

SQA-V *Gold*

Technical Specifications



V e r s i o n 2 . 4 8 / 2 . 4 9

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SQA-V Gold Technical Specifications

The SQA-V is a high performance analytical medical device that combines state-of-the-art technology in electro-optics, computer algorithms and video microscopy. The system performs a reliable, 75-second semen analysis. The SQA-V features automated self-testing and self-calibrating quality controls and two systems: An **automated system** and a **visualization system** allow the user the flexibility to analyze all types of semen samples.

Automated Test Results

Semen Variables	
Total Sperm Concentration (Count)	Functional Sperm Concentration (Prog. Motile Sperm with Normal Morphology)
Motility	Sperm Motility Index (PMSC X Average Velocity)
Progressive Motility ("a" and "b")	Average Velocity of the Progressively Motile Sperm (Average path velocity – VAP)
Non-progressive Motility ("c")	Total Sperm
Immotility ("d")	Total Motile Sperm
Normal Morphology	Total Progressively Motile Sperm
Motile Sperm Concentration	Total Functional Sperm
Progressively Motile Sperm Concentration	

Technology

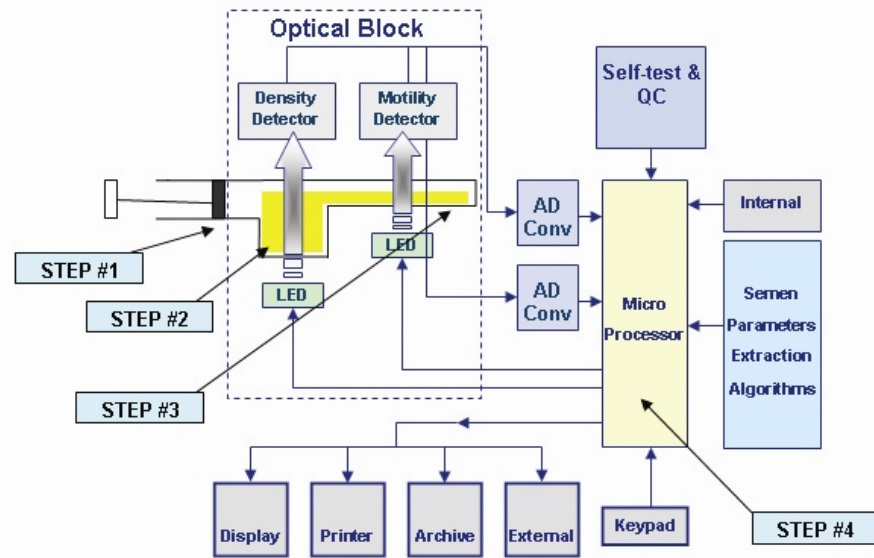
Automated System

Motility Channel

- Light disturbances caused by moving sperm cells are detected and translated into **analog signal peaks**.
- The greater the number of motile sperm cells in the field of view, the higher the **peak**.
- The slower the sperm velocity the broader the signal peaks.
- The **average analog signal** is mathematically proportional to **MSC**.

Concentration Channel

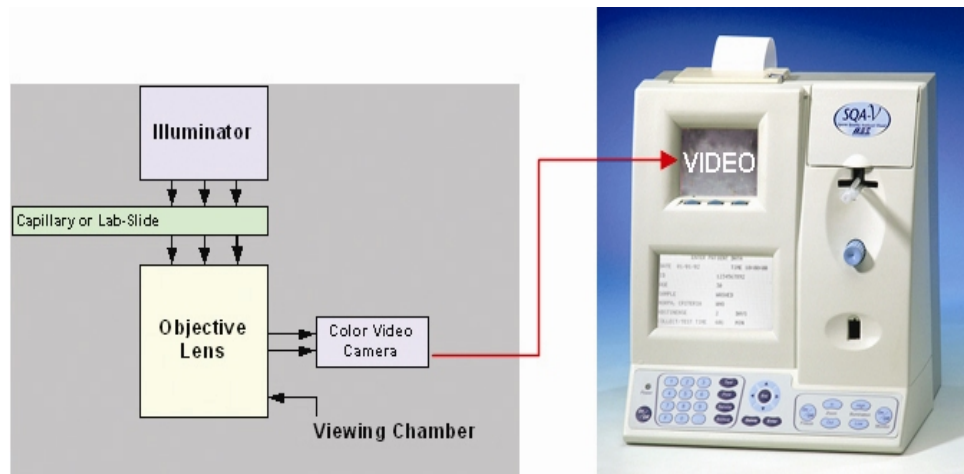
- Sperm concentration is measured in the cuvette section of the SQA-V testing capillary.
- An infrared light wavelength specific to sperm cells is maximally absorbed by sperm cells and minimally absorbed by other seminal fluid components.
- In the final calculation of sperm concentration the SQA-V algorithm makes an adjustment to account for the infrared light absorption of the seminal fluid components.



- Step 1:** The capillary is inserted into the measurement compartment.
- Step 2:** Sample concentration is evaluated in the "tall" 10 mm chamber of the capillary by measuring the amount of **optical absorption of light as a beam traverses the seminal fluid.**
- Step 3:** Motility is detected in the "thin" 0.3 mm section of the capillary by analyzing **light modulations caused by sperm motion.**
- Step 4:** This information is then digitized and routed to the microprocessor that applies algorithms to extract the required clinical semen parameters and performs internal self-testing and calibration.

Visualization System

- LED illuminator
- Objective lens with zoom capability
- Magnification: x300 to x500
- Focal depth: Approximately 30 microns
- Accommodates both a testing capillary and the SQA-V slide adaptor





Detailed System Specifications

Dimensions: 40 Height x Width 30 x 15 - 25 cm Depth
Weight: 4 kg
AC power supply: 100 to 250 VAC, 50/60 Hz, 24W
Fuse rating: 2A 250V
Power stability requirements: Voltage fluctuations \pm 5% nominal

Measurement Compartment

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

Visualization Compartment

- White LED illumination system
- CCD, 330 TV lines
- Objective: Standard, x20
- Signal Output: PAL standard
- Zoom system for magnification transition between x300 and x500
- Focus regulator

Display(s)

- Operational backlight LCD (16 lines x 40 characters)
- Video backlight LCD (8 x 10 cm): Will automatically illuminate when unit is "ON"
- Use monitor **ON/OFF** key on the keypad to independently operate the video display

Printer

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

Keypad

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

Front Panel

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

- I-Button (some models)

Rear Panel

- Power connector with fuse-holder (2 fuses: 250V, 1A)
- Video connector
- RS232 cable outlet

Specimen Testing Supplies

- **Measurement capillary:** Disposable, plastic, positive displacement testing capillary. (Testing depth of capillary section: 300-micron; Cuvette section: 10 mm).
- **Standard laboratory slide:** 20 micron depth, 22 x 22 mm cover-slip.

Operating System

- **Control:** Keypad
- **Analysis Time:** Normal Test – 75 seconds; High Sensitivity/Postvasectomy Test – 5 minutes (9 minutes in version 2.43).
- **Software:** Resides on flash memory and drives all man-machine interface functions, runs algorithms for test measurements (according to WHO '99 guidelines), and operates visual and automated screens. System can be upgraded from a PC CD-ROM.
- **Sample Testing Temperature:** Calibrated for room temperature only 22-26° C / 68-79° F. Motility results will be impacted by heating the specimen.
- **Motility channel input signal:** Analog, up to 5V.
- **Spectrophotometer channel input signal:** Modulated (1 kHz) analog, up to 5V.

Quality Control

- **Internal:** Electronic Self-Test and Auto-Calibration.
- **External:** Counts can be run on the SQA-V automated and visualization systems using commercially available assayed control material: "**QwikCheck-beads™**" (product of Medical Electronic Systems) or Stabilized Sperm as a non-assayed control in version 2.45 and higher.

PC Compatibility

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**
- **200 MB free hard disk space** for image capturing
- **Video resolution:** Minimum 640 x 480
- **Operating system compatibility:** Windows 2000, Windows XP, DirectX, DivX
- **Ports:** One serial; two USB ports
- **Monitor:** 15" color

Required Software

- **V-Sperm software for SQA-V system and I-button set-up, archive and CONTROL reporting** also permits user to benefit from many features such as real time visualization interface between PC and SQA-V visualization system, data analysis, video/picture capture and archives test records.
- **Excel/Word for exporting files and clips**

Operational Temperature and Humidity

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

Maintenance Schedule

- Daily cleaning of measurement compartment (refer to User Guide – "Cleaning") or with each 10-15 tests and/or spillage. **USE ONLY the MANUFACTURER supplied cleaning kit, brush and solution to clean the SQA-V or the system may be damaged and/or inoperable!**

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 High Sensitivity or Postvasectomy tests do not interrupt test cycle nor interfere with system or testing capillary in any way – this test requires complete stability of the system during the 5 minute testing cycle.
- Variations in ambient temperature can affect semen samples. The SQA-V is calibrated to conduct tests at room temperature: 22-26°C (68-79°F). **DO NOT HEAT SAMPLES.**
- Semen is considered a biologically hazardous material and is subject to individual laboratory protocols for handling such materials.

Factory Default Settings

Chamber standard: 1

Morphology: WHO

Date format: DD/MM/YY

Time/Date: Manufacturer's local time/date

Controls (all levels/types): Exp date 01/01

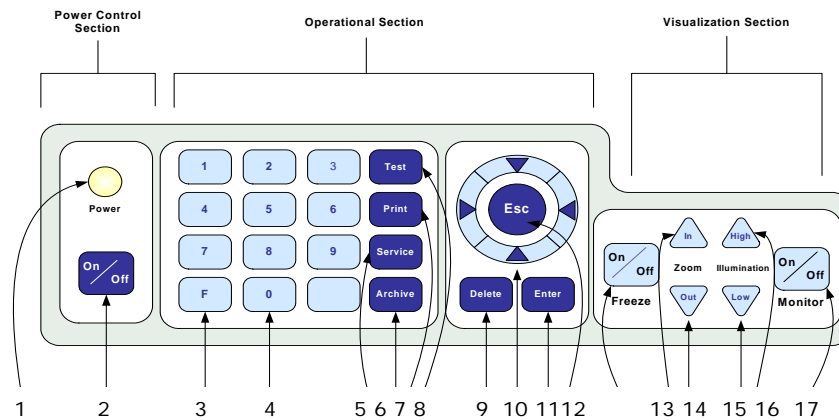
System Overview and Assemblies

Front Panel

- Printer and Paper
- Visualization Compartment
- Video Display and Controls
- Focus
- Operational Display
- Measurement Compartment
- Keypad

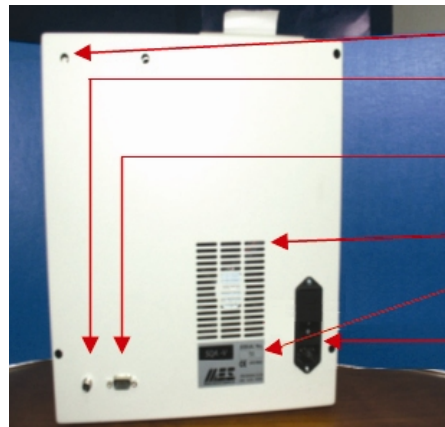


Keypad



1. Power Indicator: Illuminates when the system is "ON"
 2. ON/OFF Key: Press to activate the front panel screens
 3. F Spare Key
 4. Numeric Keys: For data entry
 5. Service Key
 6. Archive Key
 7. Print Key
 8. Test Key
 9. Delete Key
 10. Cursor Key: Up/down/right/left to move through screens
 11. Enter Key: Press to select menu options and to move to the next screen
 12. Escape Key: To return to a previous screen
 13. Zoom in
 14. Zoom out
 15. Image Illumination – decrease key
 16. Image Illumination – increase key
 17. Video Monitor – ON/OFF key
- These functions can also be operated from menus on the SQA-V operational screen.

Rear Panel



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

Side Panel

- The side panel has an I-Button port in SQA-V version 2.48.
- Refer to the SQA-V GOLD User Guide version for instruction on how to use the I-button feature.



The Chassis Assembly

The chassis assembly includes the base and rear parts of the unit. It includes the following sub-assemblies:

- Main Board
- Switching Power Supply
- AC Power Inlet Assembly
- Ventilation Fan
- Printer
- Communication Plug
- Video-out Jack
- Video Board Assembly

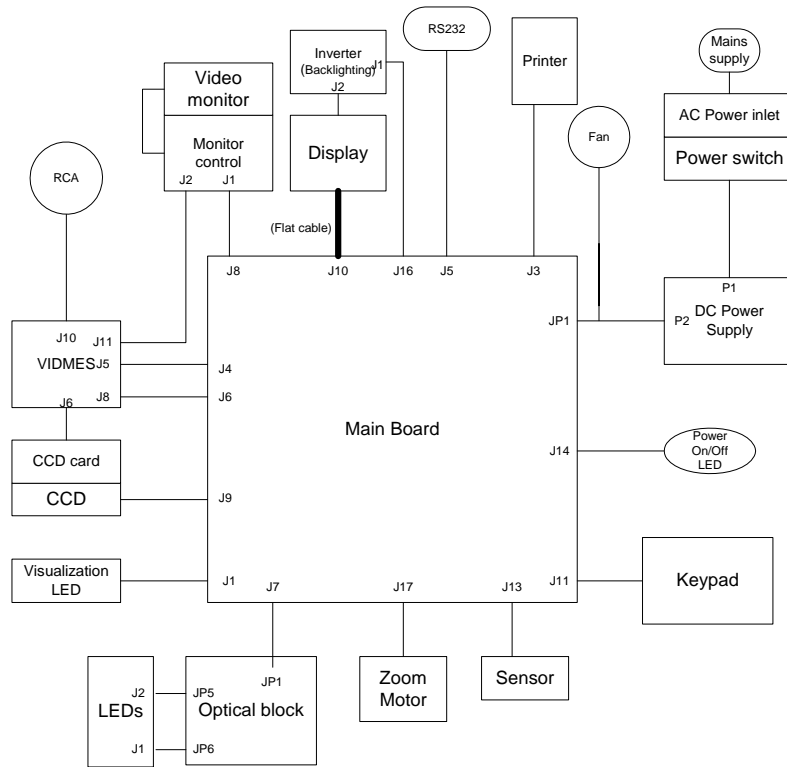
The Cover Assembly

The cover assembly includes the following:

- Operational Display
- Video Keypad
- Power Indicator LED

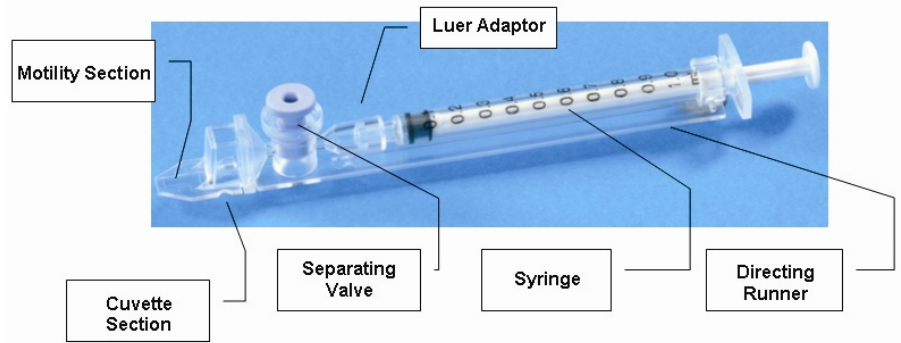
- Visualization Compartment
- Visualization Compartment Cover
- Measurement Compartment
- Focus Control

Schematic of the SQA-V Motherboard



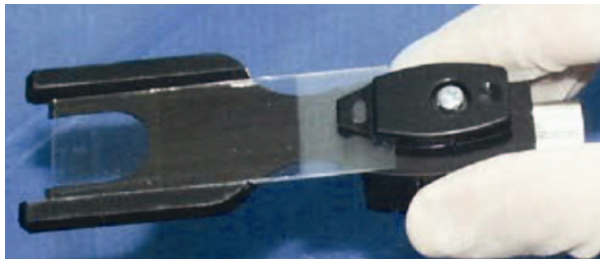
System Components and Accessories

Measurement Capillary



- Can be used in both measurement chambers of the SQA-V.
- 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 can be filled and used to measure small volume specimens (only 20 micro liters required).
- Concentration is measured in the 10 mm (tall) "Cuvette Section."
- Refer to: "Filling the Capillary for normal and low volume samples" in the Appendix section for instructions on how to use.

Slide Adaptor



- For use with a standard laboratory slide 76 x 25.6 mm and 22 x 22 mm cover-slip in the **visualization compartment** of the SQA-V to visually assess semen samples.

Cleaning Kit

- Daily cleaning is recommended or after testing 10-15 specimens.
- See Appendix section for instructions about how to perform routine cleaning.
- **Do not clean the SQA-V with any other solution, brush or cleaning material other than the Manufacturer's cleaning kit or damage may occur to the system**



Accessory Kit

- Each kit contains:
 - Slide Adaptor
 - Power Cables
 - Communication Cable
 - Printer Paper
 - Printer Ribbon
 - Instructional Guides



SECTION 5: Electronic Self-Test and Auto-Calibration

The SQA-V runs a series of tests to check its calibration and internal operating system. Testing is run automatically. Some testing is done when the SQA-V is first turned-on and other testing is done prior to each semen analysis.

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 level of electronic noise in the system to insure that noise thresholds are accurately defined to ensure effective measurement of electronic signals. The system will use this measurement prior to running a test and will automatically adjust the noise level thresholds to ensure accurate readings.
- **Self-test:** The system produces electronic signals that simulate motility and concentration 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 ranges.

Prior to testing a sample:

- **Auto calibration verification:** Reference values are read again. The concentration and motility parameters are measured (without a testing capillary).
- **System noise:** Measures the electronic noise level of the system to insure that noise thresholds are accurately defined in the system to ensure effective measurement of electronic signals. The system will use this measurement prior to running a test and 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.

The following procedure details how the user can document the system parameters to prepare for technical support if the system fails (see section of this user guide on Error Messages and Warning Messages).

How to run a copy of the system parameters version 2.48/2.49 GOLD:

- From the **MAIN MENU** select: **SERVICE>PRINT SQA-V DEFAULT SETTINGS>SELF TEST DATA**

All other versions:

- Remove any testing capillaries from the system.
- Turn the SQA-V on from rear panel and from the front keypad.
- When the MAIN MENU appears or when a FAILED SELF TEST message appears press the **SERVICE** key on the keypad to enter the SERVICE menu.
- Select **USER**.
- Press the **PRINT** key on the keypad to generate the required printout.

Refer to the table below. Enter numbers in the "SQA-V Value" column that corresponds to #1 - #10 from 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	Software version 2.45,2.46, 2.48, 2.49	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 (Internal Data, Item #12)	26 - 36			

SECTION 6: Getting Started / Set-Up

Please refer to the relevant SQA-V User Guide for start-up and set-up instructions (based upon the software version of the SQA-V).

SECTION 7: Troubleshooting

Overview: The following sections describe how to troubleshoot and repair potential problems that may occur with the SQA-V. Theses section will discuss how to provide support for three types of issues:

- **Technical**
- **Self test**
- **Clinical**

PLEASE NOTE:

- **Only a qualified MES distributor who has been trained to perform technical support is authorized to open the SQA-V.**
- **If the SQA-V is opened without authorization it may cause damage to the calibration.**
- **The electro-optical board should NEVER be touched when the SQA-V is opened – it will cause damage to the SQA-V calibration.**