HT CASA Clinical Sperm Motility Software For IVOS Clinical and CEROS Clinical Systems

HAMILTON THORNE

100 Cummings Center, Suite 465E, Beverly MA 01915 978.921.2050, 88.323.0503, Fax: 978.921.0250 www.hamiltonthorne.com, info@hamiltonthorne.com

Data Input

Analysis Info: Patient ID

Patient Name

Ejaculate Volume (manually or by scale)

Sample:Diluent

Notes: User-defined

Data Fields: 25 User-Defined Labels/Fields

Analysis Results

Counts: Total, Motile, Static, Progressive, Slow Total, Motile, Static, Progressive, Slow (%) Percentages:

Total, Motile, Static, Progressive, Slow (M/ml or B/ml) Concentrations: Sample: Total, Motile, Static, Progressive, Slow (M or B)

Kinematic Values: VAP, VCL, VSL, ALH, BCF, LIN, STR, DAP, DCL, DSL, *WOB,

Elongation (head shape) and Area (head size). Includes mean,

standard deviations and median.

Pie Charts*: WHO 4/5/*6 Percent of Total (motile vs. static)

WHO 4/5/*6 Velocity Percent of Motile

WHO Standards: WHO 4

> Reference Limits: Concentration, Motility, Progressive Velocity Distribution by WHO 4 A, B, C, D categories WHO 5 (5th centile, 95% CI, Cooper et al. 2010) Reference Limits: Concentration, Motility, Progressive

Velocity Distribution by WHO 5 Progressive, Non-progressive, and

Immotile categories

WHO 6* (5th centile, 95% CI, Cooper et al. 2021) Reference Limits: Concentration, Motility, Progressive Velocity Distribution by WHO 6 A, B, C, D categories

Replicate Analysis*: Automatic two sample analysis comparison

Based on WHO 4/5/*6 results

Override and lock of selected WHO variable Display of Mean, Delta Gate, Reference Limits Result

Live Setup Configuration

Interactive illumination setting Illumination:

Histogram showing real-time feedback* Interactive sperm identification setup

Automatic minimum tail brightness based on Photometer Offset*

Minimum head and *tail brightness

Minimum and maximum head size and head elongation

Real-time feedback through color overlays*

Quality Control

Motility Setup:

Auto Illumination*†: One Shot and Auto on Field Change Illumination Check: Quick view to confirm illumination and focus

Illumination Status: Acceptable / Unacceptable

Video Playback: Color-coded labeling of motile, progressive and static cells

Static Tail Filter*: Automatic elimination of debris

Video Playback

Full Field: Frame-by-frame playback Analysis results for selected field

Turn on/off motility and morphology overlays

Save TIFF image of individual frames

Export fields as .mp4 files for presentation purposes only*

Zoom Cell: Frame-by-frame playback

Analysis results for selected sperm

Data point coordinates Cell classifications Turn on/off motility overlay* Save TIFF image of individual frames

Save individual cell data to ASCII (requires Edit Tracks) Save data points to ASCII file (requires Edit Tracks)

Security

HT User Groups*: Administrative or Basic user Password Security:

Windows-based Users

Unlimited User IDs and passwords

Analysis Setups restricted to Administrator users Setup Access:

only

* Not available on Legacy HT CASA.

† Not available on CEROS

Included Data Management Options

Transfer of summary data and/or individual track to ASCII ASCII Export:

compatible spreadsheet or database programs.

ASCII Import: Import of select sample information.

Video Storage: Ability to save video file of each field analyzed, along with sample

information and analysis setup values. Recall and analyze video with saved settings or new settings. Re-analyze single videos or

entire analysis sets.

Report Viewer: View analysis data in report format.

Report Designer*: Report designer and manager to create unlimited professional reports from sperm analysis results. Ability to include all data

(calculated and user input), images, and logo. Drag and drop design, snap-to alignment. Ability to combine motility and Dimensions II

Morphology results in single report.

Optional Special Applications

IQC Module*: Internal Quality Control software to method of verifying objective

calibration and monitoring quality control counts. Includes Levey-Jennings Chart and application of Westgard Rules. User-selectable

Segments sperm into sub-populations based on kinematic and/or Sort:

morphometric parameters.

Save individual track data to ASCII output plus ability to manually Edit Tracks:

delete tracks from cell population.

IDENT+: Automated motility analysis of high-detritus samples using DNA-

specific, fluorescent stain and integrated fluorescent illumination. Sperm viability assessment software option. Stain sperm with non-VIADENT+:

membrane permeable DNA stain and calculate viable sperm

numbers under fluorescence (requires IDENT option).

Analysis Sets: Unlimited, User-defined by administrator

Analysis Setup Parameters (Administrative Users Only)

Setup: Setup Name

Analysis Limits: Min Motility (%) Min Progressive (%)

Min Total Count

Objective Name Calibration: X-axis Magnification Y-axis Magnification*

Camera: Exposure (ms) Gain

Integrate Enabled Integrate Time (ms)

Cell Detection: Elongation Max (%) Enable Advanced Tail Detection* Elongation Min (%) Tail Min Brightness Mode*

Head Brightness Min Head Size Max (µm²) Static Tail Filter* Head Size Min (µm²)

Tail Brightness Min* Tail Min Brightness Auto Offset*

Chamber: Capillary Correction Chamber Depth (µm)

Chamber Type (Capillary, Drop)

Illumination Primary *†

Max Photometer

Min Photometer

Illumination:

Kinematics: Cell Travel Max (µm) Slow VAP (µm/s)

Enable Motile Static Collisions Avoidance* Slow VSL (µm/s) Motile Cell Require Tail* Static Algorithm*

Motile Require Tails Max VSL (µm/s) * Static VAP (µm/s) Static VSL $(\mu m/s)$ Progressive STR (%)

Static Width Multiplier*

Progressive VAP (µm/s) Morph: Min Tail Length (µm) *

Tail Confidence (%) * Stage Temp (°C) *†

VIADENT+: VIADENT Fluorescing System

Video Capture: Frame Capture Speed (Hz)

Frame Count Image Type

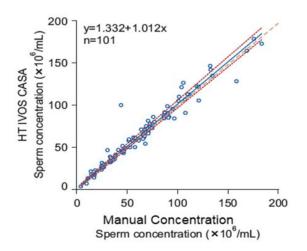
Doc. # SS-1228 Rev.F Effective Date:2023-01-13

HT CASA Clinical Sperm Motility Software For IVOS Clinical and CEROS Clinical Systems

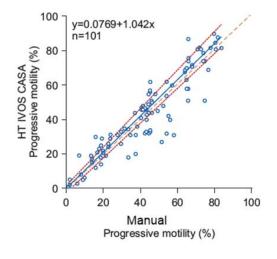


100 Cummings Center, Suite 465E, Beverly MA 01915 978.921.2050, 88.323.0503, Fax: 978.921.0250 www.hamiltonthorne.com, info@hamiltonthorne.com

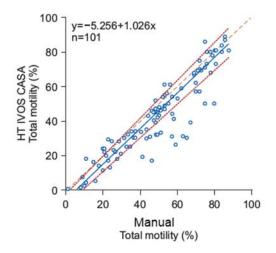
Concentration (Correlation Analysis, Pearson's correlation coefficient)



Progressive Motility (PR, Progressive Motility) (Correlation Analysis, Pearson's correlation coefficient)



Motility (TM, Total Motility) (Correlation Analysis, Pearson's correlation coefficient)



Precision and Accuracy of HT CASA II in evaluating Sperm Concentration, Total Motility and Progressive Motility compared to Manual Semen Analysis

v	Precision	Accuracy
Concentration	0.97	0.99
Total Motility	0.92	0.97
Progressive Motility	0.93	0.99

Operational Range

	Minimum	Maximum
Sperm Concentration	2 M/ml	100 M/ml
Progressive Concentration	2 M/ml	100 M/ml
Progressive Motility	2%	100%
Motility	2%	100%

Agarwal A, Panner Selvam MK, Ambar RF. Validation of LensHooke® X1 PRO and Computer-Assisted Semen Analyzer Compared with Laboratory-Based Manual Semen Analysis. World J Mens Health. 2021 Jul;39(3):496-505. doi: 10.5534/wjmh.200185. Epub 2021 Feb 5. PMID: 33663026; PMCID: PMC8255407.

Doc. # SS-1228 Rev.F Effective Date: 2023-01-13