentration. Expressed as a % of the tested sample
Dosing Mode	SET-UP	Dosing targets set-up by the user (see values below)
	TOTAL SPERM/DOSE	The desired number of sperm cells per dose (millions)
	MOTILE SPERM/DOSE	The desired number of motile sperm cells per dose in millions/ml
	DOSE VOLUME	The volume of each dose expressed in micro liters (μ l)
	DOSE PREPARATION	Instructions for the addition of semen extenders
	SEMEN VOLUME	The volume of the initial pooled semen entered by the user minus 0.1ml used for testing
	EXTENDER	The amount (ml) of extender to add to the pooled semen in order to produce the desired number of doses.
	TOTAL VOLUME	Pooled semen volume + extender volume
	NUMBER OF DOSES	The total number of doses the pooled semen will produce based upon the users set-up parameters

Appendix VII: SQA-Vt System Specifications

Dimensions: 40 x 30 x 15 cm

Weight: 4 kg

AC power supply: 100 to 250 VAC, 50/60 Hz, 10 VA

Measurement Compartment

- **Sources of radiant energy** - two 880 nm LEDs for motility and spectrophotometry channels
- **Detector system** – 2 photo detectors - Motility and Optical Density

Visualization Compartment

- White LED illumination system
- CCD, 350 TV lines
- Objective: Standard, x20
- Signal Output: PAL standard
- Zoom system for smooth magnification transition from x300 to x500
- Focus regulator

Display(s)

- Operational backlight LCD (16 lines x 40 characters)
- Video backlight LCD (8 x 10 cm)

Printer

- Built-in, Dot Matrix
- Non-thermostatic narrow paper with 20 characters per line (Citizen)
- Ribbon cassette (Citizen)

Keypad

- **Operational keys:** ON/OFF, TEST, PRINT, SERVICE, ARCHIVE, DELETE, ENTER, four cursor buttons, ESC, numeric buttons (0-9)
- **Video control keys:** ON/OFF, ZOOM IN/OUT, ILLUMINATION HIGH/LOW, and MONITOR ON/OFF (FREEZE KEY non-operational)

Front Panel

- Built-in printer
- Visualization compartment
- LCD video display and controls
- Focus knob
- LCD operational display
- Measurement compartment
- Multi-button keypad

Rear/Side Panel

- Power connector with fuse-holder (fuse 250V, 1A)
- Video connector
- RS232 cable outlet
- I-Button port (side panel)

Specimen Testing Supplies

- **Measurement capillary:** Disposable, plastic, positive displacement testing capillary (purchase from manufacturer).
- **Standard lab slide:** 20 micron depth, 22 x 22 mm cover-slip.
- **I-Button:** Required to run tests (purchase from manufacturer)

Archive Capacity

- 500 test records in each archive

Operating System

- **Control:** Keypad
- **Analysis Time:** 50 seconds
- **Software:** Resides on flash memory and drives all man-machine interface functions, runs algorithms for test measurements and operates visual and automated screens. System can be upgraded from a PC CD-ROM.
- **Sample Testing Temperature:** Calibrated for room temperature only. Motility results will be impacted by heating the specimen.
- **Motility channel input signal:** Analog, up to 5V.
- **Spectrophotometer channel input signal:** Modulated (1 kHz) analog, up to 5V.

Quality Control

- **Internal:** Electronic Self-Test and Auto-Calibration.

PC Compatibility

The SQA-Vt requires a computer in order to run T-Sperm™ software. The following are minimum requirements for running T-Sperm:

- **PC:** 1 GHz processor, Pentium 3
- **RAM:** 256 MB
- **AGP-video display card** with at least 16 MB of RAM memory
- **Video color:** At least 16 bit (65,535)
- **CD ROM drive**
- **200 MB free hard disk space** for image capturing
- **Video resolution:** Minimum 640 x 480
- **Operating system compatibility:** Windows 98SE. Optimal performance: Windows 2000, Windows XP, DirectX, DivX

- **Ports:** One serial; two USB ports
- **Monitor:** 15" color

Additional Software (supplied with system)

- **T-Sperm software:** Real time visualization interface between PC and SQA-Vt visualization system, data transfer, video/picture capture and archive.

Operational Temperature and Humidity

- System is operational at 15-38°C.
- *NOTE:* SQA-Vt operates in a wide range of ambient temperatures however the system is calibrated to measure semen samples at room temperature: 22-26°C (68-79°F).
- *NOTE:* Variations in ambient temperature may impact the accuracy of test results because of the effect of temperature semen.
- System is fully operational at up to 80% humidity and 31°C.

Maintenance Schedule

- Clean daily and after every 25 tests (refer to User Guide – "Cleaning").

Manufacturer Recommendations

- Operate the SQA-Vt away from devices that may cause electronic noise (cell phones) or other devices causing vibrations such as centrifuges.
- Turn system **OFF** at the rear-panel when not in use for an extended period of time.
- Variations in ambient temperature can affect semen samples. It is essential that semen samples are not heated when testing. The SQA-Vt is calibrated to conduct tests at room temperature: 22-26°C (68-79°F).
- Semen is considered a biologically hazardous material and is subject to individual laboratory protocols for handling such materials.

Factory Default Settings:

Date format: DD/MM/YY

Time/Date: Manufacturer's local time/date

Temperature Format: Celsius

Mode: **DOSING > TOTAL # SPERM PER DOSE > "0"** for dosing volume and total sperm per dose

Appendix VIII: Product Performance Data

Abbreviations:

TSC:	Total Sperm Concentration (Count)
MSC:	Motile Sperm Concentration
OD:	Optical Density
SD:	Standard Deviation
CV:	Coefficient of Variation

Performance Data Summary:

The performance of the SQA-Vt is summarized in the text, tables and graphs below. All sperm concentration measurements are expressed as 10^9 sperm cells per milliliter (Billion/ml). Motility is expressed as a percent (%). Unless otherwise noted all testing was performed using turkey semen samples.

Calibration:

Each SQA-Vt is biologically calibrated against two reference devices at Medical Electronic System's laboratory using turkey semen stored in liquid nitrogen.

Table 1. SQA-Vt Dynamic Range

Sample Type	TSC Bil./ml	Motility %	MSC Bil./ml
Fresh turkey semen	0-20	0-100	0-20

Precision and accuracy is based on in-house and field trials using turkey semen samples

Performance claims:

Precision (CVs)

- TSC: 4.0%
- MSC: 5.5%
- Motility: 6.0%

Accuracy (regression coefficients of the dilution and "live/dead" trend line)

- TSC: 0.90
- MSC: 0.90
- Motility: 0.9

Correlation to Manual Method

- Concentration: 0.90
- MSC: 0.65

Notes regarding performance claims:

1. Precision CV claims are higher (this represents overall lower precision) than actual values noted (Table 2).
2. Accuracy regression coefficient claims are less than actual values noted (Fig. 1 - 5).
3. Correlation to Manual Method claims are less than actual correlations noted (Fig. 6 & 7).

Precision and Accuracy

Background: A total of 71 turkey semen samples were analyzed.

Intra and Inter-device coefficients of variation (CV) were run to determine the precision of the system. The following formula is used to calculate CV:

$$CV = SD / MEAN \times 100$$

The lower the CV, the higher the precision of the method (Table 2).

Turkey semen was sequentially diluted and measured on the SQA-Vt to assess accuracy against an "expected" value. Dilution plots with regression coefficients were constructed (Figures 1 & 2).

Precision assessment: Each sample dilution was run in triplicate on the same SQA-Vt. Intra-device CV was calculated from these readings. Inter-device CV was calculated by running the same turkey semen samples on two different SQA-Vt systems. Two trials were conducted.

Accuracy assessment: dilution plots.

Accuracy was determined by testing different dilutions of fresh turkey semen providing varying TSC and MSC and relatively stable Motility. The TSC and MSC results were plotted vs. dilution factor. The linear trend line was created for TSC values (Fig. 1). Because motility is more variable than concentration, a second-degree polynomial trend line was generated for the MSC data points (Fig. 2). The regression coefficients for TSC and MSC were 0.999 and 0.993 correspondingly.

Accuracy assessment: "live/dead" sperm plots. A "live/dead" study was conducted to assess the accuracy of the SQA-Vt. Pooled fresh turkey semen was divided into two aliquots. The first aliquot was intact ("live") and the second aliquot was treated with liquid nitrogen ("dead"). Samples were prepared with varying proportions of "live-to-dead" cells while maintaining a constant TSC (varying MSC and Motility only). The samples were tested on both the SQA-Vt and under the microscope. Results are plotted in Figures 3, 4 & 5. Linear trend lines were established for motility vs. the "Live/Dead" sperm ratio and vs. the microscope. A second-degree polynomial trend line was generated for the MSC data points.

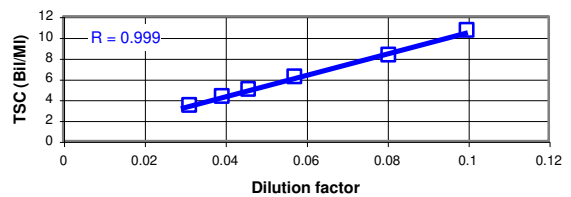
Conclusion:

Table 2. Precision, CV (%)

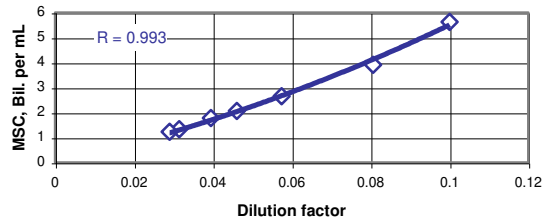
SQA-Vt	TSC	MSC	Motility
Intra-device Variability	3.69	4.99	5.41
Inter-device Variability	1.50	4.55	5.64

Accuracy: Shown in Figures 1 & 2 Dilution plots with regression coefficients R

SQA-VT TSC READINGS OF DILUTED TURKEY SEMEN

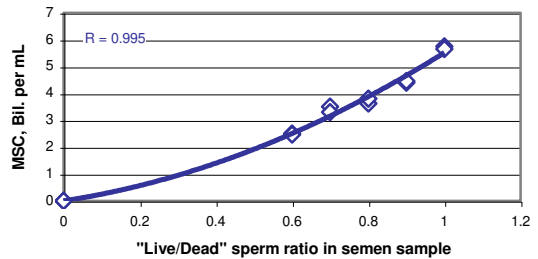


SQA-VT MSC READINGS OF DILUTED TURKEY SEMEN



Accuracy: Figure 3, 4 & 5. "Live/Dead" sperm plots with regression coefficients R

SQA-VT MSC vs. "LIVE/DEAD" SPERM RATIO IN SEMEN SAMPLE



The SQA-Vt provides precise and accurate results with low coefficients of variation (<6%) and high regression coefficients of dilution and "live/dead" trend lines (>0.95).

Method comparison

A total of 60 turkey semen samples were used to run TSC and MSC on the SQA-Vt and to compare these results to a standard microscopic assessment using a Makler counting chamber and a standard slide and based on the WHO'99 guidelines and MES protocols. Fresh turkey semen samples were diluted with 0.9% NaCl, pH 7.0. Regression plots were generated (Figure 6 & 7). The slope equations and correlation coefficients were reported. The slope coefficient for TSC was 1.0 and MSC 0.9 demonstrating no systematic error. The TSC correlation coefficient was 0.97 and MSC was 0.7.

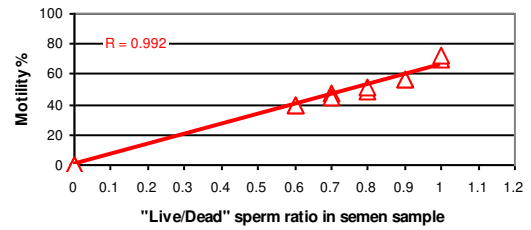
Limitations of method:

Microscopic semen analysis is highly subjective and the accuracy is impacted by statistical counting errors. 95% Confidence interval is equal to +/-1.96 Standard deviations (SD) of the mean value. SD is a square root of the number of spermatozoa counted.

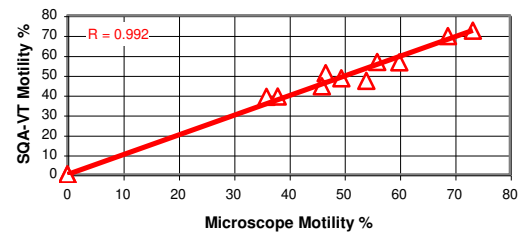
Conclusion:

The SQA-Vt accurately assesses turkey semen compared to manual methods and therefore can be used interchangeably and/or replace manual methodology.

SQA-VT MOTILITY vs. "LIVE/DEAD" SPERM RATIO IN TURKEY SEMEN SAMPLE

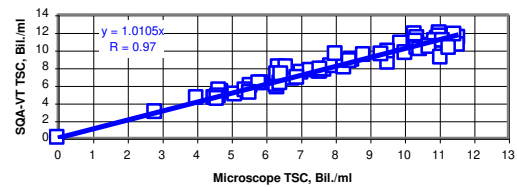


SQA-VT vs. MICROSCOPE MOTILITY IN "LIVE/DEAD" SPERM EXPERIMENT



Method comparison: Figures 6 & 7 Regression plots with correlation coefficients R

TSC: SQA-VT vs. MICROSCOPE



MSC: SQA-VT vs. MICROSCOPE

