USER GUIDE

Version 2.48 I-Button

Catalog # 5139

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SECTION 1: System Specifications and Requirements

Specifications

SQA-V Gold
Version 2.48

Dimensions: 40 x 30 x 15 cm
Weight: 4 kg
AC power supply: 100 to 250 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 3rd
Chamber standard: 1
Printing Options: Automatic
CONTROLS:
Control Media: Latex Beads
(Lot #, Target Values, +/- Ranges should be set up by the user before running controls)

Front Panel

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

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 spectophotometry channels
- **Detector system** - two photo detectors - Motility and Optical Density

Operating System

- **Analysis Time:** Normal Test – 75 seconds; Low Quality – 2 minutes; Postvasectomy – 5 minutes.

- **Software:** Resides on flash memory and drives all man-machine interface functions, runs algorithms for test measurements (according to WHO 4TH guidelines), 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 (1 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 with fuse-holder (fuse 250V, 1A)
- Video connector
- RS232 cable 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

Requirements

Maintenance Schedule

- **Daily:** Clean measurement compartment daily when running samples and after every 10-15 tests and/or for ANY spillage. Follow manufacturer's cleaning instructions using manufacturer cleaning kit. (Refer to the appendix section "Cleaning the Capillary/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 when testing. The SQA-V is calibrated to conduct tests at room temperature: 22-26ºC (68-79ºF).
- Semen is considered a biologically hazardous material and is subject to individual laboratory protocols for handling such materials.

Operating Temperature

- Operates in a wide range of ambient temperatures (15-38°C) however the system is calibrated to measure semen samples at room temperature: 22-26°C (68-79°F). Note: Extreme ambient temperature may impact the accuracy of motility test results because of the known effect of temperature on human semen
- System is fully operational at up to 80% humidity.

PC / Hardware Requirements

Minimum requirements for V-Sperm software

- **PC:** 1 GHz processor, Pentium 3
- **RAM:** 256 MB
- **AGP-video display card** with at least 16 MB of RAM memory
- **Video color**: At least 16 bit (65,535)
- **CD ROM drive**
- **2 GB free hard disk space** for image capturing (approx. 3000 clips)
- **Video resolution:** Minimum 640 x 480
- **Operating system compatibility:** Windows XP and VISTA; Excel/Word (required for V-Sperm GOLD)
- **Ports:** One serial; two USB ports
- **Monitor:** 15" color

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 non-assayed: Latex beads or stabilized sperm for concentration and negative control for motility/concentration. Assayed control: **"QwikCheck™-beads"** (product of Medical Electronic Systems).

Sample Testing

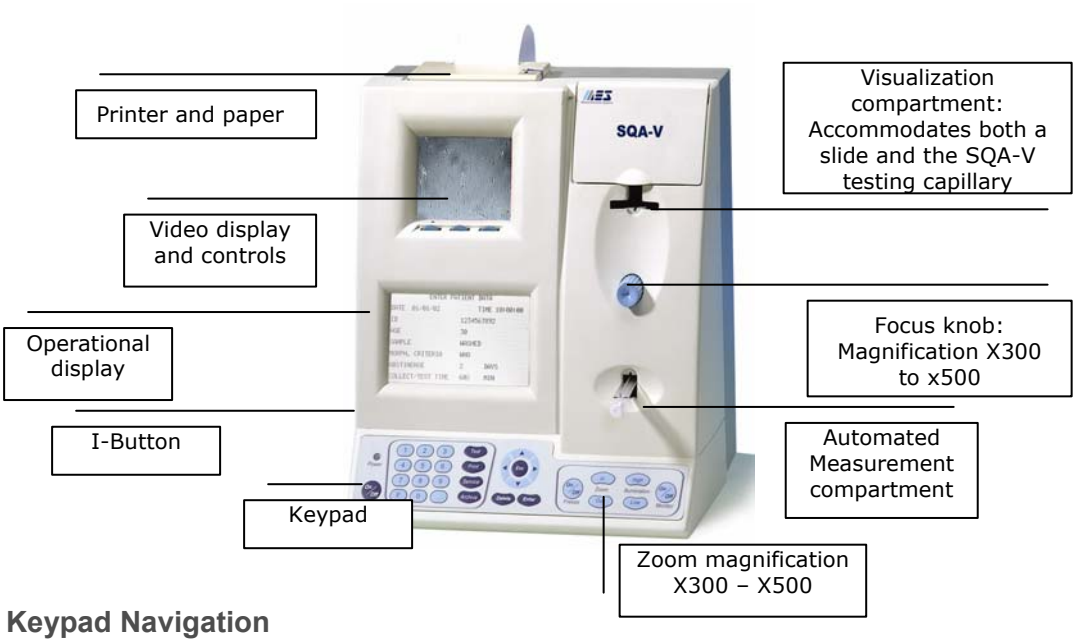
- **Sample Testing Temperature:** Calibrated for room temperature only. Motility results will be impacted by heating the specimen.
- **System calibrated to test Human semen and specified Control samples only.** Not for use with animal semen.
- **SQA-V measurement capillary:** Disposable, plastic, testing 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 (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.

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.



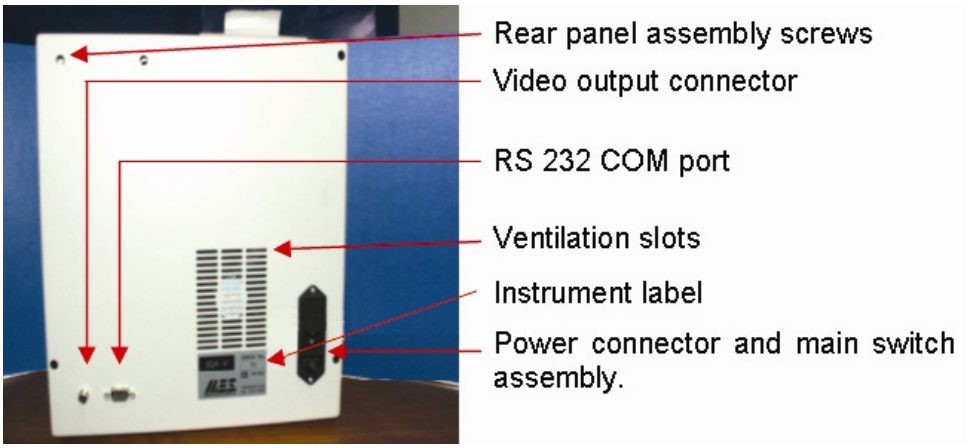
Keypad Navigation

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.

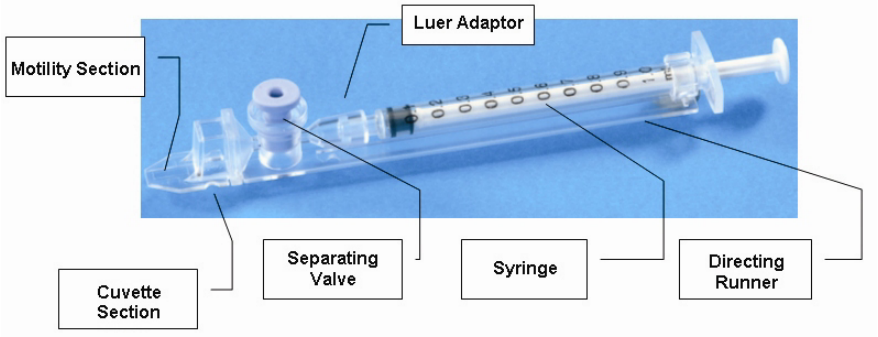
- Use **NUMERIC** keys to enter data; **ARROW** keys to move to the next field.
- Press **ENTER** to select menu options, confirm data entries and to move to the next screen or field.
- Use the **ESC** button to return to the previous screen or field.

Rear Panel



SQA-V Components

Measurement Capillary

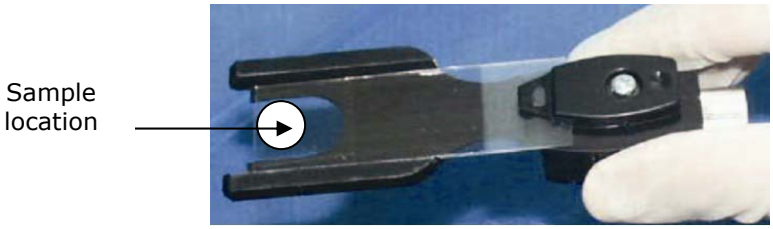


- Disposable, designed to collect and test samples in a biologically safe manner.
- Motility is measured in the 0.3 mm (thin) "Capillary Section." This section requires 20 micro liters of semen.
- Concentration is measured in the 10 mm (tall) "Cuvette Section." This section requires 450 microliters of 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

NOTE:

In order to accurately visualize the sample it must be centered approximately 12mm from the end of the glass slide.



- 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.

Semen Parameters Reported by the SQA-V

Automated Test Results

Semen Parameters with SQA-V Abbreviation in Brackets			
Sperm Concentration (SPERM CONC.)	M/ml	Motile Sperm Concentration (MSC)	M/ml
Motility (MOTILITY <a + b + c>)	%	Progressively Motile Sperm Conc (a) (PMSC <a>)	M/ml
Rapid Progressive Motility (a) (RAPID PROG. MOTILITY <a>)	%	Progressively Motile Sperm Conc (b) (PMSC <b>)	M/ml
Slow Progressive Motility (b) (SLOW PROG. MOTILITY <b>)	%	Functional Sperm Concentration: Prog. Motile Sperm w/Norm Morphology (FSC)	M/ml
Non Progressive Motility © (NON PROG. MOTILITY <c>)	%	Total Number Sperm / Ejaculate (SPERM #)	M
Immotility (d) (IMMOTILTIY <d>)	%	Total Progressive Sperm / Ejaculate (PROG. SPERM)	M
Morphology: % Normal Forms (MORPH. NORM. FORMS,WHO 3rd / 4th)	%	Total Motile Sperm / Ejaculate (MOT. SPERM)	M
Velocity (VELOCITY)	mic. /sec.	Total Functional Sperm / Ejaculate (FUNC. SPERM)	M
Postvasectomy: Motile, Immotile and Total Sperm/Scan (#SPERM/SCAN: MOTILE, IMMOTILE and TOTAL)	#	Sperm Motility Index (SMI)	#
		Postvasectomy: Motile, Immotile and Total Sperm/sample volume (#SPERM/SAMPLES VOLUME: MOTILE, IMMOTILE AND TOTAL)	M

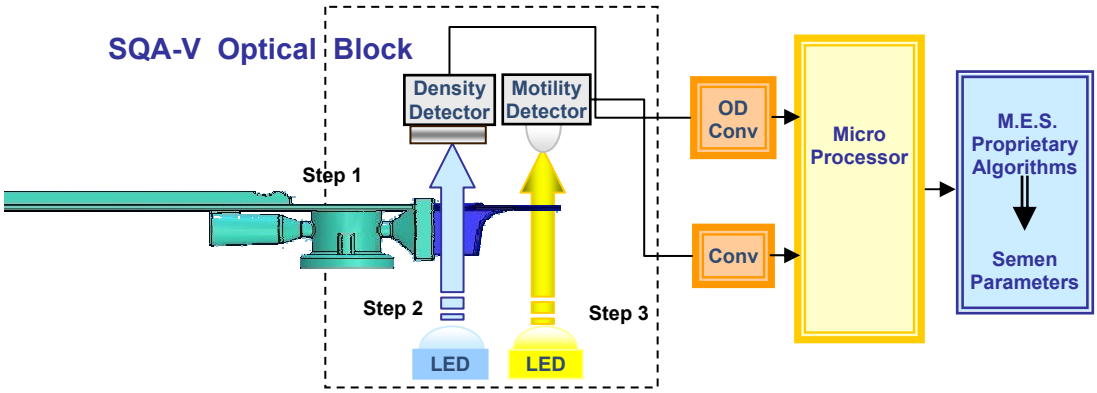
Table of the Dynamic Range of the SQA-V

Dynamic Range

DYNAMIC RANGE OF THE SQA-V Gold			
SAMPLE	**SPERM CONC in M/ml**	**MSC in M/ml**	**Motility %**
FRESH	2-400 or < 2 M/ml	0.2-400 or <0.2 M/ml	0-100%
WASHED	2-200 or < 2 M/ml	0.2-200 or <0.2 M/ml	0-100%
FROZEN	Not reported	0.2-200 or <0.2 M/ml	Not reported
POSTVASECTOMY	Manual Input	0-30 Sperm/Scan	Not reported

Technology

SECTION 3: Technology



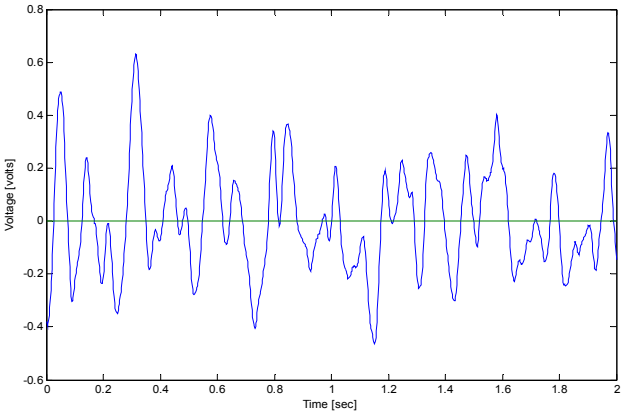
Step 1: **The capillary is inserted into the measurement compartment.**

Step 2: **Concentration:**

- Millions of sperm cells are analyzed: A very specific wavelength of light is absorbed by the sperm cells in the concentration chamber of the SQA-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

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 2.48
STANDBY POSITION

PRESS ON/OFF KEY
TO ACTIVATE THE UNIT
```

Auto-Calibration and Self-Test

```
SQA-V VERSION 2.48
PLEASE WAIT
SYSTEM STABILIZATION AND
AUTOCALIBRATION
```

NOTE:

Do not insert a capillary/slide into the device during the stabilization process.

Do not use any of the keyboard functions during stabilization.

- 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
```

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**.

SERVICE MENU

SERVICE DATA
SERVICE PERSONNEL
PRINT SQA-V DEFAULT SETTINGS
ADD I-BUTTON TESTS

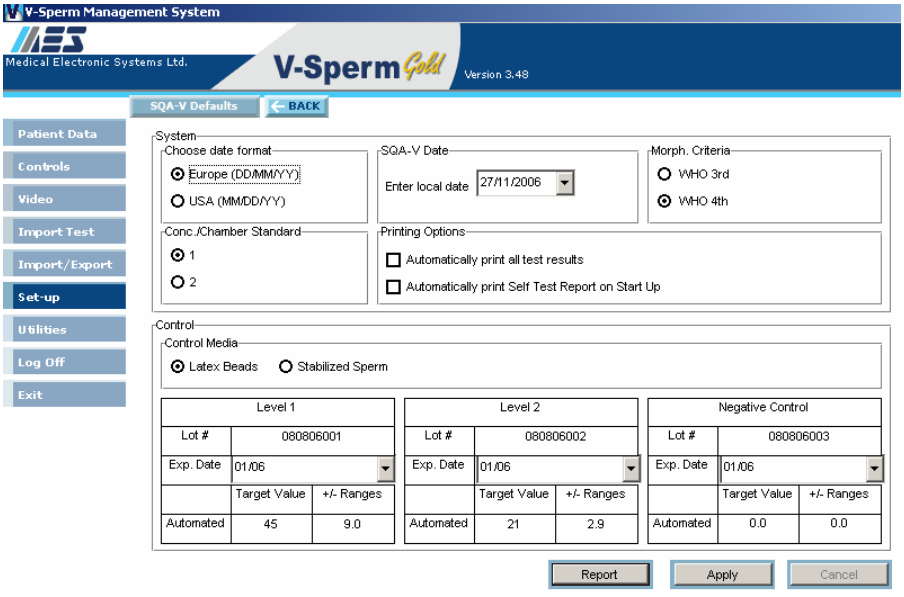
SERVICE DATA

1. 18	8. 112	15. 1.3
2. 5	9. 10	16. 110
3. 150	10. 6	17. 2
4. 28	11. 89	18. 1000
5. 77.65	12. 31	
6. 512	13. 100	
7. 0.000	14. 100	

- 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 3.48 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:

SQA-V set-up screen from V-Sperm GOLD

CONTROL set-up screen from V-Sperm GOLD



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…..

NOTE: Factory default settings are listed in **RED**.

- **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)
  - Morphology Criteria (WHO 3rd or WHO 4th Strict)
  - 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.
  - 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 not know).

- 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.

SECTION 5: Testing Semen Samples

Testing Samples

Information about the patient and sample is entered prior to the testing process. In order to accurately "classify" the semen sample by type and volume and understand the options for testing, refer to the information below.

Entering Patient and Sample Information

Patient Information

ENTER PATIENT / SAMPLE DATA
PATIENT ID: 5788114
BIRTH DATE: 01/01/85
ABSTINENCE: 4 DAYS
SAMPLE PROCESSING
SAMPLE / ACCESSION # 88
COLLECTED: DD/MM/YY HH:MM
RECEIVED: DD/MM/YY HH:MM

- 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.

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 37ºC.

Sample Information

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

```
SAMPLE TYPE
SELECT FRESH / WASHED / FROZEN / POSTVASECTOMY
VOLUME          2.5 ml
WBC CONC.       SELECT <= 1 M/ml / OR > 1 M/ml
PH              7.0
APPEARANCE      NORM./ABNORM.
LIQUEFACTION    NORM./ABNORM.
VISCOSITY       NORM./ABNORM.
```

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 1:1 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). (QwickCheck Test Strips recommended).
  - **PH** – pH of the semen sample (QwickCheck Test Strips recommended).
  - **APPEARANCE** – NORM/ABNORM visual assessment of the specimen
  - **LIQUEFACTION** – NORM/ABNORM (NORM - liquefies within 60 minutes @ room temperature).
  - **VISCOSITY** – NORM/ABNORM (See WHO 4TH guidelines).
- If **POSTVASECTOMY SAMPLE TYPE** was selected, please refer to the section "Postvasectomy Test" in this user guide.

PLEASE NOTE:

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

Sample Volume

```
IS SAMPLE VOLUME SUFFICIENT FOR
COMPLETE TESTING >= .5 ml?

YES/NO
```

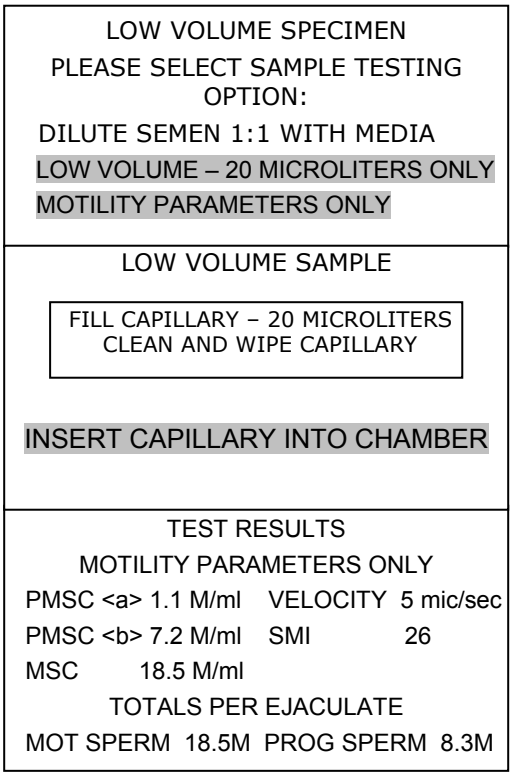
- After entering the patient and sample data, the screen above will be displayed.
- Using the left and right arrow keys and then **ENTER**, select:
  - **YES** for **NORMAL VOLUME** samples ≥0.5 ml.
  - **NO** for **LOW VOLUME** samples < 0.5 ml.

Low Volume Samples

Please note:

Prior to each running a test, the system will perform autocalibration (do not insert a capillary until instructed to do so on the screen.)

- 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 1:1 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".

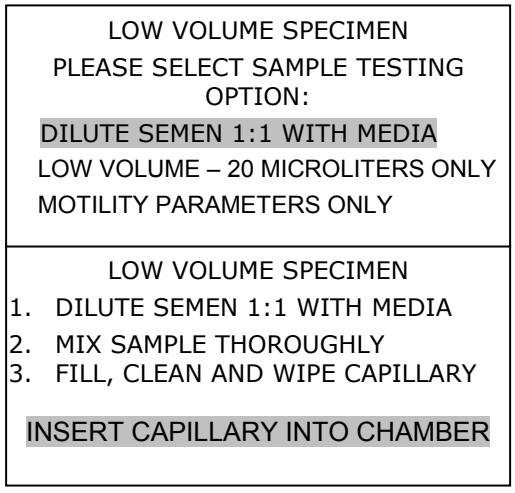


Diluted Samples

Please note:

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

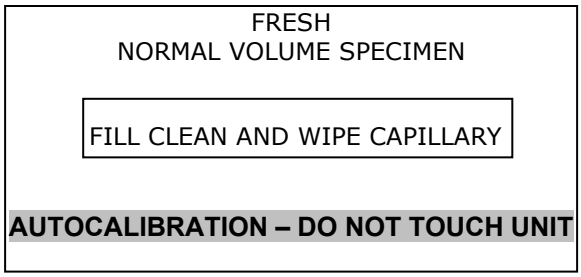
- Or the low volume sample can be diluted 1:1 with QwikCheck-Dilution media:



- 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

- 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.

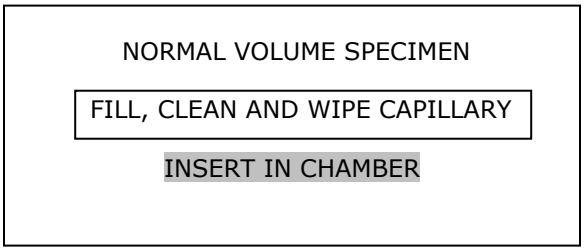
Normal Volume Samples



- 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".

PLEASE NOTE:

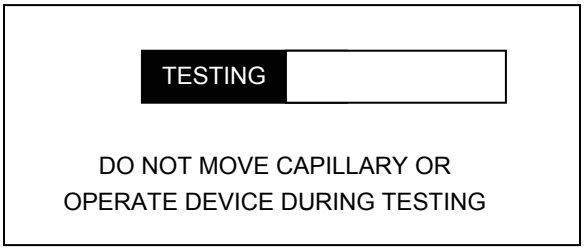
The SQA-V will begin testing when a capillary is placed into the testing chamber.

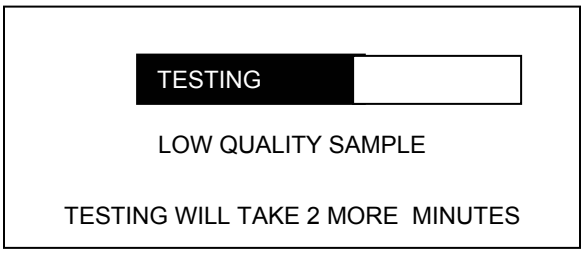


- The screen above will be displayed when it is time to INSERT the filled testing capillary in the measurement compartment, testing will begin automatically.

Testing

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





Test Results

TEST RESULTS	
SPERM CONC.	32.6 M/ml
MOTILITY <a+b+c>	28.0 %
RAPID PROG. MOTILITY <a>	5.2 %
SLOW PROG. MOTILITY <b>	14.1 %
NON PROG. MOTILITY <c>	8.7 %
IMMOTILITY <d>	72.0 %
MORPH. NORM. FORMS, WHO 3rd	20.6 %

TEST RESULTS			
MSC	9.1 M/ml	FSC	2.5 M/ml
PMSC <a>	1.7 M/ml	VELOCITY	9 mic/sec
PMSC <b>	4.6 M/ml	SMI	34
TOTALS PER EJACULATE			
SPERM #	81.5 M	MOT. SPERM	22.8 M
PROG. SPERM	15.8 M	FUNC SPERM	6.3 M

Low Quality Test Results

- Low quality sample semen parameters may be reported as < or > when one or more of the parameters falls below the SQA-V dynamic range. Only basic parameters can 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:

TEST RESULTS	
SPERM CONC.	2.7 M/ml
MOTILITY <a+b+c>	< 5 %
RAPID PROG. MOTILITY <a>	%
SLOW PROG. MOTILITY <b>	%
NONPROG. MOTILITY <c>	%
IMMOTILITY <d>	%
MORPH. NORM. FORMS, WHO 3rd	%

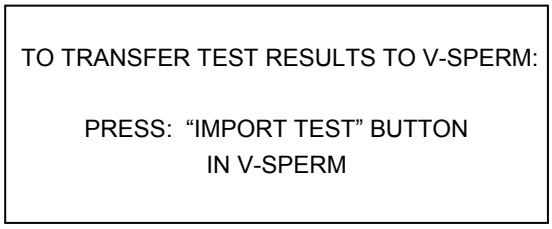
TEST RESULTS			
FSC	M/ml	MSC	< 0.2 M/ml
PMSC <a>	M/ml	VELOCITY	mic/sec
PMSC <b>	M/ml	SMI	0
TOTALS PER EJACULATE			
SPERM #	N.A.	MOT. SPERM	N.A.
PROG.SPERM	N.A.	FUNC SPERM	N.A.

- 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.

Printing Saving and Transferring Test Results to V-Sperm

- If the SQA-V default was set to automatically print/save test results, the screen below will now be activated.

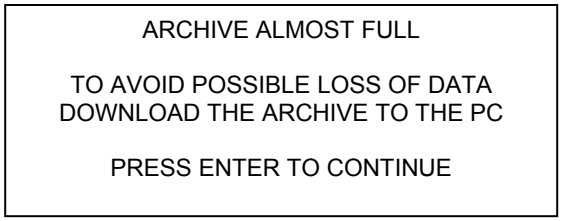
- Immediately after saving/printing test results, an option to transfer the results of the test just completed to V-Sperm is displayed on the SQA-V.
- V-Sperm Gold must be activated and the PC must be connected via the RS232 cable to the SQA-V
- Following the screen directions, simply PRESS the "Import Test" main menu navigation button in V-Sperm and the test will automatically be transferred into the V-Sperm data base.



PLEASE NOTE:

The SQA-V archive is viewed from V-Sperm only. The archive must be transferred to the V-Sperm PC in order to view, delete and edit records.

- The archive of the SQA-V can accommodate 500 Patient Test records and 750 QC tests. 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.



- To transfer the archives to the PC:
  - 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 3.48 software
  - From the V-Sperm GOLD main navigation screen select **IMPORT/EXPORT** > **IMPORT DATA** > select either **IMPORT ARCHIVE** (PATIENT RECORDS) or **IMPORT CONTROLS** (CONTROL RECORDS)
  - Press **CONTINUE** and the records will automatically be transferred.
  - After all the records have been successfully transferred to V-Sperm, select YES on the next screen to delete the SQA-V (Patient) or Control archive from the SQA-V.

Postvasectomy Test

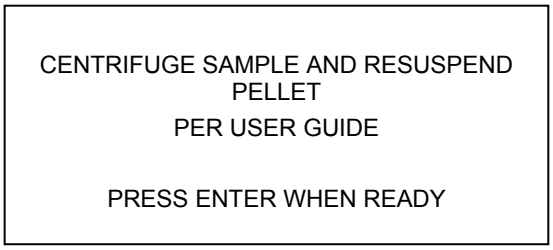
The SQA-V runs a five minute POSTVASECTOMY test that can detect the presence of a very small number of motile cells. Once the automated test has been performed, the user is given the option to follow the POSTVASECTOMY protocol outlined below and "scan" the testing capillary in the SQA-V visualization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

- There are minimal to no cells present in a POSTVASECTOMY specimen. Therefore, the specimen needs to be centrifuged and the pellet re-suspended in order to concentrate the specimen and increase the likelihood of finding cells. The screen below will instruct:

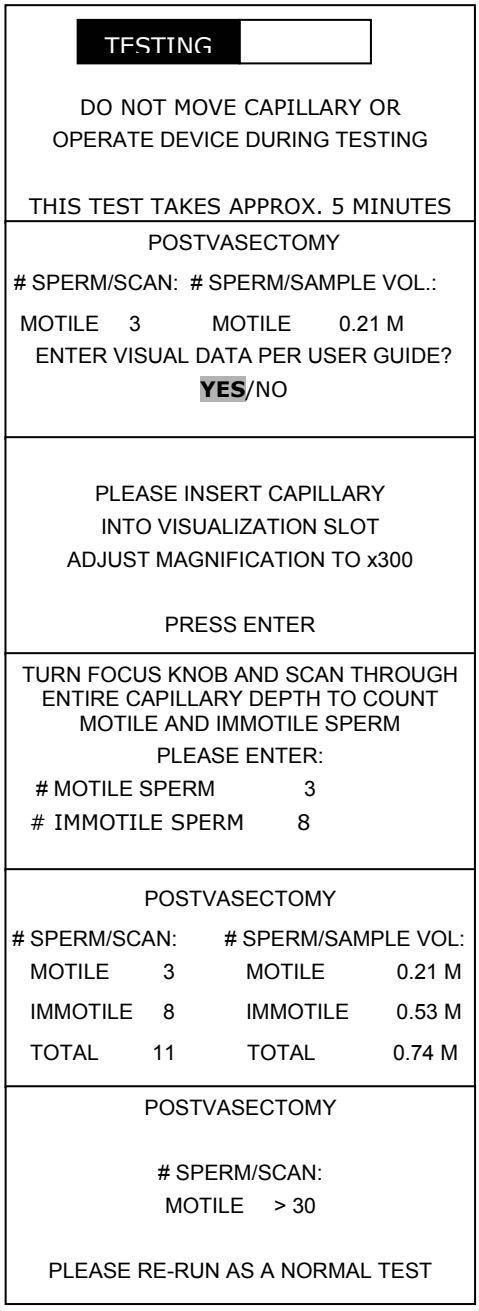


- Centrifuge the specimen at 600*g* for 15 minutes.
- Decant the supernatant and re-suspend the pellet in 0.8 ml QwikCheck dilution media, seminal plasma or other washing media.
- Fill the SQA-V testing capillary following instructions in the appendix section of this guide: "Filling the SQA-V Capillary with a Normal Volume Sample."

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.

- 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).
- 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.
- 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.



Control Set-Up and Testing

Please note:

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

Refer to section(s):

Set-up: Assayed Control and

Set-up: Non Assayed material

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 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.

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. 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 GOLD on the PC and select: **SET-UP > SQA-V** > **SQA-V Defaults** and press **CONTINUE**.

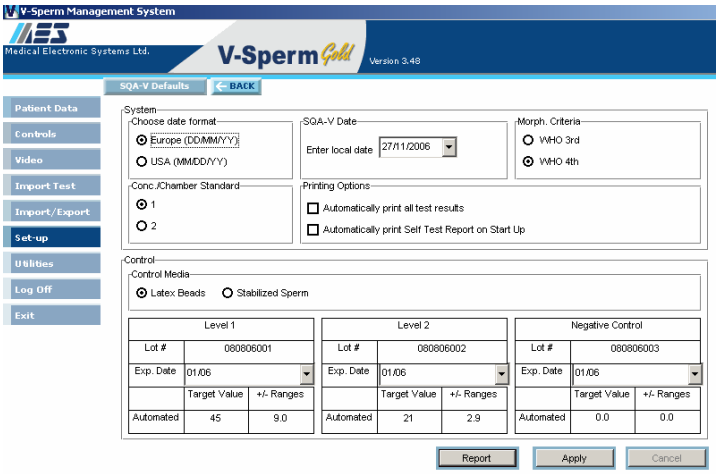
Step 4: The set-up screen below will be activated in V-Sperm GOLD on the PC:

Please note:

Level 1, 2, and NEGATIVE control set-up screen from V-Sperm GOLD.

The NEGATIVE control may also be labeled Level 3 control on the SQA-V.

For the SQA-V to work properly the CONTROLS must have set-up data inserted. If control material is not available enter current date in the EXP Date field and zeros in all other fields.



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 (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

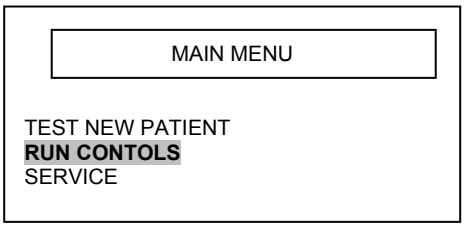
Step 8: Save settings: Press **APPLY**. The set-up takes about two minutes.

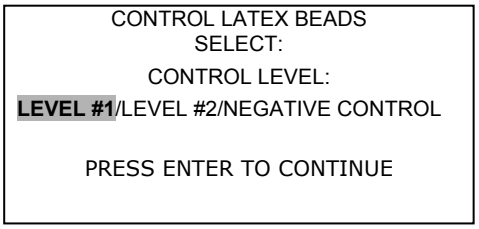
Step 9: Establish the target value and +/- range for each level:
- Fill a testing capillary and run 10 replicates following the instructions below "Control Testing."
- Calculate the mean target value. Based on laboratory protocols determine the +/- range (Example: 2SD).
- Follow steps 1-7 of "Set-Up: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

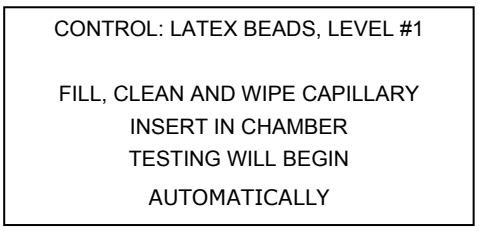
Running Controls in the SQA-V

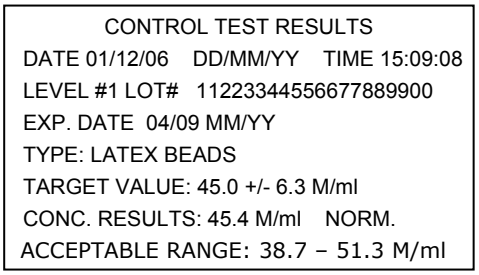
CONTROL Testing

- 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.
- 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 SQA-V DEFAULT SETTINGS>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.**

#	Parameter	S/W Ver. 2.48	SQA-V Value	Pass	Fail
1.	Ref 1	150 – 350 mV			
2.	LED Cur 1	5 – 25 mA			
3.	Amplitude	50 – 100 mV			
4.	Zero Level	500 - 525			
5.	Ref 2	2500 – 3500 mV			
6.	LED Cur 2	10 – 32 mA			
7.	CONC. 1	0 – 1 M/ml			
8.	CONC. 2	50-150 M/ml			
9.	CONC. 3	300-600 M/ml			
10.	Count (Service Data, Item #12)	26 - 36			

Archive

SECTION 7: Transferring the SQA-V Archive to V-Sperm

The SQA-V automatically saves and prints PATIENT and CONTROL test results 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 in a group. The SQA-V can store 500 patient records and 750 control records in two separate archives.

The screens below will be displayed when the PATIENT or CONTROL 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

ATTENTION:

THE CONTROL ARCHIVE IS FULL!
NO NEW RECORDS CAN BE SAVED
PLEASE TRANSFER THE ARCHIVE
TO THE PC

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 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:

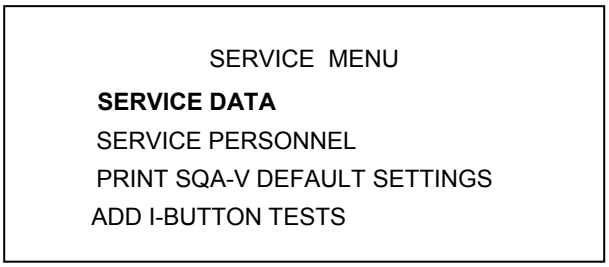
PRESS: "IMPORT TEST" BUTTON
IN V-SPERM

IMPORT PATIENT AND CONTROL ARCHIVES TO V-SPERM:

- Select the V-Sperm navigation button: **IMPORT/EXPORT**
- Select: **IMPORT DATA > IMPORT ARCHIVE** or **IMPORT CONTROLS** 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 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 Default Settings

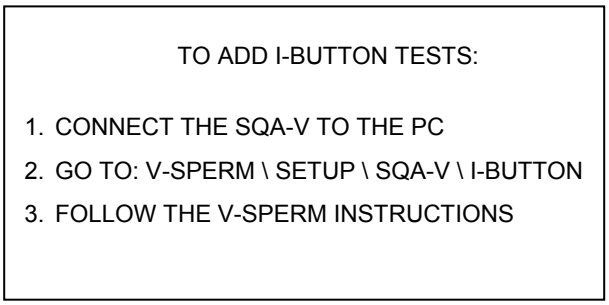
The system default settings can be printed from this option.

Please note:

I-button tests are added through the V-Sperm software.

Add I-Button Tests

Click this option to add I-button tests. Follow the instructions on the screen:



SECTION 9: Operating the Visualization System (Video Display)

Introduction

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.

Operating Instructions

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.

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.
  - Turn **BRIGHTNESS, CONTRAST** and **COLOR** buttons all the way counterclockwise.
  - Turn **FOCUS** knob fully clockwise.
  - **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.
- Turn **BRIGHTNESS** knob clockwise until the video screen just begins to lighten-up.
- Turn **FOCUS** knob counterclockwise until image is focused.
- Adjust **CONTRAST, COLOR, BRIGHTNESS, FOCUS** and object **ILLUMINATION** controls for optimal image quality.
- Use **ZOOM OUT** (x300) / **ZOOM IN** (x500) to regulate magnification.

Please note:
The visualization screen grid of the SQA-V is calibrated to a CONC STANDARD default of "1" or Makler/non-dilutional chambers.

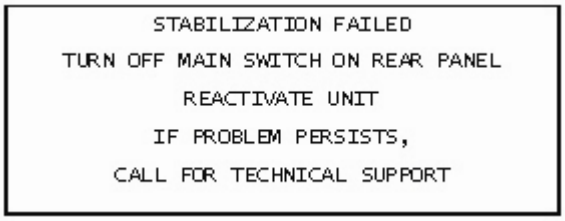
Please see the Appendix Section **"Concentration Standard – Counting Chamber"** for details

Counting Cells Using the Visualization Screen:

- Insert standard slide (10 µl sample, 22X22 mm coverslip) into the visualization compartment.
- Press **ZOOM OUT** (x300) all the way.
- Bring the image into focus.
- The screen is divided into a 20-square "grid" in order to make counting easier for the user.
- Each sperm cell seen on the ENTIRE screen represents 1 Million spermatozoa per ml.

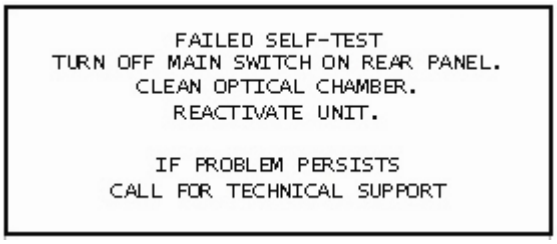
SECTION 10: Error Messages and Warning Messages

Stabilization Failed:



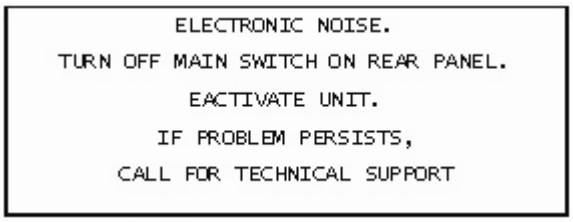
- Ensure there is no testing capillary in the measurement compartment.
- Remove the SQA-V from sources of electronic noise (cell phones, etc.) and vibrations (centrifuge).
- Clean measurement compartment (refer to Appendix).
- Reboot the SQA-V without a testing capillary in the chamber:
  - Turn system **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 (cell phones, etc.) and vibrations (centrifuge).
- 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 and 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 SQA-V DEFAULT SETTINGS>SELF TEST DATA.**
  - Press **ENTER**

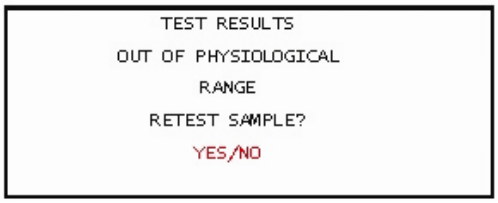
Electronic Noise:



- Ensure there is no testing capillary in the measurement compartment.
- Remove SQA-V from sources of electronic noise (cell phones, etc.) 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 and Stabilization.
- From **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 SQA-V DEFAULT SETTINGS>SELF TEST DATA.**
  - Press: **ENTER**

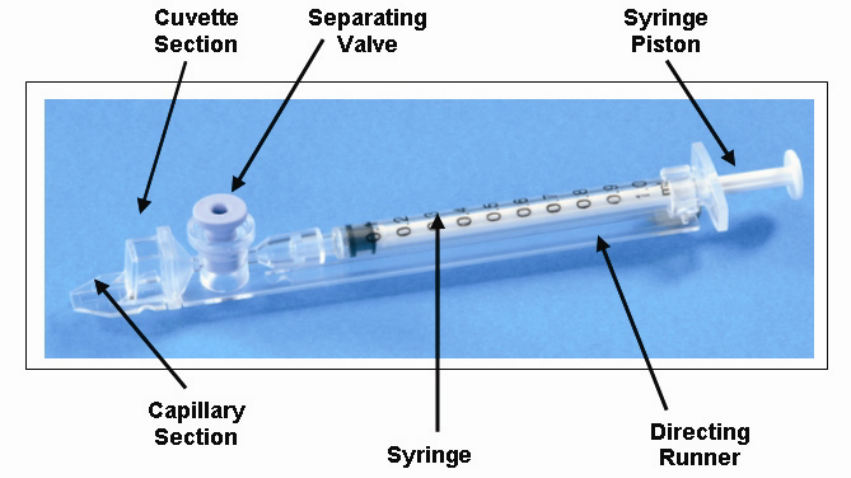
Concentration Out of Range

Testing Semen Sample:



- 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 (see 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.

APPENDIX 1: Filling the SQA-V Capillary with a Normal Volume Sample



Sample size, collection container and preparation:

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

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

Figure 1

4. **Carefully check that liquefied, fully mixed specimen is free of air bubbles** (or that there is an adequate amount of sample below the air bubbles) before immersing the capillary into the specimen, thus ensuring that no air bubbles will be aspirated into the capillary.

Filling the capillary:

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

Figure 2

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

3. Holding the capillary in a vertical position (Figure 3), **visually confirm that the sample has completely filled** the thin section (without a meniscus) and the cuvette section and appears in the Luer adaptor. **Tap on the syringe to make sure there are no air bubbles** in the sample. If, after tapping, some air bubbles appear below the Luer adaptor, dip the capillary into the semen sample again and aspirate a small quantity of semen to draw the air bubbles into the syringe.
4. Quickly (to avoid wicking) and **thoroughly wipe the outer surface of the capillary** - both top and bottom (Figure 4) with a delicate wipe (Kimwipes, etc.). It is important to remove all semen from the exterior of the capillary in order to prevent the SQA-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.

Figure 3

Figure 4

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.

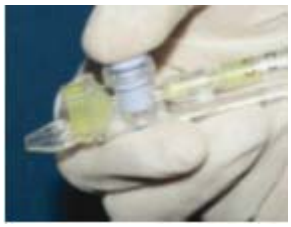


Figure 5

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.

Figure 1

Figure 2

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 (no meniscus).
3. Quickly (to avoid wicking) and **thoroughly wipe the outer surface of the capillary** - both top and bottom with a delicate wipe (Kimwipes, etc.). It is important to remove all semen from the exterior of the capillary in order to prevent the SQA-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.

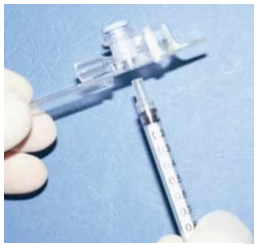
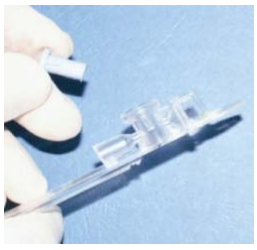


Figure 3

Figure 4



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

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 introduced 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.
3. Carefully place a standard (22 mm x 22 mm) cover-slip over the sample, closely observing that the droplet of semen sample is evenly spread across the entire surface area of the cover-slip. The sample should spread evenly without using ANY additional pressure applied to the cover-slip.

Figure 1

Figure 2

Figure 3

4. Carefully place the prepared slide on the slide adapter (with the non-loaded side towards the slide holder). Open the spring loaded slide holder by pressing on its outer edge (Figure 1). Slip the slide into the holder and release the spring (Figure 2). This is most conveniently done with the slide position adjuster in a fully clockwise position. The slide will now be firmly in place in the slide adapter.
5. Insert the fully loaded slide adapter (Figure 3) into the visualization chamber of the SQA-V.
6. Optimize the video image in the usual manner and select the desired field of view using the slide position adjuster on the slide adapter (Figure 4).

Figure 4

APPENDIX 4: Cleaning the Capillary / Slide Compartments

Medical Electronic Systems Ltd.

SQA-V / Cleaning Instructions: ONLY use the manufacturers cleaning kit and brushes to clean the SQA-V or damage will occur to the film and the system will not function.

When to clean: DAILY when running samples and…

- After every 10-15 tests and/or for ANY spillage
- If there is a Self-test or any other failure
- If the SQA-V becomes contaminated with semen

Cleaning kit components:

- 25 Blue Dot capillaries with fibrous material tips
- 25 sponge-tipped drying capillaries
- 1 cleaning brush (wooden-handled)
- Cleaning fluid

Fibrous Blue Dot cleaning capillary

CLEANING: STEP 1

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

CLEANING: STEP II

If the SQA-V still does not pass self-test, use the cleaning brush:

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

CLEANING THE VISUALIZATION COMPARTMENT:

1. Open the visualization compartment door (upper slot) and swing the cover above the lens to the left.
2. Using Lens Paper or Kimwipes wipe the lens with 70% isopropyl alcohol (not provided).

APPENDIX 5: Reference Values of Semen Variables

SEMEN PARAMETER	SQA-V TEST NAME	REFERENCE RANGE*	SOURCE
Sperm Concentration (Count)	SPERM CONC.	≥20 M/ml	WHO 4th manual*
Motility (grades a+b+c)	MOTILITY <a+b+c>	-	-
Rapid Progressive Motility (grade a)	RAPID PROG. MOTILITY <a>	≥50% <a+b> or ≥25% <a> only	WHO 4TH manual*
Slow Progressive Motility (grade b)	SLOW PROG. MOTILITY <b>		
Non Progressive Motility (grade c)	NONPROG. MOTILITY <c>	-	-
Immotility (grade d)	IMMOTILITY <d>	-	-
Morphology (% Normal Forms:WHO 3rd)	MORPH. NORM FORMS WHO 3rd	≥30%	WHO 3rd manual*
Morphology (% Normal Forms:WHO 4th)	MORPH. NORM WHO 4th Strict	≥15%? (Under investigation)	WHO 4th manual*
Motile Sperm Concentration	MSC	-	-
Progressively Motile Sperm Concentration (grade a)	PMSC <a>	≥10 M/ml <a+b> or ≥ 5 M/ml <a> only	MES Ltd.*
Progressively Motile Sperm Concentration (grade b)	PMSC <b>		
Functional Sperm Concentration	FSC	≥7 M/ml (WHO 3rd) ≥3 M/ml (WHO 4th)	MES Ltd.*
Velocity (Average path velocity – VAP)	VELOCITY	≥5 mic./sec.	MES Ltd.*
Sperm Motility Index	SMI	≥80	MES Ltd.*
Total Sperm Number	SPERM #	≥40 M/ml	WHO 4TH manual*
Total Motile Sperm	MOT. SPERM	-	-
Total Progressively Motile Sperm	PROG. SPERM	≥20 M	MES Ltd.*
Total Functional Sperm	FUNC. SPERM	≥14 M/ml (WHO 3rd) ≥6 M/ml (WHO 4th)	MES Ltd.*

*Each laboratory should establish its own reference ranges for semen parameters. The ranges established above are based on WHO 3rd or 4th standards or MES Ltd. (for proprietary semen parameters)

APPENDIX 6: Product Performance Data

Abbreviations

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

Performance Data Summary

The performance the SQA-V is summarized in the text, tables and graphs below. All values concerning sperm concentration measurements are expressed as 10^6 sperm cells per milliliter (M/ml). Motility and morphology values are expressed as a percent (%). Unless otherwise noted all testing was performed using human donor semen samples.

Calibration:

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

Dynamic Range:

Sample Type	Test Mode	Sperm Conc. M/ml	Motility %	Morph %	MSC M/ml	PMSC M/ml	#Sperm Cells/field
Fresh	Normal	2-400	0-90	0-100	.2-400	0-400	-
Washed	Normal	2-200+	0-90	0-100	.2-200+	0-200+	-
Frozen	Normal	-	-	-	.2-200+	0-200+	-
All Types	Post-Vasectomy	-	-	-	0-2	-	0-30

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:
Latex beads cannot:

- 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.

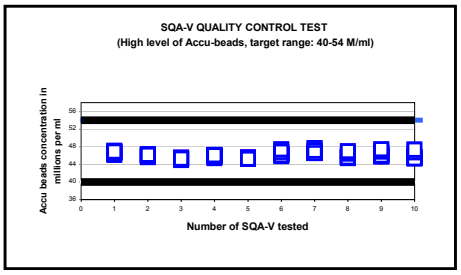
Latex beads established target values +/- ranges (Hemacytometer):

- Vial #1: 47 +/- 7.0 M/ml
- Vial #2: 24 +/- 3.4 M/ml

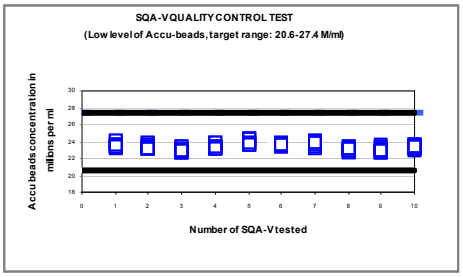
Precision

SQA-V	Accu-beads®	CV, %
Intra-device Variability	**High 47± 7.0 M/ml**	≤ 0.01
	Low 24 ± 3.4 M/ml	≤ 0.01
Inter-device Variability	**High 47± 7.0 M/ml**	≤ 2.00
	Low 24 ± 3.4 M/ml	≤ 2.50

Accuracy: High Level Control



Accuracy: Low Level Control



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: 95% of motile cells detected

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

Correlation to Manual Method
- Concentration: 0.9
- Motility: 0.85
- Morph. Norm Forms (WHO 3rd): 0.65
- Morph. Norm Forms (WHO 4th strict): 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 ≤ 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 readings using a Makler or Neubauer chamber based on WHO 4TH standards and MES protocols. Three independent clinical trials were conducted at three sites. A total of 539 human semen samples were analyzed as described below: 342 samples were of low quality and were tested in the Postvasectomy mode.

#Samples	Fresh	Washed	Frozen	High Sensitivity
539	125	42	30	342

Precision (Table #3): Duplicate samples were assessed using 2 SQA-V's. The coefficients of variation (CV) characterizing precision were calculated for Sperm Concentration and Motility and were below 6%.

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.

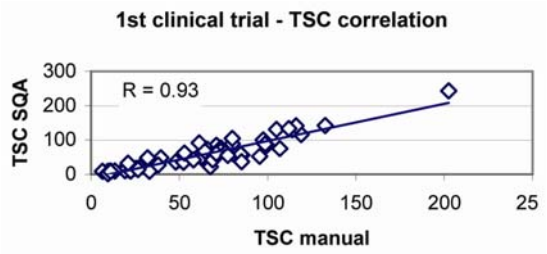
Limitations of clinical specificity:
- Highly viscous samples cannot be read accurately.
- Sample size must be >0.7ml for fully automated tests.
- % Normal Morphology is a parameter derived from the correlation between morphology and progressive motility. This is not a direct measurement.
- Results obtained from the use of the SQA-V visualization system may be affected by the subjectivity of the operator.
- Dynamic range limitation as stated above.

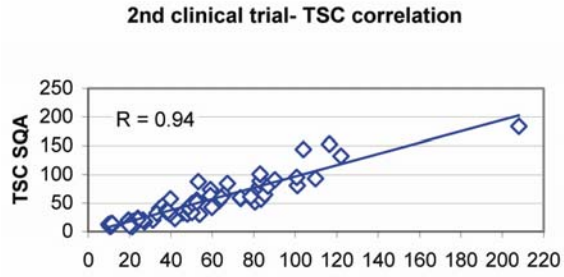
Table 1: Sensitivity/Specificity

SQA-V vs. Microscope	Sensitivity	Specificity
Trial #1:		
Concentration	100%	95%
Motility	97%	85%
Morph Norm Forms (WHO 3rd)	94%	75%
Trial #2:		
Concentration	94%	90%
Motility	87%	90%
Morph Norm Forms (WHO 4th)	69%	70%
Trial #3: High Sensitivity* (see table#4)		
Motile Sperm Cells	95%	95%
Immotile Sperm Cells	99%	100%

Table #2: Correlation to Manual Method

Parameters	Correlation Coefficients	
	Trial #1	Trial #2
Sperm Concentration M/ml	0.93	0.94
Motility %	0.86	0.87
Morphology WHO 3rd	0.66	NA
Morphology WHO 4th	NA	0.49
MSC	NA	0.79





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.

Method comparison:

- SQA-V was compared to the microscope based on WHO 4TH guidelines.
- Sensitivity and specificity were calculated using ROC curves. WHO 4TH guidelines were used to establish cutoffs for reference values (see table #1).
- The POSTVASECTOMY test 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 of the 342 semen specimens contained motile cells and were used as the basis for the method comparison (Table #4).

Table #3: Precision

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

Table #4: Percentage Motile Cells Detected

Method Comparison of 218 Samples with Motile Cells	# Samples Motile Sperm Detected	% Samples Motile Sperm Detected
SQA-V Automated System and Visualization System	207	95%
Visualization System only	193	89%
Microscope only	161	74%

SQA-V Linearity

Clinical claims:

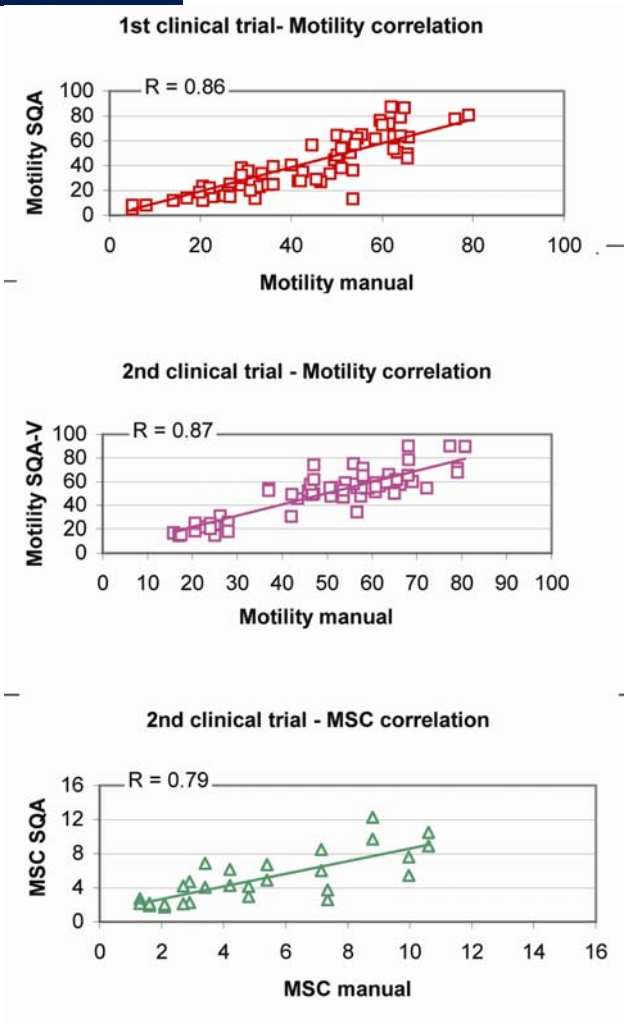
- Linear Sperm Concentration throughout the SQA-V dynamic range of 2M/ml to 400M/ml:
  - Squared regression coefficient of Dilution Curve $R^2 \geq 0.9$.
  - Averaged coefficient of variation CV of measured vs. expected sperm concentration ≤ 20%.

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.

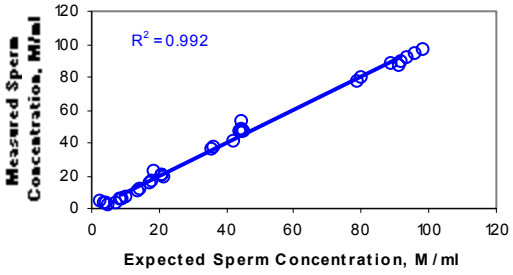
Methodology: 4 fresh human semen samples were pooled, divided into two aliquots and centrifuged at 600g for 15 minutes. The seminal plasma was decanted and the pellets were re-suspended in washing media: DPBS & HepesHTF. Sequential dilutions were run in 4 SQA-V systems.

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.



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



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%.

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). Wait 120 seconds and 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.

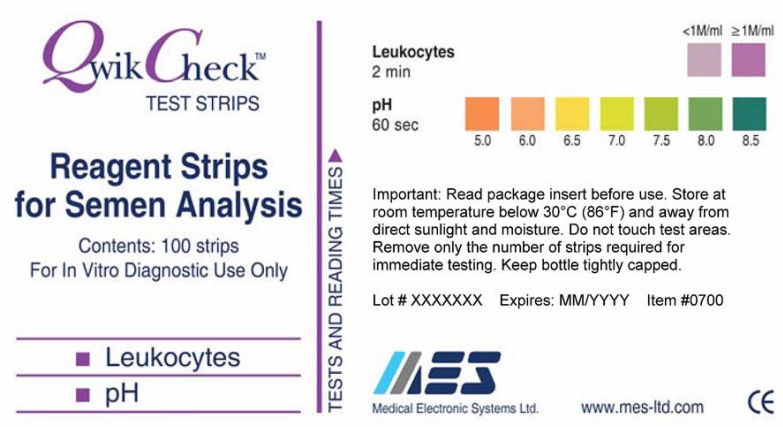
QwikCheck™ test strips were evaluated by Medical Electronic Systems Ltd. (MES) for use as a qualitative indicator (WBC's ≥ 1M/ml) of WBC's in human semen. To test this application WBC's were isolated from blood and re-suspended in seminal plasma. Varying concentrations of WBC's in seminal plasma were 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 exceed the darkest lavender color on the color chart after 120 seconds. (This reading corresponds to WBC concentration ≥ 1 Million/ml that is considered abnormal according to WHO '99 4th edition, Appendix 1A, p. 61).

References

- WHO '99 4th edition laboratory manual for the examination of human semen and sperm-cervical mucus interaction, 4th ed., 1999, Cambridge University Press.



APPENDIX 8: Dilution Media

QwikCheck™ DILUTION

Product Insert

INTRODUCTION AND INTENDED USE

The QwikCheck™ Dilution Kit is to be used to dilute semen samples prior to automated/manual testing and for semen sample preparation. The dilution media is Earle's balanced salt solution which contains ingredients to support sperm motility and viability and is recommended by WHO for semen sample preparation (WHO'99, 4th ed. manual, p. 104). 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 one-year shelf life. Note the expiration date on the box and bottle.
- Store bottle in the refrigerator upon receipt. Bring to room temperature (22-26°C) prior to use.
- Avoid prolonged exposure to light.
- 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 0.5 ml, dilute 1:1
3. Open the dilution kit bottle and pipette an amount of Earle's solution that is equal to the semen sample volume measured in step 1.
4. Add the Earle's solution to the neat semen sample and thoroughly mix the sample by rotating the container in a circular manner. This will evenly distribute the spermatozoa throughout the sample without introducing bubbles.
5. Fill the SQA-V testing capillary immediately after the sample is mixed following the SQA-V (version 2.48 and 2.48) on-screen instructions

MANUAL:

- Follow laboratory sperm preparation protocols for diluting semen samples for testing.

PRECAUTIONS AND WARNINGS

Exercise appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation.

REFERENCES:

WHO '99 Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, 4th Edition, Cambridge University Press, 1999, Reprinted 2000.

APPENDIX 9: Treating Viscous Samples

QwikCheck™ LIQUEFACTION

Product Insert

INTRODUCTION AND INTENDED USE

The QwikCheck™ Liquefaction Kit can be used to promote and accelerate the liquefaction of highly viscous semen samples that remain viscous thirty minutes after collection. Since viscosity impacts the accurate measurement of motility, concentration and antibody coating, the QwikCheck™ Liquefaction Kit is used to prepare viscous semen samples for automated or manual semen analysis and is for in-vitro use only.

KIT CONTENTS

- 20 single dose, 5 mg vials of lyophilized α-Chymotrypsin.
- Product Insert

STABILITY AND STORAGE CONDITIONS

- The product has an eighteen month shelf life. Note the expiration date on the box and vials.
- Store vials at -20°C. Warm to room temperature (22-26°C) prior to use.

INSTRUCTIONS FOR USE

1. Select one vial of α-Chymotrypsin and bring to room temperature (2-3 minutes).
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).

PRECAUTIONS AND WARNINGS

Each vial contains α-Chymotrypsin, a protease. This protease may cause irritation to eyes, respiratory system or skin. In case of contact with eyes, rinse immediately with plenty of 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.

REFERENCES:

WHO '99 Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction, 4th Edition, Cambridge University Press, 1999, Reprinted 2000.

APPENDIX 10: Assayed Control: QwikCheck™ Beads

Medical Electronic Systems Ltd.
20 Alon Hatavor Street, Caesarea Industrial Park 38900, Israel
E-mail: mes@mes-ltd.com Website: www.mes-ltd.com

QwikCheck™beads

A QUALITY CONTROL MATERIAL FOR AUTOMATED AND MANUAL SPERM COUNTING SYSTEMS

Introduction and Intended Use:

QwikCheck™ beads is an external quality control material for use in automated and manual sperm counting systems. The material is for in-vitro use only and is to be used as a tool to assess the accuracy and precision of the laboratory's sperm counting methods by providing a known target value and +/- range. Although the beads were developed for use on the SQA-V automated and visualization system, they can be used for manual proficiency testing on hemacytometers such as Neubauer counting chambers such as Makler, and conventional fixed coverslips.

QwikCheck™ beads is supplied in a kit containing two vials of known concentrations of 4-micron latex beads suspended in an aqueous solvent and one vial of negative concentration and a MSC (motile cell concentration) control. The beads are run in the same manner the laboratory runs sperm counts on the SQA-V, manual counting chambers and the SQA-V visualization system.

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** be run on the SQA-V 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/motile cell concentration control. Store the beads at room temperature (20-25 ºC or 65-77° F). The expiration date assumes that **QwikCheck™ beads** are stored at room temperature in their original containers and tightly capped to prevent evaporation.

Warning:

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

Basic Instructions for using QwikCheck™ beads

1. Thoroughly mix or vortex the QwikCheck™ beads prior to use in order to distribute the beads evenly in the suspension. It is imperative that the beads are evenly mixed in order to insure the accuracy of the target value.
2. The negative control material does not require extensive mixing.
3. Immediately withdraw a sample of the control material after opening the container.
4. Immediately and tightly close the container after withdrawing a sample to avoid evaporation or spillage.
5. Follow the same procedure normally used for manual or automated semen analysis (see detailed instructions below).

Target Value and +/- Range: SAMPLE TABLE (follow Target values and +/- Range on the box of QwikCheck-beads)

Counting Method	Level 1 (Million/mL)			Level 2 (Million/mL)			Level 3 Negative Control	
							Concentration	MSC
	Target Value	Range +/-	Between	Target Value	Range +/-	Between	Target Value	Target Value
SQA-V Automated	45	6.4	38.6 – 51.4	23	3.2	19.8 – 26.2	0.0	0.0
SQA-V Visualization	46	11.6	34.4 – 57.6	24	5.9	18.1 – 29.9	0.0	0.0
Hemacytometer (Neubauer)	45	11.1	33.9 – 56.1	21	5.2	15.8 – 26.2	0.0	N.A.
Counting Chamber (Makler)	47	11.9	35.1 – 58.9	25	6.2	18.8 – 31.2	0.0	N.A.
Fixed Coverslip	44	10.9	33.1 – 54.9	22	5.4	16.6 – 27.4	0.0	N.A.

SQA-V Automated System:

1. Refer to the SQA-V User Guide "CONTROLS" section for an explanation of how to set-up the SQA-V to test automated Level 1/Level 2 QwikCheck™ beads. Follow the instructions and screen prompts in the "Controls" section of the SQA-V User Guide.
2. Follow the basic instructions for mixing and preparing "QwikCheck™ beads" noted previously.
3. Aspirate a sample of the beads or negative control into the SQA-V capillary in the same manner you would fill the capillary for a normal volume specimen. Make sure that the cuvette section of the SQA-V capillary is completely full of liquid and free of bubbles.
4. Following the SQA-V on-screen instructions for "Controls" insert the SQA-V capillary into the SQA-V in the same manner you would test a normal sample of semen.
5. Print and save Control test results.

SQA-V Visualization System using a standard slide:

1. Refer to the SQA-V User Guide "CONTROLS" section for an explanation of how to set-up the SQA-V to test Manual Level 1/Level 2 QwikCheck™beads or negative control. Follow the instructions and screen prompts as outlined in the "Controls" section of the SQA-V User Guide.
2. Follow the basic instructions for mixing and preparing "QwikCheck™ beads" noted previously.
3. Refer to the SQA-V User Guide "Operating the Visualization System" to understand how to use a standard slide in the SQA-V.
4. Pipette 10 uL of QwikCheck™ beads or negative control onto a standard slide, cover with a 22x22 mm coverslip to provide a 20-micron

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 > SET-UP > PATIENT TESTING from the MAIN MENU.
- Select a **CONC. (concentration) STANDARD**
  - **CONC. STANDARD #1** (FACTORY DEFAULT)
  - **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:

STANDARD #1 CHAMBERS	STANDARD #2 CHAMBERS
Makler	Beurker-Tuerk
Fixed cover slip disposable chambers (i.e.Micro-Cell)	Buerker
	Fuchs-Rosenthal
	Fuchs-Rosenthal (modified)
	Improved Neubauer
	Malassez
	Neubauer
	Thoma
	Thoma Modified

Appendix 12: Postvasectomy 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 and the SQA-V and the testing capillary should not be disturbed in any way during the 5 minute testing cycle.

- Typically, there are minimal cells in a POSTVASECTOMY specimen. Therefore, in order to concentrate the cells the specimen must be centrifuged and the pellet re-suspend prior to testing. (WHO 4TH recommends centrifuging specimens with counts < 1-2/field in order to concentrate the specimen).
- Centrifuge the specimen @ 600*g* for 15 minutes (WHO 4TH)
- Decant the supernatant and re-suspend the pellet in 0.8 ml seminal plasma (can be supplemented with Earl's Buffer).
- Fill both sections of the SQA-V testing capillary by filling BOTH sections (for stability during the 9 minute test).
- If the specimen volume is not adequate to fill both sections, add Earls Buffer.
- 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.

APPENDIX 13: SERVICE REPORT

SQA-V SERVICE SUPPORT
Parameter Report

Device number: _____ SQA-V Software Version: _____ Date: _____

Instruct the user to run a SERVICE report. For version 2.48 from the MAIN MENU select: **SERVICE > PRINT SQA-V DEFAULT SETTINGS > 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.

Parameter	Service Report Item #	User Report	MES Report	Comments
CONTR.REF1	#1			
OD AMPLIF.	#13			
MSC AMPLIF	#8			
OD VALUE	#15			
OD CORR	#16			
LB OD AMP	#18			
CONTR. Z.L*	#11			

*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.

Parameter	Service Report Item #	User Report	MES Settings	Comments
MIN.SP.HEIGHT	#2		5	
MIN.SP.WIDTH	#9		10	
MAX.SP.WIDTH	#3		150	
NOISE THRESH	#10		6	
SMI THRESH	#4		28	

Self Test Parameters:

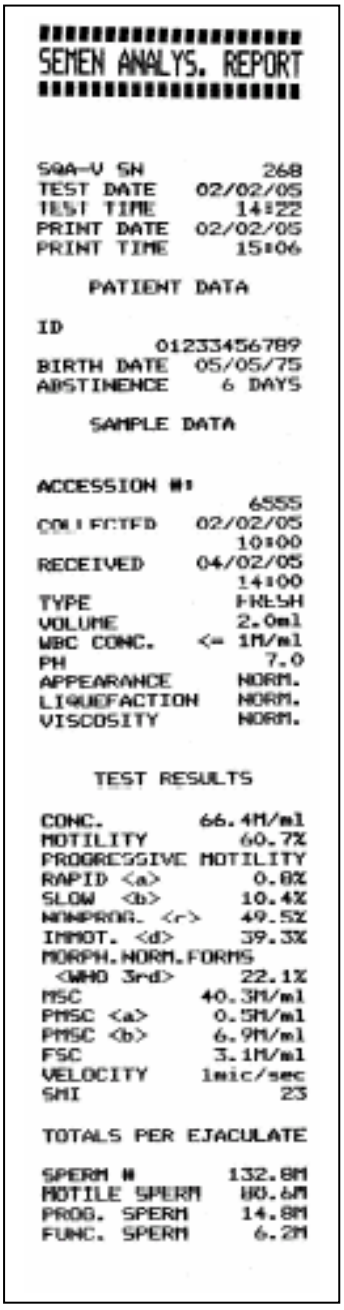
Fill-in the SQA-V SELF TEST PARAMETERS from the SELF TEST printout in V-Sperm:

- 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

Parameter	**S/W Ver. 2.48 Criteria**	**SQA-V Self-Test Parameters**	
Ref. 1	150 – 350 mV		
LED Current 1	**5 – 20 mA**		Original value
Amplitude	50 – 100 mV		
Count (#12)	26 – 36		
Zero Level	500 – 525		
Ref. 2	2500 – 3500		
LED Current 2	**10 – 32 mA**		Original value
TSC 1 or CONC 1	0 – 1 M/ml		
TSC 2 or CONC 2	50 – 150 M/ml		
TSC 3 or CONC 3	300 – 600 M/ml		

APPENDIX 14: SQA-V Reports

Semen Analysis Report



SEMEN ANALYS. REPORT

SQA-V SN	268
TEST DATE	02/02/05
TEST TIME	14:22
PRINT DATE	02/02/05
PRINT TIME	15:06

PATIENT DATA

ID	01233456789
BIRTH DATE	05/05/75
ABSTINENCE	6 DAYS

SAMPLE DATA

ACCESSION #:	6555
COLLECTED	02/02/05 10:00
RECEIVED	04/02/05 14:00
TYPE	FRESH
VOLUME	2.0ml
WBC CONC.	<= 1M/ml
PH	7.0
APPEARANCE	NORM.
LIQUEFACTION	NORM.
VISCOSITY	NORM.

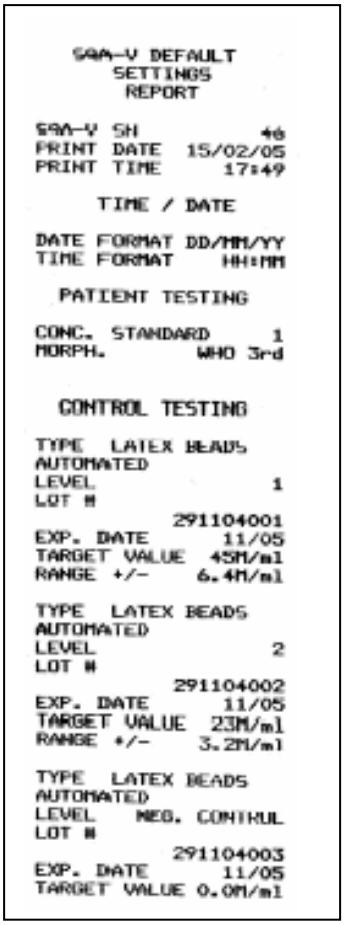
TEST RESULTS

CONC.	66.4M/ml
MOTILITY	60.7%
PROGRESSIVE MOTILITY	
RAPID <a>	0.8%
SLOW <b>	10.4%
NONPROG. <c>	49.5%
IMMOT. <d>	39.3%
MORPH.NORM.FORMS	
<WHO 3rd>	22.1%
MSC	40.3M/ml
PMSC <a>	0.5M/ml
PMSC <b>	6.9M/ml
FSC	3.1M/ml
VELOCITY	1mic/sec
SMI	23

TOTALS PER EJACULATE

SPERM #	132.8M
MOTILE SPERM	80.6M
PROG. SPERM	14.8M
FUNC. SPERM	6.2M

SQA-V Default Settings Report



SQA-V DEFAULT SETTINGS REPORT

SQA-V SN	46
PRINT DATE	15/02/05
PRINT TIME	17:49

TIME / DATE

DATE FORMAT	DD/MM/YY
TIME FORMAT	HH:MM

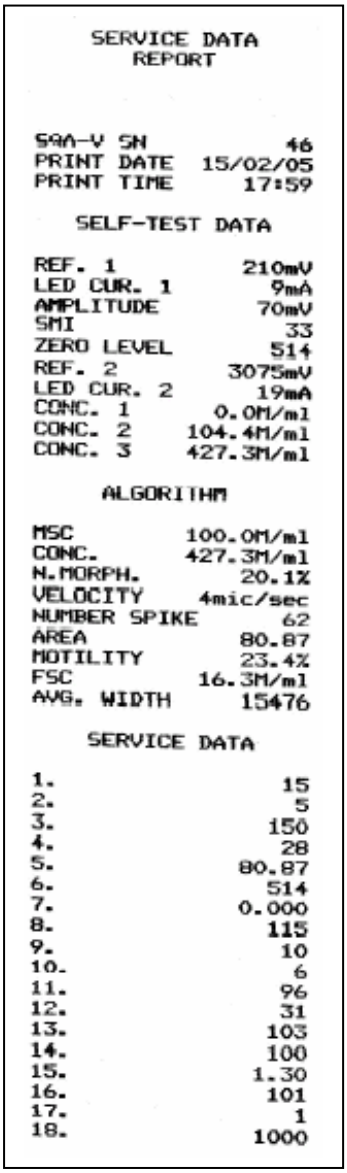
PATIENT TESTING

CONC. STANDARD	1
MORPH.	WHO 3rd

CONTROL TESTING

TYPE	LATEX BEADS
AUTOMATED	
LEVEL	1
LOT #	291104001
EXP. DATE	11/05
TARGET VALUE	45M/ml
RANGE +/-	6.4M/ml
TYPE	LATEX BEADS
AUTOMATED	
LEVEL	2
LOT #	291104002
EXP. DATE	11/05
TARGET VALUE	23M/ml
RANGE +/-	3.2M/ml
TYPE	LATEX BEADS
AUTOMATED	
LEVEL	NEG. CONTROL
LOT #	291104003
EXP. DATE	11/05
TARGET VALUE	0.0M/ml

Service Data Report



SERVICE DATA REPORT

SQA-V SN	46
PRINT DATE	15/02/05
PRINT TIME	17:59

SELF-TEST DATA

REF. 1	210mV
LED CUR. 1	9mA
AMPLITUDE	70mV
SMI	33
ZERO LEVEL	514
REF. 2	3075mV
LED CUR. 2	19mA
CONC. 1	0.0M/ml
CONC. 2	104.4M/ml
CONC. 3	427.3M/ml

ALGORITHM

MSC	100.0M/ml
CONC.	427.3M/ml
N.MORPH.	20.1%
VELOCITY	4mic/sec
NUMBER SPIKE	62
AREA	80.87
MOTILITY	23.4%
FSC	16.3M/ml
AVG. WIDTH	15476

SERVICE DATA

1.	15
2.	5
3.	150
4.	28
5.	80.87
6.	514
7.	0.000
8.	115
9.	10
10.	6
11.	96
12.	31
13.	103
14.	100
15.	1.30
16.	101
17.	1
18.	1000

APPENDIX 15: Printer Ribbon/Paper Installation

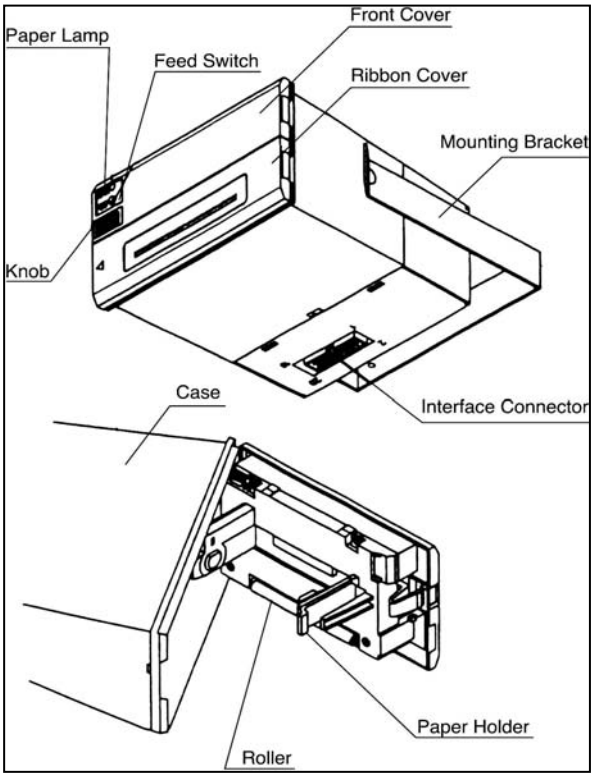


Figure 1

Setting Printing Paper

(1) Open the front cover.
(2) Cut the edge of Printing Paper as the following drawing.
(3) Insert the paper into the paper insertion of the printer mechanism.
When auto loading function is specified, paper is loaded automatically.
When auto loading function is not specified, push the
LF switch until the paper enters the printer mechanism.
(4) By holding the paper holder in the arrowed direction, insert paper roll and make sure paper holder hold the core.

- Keep the paper winding direction correct.
- While in replacing of paper, do not send data from host terminal.
- Do not pull the paper in reverse direction of paper feed. This may cause abnormality of print head.
- In case the paper is fed diagonally in paper supplying side or paper removing side, paper jam may occur. In this case, turn OFF the power switch immediately and pull out the excessive paper slowly at straight direction.

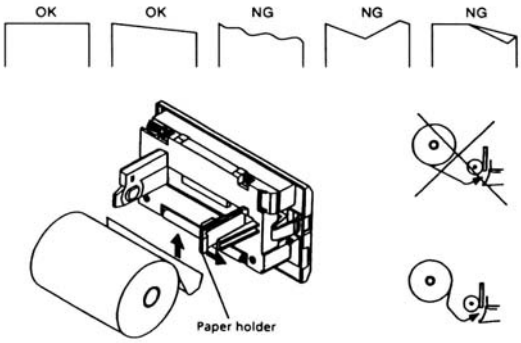


Figure 2

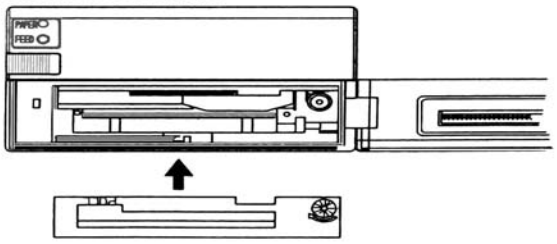
Paper Feeding

With the LF switch pressed once, paper is fed by one line.
Paper is fed while it is continuously pressed.
To feed paper, do not pull it forcibly. Use the LF switch.
During pressing the LF switch, the data can not be received.

Setting Ribbon Cassette

(1) Open the ribbon cover. Be sure to turn off power before opening it.
(2) In case the paper is out from front cover, cut the paper or remove this paper.
(3) Confirming the correct direction of a new ribbon cassette, insert ribbon between the printing head and the platen and press cassette down from the knob side.
(4) Turning the ribbon cassette knob in the arrowed direction, remove slack.
(5) On replacing a ribbon cassette, pull it out as holding the "PULL" part.

- In case the ribbon cassette is kept setting in printer so long time, there may be the case to make a paper dirty.
And in case of continuous printing under low temperature, light print may be occurred due to the characteristic of the ink.
- Do not conduct printing with no ribbon cassette, this may damage a print head.
- Replace ribbon cassette before wearing out completely.
- Use exclusive ribbon cassette.



APPENDIX 16: Warranty

Medical Electronic Systems Ltd.

Sperm Quality Analyzer

SQA-V

Warranty

Medical Electronic Systems, Ltd. ("MES") warrants that the Sperm Quality Analyzer (the "SQA") 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 SQA is shown to MES's reasonable satisfaction to be defective, MES shall, at its option, repair or replace such an SQA 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 or (ii) the SQA is used, operated, opened or serviced other than as directed by MES or is damaged as a result of use, 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 #:_____

The Sperm Quality Analyzer (SQAV) is a product of:
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P.O.Box 3017
Caesarea Industrial Park, 38900 IL
Phone: (972)-4-6373981
Fax: (972)-4-6373984

European Regulatory Authorized Representative
Medes Limited
P.O.Box 136 6 Beaumont Gate
Shenley Hill, Radlett, Herts WD7 7AR, England
Tel/Fax: +44 1923859810

APPENDIX 17: Technical Bulletins and Product Updates