Medical Electronic Systems
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Comparison of the SQA-V Gold to LensHooke™ X1 & X1 PRO

Item	SQA-V Gold	LensHooke™ X1 & X1 PRO
General view		
Product	SQA-V GOLD Sperm Quality Analyzer	LensHooke™ Semen Quality Analyzer
Manufacturer	MES Ltd.	Bonraybio Co., Ltd
Intended use	The SQA V is a point-of-care, electro-optical device with onscreen visualization that is used for semen analysis.	The LensHooke X1 Semen Quality Analyzer used with LensHooke Semen Test Cassette is an optical device for human semen analysis. There are home test OTC (X1) and professional point-of-care (X1 PRO) models.
Technology	Signal processing: Analog electronic signals detected in two independent channels are digitized and analyzed by the internal processor and proprietary algorithms are applied.	CASA device with image processing analysis and chromatography for pH detection. Desk-top unit consists of light sources, built-in video microscopy and an internal computer containing algorithms for the assessment of semen parameters. Video images of sperm cells are captured and analyzed by the software. According to FDA 510(k) device description, the sperm concentration is analyzed by the sperm unit density; the sperm motility is calculated by tracing sperm trajectories and the sperm morphology is calculated by comparing head and tail percentage. As the non-stained sperm is assessed, any morphology assessment is impossible because the acrosome area is not visualized. Besides that, comparing head and tail percentage for morphology assessment looks like a bluff and has no any relation to the WHO 5th ed. manual guidelines.

Semen parameters	**WHO 5th version: 16 semen parameters**	**Sperm concentration (10^6 per ml) Total motility (PR+NP, %) Progressive motility (%) Non-Progressive motility (%) Sperm morphology (normal forms, %) pH value**
Automation	**Fully automated**	**Fully automated**
Sample type	**Fresh, Washed, Frozen, Post Vasectomy**	**No indication of sample types except fresh semen**
Sample size	**Hundreds of µl resulting in high level of accuracy.**	**35-45 µl**
Statistical representation	**Representative due to the large sample size.**	**Representation may be distorted due to the small sample size.**
Sample preparation	**No sample dilution required.**	**The sample is tested as is though it is known that there is a lack of accuracy in CASA systems at low and high sperm count range (A. Agarwal et al., 35th Annual Meeting of ESHRE, 2019).**
WBC & pH testing	**Both parameters are tested using QwikCheck Test Strips**	**Only pH is tested**
Number of cells analyzed	**Thousands in motility channel and millions in concentration channel.**	**200 or more. Measurements of single spermatozoa tracks.**
Testing time	**~ 70 seconds**	**2-5 minutes**
Precision	**Concentration: CV = 2.1 % Motility: CV = 4.0 % Morphology: CV = 3.6 %**	**Concentration: CV <= 10 % Motility: CV <= 10 % Morphology: CV <= 10 %**
Repeatability using Control material	**• Intra-device CV ≤ 0.01 % • Inter-device CV ≤ 2.5 % (SQA-V User Guide, Product Performance Data).**	**• Intra-device CV – NA • Inter-device CV ≤ 10 %**
Consumables	**Disposable test capillaries, external controls, WBC & pH test strips, liquefaction, dilution and cleaning kits.**	**Semen test cassettes, liquefaction test cup, external controls (3 levels), QC cassettes and cleaning wipes.**
Connection to PC	**Port for connection to V-Sperm**	**USB & LAN connection**
FDA 510(k) approval	**Approved**	**Approved**

PROS & CONS	**PROS:** • **Signal processing technology providing high precision** • **Easy operation** • **Rapid analysis (70 seconds)** • **WBC and pH are pre-tested by test strips** • **16 parameters are reported** • **No sample dilution is required if volume is >= 0.5 ml** • **FDA approved** • **Acceptable cost of consumables** **CONS:** • **The sample size should not be less than 0.3 ml for testing in dilution mode.** • **No high resolution video images provided.**	**PROS:** • **Easy operation** • **High resolution video images** • **Miniature device** • **FDA approved** **CONS:** • **CASA technology with intrinsic limitations including moderate to low precision.** • **High cost of consumables** • **Slow analysis (up to 5 minutes)** • **WBC are not tested** • **Only 6 parameters are reported** • **Sample dilution is not required though CASA is not accurate at low and high concentration area.** • **Not standardized: different CASA instruments use different mathematical algorithms. The degree of comparability of measurements across all CASA systems is not yet known.** • **Factors that may affect the analytical quantitative testing based on the image processing: WBC, round cells, cell aggregations, crystals, difficulties of tail detection, counting cells without tails as spermatozoa, etc. are not taken into consideration for correction.** • **The system reports normal morphology assessed by image processing without staining by comparing head and tail percentage that does not make any sense, as head abnormalities and acrosome area are not reliably visualized.** • **Statistical counting errors of image processing impact the accuracy of system measurements.** • **The performance publication was based on the limited amount of 135 samples (Andrologia. 2019 Oct 4:e13440. doi: 10.1111/and.13440. [Epub ahead of print]).** • **No vast clinical trials proving the accuracy and precision of the LensHooke devices run by the lab staff of different clinical sites were conducted.**