Symbion DX/RX
Process Analytical Software Suites

A standardized application development, networking, and on–line monitoring environment for all process analytical technology (PAT) requirements.

Managing the Measurement Process

Symbion DX™ and Symbion RX™ provide a standard software environ–ment for controlling, sequencing, and networking analytical instruments, sampling systems, and data analysis routines. In short, Symbion™ manages the measurement process — from application development to routine on–line operation. During development it provides all of the tools needed to design virtually any analytical method. Once a method has been developed, it can be locked down and provided with a custom operator screen with access to a predetermined set of operations and displays.

In the traditional world of distributed control systems (DCS), relatively simple sensors are used to provide one dimensional (scalar) information which can be processed directly by the DCS. With the advent of process analytical technology, the situation has drastically changed. An analytical instrument, such as a near–infrared spectrometer, may provide as many as 2,000 independent spectral data points in less than a second. This large amount of data must be collected, stored, displayed, transmitted, and processed in such a way as to provide timely and manageable information about the process variables of interest. Symbion™ fills this role, bridging the gap between the instrumentation at the manufacturing process and the data historian, SCADA, or other enterprise–level data system.

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Key Elements of the Symbion™ Approach

Symbion™ is organized in such a way as to provide a high degree of flexibility within a framework specifically tailored to the needs of analytical instrumentation. Here are some of the elements that make this possible:

Database Storage: Symbion™ employs a standardized Oracle® database structure for all user information, data, and configuration protocols. This structure provides a full audit trail while facilitating networking and hand–off to other data systems.

PAT–Specific User Interface: Symbion's four main windows are designed to streamline the performance of the tasks typically encountered in process analysis.

PAT–Specific Command Structure: Symbion's command syntax is modular and hierarchical. As a result, it requires only a relatively small number of easily understood standardized commands to meet the great majority of both laboratory and process requirements.

Standardized Instrument and Software Interfacing: The unique requirements of individual instruments, sampling systems, chemometrics routines, and enterprise–wide data systems are met by specific Symbion™ drivers. These can be interchanged within Symbion's command structure by simply substituting the appropriate driver name without otherwise affecting syntax or the process.

Menu–Driven Method Development: Symbion's composer utility includes pop–up script composers for all of

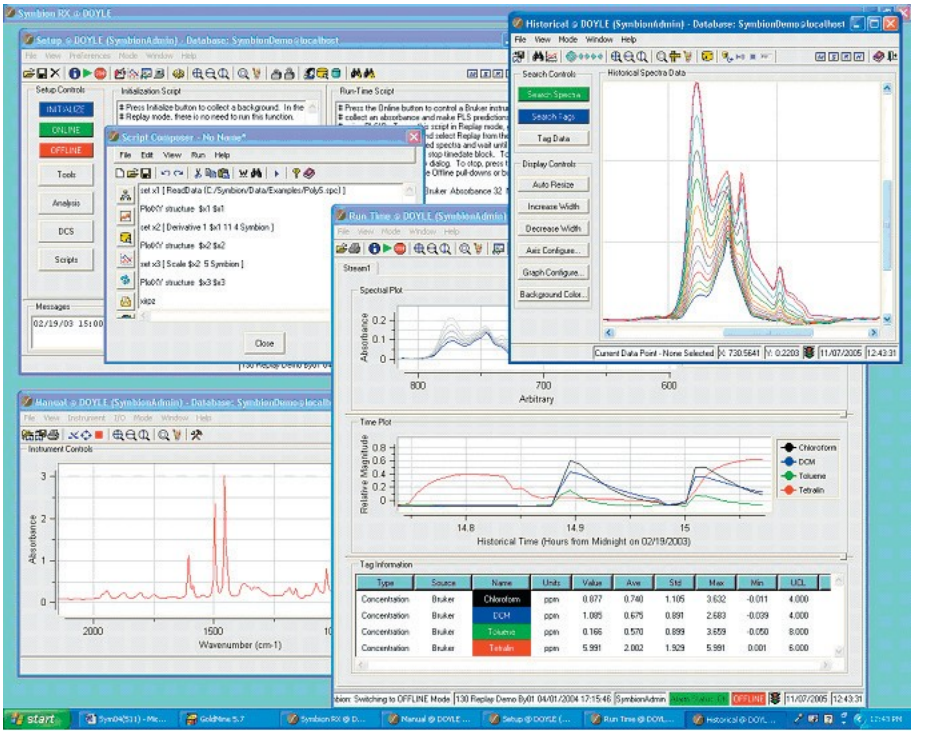

Figure 1: Simultaneous display of Symbion's four primary windows.

the standard commands. These enable you to design any analytical method by simply selecting items from pull-down menus and filling in blanks.

Symbion's Major Functions

Symbion–DX™ and Symbion–RX™ provide a common software platform to control and process data from a wide variety of analytical instruments while providing all of the capabilities required for comprehensive process analysis.

These include:

- Sample system design and control
- Simultaneous control of multiple analyzers
- Extraction of process variable information from the raw data
- Real–time trending of any number of streams
- System diagnostics and alarming
- Archiving of data in a local or remote Oracle® database
- Historical analysis
- Remote communications using OPC, Modbus, and TCP/IP

Versions to Meet Diverse Requirements

Symbion DX™ and Symbion RX™ are both fully capable process analytical software suites. The difference between the two is in the trade–off between flexibility and ease of achieving compliance with 21 CFR Part 11 and other standards prevalent in the pharmaceutical industry. Symbion DX™ provides the greater flexibility. It is appropriate for research and the early stages of methods development as well as deployment in industries that are not highly regulated. Symbion RX™, on the other hand, includes a number of safeguards to help insure compliance when operating in a highly regulated environment.

Symbion's Four Main Windows in Brief

Symbion's diverse capabilities are grouped into four categories corresponding to the program's four main windows. Access to these windows and to many of their specific functions is controlled by user privileges set by the system administrator. The four windows can be displayed individually or in any combination. (See Figure 1.) Their primary functions are as follows:

Manual Window: Allows you to operate an instrument in real time and to perform various operations on the data obtained. Simply select the instrument of choice and operating parameters from the pull–down menu and start collecting data.

Setup Window: Includes the method composer, user and database management utilities, system preference functions, and other utilities to enable you to configure an analysis method to meet virtually any need.

Run–Time Window: Displays the information required to monitor a process in real time. In its most general form it includes multiple trend plots, displays of current and recent spectra, and tabular statistical information. It can easily be customized to provide only the specific displays required for a particular application.

Historical Window: Provides access to all of the data stored in the Oracle® data base. Data can be searched by any combination of attributes such as time and date, series name, instrument, operator, process line, etc.

Unique Characteristics

A Clean Slate: Symbion™ has been developed from the start to meet a set of specific, well thought out, requirements established by key members of the process analytical community. It has been consistently organized from the top down using the most modern software tools. As a result, it provides both ease of use and broad capability, combined with freedom from legacy code and obsolete methodologies.

Extensible yet Secure: The Symbion™ high level scripting language allows the developer to design virtually any analytical configuration by means of a finite set of standard hierarchical commands. Extensibility is provided

Figure 2: The Manual operation window showing typical menus and information displays.

by the use of modular arguments referring to specific drivers which provide access to diverse instruments and third party software programs. At the same time, safeguards have been built in to prevent the user from altering the Symbion™ code in any way. The basic commands and data will always be secure and fully traceable. In addition, the RX version includes various safeguards which, for example, make it virtually impossible to delete or alter a method or configuration once it has been designed.

Seamless Linking to Third–Party Programs: The Symbion™ language enables you to link to a variety of other programs and call the commands of many of these programs from within Symbion™. This enables you to call up existing chemometric calibrations developed using programs such as MatLab™, Pirouette™, The Unscrambler, and PLSplus/IQ™ and embed them within Symbion™ commands.

Rapid Methods Development: The Symbion™ "Scripting Assistants" enable you to automatically write script by means of a series of pop–up windows and pull–down menus corresponding to all of the standard Symbion™ operational commands as well as a range of mathematical capabilities. The standard commands enable you to link to and control diverse instruments, I/O devices, and third party programs and to configure the sequencing of their operation so as to provide a comprehensive operating method or configuration. Once developed, the measurement configuration can be stored under an assigned name and revision ID for future use.

Secure, Locked–Down Operation: The design of a given measurement configuration can include provisions which specify its appearance and function during on–line operation. These can range from specifying which of the three standard displays are active, to replacing all of these with a custom operator display specific to the given application. In addition, permissions can be set so that a given operator will have access only to a designated configuration and run–time display.

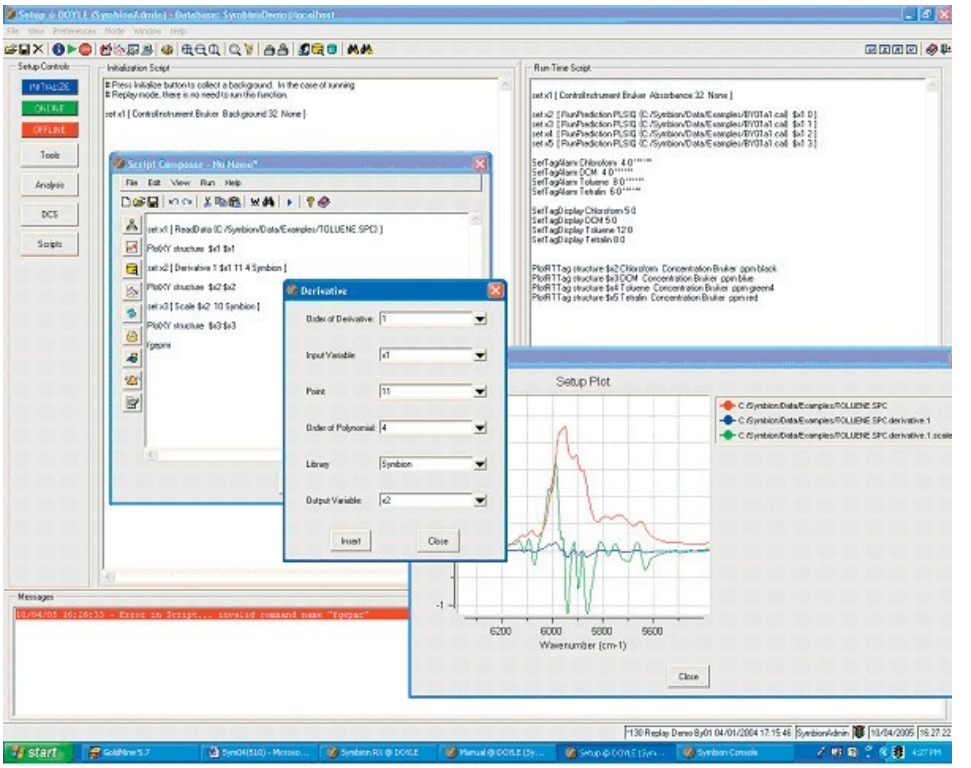

Figure 3: Setup window showing script composer, assistant pop–up, and resulting spectral display.

Modes of Operation

Manual Window: The manual window (Figure 2) allows the user to operate the analyzer and the various elements of a sampling system in real time. This mode is appropriate for laboratory operation and off–line system and data troubleshooting. It allows you to set up your instrument operating parameters, control the instrument and sampling system, save and recall spectra, and perform various operations on these spectra. In short, manual operation provides the key functions that you would expect from a laboratory instrument plus the ability to control the sampling functions. Various capabilities of the program are controlled from a set of pull–down menus at the top of the screen, as illustrated in Figure 2.

Setup Window: This window provides the tools needed for the System Administrator or Developer to configure Symbion™ to meet his specific needs and to build and test analysis configurations and routines prior to on–line deployment.

Figure 3 illustrates some of features of the Setup window. The script currently being used to initialize the system and control run time operation is displayed in the two main script text blocks. New analysis routines can be written and tested without effecting concurrent on–line operation. To do this, you simply call up the "Script Composer" shown using the "Tools" button. This button also can be used to open the Setup graph. The set of buttons at the left side of the "Script Composer" provides access to a series of "Scripting Assistants". These allow you to write commands for most operations without needing to know the syntax of the Symbion™ language. For example, the pop–up scripting assistant shown was used to write the line of code, "Setx2 [Derivative 1 $x1 11 4 Symbion]". The result of executing the illustrated script is shown in the Setup plot.

Run–Time Window: The run–time window provides the real–time display of spectra (or other data), trend plots, statistical information, alarms, and other time–dependent functions required during on–line operation. Its "Replay" mode also allows historical data to be replayed as a function of time using either the current or a new calibration. This capability can be extremely important during method development.

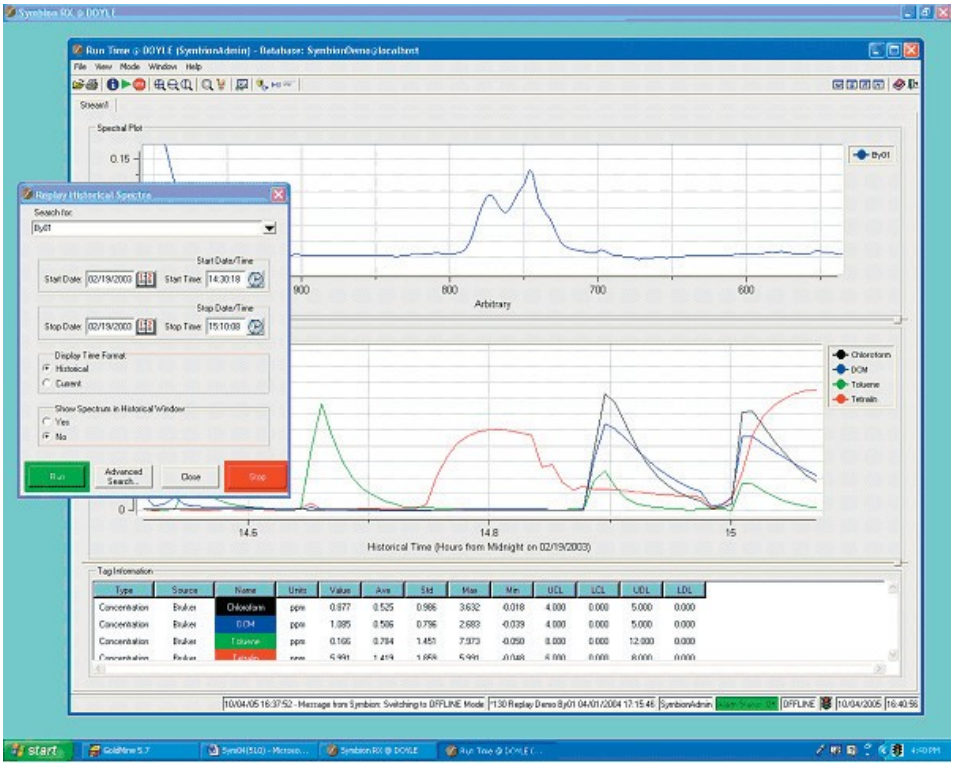

Figure 4: Run–time window showing “Replay” search screen.

The standard run–time window (Figure 4) includes three display areas. The upper area displays the most recent spectrum (or other data) acquired or replayed from memory. The middle area displays the current trend plots for each component or other process variable of interest. The bottom area provides various information about each of the components, including the component name, current value, average value, standard deviation, and upper and lower control limits. To replay existing data, one simply selects “Replay” from the “Mode” pull–down. The pop–up window shown then appears. The name of the run of interest can then be typed into the “Search for” window. Alternatively, you can use the down arrow to select from a list of available runs.

The System Administrator has the ability to tailor the run–time display to meet his specific needs. For example, he can decide to display only trend plots, numerical information, or alarms, or some combination of these along with system status information or other information as desired.

Historical Window: This window provides access to the Oracle® database, allowing historical data to be displayed either in its raw form (e.g. spectra) or as time dependent plots of predicted process variables. Searches can be performed by means of any combination of attributes such as time and data, series name, instrument ID, operator, or process stream. The results of a typical search are shown in Figure 5. As with other Symbion™ displays, various operations can be performed on the displayed plots by right clicking on the tags at the right of the screen. In this case three of the spectra were highlighted by changing their data point pixel size to medium.

Conclusion

The above illustrations provide a brief introduction to some of the central features of Symbion DX™ and Symbion RX™. But the full power of these software suites resides in the ability of the Symbion™ language to respond to virtually any need that may be encountered. At the same time, once a process has been validated, the configuration for any specific application can then be locked down, safeguarding the integrity of the on–line operation.

For further information about the Symbion™ Process Analysis Software Suites, or to request a free 30 day trial, please do not hesitate to e–mail us at info@gosymbion.com or call 1–949-757-9300.

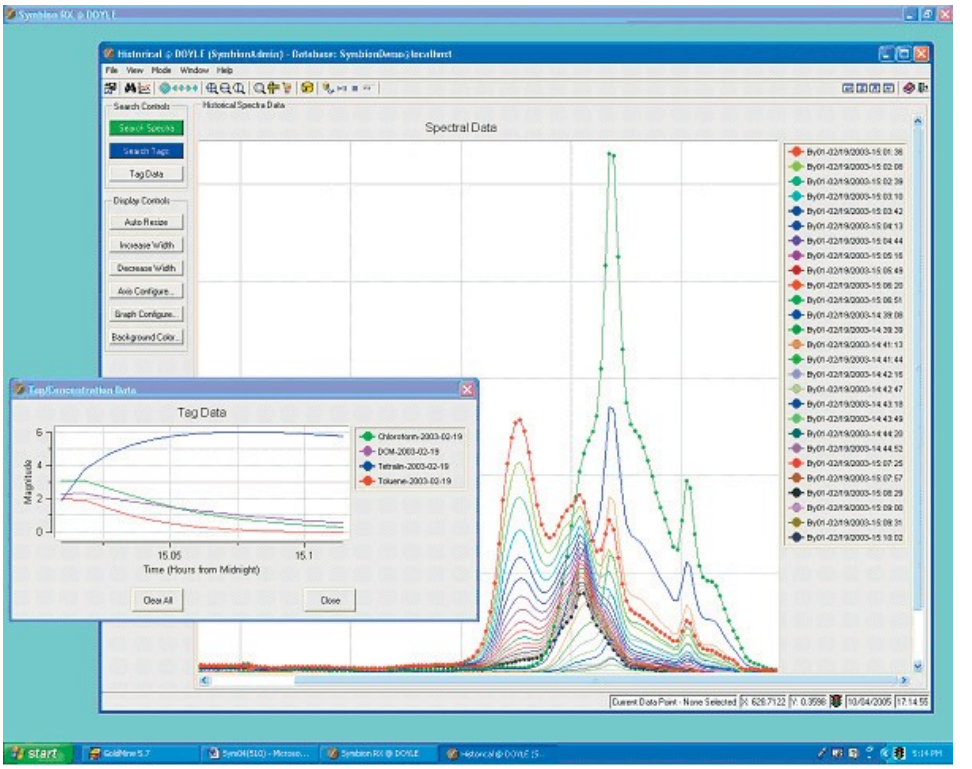

Figure 5: Historical window showing both spectral and time–dependent displays.