

# THE SPERMALITE/SQA-V TECHNOLOGY



Medical Electronic Systems, Ltd

# Description of the SQA-V

- High performance, analytical medical device
- Performs complete quantitative evaluation of semen quality and semen parameters
- Rapid results – *under 2 minutes*
- Electro-optics, computer algorithms, video microscopy
- Internal printer, patient archive, self-testing, self-calibrating
- Runs latex beads controls
- Video visualization system

# Automated Test Results

<b>Conventional WHO Parameters</b>	<b>Format</b>
<b>Total Sperm Concentration</b>	<b>TSC, M/ml</b>
<b>% Motility</b>	<b>MOTILITY, %</b>
<b>% Progressive Motility</b>	<b>PROG. MOTILITY, %</b>
<b>% Immotility</b>	<b>IMMOTILITY, %</b>
<b>% Normal Morphology (option to select WHO or Kruger criteria)</b>	<b>CALC. NORM. MORPH., %</b>
<b>SQA-V Derived Parameters</b>	
<b>Motile Sperm Concentration</b>	<b>MSC, M/ml</b>
<b>Progressively Motile Sperm Concentration</b>	<b>PMSC, M/ml</b>
<b>Functional Sperm Concentration (Progressively Motile Sperm with Normal Morphology)</b>	<b>FSC, M/ml</b>
<b>Average Velocity (Average path velocity – VAP)</b>	<b>VELOCITY, mic/s</b>
<b>Sperm Motility Index ( A number between 0=500 reflecting PMSC &amp; average velocity)</b>	<b>SMI</b>
<b>Totalized Quantities Per Sample</b>	
<b>Total Sperm</b>	<b>ALL SPERM, M</b>
<b>Total Motile Sperm</b>	<b>MOT. SPERM, M</b>
<b>Total Progressively Motile Sperm</b>	<b>PROG. SPERM, M</b>
<b>Total Functional Sperm</b>	<b>FUNC. SPERM, M</b>

## Reference Values of Semen Variables

SEMEN PARAMETER	SQA-V TEST FORMAT	REFERENCE RANGE	SOURCE
Sperm Concentration	TSC	≥ 20 M/ml	WHO' 99 MANUAL
Motility (grades a+b+c )	MOTILITY	-	-
Progressive motility (grades a+b)	PROG. MOTILITY	≥ 50%	WHO' 99 MANUAL
Non Progressive motility (grade c)	NONPROG. MOTILITY	-	-
Immotility (grade d)	IMMOTILITY	-	-
Morphology (Calculated Normal Morphology, WHO non-strict)	CALC. NORM. MORPH. (WHO)	≥ 30%-	WHO '92 MANUAL
Morphology (Calculated Normal Morphology, Kruger strict)	CALC. NORM. MORPH. (KRUGER)	≥ 15% (Under investigation)	WHO' 99 MANUAL
Motile Sperm Concentration	MSC	-	-
Progressively Motile Sperm Concentration	PMSC	≥ 10%	MES Ltd.
Functional Sperm Concentration	FSC	≥ 7 M/ml (Non-strict Morph.) ≥ 3 M/ml (Kruger Morph.)	MES Ltd.
Velocity (Average path velocity – VAP)	VELOCITY	≥ 5 microns/second	MES Ltd.
Sperm Motility Index	SMI	≥ 80	MES Ltd.

# Measurement of sperm concentration and motility begins with the capillary.....

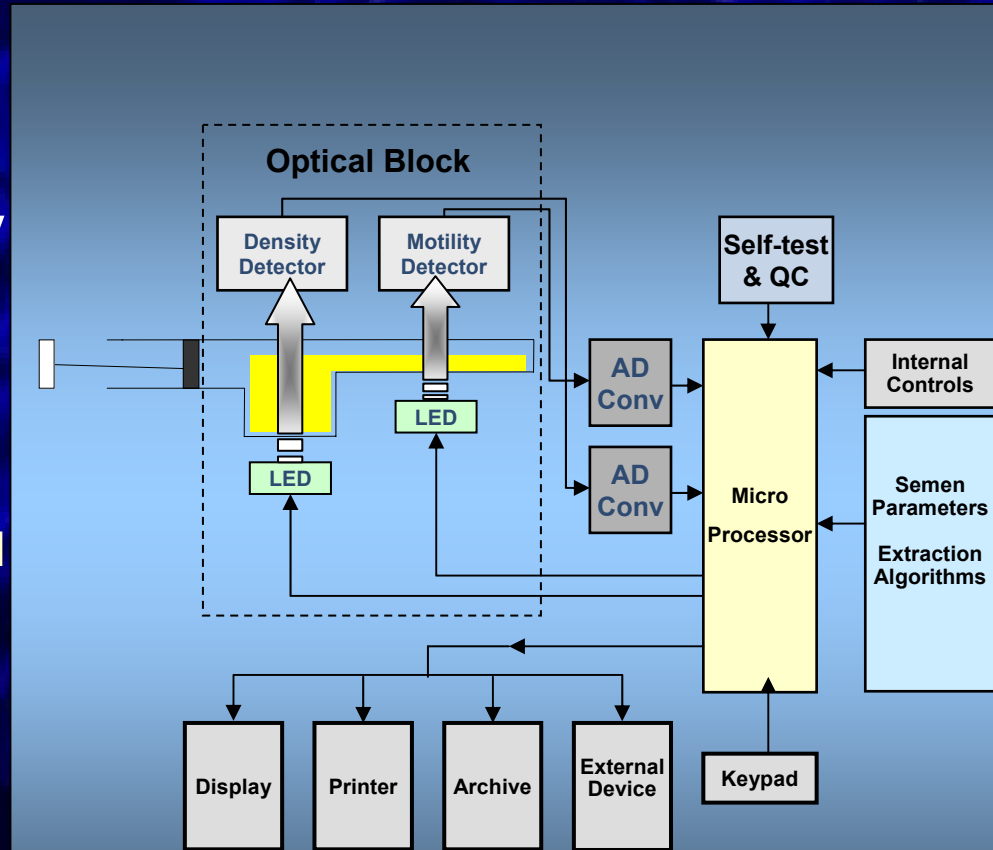


Sample **concentration** is evaluated in the “**Tall**” chamber of the capillary.

**Motility** is evaluated in the “**Thin**” section of the capillary

# SQA-V Theory of Operation

- The SQA-V capillary is inserted into the measurement compartment
- Sample **concentration** is evaluated in the “**Tall**” chamber of the capillary by measuring:
  - The amount of optical absorption/reflection of light as an IR beam traverses the seminal fluid
- **Motility** is evaluated in the “**Thin**” section of the capillary by analyzing:
  - Modulations in the SQA-V light source caused by the movement of sperm cells



# Sperm Motility:

*Tens of thousands of cells are measured*

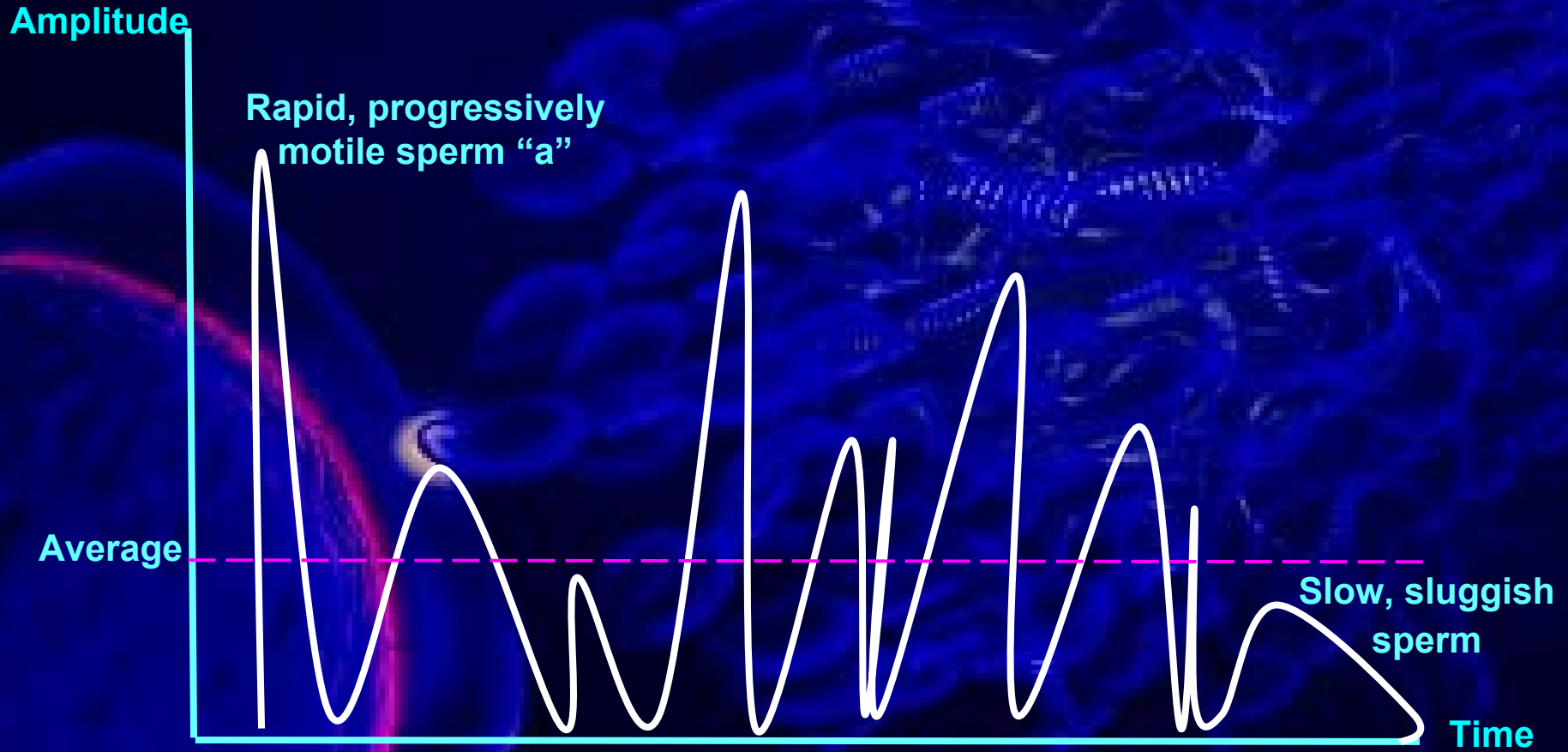
- Light interruptions (modulations) are converted into an electronic signal that displays “peaks and valleys”
- The electronic signal peaks are averaged.
- This number is translated into motility via a proprietary algorithm

# Sperm Motility:

- Because each category of sperm (a, b, c and d) move differently, the resulting modulations in the light source are *unique* and subsequently translate into *unique* electronic signals.
- Rapidly progressive sperm create light modulations that differ from those produced by slowly progressive sperm.
- Immotile sperm does not create any light disturbances at all!



# Electronic Signal of Motile Sperm



# Sperm Concentration

*Millions of sperm cells are analyzed*

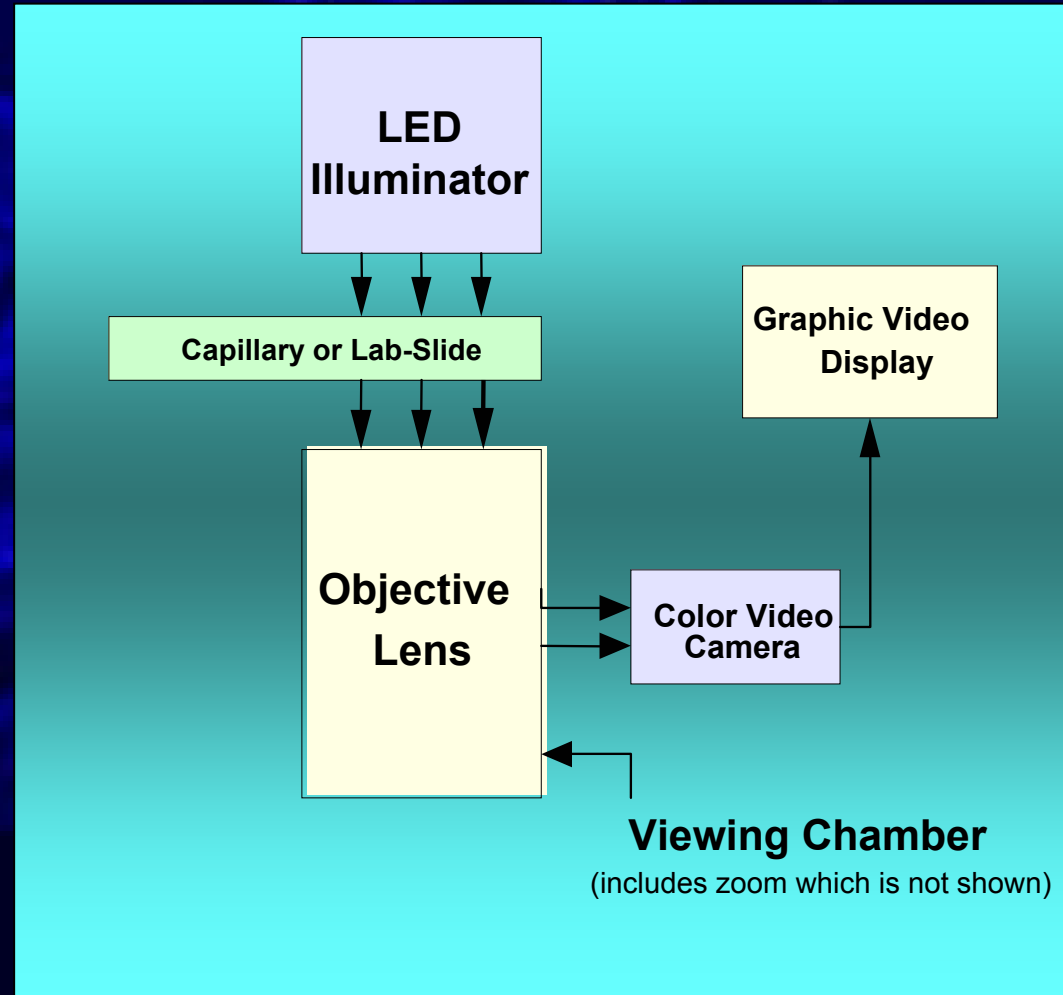
- A light beam traverses the seminal fluid and light is absorbed by sperm cells
- An optical density detector measures the amount of light absorbed by the cells
- This measurement is translated into **total cell concentration** by a microprocessor based on a proprietary algorithm

# Sperm Morphology:

- This is a calculated parameter
- Based on a correlation between sperm motility and morphology, MES developed a proprietary algorithm that expresses **NORMAL** morphology as it relates to motility, progressive motility, and velocity
- This parameter is useful as a qualitative screen for normal vs. abnormal morphology

# The Visualization System

- Color video display
- Magnification of X300 to X500
- Allows viewing of both capillary or slide samples
- At X300 cell concentration can be determined visually
- An interface with V-Sperm software allows the user to view sperm cells on a PC to more closely examine the specimen



# Electronic Self-Test and Auto Calibration

- **At start-up**
  - **Stabilization and auto-calibration:** Automatically checks system stability and reference ranges for 30 seconds
  - **System noise:** The level of electronic noise is measured and filtered in order to meet acceptable thresholds
  - **Self test:** Electronic signals are produced simulating motility and concentration to verify calibration settings are consistent with factory settings

# Electronic Self-Test and Auto Calibration

- **Prior to sample testing:**
  - **Auto calibration verification:** Reference values are re-checked. Concentration and motility parameters are measured
  - **System noise:** The level of electronic noise is measured and filtered in order to meet acceptable thresholds
  - **Electronic spikes:** Checks for any measurement points that are out of range electronically

# Product Performance Data

- **Dynamic Range:**

Sample Type	Test Mode	TSC M/ml	Motility %	Morph %	MSC M/ml	PMSC M/ml	#Sperm Cells/field
Fresh	Normal	5-400	0-90	0-100	0-400	0-400	-
Washed	Normal	2-200+	0-90	0-100	0-200+	0-200+	-
Frozen	Normal	-	-	-	0-200+	0-200+	-
All Types	High Sensitivity	-	-	-	0-2	-	0-30

# Product Performance Data

- Precision: The precision and accuracy of the SQA-V was compared to a known concentration target value of commercially available latex beads.

SQA-V	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	≤ 2.5



# Product Performance Data

## Specificity Claims:

- Concentration: 85%
- Motility: 80%
- Calculated Normal Morphology (WHO): 65%
- Calculated Normal Morphology (Kruger): 60%

## Sensitivity Claims:

- Concentration: 90%
- Motility: 85%
- Calculated Normal Morphology (WHO): 85%
- Calculated Normal Morphology (Kruger): 65%

# Product Performance Data

- **Correlation to Manual Method Claim:**
  - **Concentration: 0.90**
  - **Motility: 0.85**
  - **Calculated Normal Morphology (WHO): 0.65**
  - **Calculated Normal Morphology (Kruger): 0.45**

# Product Performance Data

## Precision – Compared to Microscope

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

# Product Performance Data

- **Post-vasectomy Mode:**

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%

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# Human Sperm

(Viewed through V-Sperm III)

