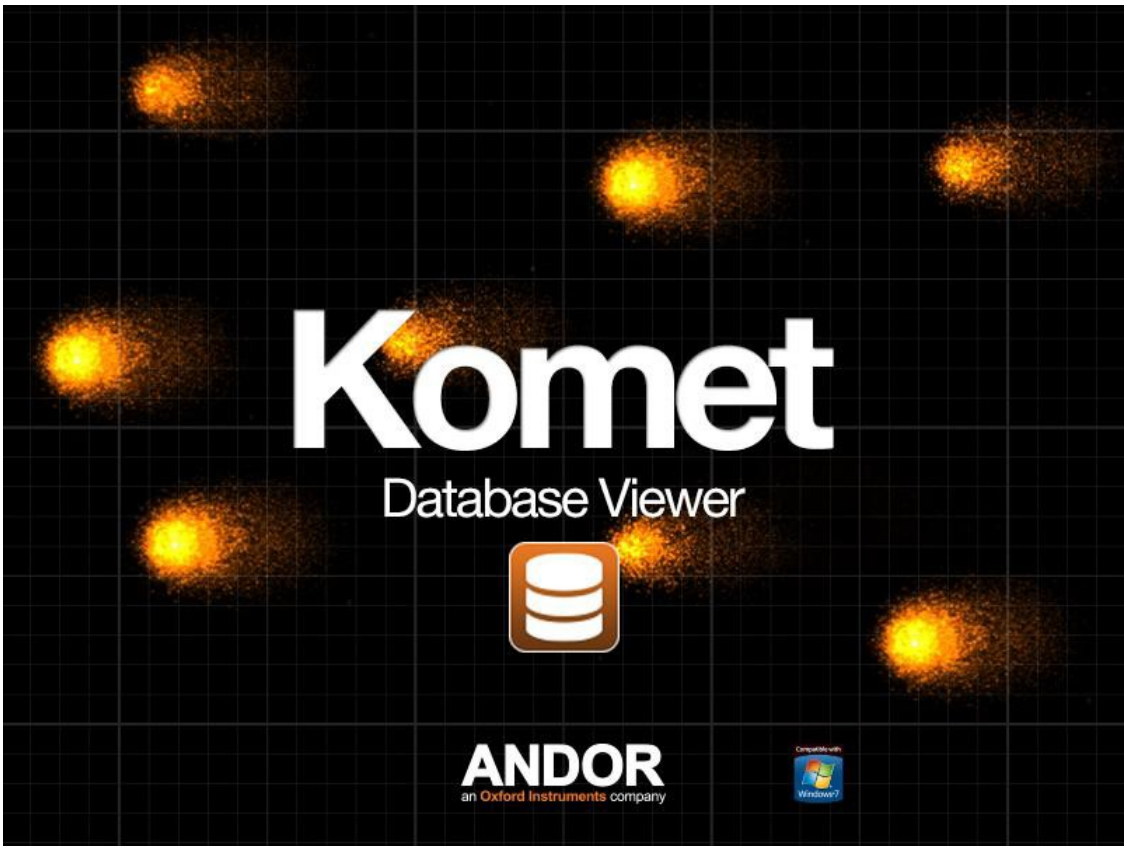
ANDOR
an Oxford Instruments company

Database Viewer

version 2.0.4 rev 27 November 2014



Software Guide

Table of Contents

Contact Information: www.andor.com/contact_us/support_request

This version updated for Database Viewer 2.0.4, revised 27 Nov 2014

SECTION 1: THE DATABASE VIEWER

1.1 Introduction

The Database Viewer (DBV) is supplied with certain products, including Komet® and Komet®GLP. This software saves data in two formats:

- Tab-delimited format, which can be read by standard spreadsheet programs such as Microsoft Excel. Excel macros are provided to ease the analysis and presentation of this data.
- A Database format, which includes images and data. The Database Viewer is the means to view, analyse and present data from these files. For GLP operation Study and Scoring audit trails can also be viewed.

The DBV is supplied via download from **my.andor.com** or on a separate installation CD and is installed as described in Appendix 1. The DBV is opened from the Kinetic Program Group and provides the following functions:

- Load and View Datasets containing images and data from a group of specimens.
- Datasets usually contain all the data from an exposure group.
- View audit trails on data, scoring sessions, study information and QC.
- Present data for comparison in graphical forms including Histograms and Response Charts.
- Decode Slide or specimen IDs into Dose or Exposure groups to support blind scoring.
- Present Data Summaries compatible with international guidelines for statistical analysis.
- Create Image Galleries to present the comets from complete or a subset of the Dataset.
- Create a stand-alone CD, which includes the selected Dataset(s), DBV program and all necessary support files to run DBV on any Windows 7 PC.

Thus, DBV provides a powerful and easy means to review, present and prepare your data for statistical analysis. Further, it provides a means to distribute Study data in the form of stand- alone CDs containing Datasets and all the necessary tools for review and presentation to colleagues, Quality Assurance Personnel, sponsors and reviewers.

Database Viewer can be distributed freely, without restriction by authorized license holders of our software.

We hope you find the product both easy and powerful to use and thank you for choosing our products.

1.2 Organization of Datasets – Security, Tables and Tabs

Datasets are databases named with either an **mdb** or **kdb** extension. Mdb files are readable in Microsoft Access. You should be aware that opening a file in Access before scoring is completed will damage its electronic signature and render the file unusable for GLP work. We recommend you use ONLY the DBV for working with these files.

The Dataset contents are organized into several tables, and each table is presented on a different tab in DBV, as described in detail in section 2.1. GLP and non-GLP Datasets are both produced by Komet products depending on the mode of operation specified. The GLP Datasets will contain additional tabs for Audit Trails - information gathered during the scoring process, when the Datasets are recorded.

Datasets can be decoded and analysed to generate additional data such as Statistical Summary data. When you operate in this way DBV will create a copy of the original Dataset, to maintain the integrity of the RAW data. In the copied Dataset it will add new tables, visible as extra tabs in DBV. These will contain additional information about the Decode and/or Data Summary actions and results.

1.3 Terminology

In the following descriptions of the DBV Software, we use some terms to explain functions in the software which may have specific meaning. We use these terms to exemplify, not to

limit the application of the product. These terms include:

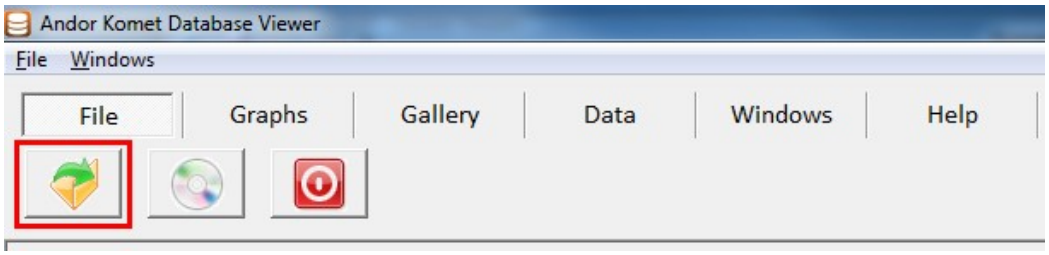
- Dose and Dose Groups which can equally refer to Exposure and Exposure Groups.
- Database and Dataset are used to refer to a collection of data organized in tables readable by the DBV.

SECTION 2: VIEWING DATASETS

DBV enables datasets (GLP and Research formats) to be viewed for analysis and auditing purposes.

2.1 Opening Datasets

Click the **Open Database** button on the **File** tab:



Or from the File Menu select **File** then select **Open Database** (**Section 2.2.1**), this will display a file open dialogue box where the user can navigate to the appropriate folder and select a Dataset to open.

Figure 2.1.1 Opening a Database

The user will then be prompted to enter the password for the Dataset.

Figure 2.1.2 Enter Password

The Dataset is then presented as shown in Figure 2.1.3. The Database Window has four tabs in the GLP version. These are Data, Data Audit, Session Record and System Audit. In the

Non-GLP version, all of these tabs will not be present. Additional tabs for Decode and Summary are added to the Decoded Dataset once they are created through the appropriate functions (**Section 2.5.2**).

2.1.1 Database Window: Data Tab

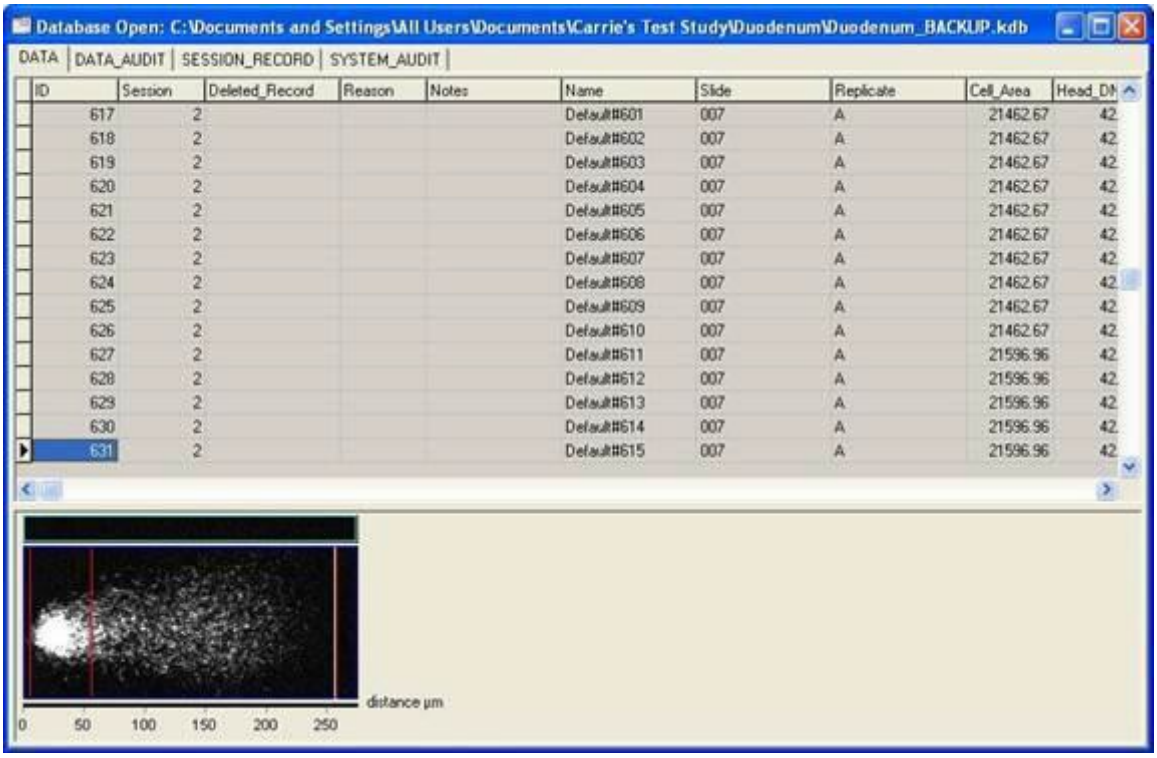


Figure 2.1.3 The Database Window Data Tab

The upper pane of the Data Tab displays the data obtained from your experiment. Each row of data displays the ID of the image from which data was obtained, the Slide ID and all the values for each analysis parameter.

When you click on a row of data, the image from which the data was obtained is displayed in the lower pane along with a calibrated ruler to show comet lengths.

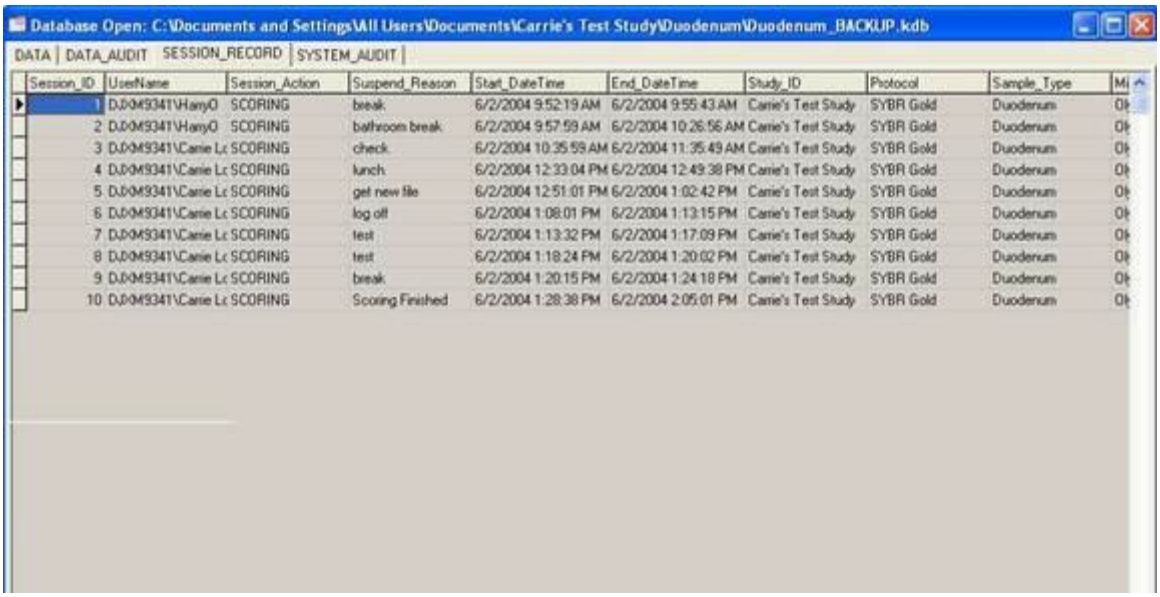
2.1.2 Database Window: Data Audit Tab

Cell_ID	Data_ID	Action	Reason
50	1	Edit Slide and Replicate ID	From '001_A' to '001_A'
53	2	Delete Cell	Debris in background
151	3	Edit Slide and Replicate ID	From '002_A' to '002_A'
195	4	Delete Cell	Scored same cell twice in error
199	5	Delete Cell	Debris in background
203	6	Delete Cell	Scored same cell twice in error
204	7	Edit Slide and Replicate ID	From '002_B' to '002_B'
226	8	Delete Cell	Scored same cell twice in error
255	9	Delete Cell	Scored same cell twice in error
256	10	Edit Slide and Replicate ID	From '003_A' to '003_A'
349	11	Delete Cell	Scored same cell twice in error
352	12	Delete Cell	Debris in background
357	13	Delete Cell	Test
357	14	Delete Cell	Test
358	15	Delete Cell	Debris in background
361	16	Edit Slide and Replicate ID	From '004_A' to '004_A'
397	17	Delete Cell	Debris in background
412	18	Edit Slide and Replicate ID	From '004_B' to '004_B'
512	19	Edit Slide and Replicate ID	From '005_B' to '005_B'
562	20	Delete Cell	Scored same cell twice in error
563	21	Edit Slide and Replicate ID	From '006_A' to '006_A'
587	22	Delete Cell	Scored same cell twice in error
614	23	Delete Cell	Debris in background
615	24	Edit Slide and Replicate ID	From '006_B' to '006_B'
685	25	Delete Cell	Scored same cell twice in error

Figure 2.1.4 The Database Window Data Audit Tab

The Data Audit Tab (Figure 2.1.4) provides a record of operator actions during the scoring process. The Cell ID, Data ID, Action, and reasons are listed for any changes made throughout the study.

2.1.3 Database Window:Session Record Tab



Session_ID	UserName	Session_Action	Suspend_Reason	Start_DateTime	End_DateTime	Study_ID	Protocol	Sample_Type	Mi
1	DJ0M9341\HarryO	SCORING	break	6/2/2004 9:52:19 AM	6/2/2004 9:55:43 AM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
2	DJ0M9341\HarryO	SCORING	bathroom break	6/2/2004 9:57:59 AM	6/2/2004 10:26:56 AM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
3	DJ0M9341\Carrie Lc	SCORING	check	6/2/2004 10:35:59 AM	6/2/2004 11:35:49 AM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
4	DJ0M9341\Carrie Lc	SCORING	lunch	6/2/2004 12:33:04 PM	6/2/2004 12:49:38 PM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
5	DJ0M9341\Carrie Lc	SCORING	get new file	6/2/2004 12:51:01 PM	6/2/2004 1:02:42 PM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
6	DJ0M9341\Carrie Lc	SCORING	log off	6/2/2004 1:08:01 PM	6/2/2004 1:13:15 PM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
7	DJ0M9341\Carrie Lc	SCORING	test	6/2/2004 1:13:32 PM	6/2/2004 1:17:09 PM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
8	DJ0M9341\Carrie Lc	SCORING	test	6/2/2004 1:18:24 PM	6/2/2004 1:20:02 PM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
9	DJ0M9341\Carrie Lc	SCORING	break	6/2/2004 1:20:15 PM	6/2/2004 1:24:18 PM	Carrie's Test Study	SYBR Gold	Duodenum	Ob
10	DJ0M9341\Carrie Lc	SCORING	Scoring Finished	6/2/2004 1:28:38 PM	6/2/2004 2:05:01 PM	Carrie's Test Study	SYBR Gold	Duodenum	Ob

Figure 2.1.5 The Database Window Session Record

The Session Record Tab (Figure 2.1.5) provides information on all of the scoring sessions. The user name corresponding to each scoring session, the session action, the reason for suspending the scoring session, start and end dates, times, Slide IDs and Scoring Protocol are presented.

2.1.4 Database Window: System Audit Tab

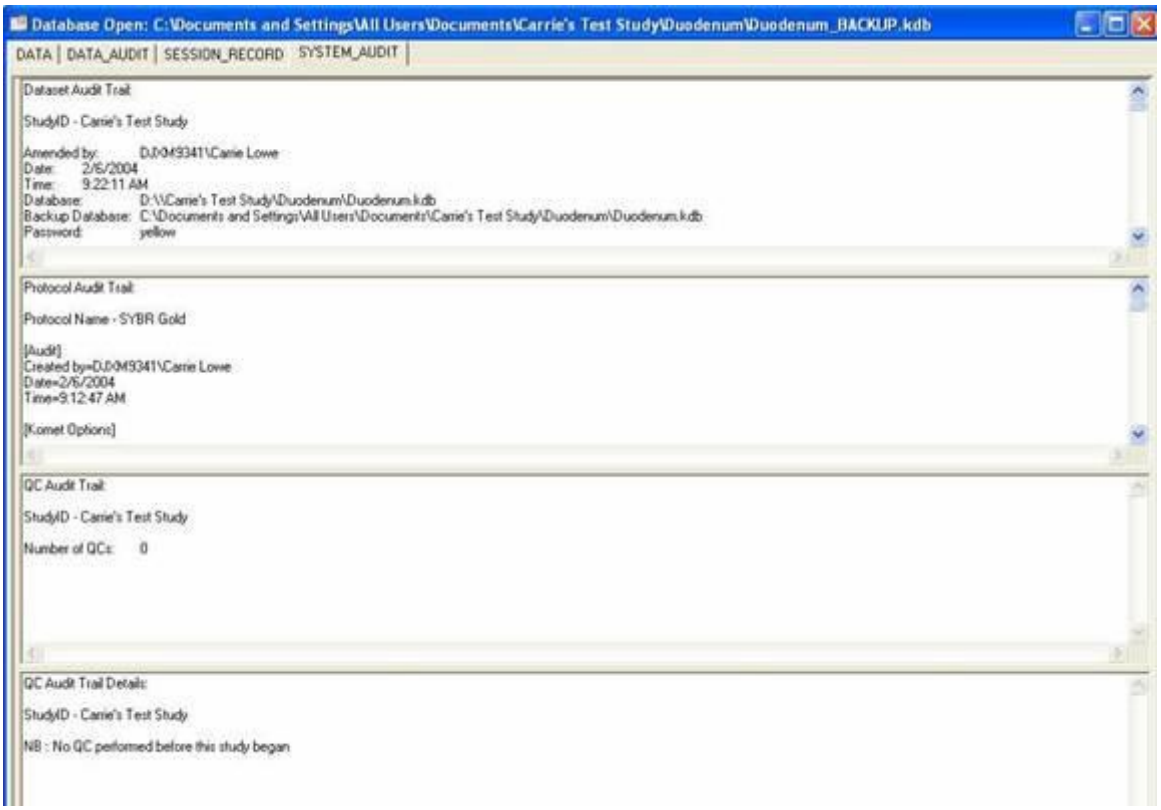


Figure 2.1.6 The Database Window System Audit Tab

The system Audit Tab provides information for all tracked changes made to the Datasets and Protocols (Figure 2.1.6). It also provides information relevant to the QC Audit Trail and the QC Audit Details.

2.1.5 Database Window: Decode Tab

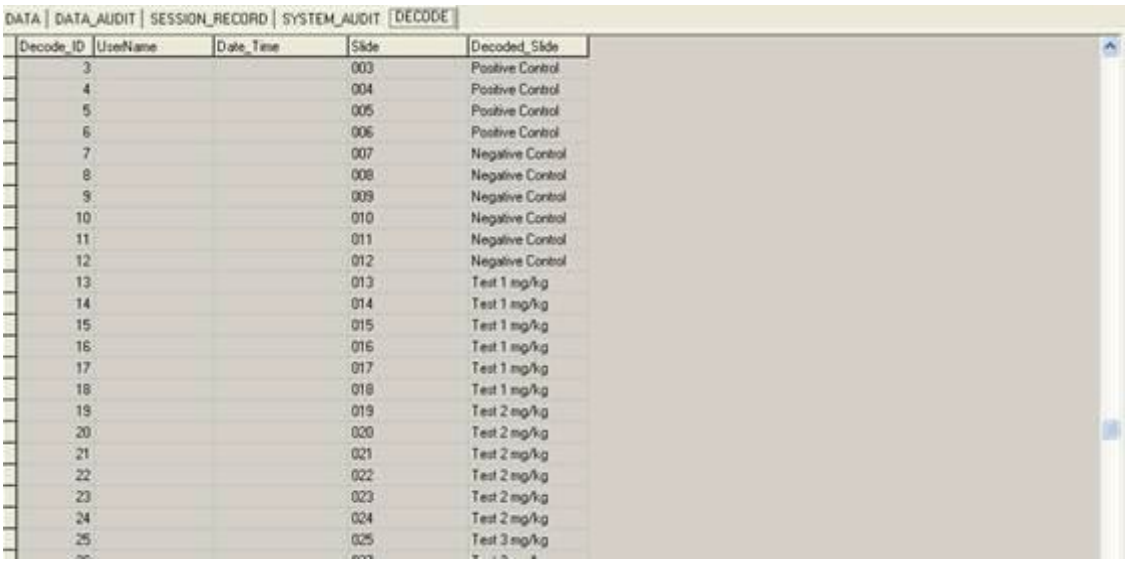


Figure 2.1.7 The Database Window Decode Tab

The Decode Tab is added to the Dataset window once a decode is performed as shown in Figure 2.1.7. However, this tab only appears in the new dataset created by the decode operation. The new dataset name is derived from the original as follows:

Original Name **Decoded Name**

Duodenum_RAW.kdb → Duodenum_RAW_DECODED.kdb

This tab provides all information relating to the decoded dataset. For information on how to decode a database (dataset) see **Section 2.5.2**.

2.1.6 Database Window: Summary Tab

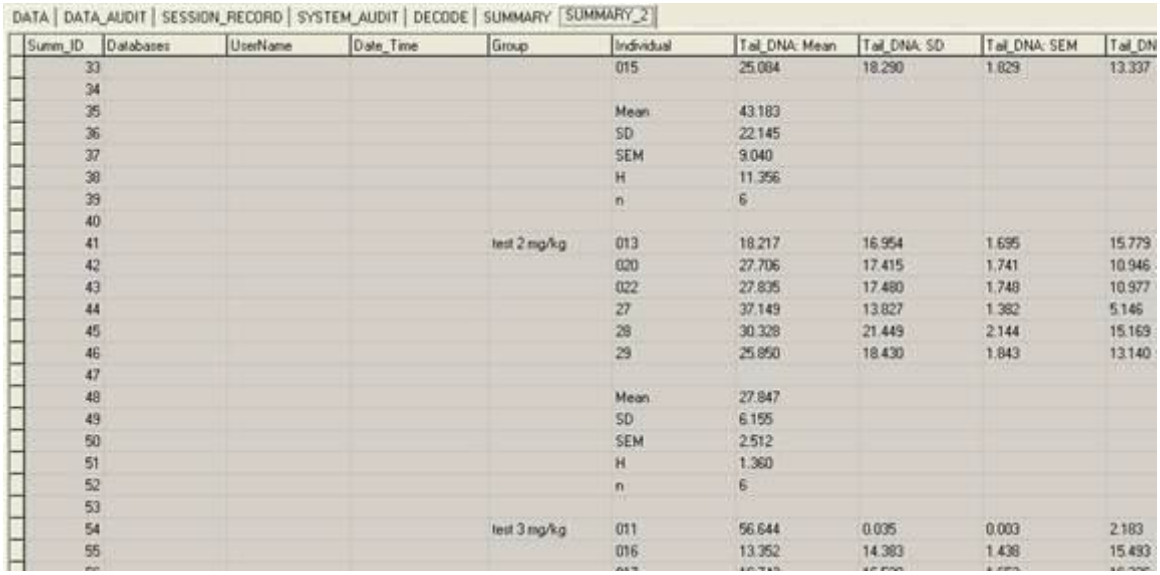
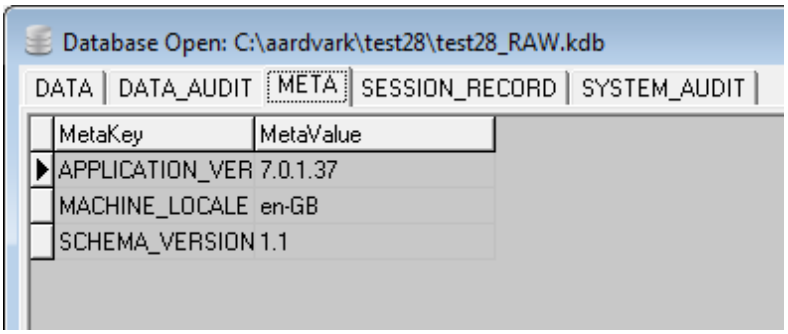


Figure 2.1.8 The Database Window Summary Tab

The Summary Tab is added to the Database window after a summary is performed. This Tab is only visible in the new dataset created through the decode operation as described in the previous section. Additional summaries can be performed and are subsequently added to the Database window as shown in Figure 2.1.8. For more information on how to create a Summary Table see **Section 2.5.1**.

2.1.7 Database Window: META Tab

This has no experiment data but contains Komet application information that is useful for technical support.



2.2 DBV Menu: File

When the DBV application is running, the relevant menus will be active. Their exact content depends on which window has focus. When a Dataset Window has focus or no Dataset is open, the menu items shown in Figure 2.2.1 are available. When other types of window such as the Gallery and Chart windows have focus the menu items on view will change (**Sections 2.4.2** and **2.8**).

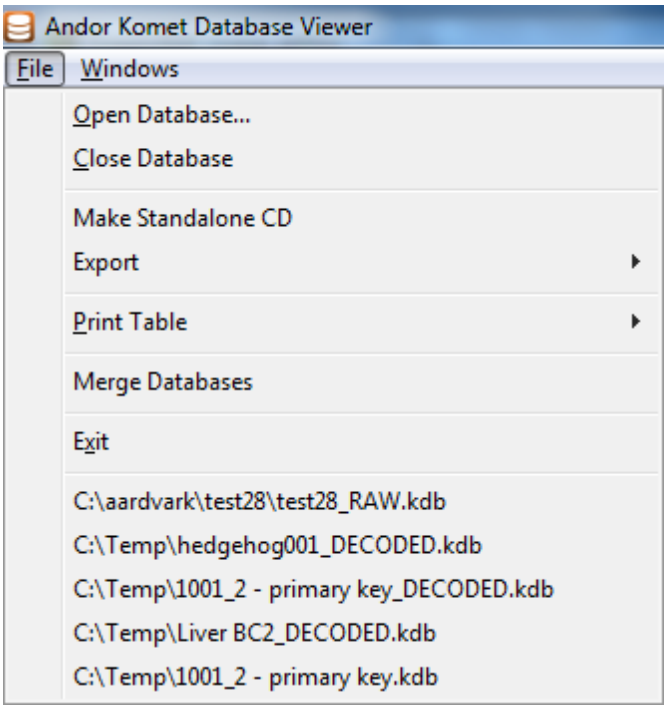


Figure 2.2.1 The File Menu

2.2.1 File: Open Database

Selecting Open Database displays a standard Window's Load File dialogue, from which you should select the Dataset to open. You can open multiple Datasets and manage or compare their contents. The Datasets will be presented as explained in Section 2.1.

2.2.2 File: Close Database

Selecting Close Database closes the currently selected Dataset.

2.2.3 File: Make Standalone CD

Selecting Make Standalone CD from the file menu will open a dialogue box allowing the user to select the location to copy the files (Figure 2.2.2). Once a location is selected, the database and DBV files are copied to the selected location (i.e. CD) that can be opened on any Windows 7 computer.

Note: If a CRW drive is selected, a formatted CD is required. CRW formatting instructions are dependent on the software being used.

Figure 2.2.2 Select Drive for Standalone CD

2.2.4 File: Export

The Export feature enables the user to export Database File (*.kdb) to MS Access (*.mdb) file (Figure 2.2.3). Support for other database platforms may be added in future.

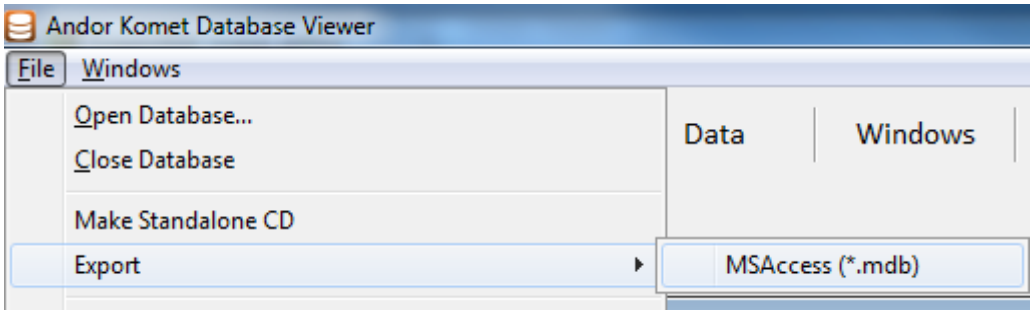


Figure 2.2.3 File Export

2.2.5 File: Print Table

Selecting Print Table from the file menu allows the user to print tables from the currently selected Dataset. All Tabs in the selected Dataset will be listed as shown in Figure 2.2.4. Select the Tab you wish to print and a standard print dialogue box will open allowing for printer selection and properties.

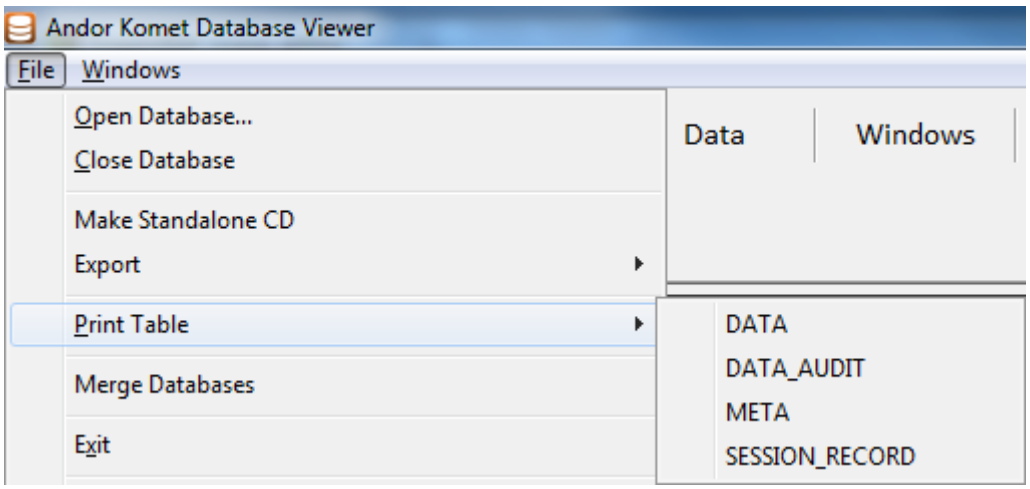


Figure 2.2.4 Print Table

2.2.6 File: Merge Databases

Selecting Merge Databases from the file menu enables user to merge several open Datasets into a new Dataset. Select the open Datasets to merge by clicking on the dataset(s) or by using the **Select All** or **Deselect All** buttons. Selected Datasets will have their checkboxes labelled with a tick. You can change the order of the Datasets by using the **Move Up** and **Move Down** buttons.

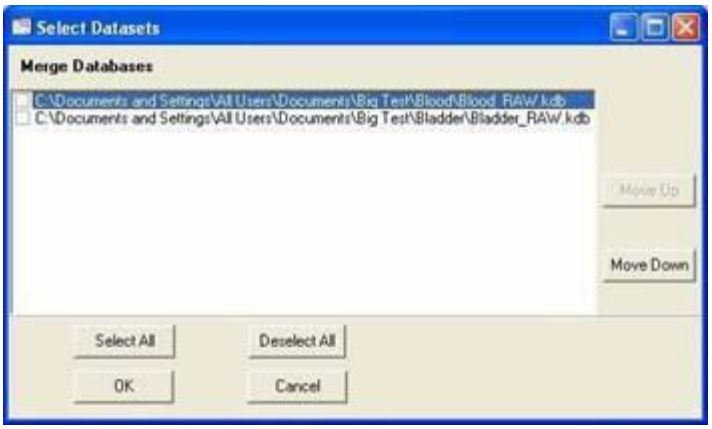


Figure 2.2.5 Select Datasets to Merge

Press **OK** to continue.

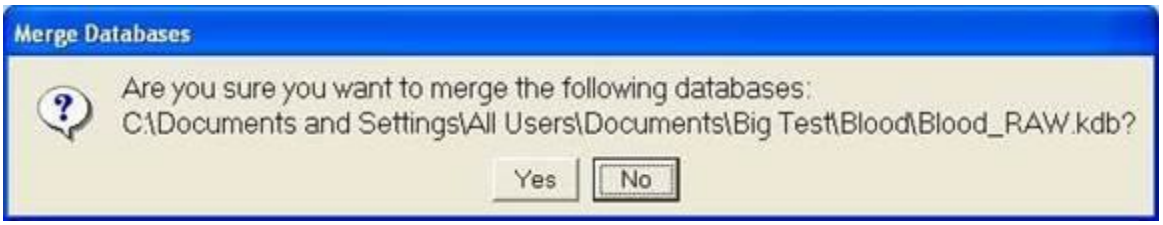


Figure 2.2.6 Merge Databases Message

You will then be prompted as seen in Figure 2.2.6. Selecting **No** will exit the process. Selecting **Yes** will merge the databases and open a Save As dialogue box (Figure 2.2.7) allowing you to name the new file.

Figure 2.2.7 Save As

2.2.7 File: Exit

Selecting Exit will close all open Datasets and exit the DBV application.

2.2.8 File: Recent File List

This feature shows the 5 most recently opened Datasets at the bottom of the menu as shown in Figure 2.2.8. Click on a file to reopen the Dataset.

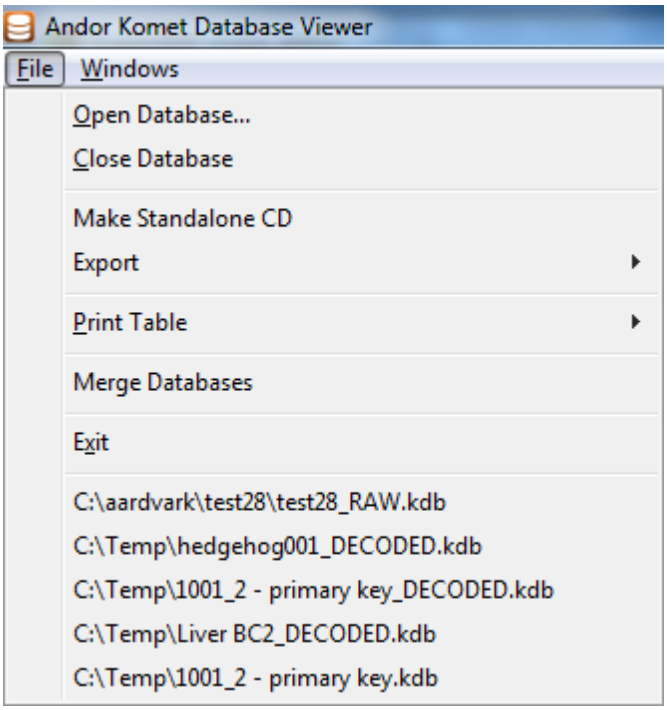


Figure 2.2.8 Recent File List

2.3 DBV Tab: Graphs

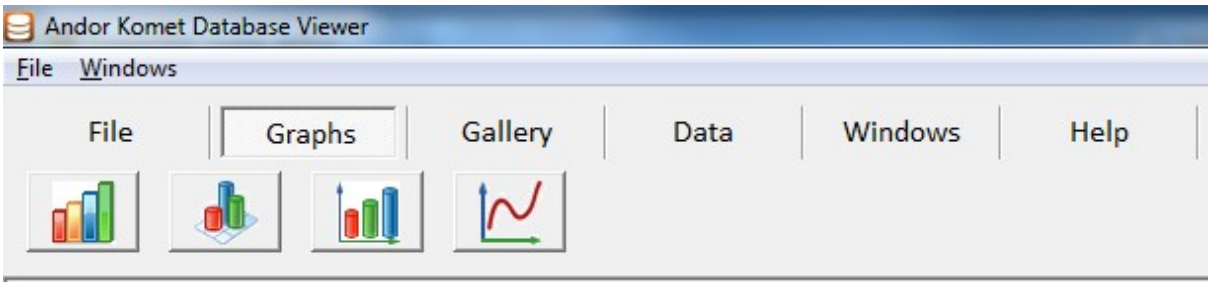


Figure 2.3.1 Graphs Tab

From the **Graphs** tab, you can select a method to present the data in a graphical form.

Note - When a Chart Window has focus, different menus are available (see **Section 2.3.5**).

2.3.1 Graphs: Histogram

Figure 2.3.2 Histogram Dose Group Selection

When a Dataset is open and selected, clicking on **Histogram** from the **Graphs** menu displays a dialogue box (Figure 2.3.2) which allows selection of the Specimens or Dose groups for which you wish to see a histogram plot.

The **Select All** and **Deselect All** buttons can also be used. When you press **OK** a histogram window will open for each selected dose.

The Histogram dialogue box shown in Figure 2.3.3 has many controls to format the histogram presentation to your needs.

From the dropdown list shown in Figure 2.3.3, select the parameter for which you want to display a histogram. All analysis parameters can be selected for review in the histogram.

Range Minimum and Maximum Settings

The **Min** and **Max** values are displayed on the left of the dialogue box (Figure 2.3.3) these are the minimum and maximum values calculated from all the cells scored in that specimen or group.

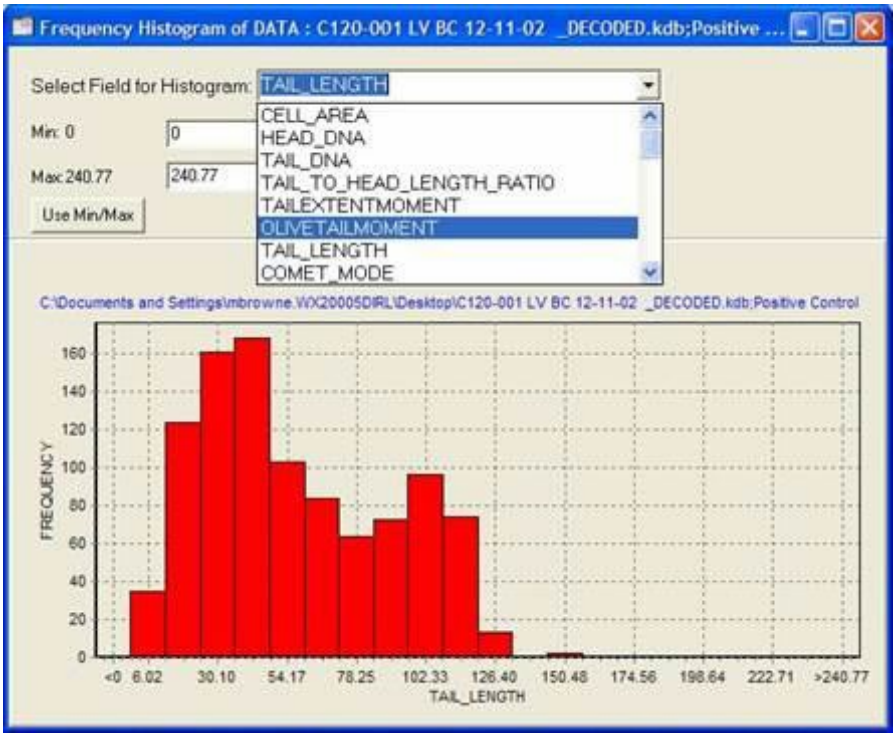


Figure 2.3.3 Histogram

The text boxes are used to enter the minimum and maximum values for the bins to display on the Histogram. You can restore the computed **Min** and **Max** values from the current sample at any time by pressing the **Use Min/Max** button.

Set Defaults

You can also set up Default Minimum and Maximum values for the histogram bins. To do this, enter the desired values into the Minimum and Maximum text boxes and press the **Set Default** button. You can then select these values at any time by pressing the **Use Defaults** button. This allows you to fix settings for standardized reporting of data with different ranges i.e. most real data.

Number of Bins

Enter the **Number of bins** - the x-axis will be split into a number of divisions equal to the value specified here. (Note that there will be two additional bins, one containing all valuesbelow the minimum bin and the other with data above the maximum. These register any data that lies outside of the specified minimum and maximum values).

Show as Percentage

When selected, the data will be displayed as a percentage of the number of cells rather than displaying the actual frequency of data. This presentation is useful for standardizing the presentation of data from specimens in which a different number of cells or fields was scored.

2.3.2 Graphs: 3D Histogram

Selecting **3D Histogram** from the **Graphs** tab opens a dialogue box which is used to create a 3D presentation. This allows you to open multiple Datasets, which is useful for data comparison. The first dialogue box will appear as shown in Figure 2.3.4. Click in the checkboxes to select the datasets to include in the histogram or use the **Select All** and **Deselect All** buttons.

You can change the order that the datasets will be displayed in the histogram using the **Move Up** and **Move Down** buttons.

Press **OK** to continue.

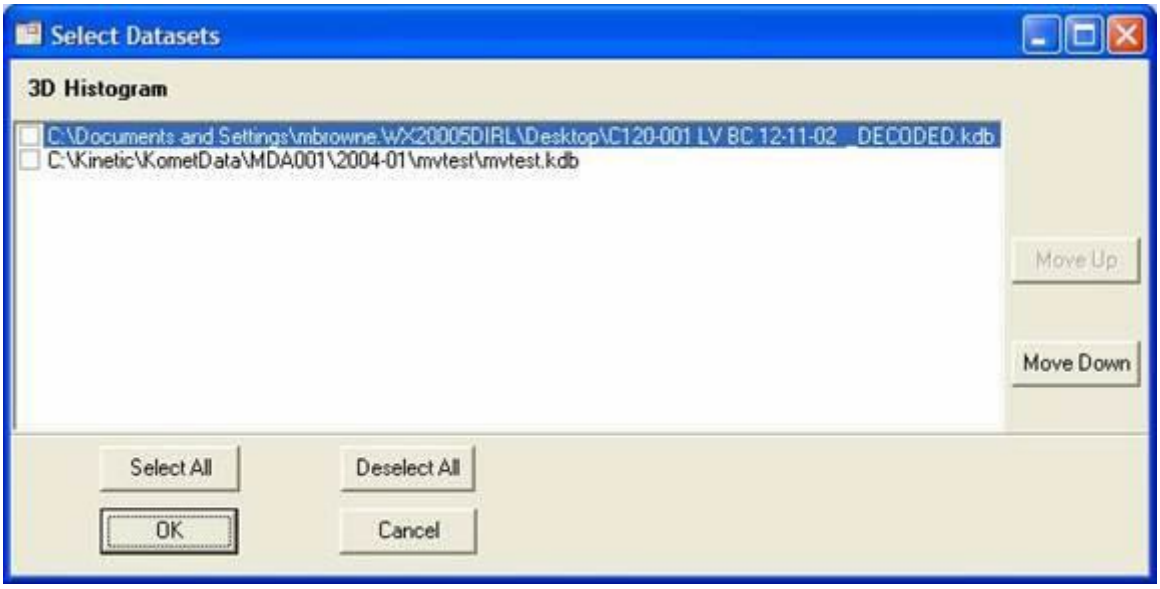


Figure 2.3.4 Select Dataset(s) for 3D Histogram

A dialogue box will then open for each selected Dataset and list the available doses in that dataset. You can change the order of the doses as above or use the **Select All** and **Deselect All** buttons. Selected Datasets will have their checkboxes labelled with a tick.

Select the doses to include in the histogram (Figure 2.3.5) and press **OK** to continue.

Figure 2.3.5 3D Histogram Dose Group Selection

After selecting the doses from the final dataset, the histogram will be displayed (Figure 2.3.6).

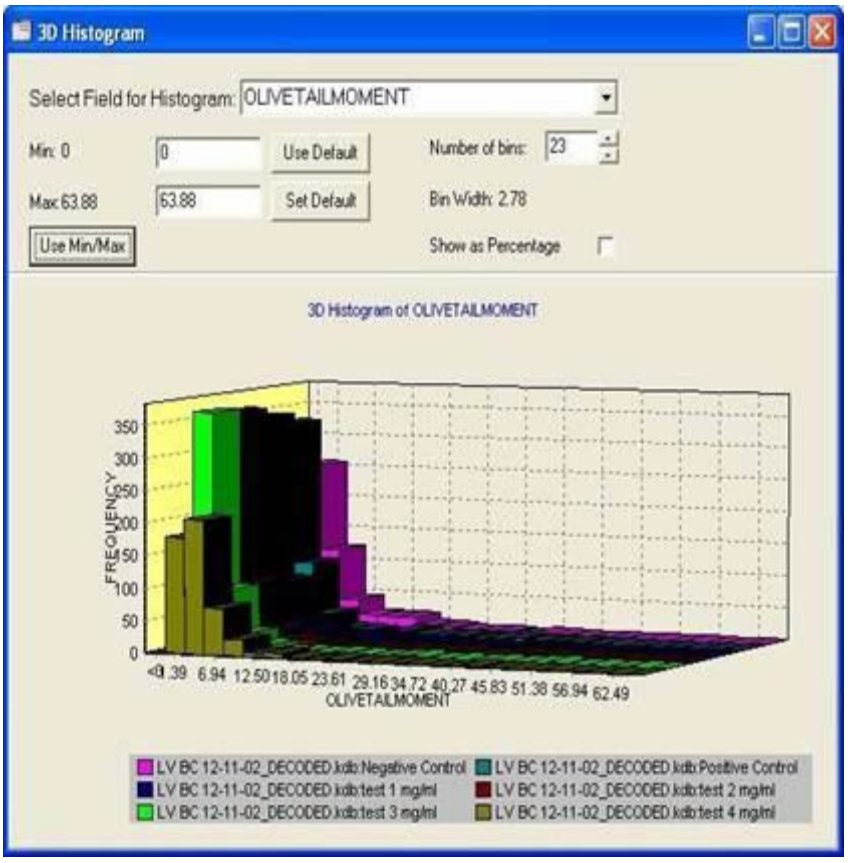


Figure 2.3.6 3D Histogram

From the dropdown list, select the parameter for which you want to display a histogram. The **Min** and **Max** values are displayed on the left of the dialogue - these are the minimum and maximum values calculated from all the comet cells scored in the selected doses.

Set Defaults

You can also set up Default Minimum and Maximum values for the histogram bins. To do this, enter the desired values into the Minimum and Maximum text boxes and press the **Set Default** button. You can then select these values at any time by pressing the **Use Defaults** button. This allows you to fix settings for standardized reporting of data with different ranges i.e. most real data.

Number of Bins

Enter the **Number of bins** - the x-axis will be split into a number of divisions equal to the value specified here. (Note that there will be two additional bins, one containing all values below the minimum bin and the other with data above the maximum. These register any data that lies outside of the specified minimum and maximum values).

Show as Percentage

When selected, the data will be displayed as a percentage of the number of cells rather than displaying the actual frequency of data. This presentation is useful for standardizing the presentation of data from specimens in which a different number of cells or fields was scored.

3D View Angles

You can change the 3D view angle by holding down the left mouse button over the 3D Histogram. Move the mouse to rotate the graph to the desired position.

2.3.3 Graphs: Bar Chart

When a Dataset is open and selected, clicking on **Bar Chart** from the **Graphs** tab displays a dialogue box in which all the doses in the Dataset are listed (Figure 2.3.7). Select the doses for which you want to display a Bar Chart (selected doses have their checkboxes labelled with a tick). The **Select All** and **Deselect All** buttons can also be used.

Figure 2.3.7 Bar Chart Dose Group Selection

When you press **OK** a Bar Chart will open for each selected dose as shown in Figure 2.3.8.

From the dropdown list in Figure 2.3.8, select the parameter for which you want to display a bar chart. Values are displayed for each cell scored in that dose. If **Use record name on x axis** is selected, each set of data is labelled with its source image. If it is not selected, they are labelled according to their identifier (a number determined by the order in which they are scored during the experiment).

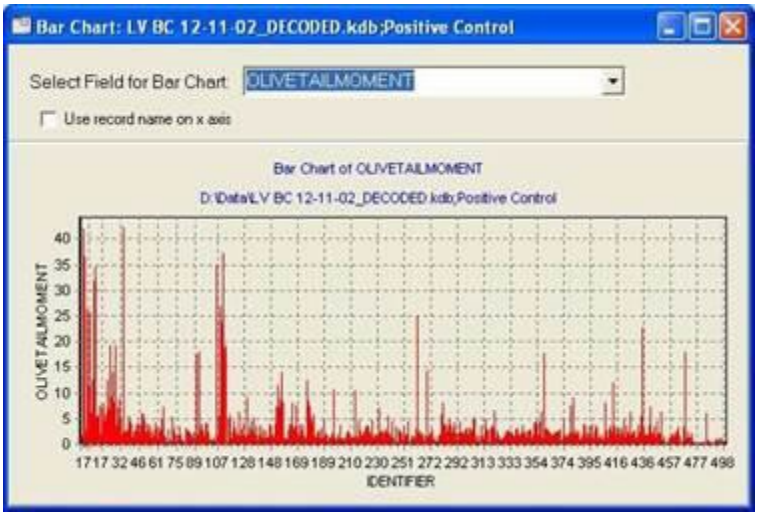


Figure 2.3.8 Bar Chart

2.3.4 Graphs: Response Curve

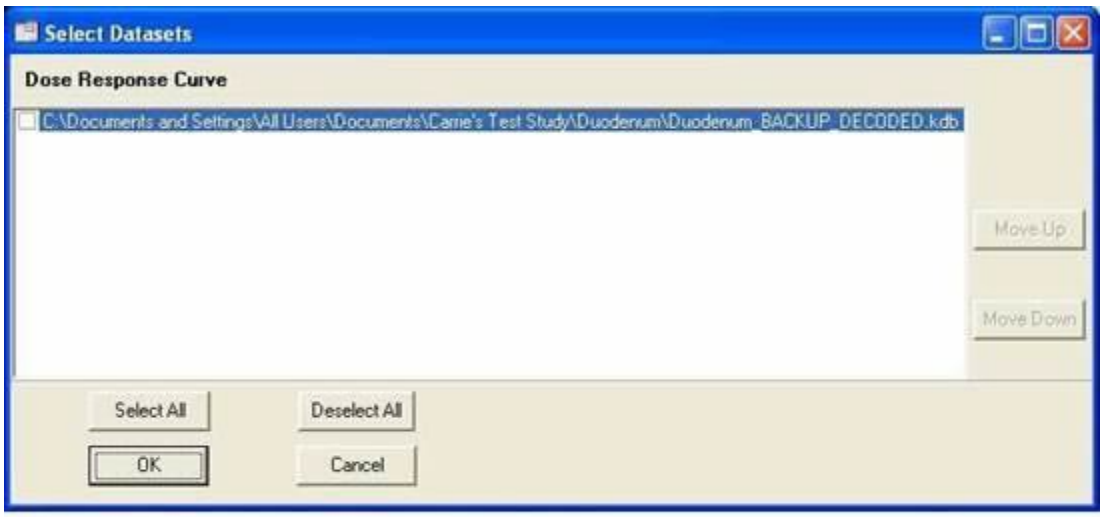


Figure 2.3.9 Select Dataset(s) for Dose Response Curve

Response Curves are used to compare data from different doses in the Experiment. If you select Response Curve from the Graphs tab, a dialogue box will list all opened Datasets (Figure 2.3.9). Click in the checkboxes to select the Datasets to include in the histogram or use the **Select All** or **Deselect All** buttons. You can change the order that the Datasets will be displayed in the curve by using the **Move Up** and **Move Down** buttons.

Press **OK** to continue.

Figure 2.3.10 Dose Selection for Response Curve

A dialogue box will then open for each selected Dataset and list the available doses in that Dataset (Figure 2.3.10.). You can change the plotting order as above. Select the doses to include in the Response Curve or use the **Select All** or **Deselect All** buttons. Press **OK** to continue.

Figure 2.3.11 Select Statistics

Select the statistics you wish to plot, selected statistics have their checkboxes labelled with a tick (Figure 2.3.11). A Response Curve will be plotted for each selected statistic. Options atthe bottom of the dialogue box allow the inclusion of error bars on the plots. When you have made your selection press **OK** to continue.

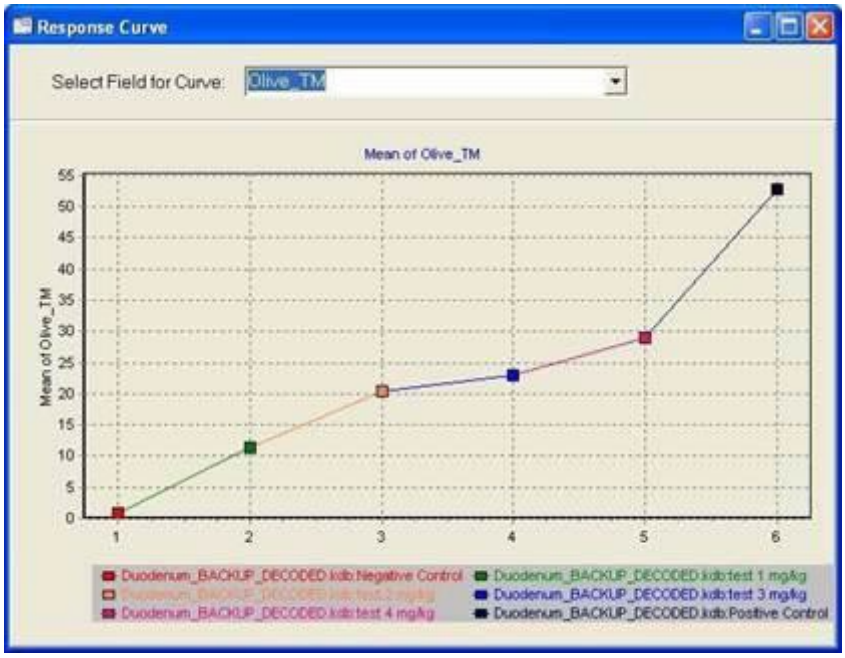


Figure 2.3.12 Dose Response Curve

From the dropdown list, select the parameter for which you want to display a Response Curve (Figure 2.3.12).

The statistic for each selected dose is represented by a point on the curve - the points are colour coordinated and a key below the curve tells you which colour corresponds to which dose.

2.3.5 Chart Menu

Different menus are available when the Histogram, 3D Histogram, Bar Chart or

Response Curve dialogue boxes are selected (Figure 2.3.13).

Figure 2.3.13 The Chart Menu Bar

Options

Defines the style of the selected chart. This includes the format, colour and position of titles and other text, and the background colour for the selected chart. The style will be remembered for the current session of the Database Viewer.

Series Colour

Allows you to select the colour in which to display the data on the selected chart.

Print

Opens the Printer Setup dialogue, from where you can print the selected chart.

Show Database

Places the Database Window on top of all other Windows.

2.4 DBV Tab: Gallery

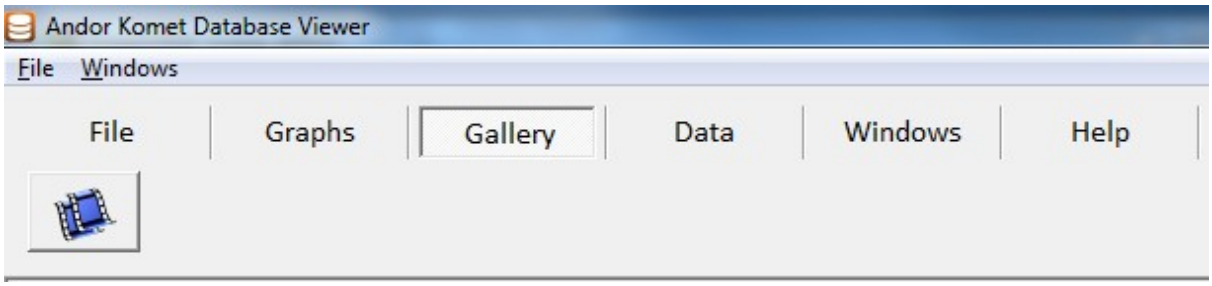


Figure 2.4.1 The Gallery Tab

2.4.1 Gallery

Selecting **Gallery** opens a dialogue box which displays messages depending on whether the dataset has been decoded or not. If the data set has not been decoded a list of all slide names will appear (Figure 2.4.2) and if the dataset has been decoded the list of dose groups will appear (Figure 2.4.3). Select the slides or dose groups to view by selecting them individually or by using the **Select All** and **Deselect All** buttons. Selected slides or groups are labelled with a tick.

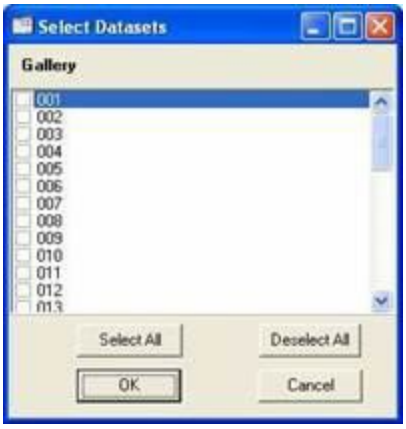


Figure 2.4.2 Gallery Slide Selection

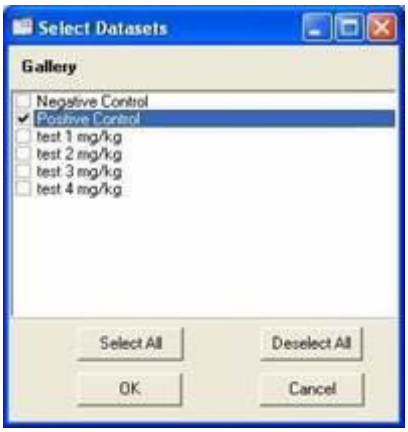


Figure 2.4.3 Gallery Dose Group Selection

Press **OK** to continue. If Datasets are large, the gallery may take a few minutes to open.

The Image Gallery shows an image of every cell scored in the selected slides or dose group(s) in the upper pane. Calipers (vertical red lines) show the start and end of the comet Head and Tail regions as analysed by Komet®. If 'Head Ellipse' is selected in Comet Options, then an ellipse will be shown delineating the Head region. Deleted Cells are also recorded in the Gallery, but to indicate their rejection from data analysis they are shown with a single diagonal Red Line indicating their status as shown in Figure 2.3.4. If Image Numbers are selected, Red numbers are shown on the individual images, indicating the data position in the current Dataset.

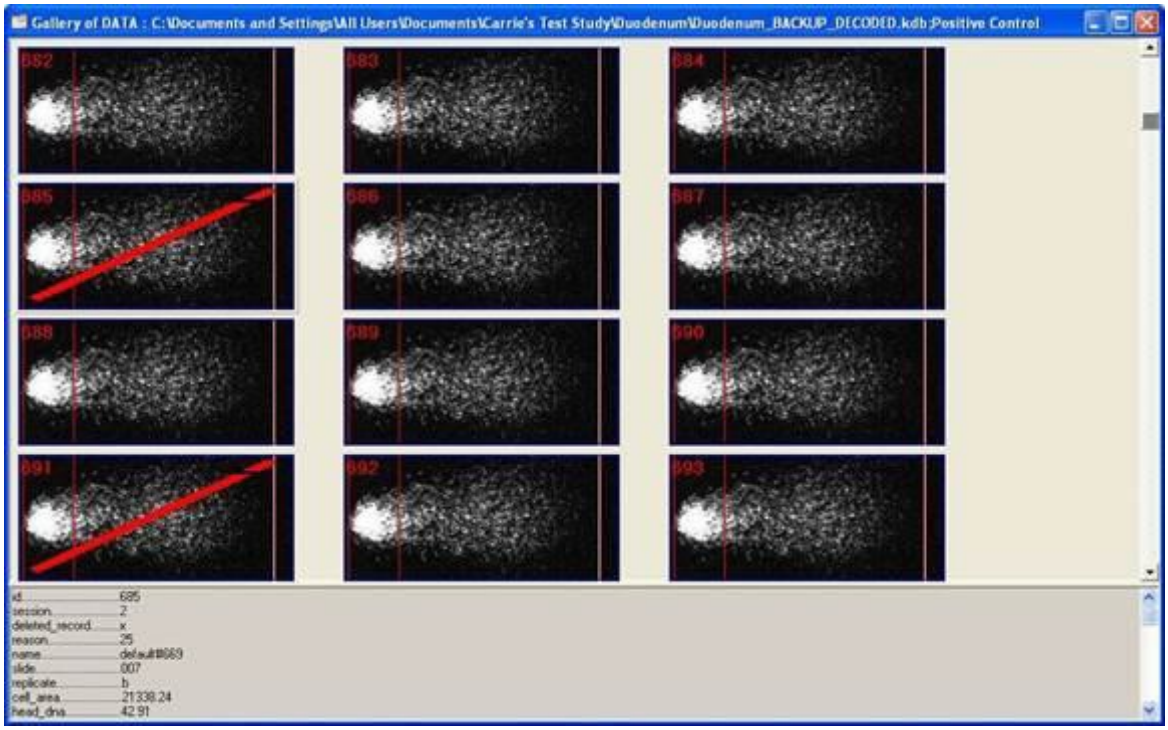


Figure 2.4.4 The Gallery Window

The lower pane shows the ID (a number determined by the order in which it was scored during the experiment), the Session in which the cell was scored, the Slide Number, Slide Replicate, and all the values for each analysis parameter. The lower pane will also show if the selected cell is a Deleted Record and if so the number referring to the Reason it was deleted as shown in Figure 2.4.4.

2.4.2 Gallery Options

When the Gallery dialogue box is open, the available menus will change.

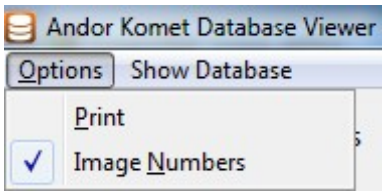


Figure 2.4.5 The Gallery Menu Options

Printing the Gallery

Selecting Print from the options menu opens the Image Print Setup dialogue box. This allows the Gallery to be printed on a user-defined number of pages by setting up the comet image density. The Number of Pages will change as the Number of Columns and Rows per page is adjusted.

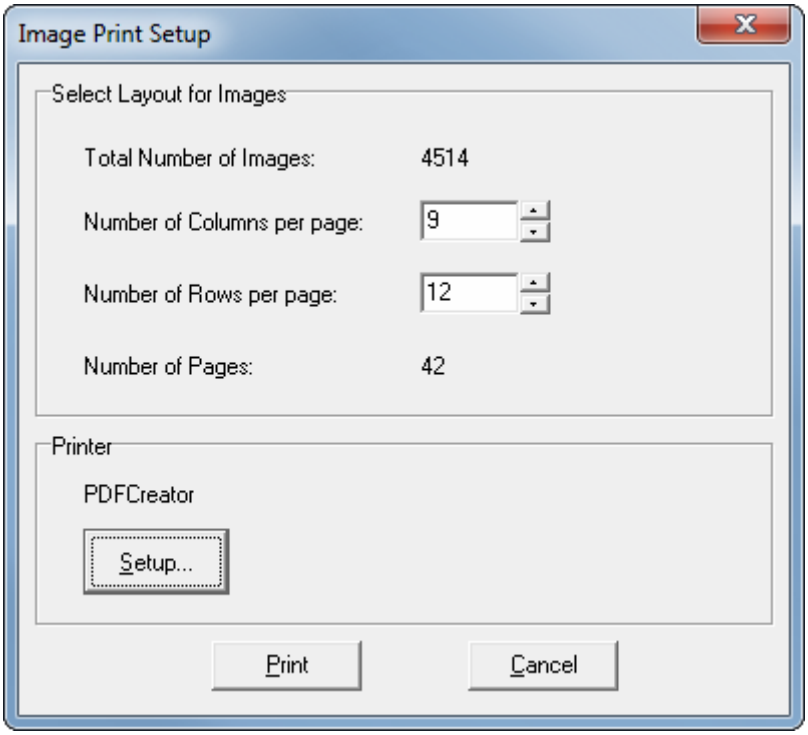
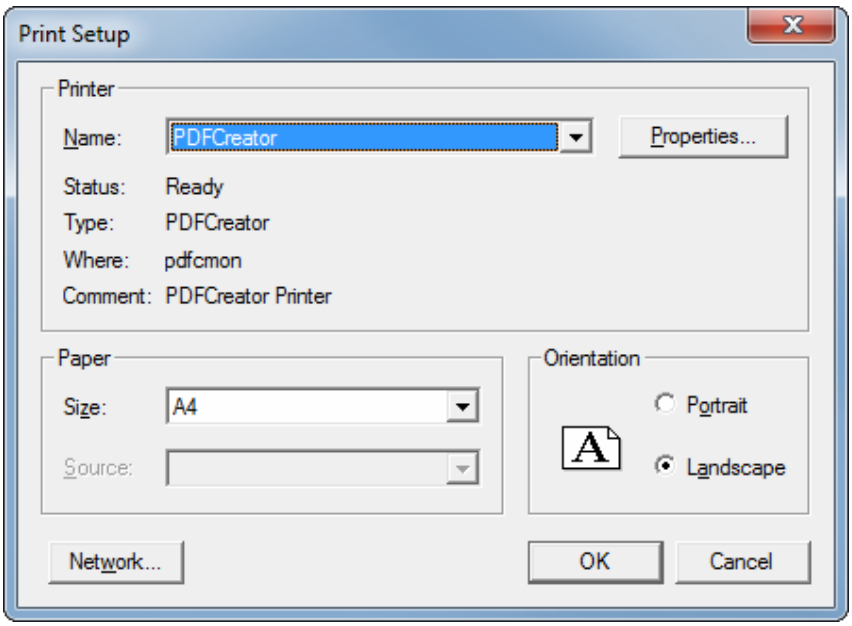


Figure 2.4.6 Image Print Setup

Clicking on **Setup**… opens the printer setup dialog



Once the printer has been setup, click OK to confirm the settings.

When the **Image Print Setup** dialog is visible, press **Print** to accept your selection and being printing.

If the assigned number of rows and columns per page is too large, an error message will be received and allow the user to re-define the parameters (Figure 2.4.7).

Figure 2.4.7Selectedparameterstoo large error message

Image Numbers

This can be toggled on and off by a mouse click. When on, the image number is displayed in the top left of each image (Figure 2.4.4). They are numbered in the order that they were opened or acquired during the scoring session.

Show Database

The Window containing the Dataset will be displayed on top of all other windows.

2.5 DBV Tab: Data

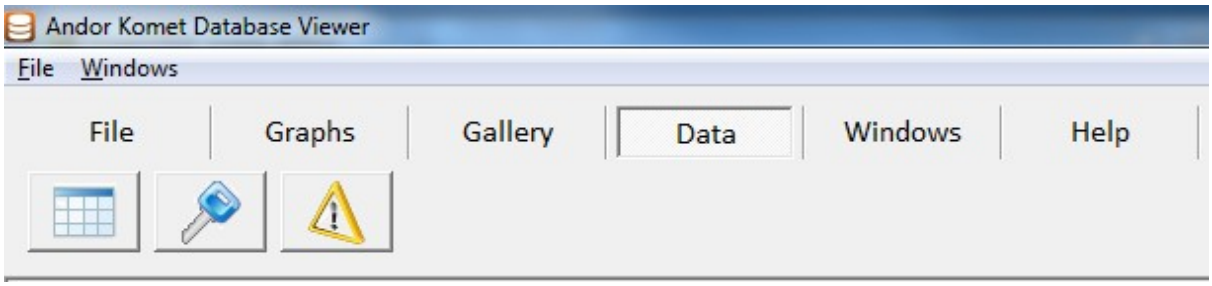


Figure 2.5.1 The Data Tab

Note: See **Appendix 2** for definitions and more information on Decoding Datasets and Creating Summary Tables.

2.5.1 Data: Create Summary Table

Note: A Dataset should be decoded before selecting Create Summary Table (See Decode Databases(s) Section 2.5.2).

When a Decoded Dataset is open and selected, clicking on **Summary Table** from the **Data** Menu displays a dialogue box in which all the doses in the decoded database are listed (Figure 2.5.2). Select the doses you want to display in a Summary Table (selected doses have their checkboxes labelled with a tick). The **Select All** and **Deselect All** buttons can be used for selecting groups. You can change the order that the doses will be displayed in the Summary Table by using the **Move Up** and **Move Down** buttons.

Figure 2.5.2 Dose Selection for Summary Table

Press **OK** to continue.

A Summary Table of DATA dialogue box will open that allows you to select the Required Parameters to measure based on what is required for data presentation (Figure 2.5.3).

Select the desired Statistics for both the Individual and Dose/Group and the number of decimal places for data presentation.

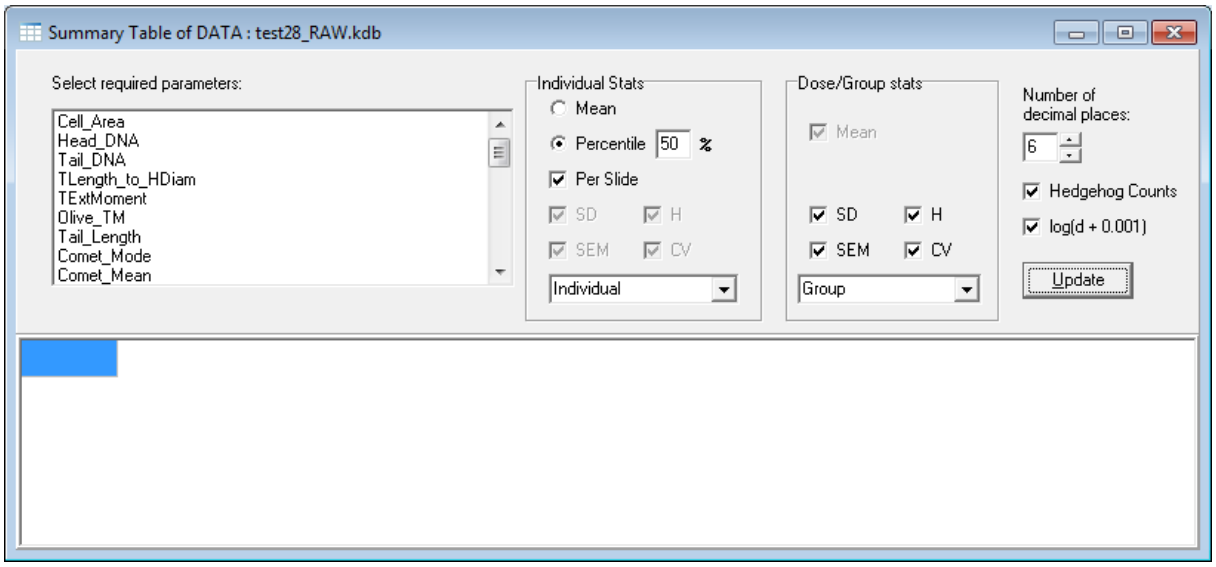
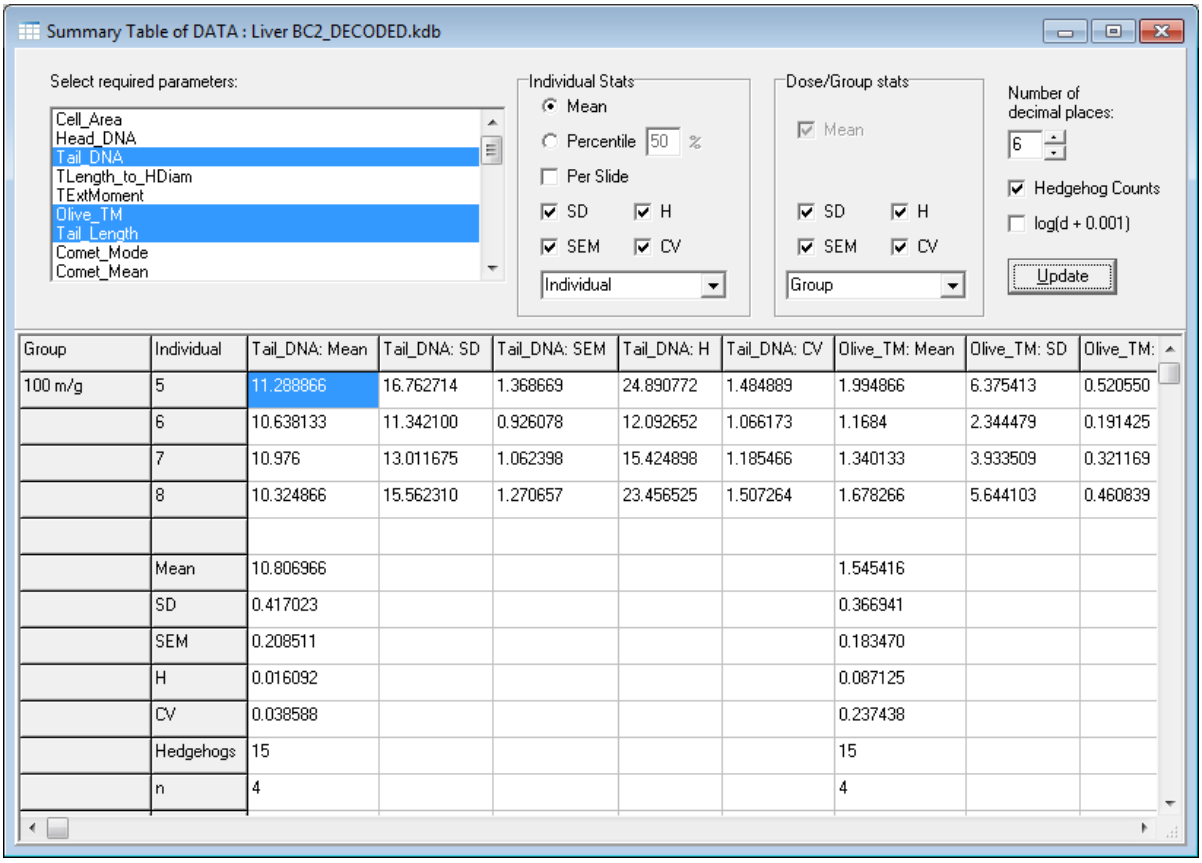


Figure 2.5.3 Summary Table Window

Once all parameters are selected, press the **Update** button. This will update the bottom window as shown in Figure 2.5.4.



Group	Individual	Tail_DNA: Mean	Tail_DNA: SD	Tail_DNA: SEM	Tail_DNA: H	Tail_DNA: CV	Olive_TM: Mean	Olive_TM: SD	Olive_TM:
100 m/g	5	11.288866	16.762714	1.368669	24.890772	1.484889	1.994866	6.375413	0.520550
	6	10.638133	11.342100	0.926078	12.092652	1.066173	1.1684	2.344479	0.191425
	7	10.976	13.011675	1.062398	15.424898	1.185466	1.340133	3.933509	0.321169
	8	10.324866	15.562310	1.270657	23.456525	1.507264	1.678266	5.644103	0.460839
	Mean	10.806966					1.545416		
	SD	0.417023					0.366941		
	SEM	0.208511					0.183470		
	H	0.016092					0.087125		
	CV	0.038588					0.237438		
	Hedgehogs	15					15		
	n	4					4		

Figure 2.5.4 Updated Summary Table Window

Once the table is updated any changes can be made and viewed by pressing the **Update** button. Once you are satisfied with the selected parameters, the Summary Table can be saved as an excel spreadsheet by clicking on save from the top left hand menu shown in Figure 2.5.5.

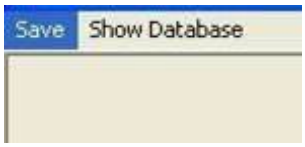


Figure 2.5.5 Save Menu

A Save Summary Table dialogue box will appear (Figure 2.5.6) to allow you to name and save as an excel spreadsheet (*.xld).

Figure 2.5.6 Summary Table Save As Option

The Summary Table is also added to the Database Window as a Summary Table Tab. Additional summaries can be created and a tab will be added to the Dataset for each Summary Table. The Summary Table Tabs in the Dataset will be numbered in the order they were created as shown in Figure 2.5.7.

SUMMARY_19 | SUMMARY_2 | SUMMARY_20 | SUMMARY_21 | SUMMARY_22 | SUMMARY_23 | SUMMARY_3 | SUMMARY_4 | SUMMARY_5 | SUMMARY_6 | SUMMARY_7 | SUMMARY_8 | SUMMARY_9 | SYSTEM_A

Summ_ID	Databases	UserName	Date_Time	Group	Individual	Notes	Tail_DNA: Mean	Tail_DNA: SD	Tail_DNA: SEM	Tail_DNA: H
14										
15				50 m/g	9	Raw data	6.7078	10.659546	0.870348	16.939372
16					10		8.5058	14.655431	1.196610	25.251200
17					1		5.603	6.868119	0.560779	8.418895
18					2		7.420799	14.258274	1.164183	27.395753
19					3		5.9726	6.475478	0.528720	7.020698
20					4		6.7884	10.042195	0.819941	14.855589
21					11		10.0164	14.556969	1.188571	21.155841
22					12		7.527466	8.944359	0.730303	10.627953
23					13		7.235866	8.087500	0.660341	9.039367
24					14		8.320133	10.751077	0.877821	13.892285
25					15		8.1288	12.215880	0.997422	18.357905
26					16		7.344533	9.166636	0.748452	11.440785
27					17		7.4412	8.696206	0.710042	10.162877
28										
29					Mean		7.462523			
30					SD		1.138844			
31					SEM		0.315858			
32					H		0.173797			
33					CV		0.152608			
34					Hedgehogs		14			
35					n		13			
36										

Figure 2.5.7 Database Window Summary Tab

2.5.2 Data: Decode Database(s)

When a Dataset is open and selected, clicking on **Decode Database(s)** from the Data Menu displays a dialogue box asking to re-enter the password for the Dataset.

Figure 2.5.8 Re-enter Password

A warning message will be received if the database has already been decoded. You can choose to overwrite existing decode as seen in Figure 2.5.9. Selecting **No** will send you back to the original Dataset.

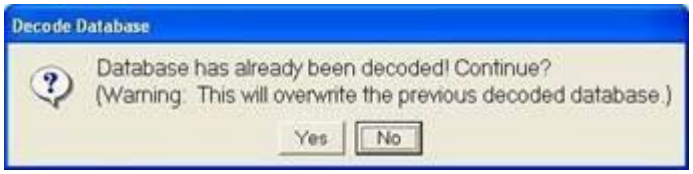


Figure 2.5.9 Decode Database Error Message

Once the password is entered the Dataset will be copied and '_DECODED' will added to the file name.

Edit Dose IDs

The ID Decoder Dialogue Box is then opened allowing you to **Edit Dose IDs** and **Add Dose IDs**. The **Clear All** and **Delete Last** buttons can be used to during the selection process

Figure 2.5.10 ID Decoder

If **Edit Dose IDs** is needed, it must be performed before the **Add Dose ID** function. If not, an error message will be received stating that this action will invalidate any Dose IDs already assigned.

The Edit Slide IDs dialogue box list the Slide Names on the left and any changes made on the right (Figure 2.5.11). To change a slide id, highlight the desired slide and press the **Change** button. Press **Cancel** at any time to exit **Edit Slide IDs**.

Figure 2.5.11 Edit Slide ID

The Update IDs dialogue box will appear and allow any necessary changes to be made. Once changes are made press **OK** (Figure 2.5.12).

Figure 2.5.12 Update Slide IDs

Once changes are complete the Edit Slide IDs Dialogue box will re-appear and show any changes made (Figure 2.5.11).

Once complete, press the **OK (**2.5.10) will once again appear.

Add Dose IDs

The ID Decoder Dialogue Box (Figure Now you are ready to Add Dose IDs.

After pressing the **Add Dose IDs** button the Create New Dose ID dialogue box will appear and allow you to select the Dose ID (Figure 2.5.13). The three options are to type in the name and units, Positive Control or Negative Control. The Drop down list for units will remember the last entry and continue to give that entry to you as an option. If no entries are present in the drop down box, you can simply type in the desired units. Press **OK**.

Figure 2.5.13 Create New Dose ID

The Assign IDs dialogue box will appear and allow you to select the slides to add to dose group. Once all slides are selected, press **OK**.

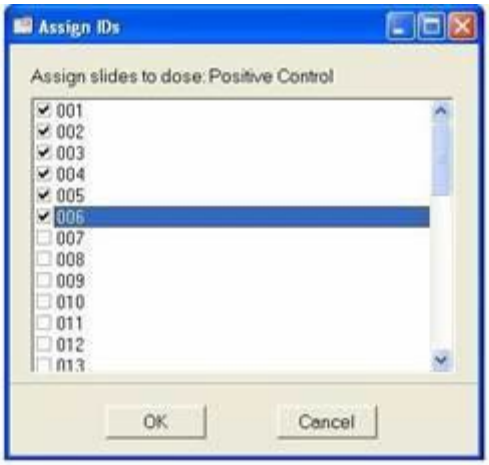


Figure 2.5.14 Assign IDs

Continue adding dose groups and assigning slides using the **Add Dose IDs** button on the ID Decoder Window (Figure 2.5.15). The Dose ID and slides assigned to that dose will appear in the window as the doses are added. Remember, the **Clear All** and **Delete Last** buttons can be used whenever needed.

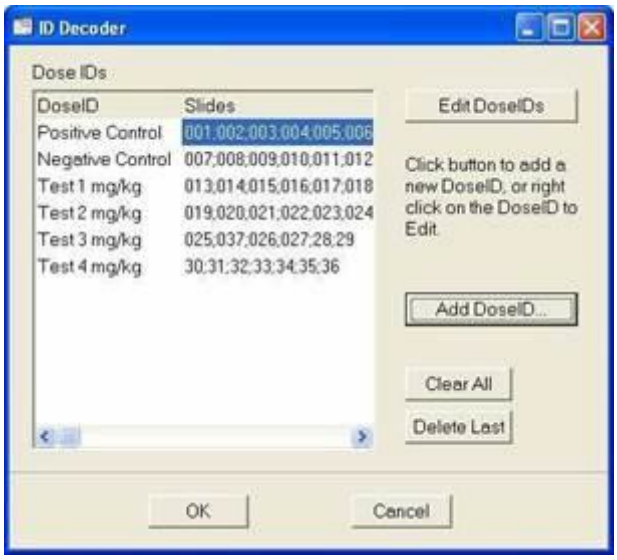
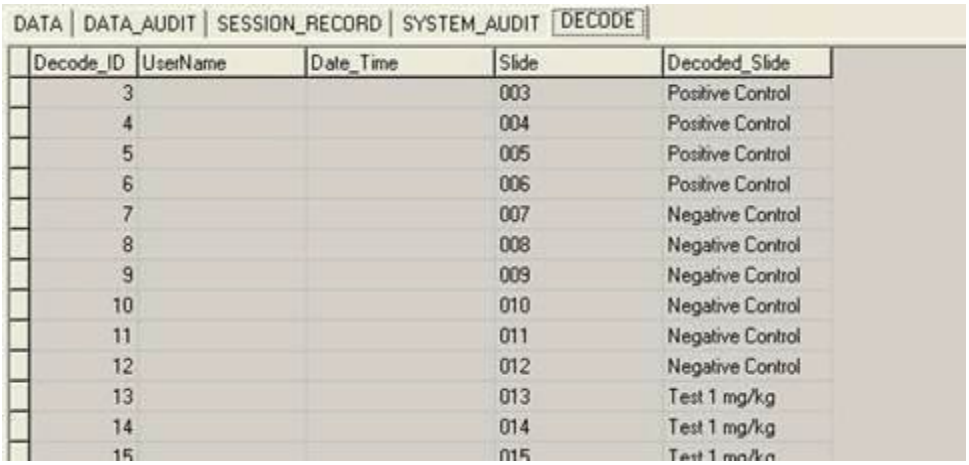


Figure 2.5.15 ID Decoder with Dose IDs Assigned

After all doses are added, press **OK**. All slides must be assigned to a dose group before proceeding.



DATA | DATA_AUDIT | SESSION_RECORD | SYSTEM_AUDIT | DECODE

Decode_ID	UserName	Date_Time	Slide	Decoded_Slide
3			003	Positive Control
4			004	Positive Control
5			005	Positive Control
6			006	Positive Control
7			007	Negative Control
8			008	Negative Control
9			009	Negative Control
10			010	Negative Control
11			011	Negative Control
12			012	Negative Control
13			013	Test 1 mg/kg
14			014	Test 1 mg/kg
15			015	Test 1 mg/kg

Figure 2.5.16 Database Window Decode Tab

A Tab will then appear in the Database Window containing all the information entered as seen in Figure 2.5.16.

2.5.3 Data: View Outliers

When a database is open and selected, clicking **View Outliers** from the **Data** Menu displays a Select Required Parameter dialogue box (Figure 2.5.17).

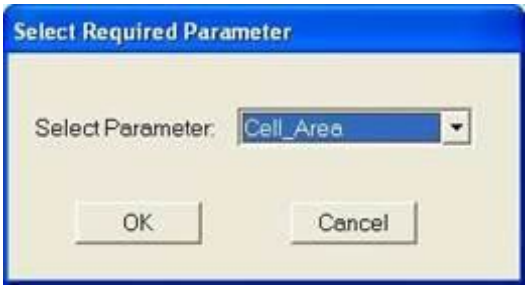


Figure 2.5.17 Select Required Parameters for Outliers

Select a parameter from the dropdown list to view and press **OK**. If the Dataset is decoded, a dialogue box will appear allowing you to select the dose groups to be included as shown in Figure 2.5.18. If the Dataset is not decoded, a list of slide ids will be listed in the dialogue box. Selected dose groups or slide ids will have their checkboxes labelled with a tick. **Select All** and **Deselect All** buttons can be used.

Figure 2.5.18 Select Dose Groups for View Outliers

Press **OK**.

Any outliers in that selected parameter will be shown in the View Outlier Window as shown in Figure 2.5.19.

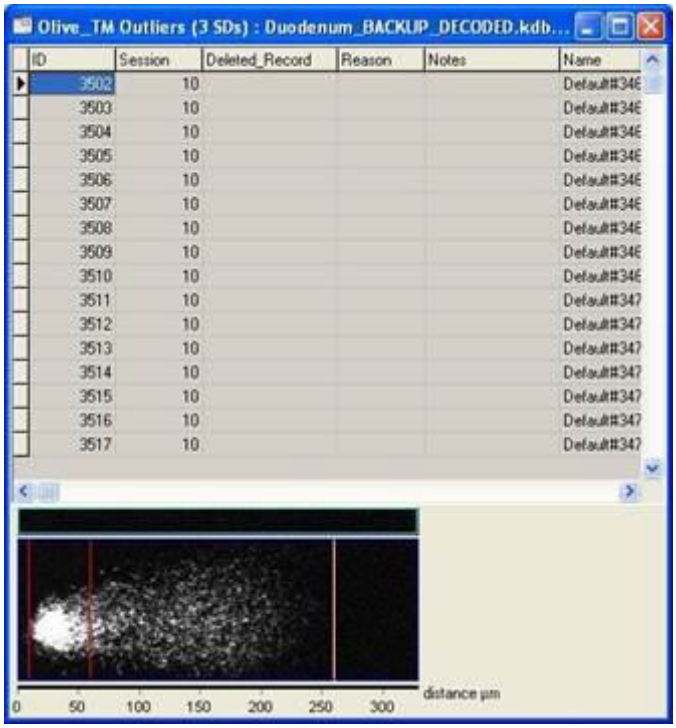


Figure 2.5.19 View Outlier Window

The upper pane of the Outliers Window shows the ID, Session, any Notes, the Name of the image, and all analysis parameters. When you click on a row of data, the image from which the data was obtained is displayed in the lower pane of the window along with a calibrated ruler to show comet lengths.

2.5.4 File Menu for View Outliers

When the View Outlier Window is open, the file options change (Figure 2.5.20).

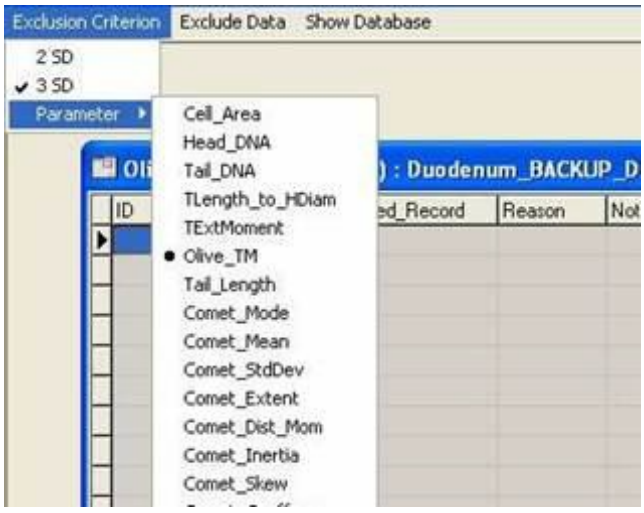


Figure 2.5.20 View Outlier Menu Bar

The View Outliers option automatically shows all outliers within three standard deviations of the mean. Under the **Exclusion Criterion** drop down menu, you have the option of selecting outliers within two standard deviations of the mean (2 SD) or three standard deviations of the mean (3 SD). If you chose two standard deviations from the mean, the View Outlier Window will automatically update. You can also change which parameter to view by selecting a different parameter from the list (Figure 2.5.20).

2.5.5 Exclude Data

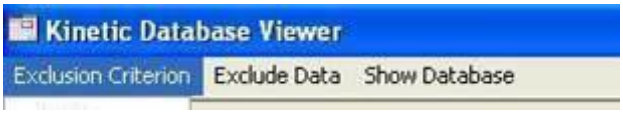


Figure 2.5.21 View Outlier Menu Bar

If you want to Exclude Outlier Data, select **Exclude Data** from the file menu. An Exclude Data Dialogue box will appear as seen in Figure 2.5.21.

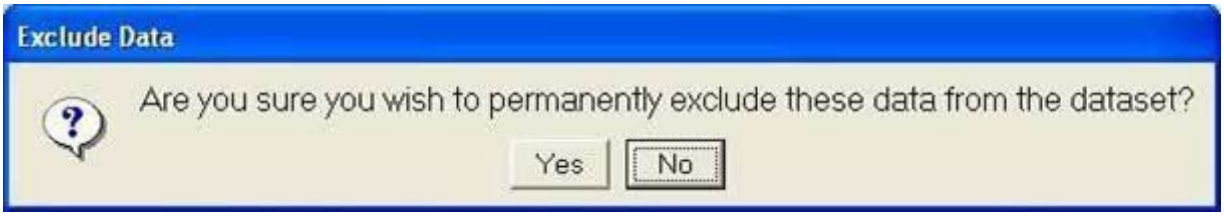


Figure 2.5.22 Exclude Data

Selecting **No** will return you to the view outlier window. Selecting **Yes** will exclude the data and the Data Tab, Data Audit Tab and Session Record Tab will show the excluded data as seen in Figures 2.5.22, 2.5.23, and 2.5.24.

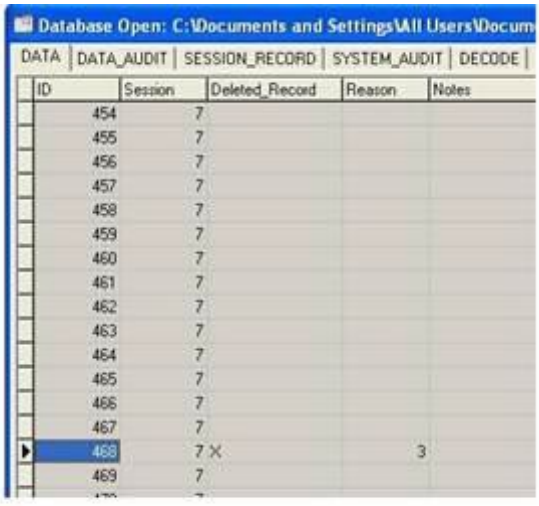


Figure 2.5.23 Excluded Data in Data Tab

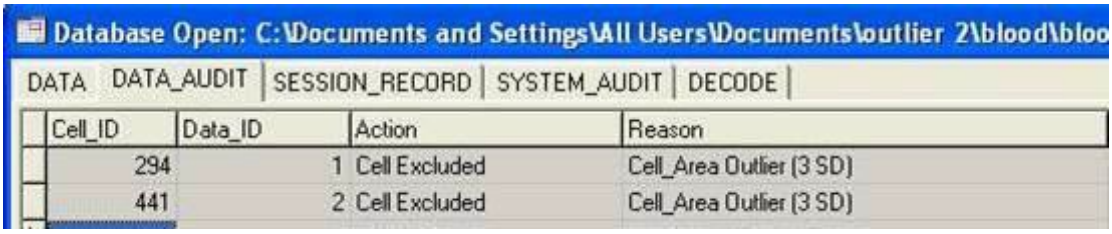


Figure 2.5.24 Excluded Data in Data Audit Tab

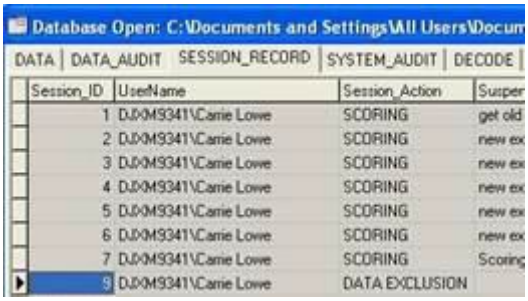


Figure 2.5.25 Excluded Data in Session Record Tab

2.5.6 Show Database

Figure 2.5.26 View Outlier Menu Bar

Show Database puts the Database Window on top of all the other windows.

2.6 DBV Tab: Windows

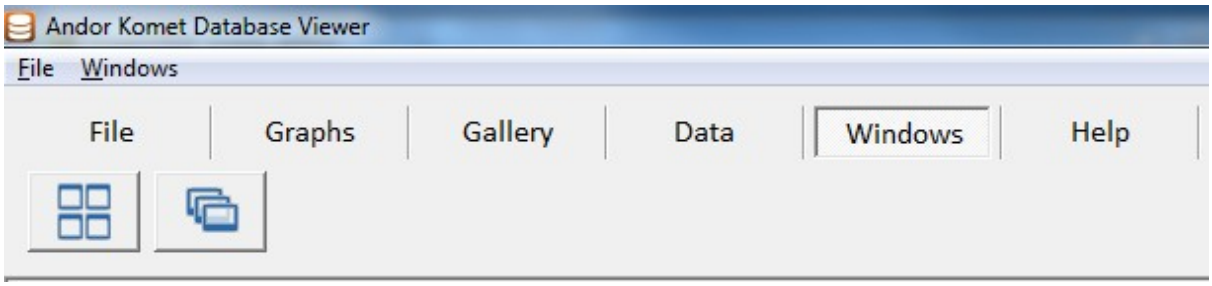


Figure 2.6.1 The Windows Tab

2.6.1 Windows: Tile

This determines how the open Datasets in the Database Viewer will be displayed. Selecting Tile will allow the user to see all open datasets in one window.

2.6.2 Windows: Cascade

This determines how the open Datasets in the Database Viewer will be displayed. Selecting Cascade will show the selected Dataset in front of all other Datasets. The Cascade option is also the default.

2.7 DBV Menu: Help

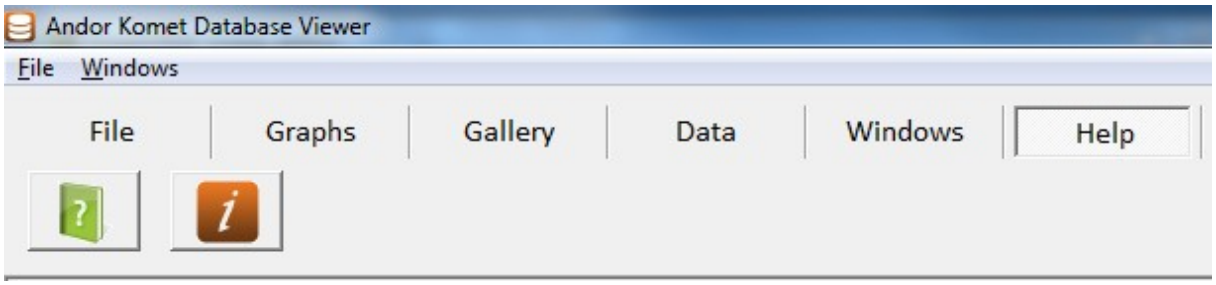


Figure 2.7.1 The Help Menu

2.7.1 Help: Help

Selecting **Help** opens the Software Guide for the Database Viewer. Note that *Adobe Reader* or similar software is required to view the Software Guide.

2.7.2 Help: About

Selecting **About** displays information about the version number and release date of the DBV, gives copyright credits and contact information.

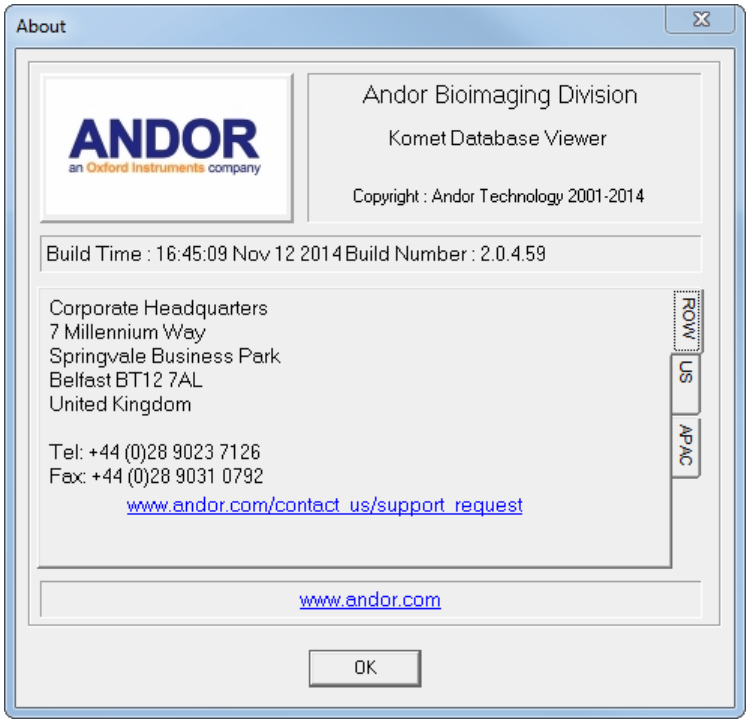


Figure 2.7.3 The About Dialogue Box

SECTION 3: INSTALLING THE SOFTWARE

Download: my.andor.com

Contact: www.andor.com/contact_us/support_request

To install the Database Viewer from the Installation CD, simply insert the CD into the drive and follow instructions. Or if the CD does not auto play, then select the Start.exe program from the root folder of the CD.

If running a standalone CD made by Komet®, Komet GLP or DBV, then just insert the CD and DBV will start and load the default Dataset. If the CD does not Auto run, then double click on the Autorun.ini file in the CD root folder.

SECTION 4: 4 DEFINITIONS AND INFORMATION ON DECODING DATASETS AND CREATING SUMMARY TABLES

Data Summary Creation as a Preliminary to Statistical Analysis in The GLP Database Viewer - Definitions

According to a recent paper on monitoring genotoxic effects in humans presented (Albertini RJ et al), the statistical analysis of data from genetic toxicology assays follows two distinct approaches, depending on whether the data is continuous or binary. The former data is produced by assays such as comet and UDS, where features of interest are respectively %DNA damage and number or area of developed silver grains, driven by DNA synthesis. The latter is represented by assays such as micronucleus (MN) or Chromosome aberration, where we are concerned with presence or absence of micronuclei or aberrations in various classes. The latter data generally follows a binomial distribution, while the former is commonly normal or normal after transformation. The techniques utilized in data analysis make no assumptions about the underlying form of the distribution, simply the nature of the data.

In this summary we will consider only the continuous forms in relation to the data summary functions within the Database Viewer.

- First of all the Study Director chooses the study design depending on the scientific questions being asked. This will establish the dataset created during scoring and will include the number of samples, number of replicates (slides) per sample. The set of sample replicates will generally be considered the unit of exposure. This is determined in Komet protocol set up. Scoring will commonly be carried out blind to minimize the potential for scorer bias, but as scoring proceeds Komet prompts the scorer to introduce replicate samples sequentially and pools the data for a sample from the set of replicates. For the purposes of a concise process definition, we will refer to the i_{th} unit of exposure $u_i(e)$.

- Next the dataset will be decoded in the Database Viewer. Using the Decoder tool, samples are grouped into dose or exposure groups or other groupings key to the nature of data analysis. Examples include comparisons of datasets from replicate experiments or the study of underlying variability in positive or negative control data from a series of datasets. For the purposes of a concise process definition, we will call the i_{th} dose or exposure group $g_i(e)$.

- The next step is to specify the parameters to be used for the data summaries and these include selections from mean, standard deviation, standard error, dispersion and coefficient of variation. Alternatively, we can choose a non-parametric description in the form of percentile, which includes the median (50 percentile). These parameters are then computed row-wise and presented for each unit of exposure and column-wise for each dose or exposure group. The computations for groups is based on computing mean of means or mean of percentiles and the standard deviation etc. is computed on the variability of means or medians.

- This is presented in mathematical notation below.

U(e)	Mean	percentile	Std Dev	Sem	Dispersion	CV	n
U_1(e)	µ1	P1	Ã1	Á1	H1	cv1	e.g.100
U_2(e)	µ2	P2	Ã2	Á2	H2	Cv2	N2
U_3(e)	µ3	P3	Ã3	Á3	H3	Cv3	N3
U_4(e)	µ4	P4	Ã4	Á4	H4	Cv4	N4
U_5(e)	µ5	P5	Ã5	Á5	H5	Cv5	N5
Group, G1	µ1(µ)	µ1(P)					
Ã(µ) or Ã(P)	Ã1(µ)	Ã1(P)					
Á(µ) or Á(P)	Á1(µ)	Á1(P)					
H(µ) or H(P)	H1(µ)	H1(P)					
CV(µ) or	CV1(µ)	CV1(P)					
CV(P)							
Number, n	e.g. 5						
U_6e)	µ6	P6	Ã6	Á6	H6	Cv6	N6
U_7e)	µ7	P7	Ã7	Á7	H7	Cv7	N7
U_8(e)	µ8	P8	Ã8	Á8	H8	Cv8	N8
U_9(e)	µ9	P9	Ã9	Á9	H9	Cv9	N9
U_{10}(e)	µ10	P10	Ã10	Á10	H10	Cv10	N10
Group, G2	µ2(µ)	µ2(P)					
Ã(µ) or Ã(P)	Ã2(µ)	Ã2(P)					
Á(µ) or Á(P)	Á2(µ)	Á2(P)					
H(µ) or H(P)	H2(µ)	H2(P)					
CV(µ) or	CV2(µ)	CV2(P)					
CV(P)							
Number, n	e.g. 5						

Table 1. Data Summary Table definition for the GLP Database Viewer

References

Richard J. Albertini, Diana Anderson, George R. Douglas, Lars Hagmar,

Kari Hemminki, Franco Merlo, A.T. Natarajan, Hannu Norppa, David E.G. Shuker, Raymond Tice, Michael D. Waters, Antero Aitio. *"IPCS guidelines for the monitoring of genotoxic effects of carcinogens in humans"* Mutation Research 463 2000 111–172