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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

- 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.

Keypad and Navigation

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

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.
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**
**Section 4: New Test**

Activate the **NEW TEST** screen to set-up the testing mode: DOSING, QC, or SORTING. The **NEW TEST** screen will be displayed automatically each time the system is turned on. See the section on how to set-up each type of testing mode.

**Section 5: Archive**

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 the section 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.

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:

- 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:

- 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

**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.

**SAMPLE PREPARATION:**

1. **NEAT SEMEN SAMPLES:**
   Extract exactly 100µl of semen using the positive displacement pipette. (Go to Step #3)

2. **DILUTED SAMPLES:**
   Extract exactly 200µl 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.
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.

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.

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).
Appendix IV: Capillary Washing/Drying Instructions

(For animal applications ONLY!)

Both testing capillaries and 10ml sample collection cups can be washed and re-used up to 10 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.
# Appendix VI: Glossary of Terms

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

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>TSC Bil./ml</th>
<th>Motility %</th>
<th>MSC Bil./ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh turkey semen</td>
<td>0-20</td>
<td>0-100</td>
<td>0-20</td>
</tr>
</tbody>
</table>

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:

\[
CV = \frac{SD}{MEAN} \times 100
\]

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: “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>
<thead>
<tr>
<th>Table 2. Precision, CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SQA-Vt</td>
</tr>
<tr>
<td>Intra-device Variability</td>
</tr>
<tr>
<td>Inter-device Variability</td>
</tr>
</tbody>
</table>

Accuracy: Shown in Figures 1 & 2

Dilution plots with regression coefficients R
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.
T-Sperm™
User Guide

Version 2.03
Catalog #7450
September 2007
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Section 1: Overview
T-Sperm is a user friendly data management software package that works together with the SQA-VT to provide the following features and benefits.

- Test results and information from the SQA-VT "Dosing", "Sorting" and "QC" modes can be downloaded from the SQA-VT and analyzed, sorted, graphed and archived on a PC.
- The user can customize the way SQA-VT information is reported and analyzed making it simpler to manage flocks and track dosing information and outcomes.
- Semen samples can be viewed in "real time" on the PC monitor.
- Video clips and images can be captured, attached to test records, and stored in the T-Sperm PC based archive.
- Information is secure – access to T-Sperm requires a password.

The T-Sperm package includes:
- T-Sperm User Guide
- Installation CD
- Security Key
- USB Instant VideoCD external device (or internal PC card)
- Video Cables

System Requirements:
- SQA-VT with communication cable and power cable
- PC requirements:
  Hardware requirements:
  - 1Ghz or higher CPU
  - 256 MB RAM
  - AGP Video Display Card with at least 16 MB of RAM memory
  - CD-ROM compatible drive
  - RS232 communication port (serial)
  - Two available USB ports
  Software requirements:
  - Compatible operation system:
  - Windows VISTA and XP
  - EXCEL (for exporting data)
  - At least 40 GB of free hard disk space recommended
  - Video resolution ≥ 640x480 (recommended 1024x768)
  - Video color quality > 16-bit
  - 15 inch color monitor
Section 2: Software / Hardware Installation

Video grabber USB device installation

Warning: The frame grabber should be installed prior to using T-Sperm!

T-Sperm requires that the user install the frame grabber provided by the manufacturer. For frame grabber installation instructions, please refer to the package insert in the T-Sperm package.

T-Sperm Software Installation:

1. Close all programs that are open or running.
2. Insert the T-Sperm CD into the PC CD-ROM. Installation will begin automatically. If installation fails to start automatically, run x:\Setup.exe (X is the letter of the PC CD-ROM drive).
3. The screen will display: Initializing Wise Installation Wizard.
4. Run the installation program
5. Click “YES” and “Next” when required.

Security Key Installation
- Plug the T-Sperm security key into a second free USB port on the computer and the T-Sperm security key will be automatically installed.

SQA-Vt Connection
- Connect one end of the RS232 communications cable to the PC.
- Connect the other end of the RS232 communications cable to the SQA-Vt.
- Follow the instructions in the SQA-Vt User Guide for setting up system defaults
Section 3: System Navigation Overview

- The T-Sperm is set-up so the user can easily navigate through the various menus and options by clicking buttons.
- Five main navigation buttons are always available in the left margin of the screen to lead the user through a variety of options.
- When a main navigation button is selected, sub-menu buttons appear across the top of the T-Sperm screen allowing the user further options to run reports, export data, etc.

A variety of icons guide the user through the T-Sperm features and options and directional indicator buttons allow the user move back to the previous menus with ease.

Section 4: Start-up

Click on the T-Sperm icon located on the PC desktop to enter the system. A log-on screen will appear. T-Sperm’s security feature requires a password in order to enter the system and the temporary (factory default) password is:

- **Password:** fertility
- Click OK

A screen will automatically appear. Enter and confirm a new password.

Section 5: Test Data

The first button in the navigation menu is **TEST DATA**. From this screen the user can locate, select and analyze test results that have been imported from the SQA-VT.

Click the navigation button **TEST DATA** and three sub-buttons will appear: **Dosing, Sorting** and **QC**.
Dosing mode:
Select this option by clicking on the DOSING button to view a complete list of all the dosing samples in the database. To customize the displayed report, click on one of the four buttons and then click on a column header to:

- **SORT**: This option will sort the report information based on the column selected (DATE, SAMPLE #, TSC, MSC, etc.)
- **HIDE**: This option will hide the column selected.
- **FREEZE COLUMNS**: This option will "FIX" the DATE/TIME/TEMP/SAMPLE ID columns while still enabling the other report data to be scrolled.
- **VIEW ALL**: This option will re-activate ALL of the hidden columns.

Three icons will be displayed in the Dosing table under the following conditions:

**Test results out of clinical range**: This icon is displayed to indicate that one or more of the test results are out of the clinical range that has been set-up by the user (please refer to section 8 – Set Up).

**Dosing mismatch**: This icon will be displayed when the semen cannot be diluted to meet the requirements the user has "set-up". This happens when:
- Set-up values have been entered incorrectly
- Low semen quality

**Video/Picture**: A camera icon will be displayed if a video clip or picture has been attached to the test results. Click the camera icon to open an image browser that will display all the images attached to the selected record.

When the Dosing table is displayed three sub-buttons will appear at the top of the screen: Video, Export, and Report.

**Video**: Click this button to activate the “real time” video display. A semen sample in the SQA-VT visualization system can be viewed on the PC screen.
NOTE: If no record is selected the video or picture will be attached to the most recently performed test.

To save a video clip or picture and attach it to a record:

- Import test results from the SQA-VT to the T-Sperm data base.
- Insert a standard slide with a semen sample into the visualization system.
- Select the desired record in T-Sperm to attach a video/picture.
- Click the VIDEO navigation button to activate the video screen in T-Sperm
- Click: CAPTURE PICTURE/CAPTURE VIDEO.
- Click: Stop Capturing to end the video capture process.
- A camera icon will now appear adjacent to the selected record in the table.

Export: Click on this button to export T-Sperm data to another database or external file in Excel format (This option is available from the IMPORT/EXPORT main navigation menu as well).

Report: Click on this button to view and/or print the semen analysis report:

- Use the page bar at the bottom of the report to move between pages.
- Click the printer icon to print the report.
- Use the ZOOM option to minimize/maximize the report view.
- Exit the report by clicking the X in the upper right hand corner of the screen.
- An indicator will be displayed if test results are out of range.
- Click the EXPORT FILE to send the report to an external file.
Sorting mode:
Select this option to display a complete list of semen analysis test results from individual toms. To customize the viewed report, click on one of the three buttons and then select/click on the column header to:

- **SORT**: This option will sort the report information based on the column selected (DATE, TOM#, TSC, MSC, etc.)
- **HIDE**: This option will hide the columns selected.
- **VIEW ALL**: This option will re-activate ALL of the hidden columns.

### Two icons will be displayed in the Sorting table under the following conditions:

- **Test out of clinical range**: This icon is displayed to indicate that one or more of the test results are out of the test range that has been set-up by the user (please refer to section 8 – Set Up).

- **Video/Picture**: A camera icon will be displayed if a video clip or picture has been attached to the test results. Click the camera icon to open an image browser that will display all the images attached to the selected record.

When the **Sorting** table is displayed the following buttons will appear at the top of the screen: **Data Analysis, Histogram, Video, Export, and Report**.

### DATA ANALYSIS: Click this button to display a table of data sorted by flock. Four parameters will be displayed for each flock:

- Number of toms
- TSC average (billion/ml)
- MSC average (billion/ml)
- Motility average (%)  

### HISTOGRAM: A flock histogram can be run for each parameter (TSC, MSC, and Motility):

- Select a cell in the table that contains the parameter
- Click the **HISTOGRAM** button.
• To **EXIT**, click the X in the upper right hand corner of the screen.

**VIDEO, EXPORT and REPORT:** These buttons perform the same functions for all modes: Dosing, Sorting and QC. Please refer to the **Dosing** mode for an explanation.

**QC mode:**
Select this option to view a complete list of all QC test results imported from the SQA-VT. To customize the viewed report, click on one of the three buttons and then select/click on the column header to:

- **SORT:** This option will sort the report information based on the column selected (DATE, TOM#, TSC, MSC, etc.)
- **HIDE:** This option will hide the columns selected.
- **VIEW ALL:** This option will re-activate ALL of the hidden columns.

<table>
<thead>
<tr>
<th>QC</th>
<th>Number of Records 10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date</td>
</tr>
<tr>
<td>&lt; &gt;</td>
<td>04/04/2004</td>
</tr>
<tr>
<td>&lt; &gt;</td>
<td>04/04/2004</td>
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<td>04/04/2004</td>
</tr>
<tr>
<td>&lt; &gt;</td>
<td>04/04/2004</td>
</tr>
</tbody>
</table>
Two icons will be displayed at the beginning of the Sorting table under the following conditions:

**Test out of clinical range:** This icon is displayed to indicate that one or more of the test results are out of the test range that has been set-up by the user (please refer to section 8 – Set Up).

**Video/Picture:** A camera icon will be displayed if a video clip or picture has been attached to the test results. Click the camera icon to open an image browser that will display all the images attached to the selected record.

**VIDEO, EXPORT and REPORT:** These buttons perform the same functions for all modes: Dosing, Sorting and QC modes. Please refer to the Dosing mode for an explanation.

### Section 6: Import / Export

In order to view test results in T-Sperm, data has to be imported from the SQA-VT. Click the IMPORT/EXPORT button in the navigation menu and two buttons will appear: Import and Export.

**Import:** Select this option to bring data into T-Sperm from the SQA-VT. To successfully Import data:

- The RS232 communication cable must be connected to both the PC and the SQA-VT
- The SQA-VT must be on and the SERVICE DATA screen displayed. To display the SERVICE DATA screen in the SQA-VT go to: MAIN MENU > SERVICE > SERVICE DATA (in the SQA-Vt).
- Click: The IMPORT/EXPORT navigation button of the T-Sperm.
- Select: IMPORT > CONTINUE on the T-Sperm import screen.

Once the data has been imported successfully (and is now saved in the T-Sperm), the user will be asked whether they want to delete the data in the SQA-Vt device.

- Select YES to “clear” all the data from the SQA-Vt device.
- Select NO and all the test data will remain both the SQA-Vt and in the T-Sperm archive.
- Dosing, Sorting and QC data is imported separately into T-Sperm.

**Export:** Select this option to send data from T-Sperm to an external file:

- Click IMPORT/EXPORT in the navigation menu.
- Select EXPORT
- Select the desired data (Dosing, Sorting or QC)
an exported table in Excel file format the page needs to be set in "landscape" format for the entire table to fit on a single page.

- Enter a path and file name; then click **SAVE**.
- The data will be saved to the designated location.
- A message box will confirm that the T-Sperm archive is being saved to the PC. Click **Yes**.

### Section 7: Real Time Video

The **REAL TIME VIDEO** feature allows the user to view semen samples “live” from the SQA-VT visualization system on the PC. The following features are available after clicking the **REAL TIME VIDEO** button:

- **FREEZE** – The screen will freeze. Click the REAL TIME button to un-freeze.
- **GRID** – A grid can be added to the screen to make counting easier. The grid color and width can be customized (see the “SET-UP > Video” section of this manual).
- **COPY** – Pictures can be copied by clicking the COPY button and then pasting the picture in an external file (WORD, Excel, etc.).
- **SETTINGS** – Video settings can be selected by the user.
- **SAVE VIDEO** – Video clips can be saved in an .avi format.
- **SAVE PICTURE** – Pictures can be saved in a .bmp format.
- **FULL SCREEN** – The screen can be maximized. To close the full screen, click the **CLOSE** button.

### Section 8: Set-Up

Before beginning the testing process, T-Sperm setting defaults must be set by the user. Click the **Set-Up** navigation button to display five options:

- Report
- Port
- Video Settings
- Password
- Temperature

**Report:** To set-up the defaults for test results (normal ranges) and to customize the language used in the T-Sperm reports, click the **Report** button.
NOTE: The manufacturer has set default test ranges. (See the SQA-VT User Guide for details).

NOTE: When in regular use (not set-up) report window must be closed before further action is performed in T-Sperm.

**Normal Ranges**: Click this button to set-up the defaults for test results (normal ranges) for the MSC and TSC for the Dosing, Sorting and QC modes of the T-Sperm.

- Click on the ARROW which points to the parameter to be set-up.
- The **Normal Range Settings** screen will appear.
  
  - Enter the desired symbol (<, >, =, BETWEEN, etc.)
  - Enter the desired values
  - Click **APPLY** to enter

**Language**: Click this button to customize the language used in the T-Sperm Reports.

- Click the Language button to display the screen
- Choose “Other” from the Language drop-down screen
- Edit the table as desired and click **Apply** to save.

**Port**: Click this button to set the communication port for the PC.
WARNING: Video clips take up a large amount of the computer memory. It is recommended to "capture" only short clips. A video compression tool has been set-up as a system default by the manufacturer.

Video Settings: Click this button to select various video options: Grid line width, Grid color, video compression tool and video device:

Password: The password can be changed by clicking the password button and entering a new password and confirmation in the entry screen. Click APPLY to save the new password. The password is immediately re-set and the user can access T-Sperm with this new password only.

Temperature: The temperature default can be set to Celsius or Fahrenheit by clicking the TEMPERATURE button and making a selection. Click APPLY to save.

Section 9: Exit

Exit the T-Sperm system by clicking the EXIT button. Confirm with a click.