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<thead>
<tr>
<th>Message</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stabilization Failed</td>
<td>29</td>
</tr>
<tr>
<td>Self-Test Failed</td>
<td>29</td>
</tr>
<tr>
<td>Electronic Noise</td>
<td>30</td>
</tr>
<tr>
<td>Concentration Out of Range</td>
<td>30</td>
</tr>
</tbody>
</table>

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**SECTION 1: System Specifications and Requirements**

**Specifications**

**Dimensions:** 32 X 30 X 24 cm  
**Weight:** 7 Kg  
**AC power supply:** 100-240 VAC, 50-60 Hz, 20 VA

**Archive Capacity**
- 500 test records / 750 QC records

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

**Factory Default Settings**

**SYSTEM:**
- **Date format:** DD/MM/YY  
- **Time/Date:** Manufacturer's local time/date  
- **Morphology:** WHO 5th  
- **Chamber standard:** 2

**Printing Options:** Automatic

**CONTROLS:**

- **Control Media:** Latex Beads, Stabilized Sperm CAP or MES (Lot #, Target Values, +/- Ranges set up by user)

**Front Panel**
- Displays: LCD video display and controls, LCD operational display.  
- Other: Multi-button keypad, I-Button port, Focus knob, Built-in printer.

**Keypad**
- **Operational keys:** ON/OFF, TEST, PRINT, SERVICE, ARCHIVE (now disabled), DELETE, ENTER, four cursor buttons, ESC, ten numeric buttons (0-9).  
- **Video control keys:** ZOOM IN/OUT, ILLUMINATION HIGH/LOW, and MONITOR ON/OFF.

**Measurement Compartment**
- **Sources of radiant energy** - two LEDs for motility and spectrophotometry channels.  
- **Detector system** - two photo detectors - Motility and Optical Density.

**Operating System**
- **Analysis Time:** Normal Test–75 seconds; Low Quality–2 additional minutes; Postvasectomy – 5 minutes.  
- **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.  
- **Motility channel input signal:** Analog, up to 5V.  
- **Spectrophotometer channel input signal:** Modulated(kHz)analog,up to 5V.

**Printer**
- Built-in, Dot Matrix with ribbon cassette (Citizen).  
- Non-thermostatic narrow paper with 20 characters per line (Citizen).

**Rear Panel**
- Power connector w/fuse-holder (fuse 250V,1A), Video connector, RS232 outlet.
Visualization Compartment
- White LED illumination system
- CCD, 330 TV lines
- Objective: Standard, x20
- Signal Output: PAL standard
- Zoom system for smooth magnification transition between x300 and x500
- Focus regulator

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/Slide Compartments” in this User Guide). **ONLY use the Manufacturers cleaning kit and cleaning brush or damage will occur to the SQA-V film and the system will not operate!**

Manufacturer Recommendations
- Operate the SQA-V 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 extended period of time.
- When running Postvasectomy 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 samples. **It is essential that semen samples are not heated** for testing. The SQA-V 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.
  - Samples handling and waste disposal in specially marked hazardous waste containers.
  - Only personnel trained to work with biologically hazardous materials such as semen should be testing and handling semen.

Operating Temperature
- Maximum operational humidity is 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 measure semen samples at room temperature: 20-25°C (68-77°F). Note: Extreme ambient temperature may impact the accuracy of motility test results because of the known effect of temperature on human semen.

Operational Environmental conditions:
- System is intended for indoor use at a maximum altitude of 2000m, mains supply fluctuations ±10%, Overvoltage Category II, Pollution Degree II.
PC / Hardware Requirements

Minimum requirements for V-Sperm software:

- **PC:** Intel Core i5 M520 2.4GHz or equivalent
- **RAM:** 4GB
- **Video card:** 3D to support high resolutions 16:10 – 1440X900
- **Video color:** At least 16 bit (65,535)
- **CD ROM drive**
- **300GB free hard disk space** for image capturing (approx. 3000 clips)
- **Monitor Screen:** Color, Wide screen – should support resolution 16:10 or 16:9 (1440X900)
- **Operating system compatibility:** Windows XP and 7; Excel/Word (required for V-Sperm GOLD)
- **Communication Ports:** Two FREE native RS232 ports (one for data transfer and one for LIS); two USB ports
- **EXCEL and WORD required for export function and printing test reports**

Quality Control

- **Internal:** Electronic Self-Test and Auto-Calibration. Runs automatically upon start-up. Reference values are verified prior to each test.
- **External:** Run daily prior to testing or per laboratory protocol. Runs assayed latex bead control: "QwikCheck™-beads" (product of Medical Electronic Systems) for concentration and negative control for motility/concentration OR non-assayed: Latex beads or stabilized sperm CAP or MES for concentration.

Sample Testing

- **Sample Testing Temperature:** Calibrated for room temperature only. Motility results will be impacted by heating the specimen.
- **System calibrated to test Human semen and specified Control samples only.** Not for use with animal semen.
- **SQA-V measurement capillary:** Disposable, plastic, testing capillary. Requires 500 µl of sample for normal volume testing, 20 µl for low volume testing, 300 µl for diluted mode. Use only manufacturers’ certified testing capillaries in the automated and visualization system.
- **Slide adaptor:** Supplied with the SQA-V. Must be used with a standard laboratory slide and 22 x 22 mm cover-slip for accurate test results.

Software Required

- **V-Sperm Gold 3.60 (included with system):** Required for setting SQA-V system defaults, archive management/data transfer, capture and storage of video images from the SQA-V and for displaying and printing self test data.
- **Excel/Word** (required for V-Sperm GOLD)
SECTION 2: System Overview

The SQA-V is a high performance analytical medical device that combines technology in electro-optics, computer algorithms and video microscopy. The system performs a 75-second semen analysis and has the ability to print test results and archive up to 500 patient records. The system is self-testing and self-calibrating and runs latex beads or stabilized sperm quality controls. Two systems: Automated and visualization allow the user the flexibility to analyze all types of semen samples.

Keypad Navigation

- Use NUMERIC keys to enter data; ARROW keys to move to the next field.
- Press ENTER to select menu options, confirm data entries and to move to the next screen or field.
- Use the ESC button to return to the previous screen or field.

Rear Panel

- Rear panel assembly screws
- Video output connector
- RS 232 COM port
- Ventilation slots
- Instrument label
- Power connector and main switch assembly.

NOTE: The TEST button of the SQA-V keypad is only active in the CALIBRATION mode.

The ARCHIVE button on the keypad is inactive because the SQA-V archive is managed through V-Sperm GOLD.
Components

- **Measurement 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 20 micro liters of semen.
  - Concentration is measured in the 10 mm (tall) "Cuvette Section." This section requires 450 microliters of semen.
  - Both the measurement and visualization chambers of the SQA-V will accommodate the testing capillary. Refer to: "Filling the SQA-V Capillary with Normal and Low Volume Samples" in the Appendix section of this guide for instructions on how to use the SQA-V testing capillary.

- **Slide Adaptor**
  - Use with a standard laboratory slide 76 x 25.6 mm and 22 x 22 mm cover-slip with a 10 µl sample placed approximately 12 mm from the end of the slide for accurate results.
  - For use in the **visualization compartment** of the SQA-V.

**NOTE:**
In order to accurately visualize the sample it must be centered approximately 12mm from the end of the glass slide.
### Semen Parameters Reported by the SQA-V

#### Table of the Reportable Range of the SQA-V

<table>
<thead>
<tr>
<th>REPORTABLE RANGE OF THE SQA-V Gold</th>
<th>SAMPLE</th>
<th>SPERM CONC in M/ml</th>
<th>MSC in M/ml</th>
<th>Motility %</th>
</tr>
</thead>
<tbody>
<tr>
<td>FRESH</td>
<td>2-400 or &lt; 2 M/ml</td>
<td>0.2-400 or &lt;0.2 M/ml</td>
<td>0-100%</td>
<td></td>
</tr>
<tr>
<td>WASHED</td>
<td>2-200 or &lt; 2 M/ml</td>
<td>0.2-200 or &lt;0.2 M/ml</td>
<td>0-100%</td>
<td></td>
</tr>
<tr>
<td>FROZEN</td>
<td>Not reported</td>
<td>0.2-200 or &lt;0.2 M/ml</td>
<td>Not reported</td>
<td></td>
</tr>
<tr>
<td>POSTVASECTOMY</td>
<td>Manual Input</td>
<td>0-30 Sperm/Scan</td>
<td>Not reported</td>
<td></td>
</tr>
</tbody>
</table>
**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-V testing capillary.

An optical density detector measures the amount of light absorbed by the 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-V capillary as they move through a light beam in the SQA-V: 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](image-url)
SECTION 4: Getting Started / Set-Up

Power-On

- Attach factory supplied electrical cable to the outlet on the rear panel.
- Plug cable into a grounded electrical source.
- Turn on SQA-V by pressing the main switch located on the rear panel. The Power indicator will illuminate and the following screen will be displayed.

![SQA-V VERSION 2.60 STANDBY POSITION PRESS ON/OFF KEY TO ACTIVATE THE UNIT](image)

Auto-Calibration and Self-Test

![SQA-V VERSION 2.60 PLEASE WAIT SYSTEM STABILIZATION AND AUTOCALIBRATION](image)

- Press ON/OFF key on the keypad and system stabilization and auto-calibration will begin.
- This process takes 5-7 minutes.
- When the system stabilization and auto-calibration processes are complete, a series of tests will be run.
- Do not insert a capillary/slide into the device or use any of the keyboard functions until instructed to do so by the system.
- The MAIN menu will appear when the self-test process is complete. The SQA-V is now ready for use.

![MAIN MENU TEST NEW PATIENT RUN CONTROLS SERVICE](image)
Set-up System Defaults

SQA-V system defaults are set-up through V-Sperm GOLD software. Therefore a connection needs to be established between the SQA-V and the PC.

- From the MAIN MENU, select SERVICE > SERVICE DATA.

The RS232 communication cable must be connected to the SQA-V and the PC.

Turn-on the PC and activate the V-Sperm GOLD version 3.60 software.

From the V-Sperm GOLD main navigation screen select SET-UP > SQA-V > SQA-V Defaults. Then press the CONTINUE button.

V-Sperm GOLD will display the SQA-V system set-up screen:
### Testing Samples

#### Patient Information

**Entering Patient and Sample Information**

<table>
<thead>
<tr>
<th>ENTER PATIENT / SAMPLE DATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT ID: 5788114</td>
</tr>
<tr>
<td>BIRTH DATE: 01/01/85</td>
</tr>
<tr>
<td>ABSTINENCE: 4 DAYS</td>
</tr>
</tbody>
</table>

**SAMPLE PROCESSING**

<table>
<thead>
<tr>
<th>COLLECTED: DD/MM/YY HH:MM</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECEIVED: DD/MM/YY HH:MM</td>
</tr>
</tbody>
</table>

- From the **MAIN MENU** select **TEST NEW PATIENT** and the **ENTER PATIENT / SAMPLE DATA** screen is displayed.
- Enter the requested sample/patient information using the SQA-V keypad:
  - **PATIENT ID** – Unique number identifying the patient (Maximum of 20 numbers can be entered).
  - **BIRTH DATE** – Birth date of the patient.
  - **ABSTINENCE** – Number of days since the patient’s last ejaculation.
  - **SAMPLE/ACCESSION #** – Up to 20 numbers identifying the sample.
  - **COLLECTED** – Date and time the sample was collected.
  - **RECEIVED** – Date and time the sample was received.

### SQA-V System Default settings:

- Date Format (DD/MM/YY) or (MM/DD/YY)
- Local date setting
- Conc./Chamber Standard 1 or 2 (See appendix section for more information).
- LES setting: Check with your distributor for set-up
- Printing options: automatically print test results/self test report on start-up.

### Control Set-up (from the manufacturer's labeling):

- Select type of control: Latex beads or Stabilized Sperm CAP.
- Enter Lot Number for each control level (enter “0” if not known).
- Enter +/- Range for each control level (enter “0” if not known).
- Enter EXPIRATION date (use current date if the EXP date is unknown).

- Press the **Report** button to view and print the selected default settings.
- Press **Apply** to accept the default settings and transfer them to the SQA-V.

### PLEASE NOTE:
The SQA-V is calibrated to run semen specimens at room temperature. It is not necessary nor will the user get accurate motility results if the sample is heated to 37°C.
**Sample Information**

Press **ENTER** to view the next screen:

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>SELECT FRESH / WASHED / FROZEN / POSTVASECTOMY</th>
</tr>
</thead>
<tbody>
<tr>
<td>VOLUME</td>
<td>2.5 ml</td>
</tr>
<tr>
<td>WBC CONC.</td>
<td>SELECT &lt; 1 M/ml OR &gt;= 1 M/ml</td>
</tr>
<tr>
<td>PH</td>
<td>7.0</td>
</tr>
<tr>
<td>APPEARANCE</td>
<td>NORM./ABNORM.</td>
</tr>
<tr>
<td>VISCOSITY</td>
<td>NORM/ABNORM</td>
</tr>
<tr>
<td>LIQUEFACTION</td>
<td>NORM./ABNORM.</td>
</tr>
</tbody>
</table>

**PLEASE NOTE:**
1:2 dilution means 1 part semen volume plus 1 part diluent volume, which results in a 1:2 dilution. MES has included (1+1) to further define this dilution in order to prevent confusion.

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.

**Sample Data**

- Select: **SAMPLE TYPE** (required entry) based on the following options:
  - **FRESH** – Sample not enriched, diluted or treated and is within 1 hour of collection. Exception: Low volume samples diluted 1:2 (1+1) with QwikCheck dilution media can be used according to User Guide instructions.
  - **WASHED** – Sample enriched or prepared for artificial insemination using a commercial media to replace seminal plasma. Frozen samples containing egg yolk buffer are excluded.
  - **FROZEN** – Samples that have been frozen. Only motility parameters will be reported (MSC, PMSC, SMI and VELOCITY) in order to quantify the impact of freezing and thawing on the motility parameters of the specimen.
  - **POSTVASECTOMY** – Fresh samples designated as postvasectomy and tested within an hour of collection.

- Enter the remaining sample information using the SQA-V keypad:
  - **VOLUME** – Volume of the whole ejaculate in milliliters.
  - **WBC CONC.** – select < 1 M/ml (normal) OR >= 1 M/ml (abnormal) leukocytes (required entry). (QwikCheck Test Strips recommended).
  - **PH** – pH of the semen sample (QwikCheck Test Strips recommended).
  - **APPEARANCE** – NORM/ABNORM visual assessment of the specimen.
  - **VISCOITY/LIQUEFACTION** – NORM/ABNORM (WHO 5th guidelines for NORM liquefaction is within 60 minutes of collection @ room temperature).

- If **POSTVASECTOMY SAMPLE TYPE** was selected, please refer to the section "Postvasectomy Test” in this user guide.

**Sample Volume**

<table>
<thead>
<tr>
<th>IS SAMPLE VOLUME SUFFICIENT FOR COMPLETE TESTING &gt;= .5 ml?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES/NO</td>
</tr>
</tbody>
</table>

After entering the patient and sample data, the screen above will be displayed. Using the left and right arrow keys and then **ENTER**, select:
- **YES** for **NORMAL VOLUME** samples ≥0.5 ml.
- **NO** for **LOW VOLUME** samples < 0.5 ml.
If the sample is < 0.5 ml two options are available: Run as a low volume sample and obtain just motility parameters or dilute the sample 1:2 (1+1) with QwikCheck Dilution media and obtain a report of all parameters.

- To run a low volume sample: Aspirate only 20 µl of sample into the motility section of the capillary following the instructions in the Appendix section of this User Guide: "Filling the SQA-V Capillary with a Low Volume Samples".

  LOW VOLUME SPECIMEN
  PLEASE SELECT SAMPLE TESTING OPTION:
  DILUTE SEMEN 1:2 (1+1) WITH MEDIA
  LOW VOLUME – 20 MICROLITERS ONLY
  MOTILITY PARAMETERS ONLY

  LOW VOLUME SAMPLE

  FILL CAPILLARY – 20 MICROLITERS
  CLEAN AND WIPE CAPILLARY

  INSERT CAPILLARY INTO CHAMBER

  TEST RESULTS
  MOTILITY PARAMETERS ONLY
  MSC 18.5 M/ml  VELOCITY 5 mic/sec
  PMSC 8.3 M/ml  SMI 26
  TOTALS PER VOLUME
  MOT SPERM 18.5M  PROG SPERM 8.3M

- Or the low volume sample can be diluted 1:2(1+1) with QwikCheck-Dilution media:

  LOW VOLUME SPECIMEN
  PLEASE SELECT SAMPLE TESTING OPTION:
  DILUTE SEMEN 1:2 (1+1) WITH MEDIA
  LOW VOLUME – 20 MICROLITERS ONLY
  MOTILITY PARAMETERS ONLY

  LOW VOLUME SPECIMEN
  1. DILUTE SEMEN 1:2 (1+1) WITH MEDIA
  2. MIX SAMPLE THOROUGHLY
  3. FILL, CLEAN AND WIPE CAPILLARY

  INSERT CAPILLARY INTO CHAMBER

Follow the instructions in the appendix section of this User Guide: Filling the SQA-V Capillary with a Normal Volume Sample.

The testing cycle and test results will be the same as a normal volume specimen (see screens below).
• The SQA-V algorithm compensates for the sample dilution as long as the sample has been diluted accurately (if the total sample volume is 0.4 ml then 0.4 ml of a clear media such as Earle’s buffer must be added).

• Recommendation: If the LOW VOLUME sample is viscous, first treat with the QwikCheck-Liquefaction kit and then dilute the sample for greater accuracy.

• If the sample was ≥0.5 ml the screen above will provide instructions for preparing a testing capillary.

• Fill the SQA-V testing capillary according to the instructions in the Appendix section of this user guide: “Filling the SQA-V Capillary with a Normal Volume Sample”.

• The screen above will be displayed when it is time to insert the filled testing capillary in the measurement compartment, testing will begin automatically.

A sample is tested in approximately 75 seconds. If the sample is low quality, the system will perform an additional 2 minute test:

- TESTING

DO NOT MOVE CAPILLARY OR OPERATE DEVICE DURING TESTING

- TESTING

LOW QUALITY SAMPLE

TESTING WILL TAKE 2 MORE MINUTES
Low Quality Test Results

- Low quality test results may be reported as < or > when one or more of the parameters falls below the SQA-V dynamic range. Only the following will be reported: Sperm Concentration, Motility, SMI and Motile Sperm Concentration due to the limited number of cells, very low motility and/or poor morphology.
- Examples of test results reported in this manner are seen in the screens below:

<table>
<thead>
<tr>
<th>Test Results</th>
<th>MSC</th>
<th>PMSC</th>
<th>SMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.2 M/ml</td>
<td>6.3 M/ml</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>FSC M/ml</td>
<td>VELOCITY mic/sec</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMI 0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TOTALS PER VOLUME</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPERM # N.A.</td>
</tr>
<tr>
<td>MOT. SPERM N.A.</td>
</tr>
<tr>
<td>PROG. SPERM N.A.</td>
</tr>
<tr>
<td>MORPH. NORM. SPERM N.A.</td>
</tr>
</tbody>
</table>

- The test results will be saved/printed automatically or an option to save and print will be displayed depending on how the SQA-V was set-up.
• If the SQA-V default was set to automatically print/save test results, the screen below will now be activated.

![DATA SAVED AND NOW PRINTING](image)

• Immediately after saving/printing test results, an option to transfer the results of the test just completed to V-Sperm is displayed on the SQA-V.

• V-Sperm Gold must be activated and the PC must be connected via the RS232 cable to the SQA-V.

• Following the screen directions, simply press the “Import Test” main menu navigation button in V-Sperm and the test will automatically be transferred into the V-Sperm data base.

![TO TRANSFER TEST RESULTS TO V-SPERM: PRESS: “IMPORT TEST” BUTTON IN V-SPERM](image)

• The archive of the SQA-V can accommodate 500 Patient Test records. A warning will appear when the archive is almost full. Data MUST be transferred to the PC or it will be lost, overwritten or the SQA-V will no longer permit testing. **Warning** QC Tests are not saved in the SQA-V (there is no QC Archive). Transfer QC Tests to V-Sperm after performing each QC test by following the screen instructions (above screen) after the test is run.

• When the screen below is displayed, **Patient Records** must be transferred from the SQA-V archive to the PC:

![ARCHIVE ALMOST FULL TO AVOID POSSIBLE LOSS OF DATA DOWNLOAD THE ARCHIVE TO THE PC PRESS ENTER TO CONTINUE](image)

• From the SQA-V, go to **MAIN MENU > SERVICE > SERVICE DATA**.

• Make sure the RS232 communication cable is connected between the SQA-V and the PC.

• Turn-on the PC and activate the V-Sperm GOLD version 3.60 software.

• From the V-Sperm main navigation screen select **IMPORT/EXPORT > IMPORT DATA** > select **IMPORT ARCHIVE** (PATIENT RECORDS). Press **CONTINUE** and the records will automatically be transferred.

• After the records have been successfully transferred to V-Sperm, select **YES** on the next screen to delete the SQA-V (Patient) archive from the SQA-V.
Postvasectomy Test

The SQA-V runs a five minute POSTVASECTOMY test that can detect the presence of a very small number of motile cells. Once the automated test has been performed, the user is given the option to follow the POSTVASECTOMY protocol outlined below and "scan" the testing capillary in the SQA-V visualization system (A POSTVACECTOMY Protocol can also be found in the appendix section of this guide).

By scanning through the depth of the testing capillary, immotile and motile sperm cells can be readily identified, easily counted and entered in the operational screen for visual confirmation of the automated test results. Clinical studies positively demonstrated that by incorporating both the SQA-V automated AND visualization system in the testing protocol, a very high level of accuracy is obtained for identifying motile and non-motile sperm cells in POSTVASECTOMY samples.

In order to obtain similar levels of accuracy it is imperative that the user strictly follow the manufacturer's protocol outlined below. Additionally, once the testing cycle is completed, test results can be documented by capturing and archiving a video clip of the postvasectomy specimen using V-Sperm™ software.

Select POSTVASECTOMY as the SAMPLE TYPE from the ENTER PATIENT / SAMPLE DATA screen.

- Fill the SQA-V testing capillary following instructions in the appendix section of this guide: "Filling the SQA-V Capillary with a Normal Volume Sample."
- Insert the testing capillary into the SQA-V lower chamber when instructed. Testing will begin automatically.
- Testing takes approximately 5 minutes.
- Test results for motile sperm are reported.
- Select YES to when asked: “ENTER VISUAL DATA PER USER GUIDE?” to manually enter the number of MOTILE/IMMOTILE sperm seen on the visualization system.
- Press ENTER to continue.
- Take the same testing capillary and insert it into the visualization (upper) compartment.
- Set the magnification to x300 (Full zoom out) and press ENTER to continue.
- "Scan" the depth of the capillary by slightly turning the visualization focus knob (10 fields can be visualized) and enter the total # MOTILE/IMMOTILE SPERM cells visualized in all 10 fields.
- The SQA-V will automatically report the GREATER # of cells found by the Automated or Visualization system.
- Press ENTER and the test results screen will be displayed.

Please note:
The POSTVASECTOMY test takes approximately 5 minutes to run and is highly sensitive to motion. Please do not disturb the SQA-V or the testing capillary during the testing cycle or the results may be impacted.
- Leave the testing capillary in the visualization chamber and transfer the test results to V-Sperm to capture and attach a video clip of the sample in the patient’s record.

- If the SQA-V reports > 30 motile spermatozoa, a screen will indicate that a NORMAL TEST should be run instead of a POSTVASECTOMY test.

- > 30 motile spermatozoa is equivalent to MSC > 2M/ml.

**POSTVASECTOMY**

<table>
<thead>
<tr>
<th># SPERM/SCAN:</th>
<th>MOTILE</th>
<th>&gt; 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLEASE RE-RUN AS A NORMAL TEST</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**POSTVASECTOMY**

<table>
<thead>
<tr>
<th># SPERM/SCAN:</th>
<th># SPERM/SAMPLE VOL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOTILE 3</td>
<td>MOTILE 0.2 M</td>
</tr>
<tr>
<td>IMMOTILE 8</td>
<td>IMMOTILE 0.5 M</td>
</tr>
<tr>
<td>TOTAL 11</td>
<td>TOTAL 0.7 M</td>
</tr>
</tbody>
</table>
SECTION 6: Controls

External quality control samples (CONTROLS) are run on the RUN CONTROLS mode from the MAIN MENU of the SQA-V. Commercially available latex beads or stabilized sperm CAP can be run as non-assayed controls. QwikCheck™ beads produced by Medical Electronic Systems are assayed for the SQA-V. It is recommended that controls be run daily or based upon laboratory protocols.

The control media is aspirated into the testing capillary and run in the same manner as a normal volume specimen in the testing compartment of the SQA-V.

For each new lot of controls, SQA-V system defaults need to be set-up/updated through V-Sperm GOLD prior to running a test. To run an assayed control use the information for Target Value and +/- Range provided on the product labeling. To run a non-assayed control, the Target Value and +/- range must be established by the laboratory or set 0 (zero) if not established. Follow instructions below to set-up an assayed or non-assayed material. The testing process is the same.

Set-Up: Assayed Control

Each time a new lot of an assayed control is to be run, the user must set-up/update the CONTROL settings through V-Sperm GOLD as described below. Previous settings (defaults) will remain in place until updated.

**Step 1:** From the SQA-V MAIN MENU select SERVICE > SERVICE DATA.

**Step 2:** Make sure the SQA-V is connected to the PC via the RS232 communication cable.

**Step 3:** Activate the V-Sperm on the PC and select: SET-UP > SQA-V and press CONTINUE.

**Step 4:** The set-up screen below will be activated in V-Sperm GOLD on the PC:

```
Step 5: Select the type of control (Latex Beads or Stabilized Sperm)
Step 6: Enter the following information from the box labeling:
  - LOT# - number identifying the control media lot.
  - EXP. DATE – control expiration date (MM = month, YY = year).
  - TARGET VALUE and +/- Range – manufacturer's "Target Value and +/- Range" for the SQA-V Automated System.
  - NEGATIVE control target values and +/- ranges are pre-set to 0.0.
Step 7: To save settings: Press APPLY. The set-up may take two minutes.
```
Please note:
To run 10 replicates:
After each completed test, remove the capillary and initiate the CONTROL test again using the same capillary.

Set-Up: Non-Assayed Material to Establish the target value and +/- range
This is also the set-up procedure for sperm concentration proficiency challenge

Follow the same Steps 1-5 for "Set-up: Assayed Control" above.

Step 6: 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 7: Enter the TARGET VALUE and +/- Range for Level 1 and Level 2:
- Enter 00 for the target value.
- Enter 0.0 for the +/- range.
- NEGATIVE control target value and +/- range is pre-set to 0.0

Step 8: Save settings: Press APPLY. The set-up takes about two minutes.

Step 9: Establish the target value and +/- range for each level:
- Fill a testing capillary and run 10 replicates following the instructions below "Control Testing."
- Calculate the mean target value. Based on laboratory protocols determine the +/- range (Example: 2SD).
- Follow steps 1-7 of "Set-Up: Assayed Control” to update the target value and +/- range for the control.

CONTROL Testing

- Select RUN CONTROLS from the MAIN MENU of the SQA-V.
- The Control defaults have already been set-up in V-Sperm.
- Select the CONTROL LEVEL: #1, #2 or NEGATIVE (LEVEL #3) that is being tested.
- Press ENTER to continue.
- Controls are run in exactly the same manner as a normal semen sample.
- Using control media, follow the same procedure for filling an SQA-V testing capillary with a NORMAL volume sample.
- Testing will begin automatically.
- Control test results will be displayed on the SQA-V screen.
- LOW, HIGH or NORM. will be displayed based on the testing outcomes vs. target value and +/- range (Disregard this for non-assayed controls target range set at "0")
- Test results will automatically be saved and printed.
Electronic Self-Test and Auto Calibration

The SQA-V automatically runs a series of tests to check calibration settings and the internal operating system. Tests are run when the system is turned on and prior to testing a sample.

Start-up:

**Stabilization and auto calibration:** Checks system stability and reference ranges. The system sensors are analyzed for several minutes to insure that the values are within a very narrow acceptable range. Once the system is stable for 30 seconds it will pass stabilization and auto calibration. The system will fail if it is not stable for at least 30 seconds and a warning message will be displayed.

**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 in order to check the performance of the system and verify that the calibration settings are consistent with the factory specifications. The SQA-V will report failures (see section on error and warning messages) and "freeze" the system if the system is not within the established self-test ranges.

Prior to testing a sample:

**Auto calibration verification** : Reference values are read again. The electronic parameters of the concentration and motility channels are measured (without a testing capillary).

**System noise** : Measures the electronic noise level of the system to insure effective measurement of electronic signals. Prior to running a test, the SQA-V will automatically adjust the noise level thresholds to insure accurate readings.

**Electronic spikes** : Checks for any measurement points that are out of range electronically. More than three such points will fault the system and a warning message will be displayed.

Instructions for printing the SQA-V system parameters to prepare for technical support:

How to print a copy of the system parameters FROM THE SQA-V:

Remove the testing capillary from the system.

When a FAILED SELF TEST message appears select: MAIN MENU > SERVICE > PRINT SELF-TEST DATA.

Press ENTER to generate a report.

How to view/print a copy of the system parameters FROM V-SPERM GOLD:

Verify that the SQA-V is connected to the PC and V-Sperm is activated.

- From the SQA-V activate: MAIN MENU > SERVICE > SERVICE DATA.
- Select the V-Sperm navigation buttons: UTILITIES>SELF-TEST DATA and click CONTINUE.

Click on the PRINT button to view a Service Data Report.

Click PRINT in the upper left hand corner of the screen to print a report.
Refer to the table below. Enter numbers in the "SQA-V Value" column that corresponds to the SQA-V system parameters printout. Compare the values. If the value from the SQA-V is within range mark the "Pass" column. If not, mark the "Fail" column.

<table>
<thead>
<tr>
<th>#</th>
<th>Parameter</th>
<th>S/W Ver. 2.60</th>
<th>SQA-V Value</th>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Ref 1</td>
<td>150 – 400 mV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>LED Cur 1</td>
<td>5 – 25 mA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Amplitude</td>
<td>50 – 100 mV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Zero Level</td>
<td>500 - 525</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Ref 2</td>
<td>2500 – 3500 mV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>LED Cur 2</td>
<td>10 – 32 mA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>CONC. 1</td>
<td>0 – 1 M/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>CONC. 2</td>
<td>50-150 M/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>CONC. 3</td>
<td>300-600 M/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Count (Service Data, Item #12)</td>
<td>26 - 36</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION 7: Transferring the SQA-V Archive to V-Sperm

The SQA-V automatically prints PATIENT and CONTROL test results when a test is completed. Only PATIENT TEST results (not CONTROL test results) are saved in the SQA-V archive when the testing cycle is complete. **To view, navigate, edit and delete records, the test results have to be transferred to V-Sperm** immediately after running a test (on-line transfer) or imported to V-Sperm as a group (Patient tests only). The SQA-V can store 500 patient records but does not store the control records.

The screen below will be displayed when the PATIENT archive of the SQA-V is almost full:

```
ARCHIVE ALMOST FULL
TO AVOID POSSIBLE LOSS OF DATA
DOWNLOAD ARCHIVE TO PC
PRESS ENTER TO CONTINUE
```

The following screen will appear after every CONTROL TEST is performed:

```
ATTENTION!
TO AVOID LOSS OF DATA
TRANSFER CONTROL RESULTS TO V-SPERM
PRESS: “IMPORT TEST” BUTTON
IN V-SPERM
```

To transfer data to V-Sperm, first connect the SQA-V to the PC and activate the V-Sperm software. There are two options for transferring test results to V-Sperm:

**IMPORT TEST RESULTS ON-LINE:**

- Immediately after saving/printing test results, an option to transfer the results of the test just completed is displayed on the SQA-V.
- Following the screen directions, simply select the “Import Test” main menu navigation button in V-Sperm and the test will automatically be transferred into the V-Sperm data base.

```
TO TRANSFER TEST RESULTS TO V-SPERM:
PRESS: “IMPORT TEST” BUTTON
IN V-SPERM
```

**IMPORT PATIENT RECORDS FROM THE SQA-V TO V-SPERM:**

- Select the V-Sperm navigation button: IMPORT/EXPORT.
- Select: IMPORT DATA > IMPORT ARCHIVE and press CONTINUE and the tests will automatically be transferred.
- Select: YES on the next screen to delete records from the SQA-V archive.
SECTION 8: Service Menu

System set-up, maintenance and calibration can be performed from the SERVICE MENU. To activate this screen, press SERVICE in the MAIN MENU.

**SERVICE MENU**
- SERVICE DATA
- SERVICE PERSONNEL
- PRINT SELF-TEST DATA
- ADD I-BUTTON TESTS

**Service Data**
Communication between the SQA-V and a PC via the RS232 interface is established through the SERVICE DATA screen. System set-up and upgrades are also performed through this screen.

The SQA-V archive can be transferred to a PC only when this screen is activated.

**Service Personnel**
A code is required to access SERVICE PERSONNEL. This option allows a qualified service technician to access calibration and maintenance settings.

**Print SQA-V SELF-TEST DATA**
The system SELF-TEST DATA can be printed from this option.

**Add I-Button Tests**
From the SQA-V MAIN MENU SELECT: SERVICE > ADD I-BUTTON TESTS and follow the on screen instructions seen below:

**TO LOAD I-BUTTON TESTS:**
1. SLIDE I-BUTTON UNDER THE CLIP
2. PRESS DOWN FIRMLY
3. BUTTON MUST CONTACT PORT EDGES

PRESS ENTER
CONTINUE TO HOLD BUTTON

The I-Button loading screen below will appear:

**PLEASE WAIT**
**I-BUTTON LOADING**

The screen below will be displayed after successfully loading tests:

**# OF TESTS ADDED:** 100
**# OF TESTS NOW REMAINING:** 110

PRESS ESC TO EXIT
SECTION 9: Operating the Visualization System (Video Display)

The SQA-V Visualization System with video display (upper screen) is used to view and count sperm cells. The visualization system is a critical "link" to V-Sperm GOLD where enhanced, real time video can be displayed on a PC monitor. The visualization system:

- Accommodates both an SQA-V testing capillary to "scan" through a depth of 300 microns or a standard slide to view samples (20 micron depth).
- Operates via control knobs to set focus, brightness, contrast and color, and via the keypad zoom, illumination, and monitor on/off functions.
- Magnification range: x300 to x500.

Standard Slide Preparation:
- Use 10 µl of semen.
- Standard slide, 22 mm x 22 mm cover-slip (to insure 20 micron depth).
- Load the prepared, standard slide into the SQA-V slide adaptor.

Testing Capillary Preparation:
- Fill the SQA-V testing capillary for either a normal or low volume specimen (see Appendix).

Visualization Process:
- The video display will automatically illuminate when the SQA-V is turned on.
- Use monitor ON/OFF key on the keypad to independently operate the video display.
- Wait for the self-test to complete (system is disabled at this time).
- 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.
- To view cells: Press ZOOM IN to maximum magnification (x500).
- To count cells: Press ZOOM OUT to minimum magnification (x300).
- Insert semen sample (either capillary or slide) into the visualization chamber.
- Adjust CONTRAST, COLOR, BRIGHTNESS, FOCUS and object ILLUMINATION controls for optimal image quality.
- Use ZOOM OUT (x300) / ZOOM IN (x500) to regulate magnification.

Counting Cells Using the Visualization Screen:
1. Follow the WHO Manual instructions for semen sample collection and preparation. Thoroughly mix the sample before step #2.
2. Pipette 10µL of the semen sample onto a standard slide and cover with a 22x22 mm coverslip. Prepare a new slide if air bubbles or liquid spillage occurs.
3. Load the slide into the slide adaptor and then insert the slide adaptor into the SQA-V visualization chamber. (Refer to the SQA-V User Guide APPENDIX 3: Using Standard Slides in the Visualization System for details).
4. Press the ZOOM-OUT button on the SQA-V keypad all the way to set the magnification to x300.
Please note:
The visualization screen grid of the SQA-V is calibrated to a CONC STANDARD default of “1” or Makler/non-dilutional chambers.

Please see the Appendix Section “Concentration Standard – Counting Chamber” for details.

5. Set the: BRIGHTNESS, CONTRAST & COLOR knobs of the video display:
   a. COLOR knob: Turn clockwise to the end (maximum color),
   b. CONTRAST: Turn counterclockwise to the end (maximum contrast),
   c. BRIGHTNESS knob: Turn clockwise from the darkest setting until the background is light (not maximum!).

6. Adjust the focus knob to maximize the image: Turn clockwise all the way. Then turn counterclockwise until a clear image appears on the screen.

7. Go to V-Sperm and click on the Real Time Video button. FREEZE the image.

8. The screen of both the SQA-V and the V-Sperm is divided into a grid containing 20-distinct squares (see below).

![Grid Image]

9. Each spermatozoon seen on the ENTIRE 20-square grid is 1 Million/ml of sperm concentration. FOR EXAMPLE: In the grid above, there are 7 spermatozoa in each cell of the grid. 7 (spermatozoa) X 20 (cells) = 140 M/ml sperm concentration for this sample.

10. To count a minimum of 200 cells (per WHO), turn the silver knob of the slide adaptor and a new field of view will be displayed in the grid.

11. When viewing multiple fields, divide the final count by the number of screens (fields of view) counted. For example, if two of the screens above are counted there would be a total number of 280 sperm cells so the sperm concentration will be: 280 ÷ 2 = 140 M/ml.

12. Refer to table 2.2 of the WHO Manual 5th Edition to determine if the duplicate counts are acceptable.
SECTION 10: Error Messages, Warning Messages and General Warning

General Warning:

- The SQA-V equipment’s built-in protection for the operator and the environment is ONLY operational if the SQA-V is operated properly following the manufacturer’s specifications.

- **CAUTION:** There is a risk of explosion or shorting if the SQA-V 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 instructions.

- Environmental condition for storage and transport: Recommended to store the SQA-V at temperatures between 20°C -30°C.

Stabilization Failed:

- Ensure there is no testing capillary in the measurement compartment.
- Remove the SQA-V from sources of electronic noise and vibrations.
- Clean measurement compartment (refer to Appendix).
- Reboot the SQA-V without a testing capillary in the chamber:
  - Turn system **OFF** then back **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:

- Ensure there is no testing capillary in the measurement compartment.
- Remove the SQA-V from sources of electronic noise and vibrations.
- Clean measurement compartment (refer to Appendix).
- Reboot the SQA-V 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/Stabilization.
- Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the SQA-V SERVICE DATA:
  - Press the SERVICE key on the SQA-V keypad to activate the SERVICE MENU screen.
  - Select: PRINT SELF TEST DATA.
  - Press ENTER.

Electronic Noise:

Electronic Noise.

TURN OFF MAIN SWITCH ON REAR PANEL.
ACtivate UNIT.
IF PROBLEM PERSISTS,
CALL FOR TECHNICAL SUPPORT

- Ensure there is no testing capillary in the measurement compartment.
- Remove SQA-V from sources of electronic noise and vibrations (centrifuge).
- Clean measurement compartment (refer to Appendix) and after cleaning:
  - 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/Stabilization.
- From the main menu: Select TEST NEW 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-V SERVICE DATA:
  - Press the SERVICE key on the SQA-V keypad to activate the SERVICE MENU screen.
  - Select: PRINT SELF TEST DATA.
  - Press: ENTER.

Concentration Out of Range

Testing Semen Sample:

TEST RESULTS
OUT OF PHYSIOLOGICAL RANGE
RE-TEST SAMPLE?
YES/NO

- A message will appear indicating that the tests results for Sperm Conc 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-V reads:
  - SPERM CONC > 500 M/ml or MSC > 450 M/ml
- Review sample handling technique (Appendix "Filling the SQA-V Capillary").
- Re-test the sample in a new SQA-V capillary. If the message appears again, reboot the system.
- Call for technical assistance if problem persists.
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.

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.

**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-V 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.

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 one of the SQA-V compartments for testing or viewing.

6. **For automated testing push 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.

7. **To visualize the specimen, insert the capillary into the visualization compartment with the blue stopper up.**
APPENDIX 2: Filling the SQA-V Capillary with a Low Volume Sample

Sample size, collection container and preparation:

1. A sample as small as 20 micro liters 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.

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 20 micro liters 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 (nomeniscus).

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-V 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-V.

5. **PLEASE NOTE:** Test Low Volume samples as soon as the sample is aspirated into the capillary.
APPENDIX 3: Using Standard Slides in the Visualization System

Introduction
The SQA-V has a specially designed slide adaptor that enables the user to use standard slides to view semen samples in the SQA-V visualization compartment. A slide is "seated" in a stable and secure manner as described below and the slide adaptor is inserted into the SQA-V for testing.

User Instructions:
1. The slide adapter is designed for standard laboratory slides that are 76 mm long and 25.6 mm wide. Thickness may vary from 1 mm to 2 mm. The viewing section of the slide must be completely transparent.
2. Center a 10 micro-liter drop of semen at a distance of approximately 12 mm from the edge of the slide and cover with a standard (22 mm x 22 mm) cover-slip. 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:

3. Carefully place the prepared slide into the slide adapter (with the non-loaded side towards the slide holder):

4. Open the spring loaded slide holder by pressing on its outer edge. Slip the slide into the holder and release the spring:

5. Align the edge of the slide with the distal edge of the slide adapter by turning the silver slide position adjuster as seen below. The slide will now be firmly in place in the slide adapter:

6. Insert the fully loaded slide adapter into the visualization chamber of the SQA-V:

7. Optimize the video image in the usual manner (please see the SECTION 9: Operating the Visualization System) and move to additional fields of view by turning the silver knob of the slide adapter.
APPENDIX 4: Counting Cells using the SQA-V Visualization System

1. Follow the WHO Manual instructions for semen sample collection and preparation. Thoroughly mix the sample before step #2.

2. Pipette 10uL of the semen sample onto a standard slide and cover with a 22x22 mm cover slip. Prepare a new slide if air bubbles or liquid spillage occurs.

3. Load the slide into the slide adaptor and then insert the slide adaptor into the SQA-V visualization chamber. (Refer to the SQA-V User Guide APPENDIX 3: Using Standard Slides in the Visualization System for details).

4. Press the ZOOM-OUT button on the SQA-V keypad all the way to set the magnification to x300.

5. Set the: BRIGHTNESS, CONTRAST & COLOR knobs of the video display:
   a. COLOR knob: Turn clockwise to the end (maximum color),
   b. CONTRAST: Turn counterclockwise to the end (maximum contrast),
   c. BRIGHTNESS knob: Turn clockwise from the darkest setting until the background is light (not maximum!).

6. Adjust the focus knob to maximize the image: Turn clockwise all the way. Then turn counterclockwise until a clear image appears on the screen.

7. Go to V-Sperm and click on the Real Time Video button. FREEZE the image.

8. The screen of both the SQA-V and the V-Sperm is divided into a grid containing 20-distinct squares (see below).

9. Each spermatozoon seen on the ENTIRE 20-square grid is 1 Million/ml of sperm concentration. FOR EXAMPLE: In the grid above, there are 7 spermatozoa in each cell of the grid. 7 (spermatozoa) X 20 (cells) = 140 M/ml sperm concentration for this sample.

10. To count a minimum of 200 cells (per WHO), turn the silver knob of the slide adaptor and a new field of view will be displayed in the grid.

11. When viewing multiple fields, divide the final count by the number of screens (fields of view) counted. For example, if two of the screens above are counted there would be a total number of 280 sperm cells so the sperm concentration will be: 280 ÷ 2 = 140 M/ml.

12. Refer to table 2.2 of the WHO Manual 5th Edition to determine if the duplicate counts are acceptable.
APPENDIX 5: Cleaning the Capillary / Slide Compartments

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
- Blue Dot capillaries (single use)
- Sponge-tipped drying capillaries
- Cleaning fluid (single drop dispenser)

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

NOTE: Do not move this drying capillary in and out.
APPENDIX 6: Reference Values of Semen Variables

<table>
<thead>
<tr>
<th>SEMEN PARAMETER</th>
<th>SQA-V TEST NAME</th>
<th>REFERENCE RANGE*</th>
<th>SOURCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sperm Concentration (Count)</td>
<td>SPERM CONC.</td>
<td>≥15 M/ml</td>
<td>WHO 5th manual*</td>
</tr>
<tr>
<td>Total Motility (PR+NP)</td>
<td>TOTAL MOTILITY &lt;PR+NP&gt;</td>
<td>≥40 %</td>
<td>WHO 5th manual*</td>
</tr>
<tr>
<td>Progressive Motility (PR)</td>
<td>PROG. MOTILITY &lt;PR&gt;</td>
<td>≥32 %</td>
<td>WHO 5th manual*</td>
</tr>
<tr>
<td>Non-progressive Motility (NP)</td>
<td>NONPROG. MOTILITY &lt;NP&gt;</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Immotility (IM)</td>
<td>IMMTILITY &lt;IM&gt;</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sperm Morphology (normal forms, %)</td>
<td>MORPH. NORM FORMS, WHO 5th</td>
<td>≥4%</td>
<td>WHO 5th manual*</td>
</tr>
<tr>
<td>Motile Sperm Concentration</td>
<td>MSC</td>
<td>≥6 M/ml</td>
<td>MES*</td>
</tr>
<tr>
<td>Progressively Motile Sperm Concentration</td>
<td>PMSC</td>
<td>≥5 M/ml</td>
<td>MES*</td>
</tr>
<tr>
<td>Functional Sperm Concentration</td>
<td>FSC</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Velocity (Average path velocity – VAP)</td>
<td>VELOCITY</td>
<td>≥5 mic./sec.</td>
<td>MES*</td>
</tr>
<tr>
<td>Sperm Motility Index</td>
<td>SMI</td>
<td>≥80</td>
<td>MES*</td>
</tr>
<tr>
<td>Total Sperm Number</td>
<td>SPERM #</td>
<td>≥39 M</td>
<td>WHO 5th manual*</td>
</tr>
<tr>
<td>Total Motile Sperm</td>
<td>MOT. SPERM</td>
<td>≥16 M</td>
<td>MES*</td>
</tr>
<tr>
<td>Total Progressively Motile Sperm</td>
<td>PROG. SPERM</td>
<td>≥12 M</td>
<td>MES*</td>
</tr>
<tr>
<td>Total Functional Sperm</td>
<td>FUNC. SPERM</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total Morphologically Normal Sperm</td>
<td>MORPH. NORM. SPERM</td>
<td>≥2 M</td>
<td>MES*</td>
</tr>
</tbody>
</table>

The ranges established above are based on WHO 5th reference values or MES (for proprietary semen parameters).
APPENDIX 7: Measuring WBC's in Semen

SQA-V Visualization System

Follow directions for preparing a standard slide with 10 µl of semen and refer to the "Using the Visualization System" section of this guide. View up to 10 fields by turning the silver slide adaptor knob. Search for leukocytes. If >1 M/ml are seen on the visualization system, select ABNORMAL (ABNORM) in the SAMPLE DATA screen.

QwikCheck™ Test Strips for Semen

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. If the patch exceeds the darkest lavender color on the scale it indicates that WBC concentration in the sample is abnormal or >1 Million/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. Esterases cleave to indoxyl ester, liberating the indoxyl which then reacts to diasonium 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 Ltd. (MES) for use as a qualitative indicator (WBC's >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 >1 Million/ml the WBC patch of the QwikCheck™ test strips exceeds the darkest lavender color on the color chart after the testing time. (This reading corresponds to WBC concentration > 1 Million/ml that is considered abnormal according to WHO 2010 5th edition, Pg. 107). A NEG includes both the NEG color on the label AND any color of lavender LIGHTER than the >1M patch on the label.

References

WHO 2010 5th edition laboratory manual for the examination of human semen, Pg. 16 (pH) and 107 (Leukocytes), Cambridge University Press.
APPENDIX 8: Dilution Media

QwikCheck
DILUTION

PRODUCT INSERT

INTRODUCTION AND INTENDED USE:
The QwikCheck™ Dilution kit is used to dilute semen prior to automated or manual semen testing, when indicated. It is also used for sample preparation. The dilution media is Earle’s balanced salt solution which contains ingredients known to support sperm motility and viability. It is recommended by WHO for semen sample preparation (WHO 2010, 5th edition manual, page 163). The product is intended for in vitro use only.

KIT CONTENTS:
- 50 ml of sterile Earle’s Balanced Salt solution / Product Insert

STABILITY AND STORAGE CONDITIONS:
- The product has a one year shelf life. Note the expiration date on the box and bottle
- Store unopened bottle at room temperature. Refrigerate at +4°C after opening.
- Bring to room temperature (22-26 °C) prior to use to prevent cold shock.
- Do not use if the solution contains precipitate or is cloudy.

INSTRUCTIONS FOR USE:

AUTOMATED SQA-V:
1. Measure the volume of the neat semen sample.
2. If the volume is less than 0.5ml, dilute 1:1.
3. Open the dilution kit bottle and pipette the amount of solution equal to the sample volume measured in step 1.
4. Add the solution to the neat semen and thoroughly mix with gentle circular motion, without introducing air bubbles.
5. Fill the SQA-V testing capillary immediately following the directions in the SQA-V user manual.

MANUAL:
1. Follow the laboratory sperm preparation protocols for diluting semen samples for testing.

CLINICAL PERFORMANCE OF SEMEN SAMPLES DILUTED WITH EARLE’S BUFFER (DILUTION KIT CONTENTS):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Correlation Coefficients: Comparison Neat vs. Diluted</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>R = 0.99</td>
<td>Test results demonstrated high correlations for Concentration, Motility, Progressive Motility and Morphology between neat semen samples and those same samples diluted with Earle’s buffer (QwikCheck-Dilution kit) when run on the SQA-V.</td>
</tr>
<tr>
<td>Motility</td>
<td>R = 0.84</td>
<td></td>
</tr>
<tr>
<td>Progressive Motility</td>
<td>R = 0.96</td>
<td></td>
</tr>
<tr>
<td>Morphology</td>
<td>R = 0.96</td>
<td></td>
</tr>
</tbody>
</table>

PRECAUTIONS AND WARNINGS:
Exercise appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation.

REFERENCES:
INTRODUCTION AND INTENDED USE

The QwikCheck™ Liquefaction Kit can be used to accelerate the liquefaction of viscous semen samples that remain viscous thirty minutes after collection. High viscosity can impact the accurate measurement of motility and concentration. Use QwikCheck™ Liquefaction to prepare viscous semen samples for automated or manual semen analysis. For in-vitro use only.

KIT CONTENTS

- 20 single dose, 5 mg vials of lyophilized α-Chymotrypsin and a product insert.

STABILITY AND STORAGE CONDITIONS

The product has a one year shelf life. Note the expiration date on the box and vials. Vials can be stored at room temperature.

INSTRUCTIONS FOR USE

1. Select one vial of α-Chymotrypsin.
2. Tap the vial to move the contents to the bottom of the vial prior to opening.
3. Add the entire contents of one vial to a viscous semen sample.
4. Gently mix the sample to dissolve the powder.
5. Once the sample has liquefied (5-10 minutes), immediately perform automated testing or neutralize the enzymatic activity (optional) by adding of Human Serum Albumin (HSA) (not provided in this kit).

CLINICAL PERFORMANCE: Semen Samples Treated with QwikCheck Liquefaction:

<table>
<thead>
<tr>
<th>Parameter:</th>
<th>Correlation Coefficients: Semen samples Treated with Chymotrypsin vs. Non-treated semen samples</th>
<th>Conclusions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>R = 0.98</td>
<td>Test results demonstrated high correlations for Concentration, Total Motility, Progressive Motility and Morphology between the treated with chymotrypsin (QwikCheck Liquefaction Kit) and non-treated semen samples when run on the SQA-V.</td>
</tr>
<tr>
<td>Total Motility</td>
<td>R = 0.99</td>
<td>No detrimental effect is seen when treating semen samples with QwikCheck™ Liquefaction kit containing 5 mg chymotrypsin.</td>
</tr>
<tr>
<td>Progressive Motility</td>
<td>R = 0.99</td>
<td></td>
</tr>
<tr>
<td>Morphology</td>
<td>R = 0.95</td>
<td></td>
</tr>
</tbody>
</table>

PRECAUTIONS AND WARNINGS

Each vial contains α-Chymotrypsin, a protease. This protease can cause irritation to eyes, respiratory system or skin. In case of contact with eyes, rinse immediately with water and seek medical attention. Observe the following precautions when handling the product:

- Wear suitable protective clothing: Mask, gloves and laboratory coat.
- Avoid dispersing material over the working area.

APPENDIX 10: Assayed Control: QwikCheck™ Beads

A QUALITY CONTROL MATERIAL FOR AUTOMATED AND MANUAL SPERM COUNTING SYSTEMS

Introduction and Intended Use:
QwikCheck™ Beads is an in-vitro use only external quality control material for automated and manual sperm counting systems. It has been developed as a tool to assess the accuracy and precision of the laboratory’s sperm counting methods by providing a known target value and +/- range. The beads were used for the SQA semen analyzer however, they are also labeled for manual proficiency testing and calibration on hemacytometers such as Neubauer counting chambers, Makler chambers and conventional fixed coverslip chambers.

QwikCheck™ Beads is supplied in a kit containing known concentrations of 4-micron latex beads suspended in an aqueous solvent and negative concentration/motility control. The beads should be run according to the directions below for the type of system used in the lab. According to the CLIA ’88 regulations, “for most moderately complex tests, the general requirement is to analyze two levels of QC materials on each day of testing.” It is recommended that QwikCheck beads are run on both the SQA automated and visualization systems prior to each day of semen analysis testing.

For in-vitro use only:
Each kit contains two known concentrations of QwikCheck™ beads in two 5 ml aliquots and one 5 ml negative concentration and motility control. Store the beads at room temperature (20-25°C or 68-77°F). The expiration date assumes that QwikCheck™ beads are stored at room temperature in their original containers and tightly capped to prevent evaporation. Open vial shelf-life is 90 days (tightly capped, stored in the original container at room temperature or refrigerated @ 5-15 degrees Centigrade). QwikCheck™ beads are stable and show no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20°C to +37°C.

Target Value and +/- Ranges
Target Values and +/- Ranges unique to the batch have established for each batch of QwikCheck beads. Each box and each control bottle is labeled with these Target Values and Ranges. In addition, the MES website: www.mes-global.com provides Batch Release Forms by batch # with details.

Warning:
Contains 0.1% Sodium Azide as a preservative. Other ingredients are not harmful due to the low concentration in the beads. For additional information, please refer to the QwikCheck beads Safety Data Sheet # QCB 001

Basic Instructions for using QwikCheck™ beads:

1. BEFORE initially opening new beads, turn the bottle upside down and gently shake. During shipment some beads adhere to the top of the bottle.
2. Mix the beads in the closed container by gently rotating by hand. This will evenly distribute the beads in the suspension and ensure accurate test results. Do not use a vortex except for the Neubauer chamber which requires vortexing because the beads are diluted with water.
3. Open the container and immediately withdraw a sample of the control material. Tightly close the container after withdrawing the sample.
4. Follow the detailed instructions below for the type of system/manufacturer used.

Instructions for running QwikCheck™ beads QC material on automated and manual sperm counting systems:

SQA Automated System:
1. Refer to the SQA User Guide “CONTROLS” section for an explanation of how to set up the SQA to test automated Level 1/Level 2 and Negative Control QwikCheck™ beads. Follow the SQA on-screen instructions in the “Controls” section of the SQA User Guide.
2. Before opening new beads, gently rotate the closed container of beads upside down to remove any beads that may have adhered to the top liner.
3. Mix opened beads by gently rotating the closed container (do not use a vortex).
4. Aspirate a sample of the beads or negative control into the SQA capillary in the same manner you would fill the capillary for a normal volume specimen. Make sure that the cuvette section of the SQA capillary is completely filled with liquid and free of bubbles.
5. Insert the testing capillary into the SQA measurement chamber when prompted.
6. Use a new capillary for running each level of beads.

SQA Visualization System using a standard slide:
1. Refer to the SQA / VISION User Guide for Instructions on how to use slide in the SQA visualization.
2. Gently rotate the closed container of beads by hand (do not use a vortex).
3. Pipette 10 µL of QwikCheck™ beads onto a standard slide, cover with a 22x22 mm coverslip to provide a 20-micron sample depth.
4. If liquid spills onto the slide or air bubbles are seen, prepare a new slide to ensure accurate results.
5. Insert the slide into the slide adaptor and then into the visualization chamber of the SQA. Press Zoom-Out all the way to set the magnification at x300 and FREEZE the image.
6. Count the beads manually per WHO guidelines: Duplicate counts of at least 200 beads are required (turn the slide adaptor knob to view multiple fields). Divide the total number of beads counted in the multiple fields by the number of screens viewed. Each bead on the SQA / VISION screen represents 1 µm.
7. Refer to the WHO Manual 5th Edition Manual, table 2.4 to determine if the duplicate counts are acceptable.
Appendix 11: 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-V 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-V will automatically run semen samples based on that standard.

**SQA-V Set-Up:**

Select SERVICE > SERVICE DATA.

Log into V-Sperm and go to SET-UP > SQA-V > CONTINUE

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:

<table>
<thead>
<tr>
<th>CHAMBER STANDARD #1</th>
<th>CHAMBER STANDARD #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Makler</td>
<td>Beurker-Tuek</td>
</tr>
<tr>
<td>Micro-Cell</td>
<td>Buerker</td>
</tr>
<tr>
<td>Fixed Cover slip disposable chambers</td>
<td>Fuchs-Rosenthal</td>
</tr>
<tr>
<td></td>
<td>Fuchs-Rosenthal (modified)</td>
</tr>
<tr>
<td></td>
<td>Improved Neubauer</td>
</tr>
<tr>
<td></td>
<td>Neubauer</td>
</tr>
<tr>
<td></td>
<td>Malassez</td>
</tr>
<tr>
<td></td>
<td>Thoma</td>
</tr>
<tr>
<td></td>
<td>Thoma Modified</td>
</tr>
</tbody>
</table>
Appendix 12: Post-vasectomy Protocol

The SQA-V runs a five minute POSTVASECTOMY test that can detect the presence of a very small number of motile cells. Once the automated test has been performed the user is given the option to follow the POSTVASECTOMY protocol outlined below (also refer to the Appendix section of this guide) and "scan" the testing capillary in the SQA-V visualization system.

By scanning through the depth of the testing capillary the user is able to identify and readily count immotile cells and visually confirm automated test results. Clinical studies positively demonstrated that by incorporating both the SQA-V automated AND the visualization system in the testing protocol, a very high level of accuracy is obtained for identifying motile and non-motile cells in POSTVASECTOMY samples.

In order to obtain similar levels of accuracy it is imperative that the user strictly follow the manufacturer’s protocol outlined below. Additionally, once the testing cycle is complete, the user has an opportunity to document test results by capturing and archiving a video clip of the postvasectomy specimen using V-Sperm™ software.

This test is highly sensitive to any movement. The SQA-V and the testing capillary should not be disturbed in any way during the 5 minute testing cycle.

- Fill BOTH sections of the SQA-V testing capillary (for stability during the 5-minute test).
- If the specimen volume is not adequate to fill both sections, dilute it with Earle's Buffer and multiply results by the dilution factor.
- Follow the user guide for instructions on running a POSTVASECTOMY sample.
- Run the automated 5-minute test for motility parameters.
- Remove the capillary and insert it into the visualization system and "scan" ten fields of the SQA-V capillary following the user guide instructions.
- Enter the number of motile and immotile sperm cells visualized.
- The final test results will report the greater number of cells found in the automated or visualization test.
- Leave the testing capillary in the visualization system.
- Save the test to the SQA-V archive and import it to the V-Sperm GOLD software.
- Following the V-Sperm user guide instructions, import the test into the V-Sperm data base and attach a live VIDEO clip to the patient’s test record for documentation purposes.
- **NOTE:** If the SQA-V is reporting > 30 motile spermatozoa, a screen will indicate that a NORMAL TEST should be run instead of POSTVASECTOMY > 30 motile spermatozoa is equivalent to MSC > 2M/ml.
ASSESSING GLOBOZOOSPERMIC SAMPLES ON THE SQA-V
(Versions: All Human SQA-V GOLD Systems)

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-V. This technical bulletin describes the incidence of this disorder and demonstrates how to identify these samples prior to running the automated SQA-V 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-V:

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

Device number: _______ SQA-V Software Version: _________ Date: _________

Instruct the user to run a SERVICE report. For version 2.60 from the MAIN MENU select: SERVICE > PRINT SELF TEST DATA.

**Calibration parameters:**

Fill-in the USER REPORT column with the calibration parameters found in the INTERNAL DATA SECTION of the SERVICE DATA REPORT run on the “defective” SQA-V. Contact MES for the initial calibration parameters. These parameters should not have changed.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Service Report Item #</th>
<th>User Report</th>
<th>MES Report</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTR.REF1</td>
<td>#1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OD AMPLIF.</td>
<td>#13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MSC AMPLIF</td>
<td>#8</td>
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<tr>
<td>OD VALUE</td>
<td>#15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OD CORR</td>
<td>#16</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LB OD AMP</td>
<td>#18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTR. Z.L*</td>
<td>#11</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*CONTR. Z.L. can be adjusted in the field by a MES trained service technician.

**Algorithm parameters:**

Fill-in the User Report values for the following algorithm parameters found in the SERVICE DATA REPORT. The SQA-V algorithm settings are defined and should not have changed.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Service Report Item #</th>
<th>User Report</th>
<th>MES Settings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIN.SP.HEIGHT</td>
<td>#2</td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>MIN.SP.WIDTH</td>
<td>#9</td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>MAX.SP.WIDTH</td>
<td>#3</td>
<td></td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>NOISE THRESH</td>
<td>#10</td>
<td></td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>SMI THRESH</td>
<td>#4</td>
<td></td>
<td>28</td>
<td></td>
</tr>
</tbody>
</table>
**Self Test Parameters:**

Fill-in the SQA-V SELF TEST PARAMETERS from the SELF TEST printout in V-Sperm:

The SQA-V must be connected to the PC and V-Sperm activated.

From the **SERVICE>SERVICE DATA** screen of the SQA-V:

- Go to the V-Sperm navigation buttons: **UTILITIES>SELF TEST DATA**
- Select **PRINT**
- Verify that the parameters listed below fall within the established range
- Highlight the discrepancies and report to MES

<table>
<thead>
<tr>
<th>Parameter</th>
<th>S/W Ver. 2.60 Criteria</th>
<th>SQA-V Self-Test Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref. 1</td>
<td>150 – 400 mV</td>
<td></td>
</tr>
<tr>
<td><strong>LED Current 1</strong></td>
<td><strong>5 – 25 mA</strong></td>
<td>Original value</td>
</tr>
<tr>
<td>Amplitude</td>
<td>50 – 100 mV</td>
<td></td>
</tr>
<tr>
<td>Count (#12)</td>
<td>26 – 36</td>
<td></td>
</tr>
<tr>
<td>Zero Level</td>
<td>500 – 525</td>
<td></td>
</tr>
<tr>
<td>Ref. 2</td>
<td>2500 – 3500</td>
<td></td>
</tr>
<tr>
<td><strong>LED Current 2</strong></td>
<td><strong>10 – 32 mA</strong></td>
<td>Original value</td>
</tr>
<tr>
<td>TSC 1 or CONC 1</td>
<td>0 – 1 M/ml</td>
<td></td>
</tr>
<tr>
<td>TSC 2 or CONC 2</td>
<td>50 – 150 M/ml</td>
<td></td>
</tr>
<tr>
<td>TSC 3 or CONC 3</td>
<td>300 – 600 M/ml</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 15: SQA-V Reports

Semen Analysis Report

-----------------------------
SEMEN ANALYSIS REPORT
-----------------------------

SQA-V SN 992
S/W VER. 02.60.15
TEST DATE 15/07/13
TEST TIME 10:32
PRINT DATE 15/07/13
PRINT TIME 11:44

PATIENT DATA

ID 4
BIRTH DATE 11/11/11
ABSTINENCE 4 DAYS

SAMPLE DATA

ACCESSION #: 5
COLLECTED 12/12/11
RECEIVED 10/05/13
TYPE WASHED
VOLUME 7ml
WBC CONC. < 1/m1
PH 7
APPEARANCE NORM.
VISCOITY NORM.
LIQUEFACTION NORM.

TEST RESULTS

CONC. < 2.0/m1
TOTAL MOTILITY < 17%
MOTILITY GRADES:
PROG. < PR>
NONPROG. < NP>
IMOT. < IM>
MORPH. NORM. FORMS < 2%
WHO SWI < 0.2/m1
PMSC M/m1
FSC N/m1
VELOCITY mic/sec
SNI 3

TOTALS PER VOLUME

SPERM #: M.A.
MOBILE SPERM M.A.
PROG. SPERM M.A.
FUNC. SPERM M.A.
MORPH. NORM. SPERM M.A.

SERODI DATA

5 1.00
7 1.00
12 4
AI 1.00
17 1.2
Conc.Hd. 2

---

Service Data Report

SECRET DATA REPORT

SQA-V SN 93
S/W VER. 02.60.04
PRINT DATE 02/06/11
PRINT TIME 10:49

SELF-TEST DATA

REF. 1 370mV
LED CUR. 1 19mA
AMPLITUDE 68mV
SNI 33
ZERO LEVEL 314
REF. 2 2930mV
LED CUR. 2 35mA
CONC. 1 0.9/m1
CONC. 2 102.6/m1
CONC. 3 418.9/m1

ALGORITHM

MSE 40.6/m1
CONC. 418.9/m1
N.MORPH. 3%
VELOCITY 4mic/sec
NUMBER SPIKE 61
AREA 40.84
MOBILITY 10%
FSC 1.4/m1
AVG. WIDTH 48.26

SERVICE DATA

1. 30
2. 5
3. 150
4. 10
5. 40.84
6. 514
7. 0.000
8. 60
9. 10
10. 8
11. 120
12. 31
13. 216
14. 100
15. 1.70
16. 100
17. 3
18. 1000
19. 1
Installing the Printer Ribbon:

1. Turn off the power and open the Ribbon Cover – remove old ribbon cassette
2. Cut away any paper that is obstructing the ribbon installation area
3. Confirm that the new ribbon cassette is placed in the correct way (see below)
4. Insert the new ribbon between the printing head and the platen – press the cassette down from the knob side
5. Remove the ribbon slack by turning the ribbon in the correct direction to tighten it

PLEASE NOTE:
- Use only M.E.S. supplied ribbons
- Do not print if there is no ribbon in the holder
- Ribbons will dry out if sitting for a long time in the printer

Installing Printer Paper:

1. Open the front cover to expose the paper holder and roller
2. Cut the edge of the paper as shown below
3. Insert the paper into the printer mechanism as shown below. The paper will automatically advance OR press the FEED SWITCH to advance the paper (advance one line at a time by pressing once; press and hold to feed continuously)
4. Load the paper roll into the brackets – make sure the paper roll is feeding paper in the correct direction – see example below.

PLEASE NOTE:
- Load the paper in the direction shown above
- Use only M.E.S. supplied paper – standard rolls are too large for this printer and will damage it
- Do not print when there is no paper or during loading
- Do not pull on the paper in the reverse direction
- Paper will jam if fed diagonally or incorrectly, in this case turn the printer OFF and gently pull the paper in the right direction
Medical Electronic Systems ("MES") warrants that the Sperm Quality Analyzer will be free from defects in workmanship and materials for a period of twelve (12) months from date of purchase. During the warranty period, if the device is shown to MES's reasonable satisfaction to be defective, MES shall, at its option, repair such a device without charge for parts or labor. The foregoing remedy shall be purchaser’s sole and exclusive remedy under this warranty. In the event (i) purchaser makes any modifications or alterations to the SQA/QwikCheck GOLD or (ii) the SQA/QwikCheck GOLD is used, operated, opened or serviced other than as directed by MES or is damaged as a result of use, careless transportation (not in its original box, or within the allowed temperature range, operation or servicing other than as directed by MES, the foregoing warranties shall be void and of no further force or effect. EXCEPT FOR THE FOREGOING WARRANTIES, THE PRODUCTS ARE SOLD AS-IS AND WITHOUT ANY OTHER WARRANTY OF ANY NATURE WHATSOEVER. MES HAS NOT MADE AND DOES NOT MAKE ANY OTHER REPRESENTATION, WARRANTY, GUARANTY, OR COVENANT, EXPRESS OR IMPLIED, WITH RESPECT TO THE DESIGN, CONDITION, DURABILITY, SUITABILITY, FITNESS FOR USE, FITNESS FOR A PARTICULAR PURPOSE, OR MERCHANTABILITY OF THE SQA IN ANY RESPECT. UNDER NO CIRCUMSTANCES AND IN NO EVENT, WHETHER AS A RESULT OF BREACH OF CONTRACT OR WARRANTY, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, INCLUDING BUT NOT LIMITED TO INACCURATE RESULTS OR OPERATOR ERROR, SHALL MES BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL MES'S LIABILITY WITH RESPECT TO THE PRODUCT EXCEED THE PURCHASE PRICE FOR SUCH PRODUCT.

Extended service contracts are available for purchase.
Please contact the dealer or supplier for information.

Serial Number: __________________________ Date Purchased: ________________
Dealer: ________________________________ Dealer Phone#: __________________
Purchaser: ____________________________ Purchaser Phone #: __________________
APPENDIX 18: Product Performance Data

Abbreviations:
- TSC: Sperm Concentration (Count)
- MSC: Motile Sperm Concentration
- PMSC: Progressive Motile Sperm Concentration
- OD: Optical Density
- Morph Norm Forms: Morphologically Normal Forms
- MV: Millivolt

Performance Data Summary

The performance of the SQA-V is summarized in the text, tables and graphs below. All values concerning sperm concentration measurements are expressed as $x10^6$ 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.

Calibration:

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

Dynamic Range:

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Test Mode</th>
<th>Sperm Conc. M/ml</th>
<th>Motility %</th>
<th>Morph %</th>
<th>MSC M/ml</th>
<th>PMSC M/ml</th>
<th>#Sperm Cells/field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh</td>
<td>Normal</td>
<td>2-400</td>
<td>0-100</td>
<td>0-100</td>
<td>.2-400</td>
<td>0-400</td>
<td>-</td>
</tr>
<tr>
<td>Washed</td>
<td>Normal</td>
<td>2-200+</td>
<td>0-100</td>
<td>0-100</td>
<td>.2-200+</td>
<td>0-200+</td>
<td>-</td>
</tr>
<tr>
<td>Frozen</td>
<td>Normal</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>.2-200+</td>
<td>0-200+</td>
<td>-</td>
</tr>
<tr>
<td>Post-Vasectomy</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0-2</td>
<td>-</td>
<td>0-30</td>
</tr>
</tbody>
</table>

Precision and Accuracy Established Against a Known Target (Latex beads)

**Background**: The precision and accuracy of the SQA-V was compared to a known target value using latex beads (Accu-beads®).

Latex beads are used as a quality control product to validate the accuracy of sperm counting methods for two known levels of concentration. In accordance with CLIA regulations such a control is used to demonstrate operator proficiency using the microscope and for validation of automated sperm counting methods. The latex beads were run in the SQA-V in the same manner semen samples are run on the system.

**Limitations of method**:

- Measure sperm motility or morphology
- Correct for inaccurate chamber depths or technician errors

**Method comparison**:

A total of 320 latex bead samples were tested on ten SQA-V systems (32 samples/SQA-V). SQA-V concentration readings were compared to established target values +/- acceptable range.

**Latex beads established target values +/- ranges (Hemacytometer)**:

- Vial #1: 47 +/- 7.0 M/ml
- Vial #2: 24 +/- 3.4 M/ml
Precision and accuracy established in clinical trials using human semen samples

Clinical claims:

Specificity
Concentration: 85%
Motility: 80%
Morph. Norm Forms (WHO 3rd): 65%
Morph. Norm Forms (WHO 4th): 60%
Postvasectomy: 90% of motile cells detected

Sensitivity
Concentration: 90%
Motility: 85%
Morph. Norm Forms (WHO 3rd): 85%
Morph. Norm Forms (WHO 4th): 65%
Morph. Norm Forms (WHO 5th): 90%

Correlation to Manual Method
Concentration: 0.9
Motility: 0.85
Morph. Norm Forms (WHO 3rd): 0.65
Morph. Norm Forms (WHO 4th): 0.45
Morph. Norm Forms (WHO 5th): 0.45

Linearity
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 $\leq 20\%$.

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

Background: The SQA-V concentration, motility and morphology readings were compared to standard microscopic results based on WHO 3rd, 4th and 5th standards and MES protocols. Four independent clinical trials were conducted at MES lab, Tel Hashomer andrology dept and Ramat Marpe lab (Israel) and ART laboratory, University Hospital of Nantes (France). 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. Among them, 246 semen samples were tested at University Hospital of Nantes.

<table>
<thead>
<tr>
<th>#Samples</th>
<th>Fresh</th>
<th>Washed</th>
<th>Frozen</th>
<th>High Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;750</td>
<td>&gt;300</td>
<td>42</td>
<td>30</td>
<td>&gt;350</td>
</tr>
</tbody>
</table>

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 $>0.7$ml for fully automated tests.
- 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-V visualization system may be affected by the subjectivity of the operator.
- Dynamic range limitation as stated above.

Table 1: Sensitivity/Specificity

<table>
<thead>
<tr>
<th>Parameters</th>
<th>SQA-V vs. Microscope</th>
<th>Trial #1</th>
<th>Trial #2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
<td></td>
</tr>
<tr>
<td>Concentration</td>
<td>100%</td>
<td>95%</td>
<td></td>
</tr>
<tr>
<td>Motility</td>
<td>97%</td>
<td>85%</td>
<td></td>
</tr>
<tr>
<td>Morph Norm Forms (WHO 3rd)</td>
<td>94%</td>
<td>75%</td>
<td></td>
</tr>
</tbody>
</table>

Trial #3: High Sensitivity (Postvasectomy - see table #5)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Trial #4 (ART laboratory, University Hospital of Nantes, France):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SQA-V vs. Microscope</td>
</tr>
<tr>
<td>Morph Norm Forms (WHO 5th)</td>
<td>92.5</td>
</tr>
</tbody>
</table>

Table 2: Correlation to Manual Method

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Correlation Coefficients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trial #1</td>
</tr>
<tr>
<td>Sperm Concentration</td>
<td>0.93</td>
</tr>
<tr>
<td>Motility</td>
<td>0.86</td>
</tr>
<tr>
<td>Morphology WHO 3rd</td>
<td>0.66</td>
</tr>
<tr>
<td>Morphology WHO 4th / 5th</td>
<td>-</td>
</tr>
<tr>
<td>MSC</td>
<td>-</td>
</tr>
</tbody>
</table>

* Correlation is low due to narrow dynamic range of this parameter per strict criteria and manual analysis subjectivity.
Method comparison:

SQA-V was compared to the microscope based on WHO 3rd (Trial #1), 4th (Trial #2) and WHO 5th (Trial #4) guidelines. **Sensitivity and Specificity** were calculated using ROC curves with the cutoffs based on the reference values of WHO 3rd, 4th and 5th 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 characterizing precision were calculated for multiple semen parameters.

The **POSTVASECTOMY** test (Trial #3) compared three assessment methods:
- Microscope (standard slide: X400; 10 fields of view)
- SQA-V (SQA-V + SQA-V visualization)
- SQA-V visualization system (see table #2).

Immotile cells were analyzed by use of the SQA-V visualization system.

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)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>SQA-V CV%</th>
<th>Microscope CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sperm Concentration</td>
<td>Entire Range</td>
<td>3.1</td>
<td>6.1</td>
</tr>
<tr>
<td></td>
<td>5-40</td>
<td>5.2</td>
<td>5.9</td>
</tr>
<tr>
<td></td>
<td>41-80</td>
<td>2.1</td>
<td>5.5</td>
</tr>
<tr>
<td></td>
<td>&gt;80</td>
<td>2.5</td>
<td>3.2</td>
</tr>
<tr>
<td>Motility</td>
<td>Entire Range</td>
<td>5.1</td>
<td>7.2</td>
</tr>
<tr>
<td></td>
<td>10-50</td>
<td>7.6</td>
<td>10.3</td>
</tr>
<tr>
<td></td>
<td>51-55</td>
<td>1.5</td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>&gt;55</td>
<td>6.0</td>
<td>4.1</td>
</tr>
</tbody>
</table>

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

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

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.

Table #5: Percentage Motile Cells Detected: Trial #3

<table>
<thead>
<tr>
<th>Method Comparison of 218 Samples with Motile Cells</th>
<th># Samples Motile Sperm Detected</th>
<th>% Samples Motile Sperm Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st clinical trial - Motility correlation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd clinical trial - Motility correlation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd clinical trial - Motility correlation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4th clinical trial - Sperm Concentration correlation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 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.

## Results:
1. 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).
2. Averaged coefficient of variation CV of measured vs. expected sperm concentration was 10%.
V-Sperm Gold

USER GUIDE

Version 3.60
I-Button
WHO 5th

Catalog # V-A-00733-00

April 2016
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SECTION 1: Overview

Features and Benefits

- Import patient and control data from the SQA-V in a large archive.
- Import test results on-line.
- Attach a sperm image to a consolidated semen analysis report.
- View semen samples in "real time" on a PC screen.
- Attach video clips of semen samples to patient’s records.
- Edit patient files and track changes with built-in traceability feature.
- Save, view and graph PATIENT and CONTROL test results.
- Set-up SQA-V system defaults.
- Customize reports by language, test range, test descriptions.
- Access V-Sperm via person/password security.

V-Sperm package includes the following:

- User Guide
- Installation CD
- V-Sperm Security device
- RCA video cable

System Requirements

- SQA-V with communication cable and power cable

PC / Hardware Requirements

Minimum requirements for V-Sperm software

- **PC:** Intel Core 15 M520 2.4GHz or equivalent
- **RAM:** 4GB
- **Video card:** 3D to support high resolutions 16:10 – 1440X900
- **Video color:** At least 16 bit (65,535)
- **CD ROM drive**
- **300GB free hard disk space** for image capturing (approx. 3000 clips)
- **Monitor Screen:** Color, Wide screen – should support resolution 16:10 or 16:9 (1440X900)
- **Operating system compatibility:** Windows XP and 7; Excel/Word (required for V-Sperm GOLD)
- **Communication Ports:** Two FREE native RS232 USB; two USB ports
- **EXCEL and WORD required for export function and printing test reports**
SECTION 2: Log-on
After successfully installing V-Sperm, an icon will appear on the desktop of the computer. To start the program:

- Double click the V-SPERM icon

Enter the system from the log-on screen by typing in:

- User Name: administrator
- Password: fertility
- Click OK

SECTION 3: Navigating through V-Sperm

- Nine navigation buttons reside in the left margin of the V-Sperm screen. To navigate through the system, click on one of the buttons.
- When a navigation button is selected, sub-menu buttons appear across the top of the screen making it easy to access the features of the program.
- A variety of icons guide the user through V-Sperm features and options. Directional indicator buttons allow the user to easily move back to the previous menu.

SECTION 4: Patient Data

Locating, Selecting and Authorizing Records

Click the Patient Data button and three options will appear: Patient List, Search by Patient and Authorization List.

- Patient List – a complete list of all the patient records in the database.
  - Click on the COLUMN TITLES to sort the records by Patient ID, Name, Test date, etc.
  - Select a record by clicking on the ARROW pointing to the record.

NOTE: Each V-Sperm user can be set-up with a unique user name and password - please see the Set-up section of this User Guide.

NOTE: Before using V-Sperm, the system defaults must be set-up. See the Set-up section of this guide for instructions on how to do this.

NOTE: Records must be imported from the SQA-V in order to locate them in V-Sperm.

To select a record, click this icon.
PATIENT DATA > PATIENT LIST > then select a patient record to view the:

**PATIENT DATA SCREEN**

- The **Patient Data Screen** will now appear and display all of the test records for the selected patient.
- The title bar above each test displays the sample number and icons indicating various attachments to the file such as pictures and videos.
- A graph icon is display to the right of the list of test parameters.

A number of functions can be performed from this screen:

**Enter Patient Name:**

- From the **Patient Data Screen**, click on the field for First Name, Last Name and type-in the information.
- Click: **Apply** to save.

**Attach Video/Picture to a Test Record**

- Insert a slide or testing capillary into the visualization system of the SQA-V.
- From the patient data screen, select the record (there could be multiple records for the same patient) by clicking the record **TITLE** bar to mark the test column.
- Click the **PREVIEW VIDEO** button to view the live specimen.
- Click **CAPTURE PICTURE** to attach a still image to the patient record.
- Click **CAPTURE VIDEO** to attach a live video to the patient record.
- A timer will indicate the recording time.
- Click the **STOP CAPTURING** button to stop the process.
- A message will indicate Video Saved.
- Click OK to end.

**Graph Semen Parameters:**

- Graphs can be run if a patient has more than one semen analysis record on file.
- From the **Patient Data Screen**, click the graph icon to the left of the semen analysis parameter. A graph will display the test results history for the selected parameter.
Enter Data: Patient Data>Patient List>Enter Data

Select a test record before clicking the enter data button. Please note that there can be more than one test per patient in the data base.

- Click the **Enter Data** button to input manual test results and add comments to the semen analysis record.
- Type-in the desired information – only editable fields will allow entries.
- All manual entries are tracked via a traceability function.
- Click the **Traceability** button at the bottom of this screen to run a **Traceability Report**.

Test Report Patient Data>Patient List>Test Report

The test report contains test results imported from the SQA-V AND manual data that is entered by the user.

Click the **Test Report** button to view and print the two-page semen analysis report (from the patient data screen).

- To move between pages, use the page bar at the bottom of the screen.
- Click the printer icon to print a report.
- Use the **ZOOM** to minimize/maximize the view of the report.
- Click the **X** in the upper right hand corner of the screen to exit the report.
- A yellow arrow will be displayed if the test results are out of range.
- Click the **FILE EXPORT** icon to export the report to a .doc file. Enter the path and file name; then click **SAVE**.
**View/Attach Images: Patient Data > Patient List > View/Attach Images**

- To view an image: From the Patient Data Screen select a test record with a video/camera icon displayed in the title bar.
- Click the View/Attach Images button.
- An Image Browser will display all the images attached to the selected patient’s record.
- Select an image and it will be displayed in the preview pane.
- Click on the image to enlarge it.
- Click the SAVE AS button to save the picture to an external file on your PC.
- To attach an image (not video) to a semen analysis report, click on the report icon column in the row of the picture to be attached.
- A report icon will now appear in the column indicating that the picture is attached to the semen analysis report.
- To delete an image from the report, click on it and the report icon will disappear from the corresponding row.

**Authorize:** See “Authorizing Test Results” for single tests below.

**Search by Patient** – use this option to locate records by patient name or ID number.

- Enter the first or last name or ID number of the patient and click SELECT.
- The PATIENT DATA SCREEN will appear.

**Authorizing Test Results:**

- Click on the REPORT icon to view a record before authorizing it.
- **Single Tests:** Click on the √ column to the left of the record to be authorized.
- Click the Authorize button.
- The record will be deleted from the authorization list.
- **Group Authorization:** Refer to the section: Patient Data: Locating, Selecting and Authorizing Records.
Delete Records
To delete Patient Records, Test Records or images in V-Sperm: Highlight the patient record, test record, or image and use the delete key on the PC keyboard.

SECTION 5: Controls
SQA-V Control Archive:
Control test results should be imported from the SQA-V online (See Import Test section).

Running a Control Test Report:
- Click the CONTROLS navigation button.
- From the Controls screen select:
  - Control Media – Latex Beads or Stabilized Sperm CAP or MES
  - Control Level – Level 1, 2 or Negative Control
  - Date Range
- Click the RUN REPORT button to display a list of Control Test Results based on the selected parameters.
- Click on the columns to sort data.
- Tests that are out of range will be noted.
- Select a corrective action for tests out of range by clicking on the appropriate “cell” in the “Corrective Action” column.
- A menu of corrective actions will be displayed. Select the appropriate corrective action.
- Click the TEST REPORT button to view the report.

Control Test Report
- Use the PAGE BAR to move between pages (if necessary).
- Use the ZOOM function to maximize/minimize the report.
SECTION 6: Video

Click on the VIDEO navigation button to view semen samples "live" from the SQA-V visualization system and to determine the video settings.

- **Real Time Video** – activates the video so samples can be viewed. Double click the mouse to maximize the image to full screen. Double click the mouse to return to normal size.
- **Video Settings** – select grid line width and color, video device, etc. (Note: video size is locked).

Click **REAL TIME VIDEO** and six options are available:

- **Freeze** – Use this option to make cell counting easier.
- **Grid** – Use this option to display or remove the grid. The displayed grid is exactly the SAME as the SQA-V grid. 20 squares are displayed for ease of counting. If the ZOOM on the SQA-V is set to X300 each sperm cell visualized in the entire screen = 1M/ml.
- **Copy** – Copy a picture and paste it to another application (such as Word).
- **Settings** – Displays the video capture device settings.
- **Save Video** – Captures and saves a video clip to an external file.
- **Save Picture** – Captures and saves a picture to an external file.

SECTION 7: Import Test; Import/Export from the SQA-V

Importing SQA-V test results to V-Sperm

Patient test results and Control test results can be imported individually from the SQA-V to V-Sperm by clicking the **Import Test** button directly after running the test. Patient test results can also be imported in batches (Import/Export) from the SQA-V to V-Sperm when the SQA-V and V-Sperm software are running:

**Import a single test:**

- After running a patient test a message will be displayed on the SQA-V a screen instructing the user: **TO TRANSFER TEST RESULTS TO V-SPERM: PRESS IMPORT TEST BUTTON IN V-SPERM.**
- After running a Control test the following message will appear on the SQA-V instructing the user: **ATTENTION! TO AVOID LOSS OF DATA TRANSFER CONTROL RESULTS TO V-SPERM. PRESS: "IMPORT TEST" BUTTON IN V-SPERM.**

**Import the SQA-V archive (batches) of tests:**

- The **SERVICE DATA** screen of the SQA-V must be displayed. this screen go to: **MAIN MENU>SERVICE>SERVICE DATA.**
- From the **V-Sperm** main screen select: **IMPORT/EXPORT>IMPORT DATA.**
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SECTION 7: Import SQA-V Archive

- Click **CONTINUE** on the opened V-Sperm Import SQA-V Archive screen.
- Select **YES** or **NO** to delete the SQA-V archive once the tests have been imported to V-Sperm.

Exporting the SQA-V data:

The Export data option allows the user to export the Patient data archive and the Controls archive to an external file (Excel format) on the PC:

- Click the **IMPORT/EXPORT** navigation button of the V-Sperm.
- Select **EXPORT DATA**.
- Select **EXPORT ARCHIVE** (Patient Data) or **EXPORT CONTROLS**.
- Enter the path and file name; then click **SAVE**.

SECTION 8: Set-Up

Click the **Set-Up** button to select the system defaults for the:

- V-Sperm:
  - Authorized Users
  - Report (Test Parameters, Normal Ranges, Testing Facility and Language)
  - Ports
  - Auto Export
- SQA-V: **SQA-V Defaults**

**V-Sperm Set-Up**

**Set-Up: Authorized Users**

Select **SET UP > V-SPERM > AUTHORIZED USERS** and the screens below will be displayed. Assign rights, passwords and enter information in the sections provided to add users. Only the administrator has the authorization to set-up passwords and new users.

<table>
<thead>
<tr>
<th>Title</th>
<th>First Name</th>
<th>Last Name</th>
<th>User Name</th>
<th>Password</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrator</td>
<td>Administrator</td>
<td>Administrator</td>
<td>Administrator</td>
<td>****</td>
</tr>
</tbody>
</table>

There are four types of users. Each type is permitted different "rights" to the system:

- **Administrator**: Has all rights, can authorize reports, set-up passwords and add new users.
- **Authorizing Signature**: Has all rights except for setting-up users/passwords.
- **Test Performed By**: Has all rights except for authorizing reports and setting-up users/passwords.
- **Ordering Physician**: Has no rights and can only view information.
• Changes can be made to Authorized User’s passwords at any time by entering a new one over the old one and clicking apply.
• Changes cannot be made to an authorized user’s "title" if a test report in the database contains their name/title.
• An authorized user cannot be deleted if a test report in the database contains their name/title.

Set-up: Report
To set-up the test report, click SET-UP > V-SPERM > REPORT.

Four option tabs will be displayed. Click one of the option tabs:

- TEST PARAMETERS
- NORMAL RANGES
- TESTING FACILITY
- LANGUAGE

Test Parameters: Set-up>V-Sperm>Report>Test Parameters
• Select the information to be viewed on the V-Sperm screens and reported on the test report.
• Click the √ column to select the test report parameters.
• Check / Uncheck “Show morphology recommendation note”
• Click Apply to enter.

Normal Ranges: Set-up>V-Sperm>Report>Normal Ranges
• To set the normal range for a test result, click the ARROW pointing to the parameter to be set.

- The Normal Range Settings screen will appear.
- Enter the desired symbol (≥, <, =, etc.).
- Enter the desired value.
- Click Apply to enter.
Testing Facility: Set-up>V-Sperm>Report>Testing Facility

- Enter the details of the testing facility that is to be displayed on the semen analysis report.
- Check the Show in Report box.
- Click Apply to save the changes.

Language: Set-up>V-Sperm>Report>Language

- The system default is English.
- Select “Other 1” or “Other 2” from the Language drop-down menu to enter text in another language.
- Click Apply to save the changes.

Set-up: Ports

- Select Set-up>V-Sperm>Ports to view Communication Port options.
- Select the correct port for the PC and press Apply.

Set-up: Auto Export

- Select Set-up>V-Sperm>Auto Export to view the setting options.
- Check (√) Automated Data Save, define the Tests File Path and Controls File Path and click Apply.
- Each patient test and control result will be saved online automatically to the corresponding text file.
- Two separate files for patient tests and controls will be created.
- Only the last results will be presented.
- This feature can be used to send data to another online source.
SQA-V Set-up (SQA-V version 2.60):

- In order to set-up SQA-V (patient testing and controls) defaults both the SQA-V and V-Sperm must be connected and activated:
- Activate the SERVICE DATA screen of the SQA-V by going to: MAIN MENU > SERVICE > SERVICE DATA.

- Click: SET-UP > SQA-V > CONTINUE and the screen below will be displayed. Data must be entered in all fields of the table below or the SQA-V will not accept the default settings.

**SQA-V System Default settings:**
- Date Format (DD/MM/YY) or (MM/DD/YY)
- Local date setting
- Conc./Chamber Standard 1 or 2 (See appendix section for more information)
- LES: Check with your distributor for any changes
- Printing options: automatically print test results/self test reports
- Printer type: enter thermal or ink depending on the printer on the SQA-V

**Control Set-up (from the manufacturer’s labeling):**
- Select type of control: Latex beads or Stabilized Sperm.
- Enter Lot Number for each control level (enter "0" if not known).
- Enter +/- Range for each control level (enter "0" if not known).
- Enter EXPIRATION date (use current date if EXP date is not known).

- Press the Report button to print the selected default settings.
- Press Apply to accept the default settings and transfer settings to the SQA-V.

**NOTE:** All Set-up fields must have data in order to transfer information to the SQA-V. If CONTROL settings are not known, enter "0" LOT #/Target Value/+-Range. Enter current date for the date field.

**NOTE:** The Set-up data transfer may take several minutes! Please wait.....
SECTION 9: Utilities

To view and print the SQA-V SELF TEST DATA for technical support purposes:

- Click on the UTILITIES navigation button
- Select: SELF TEST DATA
- Select: PRINT or SAVE

SECTION 10: Log-Off

LOG-OFF V-Sperm by clicking the navigation button and confirming with a click.

- A new user can immediately log-on from the screen. The V-Sperm program does not need to be shut-down when a user logs-off.

SECTION 11: Exit

To Exit – Click on the OK button.
SECTION 12: Installation of V-Sperm Software and Hardware

Overview: The Video Capture Device should be installed prior to using V-Sperm.

Step 1: Video Capture Device Installation
V-Sperm requires that the user install the video capture device provided by the manufacturer. For video capture device installation instructions, please refer to the package insert in the V-Sperm package.

Step 2: USB to RS232 driver installation
An RS232 link is required between the V-Sperm and the SQA-V. If the V-Sperm computer does not have an RS232 port an external USB to RS232 cable must be installed. For Windows 7, the drivers are installed automatically when the cable is plugged into the computer. For Windows XP, the drivers must be installed. Installation instructions are provided in Section 14 of this guide for XP operating systems.

Step 3: V-Sperm Software Installation (Refer to User Guide for PC specifications)

Step 1: Insert the V-Sperm CD into the PC CD-ROM to automatically begin installation.
Step 2: The screen will display: Initializing Wise Installation Wizard.
Step 3: Close any programs that are open or running.
Step 4: Run the installation program and click YES when finished.

Step 4: MDAC Installation
(This step is required only if the MDAC component was not already installed in the computer)

Step 1: A message will appear if MDAC (2.6 or above) is not installed on the PC.
Step 2: Click OK to install.
Step 3: Once installed, restart the computer by clicking OK when prompted.
Step 4: After re-start, click YES to proceed.

Step 5: Collecting Information

Step 1: Click NEXT when the Welcome screen is displayed.
Step 2: Click NEXT when the default directory for V-Sperm is displayed.
Step 3: Click NEXT when the default name for V-Sperm is displayed.
Step 4: Click NEXT to begin copying files.

Step 6: Installation Completion

Step 1: When all files have been copied the message: Updating System Configuration, please wait... will be displayed.
Step 2: The security device driver will be installed and the screen will indicate that this operation is in process.
Step 3: When a screen is displayed to ask if you want to restart the PC to complete the software installation, Click OK.
SQA-V Communications Cable

**Step 1:** Connect one end of the RS232 communication cable to the PC (Refer to picture: Communication Cable Connect Ver. 1 image) or to the USB to RS232 convertor (Refer to picture: Communication Cable Connect Ver. 2).

**Step 2:** Connect the other end of the RS232 communications cable to the SQA-V as shown in the same Ver. 2 picture.

**Video Capture Device Settings**

**Step 1:** Log into V-Sperm
- User Name - administrator
- Password - fertility

**Step 2:** Go to: Video > Video Settings and this screen will appear

**Step 3:** Select these settings:
- Video compression: DivX MPEG-4 Video Codec
- Video device – WDM
- Video input – Composite
- Video size and subtype – 640 x 480
- Analog Video – PAL B

**Step 4:** Press: Apply, to save the changes.

**Step 5:** Place a slide/sample in the SQA-V and select the VIDEO function in V-Sperm to test if the device is functioning properly.

**Step 6:** Adjust the Video Settings to the optimal values
- From the V-Sperm GOLD main navigation screen select Video > Real Time Video > Settings, and go to the "Video Proc Amp" tab.
- The optimal settings are:
  - Brightness: 50
  - Contrast: 60
  - Saturation: 0

- Please note: The values of the "Brightness" and "Contrast" parameters can be slightly adjusted by the user is order to fit the preferences of every individual.

**V-Sperm Settings Configuration**

**Step 1:** From the SQA-V MAIN MENU select: SERVICE and press ENTER.

**Step 2:** From the V-Sperm GOLD main navigation screen select SET-UP > SQA-V > SQA-V Defaults.
Step 3: Press: **CONTINUE** to view the screen below:

- Select the SQA-V Default settings by clicking on the desired preferences:
  - Date Format: Europe (DD/MM/YY) or USA (MM/DD/YY)
  - Local date setting
  - Morphology Criteria (WHO 3rd or WHO 4th Strict) for version 2.60/3.60 only WHO 5th is available.
  - Conc./Chamber Standard 1 or 2 (See the Appendix of the SQA-V User Guide for detailed information)
  - Printing options: automatically print test results/self test report on start-up.
- Control Set-up (from the manufacturer's labeling):
  - Select type of control: Latex beads or Stabilized Sperm CAP or MES depending on what controls will be run routinely (for proficiency testing, other options can be selected just to run those samples).
  - Enter Lot Number for each control level (enter “0” if not known).
  - Enter EXPIRATION date (use current date if EXP date is not know).
  - Enter +/- Range for each control level (enter “0” if not known).
  - Press: **APPLY** to transfer the settings to the SQA-V (may take 2 minutes).

**SECTION 13: V-Sperm Uninstall**

**STEP 1:** From the desktop of the PC select: **START > PROGRAMS > V-SPERM > UNINSTALL.**

**Step 2:** A message will be displayed: **Initializing Wise Uninstall Wizard...**

**Step 3:** Select **AUTOMATIC** when the screen asks for an uninstall method.

**Step 4:** Click **NEXT** to continue.

**Step 5:** Click **FINISH** when the next screen notes the uninstall has been completed.

**Step 6:** Select **YES TO ALL** if a message asks to remove shared components.

**Step 7:** Uninstall will remove files and close automatically when finished.
SECTION 14: Installation Instructions: USB to RS232 Converter

General Description

The USB to RS232 device provides the connection between the SQA-V and V-Sperm required to import test results which then can be viewed and analyzed from the V-Sperm PC. In order to properly install the USB to RS232 device, please follow the instructions below.

PLEASE NOTE: These instructions are for Windows XP users only. In Windows 7 the appropriate driver is automatically installed.

USB to RS232 Device Driver Installation

1. Close all open programs.
2. Insert the USB to RS232 FTDI Drivers CD into the PC CD-ROM.
3. From the PC click: START > RUN and type in: X:\Win200-XP-Vista\CDM 2.04.06.exe (X = letter of PC CD-ROM drive)
4. Wait a few seconds until the installation process is completed (the DOS window displayed below will disappear)
5. Plug-in the USB cable of the USB to RS232 device into a USB port on the PC.

Verifying Proper Installation

1. Click on START > RUN
2. Type: devmgmt.msc and click ENTER in order to open the Device Manager.
3. Verify that the driver is installed (check to see the driver in the red boxed area displayed above).