

IVOS II & CEROS II

Clinical CASA Systems

The screenshot displays the Human Clinical II software interface. The main window shows a grayscale image of a sperm cell with a blue trajectory line. The interface includes several panels:

- Results:** A table of kinematic measures.
- Data Points:** A table of frame-by-frame data.
- Classifications:** A list of classification categories.
- Analysis Info:** Patient information and analysis parameters.
- Velocity Distribution:** A table of velocity distribution data.

Kinematic Measures

Metric	Value	Units
DAP	26.30	µm
DSL	23.53	µm
DCL	40.08	µm
VAP	54.26	µm/sec
VSL	48.55	µm/sec
VCL	82.70	µm/sec
ALH	5.41	µm
BCF	12.47	Hz
LIN	58.71	%
STR	89.48	%
WOB	65.61	%
FDM	1.19	

Data Points

Frame	Point-X	Point-Y	Avg Path-X	Avg Path-Y
1	342.4	335.4	342.4	335.4
2	341.8	334.5	341.6	334.6
3	340.5	333.9	341.3	333.4
4	340.8	332.4	341.7	332.8
5	341	330.9	342.1	331.9
6	342.1	331.3	342	331
7	343.1	331.1	341.9	330
8	343.8	329.3	342	329.1
9	343.5	327.8	342.2	328.3
10	341.9	327.7	342.4	327.6
11	341.5	326.3	342.7	326.8
12	341.2	324.5	342.9	326
13	342.3	324.9	343	325.2
14	342.8	325.3	343	324.3
15	343.5	324.2	343	323.5
16	344.2	322.7	343.1	322.7
17	343.8	322.5	343.2	322
18	344.3	321.6	343.3	321.3
19	344.2	319.8	343.5	320.6
20	343.5	319	343.7	319.7
21	343.2	318.6	344	319.1
22	342.1	318.5	344.2	318.3
23	342.8	317.5	344.4	317.5
24	343.8	316.8	344.4	316.7
25	345.2	316	344.3	315.9
26	346.9	316.6	344.5	315.3
27	346.5	314.9	345.1	314.5
28	346	313.3	345.3	313.8
29	344.7	312.3	344.5	312.5
30	342.7	311.9	342.7	311.9

Classifications

Classification	Count
Progressive	282
Motile	421
Rapid	421
Total	421

Analysis Info

Patient ID: 61-978959
First Name: Peter
Last Name: Smith
Date Of Birth: 7/ 6/1984
Physician: John Dillon, MD
Volume: 1.00
Sample Diluent 1: 0.0
Lab Technician: HT

Velocity Distribution

WHO4 Category	Count	Sample (M)	Conc (M/ml)	%
A WHO 4 Rapid Progressive	282	4.21	4.21	1
B WHO 4 Slow Progressive	60	0.90	0.90	4
C WHO 4 Non-Progressive	60	0.90	0.90	4
D WHO 4 Immobile	1032	15.42	15.42	72
WHO 4 Progressive	342	5.11	5.11	2
WHO 4 Motile	421	6.01	6.01	1

The image also shows a physical sperm motility analysis system (IVOS II) and a computer monitor displaying the software interface. A baby is sitting in front of the system.

Featuring
Human Clinical II
Sperm Motility Software



Accurate & Precise Sperm Analysis

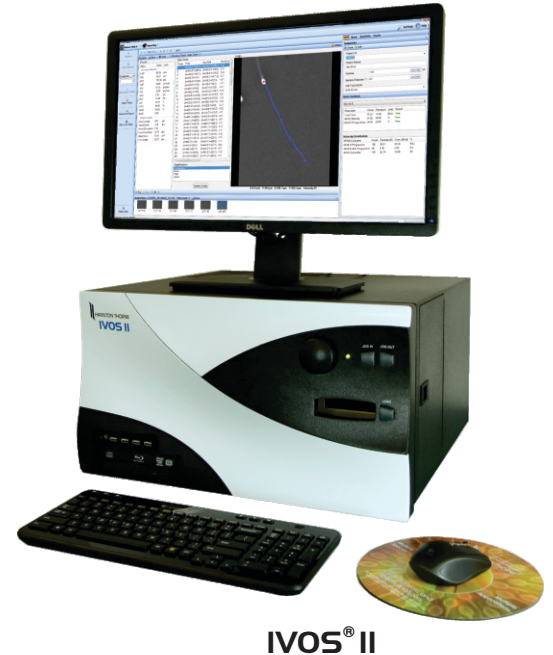
With the accuracy and precision of our sperm analyzers, you can trust in the sperm analysis results our CASA systems provide. To meet your specific needs, we offer two analyzer models, the IVOS™ II and the CEROS™ II, to the assisted reproduction, andrology and pathology laboratories.

Our sperm analyzers provide:

- Accurate, objective and repeatable results
- Intuitive software interface for ease of operation
- Rapid analysis with automatic adjustment of minimum tail brightness for consistency across all analysis fields
- Compatibility with reusable and disposable analysis chambers
- Real-time quality control through interactive illumination settings
- Labor savings

Detailed analysis results include:

- Counts & Concentrations
- Motility, Progressive Motility, Velocities and Kinematic Measures
- Direct WHO comparisons with simple switch between WHO 4th and 5th editions

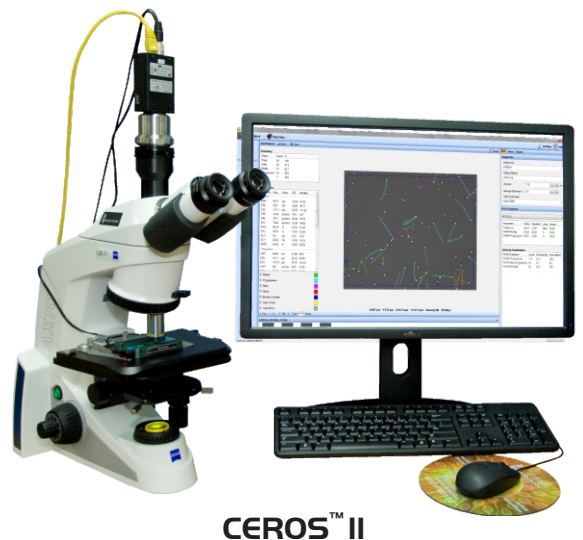


IVOS® II

- Automation for speed, increased precision and decreased technical variation
- Computer controlled auto-illumination standardizes analysis setup across all users
- Auto-selection of fields for fastest analysis
- All optics components combined into one integrated unit - the microscope is inside!
- Strobe illumination provides sharpest imaging
- Automated stage for precise temperature control and sample positioning

CEROS™ II

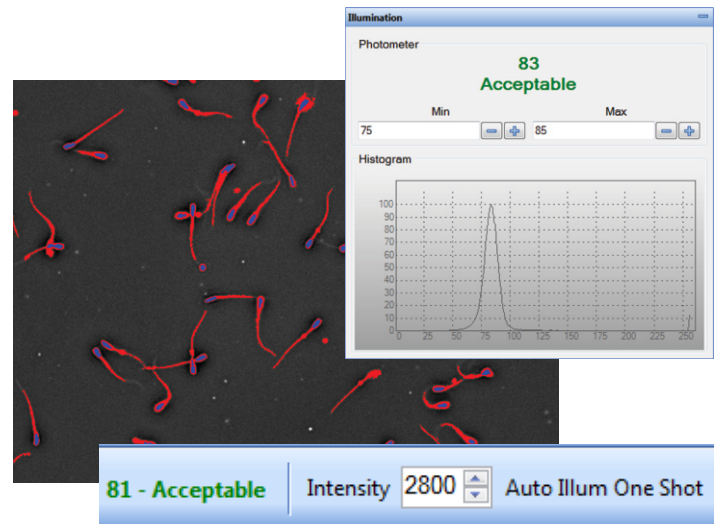
- External negative phase contrast microscope (included)
- Choice of desktop computer with widescreen HD monitor or full HD laptop computer
- Familiar, standard microscope illumination controls
- Portable MiniTherm Stage Warmer (optional) maintains samples at 37°C
- X-Y stage movement increases number of fields available for motility and morphology analyses



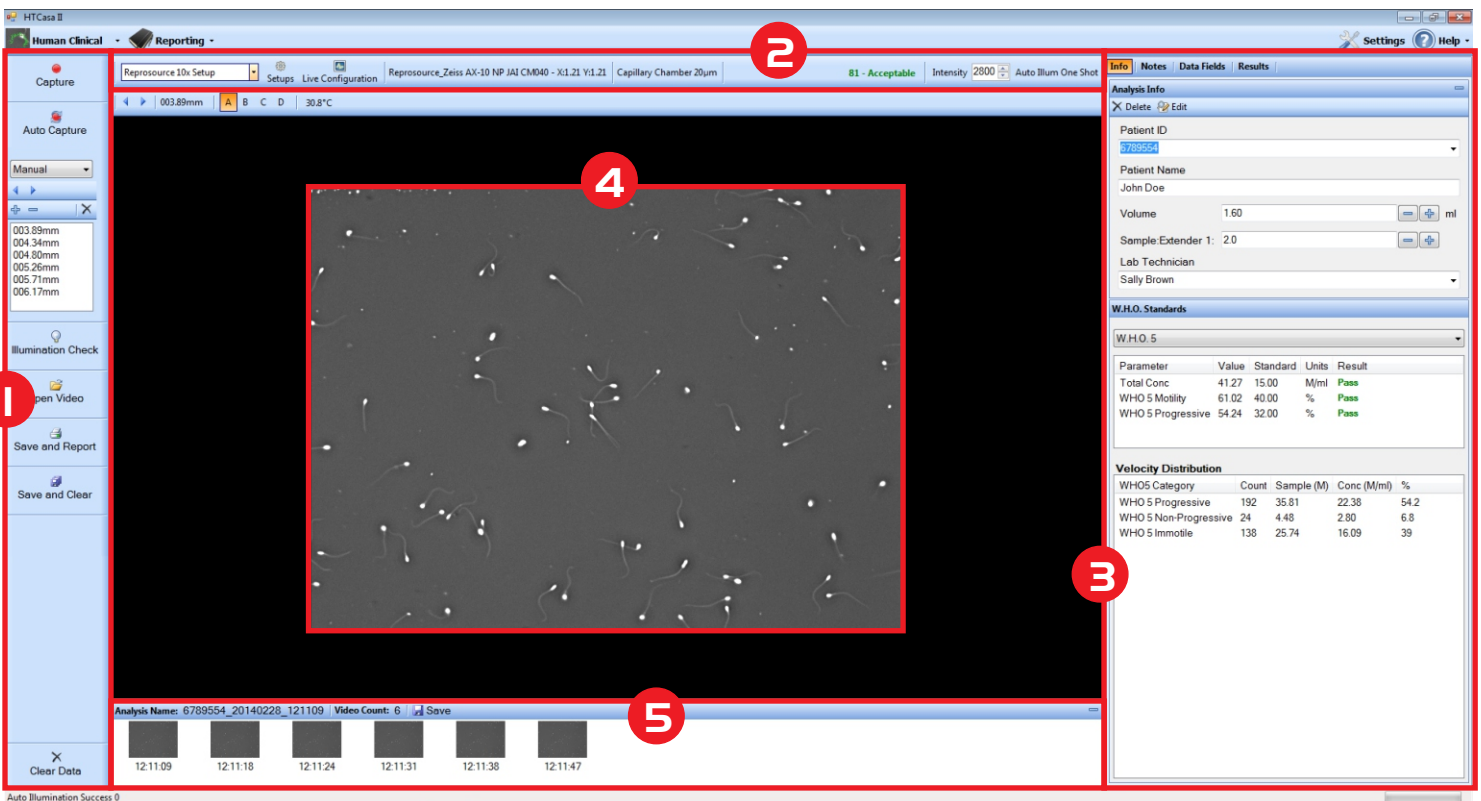
Software Overview

Interactive Illumination Check

Human Clinical II sperm motility software features the unique color-coded Illumination Check to optimize identification of the sperm head and sperm tail. This feature removes any guess work in setting the illumination and promotes consistency between all users, especially when used in tandem with the auto-illumination feature (IVOS II only). When the illumination is set correctly, the sperm heads will be colored blue and tails will be colored red.



Screen Layout



- 1 Controls for initiating analysis, checking illumination, saving, printing and clearing data, and opening saved video files.
- 2 Quick selection of analysis setup to be used and access to various system hardware and software settings.
- 3 Tabbed menu panels for input of Analysis Info, Notes, and custom Data Fields. Output of WHO Standards and Summary and Kinematic Results, updated in real-time.
- 4 Live image area, display of Illumination Check, full screen playback images, and zoomed cell images.
- 5 Thumbnail gallery for storage of captured video images, which may be played back individually for QC.

Analysis Results

Real-time Updating

Data in the Results panel on the right side of the screen reflect the entire population of cells analyzed. WHO Standards and Analysis Results are updated in real-time as each field is added to the analysis.

Full Field Playback

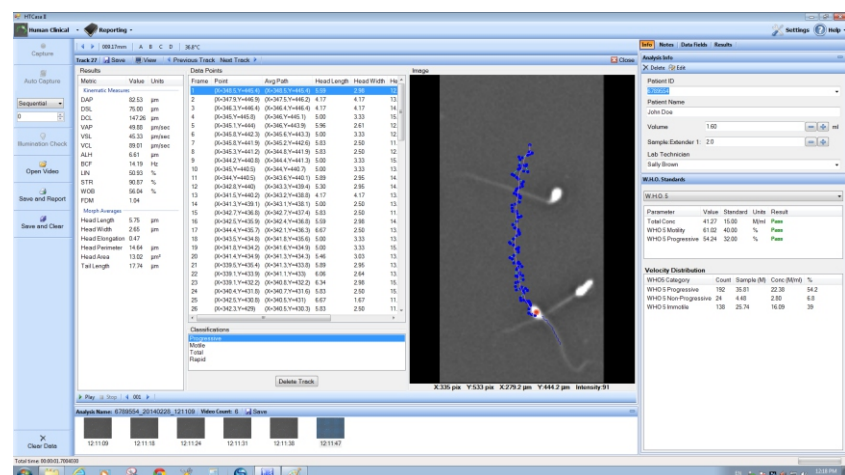
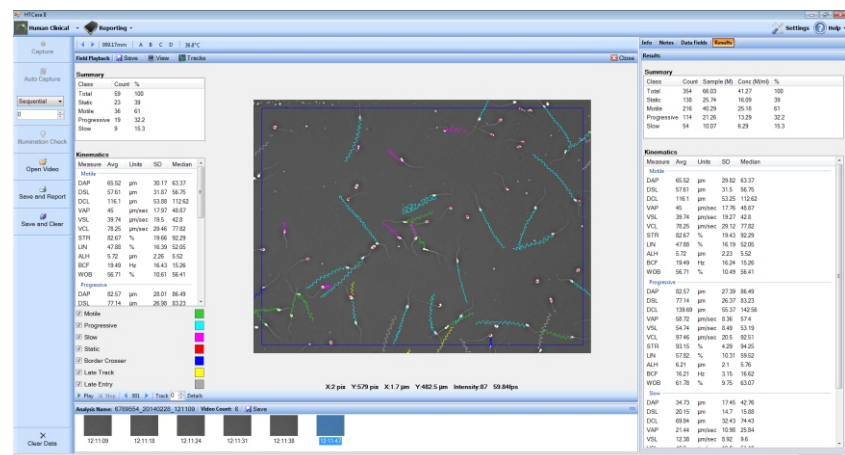
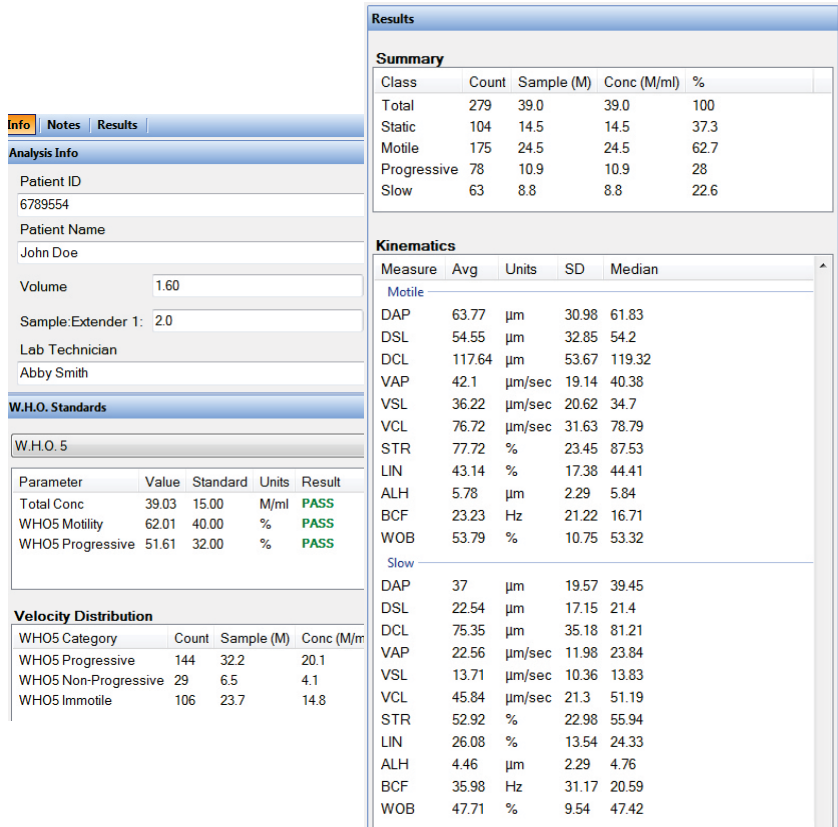
Selecting a thumbnail image from the gallery opens the captured video. The video may be replayed in full or you may scroll through frame by frame. The results along the left side of the image represent only the analysis data of selected field. The color overlays on the playback image and the field results may be turned on or off.

Zoom Cell Playback

Selecting a track from the playback image opens up a zoomed image of the cell. The Kinematic Measures shown on the left are relative only to the selected track. The video focusing on the individual cell may be played or scrolled through frame by frame. You may jump to a specific frame by selecting a point on the track or the associated data points. Both motile and static cells may be selected.

Saving & Recalling Video

For every analysis, you may choose to save the complete video image of each field analyzed. Each field is saved with all set up parameters and patient information. When opening saved videos, you may re-analyze with the saved settings or apply a new set of parameters.



Quality Control

Replicate Analysis

Replicate Analysis provides labs with an automated method of comparing analyses from two aliquots of the same sample, allowing easy compliance and tracking to meet WHO recommendations.

For each aliquot, a minimum of 200 cells and 6 fields must be analyzed. The most common motility category (the category with the highest average percentage of cells) is the default category used to determine if the replicate samples are within the acceptable difference. You may also select a specific WHO category rather than the default.

Videos may be saved when using the Replicate Analysis feature for later recall and reanalysis.

Replicate Analysis Results

Aliquot Requirements Achieved

A. WHO 4 Rapid Progressive

☐ Lock

Aliquot 1 %	Aliquot 2 %	Mean %	Delta	Gate	Result
55.65	63.30	59.48	7.65	10.00	Pass

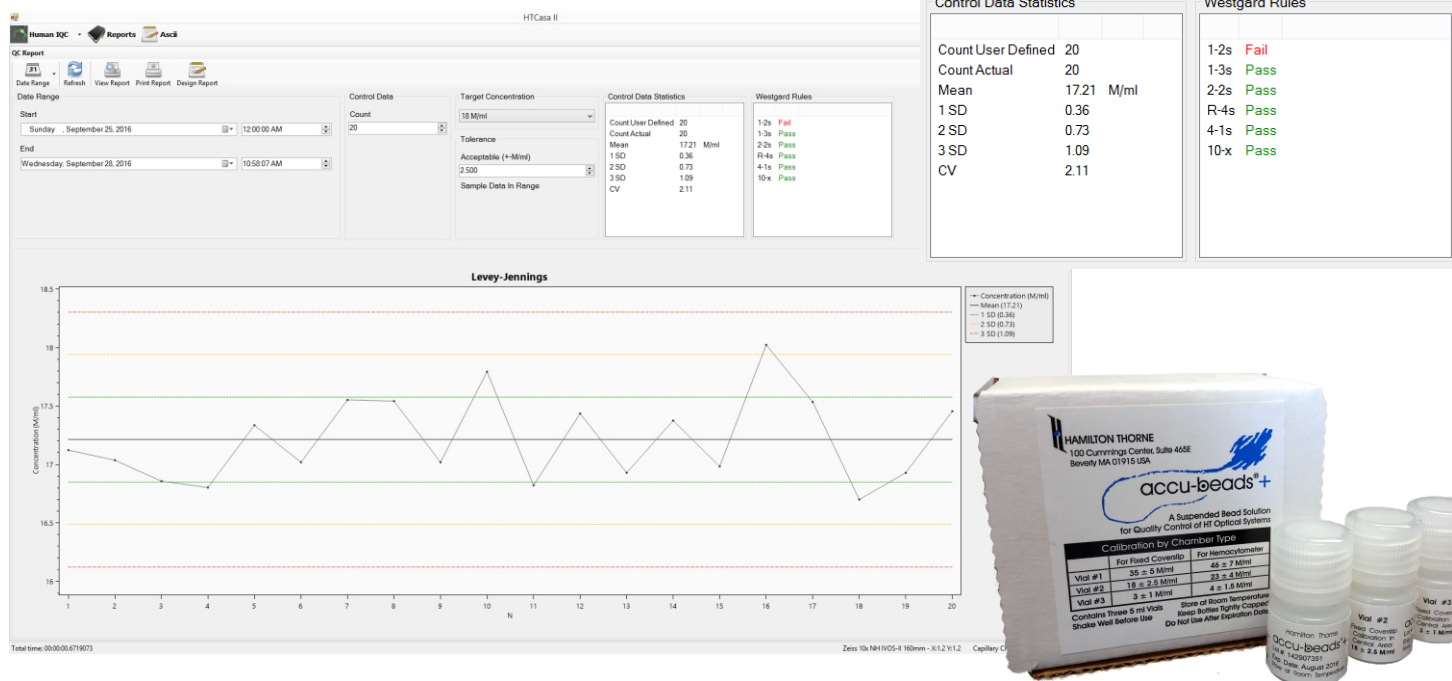
Replicate Analysis Results

Aliquot Requirements Achieved

WHO 5 Immotile

☐ Lock

Aliquot 1 %	Aliquot 2 %	Mean %	Delta	Gate	Result
70.00	82.14	76.07	12.14	9.00	Fail



Internal Quality Control Mode

The Internal Quality Control (IQC) module provides a method of verifying microscope objective calibration and monitoring precision of quality control materials, utilizing a historical database for tracking daily quality control assays with alerts for any instability in data. Multiple materials may be tracked.

The IQC module allows the tracking of quality control counts over a user-specified period of time. A Levey-Jennings chart for the selected time period provides a quick overview of the precision of the quality control material. Application of Westgard Rules provides a Pass/Fail result specifying the acceptability of an analytical run using a quality control material, such as Hamilton Thorne's accu-beads® + solutions.



Report Designer

The Report Designer lets you customize the pre-designed forms or create entirely new forms. The user-friendly, “drag and drop” designer gives you complete control over the look and content of the report. Any input or output data may be added to the report. Free-form fields also allow the inclusion of non-analysis data such as contact information or company logo.

CASA II Options

Sort

The optional Sort feature provides the ability to isolate a certain sub-population of cells (i.e. hyper-activated cells) for analysis.

Three independent Sort sets are available. For each analysis performed, the software applies the enabled Sort sets separately to the cell population. The fraction of cells passing the sort criteria are calculated and presented under Analysis Results.

Edit Tracks

The Edit Tracks option provides the opportunity to save individual track data to an ASCII file for detailed statistical analysis. Edit Tracks also allows removal of tracks or individual cells from the analysis (manual elimination of false positive debris).

DIMENSIONS II

DIMENSIONS II offers automated and validated analysis of human sperm cells according to Tygerberg strict criteria. Focusing on ease of use, the redesigned DIMENSIONS II software works seamlessly with both the IVOS II and CEROS II platforms. DIMENSIONS II, compatible with both Diff-Quik and Papinicolaou stains, classifies sperm as normal, sub-normal or abnormal, based on head size and shape, acrosome, midpiece, and tail.

IVOS® II Options

IDENT Fluorescence

- The only CASA system with **strobed fluorescence illumination for sperm-safe motility**
- Choice of Xenon or new LED fluorescence illumination source
- Highest precision in sperm counting
- IDENT Stain permeates all sperm cells
- Analysis of both motile and static cells under fluorescence

VIADENT Software

- Requires IDENT Fluorescence
- Performs motility and viability on the same LIVE sample
- VIADENT Stain permeates only non-viable cells
- Motility analysis performed under standard illumination and viability analysis under fluorescence

Analysis Output

Counts, Sample, Concentrations, Percentages:

Total, Static, Motile, Progressive, Slow

WHO Standards:

WHO 4 & WHO 5 available

Kinematic Measures:

DAP, DSL, DCL, VAP, VSL, VCL, ALH, STR, LIN, BCF, WOB

Morph Averages:

Head Length, Head Width, Head Perimeter, Head Area

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