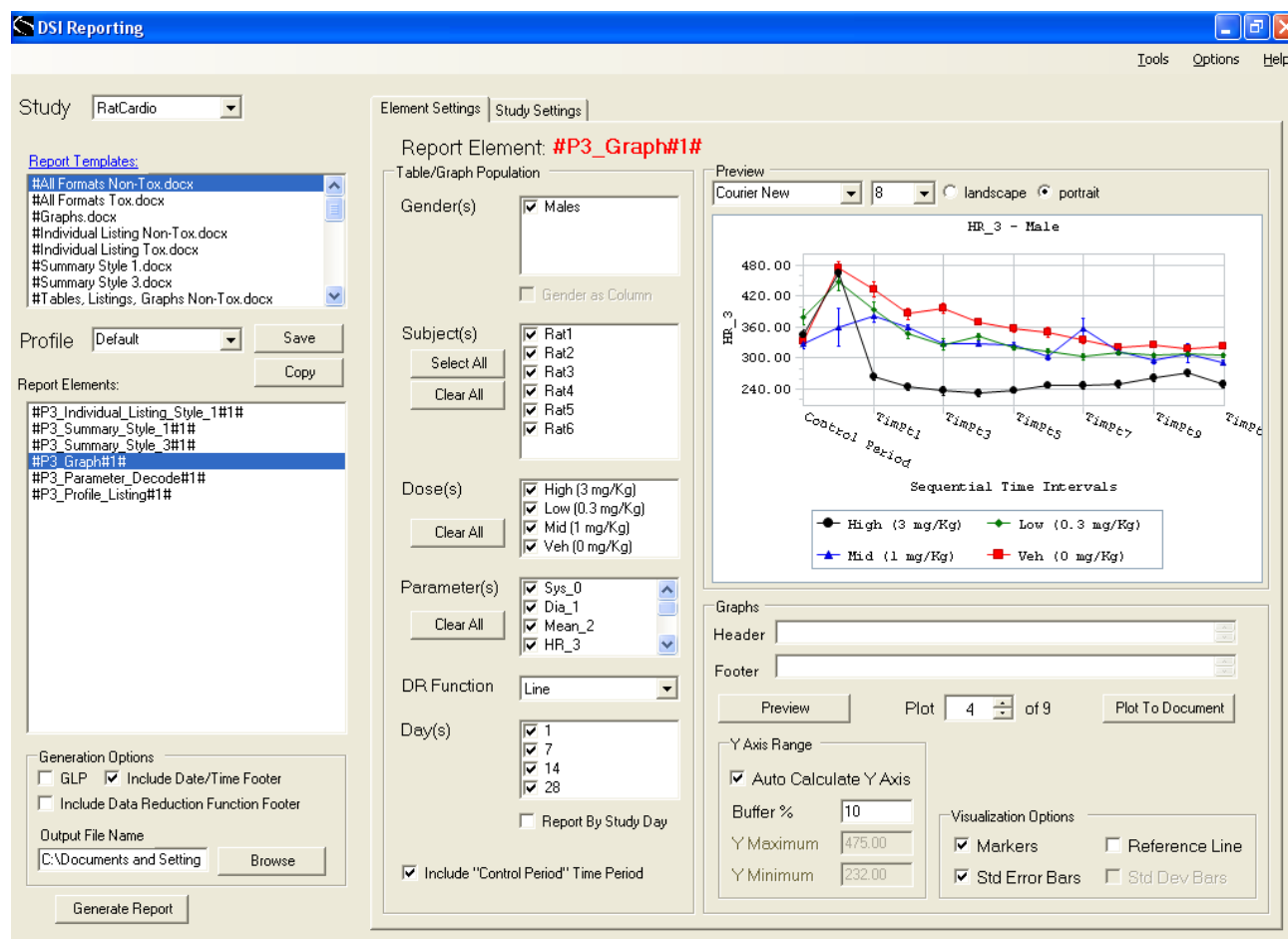


DSI Reporting

Models: PNM-REPORT-200

Manual: MU00283-001

Revision 52





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Overview

Introduction

DSI Reporting software was designed exclusively for DSI (Data Sciences International) by Integrated Nonclinical Development Solutions, Inc. It is an option within Ponemah that allows a User to generate individual listings, summary group tables and graphs using data generated from the Ponemah application. The DSI Reporting program will use data from the Ponemah Study databases as the data source. DSI Reporting uses the data reduction information generated from Study; derived data is not used.

DSI Reporting optimizes reporting of data collected by Ponemah Study by replacing the commonly used paper and excel-based data consolidation, graphing, analysis and reporting. The User only needs to acquire data from Study for it to be shown in DSI Reporting GUI (graphical user interface). The DSI Reporting option will not work with the any ASCII generated data files from the Ponemah application.

Installation

The **DSI Reporting** option is installed as an option when Ponemah is installed. The DSI Reporting option is a separately purchased option. If it was not purchased, it will not be available.

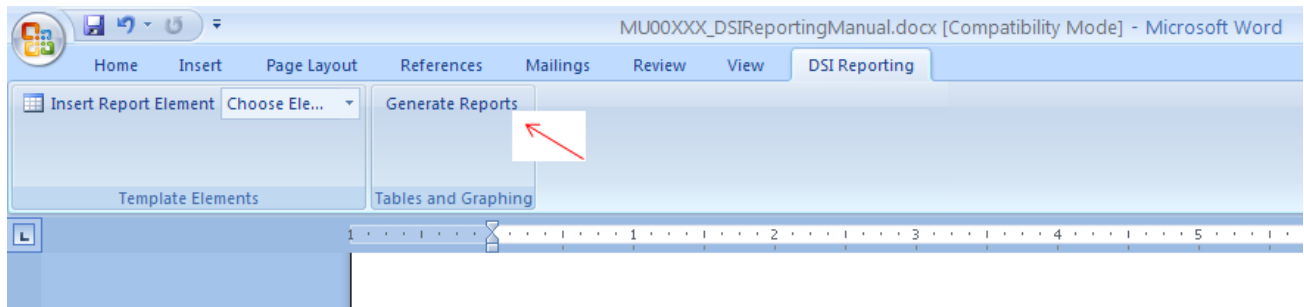
Getting Started

Overview

DSI Reporting is an option within Ponemah that allows the user to generate report quality tables and graphs from data acquired the through Study module. The DSI

Reporting option makes use of the ribbon interface feature found in MS (Microsoft) Word 2007 or Word 2010. To open the DSI Reporting interface the user must select the **DSI Reporting** tab in the Word ribbon and then choose **Generate Reports** located within “Tables and Graphing” sub-tab.

MS Word with DSI Reporting tab selected tab



Generate Reports

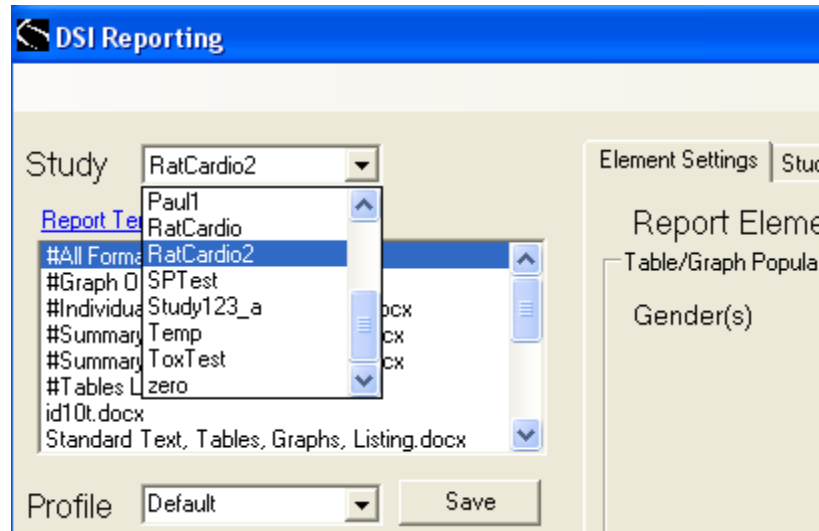
Tables and Graphing

From the **DSI Reporting** interface the user will select the desired study from the pull-down arrow next to **Study** in the upper left-hand corner of the interface. The contents of **Element Setting** window shows available study elements (subjects, doses, parameters and days) present in the selected study. Chosen elements for inclusion in the tables and graphs are marked with a checked box. By default, all elements are selected for inclusion in the report (e.g., no filtering is applied).



Study

The **Study** pull-down arrow will list the Ponemah studies available for reporting on the current workstation. The selected study displays in the Study window.

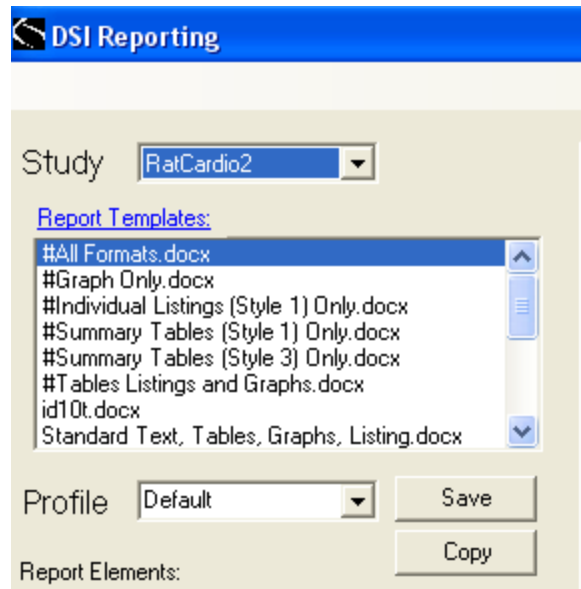


Study pull-down menu

A study report is a Word document which is the result of applying selected study data to a desired report template. The name of the study report Word document can be specified by the end-user.

A **report element** is one of many different reporting components that can be included in a study report. A report element identifies the desired layout and format for study data. A report element can be an individual animal listing, a summary table, or a graph, in several pre-defined formats. Filtering criteria (e.g., selection of all or a subset of genders, animals, dose groups, parameters, and days) can be applied to any or all report elements.

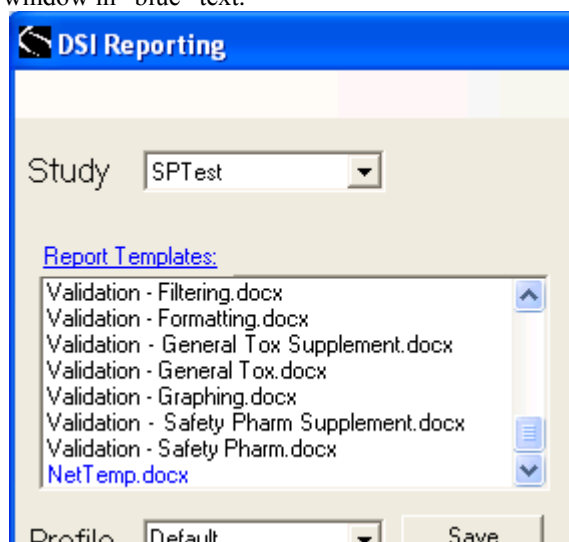
Just below the Study window is the **Report Templates** menu.



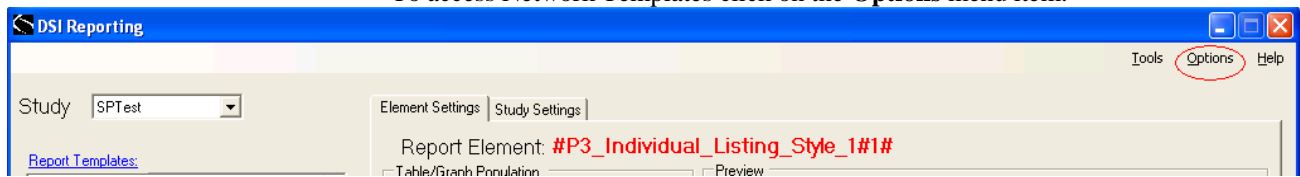
The **Report Templates** menu allows the user to select an existing report template or to add a user-defined report template. A **report template** is a Word 2007 or Word 2010 template comprised of one or more report elements. The report template may also include static textual content interspersed with placeholders for study metadata. When a report is generated from a template, data from the selected study populate the report elements and study metadata, and static text is incorporated verbatim.

A given report template may be used with any study (although the static textual content present in a particular template may not make sense for all studies). Report characteristics set via the report template include margins, page size (i.e., letter, legal, A4), and ordered report elements.

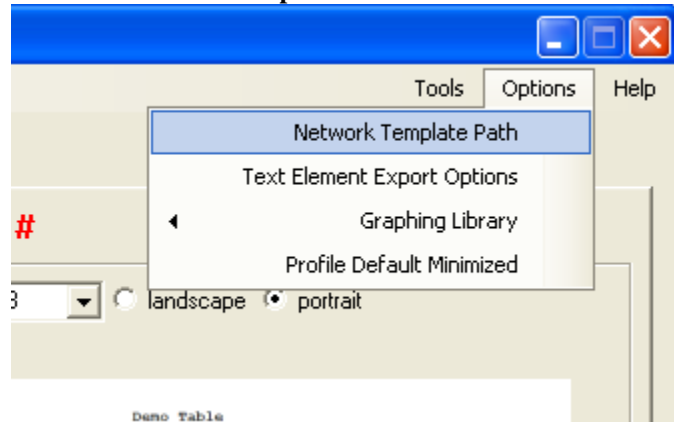
Report templates stored on a Network directory appear in the Report Templates window in “blue” text.



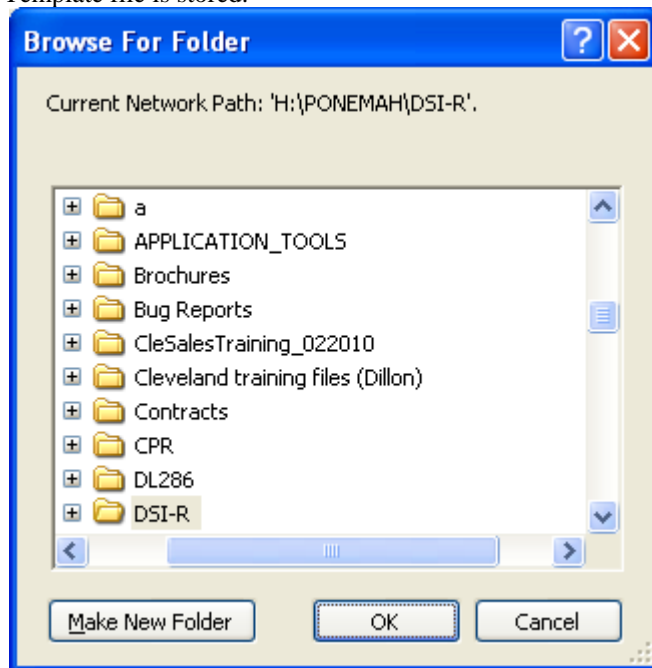
To access Network Templates click on the **Options** menu item.



Select the **Network Template Path** sub-menu item.



Using the **Browser Dialog** window, select the network path where the Network Template file is stored.



Multiple *predefined report templates* have been provided with DSIR; *user-defined report templates* can also be created. To differentiate predefined templates from user-defined templates, a naming convention has been established such that predefined report templates begin with “#”. A given report template can be applied to a number of studies or a report template can be created specifically for one-time use with a single study.

Profile

The *study profile*, or simply the *profile*, is the collection of element settings across all report elements in a template for a given study. The *default profile* includes all selections across all report elements for a given study (e.g., no filtering is applied). The user can create a new profile by making filtering selections for one or more element settings for any or all of the report elements.

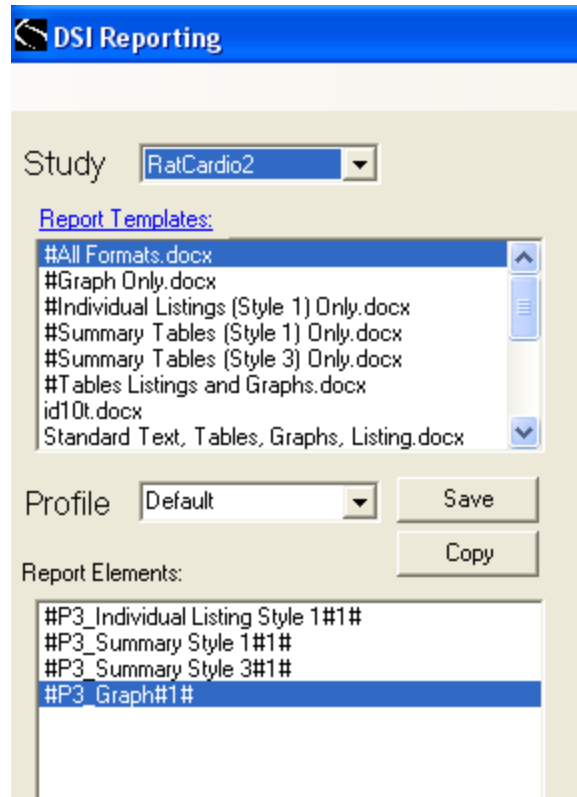
When the default profile is modified, the user will be prompted to rename the profile. The user is encouraged to name the profile in such a way as to help identify what filtering criteria were specified. Selections made to the default profile will be applied across all report elements in the report template. Any changes made to a non-default profile will only be applied to the selected report element. Non-default profiles can be deleted by left clicking on the **Profile** label.

Each predefined report template provided with DSIR includes a Profile Listing report element. This report element will produce a listing of every filtering selection made for each report element in the template and will provide documentation of what data are included in the generated report.

Report Elements

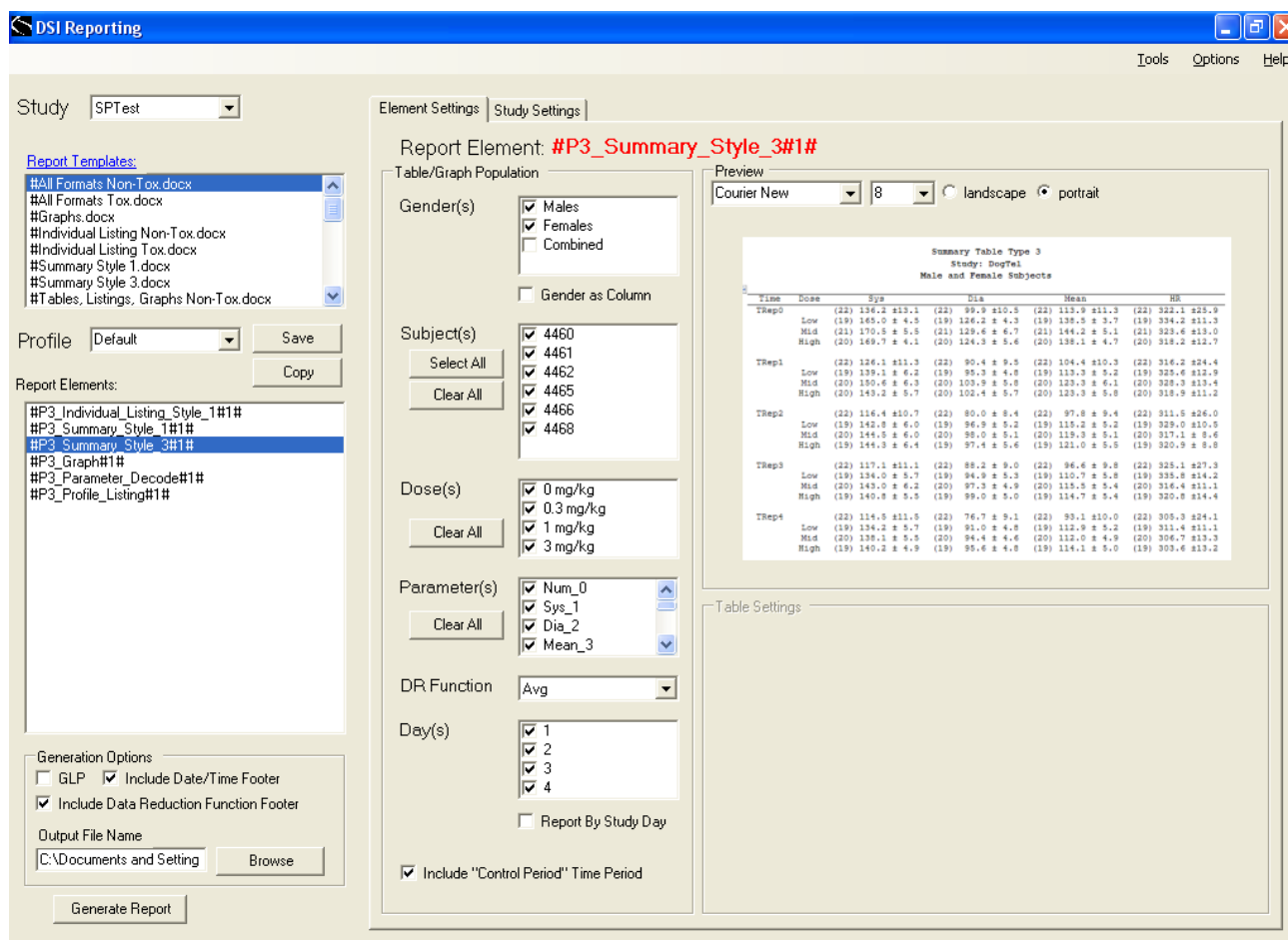
The Report Elements window displays the elements associated with the selected Report Template. *Element settings* refer to the filtering selections applied to a given report element. Default element settings for each report element include no filtering selections; that is, all available study data are included. However, the end user can change default element settings so the resulting report component (table, listing or graph) reflects the subset of data selected. Element selections include filtering on genders, subjects, dose groups, parameters, and/or study days.

For example, a user may only want to generate a report on a subset of parameters or a subset of study days. Perhaps the user wishes to generate a summary table after eliminating an animal identified as an outlier. Instead of graphing group means, a user may want to generate a graph displaying data for a single animal over time. In each of these cases, the user can apply filtering selections to one or more report elements so that the generated report reflects the desired subset of data.



Report Elements window

A preview example of the highlighted Report Element displays within the Element Settings tab. Previews of graphical report elements are representations of the actual data, whereas previews of individual listings and summary tables are not.



DSI Reporting user interface showing preview of Summary Style 3

Gender(s)

The **Gender(s)** window shows which gender(s) were present in the selected study and allow the user to select which gender (or both genders) to include in the report. By default, the subject gender is displayed in the report title; however, the user may elect to include gender information as a column in the table by checking the **Gender as Column** box. The user may choose to display summary data by gender and/or by combined genders. The order the genders appear in the window and in the generated report can be changed by dragging and dropping the selected group label.

Subject(s)

The **Subject(s)** list shows the test subjects that are configured for the current Study Profile.

Dose(s)

The **Dose(s)** list shows the dose levels that are configured for the current Study Profile.

Parameter(s)

The **Parameter(s)** list shows the parameters that are configured for the current Study Profile.

DR Function

The **DR Function** displays the data reduction functions that are available from the current Study. Only one DR function can be selected for each report element.

Day(s)

The **Day(s)** list shows the treatment days that are configured for the current Study. When the **Report By Study Day** box is checked a table of data elements sorted by day is generated and summary statistics are generated separately by study day (instead of pooled across all study days).

Include “Control Period” Time Period

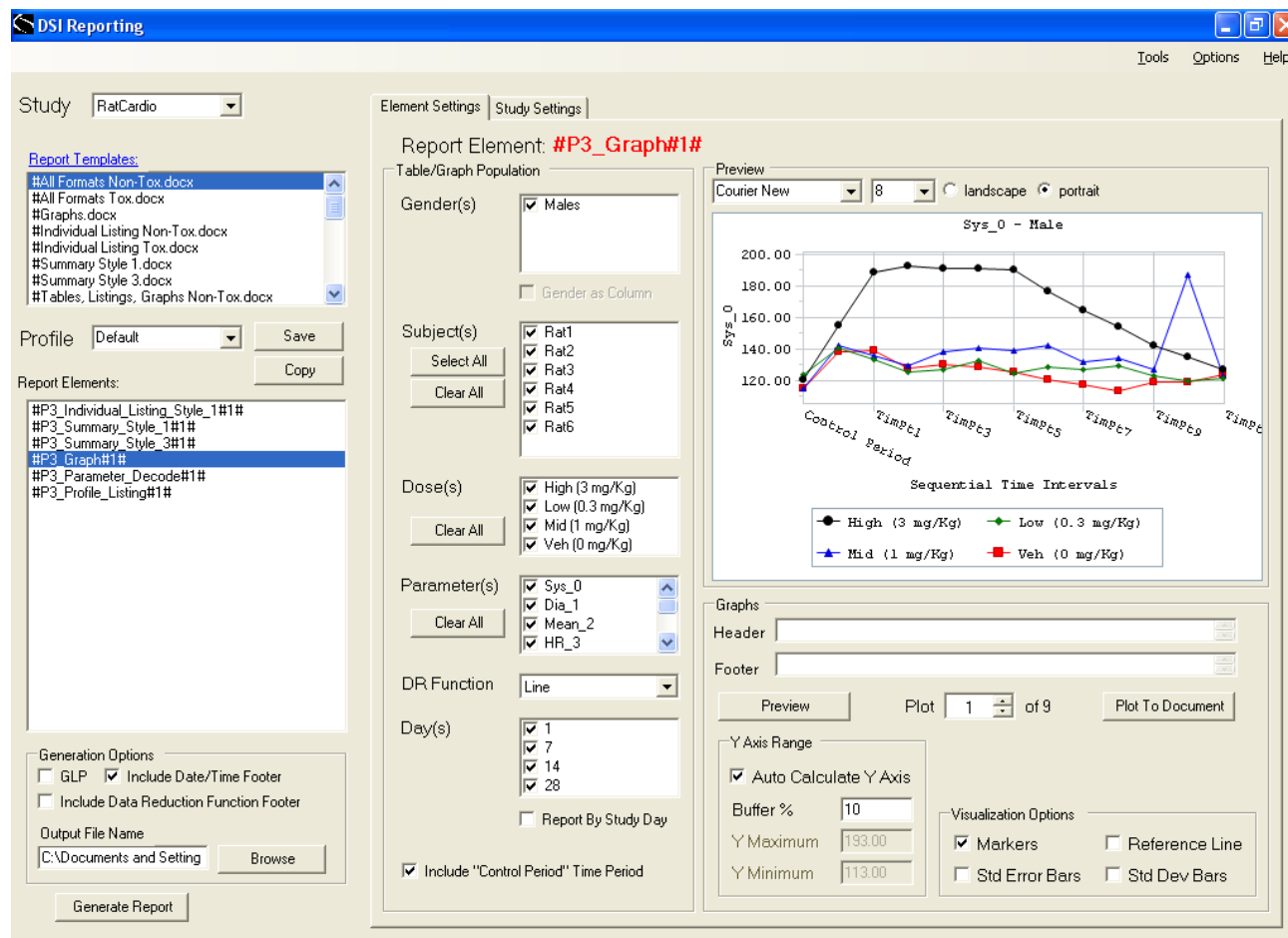
The **Control Period** can be excluded from the tables and graphs by deselecting the check box.

Font & Page Layout

Located near the top of the Preview panel are windows for **Font** style and font size selections. The user selects either Courier New or Lucida Console font styles in font sizes from 8 to 12. The user can also select the page layout (landscape or portrait). These selections are applied separately for each report element, so that it is possible, for example, for a report to contain portrait-oriented tables and landscape-oriented graphs.

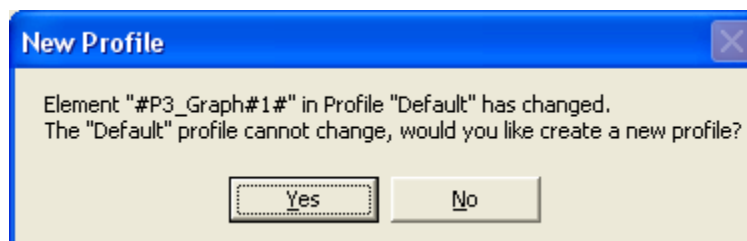
Report Elements Graphs

Previews of graphical report elements are actual representations of the data.



DSI Reporting user interface with graph thumbnail of actual study data

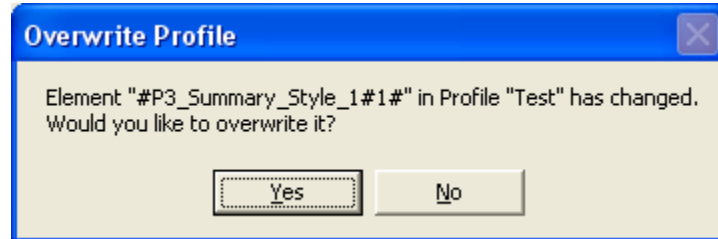
If any of the selections in the Table/Graph Population sections are changed, a message similar to the following message will appear to indicate that the default profile has been altered:



Selecting yes will enable the user to save the filtering changes as a separate profile. The Profile window will display the newly created Profile, but the original Profile

can also be selected using the Profile pull-down arrow. Selecting No will discard the changes to the profile.

If any of the selections in the Table/Graph Population sections are changed in a non-default profile, a message similar to the following message will appear:



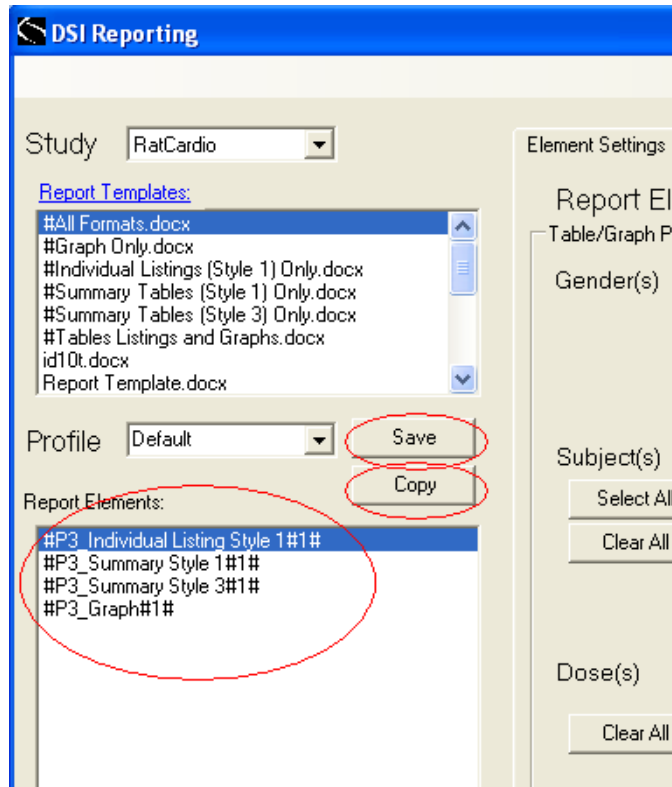
Selecting yes will enable the user to save the filtering changes and overwrite the previous profile selections. Selecting No will discard the changes to the profile.

If the user elects to create an addition new profile selecting the **Copy** button located just beneath the Profile **Save** button will bring up the pop up user interface:

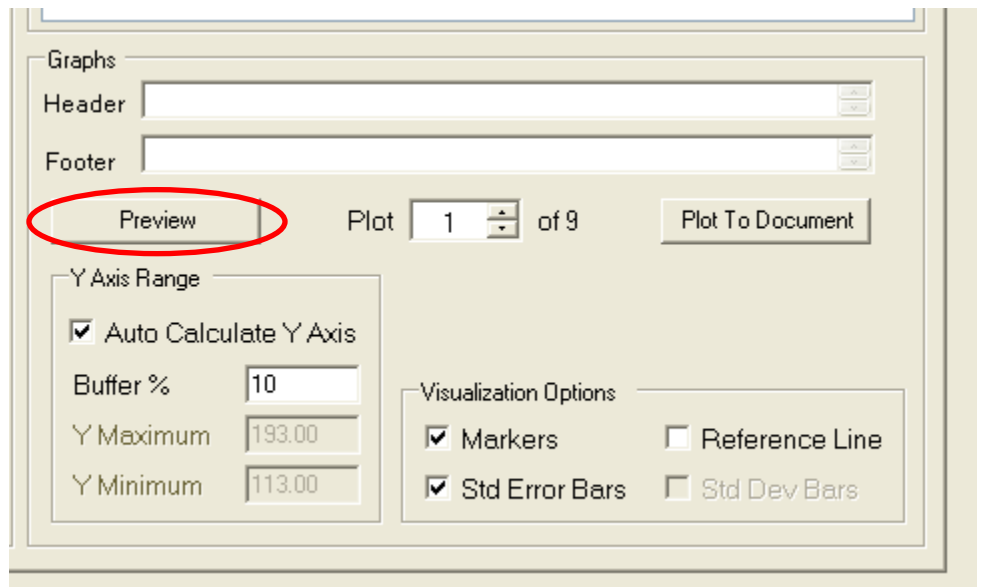


The user can then create a new Profile Name containing the desired filtering changes.

A profile can also be saved explicitly by selecting the **Save** button next to the profile window. It is always a good idea to click on each report element and review the selections in the **Table Graph Population** panel to ensure that the generated report reflects the desired population. If the **Profile Listing** report element is included in the report, it will identify what selections were made for each of the report elements in the report.

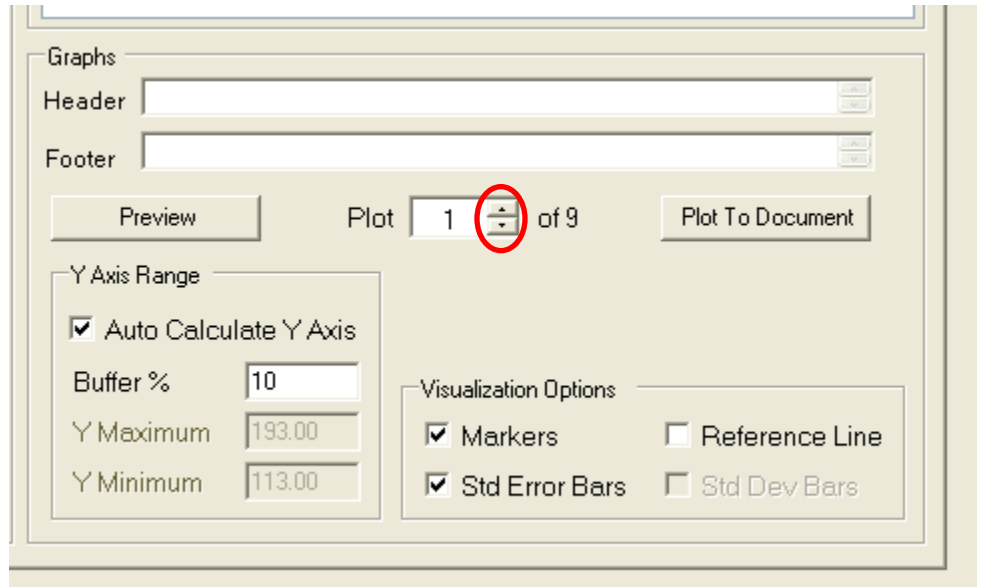


To preview the change(s) to the graph as a result of selecting or de-selecting Graph Population elements the user must click on the **Preview** button located below the graph to refresh its contents.



Element Settings Graph controls

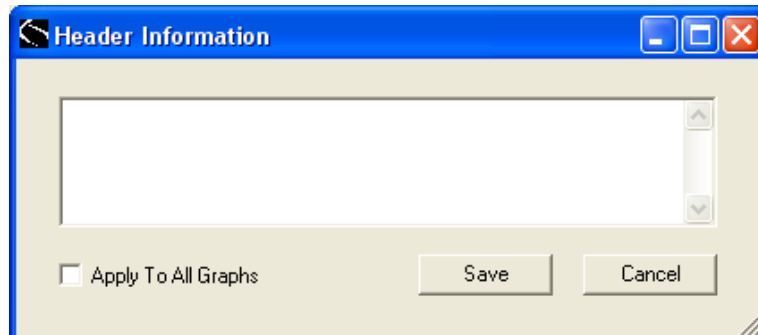
Clicking the up/down arrow next to plot will change the plot displayed in the preview window. A separate graph appears for each gender/parameter combination.



The screenshot shows a 'Graphs' configuration window. It has a 'Header' text box and a 'Footer' text box. Below these are 'Preview' and 'Plot To Document' buttons. The 'Plot' section shows '1 of 9', with a red circle highlighting the up/down arrow next to the number '1'. Below the plot section is a 'Y Axis Range' group box containing a checked 'Auto Calculate Y Axis' checkbox, a 'Buffer %' field set to '10', and 'Y Maximum' and 'Y Minimum' fields set to '193.00' and '113.00' respectively. To the right is a 'Visualization Options' group box with checkboxes for 'Markers' (checked), 'Reference Line' (unchecked), 'Std Error Bars' (checked), and 'Std Dev Bars' (unchecked).

Graph Header

Click in the **Header** box to activate the **Header Information** pop up user interface:

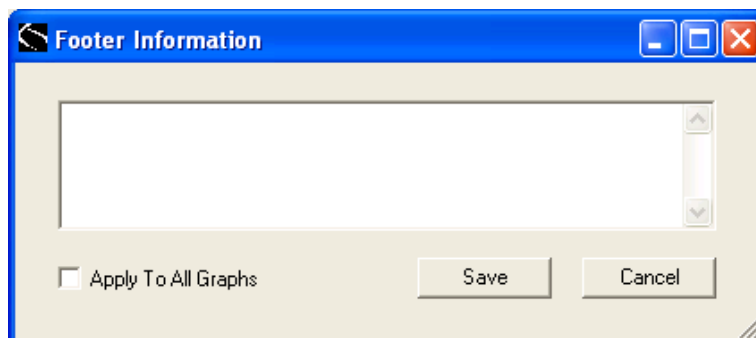


The screenshot shows a 'Header Information' pop-up window. It has a title bar with a blue background and a small icon. The main area is a large text box for entering header text. At the bottom, there is a checkbox labeled 'Apply To All Graphs' and two buttons: 'Save' and 'Cancel'.

From this interface the user can insert up to three lines of graph header text. Check the **Apply To All Graphs** box and then Save to apply the header text to all parameters for this report element. It is also possible to create and save a separate header for each graphed parameter.

Graph Footer

Click in the **Footer** box to activate the **Footer Information** pop up user interface:



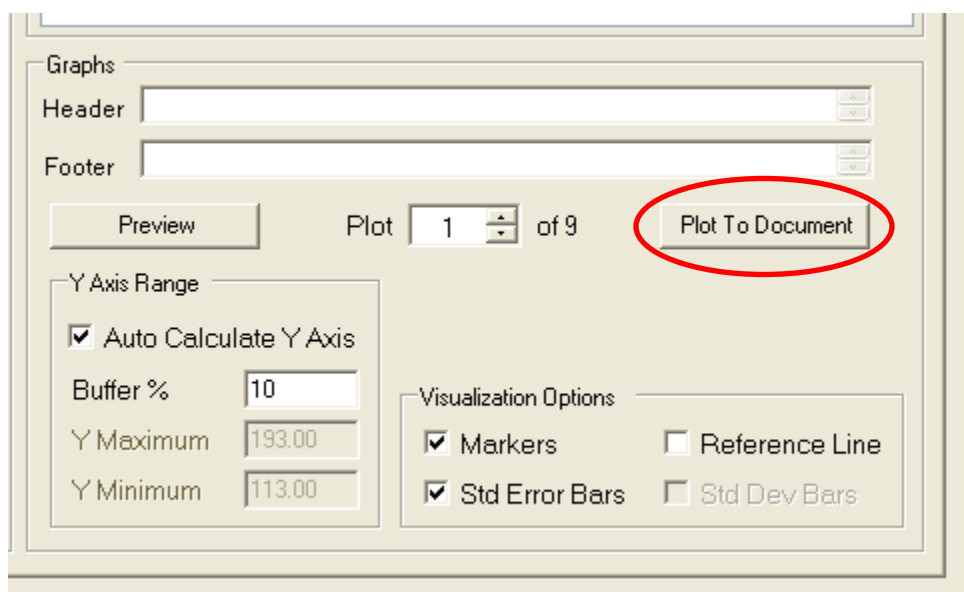
From this interface the user can insert one to five lines of graph footer text. Check the **Apply To All Graphs** box and then Save to apply the same footer text to all parameters for this report element. It is also possible to create and save a separate footer for each graphed parameter.

Plot

The **Plot** window shows the plot number being displayed in the Preview screen. Choosing the up and down arrows next to the Plot window changes the parameter being viewed. A separate plot appears for each parameter/gender combination (or parameter/gender/day combination if “Report by Study Day” is selected)

Plot To Document

Selecting the **Plot To Document** button will insert the previewed graph into the Word document at the cursor. This feature is useful if a single graph needs to be regenerated (with altered header/footer information, with custom axes, or other alteration) without regenerating the graphs for all parameters.



Y Axis Range

By default the **Auto Calculate Y Axis** box is checked. De-selecting the **Auto Calculate Y Axis** box allows the user to set the **Y Maximum** value and **Y Minimum** value for the Y Axis used for the current parameter. By default, the

minimum and maximum mean values present for the selected parameter appear in the y-min and y-max boxes, so the user can specify a common y-min and y-max value for a parameter across males and females. The **Buffer %** window allows the user to specify the amount of white space above and below the min/max y-values. The value in the **Buffer %** window can be changed by manually typing in a value. To see the effect of the new Buffer % value on the graph click on the **Preview** button.

Visualization Options

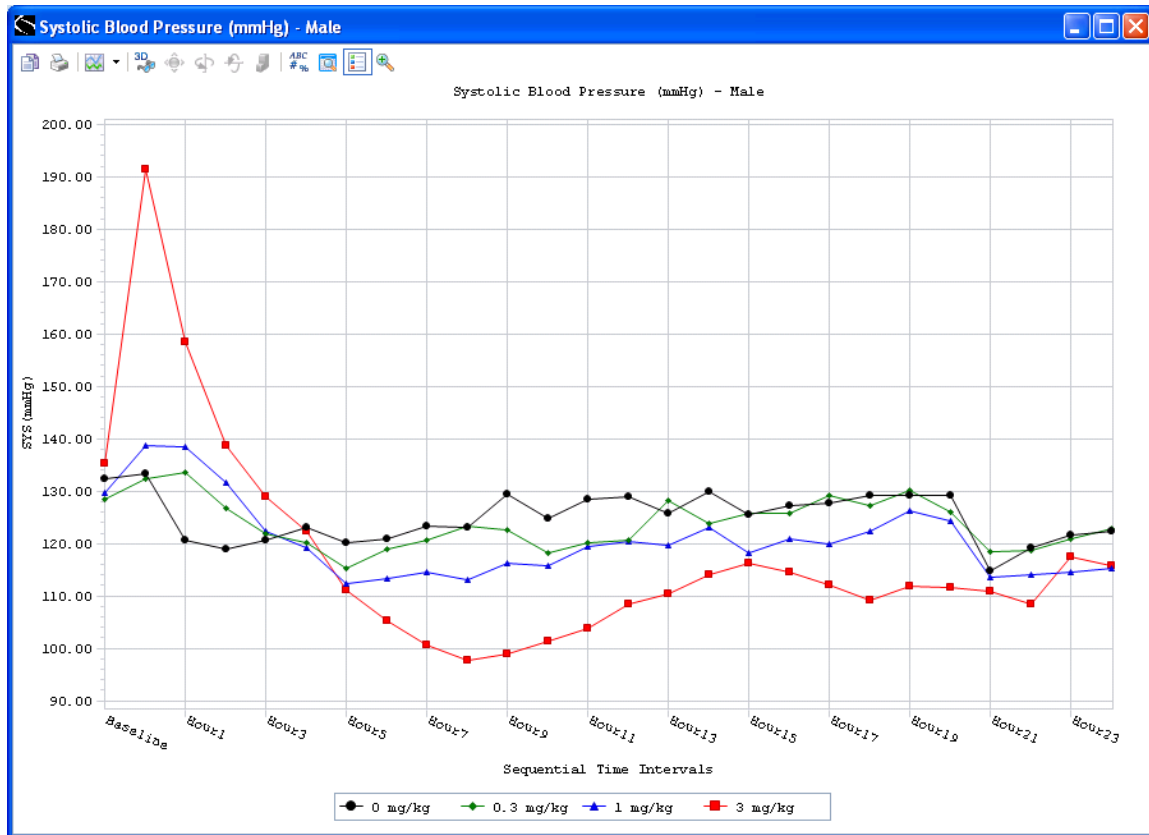
By default the **Show Markers** box is checked which places a symbol at the mean value for each time point.

The screenshot shows a software dialog box titled "Visualization Options". It contains several sections: "Graphs" with "Header" and "Footer" text fields; a "Plot" section with a "Preview" button, a dropdown showing "1 of 9", and a "Plot To Document" button; a "Y Axis Range" section with a checked "Auto Calculate Y Axis" box and input fields for "Buffer %" (10), "Y Maximum" (193.00), and "Y Minimum" (113.00); and a "Visualization Options" section with four checkboxes: "Markers" (checked and circled in red), "Reference Line" (unchecked), "Std Error Bars" (checked), and "Std Dev Bars" (unchecked).

De-selecting the **Show Markers** box removes the graph point markers and just displays the graph lines. Selecting the **Standard Error Bars** box includes standard error bars into the graph and disables the Standard Deviation Bars. Selecting the **Standard Deviation Bars** box includes standard deviation bars into the graph and disables the Standard Error Bars. The **Reference Line** option displays a horizontal baseline for each dose group. Each dose group will show a horizontal line which represents the parameter value at baseline, using the color of the corresponding dose group.

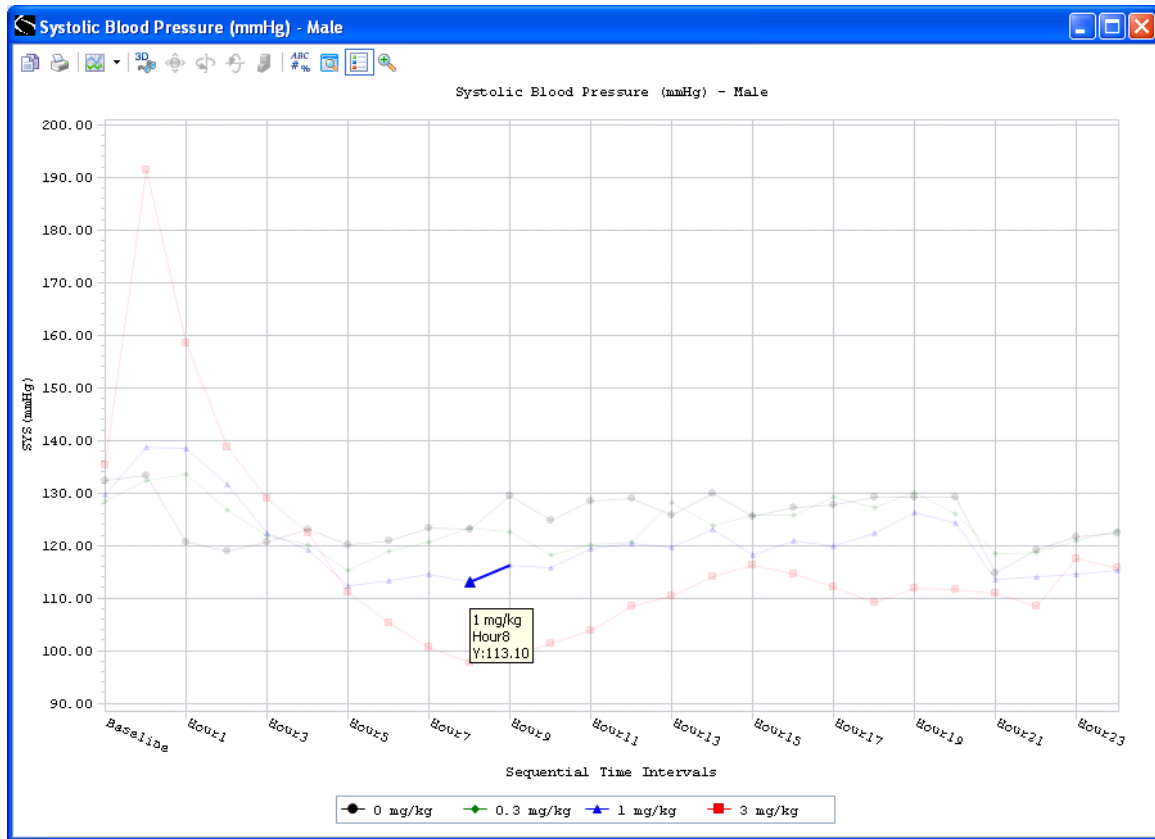
Graphing Options

Detailed graphical views can be obtained by double left clicking on the graph in the preview window. A separate **independent graph page** will appear. From the graph page it possible to edit the view and style of the data without impacting the graphical image that appears in the report.

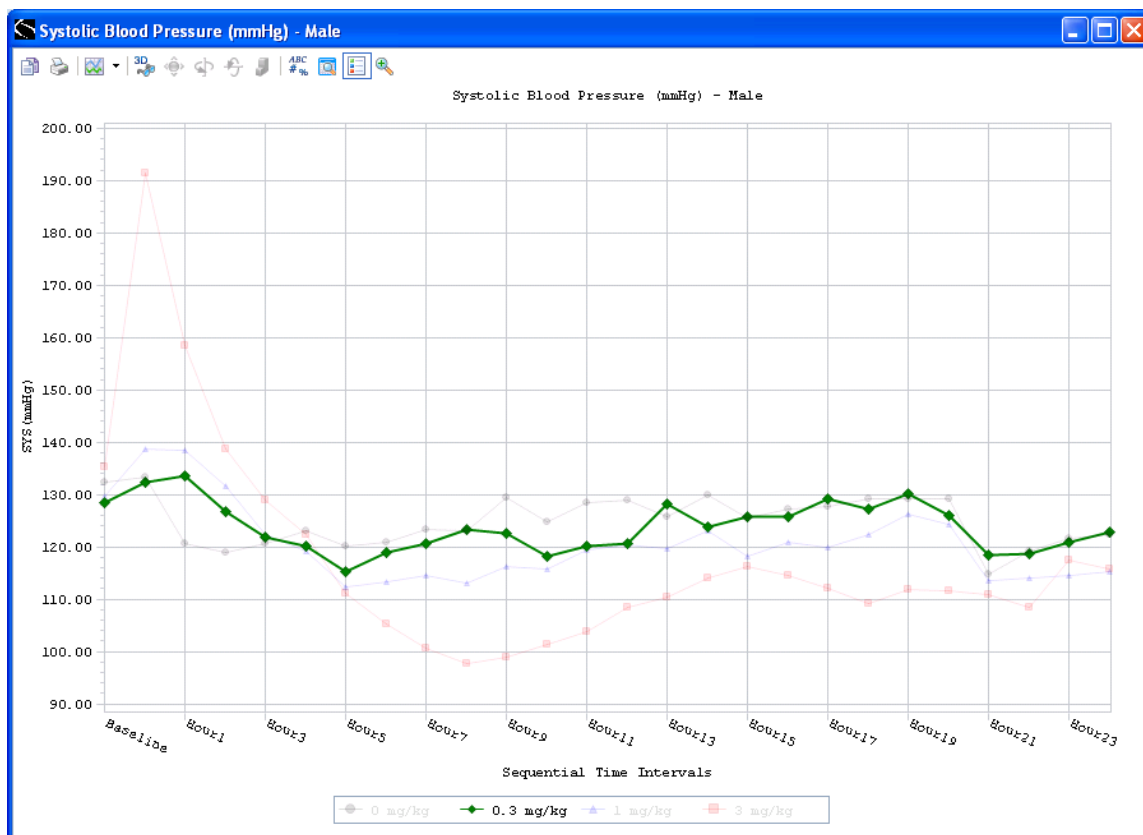


Sample independent graph page

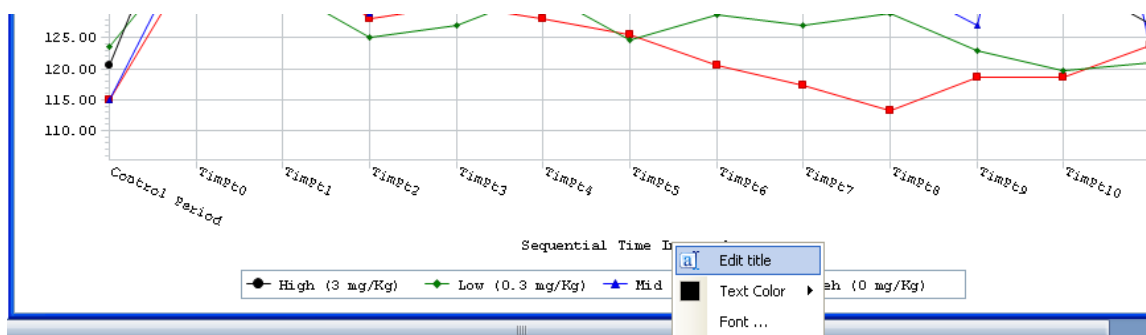
Placing the cursor over a point on the graph will display the numeric source of the particular point.



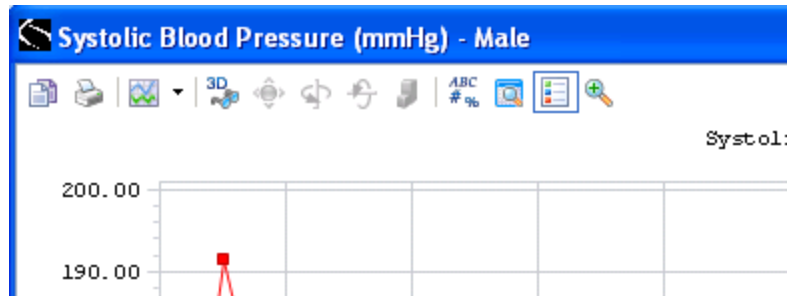
Placing the cursor on one of the legend points will highlight that particular dose on the graph page:



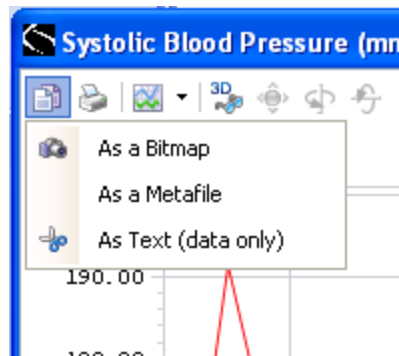
Right click on the graph title or axis label to change the label text by selecting **Edit title** or the label color by selecting **Text Color** or the font size and style by selecting **Font**.



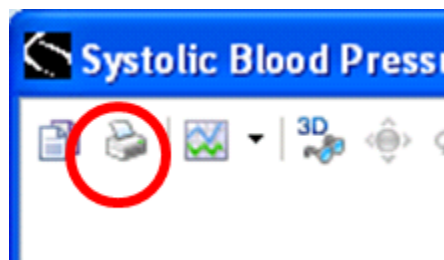
Along the top of the graph page is a series of icons which enable the user to further edit the graph page. The icon functionality can also be activated by left clicking on a symbol within the graph.



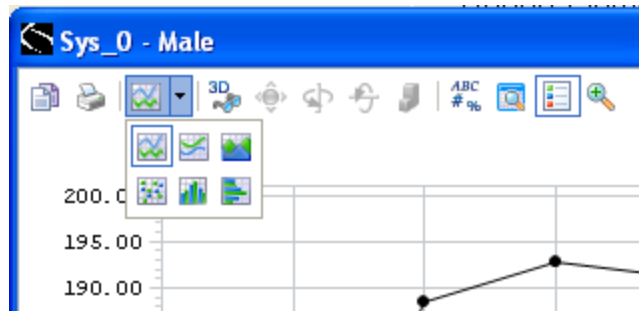
The first icon **Copy To Clipboard** contains functions to save the graph page **As a Bitmap** or **As a Metafile** or **As Text (data only)**.



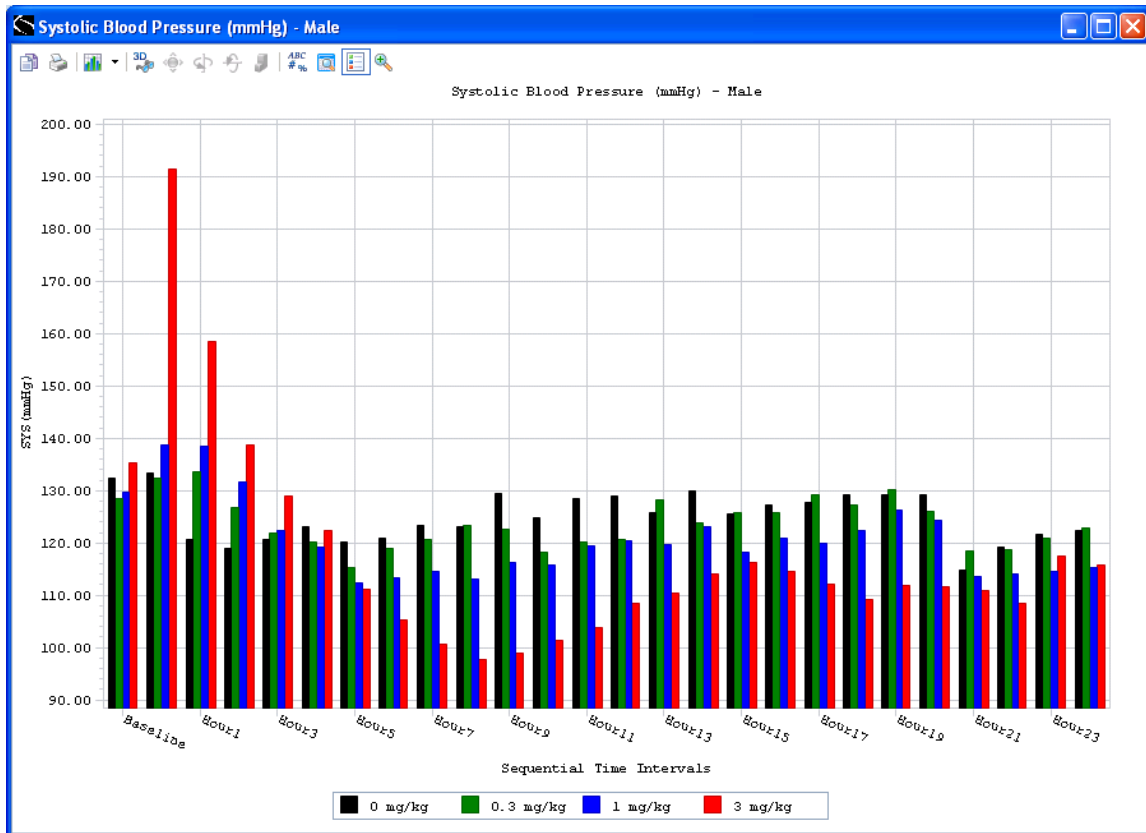
The **Print** function is the second icon. This routes the graph page to available printers.



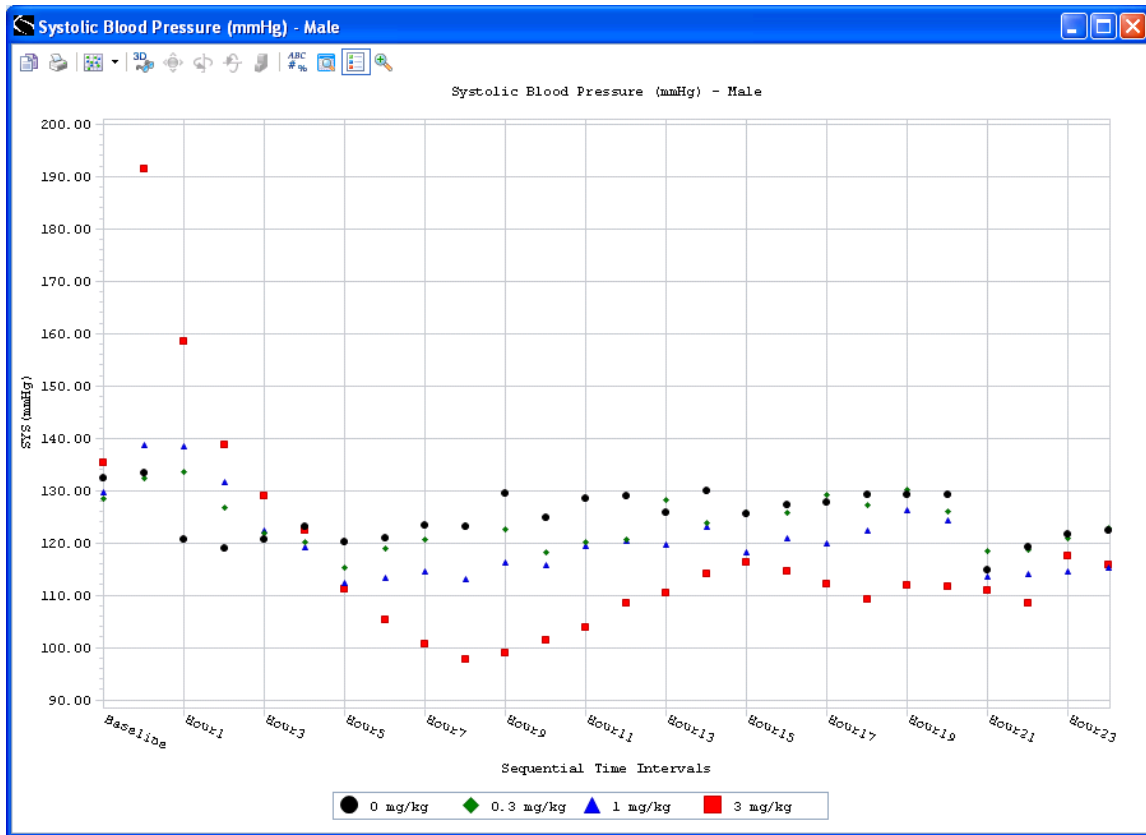
The graph **Gallery** is the fourth icon which enables the user to change the style of graph from styles like smooth line plots, bar graphs, symbol plots, etc..



Sample of smooth line plot

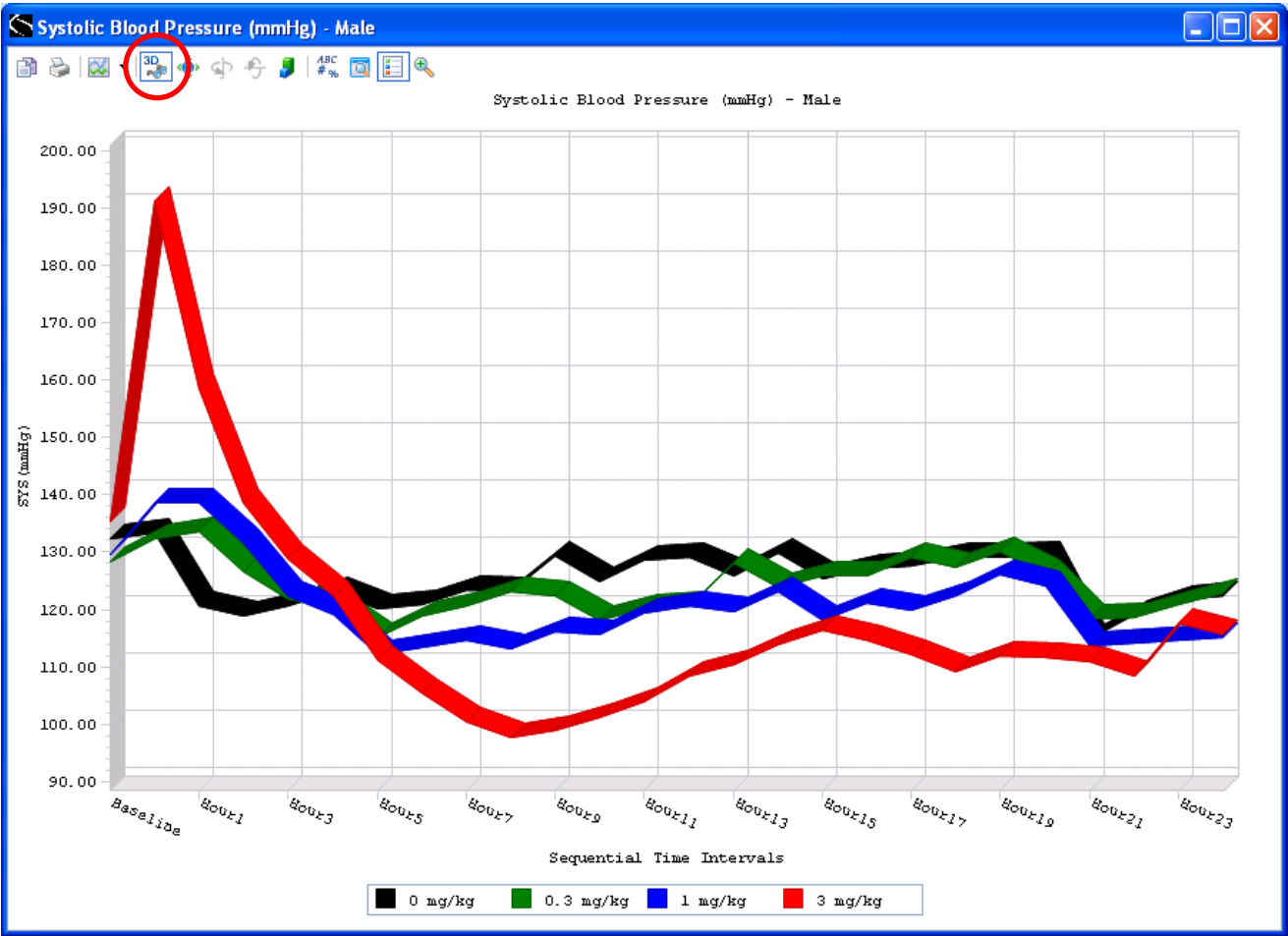


Sample bar graph



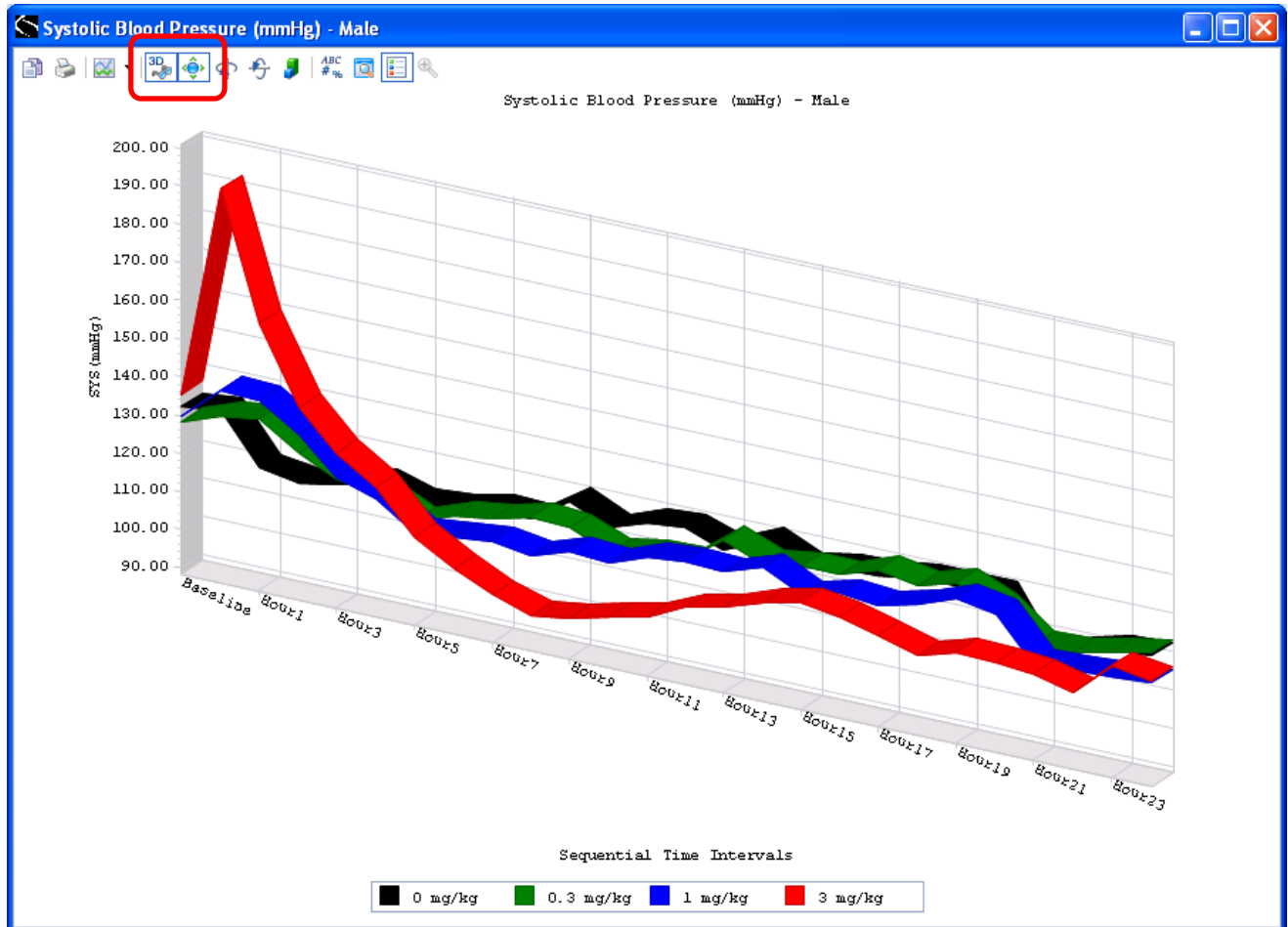
Sample symbol plot

The **3D/2D** icon changes the graph from a 2 dimensional graph to a 3 dimensional graph or back to a 2 dimensional graph.



Sample of a 3 dimensional graph

Three dimensional graph views can be rotated by selecting the **Rotate View** icon.

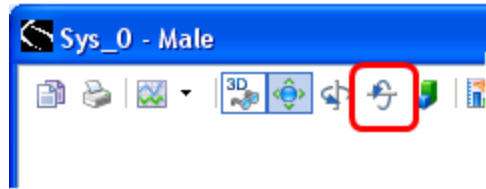


Sample rotated view of 3 dimensional graph

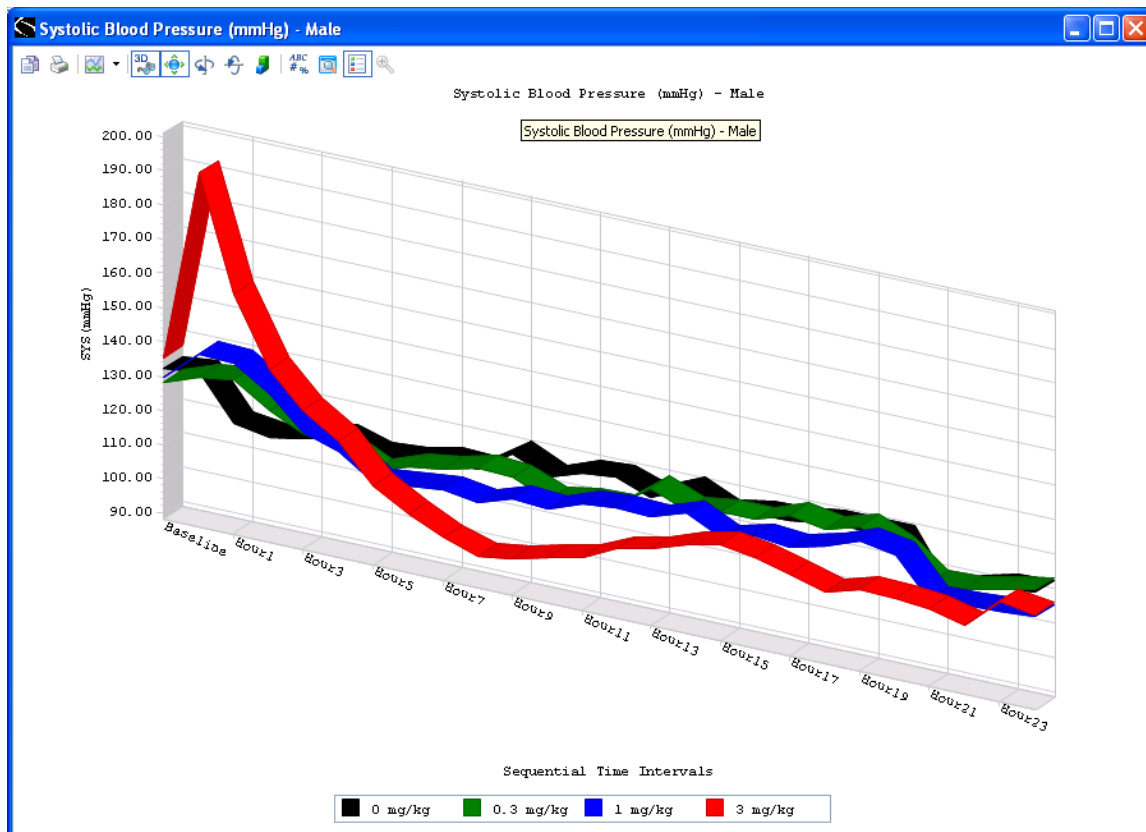
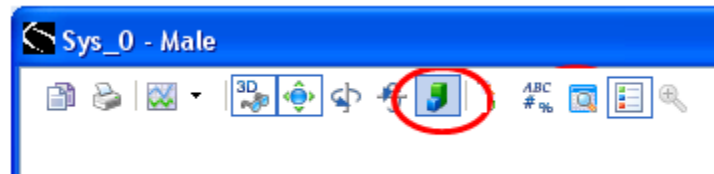
Three dimensional graphs rotation around the Y axis is controlled using the **Rotate Around Y Axis** icon.



Three dimensional graphs rotation around the X axis is controlled using the **Rotate Around X Axis** icon.

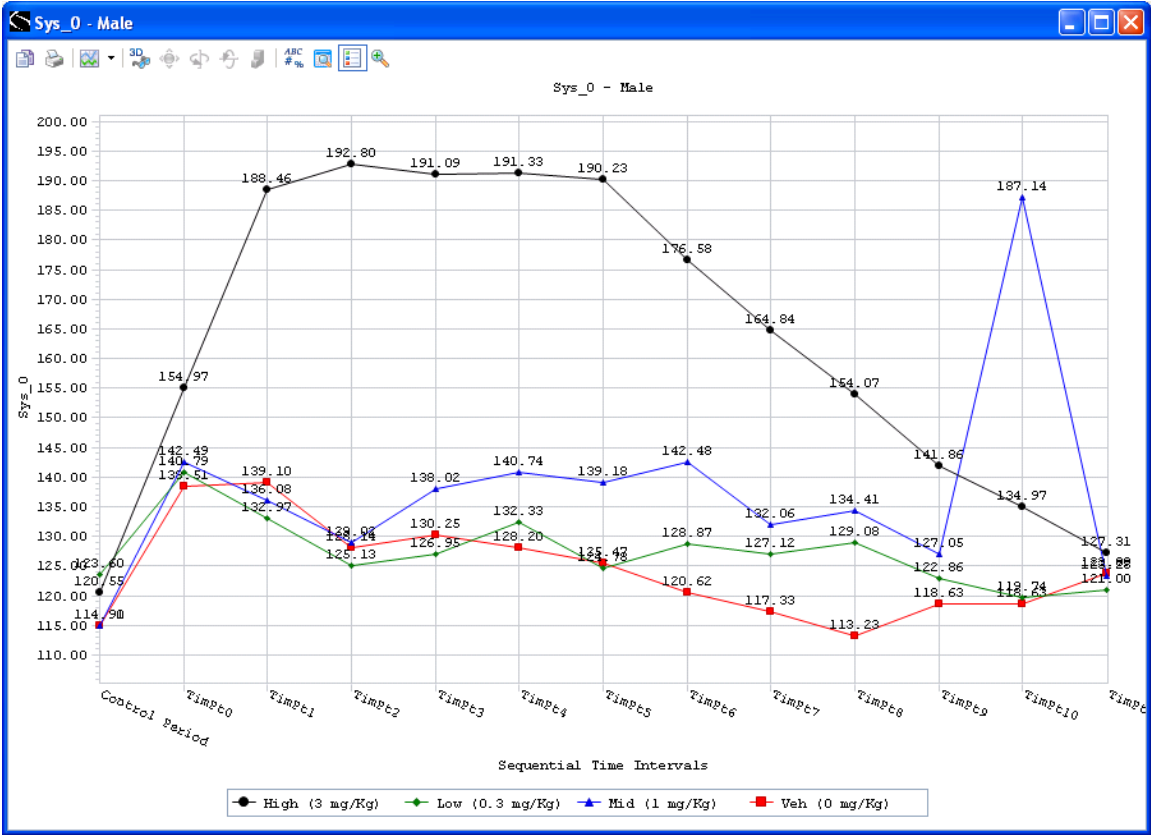


Axis dimension can be altered by selecting the Clustered (Z-Axis) icon.



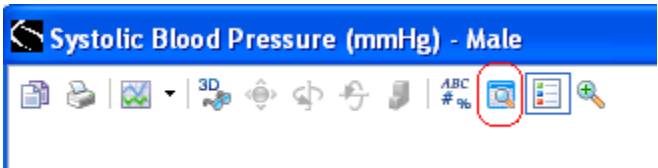
Sample three dimensional graph with Clustered (Z-Axis)

The **Point Labels** icon displays the numeric values of the graphical point.



Sample graph with Points Labels selected.

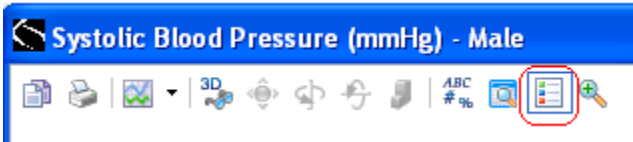
The **Data Grid** displays the numeric values of the graphical point in a table located below the graph legend.



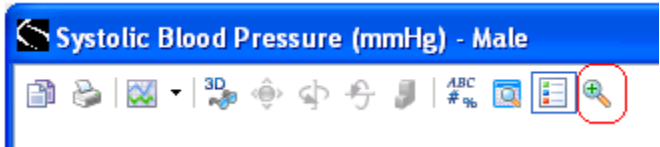
Sample graph with Data Grid selected.

Mouse over cells in the data grid to highlight corresponding graph data points.

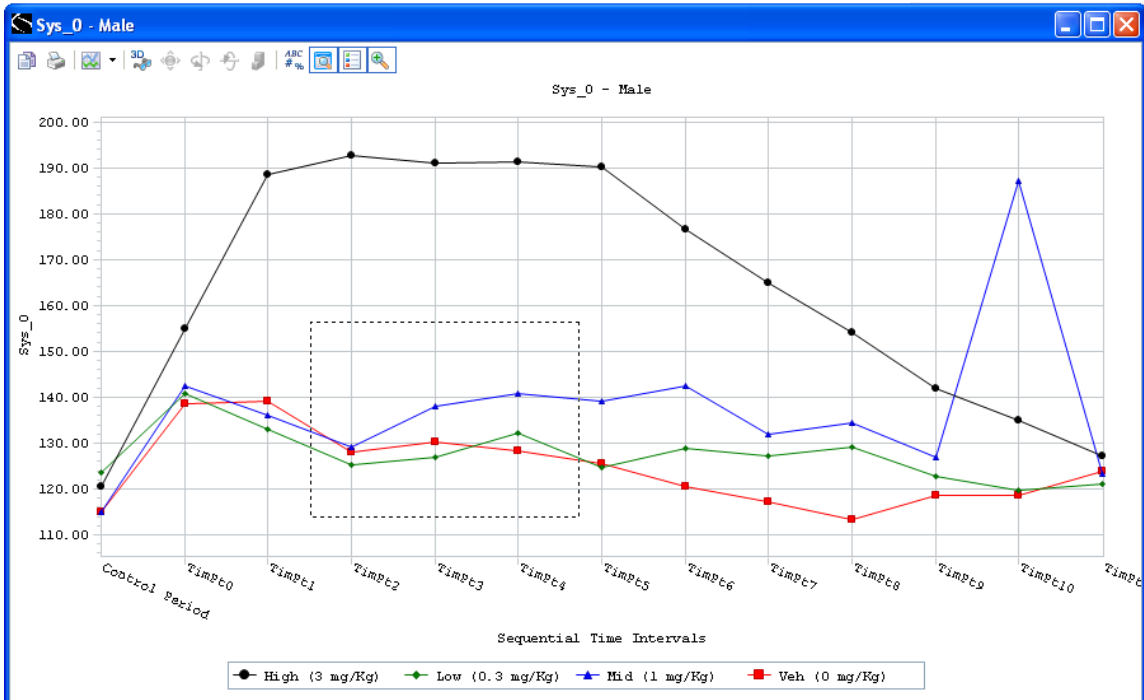
Selecting the **Legend Box** icon hides the graph legend. Selecting the Legend Box icon a second time displays the graph legend.



The **Zoom** icon enables the user to select a portion of the graph and display that portion of the graph.

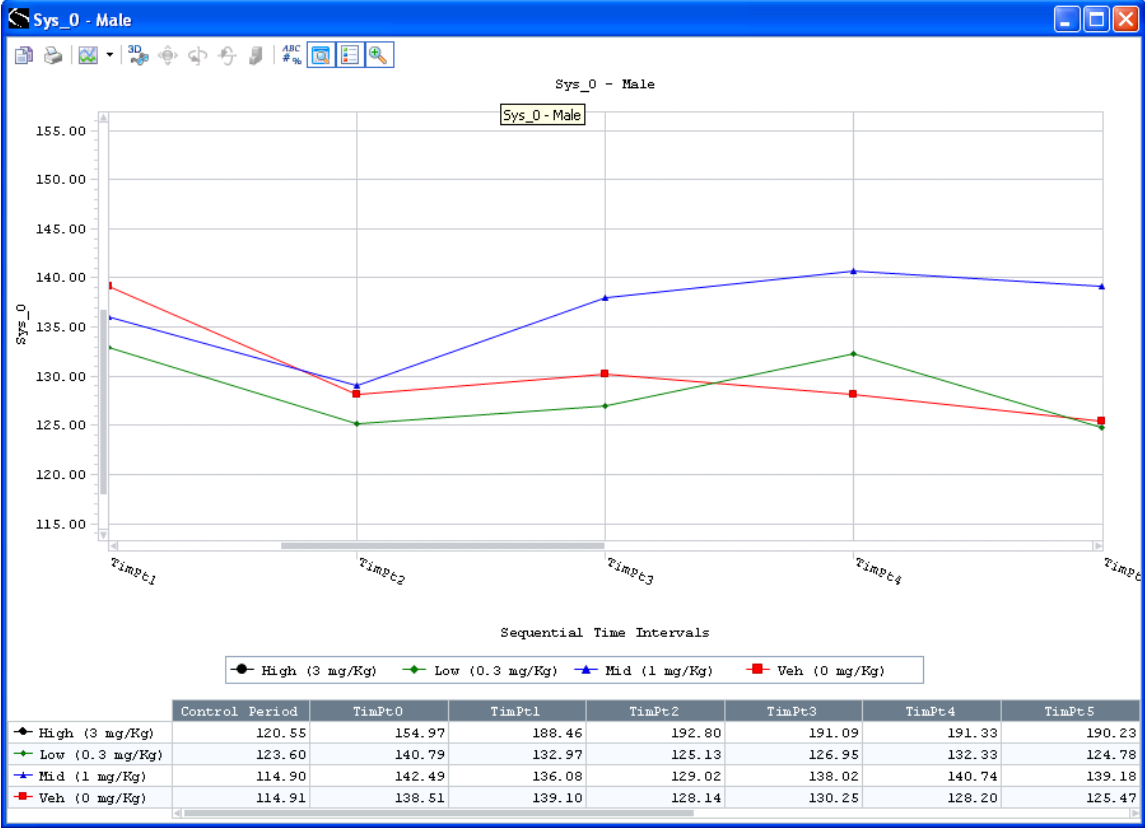


To enable Zoom select the Zoom icon then mouse to the portion of the graph to be detailed



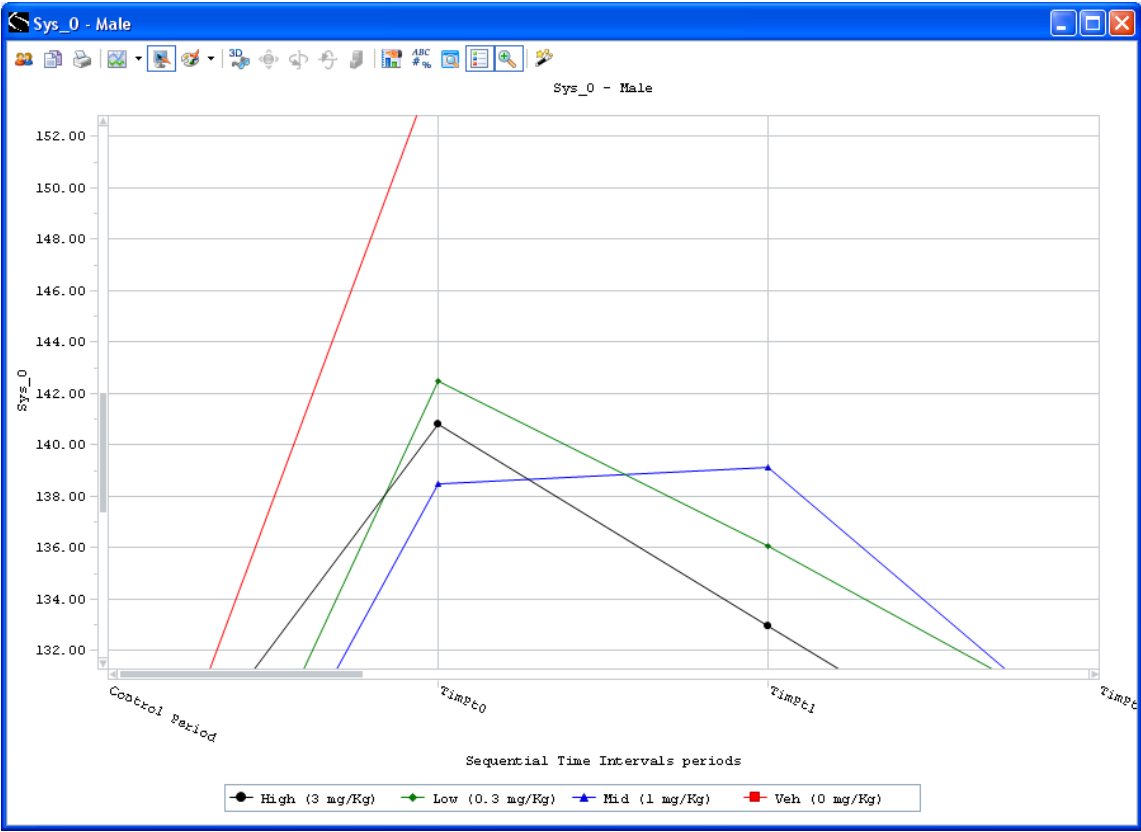
Sample graph with Zoom area selected.

Display of selected Zoom area:



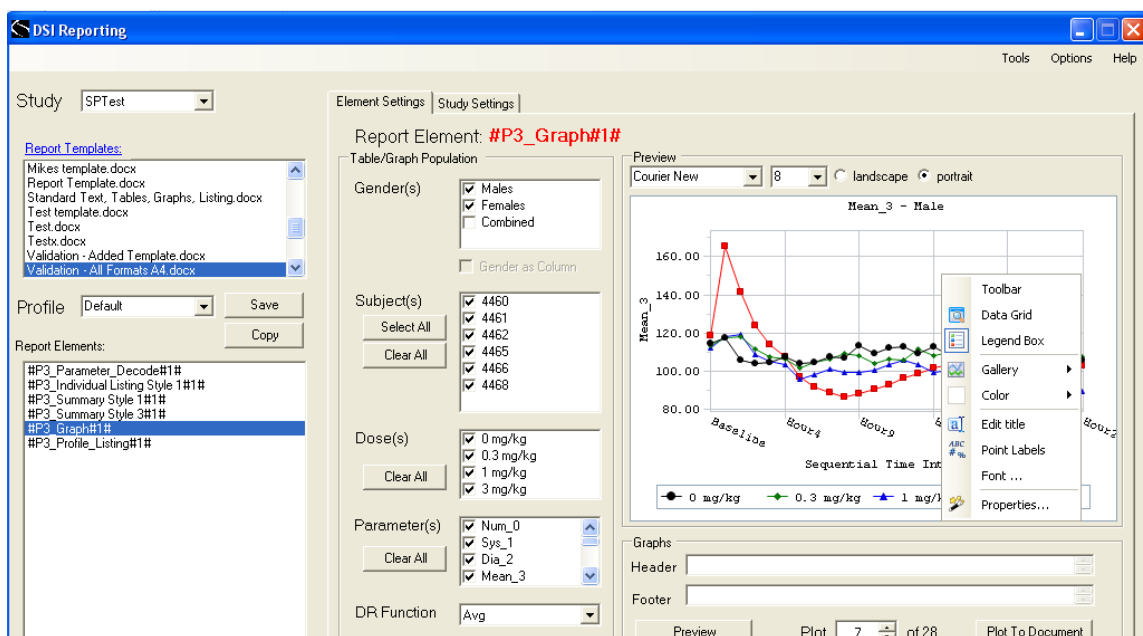
Finer detail can be achieved by mousing over desired region again. To return graph page to its original format re-select the zoom icon.

Selecting an area within a zoomed graphical display can display further detailed graph:



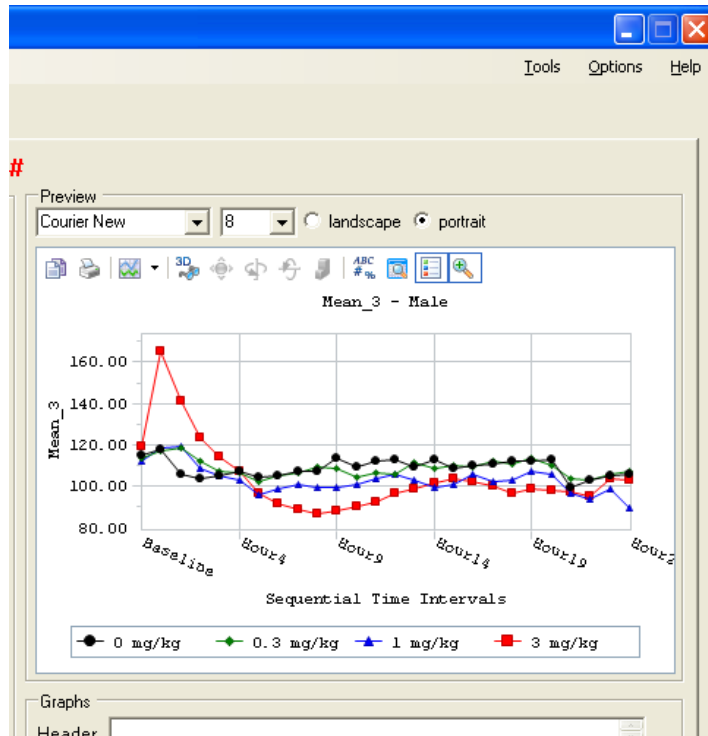
Selecting the Zoom icon a second time will restore a full graphical display.

To display a **Context Menu** right click within any blank area of the graph box where the data is displayed (do not click on the data).

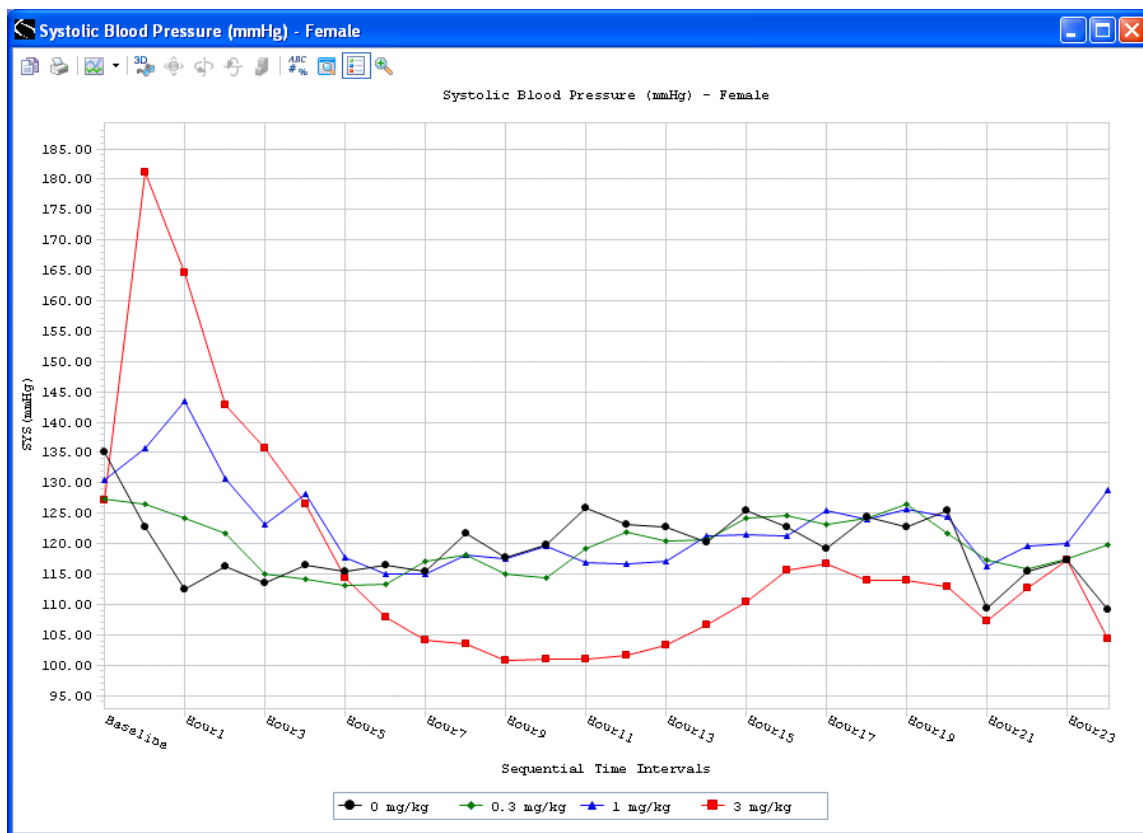


DSI Reporting interface with Context Menu displayed

Selecting the **Toolbar** context menu item moves the toolbar menu to the top of the graph thumbnail.

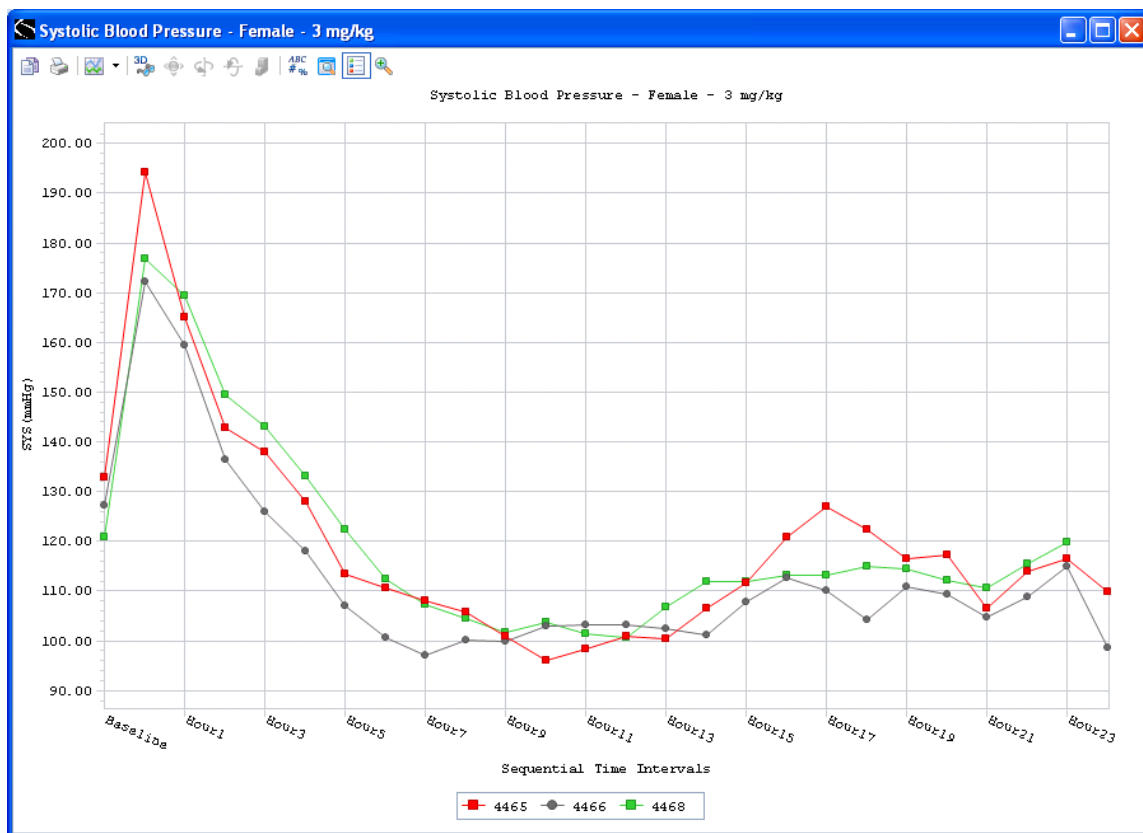


It is possible to see in finer detailed graphs by using the **Drill Down** feature. To drill down open an independent graph by double left clicking on the graph in the preview window.



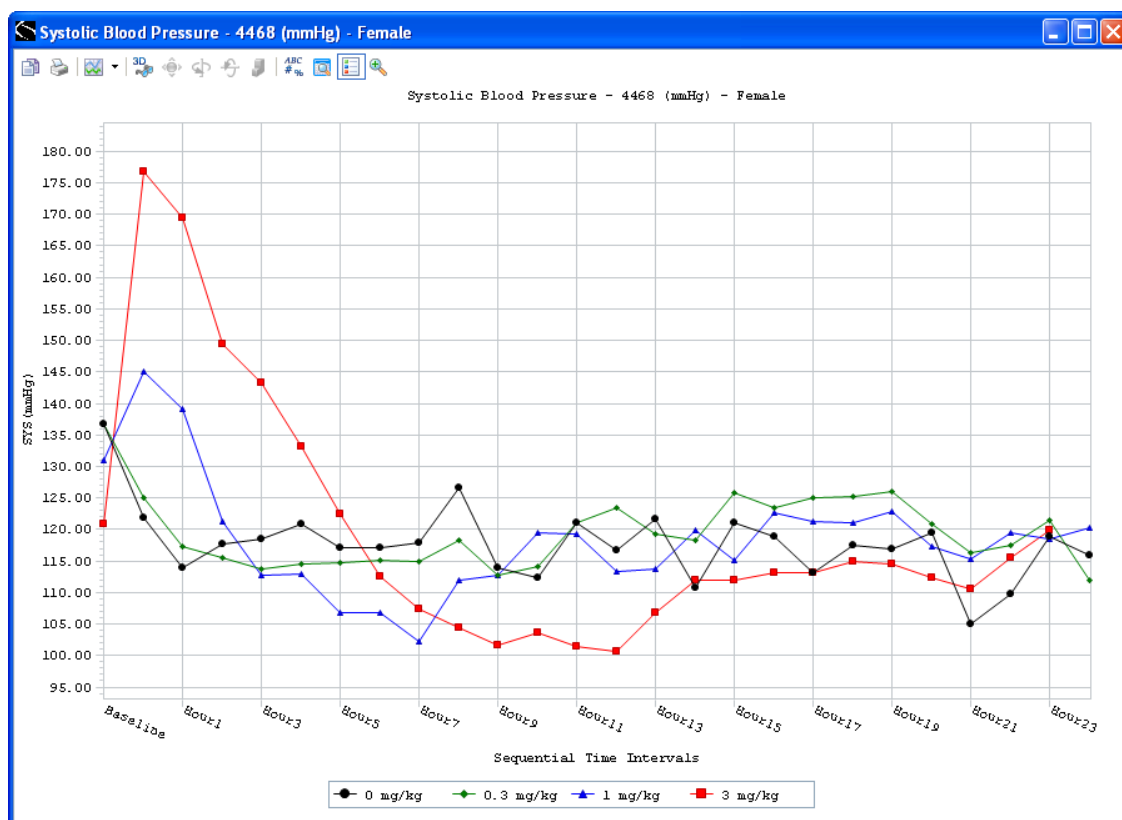
Sample independent graph page

Double click on a dose name in the independent graph's legend or any data point in the graph. A new independent graph page will open displaying to individual data points that make up the selected dose line. In the example below the 3 mg/kg dose was selected:



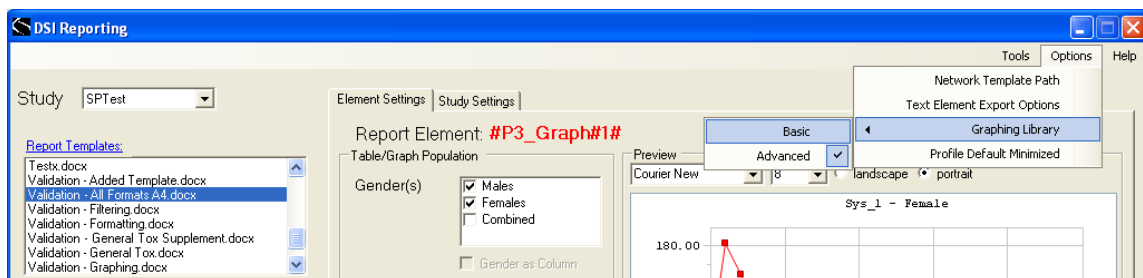
Drill Down graph page showing plots of the 3 animal's individual data points constituting the 3 mg/kg dose.

It is possible to gain further detail pertaining to individual animals. From the drill down graph page double click on a subject name in the graph legend or any data point in the graph. Another independent graph page will open and display the selected subject's data points. In the example below subject 4468 was selected:



Drill Down graph page showing plots of the 4 doses received to subject 4468.

The Advanced Graphing capabilities demonstrated can be disabled by selecting the DSI Reporting **Options** menu item. From the sub-menu then select **Graphing Library** sub-menu item and then select the **Basic** sub-menu item.



DSI Reporting Options menu with Graphing Library sub-menu

Selecting the **Basic** option will permit the user to open independent graph pages but disables the Drill Down capabilities. To regain access to the Drill Down capabilities select **Advanced** for the Graphing Library sub-menu.

Study Settings

The second tab within the DSI Reporting interface is the **Study Settings** tab:

Study: SPTest

Report Templates:

- Standard Text, Tables, Graphs, Listing.docx
- Test template.docx
- Test.docx
- Testx.docx
- Validation - Added Template.docx
- Validation - All Formats A4.docx
- Validation - Filtering.docx
- Validation - Formatting.docx

Profile: Default

Report Elements:

- #P3_Parameter_Decode#1#
- #P3_Individual Listing Style 1#1#
- #P3_Summary Style 1#1#
- #P3_Summary Style 3#1#
- #P3_Graph#1#
- #P3_Profile_Listing#1#

Generation Options:

☐ GLP ☒ Include Date/Time Footer

☐ Include Data Reduction Function Footer

Output File Name: C:\Documents and Settings\verico\ Browse

Study Level Settings

Study Title: Safety Pharmacology Cardiovascular Study in Rats

Test Article: CMPD-123

Lot/Unit: L112-10 Species: Rat

Control Time Period Label: Baseline

☒ Standard Deviation ☐ Standard Error

Dose Order:

- 0 mg/kg
- 0.3 mg/kg
- 1 mg/kg
- 3 mg/kg

Workup Order:

Parameter Table

	Original Name	Long Name	Short Name	Units	Raw Precision	Mean Precision	SD or SE Precision
▶	Num_0	BP Cycle Count	Num		0	0	0
	Sys_1	Systolic Blood Pressure	SYS	mmHg	1	2	2
	Dia_2	Diastolic Blood Pressure	DIA	mmHg	1	2	2
	Mean_3	Mean Blood Pressure	MEAN	mmHg	2	3	3
	HR_4	Heart Rate	HR	bpm	0	1	2
	Num_5	ECG Cycle Count	NUM ECG		0	0	0
	RR-I_6	RR Interval	RR-I	ms	1	2	3
	HR_7	Heart Rate ECG	HR ECG	bpm	0	1	2
	ST-I_8	ST-Interval	ST-I	ms	2	3	4
	QRS_9	QRS Interval	QRS	ms	2	3	4
	PR-I_10	PR-Interval	PR-I	ms	2	3	4

Save Parameters Cancel Parameter Changes

DSI Reporting user interface Study Settings tab

This is where the user can control the Study Level Settings.

Study Title

Text box limited to 200 characters which are applied to the top of each page of the study report tables, graphs and profile listing. The **Study Title** can be inserted into a **Report Template** as a **Report Element**.

Test Article

Text box limited to 50 characters describing the compound being used which is applied to the profile listing. The **Test Article** can be inserted into a **Report Template** as a **Report Element**.

Lot/Unit

Text box limited to 50 characters describing the compound lot number or unit being used which is applied to the profile listing. The **Lot/Unit** can be inserted into a **Report Template** as a **Report Element**.

Species

Text box limited to 30 characters describing the test subject being used which is applied to the profile listing. The **Species** can be inserted into a **Report Template** as a **Report Element**.

Control Time Period Label

By default the Control Time Period is labeled as “Control Period”. The user has the option to change the Control Time Period Label by typing the desired text in the text box. The text box is limited to 30 characters and is applied to tables and graphs.

Standard Deviation

Is a radio button selection which applies a standard deviation values (\pm) to the summary tables. The ***Standard Deviation*** calculation used is the “n-1” formula for sample populations:

$$s = \sqrt{\frac{\sum (x - \bar{x})^2}{(n - 1)}}$$

Standard Error

Is a radial button selection which applies a standard error values (\pm) to the summary tables. The ***Standard Error*** calculation used is the standard deviation divided by square root of the sample size:

$$SE_{\bar{x}} = \frac{s}{\sqrt{n}}$$

Dose Order

The ***Dose Order*** listed is in the window display is the order in which dose groups will appear in the summary tables and graphs. The order the doses appear in the window and the generated report can be changed by dragging and dropping the selected group label.

Workup Order

The ***Workup Order*** listed is in the window display is the order in which workups will appear in the summary tables and graphs. The order the workups appear in the window and the generated report can be changed by dragging and dropping the selected group label.

Save Settings

Selecting the ***Save Setting*** button preserves the user changes made in the Study Level Settings display window.

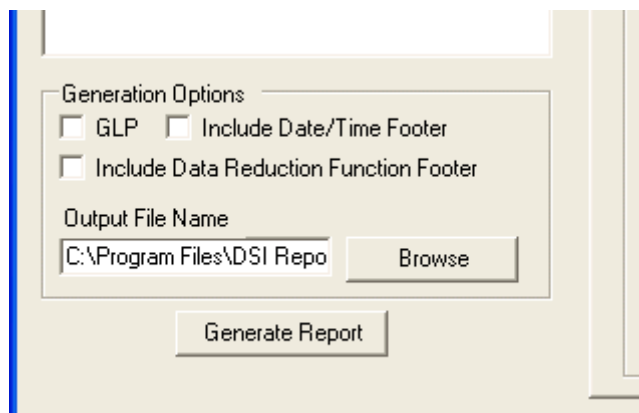
Parameter Table

The **Parameter Table** enables the user to enter each parameter **Long Name** and **Short Name** and parameter **Units**. By default the Long Name and Short Name is populated with the same text found in the **Original Name** column and the **Units** column is blank. This “naming” text and “units” text is used to populate **Parameter Decode** table. The Short Name is used along with the Units (in parenthesis) as the column heading for the individual listing tables and axis label for the graphs. The Long Name and Units (in parenthesis) are listed in title header of the summary tables and graphs.

Numbers displayed in the **Raw Precision** column indicate the number of decimal points used when reporting the acquired parameter data (Individual Listing tables). The numbers in the **Mean Precision** column are the number of decimal points used when reporting any mean parameter data (Summary Listing tables). The **SD or SE Precision** sets the number of decimal points used when reporting standard deviation values or standard error values (Summary Listing tables).

Generation Options

Located in the lower left hand corner of the DSI Reporting user interface are the Generation Options.



GLP Option

The **GLP** option locks-down contents of tables and listings to ensure that output generated by the application cannot be modified. The user will still have the ability to modify headers, footers and add comments.

Include Date/Time Footer Option

The **Include Date/Time Footer** option gives the user a means of time stamping generated reports.

Include Data Reduction Function Footer Option

The **Include Data Reduction Function Footer** option gives the user a means of displaying the Data Reduction data being reported on each table and graph page of the report.

Browse

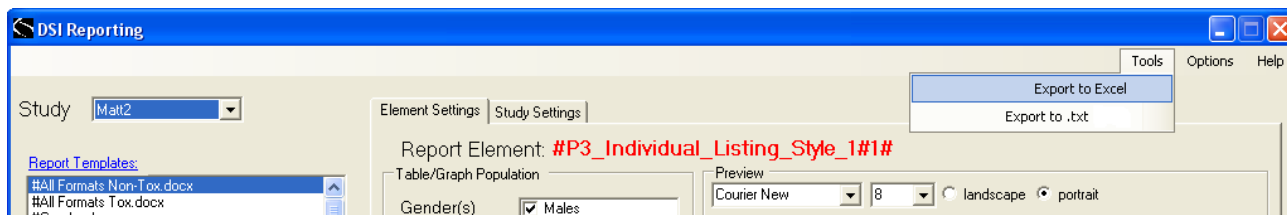
Enables the user to navigate to where the output from the generated report will be placed.

Generate Report

Once all desired options and setting have been made the final step is selecting the **Generate Report** button. This generates the tables, listings and graphs as specified by the selections within the interface screen. The report will appear on screen and the interface screen will close.

Export Options

The DSI Reporting database information can be exported to either a Microsoft Excel file or tab delimited text file. To export DSI Reporting database information to Excel, select the **Tools** menu item and then **Export to Excel** sub-menu.



Book1 - Microsoft Excel

Home Insert Page Layout Formulas Data Review View Add-Ins

Calibri 11 A A

B I U L Font Merge & Center Alignment

General \$ % Number

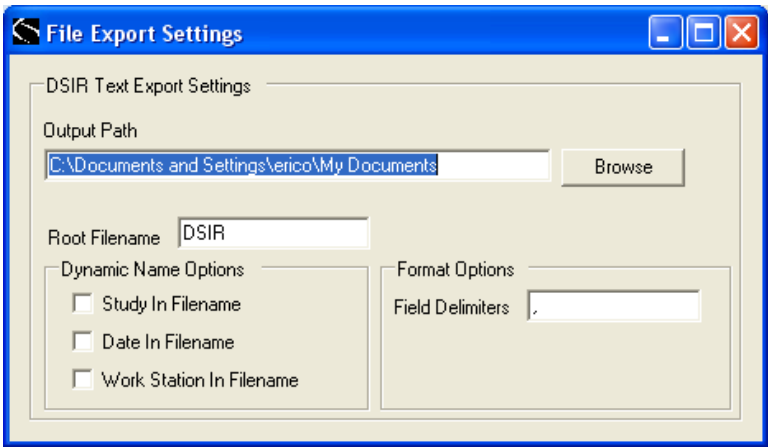
Conditional Formatting Styles Cell Styles Insert Delete Format Cells AutoSum Fill Clear Sort & Find & Select

A1	SubjectName																		
	SubjectName	Gender	GroupID	DoseName	DoseOrder	TestDay	WORKUP	WorkUp	ColumnID	Run	Label	DRFunc	EndTime	RealTime	Sys_0	Dia_1	Mean_2	HR_3	RR
1	Rat2	M	1	Veh (0 mg/Kg)	3	1			0	23450002	TimPt0	Line	1:06:07 3/23/2006 9:08	143.27	109.49	124.15	521.74		
2	Rat2	M	1	Veh (0 mg/Kg)	3	1			1	23450002	TimPt1	Line	1:16:07 3/23/2006 9:08	151.58	121.27	134.32	545.45		
3	Rat2	M	1	Veh (0 mg/Kg)	3	1			2	23450002	TimPt2	Line	1:26:07 3/23/2006 9:08	119.74	87.763	103.83	387.1		
4	Rat2	M	1	Veh (0 mg/Kg)	3	1			3	23450002	TimPt3	Line	1:36:07 3/23/2006 9:08	140.73	111.19	124.62	461.54		
5	Rat2	M	1	Veh (0 mg/Kg)	3	1			4	23450002	TimPt4	Line	1:46:07 3/23/2006 9:08	126.28	93.606	108.76	363.64		
6	Rat2	M	1	Veh (0 mg/Kg)	3	1			5	23450002	TimPt5	Line	1:56:07 3/23/2006 9:08	134.58	102.85	116.93	400		
7	Rat2	M	1	Veh (0 mg/Kg)	3	1			6	23450002	TimPt6	Line	2:06:07 3/23/2006 9:08	135.9	105.43	119.01	413.79		
8	Rat2	M	1	Veh (0 mg/Kg)	3	1			7	23450002	TimPt7	Line	2:36:07 3/23/2006 9:08	113.44	82.437	96.273	342.86		
9	Rat2	M	1	Veh (0 mg/Kg)	3	1			8	23450002	TimPt8	Line	3:06:07 3/23/2006 9:08	125.45	94.156	108.99	333.33		
10	Rat2	M	1	Veh (0 mg/Kg)	3	1			9	23450002	TimPt9	Line	3:36:07 3/23/2006 9:08	118.34	85.156	102.99	333.33		
11	Rat2	M	1	Veh (0 mg/Kg)	3	1			10	23450002	TimPt10	Line	4:06:07 3/23/2006 9:08	120.23	92.066	104.24	342.86		
12	Rat2	M	1	Veh (0 mg/Kg)	3	1			11	23450002	TimPt11	Line	4:36:07 3/23/2006 9:08	142.25	108.06	124.21	352.94		
13	Rat2	M	2	Low (0.3 mg/Kg)	1	7			0	23450004	TimPt0	Line	1:09:16 3/27/2006 9:12	158.93	127.36	138.66	555.56		
14	Rat2	M	2	Low (0.3 mg/Kg)	1	7			1	23450004	TimPt1	Line	1:19:16 3/27/2006 9:12	151.45	119.88	133.06	517.24		
15	Rat2	M	2	Low (0.3 mg/Kg)	1	7			2	23450004	TimPt2	Line	1:29:16 3/27/2006 9:12	124.89	97.375	110.64	394.74		
16	Rat2	M	2	Low (0.3 mg/Kg)	1	7			3	23450004	TimPt3	Line	1:39:16 3/27/2006 9:12	128.27	100.27	113.24	416.67		
17	Rat2	M	2	Low (0.3 mg/Kg)	1	7			4	23450004	TimPt4	Line	1:49:16 3/27/2006 9:12	144.28	112.02	127.33	375		
18	Rat2	M	2	Low (0.3 mg/Kg)	1	7			5	23450004	TimPt5	Line	1:59:16 3/27/2006 9:12	123.19	98.81	108.01	357.14		
19	Rat2	M	2	Low (0.3 mg/Kg)	1	7			6	23450004	TimPt6	Line	2:09:16 3/27/2006 9:12	131.46	102.79	115.44	340.91		
20	Rat2	M	2	Low (0.3 mg/Kg)	1	7			7	23450004	TimPt7	Line	2:39:16 3/27/2006 9:12	126.35	96.506	109.35	340.91		
21	Rat2	M	2	Low (0.3 mg/Kg)	1	7			8	23450004	TimPt8	Line	3:09:16 3/27/2006 9:12	119.26	93.011	104	340.91		
22	Rat2	M	2	Low (0.3 mg/Kg)	1	7			9	23450004	TimPt9	Line	3:39:16 3/27/2006 9:12	120.95	92.263	104.94	326.09		
23	Rat2	M	2	Low (0.3 mg/Kg)	1	7			10	23450004	TimPt10	Line	4:09:16 3/27/2006 9:12	114.07	87.9	99.149	319.15		
24	Rat2	M	2	Low (0.3 mg/Kg)	1	7			11	23450004	TimPt11	Line	4:39:16 3/27/2006 9:12	117.53	89.746	102.33	312.5		
25	Rat2	M	3	Mid (1 mg/Kg)	2	14			0	23450006	TimPt0	Line	1:05:27 3/30/2006 9:19	151.18	117.53	133.94	500		
26	Rat2	M	3	Mid (1 mg/Kg)	2	14			1	23450006	TimPt1	Line	1:15:27 3/30/2006 9:19	139.05	109.52	125.76	375		

Ready RatCardio Sheet2 - Sheet3 100%

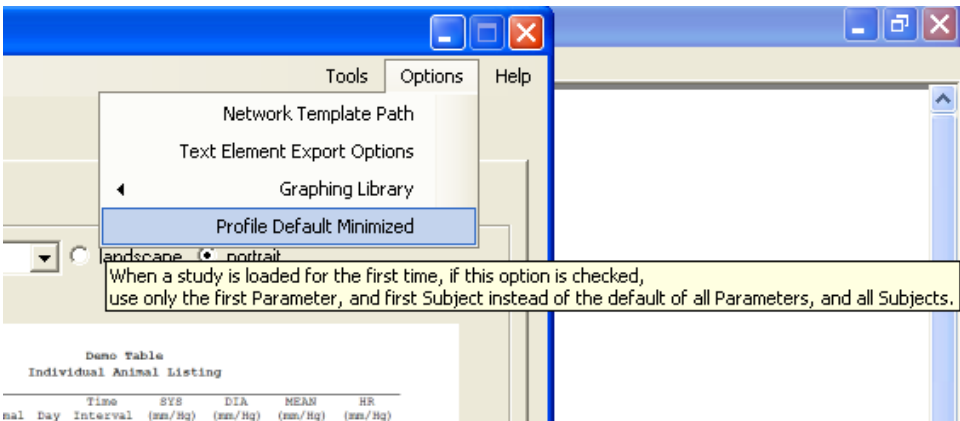
Sample database information export to Excel

The **File Export Settings** window displays the options for exporting data to a text file.



To access the File Export Settings window select the **Options** menu item and then click on the **Text Element Export Options**. Then to export DSI Reporting database information to a text file select the **Tools** menu item and then **Export to .tex** sub-menu. Selection of the DSI Reporting menu and sub-menu items can alternatively be performed by holding down the 'alt' key and then the key underlined for the DSI Reporting menu item.

To decrease the first time loading time of very large datasets select the **Profile Defaults Minimized** option. The Default setting for loading studies is all parameters, all genders and all subjects chosen. The Profile Defaults Minimized option loads studies with only the first parameter and the first subject selected. **Profile Defaults Minimized** is a sub-menu item under the **Options** menu.



Layout of Information

Introduction

The output from DSI Reporting appear in the Summary window is configured in a specific way. The following information indicates the layout of each different configuration.

Individual Summary

Below is an example of an Individual Listing Style 1.

Features of this format:

- Single animal, multiple parameter view

- Landscape or portrait orientation

- Customizable page header, table footer, and page footer

- Repeated fields suppressed (e.g., dose, animal, day)

- Ability to specify # decimal places by parameter (as set via the parameter table)

SPTest: Safety Pharmacology Cardiovascular Study in Rats (UAT-1.0-01 Part 1)
Individual Animal Listing - Male

Animal	Dose	Day	Time	NUMBP	SYS (mmHg)	DIA (mmHg)	MEAN (mmHg)	HR_BP (bpm)
4460	0 mg/kg	4	Hour0	49006	128.11	102.37	113.980	358.83
			Hour1	68442	113.99	90.56	101.090	323.94
			Hour2	87177	118.89	92.22	104.140	312.24
			Hour3	5815	119.04	91.92	104.060	310.61
			Hour4	24727	119.55	91.62	104.210	315.20
			Hour5	43379	118.77	89.91	102.900	310.87
			Hour6	62860	121.12	91.22	104.930	324.68
			Hour7	82032	118.09	88.13	101.770	319.55
			Hour8	2488	125.89	94.80	109.030	340.91
			Hour9	24688	124.64	93.97	108.120	369.99
			Hour10	46575	125.01	93.54	108.050	364.80
			Hour11	69398	126.31	95.25	109.410	380.37
			Hour12	93498	129.55	97.36	112.050	401.67
			Hour13	15435	123.03	90.99	105.590	365.60
			Hour14	37532	125.71	93.06	107.860	368.28
			Hour15	59535	124.76	91.45	106.250	366.72
			Hour16	82176	128.00	94.17	109.460	377.35
			Hour17	4369	128.16	94.36	109.660	369.86
			Hour18	25784	127.06	93.29	108.560	356.92
			Hour19	47986	128.82	94.11	109.850	370.05
			Hour20	69699	126.76	95.04	109.360	361.88
			Hour21	88222	110.62	83.51	95.307	308.72
			Hour22	6948	116.41	87.52	100.240	312.08
			Hour23	25593	116.20	88.44	100.640	310.74
			Hour24	38561	124.51	94.07	107.780	332.88
	0.3 mg/kg	3	Hour0	39426	132.03	107.29	117.670	320.29
			Hour1	57050	143.38	116.69	128.380	293.73
			Hour2	75436	127.12	102.96	113.480	306.44
			Hour3	93507	123.64	100.05	110.240	301.18
			Hour4	11007	122.34	99.22	109.120	291.66
			Hour5	28561	117.62	95.53	104.890	292.56
			Hour6	45751	118.40	92.80	103.730	286.51
			Hour7	61449	121.86	94.51	106.330	261.63
			Hour8	80106	128.32	104.03	114.600	310.95
			Hour9	99632	125.71	98.23	110.280	325.44
			Hour10	19619	116.81	90.81	102.210	333.10
			Hour11	39828	118.30	94.91	104.960	336.81

Individual Summary General Toxicology (Tox) Study Design

Below is an example of an Individual Listing Style 1 General Toxicology.

Features of this format:

- Single parameter, multiple animal view
- Landscape or portrait orientation
- Optionally include summary statistics
- Customizable page header, table footer, and page footer
- Ability to suppress repeated fields (e.g., dose)
- Ability to specify # decimal places

DogTox: ECG Parameters in General Tox Dog Study (UAT-1.0-02)
Individual Animal Listing

Dose	Gender	Animal	Day	Time	RR-I	HR	R-H	P-H	QRS11	PR-I	QT-I
low	Male	Dog1	1	Analysis-0	270.20	57.100	0.9	0.1	25.0	48.5	105.5
			3	Analysis-0	612.80	99.150	0.7	0.2	49.8	107.2	209.2
			7	Analysis-0	500.05	121.150	1.6	0.3	51.8	93.8	201.2
			15	Analysis-0	612.80	99.150	0.7	0.2	49.8	107.2	209.2
	Female	Dog2	1	Analysis-0	277.10	56.050	0.9	0.1	24.9	48.7	107.6
			3	Analysis-0	633.50	95.500	0.7	0.2	49.8	112.0	209.7
			7	Analysis-0	500.05	121.150	1.6	0.3	51.8	93.8	201.2
			15	Analysis-0	633.50	95.500	0.7	0.2	49.8	112.0	209.7
	Male	Dog3	1	Analysis-0	270.80	57.300	0.9	0.1	25.0	48.1	105.3
			3	Analysis-0	503.25	120.550	1.6	0.3	55.0	99.0	208.5
			7	Analysis-0	597.05	103.550	1.3	0.3	50.4	99.8	221.9
			15	Analysis-0	642.80	96.350	1.9	0.4	51.2	93.4	221.2
	Female	Dog4	1	Analysis-0	270.80	57.300	0.9	0.1	25.0	48.1	105.3
			3	Analysis-0	500.05	121.150	1.6	0.3	51.8	93.8	201.2
			7	Analysis-0	566.90	108.050	1.4	0.3	50.5	98.9	224.6
			15	Analysis-0	612.35	100.350	1.9	0.3	50.3	92.3	221.4
high	Male	Dog5	1	Analysis-0	270.80	57.300	0.9	0.1	25.0	48.1	105.3
			3	Analysis-0	633.50	95.500	0.7	0.2	49.8	112.0	209.7
			7	Analysis-0	549.80	111.450	1.5	0.3	50.2	98.8	228.4
			15	Analysis-0	623.05	100.200	1.4	0.3	49.8	99.7	222.4
	Female	Dog6	1	Analysis-0	270.80	57.300	0.9	0.1	25.0	48.1	105.3
			3	Analysis-0	636.75	95.000	0.7	0.2	50.4	109.8	210.0
			7	Analysis-0	554.80	111.950	1.5	0.3	52.3	98.8	223.4
			15	Analysis-0	584.55	105.650	1.3	0.3	49.8	99.9	220.7

Generated On: Tuesday, October 07, 2008 9:15 AM

Group Summary

Below is an example of a Group Summary Style 1.

Features of this format:

Single parameter view

Landscape or portrait orientation

Customizable page header, table footer, and
page footer

Ability to suppress repeated fields (e.g., day)

Ability to specify # decimal places

Alternatively - Gender as column rather than in header

SPTes: Safety Pharmacology Cardiovascular Study in Rats (UAT-1.0-08)

Mean Blood Pressure (mmHg) - Male

Group Summary Statistics

Time	3 mg/kg	1 mg/kg	0.3 mg/kg	0 mg/kg
Hour0	(3) 165.2333 ±5.1220	(3) 118.4147 ±13.0297	(3) 117.3733 ±0.9384	(3) 117.6267 ±2.1102
Hour1	(3) 141.5667 ±6.0194	(3) 119.1850 ±15.6944	(3) 118.3367 ±5.0338	(3) 105.8467 ±4.2425
Hour2	(3) 123.7900 ±6.6966	(3) 108.8777 ±18.3974	(3) 112.0133 ±1.8543	(3) 103.9367 ±0.3142
Hour3	(3) 114.2167 ±3.7166	(3) 105.3850 ±10.8056	(3) 107.4100 ±2.0110	(3) 104.8567 ±0.4208
Hour4	(3) 107.4100 ±2.0777	(3) 103.2780 ± 8.3762	(3) 106.3600 ±2.1608	(3) 107.5333 ±2.2105
Hour5	(3) 96.8850 ±2.0838	(3) 96.0820 ±10.1879	(3) 102.0580 ±2.8070	(3) 104.3933 ±0.7584
Hour6	(3) 91.9390 ±3.8468	(3) 98.4937 ± 4.5397	(3) 104.9833 ±0.9214	(3) 104.8333 ±1.0432
Hour7	(3) 88.7190 ±4.6931	(3) 101.2330 ± 3.9600	(3) 106.5433 ±1.2459	(3) 107.4633 ±2.9367
Hour8	(3) 86.8483 ±5.4070	(3) 99.2473 ± 7.2291	(3) 109.5500 ±3.3093	(3) 107.0933 ±1.9467
Hour9	(3) 88.1113 ±5.1451	(3) 99.3040 ± 8.4806	(3) 108.4033 ±0.9581	(3) 113.5400 ±2.7605
Hour10	(3) 90.5410 ±4.8363	(3) 100.7330 ± 6.6652	(3) 104.3700 ±1.8073	(3) 109.1000 ±0.6504
Hour11	(3) 92.7910 ±6.2697	(3) 103.4553 ± 6.5902	(3) 106.3800 ±2.3005	(3) 112.4800 ±1.5351
Hour12	(3) 96.6953 ±6.1777	(3) 105.7960 ± 5.8531	(3) 106.0267 ±1.7119	(3) 112.9400 ±0.5054
Hour13	(3) 98.6460 ±3.5266	(3) 103.2687 ± 5.2381	(3) 111.8933 ±1.5207	(3) 109.3500 ±2.3914
Hour14	(3) 101.8633 ±1.1383	(3) 99.6027 ± 6.0414	(3) 108.3767 ±4.5583	(3) 112.9100 ±2.6977
Hour15	(3) 103.7733 ±2.2826	(3) 100.8080 ± 6.0106	(3) 109.7867 ±1.6692	(3) 108.6733 ±1.9269
Hour16	(3) 102.4567 ±1.1795	(3) 105.7957 ± 7.6302	(3) 109.5433 ±1.6379	(3) 110.3900 ±0.7572
Hour17	(3) 100.1347 ±1.2261	(3) 102.1620 ± 5.0666	(3) 112.3867 ±1.9499	(3) 110.6000 ±1.6116
Hour18	(3) 96.9047 ±1.0983	(3) 102.8847 ± 9.6538	(3) 110.6400 ±0.2401	(3) 112.0400 ±1.7524
Hour19	(3) 98.9190 ±1.8975	(3) 107.1207 ± 8.3994	(3) 113.3967 ±2.3034	(3) 112.1333 ±1.7754
Hour20	(3) 98.2980 ±1.1016	(3) 105.7323 ± 7.7537	(3) 110.3833 ±2.5432	(3) 112.8500 ±1.7702
Hour21	(3) 97.5773 ±1.9870	(3) 96.6903 ± 5.8647	(3) 103.5167 ±0.7021	(3) 99.6490 ±2.3166
Hour22	(3) 95.1783 ±2.7701	(3) 93.8713 ±10.2613	(3) 103.2600 ±1.6028	(3) 102.9300 ±2.3677
Hour23	(3) 103.5253 ±1.9037	(3) 99.0863 ± 6.8015	(3) 105.7733 ±2.4578	(3) 105.1867 ±2.4051
Hour24	(2) 103.0540 ±4.2360	(3) 89.3617 ±14.7458	(3) 107.4980 ±5.0561	(3) 106.0200 ±2.0152

Summary Statistics: (Number of Animals) Group Mean ± Standard Error

Generated On: Monday, September 29, 2008 10:18 AM

Group Summary

Below is an example of a Group Summary Style 3.

Features of this format:

Multiple parameter view

Landscape or portrait orientation

Customizable page header, table footer, and
page footer

Ability to suppress repeated fields (e.g., day)

Ability to specify # decimal places

Alternatively - Gender as column rather than in header

SPTTest: Cardiovascular Study in Rats with Formatting (UAT-1.0-05)

Group Summary Statistics - Male

Time	Dose		RR-I (ms)		HR_ECG (bpm)		ST-I (ms)
Hour0	0 mg/kg	(3)	152.97 ± 8.30	(3)	394.53 ±21.211	(3)	75.998 ± 8.315
	0.3 mg/kg	(3)	171.41 ± 9.95	(3)	352.35 ±19.877	(3)	86.873 ± 6.523
	1 mg/kg	(3)	171.86 ± 5.50	(3)	349.81 ±10.856	(3)	83.351 ± 1.603
	3 mg/kg	(3)	256.51 ±30.82	(3)	240.34 ±26.885	(3)	94.064 ±15.629
Hour1	0 mg/kg	(3)	171.10 ± 7.98	(3)	352.15 ±15.930	(3)	82.352 ± 7.490
	0.3 mg/kg	(3)	195.44 ±11.74	(3)	309.36 ±19.686	(3)	100.577 ± 5.473
	1 mg/kg	(3)	206.20 ±15.60	(3)	294.38 ±22.531	(3)	94.872 ± 2.528
	3 mg/kg	(3)	236.84 ±21.20	(3)	257.87 ±25.339	(3)	100.342 ±15.532
Hour2	0 mg/kg	(3)	185.18 ± 6.62	(3)	324.83 ±11.665	(3)	88.712 ± 7.671
	0.3 mg/kg	(3)	194.58 ± 8.37	(3)	309.52 ±13.477	(3)	99.194 ± 2.935
	1 mg/kg	(3)	197.02 ±11.08	(3)	306.44 ±16.984	(3)	103.084 ± 6.070
	3 mg/kg	(3)	219.21 ±16.72	(3)	277.19 ±22.885	(3)	95.211 ±15.280
Hour3	0 mg/kg	(3)	210.53 ±20.56	(3)	290.05 ±25.909	(3)	90.784 ± 5.439
	0.3 mg/kg	(3)	198.31 ± 6.80	(3)	303.27 ±10.483	(3)	101.722 ± 1.372
	1 mg/kg	(3)	218.10 ±11.59	(3)	276.72 ±15.236	(3)	104.543 ± 5.895
	3 mg/kg	(3)	221.44 ±18.64	(3)	275.22 ±25.282	(3)	93.247 ±13.326
Hour4	0 mg/kg	(3)	192.84 ±10.75	(3)	313.14 ±17.997	(3)	88.637 ± 4.265
	0.3 mg/kg	(3)	197.96 ± 6.59	(3)	303.79 ±10.447	(3)	102.253 ± 2.222
	1 mg/kg	(3)	198.52 ± 9.41	(3)	303.56 ±13.874	(3)	103.262 ± 6.409
	3 mg/kg	(3)	230.23 ±24.16	(3)	267.07 ±30.790	(3)	86.900 ± 9.758
Hour5	0 mg/kg	(3)	209.02 ±21.35	(3)	292.71 ±27.787	(3)	91.169 ± 5.785
	0.3 mg/kg	(3)	200.81 ± 5.67	(3)	299.27 ± 8.677	(3)	103.953 ± 1.751
	1 mg/kg	(3)	204.01 ± 6.50	(3)	294.69 ± 9.325	(3)	103.828 ± 5.813
	3 mg/kg	(3)	229.87 ±26.42	(3)	267.92 ±30.253	(3)	93.083 ±15.647
Hour6	0 mg/kg	(3)	189.73 ± 4.45	(3)	316.59 ± 7.551	(3)	91.296 ± 3.875
	0.3 mg/kg	(3)	197.26 ± 9.80	(3)	305.75 ±15.904	(3)	98.614 ± 1.774
	1 mg/kg	(3)	194.35 ± 7.69	(3)	309.71 ±12.543	(3)	99.307 ± 3.170
	3 mg/kg	(3)	228.88 ±28.70	(3)	269.72 ±30.195	(3)	94.347 ±12.350
Hour7	0 mg/kg	(3)	184.22 ±16.52	(3)	330.75 ±28.204	(3)	87.162 ± 6.955
	0.3 mg/kg	(3)	203.11 ±21.03	(3)	301.74 ±30.713	(3)	96.356 ± 2.965
	1 mg/kg	(3)	186.95 ± 8.98	(3)	322.47 ±15.922	(3)	95.925 ± 2.925
	3 mg/kg	(3)	223.60 ±22.42	(3)	273.33 ±24.903	(3)	91.958 ±13.626
Hour8	0 mg/kg	(3)	195.64 ±20.01	(3)	312.64 ±29.070	(3)	86.547 ± 5.149
	0.3 mg/kg	(3)	184.15 ± 8.94	(3)	327.37 ±16.020	(3)	93.296 ± 1.828
	1 mg/kg	(3)	183.75 ± 6.00	(3)	327.22 ±10.587	(3)	92.807 ± 1.169
	3 mg/kg	(3)	224.43 ±18.82	(3)	270.87 ±20.990	(3)	92.932 ±14.596

DSI Reporting software was designed exclusively for DSI by Integrated Nonclinical Development Solutions, Inc.



Integrated Nonclinical Development Solutions, Inc.
3005 Miller Road
Ann Arbor, MI 48103

Product Issue Report

Product Issue Report Form

Sales Person:	Issue:
Customer Name:	
Company:	
Address:	
Phone Number:	
Email Address:	
Ponemah Version (including Service Pack):	
Serial Number:	
Priority:	
Date:	
Hardware:	Steps to Repeat
Status of issue (check one)	
<input type="checkbox"/> Unreproduced <input type="checkbox"/> Reproduced	
<input type="checkbox"/> Needs repair <input type="checkbox"/> As intended	
Computer hardware/software	
Brand/Model:	
CPU Speed:	
RAM:	
Operating System (including Service Pack):	
Networked	
<input type="checkbox"/> Yes <input type="checkbox"/> No	

Feature Request

Feature Request Form

Sales Person:

Customer Name:

Company:

Address:

Phone Number:

Email Address:

Ponemah Version (including Service Pack):

Serial Number:

Priority:

Date:

Hardware:

Feature (check one)

☐ Unevaluated

☐ Pending

☐ Implement

☐ Already Exists

Description: