THE ULTIMATE COMET ASSAY SCORING SYSTEM

Comet Assay IV™ is an interactive live video-based system for scoring cells subjected to the single cell gel electrophoresis technique (comet assay). The system is the very latest in a highly successful series of comet assay scoring systems from Perceptive Instruments that have evolved and developed since the release of our first system in 1992.

- **Single click automatic scoring**
  for unrivalled speed and reproducibility

- **Includes all major measurement parameters**
  including Tail % DNA, Tail Moment, Tail Length and more

- **Powerful Spreadsheet Generator**
  provides analysis & comparison of data

- **Flexible study management facilities**
  help you work your own way

- **Meet regulatory requirements**
  comprehensive compliance options for GLP & 21CFR

- **Detailed and comprehensive audit trails**
  Including saved images of scored cells

- **Oracle database connectivity**
  for optimal security of result and audit data

- **Comprehensively tested and validated**
  in accordance with our Quality Management System which is approved to ISO 9001:2008 incorporating ISO 90003

PERCEPTIVE
INSTRUMENTS

ISOQAR QUALITY ASSURED
ISO 9001

UKAS QUALITY MANAGEMENT

ANAB ACCREDITED

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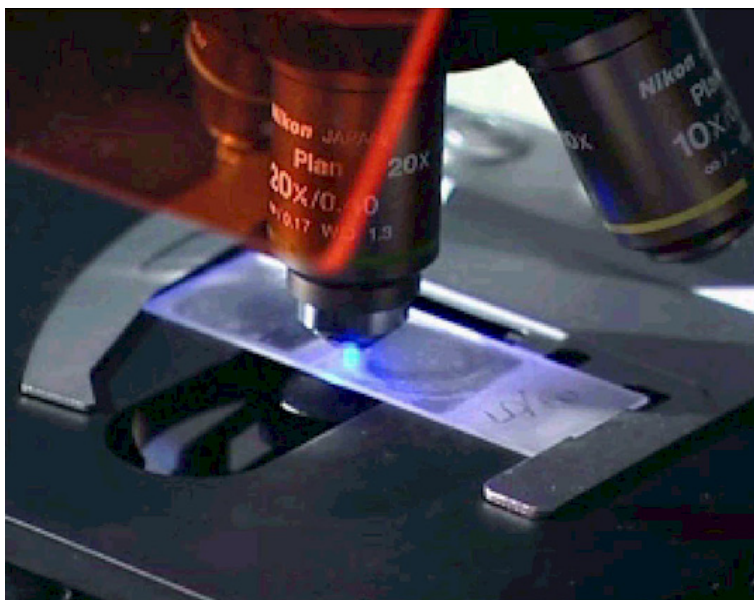## Live video-based scoring *provides instant feedback to increase user productivity*
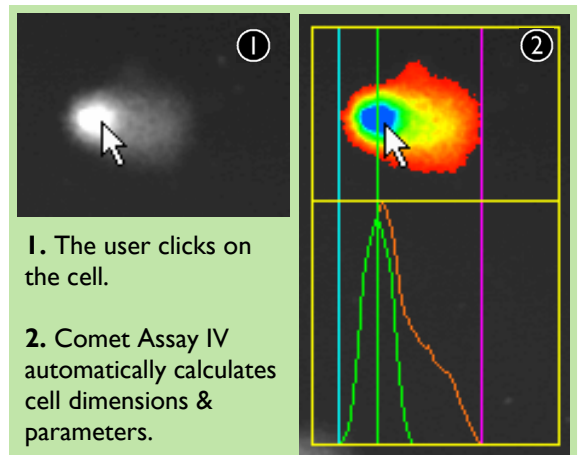
Using a high-resolution video camera attached to your microscope, **Comet Assay IV** transfers a live video picture to your computer monitor. The image displayed on the monitor mirrors what you would see by looking down the microscope's eyepiece. Any refocusing or stage movements performed at the microscope level are shown live on screen without any lag or delay.

Scoring cells with **Comet Assay IV** is a uniquely effortless process. Simply use the mouse to select a cell and **Comet Assay IV** will instantly calculate all measurement parameters and then add the data for the cell to your list of results. Click on the next cell to be scored and the process is repeated.

Once all the cells in a field of view have been scored, use the microscope's stage controls and the onscreen video picture to find the next set of cells to be scored. In no time at all, you will be able to score all the cells on a typical slide within two minutes.

After the required number of cells have been scored, the results can be saved in Microsoft Excel file format and used to produce reports on your collected data.

In addition to saving data to Excel, **Comet Assay IV** also incorporates powerful database capabilities. When used in conjunction with an Oracle database, result and audit data for each measurement is saved to the database the instant a measurement is performed.

1. The user clicks on the cell.

2. Comet Assay IV automatically calculates cell dimensions & parameters.

Comet Assay IV's use of live video technology means any refocusing or stage movements made at microscope level are shown live on screen without any lag or delay
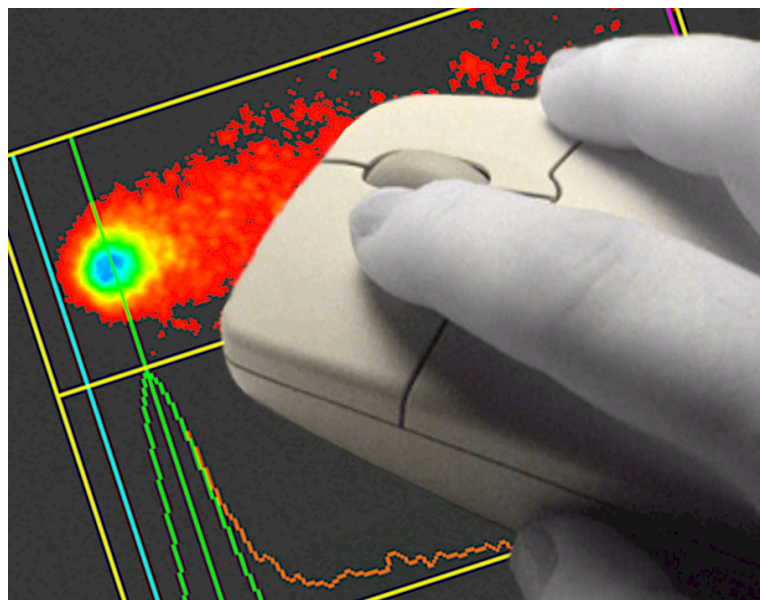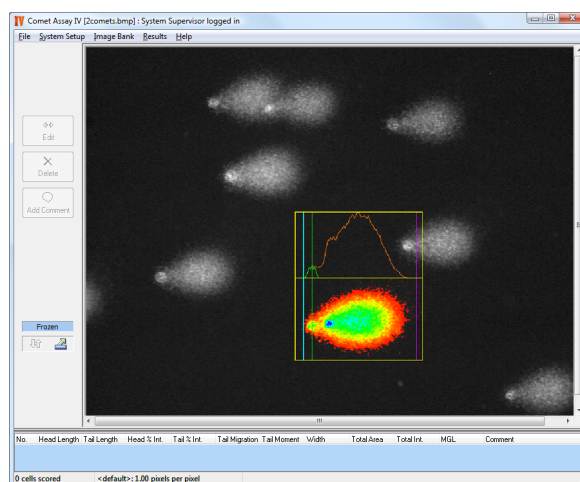
Single click automatic scoring *for unrivalled reproducibility and ease of use*

Comet Assay IV introduces **Click&Score**, a revolutionary automatic scoring method in which a single click on a comet is enough to complete the entire measurement cycle, including background correction, determination of head & tail regions and computation of all parameters.

With **Click&Score**, you simply identify the comet to be scored with a single click of the mouse. This has speed and reproducibility advantages over manual framing methods that require manual positioning of a measurement frame around each individual cell.

The **Click&Score** method removes user configuration of parameters, eliminating all subjectivity from the scoring process. **Click&Score** automatically compensates for slides with uneven backgrounds or varying levels of brightness, ensuring comparable results across a wide range of slides; even highly damaged 'hedgehog' comets can be accurately and consistently measured.
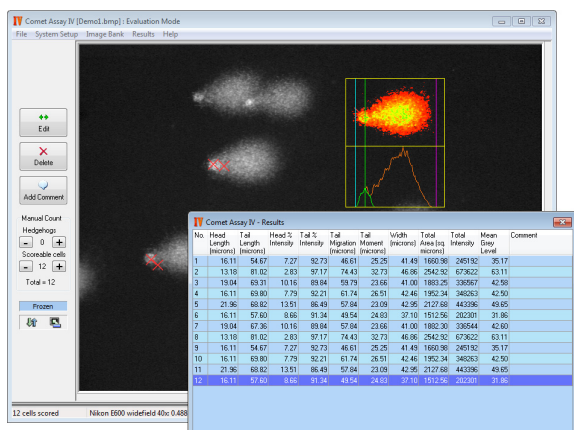
In addition to this, Comet Assay IV's **Hedgehog Counter** provides a simple mechanism for users to integrate 'hedgehog' cell counts with the rest of the measurement data.

With the Click&Score automatic scoring method, you simply identify the cell to be scored with a single click of the mouse

Comprehensive measurements *the new standard for accurate, repeatable results*

Comet Assay IV incorporates all major measurement parameters, including Olive tail moment, tail % intensity and tail length - widely regarded as the most informative measures of DNA damage in the Comet assay.
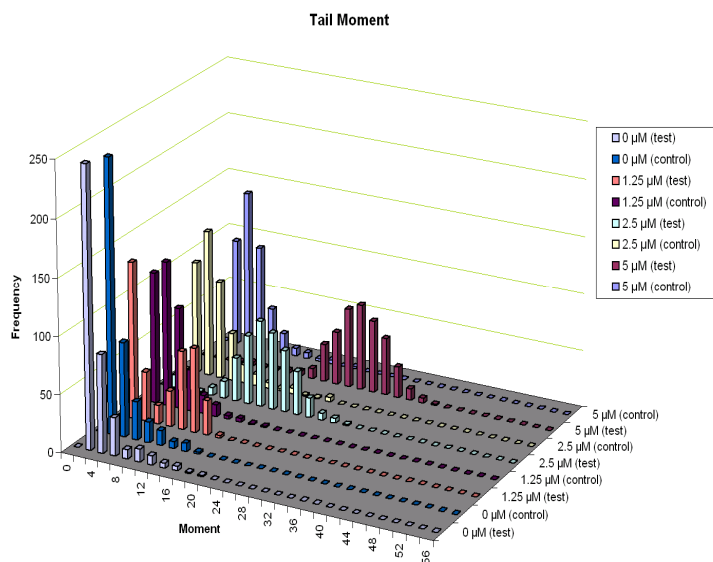

Measurements accumulated for each slide are viewable within a scrolling results window, which can be split from the main application and placed on a second screen in dual-monitor systems. The results window can also be hidden entirely for those wishing to score blind.

Once the target number of cells for a particular slide have been scored, the user is prompted and the data can be saved to **Microsoft Excel** before moving on to score the next slide. Alternatively, the system can be configured to save data to an **Oracle** database for additional security. The optional **Data Extractor** utility is then used to examine data and extract results and audit data from the database into Excel.

Any results files produced by **Comet Assay IV** or the **Data Extractor** can be used with the **Spreadsheet Generator** macro supplied with the system. With the Spreadsheet Generator, you can amalgamate data, produce a wide range of graphs and statistics over any set of result files you choose, merging files where, for example, there are several slides of the same dose & treatment.

Comet Assay IV establishes new standards for accurate, repeatable results through a combination of Click&Score and intelligent new background correction algorithms
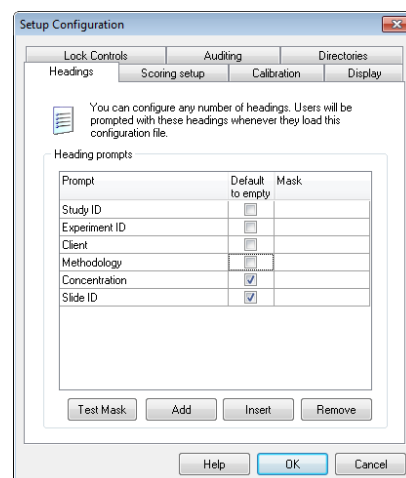
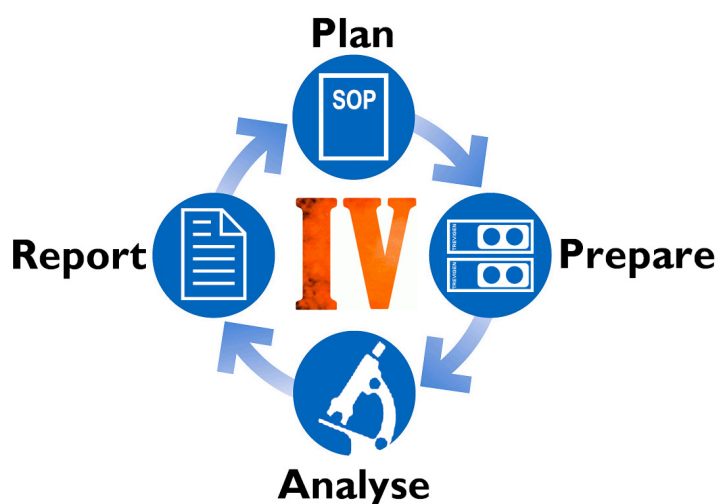## Flexible study management *to help you work your own way*

Comet Assay IV does not constrain you in how you organise and run your Comet assay studies. Instead, the program uses the simple concept of configurable headings for individual measurement sessions to quickly and easily organise your study data. **Comet Assay IV** uses **configurations** to manage the setup of the program for a range of different experiment protocols.

Comet Assay IV will allow you to use any number of headings for a session of measurements, and headings can be set to use the last known entries for details that are common across sessions of measurements, such as Study ID or Client. Other headings might include Slide ID, Methodology or Concentration among any others you wish to use. Normally, a single measurement session is used to score the required number of cells from a single slide.

Comet Assay IV's Save using headings feature makes it easy to organise your result files by using the heading entries to automatically define file and folder names. If you intend to use an **Oracle** database for secure storage of data, all heading entries will be saved to the database along with the corresponding result data.

For those requiring the ability to score their slides blind with **Comet Assay IV**, the detailed help system gives examples on how to operate **Comet Assay IV** using randomised slide numbers and also shows how to set up the system so users cannot see the results of the cells they are scoring, removing any possibility of bias. The help system also offers a range of tutorials and other useful tips on setting up and using **Comet Assay IV**.

Comet Assay IV's open and adaptable study management makes it easy to incorporate the system within your existing framework

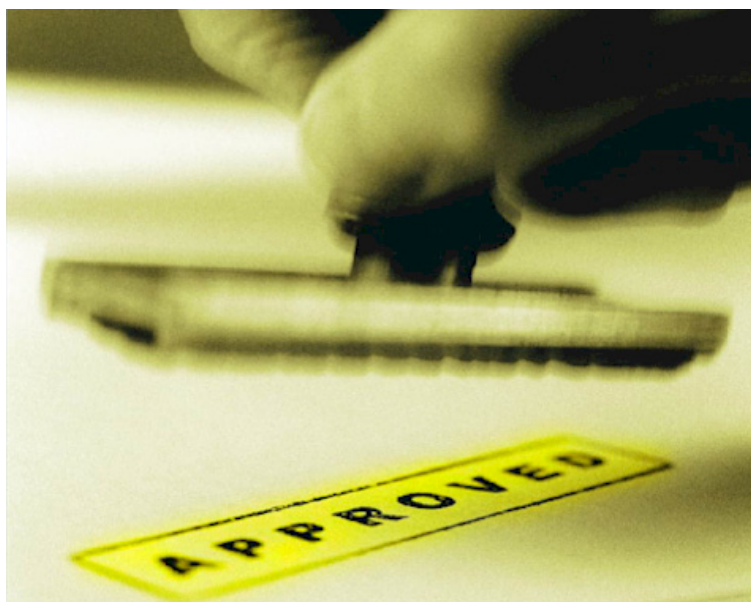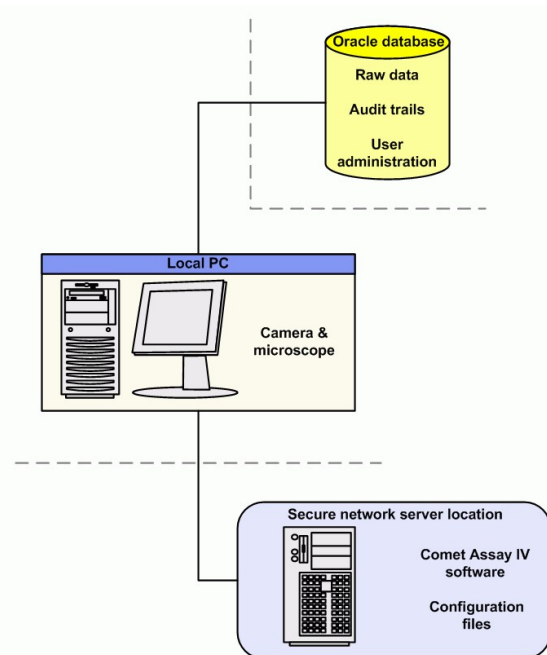# Auditing and user administration *helping you meet regulatory requirements*

Comet Assay IV has a wide range of powerful auditing and security features that can be implemented according to your own requirements. The program generates in-depth audit trails that include details of every action performed by the users of the system, with date, time, full user details and a description of each event.

Comet Assay IV has been designed and developed with reference to a wide range of regulatory guidelines and is fully compliant with the Good Laboratory Practice standards as set down by the OECD, and has been comprehensively tested and validated in accordance with our Quality Management System which is approved to ISO 9001:2008 incorporating ISO 90003.

For the ultimate in system security, the software components of **Comet Assay IV** can be run entirely from secure remote network locations and has a range of user account management options. The system is supplied with our basic user administration package as which provides generic logon accounts for each access level (user & supervisor). The optional **System Access Manager** program provides those wishing to achieve compliance with FDA 21 CFR Part 11 the ability to uniquely identify users, define account rules and monitor system access.

The system can be configured to automatically save an image whenever a cell is measured. Upon retrieval of one of these images, it is possible to repeat and review the measurement.

Users can be prompted for a reason when they want to edit or delete a measurement or clear unsaved data. Menus and buttons can be locked so users are restricted from accessing certain functions such as those for editing or deleting cells.

With optional user administration, powerful auditing and forced entry of reasons for edits, deletes etc., Comet Assay IV satisfies the requirements of GLP and CFR Part 11

Oracle database connectivity *for security of data and flexible data processing*
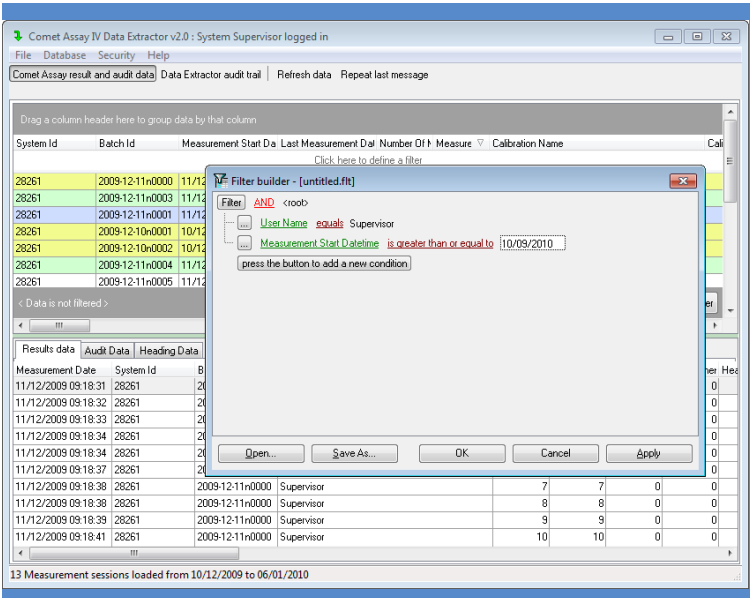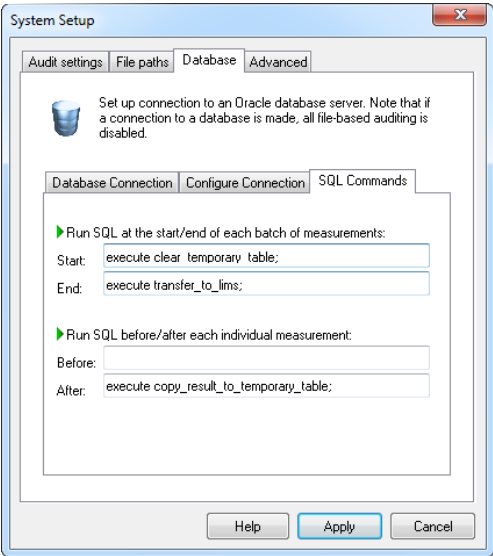
For those interested in running **Comet Assay IV** in a GLP & FDA compliant environment, **Comet Assay IV** offers the ability to connect to an Oracle database for secure storage of all measurement and audit data.

The system can easily be configured to run SQL statements or PL/SQL procedures at the start and end of each session of measurements, and before and after each cell scored. This gives ultimate flexibility for those looking to transfer data from the **Comet Assay IV** database into a proprietary system, such as a Laboratory Information Management System (LIMS).

The optional **Data Extractor** utility gives authorised users the ability to browse all the data within the database and includes facilities to group or filter data on any combination of fields and field values. Users can also retrieve measurement and audit data and export it for use with the **Spreadsheet Generator** macro and any custom or third-party data processing and reporting tools.

The logical, simple structure of the database makes extracting data from the underlying tables a quick and simple task. The program's help includes tutorials on extracting data from the database into Excel.

Comet Assay IV is designed to allow multiple scoring systems to connect to the same database. The database forms a secure central repository for all your data, and use of unique system and batch IDs makes it easy to identify all the data for a specific system and session of measurements.

Maintaining a secure database environment for your study data is made easy with Comet Assay IV's powerful database capabilities.

Scoring	**Click&Score™** - a single click on a comet completes the entire measurement cycle. Measurements performed & results returned instantly. Ability to score 'blind' removes any operator bias. Comets can be scored live or from saved images.
Study Scope	No constrains on study scope or layout. Any number of cells per slide. Configurable message appears when set number of comets have been scored.
Productivity	With **Click&Score**, users can score a typical slide within two minutes. Individual cells are scored in <0.5 second.
Help & Tutorials	In-depth help system includes tutorials and comprehensive guides on system setup and configuration.
Configurations	Unlimited number of system configurations can be created for different study requirements. Configurations include setup information on how the system will operate in a specific situation.
Calibrations	Unlimited number of calibrations can be saved for different microscope objectives.
Headings	Each system configuration can be configured with any number of headings for study ID, slide ID, dose etc. Configurable as revert to blank or revert to previous entry.
Electronic Records & Signatures	Compatible with the System Access Manager for compliance with FDA 21 CFR Part 11 Final Rule on Electronic Records & Electronic Signature.
Auditing	Encoded audit trail files automatically record all system activity including settings, measurement data and edits. Audit trail data can also be sent directly to an Oracle database. System can automatically save image after each measurement with information about how the user scored the cell.
User Access Rights	Supervisor & User levels. Supervisors may lock any of the menus, or selected options within them, to deny Users access to particular functions.
Validation	Comprehensively tested and validated in accordance with our Quality Management System which is approved to ISO 9001:2008 incorporating ISO 90003. All project documentation, testing and validation provided free.
Visualisation	Full pseudocolour overlay and onscreen gamma correction to help users visualise cells.
Data Processing & Transfer	Powerful **Spreadsheet Generator** allows users to compare data across dose ranges. Includes statistics, log transforms & frequency distribution graphs. Configurable data transfer to Oracle database.
Measurements	All core Comet assay measurement parameters: Head length, Tail length, Head intensity, Tail intensity, Tail migration, Olive tail moment, Total area, Mean grey level, Width, Total Intensity.
Editing	Editing of head, middle of head and tail positions for badly damaged cells.
Video Picture	High sensitivity monochrome FireWire CCD camera provides live video at 25 frames per second.
Background Correction	Fully automatic adaptive background correction removes subjectivity and requires no configuration of settings.
Invert Video	Invert video option for scoring autoradiography slides.
Image functions	Freeze image, Go live, Save to file, Load from file. Range of image loading functions including compatibility with TWAIN devices. Audit image save & retrieve.
Minimum Specification	Microsoft Windows XP, Vista or 7 (32-bit and 64-bit versions). Microsoft Office 2000 or later. Oracle 9i, 10g or 11g if you intend to connect to a database. One free FireWire port, or one free PCIe slot for FireWire expansion board.

PERCEPTIVE INSTRUMENTS