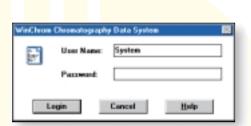


# GLP features for regulatory compliance

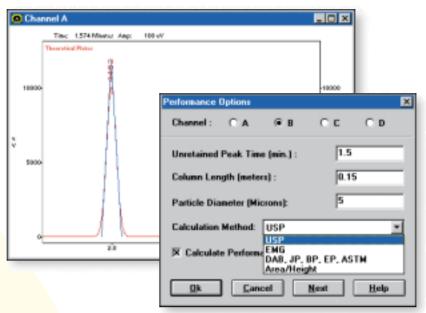


#### System Security

With WinChrom, your system security is assured. Password protection and multi-level access provides isolation and limits accessibility to chromatographic data and stored methods to authorized individuals. User selectable GLP data over-write protection ensures that your valuable data files will never be accidentally overwritten. WinChrom's on-board electronic system log provides automated tracking of all critical system operations for monitoring of system usage as well as future reference.

#### Data Integrity and Traceability

Traceability of reported data back to raw data is important for GLP compliance. US FDA GLP regulations have stipulated that "any change in automated data entries shall not obscure the original entry..." (US FDA GLP 58.130 Part e). With WinChrom, data integrity and traceability is assured with its encapsulated data file format. The chromatographic raw data, original method parameters and processed results, user identity, date and time of entry and last modification, as well as other run information are all saved in one file for effective tracking and portability.



WinChrom
Performance
Calculation facility
is supplied as
standard. It
provides
automated
calculation of all
performance
variables with the
pharmacopoeia
method of your
choice.

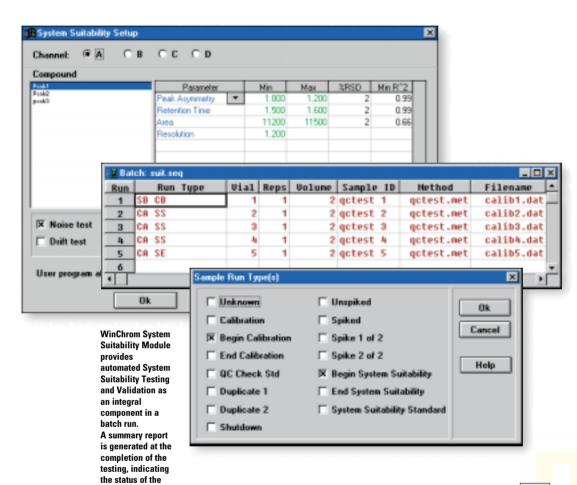
# System Suitability Testing and Performance Calculation

The US and other Pharmacopoeias have proposed system suitability tests for chromatographic systems. This involves the calculation of performance variables relating to efficiency, capability, resolution and reproducibility. Manual calculations of these variables are tedious if not impossible. With WinChrom, these calculations are performed and reported automatically for you with activation of the WinChrom Performance Option. Simply select the Pharmacopoeia methods required, and leave the rest to WinChrom.

#### **Additional GLP Features**

In addition to the powerful GLP features that are incorporated as standard, WinChrom also provides a System Suitability Module with enhanced testing and reporting capabilities. This module offers customized system suitability parameters for individual components, noise and drift test calculations, suitability test corrective action, and a system-wide System Suitability Summary Report with a signature line for instrument validation.

system.





#### **WinChrom on Your Network**

Whether you have an existing network such as Novell Netware or DECnet™, or are starting out with Windows for Worksgroups™, using WinChrom on a network increases your system security and productivity. You can share disk drives and printers or do method development in your office, using data acquired on your laboratory PC.



#### Quality and Certificate of Validation

GBC's commitment to quality is reflected by our certification to ISO 9001 for all products manufactured within our facility. All modules controlled by WinChrom are functionally validated, individually and as a system, prior to shipment. Each module is issued with both a Certificate of Conformance and an unique serial number. The same commitment applies to our software development, and a Certificate of Validation is supplied with every installation of WinChrom.

# Automated data acquisition and enhanced integration capabilities



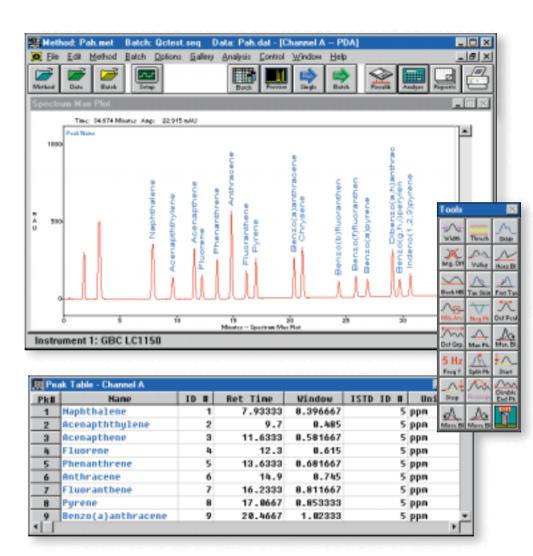
# Preview—easy access to preliminary chromatograms

Use the "Preview" function to check your assay baseline and capture chromatograms before defining all method parameters. This saves time and effort in performing essential trial runs. Save these run data and finalize the setting up of your method parameters using WinChrom powerful on-screen tools for method programming.



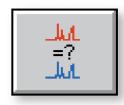
# Analyze—data processing with single-button operation

Press the "Analyze" icon to integrate your chromatogram. You can even process your trace in the middle of a run.



Optimize your method parameters using WinChrom integration tools.

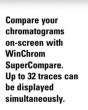
Import your retention time data to create the required Peak Table with the pressing of one button.

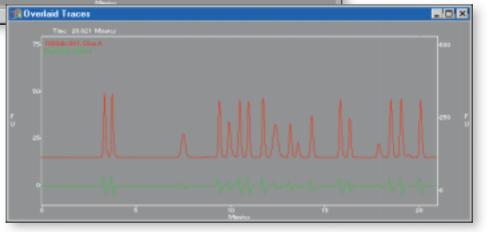


# SuperCompare - Untitled.gro File Edit View Options Adjust Reptot Mindow Help Files Group Despte Tind Overlay Sances at 22 Add Sales Medical Development of the Control of

# Versatile Chromatogram Comparisons with SuperCompare

Compare your chromatograms using WinChrom's powerful SuperCompare. Overlay, tile, align, stretch, and normalize groups of chromatograms using SuperCompare's built-in tools. You can even perform on-screen-mathematical operations on chromatograms (subtraction, addition, multiplication, division, smoothing, 1st and 2nd derivatives) with the press of a single button.





Print a hardcopy of this comparison for documentation, or copy and paste it via the Clipboard directly into your text document. Save your selection of chromatograms as a Group file for easy retrieval in future reference. With WinChrom, chromatogram comparison is fun.

# Customized reporting, easy data export/import features

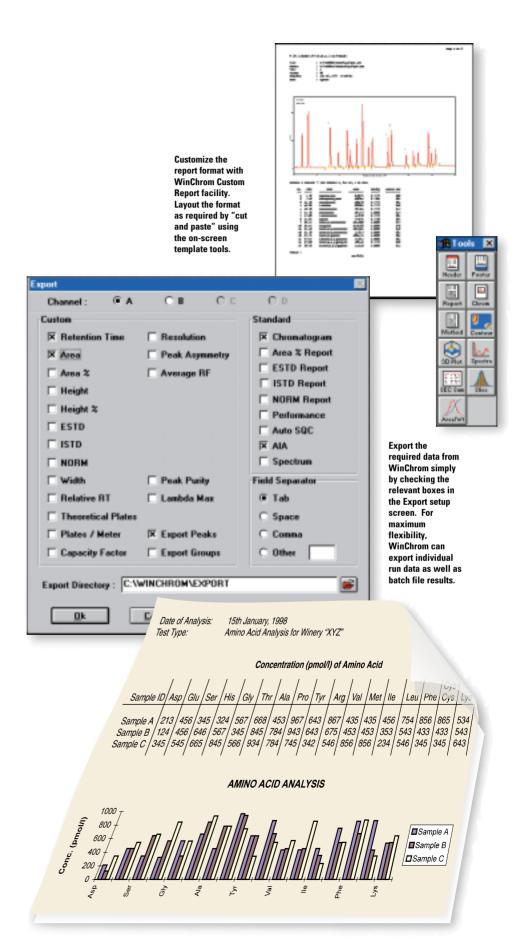


#### **Reports the Way You Want Them**

WinChrom provides a complete list of report formats. These include Area %, Internal and External Standard, Normalized, Spike, Duplicate, QC Check, Calibration and Batch Summary. In addition, create your own customized reports to provide the information that is most important to your laboratory with WinChrom Custom Report Generation facility. Add custom headers and footers, include multiple chromatograms sized and placed as you want them, and incorporate result tables with the relevant parameter fields. Preview the report before it is printed, save the format as a template if required, or customize the report with a simple "cut and paste".

# Easy Export/Import of Data to and from Other Applications

Many laboratories use spreadsheets, databases, or other programs to perform specialized tasks. With WinChrom, simply tick the required export data (whether chromatograms or batch results) in the Export Option screen and the task will be automatically performed. Activate WinChrom's built-in Dynamic Data Exchange (DDE) feature and the required data will be transferred directly to your spreadsheet, saving you time and eliminating potential manual data transfer errors. For inter-laboratory result comparison and publication, take advantage of WinChrom's data export and import facility which handles files in both ASCII and AIA formats.



Improve your laboratory throughput with WinChrom batch facility for unattended, automated runs



#### Automated batch runs

Setup a batch run using WinChrom's "New Batch" facility, or simply modify an existing one. Up to 750 samples can be automatically generated in the Batch table, satisfying your most demanding automated sample throughput requirements.

Start the Batch Run by pressing the "Batch" button, and leave the rest of the sampling task to WinChrom.

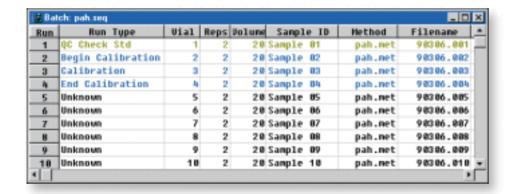
If you have requirements for Spike, Duplicate or QC Check experiments, simply specify the Run Type in your Batch and WinChrom will conduct the checks as specified.

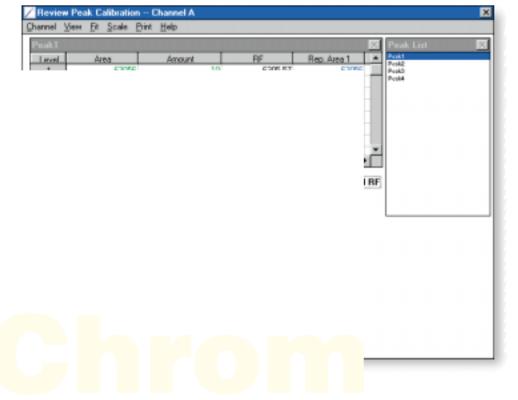


#### **Powerful calibration**

For a new method, create your peak table graphically using the WinChrom on-screen "Peak Definition" tool. Peak retention times will be entered automatically. Complete the table simply with peak names, internal standard ID, standard concentration, and required calibration method.

Whether your calibrations are simple or complex, WinChrom handles them with ease. Review your calibration curves with the press of the "Calibration Review" button, and re-optimize the method settings through on-screen comparison of different fit types and selection of outliners if required.





Review your calibration curves and select the most appropriate fit type and data weighting through simultaneous on-screen display.

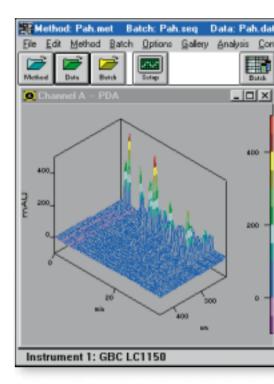
# WinChrom provides powerful multi-tasking operation

GBC WinChrom operates within the popular Microsoft Windows® operating environment. It provides reliable multitasking for simultaneous instrument control and data acquisition of up to four HPLC systems, even while you re-process previous results, re-optimize your methods, and/or run other software applications.

# System control and peace of mind

WinChrom controls a range of GBC HPLC modules. The user-friendly screens enable simple, central control for integrated system operation. With the press of an on-screen button, you can execute a multiple sample batch run from start to finish, including system suitability test, assay calibration, result quantitation, report preparation, LIMS data export, and post-run system shutdown with a specific wash solvent.

WinChrom can also react in emergency situations common in real life operations, such as power failure or abnormal system pulsation. It incorporates a novel Real Time Fault Handling protocol to minimize hazardous situations and costly malfunctions.



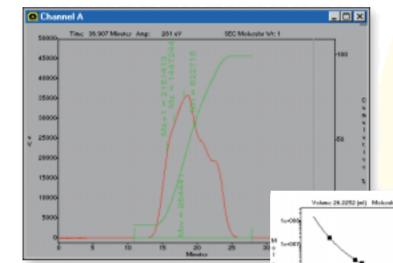
# **Fully automated error recovery**

For non-critical errors such as low solvent level detection, the software error recovery function automatically shuts down the system according to previous user instructions, preventing damage to costly columns. For critical errors, such as underpressure detection indicating a fluid leak or over-pressure error due to flow blockage, WinChrom shuts down the system immediately to avoid potentially costly repair.

WinChrom provides full system control, with the confidence that comes from precise and accurate sampling and protection for your HPLC investment.



# WinGhrøm



WinChrom SEC Software Module offers both Narrow Range and Universal calibrations, accommodating all your SEC/GPC needs.

# Size Exclusion/Gel Permeation Chromatography

Determine the molecular weight distribution of large molecules and polymers using Size Exclusion/Gel Permeation Chromatography (SEC/GPC) with the WinChrom SEC Software Module. The software supports both Narrow Range and Universal calibrations. Curve fit type features both polynomial and spline. Display and print the chromatograms with your required annotation, including points of various molecular weight average results and integral line for cumulative area percent. In addition, the software's extensive reporting facilities ensure the effective analysis and presentation of your results.

# Report facilities include:

- Summary Reports with molecular weight distribution calculated values (Mn, Mw, Mz, Mz+1 and polydispersity)
- Histograms of cumulative weight fraction
- Slice Reports showing elution time/volume, area, molecular weight and other parameters for each time slice
- Calibration Report including goodness of fit, molecular distribution and more.

# Why WinChrom is the preferred Chromatography Management System

- Control and data acquisition of up to four complete HPLC systems
- Multi-tasking MS Windows® environment
- Easy-to-use interface with single screen method programming and drop-down menus
- Powerful graphic icon-based integration
- GLP features for regulatory compliance
- System Suitability software module for automated System Suitability testing
- SuperCompare graphic display for chromatographic comparison
- Customized report formatting
- Multiple data export functions including AIA format and DDE (Dynamic Data Exchange)
- Network capabilities and user program facility for LIMS integration
- Advanced photo diode array control and graphics
- SEC/GPC software option for Gel Permeation Chromatography

Photo Diode Array detection control and Gel Permeation Chromatography

#### **Full PDA Detector Control**

WinChrom provides you with complete control of the GBC range of PDA detectors. Its intuitive user interface provides "real time" simultaneous display of contour map, chromatogram and spectrum. Check the chromatogram at any wavelength and/or spectrum at any time slit simply by sliding the contour map cursors to the required positions.

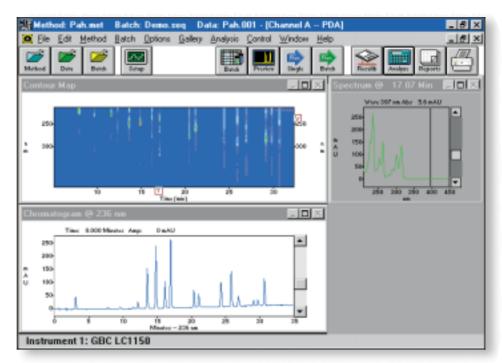
Review your chromatograms with WinChrom 3-dimensional plot, showing absorbance against both time and wavelength data. Rotate the plot to any desired angle using on-screen PDA tools and check for any hidden peaks.

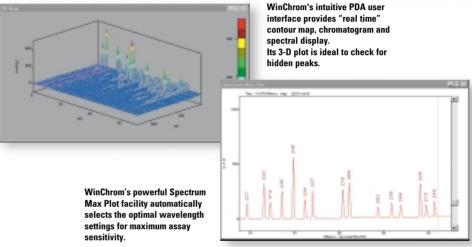
For multi-chromatogram display, the software offers up to nine simultaneous wavelength settings. Increase your assay sensitivity with WinChrom's powerful Spectrum Max Plot facility, which automatically selects the optimal wavelength settings in "real time"!

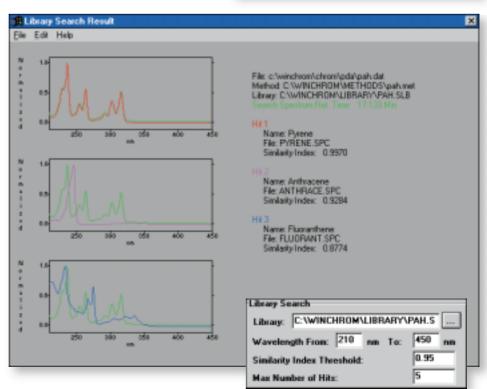
#### **Confirming Your Peak and Its Purity**

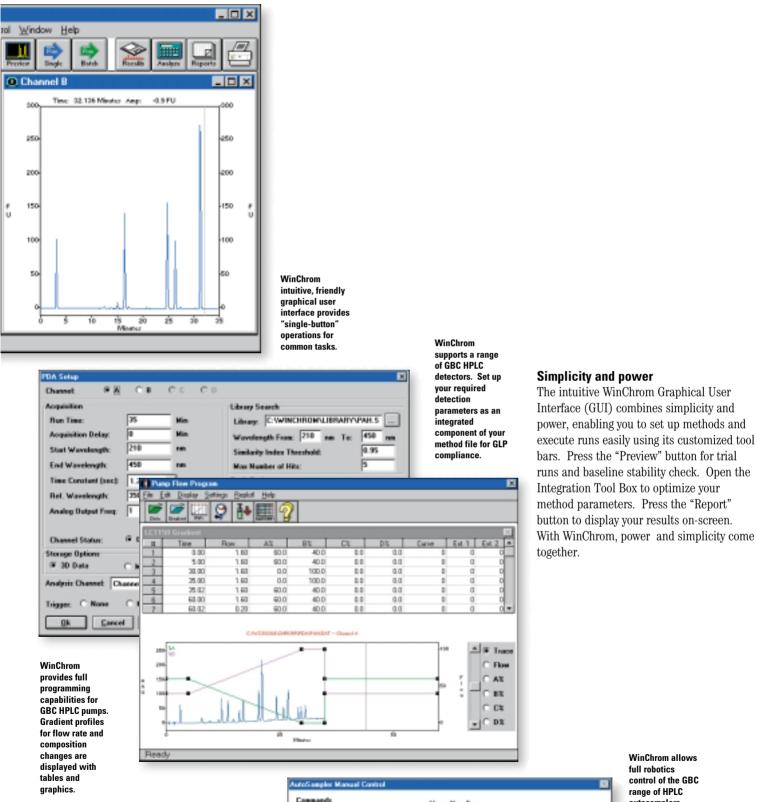
Confirm the purity of your peaks with Peak Purity Check and Chromatogram Ratio Plot. This helps to identify possible co-eluting components and establish the reliability of area quantitation. Activate the Spectral Library Search function and WinChrom will perform the identity match automatically for you using the selected library.

WinChrom Spectral Library Search provides automatic matching for peak identity confirmation.









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Operation

Close

WinChrom allows full robotics control of the GBC range of HPLC autosamplers. This enables automatic dilution and pre-column derivatizations, improving assay precision and saving many hours of manual preparation time.

@ Wal

C Access

Position by

C Selection

C Inject

**G** Wash





GBC supplies a wide range of HPLC equipment and applications information for almost every aspect of High Performance Liquid Chromatography, including:

- Isocratic and gradient HPLC pumps
- UV-Vis detectors (variable, programmable single- and dualwavelength, and photo diode array)
- Programmable fluorescence detector
- Electrochemical detector
- Refractive index detector
- Conductivity detector and suppressor for ion chromatography
- Auto-injector (pre-injection derivatization, small volume, variable volume capabilities)
- Chromatography software (Windows® and MS-DOS®)
- HPLC Column ovens
- · Columns and accessories

# **Ordering Information**

99-0258-00 WinChrom 1-2 System Standard system

For information on other configurations please contact your GBC representative.

Designed and manufactured by GBC Scientific Equipment Pty Ltd A.C.N. 005 472 686

GBC reserves the right to change specifications without prior notice.
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April 1998 Australia

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Manufacturer of premier instrumentation—
AAS, ICP-OES, ICP-MS, HPLC and UV-Vis

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