

# SQA-Vision Service Manual

Version 109.14.3

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## **SECTION I: Introduction**

The SQA-Vision is a high-performance PC-based analytical medical device that combines technology in optoelectronics, computer algorithms and video microscopy. The SQA-Vision and a fully integrated TOUCH-SCREEN work together to provide user friendly semen analysis testing. Samples are run in the SQA-Vision testing device and all data entry and user interface is computer based.

FRESH, POSTVASECTOMY, WASHED, SWIM-UP, DENSITY GRADIENT and FROZEN semen samples as well as LONGEVITY testing can be performed on the SQA-Vision. Additionally MANUAL testing can be performed utilizing the on-screen MANUAL COUNTER. The high resolution visualization component of the SQA-Vision permits assessment of oligospermic specimens and poor quality IVF samples.

When results fall below the automated dynamic range of the system, a LOW QUALITY COUNTER opens automatically to permit manual sperm counting. Debris and round cell assessment is performed using the DEBRIS/ROUND CELLS SCANNER. % Normal morphologically is assessed automatically along with other semen parameters. Vitality and Morphology differentials can be assessed manually using the enhanced visualization system and on-line counters.

The analysis time varies according to the type of sample being tested: Normal quality samples – 75 seconds; Low quality – 2 additional minutes; Post vasectomy – 5 minutes.

The system runs a self-test and auto-calibration upon start up. It also runs latex beads or stabilized sperm external quality controls.

#### Automated Test Results and Reportable Range

Automated Test Results			
Concentration	M/ml	Motile Sperm Concentration (MSC)	M/ml
Total Motile PR+NP	%	Progressively Motile Sperm Concentration (PMSC)	M/ml
Progressive PR	%	Functional Sperm Concentration (FSC) (Progressively motile sperm with normal morphology)	M/ml
Non-progressive NP	%	Velocity	mic /sec
Immotile IM	%	Sperm Motility Index (SMI)	#
Normal forms (WHO 5 <sup>th</sup> )	%		
	TOT	TALS PER SEMEN VOLUME	
Sperm #	M/ejac	Functional Sperm	M/ejac
Motile Sperm	M/ejac	Morphologically Normal Sperm	M/ejac
Progressively Motile Sperm	M/ejac		
		POSTVASECTOMY	
Motile, Immotile and Total Sperm	M/ml	# Motile, # Immotile and # Total Sperm/semen volume	М

SQA-Vision Reportable Range (Automated Results)						
Sample Type	Sperm Conc. M/ml	Motility %	Morph %	MSC M/ml	PMSC M/ml	Motile / Immotile / Total Sperm M/ml
Fresh	<2 - 400	0 - 100	2 - 30	<0.2 - 400	0 - 400	-
Washed	<2 - 200+	0 - 100	2 - 30	<0.2 - 200+	0 - 200+	-
Swim-up, Density Gradient, Frozen	-	-	-	<0.2 - 200+	0 - 200+	-
Post-Vas	-	-	-	-	-	0 - 400

# Technology Automated System

**Motility Channel** 

- Light disturbances caused by moving sperm cells are detected and translated into **analog signal peaks.**
- The greater the # 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-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-Vision algorithm makes an adjustment to account for the infrared light absorption of the seminal fluid components.



- **#1:** The capillary is inserted into the measurement compartment.
- **#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.**
- **#3:** Motility is detected in the "thin" 0.3 mm section of the capillary by analyzing **light** modulations caused by sperm motion.
- **#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.

# SQA-Vision | SECTION II: System Specifications and Requirements

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

**Front Panel** 

- Displays: LCD display
- Testing: Measurement and Visualization compartments
- Other: Multi-button keypad, Focus knob, FOV (Field Of View) knob

Keypad

- **Operational keys:** I-Button, Service, Enter, Esc, Delete, four cursor buttons and ten numeric buttons (0-9).
- Video control key: Zoom In/Out

### **Measurement Compartment**

• Sources of radiant energy - two LEDs for motility and concentration channels

Detector system - two photo detectors - Motility and Optical Density

- **Operating System** 
  - Analysis Time: Normal Test 75 seconds; Low Quality 2 additional minutes; Postvasectomy (automated) – 5 minutes
  - Software: Resides on flash memory. System can be upgraded from a PC CD-ROM
  - Motility channel input signal: Analog, up to 5V.
  - **Concentration channel input signal:** Modulated (kHz) analog, up to 5V.

**Rear Panel** 

 Power inlet w/fuse-holder (fuses: 250V,2A), RS232 connector, 2 USB 2.0 B-Type Male, On/Off switch of the blue surrounding LEDs (located on bottom side of the panel).

Left Side Panel

- Power On/Off switch
- I-Button port

**Visualization Compartment** 

- White LED illumination system with max luminous intensity 35,000 mcd.
- Digital Camera, max resolution: 1280 x 1024 pixels, high resolution of "live" and "frozen" images provided by capturing a high # of FPS (frames per sec).
- Objective: Standard, x40, chromatic aberration correction.
- Zoom system for smooth magnification transition between x1188 and x1725
- Focus adjustment knob
- Field of View Stage knob

## SQA-Vision 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 Compartment" in this User Guide).

ONLY use the Manufacturer's cleaning kit and cleaning brush or damage will occur to the SQA-Vision film and the system will not operate!

**Manufacturer Recommendations** 

• Operate the SQA-Vision away from devices that may cause electronic noise or other devices causing vibrations such as centrifuges.

- Turn the system **OFF** when not in use for an 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 sample parameters. It is essential that semen samples are not heated for testing. The SQA-Vision is calibrated to conduct tests at room temperature: 20-25°C (68-77°F).
- Semen is considered a biologically hazardous material and is subject to individual laboratory protocols for handling such materials and at a minimum:
  - Laboratory coat, mask and gloves for operating personnel protection
  - Samples handling and waste disposal in specially marked hazardous waste containers
  - Only personnel trained to work with biologically hazardous materials such as semen should be testing and handling semen

**Operating Temperature and Humidity** 

- Maximum operational humidity is up to 80% for temperatures of up to 31°C with decreasing linearly to 50% at 38°C.
- Operates in a wide range of ambient temperatures (15-38°C) however the system is calibrated to measure semen samples at room temperature: 20-25°C (68-77°F). Note: Extreme ambient temperature may impact the accuracy of motility test results because of the known effect of temperature on human semen.

#### **Operational Environmental conditions:**

• System is intended for indoor use at a maximum altitude of 2000m, mains supply fluctuations ±10%, Overvoltage Category II, Pollution Degree II.

#### PC / Hardware

• **PC and device:** "All in One" - computer with SQA-Vision software and device.

**Quality Control** 

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

### Sample Testing

- **Sample Testing Temperature:** Calibrated for room temperature only. Motility results will be impacted by heating the specimen (not recommended).
- System calibrated to test Human semen and specified Control samples only. Not for use with animal semen.
- **SQA-Vision 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 system.
- Field of View Stage: This stage is an integral part of the SQA-Vision visualization compartment. Vision<sup>™</sup> fixed cover slip slides (obligatory for accurate test results when manual sperm counting is required), standard slides (for debris scans and image capturing) are accepted in the field of view stage using the supplied slide holder.







failure will be displayed if it is not stable for at least 30 seconds and the reference parameters are not within acceptable ranges.

- **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-Vision will report the Self-Test failure (see section on error and warning messages) if the system is not within the established Self-Test ranges.

Prior to testing a sample:

- **Autocalibration verification**: Reference parameters of the concentration and motility channels are measured again (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-Vision will automatically adjust the noise level threshold to insure accurate readings.
- **Electronic spikes:** Checks for measurement points that are out of range electronically and displays a warning message if out of range.

Service Instructions for printing the SQA-Vision SERVICE parameters to prepare for technical support:

• If a Self-Test failure occurs, the related status icon in the HOME screen will turn red:

TEST PATIENT	SERVICE DATA - KEY PARA	METERS		CONTROLS - LATEX B	EADS DATA		
	REFERENCE 1 (mV):	310	0	LAST RUN:	1/18/2016		
	LED CURRENT 1 (mA):	11	0	LEVEL 1:	3.7 (M/ml)	0	
QC / PROFICIENCY	REFERENCE 2 (mV):	2645	0	LEVEL 2:	PENDING		
	LED CURRENT 2 (mA):	15	0	NEG. CONTROL:	3.6 (M/ml)	8	
VISUALIZATION	ZERO LEVEL:	515	0	I-BUTTON / TEST STA	TS		
	AMPLITUDE (mV):	57.1	0	TESTS REMAINING:	864	0	
	SELE-TEST STATUS		0	AVG. TESTS / DAY:	11	000	
ARCHIVE	CALIBRATION AND STABIL	ZATION:	0	TOTAL TESTS RAN:	23		
	CLICK ICON(8) FOR DETAIL	S			TATUS		
SERVICE		2.2		LAST BACKUP	1/18/2016	0	REPORT
and a second second				NEXT BACKUP:	1/19/2016		
and the second second				HDD SPACE USED:	24.6%	0	MAINTENANCE
SETTINGS						122	REFRESH

• Click: **SELF-TEST STATUS** icon to open a warning message with instruction on how to resolve the problem:

F-TEST FAILED	
EN TROUBLESH	IOOTING
GUIDE	
TROUBLESHOOT	
	F-TEST FAILED EN TROUBLESH GUIDE

• Click: **REPORT** from the **HOME** or **SERVICE** screen to generate a **SERVICE REPORT**. This may be required for troubleshooting and technical support.

## SECTION VI: Getting Started / Set-Up

(Refer to the User Guide)

Troubleshooting	SECTION VII: Troubleshooting Overview: The following sections describe how to troubles that may occur with the SQA-Vision. Theses section will o three types of issues: Technical - Self test - Clinical	shoot and repair potential problems discuss how to provide support for
	<ul> <li>PLEASE NOTE:</li> <li>Only a qualified, technical support trained MES distine SQA-Vision.</li> <li>If the SQA-Vision is opened without authorization calibration AND will VOID THE WARRANTY.</li> </ul>	stributor is authorized to open it may cause damage to the
	<ul> <li>The electro-optical board should NEVER be touche opened – it will cause damage to the system's cali</li> </ul>	d when the SQA-Vision is bration.
Technical	SECTION VIII: Technical Support/Part Replacement	
Support and	Opening the SQA-Vision	· 👞 💋 💋
Part Replacement	• Turn off the main switch located on the side panel and disconnect the SQA-Vision from the electrical supply.	
	<ul> <li>Using a Philips screwdriver, remove</li> </ul>	
	all screws on the rear panel.	
	Closing the SQA-Vision	
	<ul> <li>Grip each panel from the side and gently push them back together making sure that all cables and connectors are free and not "pinched" between the panels.</li> <li>Use a standard Phillips screwdriver to reconnect the panels.</li> </ul>	

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Keypad (Part # VS-E-00851-00) ISSUE: The Keypad is not working	
<ul> <li>Open the SQA-Vision</li> <li>Verify that keypad cable is connected firmly to connector J11 on the Main board (connector is not loose)</li> </ul>	
<ul> <li>Confirm that the cable is connected in the correct orientation: The golden wide stripe on the cable connector should be facing the rear panel</li> </ul>	
<ul> <li>If the cable is connected properly and the keypad is still not working- replace the keypad:</li> </ul>	
<ul> <li>Disconnect the keypad cable connector from location J11 on the Main board</li> </ul>	Verify connection of Keypad
<ul> <li>Using a flat screwdriver, carefully peel off the damaged keypad from the front panel. Clean the surface with alcohol and let it dry.</li> </ul>	
<ul> <li>Pull the keypad cable through slit in the front panel</li> </ul>	"Remember, it All Started With A Sperm!"
<ul> <li>Please note: DO NOT connect it currently.</li> <li>Attach the keypad to its designated location on the front panel by gradually removing the paper while pressing it firmly into place from one side to the other.</li> <li>Please note: DO NOT bend the keypad during this</li> </ul>	Peel off the damaged Keypad
<ul> <li>process or electrical wires/connectors will be damaged.</li> <li>Attach the keypad connector to the J11 location on the main board.</li> <li>Please note: The golden stripe on the cable connector should face the rear panel (the fan side).</li> </ul>	O O O O O O O O O O O O O O
Close the SQA-Vision using 4 screws on the rear panel of the device.	Attach the NEW Keyboard Connector
	Apply the New Keypad
-	
	<ul> <li>Keypad (Part # VS-E-00851-00) ISSUE: The Keypad is not working</li> <li>Open the SQA-Vision</li> <li>Verify that keypad cable is connected firmly to connector J11 on the Main board (connector is not loose)</li> <li>Confirm that the cable is connected in the correct orientation: The golden wide stripe on the cable connector should be facing the rear panel</li> <li>If the cable is connected properly and the keypad is still not working- replace the keypad:</li> <li>Disconnect the keypad cable connector from location J11 on the Main board</li> <li>Using a flat screwdriver, carefully peel off the damaged keypad from the front panel. Clean the surface with alcohol and let it dry.</li> <li>Pull the keypad cable through slit in the front panel</li> <li>Piesse note: DO NOT connect it currently.</li> <li>Attach the keypad to its designated location on the front panel by gradually removing the paper while pressing it firmly into place from one side to the other.</li> <li>Piesse note: DO NOT bend the keypad during this process or electrical wires/connectors will be damaged.</li> <li>Attach the keypad connector to the J11 location on the main board.</li> <li>Piesse note: The golden stripe on the cable connector should face the rear panel (the fan side).</li> <li>Close the SQA-Vision using 4 screws on the rear panel of the device.</li> </ul>

## Power issues: fuses, PSU, power inlet

## Notes:

- 1. Turn off the power supply and disconnect the power supply cable from the back of the SQA-Vision before opening.
- 2. Refer to the Appendix section for instructions on how to address power supply problems.

#### Note:

Before checking the input\ output connectors of the main PSU, turn on the SQA-Vision. Power issues - fuses, PSU, power inlet.

**ISSUE:** The main switch is **ON**, but the power indicator does not light up and the fan is not working

- Check the fuses in the fuses box located on the rear panel of the SQA-Vision.
- Replace the fuse if it is burned out.
- Reconnect the power cord and turn the unit back on.
- If the unit still does not work, check the input/output voltage of PSU as instructed below.

## How to check the input voltage of PSU:

- Check the voltage on the input connector of the main PSU using a multimeter
  - The voltage should be ≈220V AC between the black and the red wires
  - If no voltage is evident, replace the power inlet (see the relevant section below)
- If voltage is being supplied to the input connector, check the output connector.

## How to check the output voltage of PSU:

- Disconnect the output cable from the motherboard.
- Check the voltage on the output connector of the main PSU using a multimeter:
  - 0V: black wire
  - +5V: red wire
  - +12V: purple wire
  - -12V: white wire

Replacing the Power Supply Unit -

- If there is no voltage on the output connector or the voltage is not correct, please replace the main PSU as instructed below
- If the problem persists, please contact Customers Support.

## Power Supply Unit (PSU)

**ISSUE**: The power supply and/or cables are not working

• Open the SQA-Vision.

part #Fpe-E-00146-00

- Disconnect the input connector of the power supply unit- location CN1.
- Disconnect the output connector of the power supply unit- location CN2.
- Using a #2 Philips screwdriver, unscrew the four screws that connect the PSU to the rear panel.
- Remove the old PSU.
- Secure a new PSU to the rear panel using the same four screws.
- Re-connect the input and output cable connectors to the PSU.



Fuses box



**PSU Input connector** 



**Power Supply Output Cable** 



Unscrew 4 screws of PSU



**Power Supply Unit** 

Close the SOA-Vision. Reconnect the power cord and turn the unit back on. If the problem persists -Contact Customers Support

# **Power Inlet**

#### Notes:

1. Turn off the On/Off switch and disconnect the power cord from the SQA-Vision before opening.

2. Refer to the Appendix section for a flow chart of power supply problems and solutions.

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- Power Inlet (Part# VS-E-00850-00)

**ISSUE:** There is no voltage supplied to the PSU from the inlet.

- Open the SQA-Vision.
- Unscrew the power-inlet screws at the rear panel of the device.
- Disconnect the power supply connector from the power supply board. •
- Gently pull the rubber cover of the power inlet until the connectors are exposed. .
- Please note how all connector are connected to the power inlet.
- . Disconnect all connectors from the power inlet.
  - Gently pull the power inlet out of the SQA-Vision through the rear panel.
- Insert a new power inlet and re-connect the cables.
- Re-connect the internal cables, re-place the internal cover and re-connect the power supply cable to the power supply board.



screws





Gently pull the power inlet from the rear panel

## Fan Assembly

Fan Assembly (part # V-H-00575-00)

**ISSUE:** The master switch is **ON**, the power indicator is lit but the fan is not rotating

- Open the SQA-Vision.
- Confirm that all the fan connecting cables are in place.
- Check that the voltage in the main board connector of the fan (location JP1) is:
  - 0V: black wire
  - +12V: purple wire
- If no power is evident, replace the main PSU (see previous section)
- If the voltage is as described above, replace the fan:
  - Unscrew the four fan screws.
  - Replace the fan assembly (fan + cable). .
  - Re-connect the cables and screw the new fan to the rear panel of the SQA-Vision. .
  - Do not change the direction of the outlet air flow! (the arrow on the fan should point outwards)



Fan Assembly



#### SECTION 1: SN #5228 and below

#### WARNING:

The two ends of the Data flat cable must be connected in the same way at each of the nodes (Operation monitor, Motherboard) or the LCD may be burned!

#### ISSUE #2- Blank Screen:

There is no data displayed on the screen although the SQA-Vision is ON, both power indicators are functioning and the fan is working.

PLEASE NOTE: The instructions depend on the SERIAL NUMBER (SN#) of the SQA-V.

- SN# 5228 and below follow the instructions in SECTION 1
- SN# 5229 and above follow the instructions in SECTION 2
- Re-install SQA-Vision software.
- If the software was not installed successfully- please refer to the technical bulletin in the appendix section for further instructions
- If the software was installed successfully and the problem remains- check the Data flat cable:
  - Open the SQA-Vision and verify that the Data flat cable, with the red lined side up is connected to the section designated with a 12 on the main board
  - Replace the flat cable if it appears damaged in any way.
- If replacing the cable does not work- replace the processor on the main board (see Appendix section for instructions).





Note the alignment of the red line on the Data cables

- If replacing the processor does not work:
- Re-start the SQA-Vision and see if the LCD Operation Monitor is still blank. If yes, replace the screen:
  - Disconnect the Operation Monitor Data and Backlight lamp cable
  - Unscrew the four screws.
  - Replace the screen & reconnect the Data and Backlight lamp cables.
- In case the problem persists after replacing the LCD screen- contact MES Customer Support.



**Backlight lamp cable** 



**Unscrew the four screws** 

#### SECTION 2: SN #5229 and above

#### WARNING:

The two ends of the Data flat cable must be connected in the same way at each of the nodes (Operation monitor, Backlight PCB and Motherboard) or the LCD may be burned!

Note: For more detailed explanations regarding blank screen issues, please refer to the "blank screen technical bulletin" in the appendix section

- Re-install SQA-Vision software.
- If the software was installed successfully but the problem remains check the LCD flat cable:
  - MB side: Open the SQA-Vision and verify that the LCD flat cable is oriented with the red lined side toward J1 connector (as shown in the picture below).
  - Replace the long flat cable which connects the main board and the Backlight PCB. (Item #KHD-908-000858)
  - If replacing the long flat cable does not work Replace the short flat cable which connects the LCD screen and the Backlight PCB. (Item#V-H-01411-00)
  - If replacing the short flat cable does not work Replace backlight PCB. (Item#V-B-01410-00)





- If replacing the backlight PCB does not work replace the processor on the main board (see Appendix section for instructions)
- If replacing the processor does not work, re-start the SQA-Vision and see if the LCD operational screen is still blank. If yes, replace the screen:
  - Disconnect the operational display data and power cable note the four screws.
  - Replace the screen & reconnect the data and power cables



• If the problem persists with the new screen – perform an MBOB replacement OR send the SQA-Vision back to the manufacturer (MES) for a repair RMA

**Focus Knob** Focus knob (Part# PE-MA-00538-00)

#### Please be advised:

Only an experienced and licensed electrical technician or electrician should perform this repair. **ISSUE:** When using the focus knob there is no change in the visualization system (the focus shown on the PC screen is not changed).

- Open the SQA-VISION.
- Unscrew the focus knob cover
- Pull out the focus knob base.
- Disconnect the optical assembly from the front panel (five screws).
- Disconnect the focus knob from the optical assembly by unscrewing three screws
- Remove the old focus knob
- Insert the new focus knob making sure it is turned all the way counterclockwise before replacing
- Re-connect the optical assembly to the front panel and close the SQA-VISION



focus knob



focus knob

Replace the New



New focus knob

Field Of View Knob (Part# VS-M-01105-00) Field of **View Knob ISSUE:** When using the FOV knob there is no change in the field of view. **SOLUTIONS:** This is described in a separate technical bulletin- please contact MES support services for further instructions. Surge Protector Replacement (PN: V-A-00475-01) Surge Protector Electrical surges or high voltage spikes in mains may cause damage to the SQA-Vision surge protector. Follow below instructions to check if the surge protector is intact or to replace the damaged surge protector to prevent further damage of SOA-Vision internal components. How to check the Surge Protector: Turn off the power and unplug the power cord from the inlet on rear panel of SQA-Vision Green color inside the windows Open the SQA-Vision Look through 3 small windows located on the front face of the surge protector and verify that the surface inside the windows is green If at least one of the surfaces inside the windows is not green, replace the surge protector

How to replace the Surge Protector:

- Follow the instructions from the section above to open the SQA-Vision
- In order to remove the defective Surge Protector all its 3 wires should be released
- Insert a small flat screwdriver into square opening in PDP (tri-colored contact block) right below the wire
- Simultaneously gently push down the screwdriver in order to release the wire and pull out the released wire
- Release and pull out from the PDP all 3 wires of Surge Protector (2 black and 1 yellowgreen)
- Cut all tie wraps attaching the wires to the rear panel
- Using 5.5mm socket screwdriver unscrew the nut connecting the Surge Protector to the rear panel
- Replace the defective Surge Protector with the new one and reconnect all its wires back to the PDP



Capillary<br/>SensorCapillary Sensor Troubleshooting and Replacement (KHD-908-000846 REV 02)Issue:When the SQA-Vision is turned on, it fails SELF-TEST

- Ensure there is no testing capillary in the measurement compartment
- Remove the SQA-Vision from sources of electronic noise (cell phones, etc.)
- Clean the measurement compartment per User Guide instructions
- Reboot the SQA-Vision without a testing capillary in the chamber:
  - Turn the system off then back on at the main switch on the side panel.
- If the self- test continues to fail after the reboot do the following:
  - Print a copy of the SELF- TEST parameters
  - Check parameter #17. This parameter represents the noise level. If the value is higher than 3- the noise level is too high. In this case replace the cables which connect the Optical Board to the LED Board
  - Check the values of Conc 1, Conc 2 and Conc. 3. If these values are ZERO, the capillary sensor may be damaged and will need to be replaced
- Turn off the power and open the SQA-Vision by unscrewing the screws from the rear panel using a #2 Philips screwdriver
- Pull out the focus knob
- Using a #2.5 Allen key, remove the <u>five</u> screws connecting the optical column to the front panel of the SQA-Vision



- Carefully pull the optical assembly to gently release it from the front panel
- Place the optical assembly on its side
- Release the 4 screws holding the Dust Buster using a #2 Philips screwdriver
- Release the screw holding the capillary sensor using a #2 Philips screwdriver







Release the Capillary Sensor Screw

Pull the Optical Assembly

- Unwind the white plastic cable wrap that holds the capillary sensor and other cables
- Remove the damaged capillary sensor from the optical block and unplug the cable connector from its location on the main board J13
- Attach a new capillary sensor to the optical block using a screw.
- Gently re-attach the Dust Buster to the Optical Block using the 4 Phillips screws.
- Re-attach the cable to the cable bundle, fasten the cables using the white plastic cable wrap.
- Connect the cable connector to its designated location on the main Board- J13.
- Attach the optical column to the front panel of the SQA-Vision using the original 4 screws.
- Close the back the front and rear panels of the SQA-Vision using a #2 Philips screwdriver.



Unwind the Plastic Cable Wrap



**Connector J13** 



New Capillary Sensor

Sensor

**CCD** Camera Replacement (Part # VS-MA-01174-00)

- **Issue:** When the camera is dirty or malfunctioning, then the CCD sensor including the assembly of the mount and the dust sleeve should be replaced.
- Turn off the power and open the SQA-Vision by unscrewing the screws from the rear section of the rear panel using a #2 Philips screwdriver.
- Pull out the focus knob.
- Disconnect the optical assembly from the front panel by unscrewing 5 screws using a #2.5 Allen Key.







- Release the screws at the rear section of the optical column using a #2.5 Allen key
- Release the zoom DC motor by unscrewing 2 screws using a #2.5 Allen Key







Remove the screws at the rear section

 Release the USB protector and the bottom cover by unscrewing 4 screws using a #2.5 Allen Key





Remove the USB protector and the bottom cover

• Release the camera USB stopper by unscrewing 2 screws using #0 Phillips screwdriver



Remove the USB stopper and disconnec the camera USB cable

- Release the stopper from the bench at the bottom of the optical column by unscrewing 2 screws using a #2 Allen Key
- Line up the false track with the steel rail



**Remove the Camera stopper** 



Lining up the false track

### Note:

The linear slide contains many small bearing balls that can be dislodged unless a false track is used to secure them.

Make sure that the false track is pressed securely against the steel rail in order to avoid dislodging the small bearing balls Slide the old camera tray over false track and seal it with the two plastic stoppers to prevent the tray from slipping out



**Remove the front plastic** stopper



Slide the old Camera tray over the false track



Slide the new camera assembly back

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Re-attach the Camera Stopper

Slide the entire new camera

- Reassemble the optical assembly by screwing the four screws on the rear section of the optical column
- Reconnect the USB Camera cable connector and put it back into place
- Reattach the base of the optical column on the assembly
- Reattach the zoom DC motor, and make sure the cogwheel is matched with the teeth of • the white plastic rack
- Reattach the optical column to the front panel •
- Reinstall the focus knob on the designated axis
- Ship to MES both false tracks, the old camera assembly and the empty one in coordination • with the customer support department

## Optical Board Cables

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#### Note:

The following instructions for replacing the **Optical Board** cables are applicable only for devices where aforementioned cables are joined with the boards by means of connectors. For those devices where the Optical Board cables are joined with the boards using soldering method the following instructions are not applicable! Please contact the MES customer support team for appropriate solution.

Optical Board to LED Cables - Replacement (Part # KHD-908-000689 - Rev. 01) Issue: When the noise level of the SQA-Vision (Parameter #17) is higher than 3, then the cables connecting the Optical Board to the LED Board need to be replaced.

- Turn off the power and open the SQA-Vision by unscrewing the screws from the rear panel using a #2 Philips screwdriver.
- Pull out the focus knob.



**Open the SQA-Vision** 

Using a #2.5 Allen Key, release the 5 screws which hold the Optical column to the front panel (shown in the pictures below)





- Remove the damaged cables from the Optical board by disconnecting the J5 and J6 connectors
- Carefully lay down the Optical Base
- Remove the damaged cables: disconnect the J1 and J2 connectors from their locations on the LED board
- Connect a new pair of cables as follows:
  - Connect the cables back to the J1 and J2 connectors on the LED Board
  - Connect the cables back to the J5 and J6 connectors on the Optical Board

Important Note: Pay close attention to connect the cables in the correct direction (from J1 to JP6 and from J2 to JP5)

- Reattach the optical column to the front panel using the same 5 screws
- Close the SQA-Vision.



Disconnect the J5 and J6 connectors



Disconnect the J1 and J2 connectors

## **SECTION IX: Appendixes**

Appendix 1: SQA Cleaning Instructions



Appendix 2: Replacing the Processor	Instructions for RE-SEATING Applies to all	G or REPLACING the SQA-Vision PROCESSOR I SQA-Vision system versions
FICESSO	Stage 1: Re-seating the processor to the correct position	
	<ol> <li>Turn off the SQA-Vision and disconnect the power supply cable</li> </ol>	
	<ol> <li>Loose the 4 screws on the rear panel using a Philips screwdriver #2 and open the SQA-Vision</li> </ol>	
		Open the SQA-Vision
	<ol> <li>Slightly press the center of the processor with an index finger to re-seat it into the correct position</li> </ol>	
	<ol> <li>Close the SQA-Vision and tighten all screws of the rear panel</li> </ol>	
	5. Connect the power cable of the SQA-Vision	
	<ol><li>Turn the SQA-Vision on and run the SELF-TEST</li></ol>	
	<ol><li>If the SQA-Vision passes, the repair process is complete</li></ol>	Slightly press the center of
	<ol> <li>If the SQA-Vision does not turn-on or fails the self- test, go to Stage 2</li> </ol>	the processor
	Stage 2: Replace the damaged processor	
	<ol> <li>Turn off the SQA-Vision and disconnect the power supply cable</li> </ol>	
	<ol> <li>Release the 4 screws on the rear panel using a Philips screwdriver #2 and open the SQA-Vision</li> </ol>	
	<ol> <li>Remove the damaged processor using extractor tweezers as shown on the figure to the right</li> </ol>	Para and Pa Para and Para and
		Remove the damaged processor

4. Replace the damaged processor with a new processor according to the following directions: Align the "dot" which is marked on the processor with the "Arrow" mark on the processor socket (see the figure to the right)



Arrow mark

5. Slightly press the center of the processor with an index finger to re-seat it into the correct position (see the figure to the right)



Slightly press the center of the processor

- 6. Close the SQA-Vision and tighten all screws of the rear panel
- 7. Connect the power cable of the SQA-Vision
- 8. Turn on the SQA-Vision and verify that it successfully passes the SELF-TEST



Appendix 4:		Parameters: Description and Troubleshooting Guide SELF-TEST Parameters	
Parameter	Acceptable Range	Describing and Troubleshooting Parameters Out of Range (High or Low)	
REFERENCE 1 (REF 1)	150 – 350 mV	REFERENCE 1 PASSED THE SELF-TEST ACCEPTABLE RANGE: 150mV – 350mV	
REFERENCE 1 (REF 1)	150 – 350 mV	REFERENCE 1 FAILED THE SELF-TEST If the REFERENCE 1 (REF 1) is not within the acceptable range of 150-350mV it indicates an: • Optical board problem. New motherboard/optical block, "MBOB" required (RMA)	
LED CURRENT 1 (LED 1)	5 – 20 mA	LED CURRENT 1 PASSED THE SELF-TEST ACCEPTABLE RANGE: 5mA – 20mA	
LED CURRENT 1 (LED 1)	5 – 20 mA	LED CURRENT 1 FAILED THE SELF-TEST         If the LED CURRENT 1 (LED 1) is not within the acceptable range of 5-20mA         and is not identical to the initial manufacturer's setting (you must compare)         it indicates the following:         If the LED CURRENT 1 (LED 1) is not within the acceptable range of 5-20mA         and is not identical to the initial manufacturer's setting (you must compare)         it indicates the following:         Initial Setting:         Dirt on motility channel (CLEAN)         Low vs. Initial Setting:         Scratched film requiring a new         motherboard/optical block, "MBOB" (RMA required)         Optical board problem if not resolved	M O T I L I T Y
Amplitude	50 - 100 mV	AMPLITUDE PASSED THE SELF-TEST ACCEPTABLE RANGE: 50mV – 100mV	
Amplitude	50 – 100 mV	AMPLITUDE FAILED THE SELF-TEST If the AMPLITUDE is not within the acceptable range of 50-100mV it indicates the following: • <u>High:</u> Scratched film requiring a new motherboard/optical block, "MBOB" (RMA required) • <u>Low:</u> Dirt on the motility channel (CLEAN) • Optical board problem if not resolved	

Parameter	Acceptable Range	Describing and Troubleshooting Parameters Out of Range (High or Low)	
Zero Level	500 - 525	ZERO LEVEL PASSED THE SELF-TEST ACCEPTABLE RANGE: 500 - 525	
Zero Level	500 - 525	ZERO LEVEL FAILED THE SELF-TEST         If the ZERO LEVEL is not within the acceptable range of 500-525 it indicates the following: <b>High:</b> • The light source is obstructed with dirt or debris (CLEAN)         • Ambient temperature is below 20°C / 68°F (maintain room temperature between 20-25°C / 68-77°F per user guide)         Low:         • The light source is obstructed with dirt or debris (CLEAN)       • Ambient temperature is above 25°C / 77°F (maintain room temperature between 20-25°C per user guide)         • Ambient temperature is above 25°C / 77°F (maintain room temperature between 20-25°C per user guide)       • Optical board problem if not resolved	
REFERENCE 2 (REF 2)	2500 - 3500	REFERENCE 2 PASSED THE SELF-TEST ACCEPTABLE RANGE: 2,500mV – 3,500mV	
REFERENCE 2 (REF 2)	2500 - 3500	REFERENCE 2 FAILED THE SELF-TEST         If the REFERENCE 2 (REF 2) is not within the acceptable range of 2500-3500mV it indicates the following:         Low:       The light source is obstructed with dirt or debris (CLEAN)         High:       Optical board problem. New motherboard/optical block, "MBOB" required (RMA)         REF2=0:       Damaged Optical board to LED board cables/ Optical board problem         • Replace cables in the field       • Optical board problem. New motherboard/optical block, "MBOB" required (RMA)	
REFERENCE 2 (REF 2)	2800 - 3200	REFERENCE 2 PASSED THE SELF-TEST BUT IS NOT OPTIMAL OPTIMAL RANGE: 2,800mV – 3,200mV (CLEAN)	T R A T
LED CURRENT 2 (LED 2)	10 – 32 mA	LED CURRENT 2 PASSED THE SELF-TEST ACCEPTABLE RANGE: 10mA – 32mA	C N
LED CURRENT 2 (LED 2)	10 – 32 mA	<b>LED CURRENT 2 FAILED THE SELF-TEST</b> If the LED CURRENT 2 (LED 2) is not within the acceptable range of 10-32mA <b>and is not</b> identical to the initial manufacturer's setting (you must compare) it indicates an optical board or LED problem requiring a new motherboard /optical block, "MBOB" <b>(RMA)</b>	

Parameter	Describing and Troubleshooting Parameters Out of Range
Auto-calibration and stabilization	AUTO-CALIBRATION AND STABILIZATION PASSED
	ZERO LEVEL parameter is stable
	<b>AUTO-CALIBRATION AND STABILIZATION FAILED</b> If the auto calibration and stabilization process fails, the following steps should be taken:
Auto-calibration and stabilization	• <b>Remove testing capillary</b> from the measurement compartment.
	• Remove the SQA-Vision from sources of vibrations (centrifuge)
	Clean the measurement compartment
•	<ul> <li>Reboot the SQA-Vision without a testing capillary in the chamber: Turn the SQA-Vision OFF then back ON</li> </ul>
	Call technical support if failure recurs
Self-Test	SELF-TEST PASSED
<b>Ø</b>	The key system parameters are in range
Control Level 1\2\ 3\ negative	CONTROL LEVEL TEST PASSED
	The control level 1 <b>OR</b> control level 2 <b>OR</b> control level 3 <b>OR</b> negative control is within the acceptable range (as specified on the controls box)
Control Level 1\2\ 3\ negative	CONTROL LEVEL TEST STATUS IS NOT DEFINED
	If there is a probability that the control test result is out of range. For example, the control test result is CONC. < $2.0 (M/ml)$ and the acceptable range is $0.0$
	CONTROL LEVEL TEST FAILED
Control Level 1\2\ 3\ negative	If the control level 1 <b>OR</b> control level 2 <b>OR</b> control level 3 <b>OR</b> negative control is not within the acceptable range (as specified on the controls box), the the following steps should be taken:
	Make sure to mix the controls before testing
8	<ul> <li>Check the expiration date of the controls</li> </ul>
	If expired, run a new box of controls
	Call for technical assistance if controls are still out of range
I-Button tests remaining	
	I-BUTTON TESTS REMAINING: > 10
<b>V</b>	There is more than 10 1-button tests remaining in the system
I-Button tests remaining	I-BUTTON TESTS REMAINING: < 10
	I-Button tests should be added to the system
I-Button tests remaining	I-BUTTON TESTS REMAINING: 0
8	In order to perform automated tests, I-Button tests should be added to the system

Next Backup	<b>A SYSTEM BACKUP NEEDS TO BE PERFORMED</b> The system backup was not performed yet. Open the Vision Service screen (PC)
Last Backup	<ul> <li>MESSQAV.mdf FILE WAS NOT FOUND IN SQA-VISION'S LOCAL PATH</li> <li>Perform the following actions: <ul> <li>Make sure that MESSQAV.mdf file is closed</li> <li>Restart the PC</li> </ul> </li> <li>Call for technical assistance if the problem remains</li> </ul>
Last Backup	ERROR DURING BACKUP PROCESS The following actions should be taken: • Make sure there is enough space on HDD for the backup file to be saved • MESSQAV.mdf file is closed properly Call for technical assistance if the problem remains
Last Backup	BACKUP DESCRIPTION FILE WAS NOT SAVED THIS ERROR DOES NOT CAUSE THE BACKUP PROCESS TO FAIL, SO YOU MAY IGNORE IT
Last Backup	<b>BACKUP PROCESS HAS BEEN FINISHED SUCCESSFULLY</b> The relevant MESSQAV.mdf file is saved in the defined backup location
HDD Space Used	THERE IS STILL HDD SPACE REMAINING (USAGE < 80 %) The HDD free space is enough for the system optimal performance
HDD Space Used	IT IS RECOMMENDED THAT YOU FREE SOME HDD SPACE DELETE UNUSED FILES
HDD Space Used	THE HDD IS OUT OF SPACE PLEASE DELETE UNUSED FILES TO FREE-UP SPACE The HDD free space is not enough for the system optimal performance. The free space can be enlarged by unused files deletion