### TYPICAL VALUES

The table contains typical values for different heart rates. Use these values as guidelines for a first-time setup. Under different situations, values above or below the typical values may need to be used.

| Heart Rate | Attribute | Setting | Units |
|---|---|---|---|
| **40-600 (All)** | Minimum Pulse Height | 5% of Pulse | mmHg |
| | Percent Recovery | 50-75 | % |
| | Q-A Trigger Channel | NA | NA |
| **40-200 (Dog and Monkey)** | Systolic Validation Time | 100-150 | mSec |
| | Non-Detection Time | 50 | mSec |
| **200-400 (Rat)** | Systolic Validation Time | 50-100 | mSec |
| | Non-Detection Time | 25 | mSec |
| **400-600 (Mouse)** | Systolic Validation Time | 20-50 | mSec |
| | Non-Detection Time | 20 | mSec |

## Derived Parameters

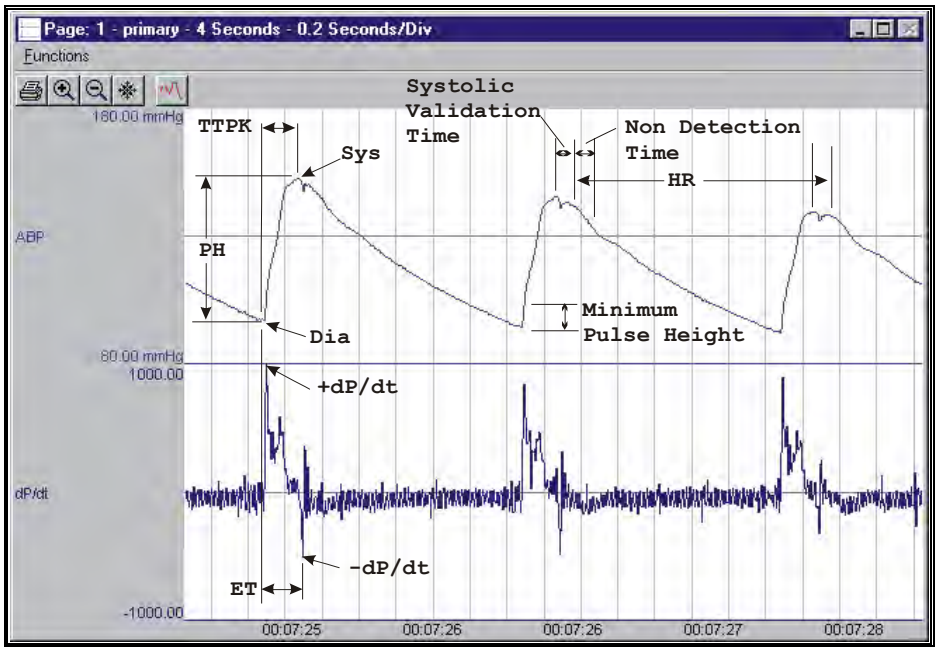
**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The **Derived Parameters** selected in this dialog will be calculated, and the results will be placed in the Derived Parameter List View(s). The following details the available **Derived Parameters** from the Blood Pressure module and the averaging method used within Review.

| Name | Definition | Review Averaging Method |
|---|---|---|
| **Num** | The number of the cardiac cycle. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. | Recent |
| **Sys** | The systolic pressure is the maximum pressure that occurs during the cardiac cycle. | Mean |
| **Dia** | The diastolic pressure is the minimum pressure that occurs during the cardiac cycle. | Mean |
| **Mean** | The mean blood pressure is calculated by averaging the data from the current diastolic mark to one sample prior to the following diastolic mark.<br><br>$\frac{1}{n}\sum_{i=1}^{n} d_i$ ,where d is the value of the signal, i=1 is at the current diastolic mark and n=number of points to the subsequent diastolic mark. | Mean |
| **PH** | The pulse height is the difference between the systolic pressure and the diastolic pressure for a cardiac cycle. | Mean |
| **HR** | The heart rate is computed in beats-per-minute. It is calculated by taking the reciprocal of the time interval for the cardiac cycle multiplied by 60. Note: When running in a logging rate other than 1 epoch, sum the cycles in seconds in the logging period, divide by the number of cycles, take the reciprocal, and multiply the value by 60. | Harmonic Mean |

| Name | Definition | Review Averaging Method |
|---|---|---|
| **TTPK** | Time to peak is the time from the rise of the systolic pressure to the peak pressure. The value is reported in milliseconds. | Mean |
| **ET** | Ejection time is the time from the rise of the systolic pressure to the point of -dP/dt. The time value is reported in milliseconds. | Mean |
| **+dP/dt** | +dP/dt is the maximum positive value of the first derivative of the pressure that occurs during the cardiac cycle. | Mean |
| **-dP/dt** | -dP/dt is the maximum negative value of the first derivative of the pressure that occurs during a cardiac cycle. | Mean |
| **%REC** | The %REC is the amount of time it takes the pressure to recover from the rise of the systolic pressure to the Percent Recovery point. The time is in milliseconds. | Mean |
| **NPMN** | The NPMN is the non-pulsatile mean pressure reported for a logging period. This parameter is reported even if no pulse pressure exists. | Analysis |
| **Q-A** | The Q-A Interval is the time in milliseconds from the start of the Q-wave, in the ECG trigger channel, to the start of the systolic pressure rise. | Mean |
| **RNum** | Now available only in the BPR module. The analysis will report 0's if selected during acquisition and X's when in Review. | Not available. Must be configured as a separate BPR channel to utilize Review. |
| **RInt** | Now available only in the BPR module. The analysis will report 0's if selected during acquisition and X's when in Review. | Not available. Must be configured as a separate BPR channel to utilize Review. |
| **RBpm** | Now available only in the BPR module. The analysis will report 0's if selected during acquisition and X's when in Review. | Not available. Must be configured as a separate BPR channel to utilize Review. |
| **Mean2** | An alternate representation for Mean calculated as (Systolic + 2 * Diastolic)/3. | Mean |
| **PTT** | Pulse Transit Time (PTT) is the time between the prior systolic time of the upstream channel and the systolic time of the selected channel. This time is reported in ms. | Mean |
| **PWV** | Pulse Wave Velocity (PWV) is the velocity calculated by using the Pulse Wave Distance (PWD) and Pulse Transit Time (PTT).<br><br>PWV is calculated as:<br>Pulse Wave Velocity = Pulse Wave Distance / Pulse Transit Time. | Mean |
| **Count** | This parameter will provide a total of the number of marked cycles within the defined logging period. This is different from the Num parameter which will simply list the last cycle within the logging period. | Sum |

## Online Screens and Functions

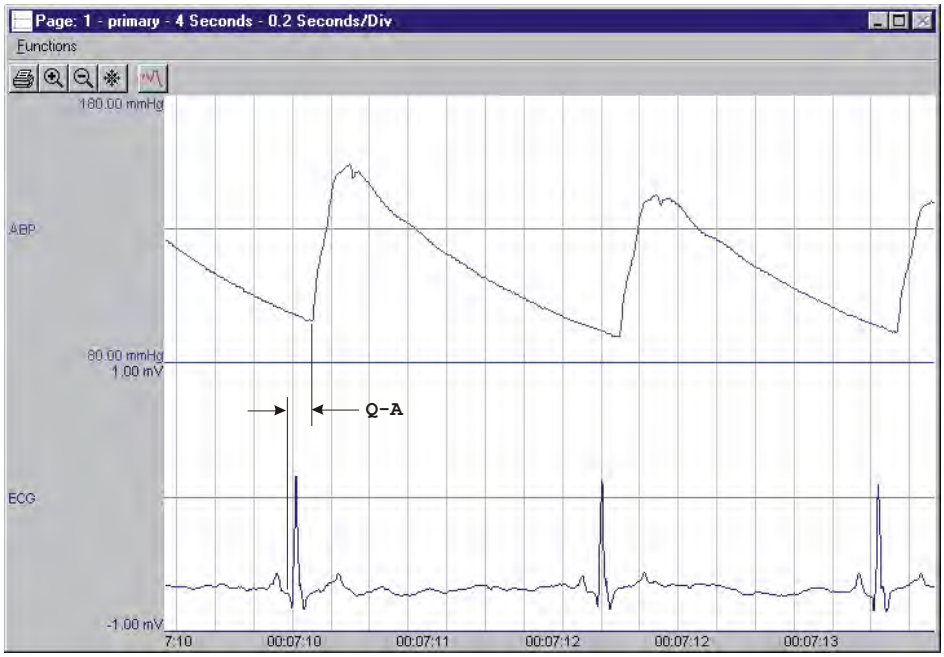
The following is an example of a **Primary** graph displaying an aorta blood pressure signal along with its differential.




*Blood Pressure Key Marks*

In the above figure, the **Blood Pressure** is displayed with validation tick marks and their meanings. The validation marks identify the ***Systolic Pressure***, ***Diastolic Pressure***, and the ***%Recovery*** point.

The image below defines the measurement of Q-A Interval.




*Blood Pressure Q-A Interval Mark*

## Presentation Signals

Below is a list of presentation signals that are available for the BP Analysis Module:

| Signal | Description |
|---|---|
| **Pressure** | This is the original pressure signal after applying any software filters. |
| **Derivative** | This will display the derivative of the pressure signal. |
| **Mean** | This will display the mean pressure updated at every cardiac cycle. |
| **Heart Rate** | This will display the heart rate updated at every cardiac cycle. |
| **Difference** | This will display the difference between this input signal, and an input signal selected in the **Advanced Attributes** tab (other available pressure signals). The analysis module will subtract the current blood pressure signal from the signal selected from the list box and make the resulting signal available to be graphed. |

## Data Review

This is a list of the Data Review related features of the Blood Pressure Analysis Module. The analysis specific portion of Data Review centers on the marks that the user is permitted to display, insert, and delete and how the User is permitted to move them.

| Action | **Description** |
|---|---|
| Displaying Marks and Cycle Numbers | The marks and cycle numbers displayed in a Review **Primary** graph page **Display Pane** are controlled through the **Marks** Tab in the **Analysis Attributes** dialog. The **Analysis Attributes** dialog is accessed through the right click menu – **Analyze [Attributes]**. |
| Mark Operations | Blood Pressure marks are divided into two types, marks that always exist when a valid cycle is found (**Diastolic, End Diastolic**, and **Systolic**) and marks that may or may not exist, depending on the signal morphology (**Percent Recovery**). |
| Inserting Marks | **Marks** may be inserted by right clicking at the point of insertion in the **Primary Graph Display Pane** of the Channel of interest. The pop-up menu that is displayed will provide the option to insert marks as appropriate. The list of marks available for insertion will depend on the marks adjacent to the point of insertion; signal morphology is not considered. |
| Insert BP Cycle | Inserts an entire **Blood Pressure cycle**, **Diastolic**, **End Diastolic**, **Systolic**, and **Percent Recovery**, if applicable. This set of marks may be inserted between a **Percent Recovery** Mark and a **Diastolic Mark**. If a **Percent Recovery Mark** is not present, the cycle may be inserted between a **Systolic Mark** and a **Diastolic Mark**. When a **Blood Pressure cycle** is inserted, it is assigned a sequential cycle number and subsequent cycle numbers are incremented. |

| Action | Description |
|---|---|
| Deleting Marks | **Marks** are deleted by positioning the mouse cursor on the mark to be deleted and bringing up the right click menu. A Blood Pressure cycle's marks cannot be deleted individually. They are linked to the **Systolic Mark**. To delete these marks, the entire cycle must be deleted; the cursor is positioned on the **Systolic Mark** and the right mouse button is clicked to delete the marks. One of the selections in the pop-up menu will permit deletion of all the marks in the cycle. |
| Moving Marks | Moving of the **Diastolic** and **End Diastolic** and **Systolic Marks** follow the standard rules used in Data Review. There are special considerations when dealing with the **Percent Recovery Mark**. The **Percent Recovery** Mark is a calculated mark; its position is dependent on the systolic and diastolic levels and cannot be adjusted by the user. If the user changes the position of either the **Diastolic** or **Systolic Marks**, the **Percent Recovery Mark** will be recalculated. |
| Calculations | The calculations of derived parameters are identical to those performed during acquisition, with the exception of +dP/dt and -dP/dt. For non-pulsatile parameters, the start point is the point after the previous log time. The end point is the point at which the line is logged.<br><br>The -dP/dt parameter is obtained from the data between the peak and the end of the peak detection time.<br><br>In Review, +dP/dt is obtained from the data between the end diastolic point and the systolic point. |
| Logging Mark | The **Logging Mark** for a **Blood Pressure cycle** is the **Systolic Mark**. The time at the L**ogging** M**ark** is the time used to report a cycle's derived data. |
| End of Cycle | The end of a **Blood Pressure cycle** occurs one sample prior to the next cycle's diastolic mark. When BP and ECG data are brought into Review, the ECG channel should be used as the epoch channel to ensure that related cycles are kept together. |

## ATTRIBUTE TYPES IN REVIEW

The following table describes the effects of changing BP attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| Attribute | Effect On Review |
|---|---|
| **Minimum Pulse Height** | Signal Interpretation |
| **Systolic Validation Time** | Signal Interpretation |
| **Non Detection Time** | Signal Interpretation |
| **Percent Recovery** | Calculation, Redraw |
| **QA Trigger Channel** | Calculation |
| **High Pass Filter** | Signal Conditioning, Calculation, Redraw |
| **Low Pass Filter** | Signal Conditioning, Calculation, Redraw |
| **Barometric Adjust** | Signal Conditioning, Calculation, Redraw |
| **Barometric Channel** | Signal Conditioning, Calculation, Redraw |
| **Diff Pressure Chan** | Signal Conditioning, Calculation, Redraw |
| **BP Epoch Channel** | None |
| **Marks and cycle numbers** | Redraw |

| | |
|---|---|
| **Precision** | Precision |
| **Pulse Wave Distance** | Calculation |
| **Upstream Pressure Channel** | Calculation |
| **Pulse Wave Velocity units** | Calculation |
| **Enable Noise Detection** | Signal Interpretation |
| **Minimum Signal Value** | Signal Interpretation |
| **Maximum Signal Value** | Signal Interpretation |
| **Maximum Heart Rate** | Signal Interpretation |
| **Minimum Heart Rate** | Signal Interpretation |
| **Minimum Good Data Time** | Signal Interpretation |

## Troubleshooting

Use the following table to assist in troubleshooting the analysis:

| Issue | Solution |
|---|---|
| **Heart Rate is doubled** | The analysis is triggering on the dicrotic notch. This can be rectified by lengthening the **Systolic Validation Time** and **Non-Detection Time** values. Refer to the chart of **Typical Values** for a specific heart rate range. |
| **Heart Rate is halved** | The analysis is pausing too long for the specified heart rate. The problem can be rectified by shortening the **Systolic Validation Time** and **Non-Detection Time** values. Refer to the chart of **Typical** Values for a specific heart rate. |
| **All Derived Parameters are reporting zero** | The **Minimum Pulse Height** may be set too high for the specified signal. Lower the **Minimum Pulse Height**. |
| **Heart Rate is out of range (very high)** | The analysis may be triggering on noise. The two solutions for this are:<br>1. Increase the **Minimum Pulse Height** to a value of 10% of pulse pressure.<br>2. Increase the **Low Pass Filter** (in the **Adv Attrib** tab) to remove the noise or artifact. Select a lower value in the list box. |
| **"x" in** Derived Parameter List View **window instead of a number** | The **Derived Parameter** value is too large for the field. An "x" was placed here, so that a truncated number would not be displayed. |
| **Cannot find the analysis module in the** Subject Setup \| Subject Details **dialog** | The analysis module is likely not enabled in the Ponemah License. Check License options via **Help \| View License**. |
| **Analysis does not trigger (No marks)** | Reduce the sample rate to 250-1000Hz (Sample Rate within the Acquisition Interface dialog). |
| **0 or "x" reported for PWV** | No upstream pressure channel available for the selected channel.<br>Cycles that have 0 Pulse Transit Time (PTT) reported. |
| **Pulse Transit Time (PTT) and Pulse Wave Velocity (PWV) report "x" in review** | No cycles exist between the downstream cycle's systolic mark and a segment start or a bad data mark end. |

## Blood Pressure Respiration (BPR)

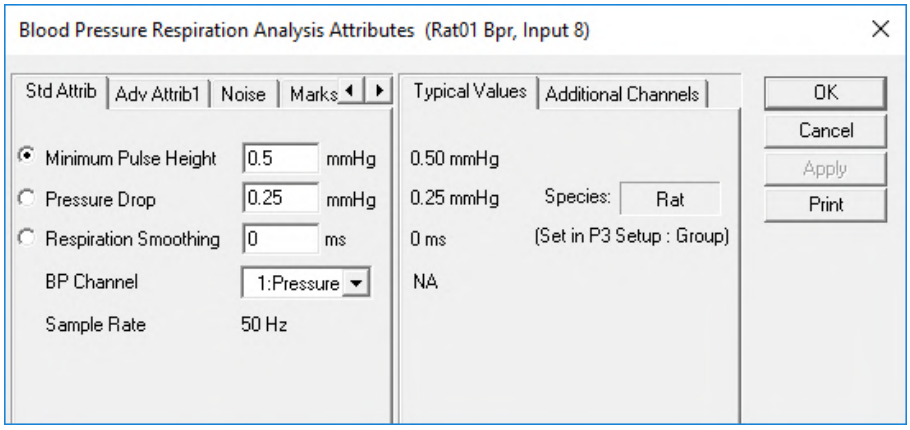
The **Blood Pressure Respiration** (BPR) analysis can analyze any pressure from the circulatory system and derive, on a beat-to-beat basis, respiration values from the cardiac cycle. For the BPR analysis to function properly, a BP channel needs to be configured and the BPR channel must be associated with the acquired BP channel.

### Attributes Dialog

The **Blood Pressure Respiration Analysis Attributes** dialog allows you to modify the signal analysis for different types of blood pressure signals and signal conditions. If an analysis change in the **Attributes** dialog is performed mid-cycle, then the attribute change will not take effect until the following cycle.

#### STANDARD ATTRIBUTES

The **Standard** attributes allow setting the most common attributes that would need to be changed during Acquisition or Review.




*Blood Pressure Respiration Standard Attributes Tab*

**Minimum Pulse Height** — Sets the minimum developed pressure that must be achieved before the analysis will detect and validate a cycle. The **Minimum Pulse Height** is useful for preventing the analysis from triggering on small variations in the signal.

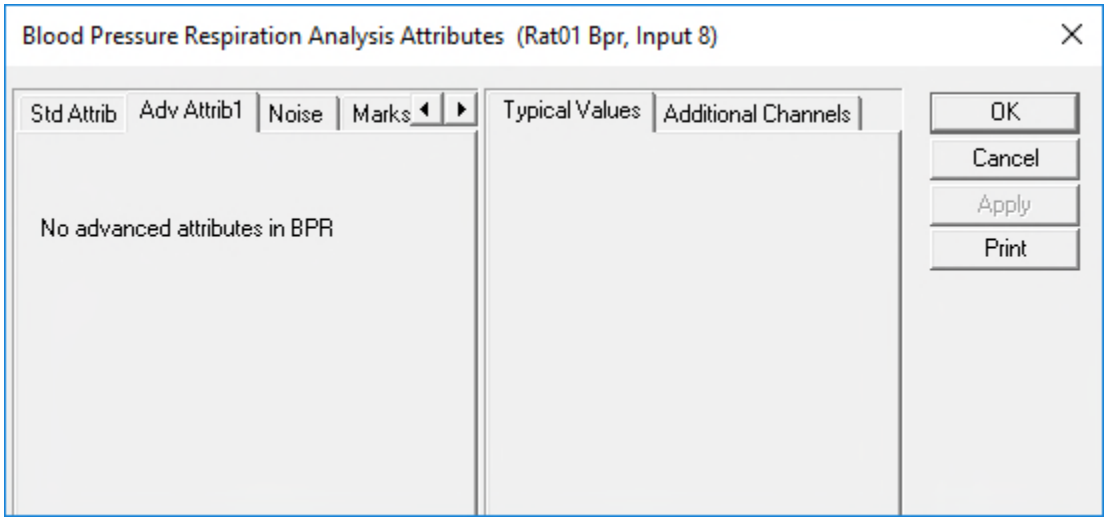
**Pressure Drop** — This setting is used to set the minimum level by which the signal must fall, relative to its recent maximum, for the analysis to identify a cycle. This setting is useful in eliminating false triggering on small variations in the signal.

**Respiration Smoothing** — This sets the duration over which data derived from the blood pressure signal is smoothed to yield the respiration signal. This should be set to approximately ¼ of a respiration cycle. If this parameter is set too small,

| | |
|---|---|
| | the respiration signal will appear jagged. If it is set too large, the respiration signal will appear washed out, and the pulse height of individual cycles will become smaller. |
| **BP Channel** | This associates the proper BP channel from which the BPR channel is derived. These two channels must be configured in the same Subject. If no BP channel is associated with the BPR channel, the analysis will not trigger.<br><br>*Note*: The BP channel must be sampled at, or faster than the BPR sample rate. |
| **Sampling Rate** | Rate at which the Blood Pressure Respiration is derived from the Blood Pressure channel and collected during the Acquisition. |

## ADVANCED ATTRIBUTES

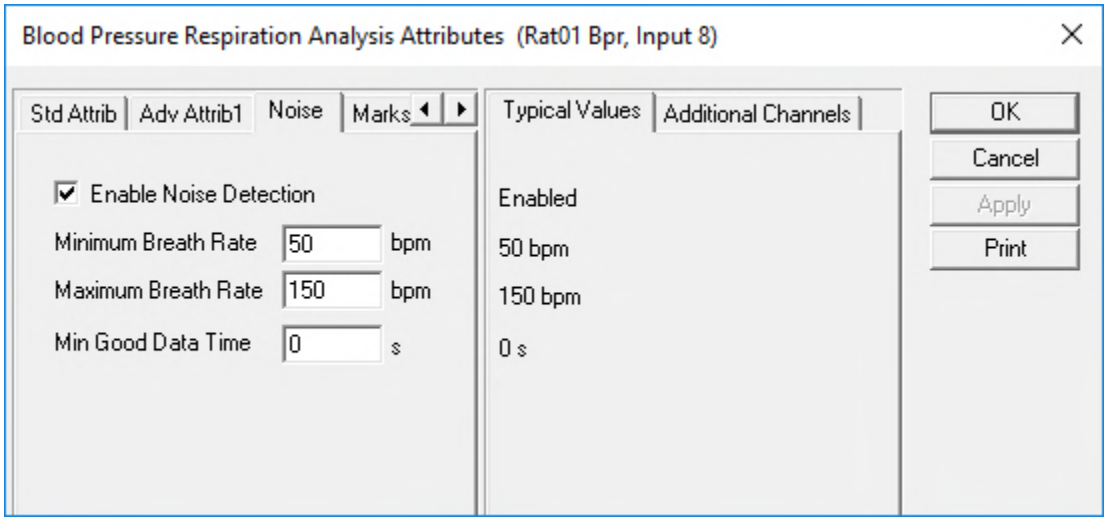
The BPR Analysis modules does not have **Advanced** attributes.




*Blood Pressure Respiration Advanced Attributes Tab.*

## NOISE TAB

The **Noise Tab** contains attributes that are used to identify noisy data. On identifying "noisy" data, as defined by the user, **Bad Data Marks** will be placed to span the noisy sections.

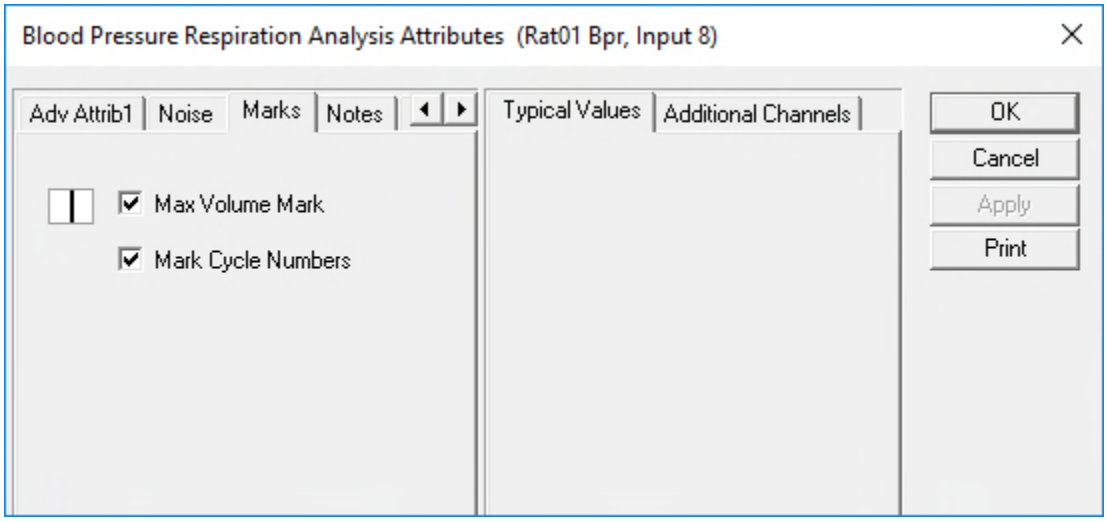



*Blood Pressure Respirations Noise Tab*

| | |
|---|---|
| **Enable Noise Detection** | Enables the **Noise Detection** attributes for the automatic placement of **Bad Data Marks**. |
| **Minimum Breath Rate** | User defined threshold for determining the **minimum breath rate** for acceptable data. Data that falls below this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Maximum Breath Rate** | User defined threshold for determining the **maximum breath rate** for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Minimum Good Data Time** | Provides the user the ability to mark data as bad between two **Bad Data Mark** regions. If the time between the regions is less than the value specified. If the time is less than what is specified, the **Bad Data Mark** region will appear as one contiguous segment. |

## MARKS (VALIDATION) TAB

The **Blood Pressure Respiration** analysis displays validation tick marks for each cardiac cycle. Each cardiac cycle should have only one set of validation marks. These marks verify that the system is analyzing the blood pressure signal correctly. If there is more than one set of validation marks per cardiac cycle, correct the problem by changing the analysis attributes.




*Blood Pressure Respirations Marks Tab*

The validation marks and their meanings are listed below:

| **Color** | | **Meaning** |
|---|---|---|
| Black | | Max Volume Mark |
| | | Mark Cycle Numbers |

### TYPICAL VALUES

The table contains typical values for different heart rates. Use these values as guidelines for a first-time setup. Under different situations, values above or below the typical values should be used.

| Species | Attribute | Setting | Units |
|---|---|---|---|
| **(All) Dog, Ferret, Guinea Pig, Hamster, Minipig, Monkey, Mouse, Rabbit, Rat, Sheep, Swine** | Minimum Pulse Height | 5% of Pulse | mmHg |
| | Pressure Drop | 5% of Pulse | mmHg |
| | Respiration Smoothing | 2000 | mSec |
| | BN Channel | NA | NA |

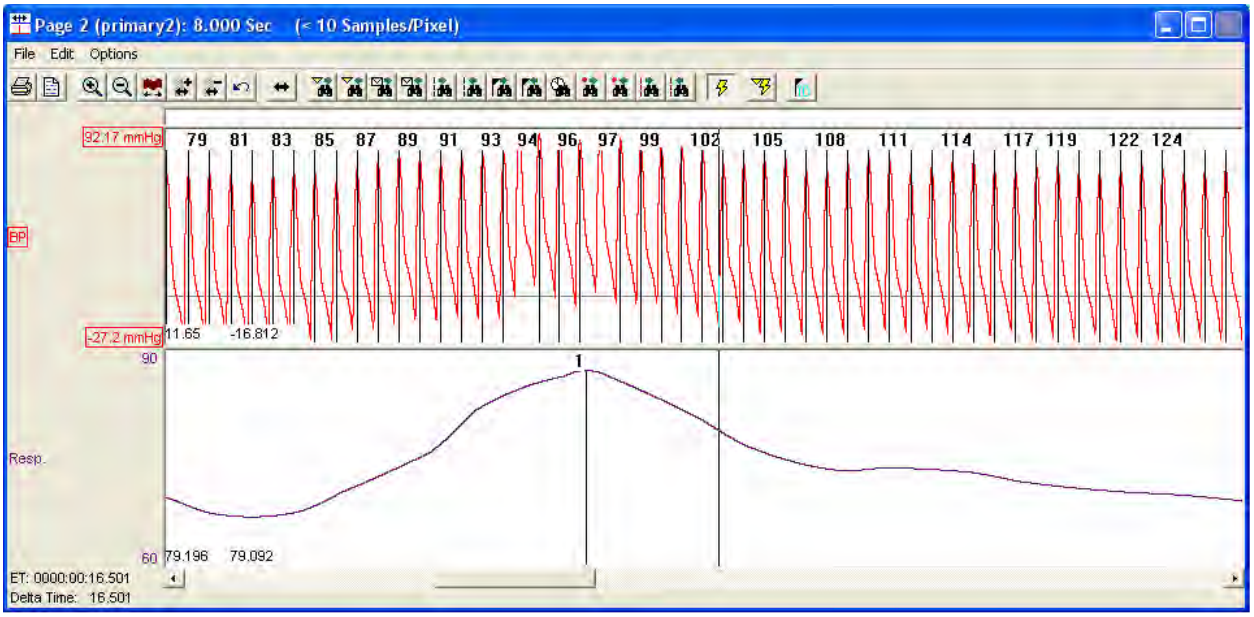
## Derived Parameters

**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The **Derived Parameters** selected in this dialog will be calculated, and the results will be placed in the Derived Parameter List View(s). The following details the available **Derived Parameters** from the Blood Pressure module and the averaging method used within Review.

| Name | Definition | Review Averaging Method |
|---|---|---|
| **RNum** | The number of the respiration cycle. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. | Recent |
| **RInt** | The time, in milliseconds, over which a full respiration waveform is detected. | Mean |
| **RBpm** | Respiration rate in breaths per minute. | Harmonic Mean |

## Online Screens and Functions

The following is an example of a **Primary** graph displaying an aorta blood pressure signal along with its differential.




*Blood Pressure Respiration Key Marks*

In the above figure, the **Blood Pressure Respiration** signal is displayed with validation tick marks and their meanings. The validation mark identifies the Max Volume Mark point.

## Presentation Signals

Below is a list of presentation signals that are available for the BP Analysis Module:

| **Signal** | **Description** |
|---|---|

| | |
|---|---|
| Respiration | This will display the calculated respiration signal. |

## Data Review

This is a list of the Data Review related features of the Blood Pressure Analysis Module. The analysis specific portion of Data Review centers on the marks that the user is permitted to display, insert, and delete and how the User is permitted to move them.

| | |
|---|---|
| **Displaying Marks and Cycle Numbers** | The marks and cycle numbers displayed in a Review **Primary** graph page **Display Pane** are controlled through the **Marks** Tab in the **Analysis Attributes** dialog. The **Analysis Attributes** dialog is accessed through the right click menu – **Analyze [Attributes]**. |
| **Mark Operations** | **Marks** are divided into two types, marks that always exist when a valid cycle is found (**Diastolic, End Diastolic**, and **Systolic**) and marks that may or may not exist, depending on the signal morphology (**Percent Recovery**). BPR has only a single mark (**Max Volume Mark**) that exists when a valid cycle is found. |
| **Inserting Marks** | **Marks** may be inserted by right clicking at the point of insertion in the **Primary Graph Display Pane** of the Channel of interest. The pop-up menu that is displayed will provide the option to insert marks as appropriate. The list of marks available for insertion will depend on the marks adjacent to the point of insertion; signal morphology is not considered. |
| **Insert BPR Cycle** | Inserts an entire **Blood Pressure Respiration cycle** with the associated **Max Volume Mark**. This mark may be inserted at any point along the waveform. When a Blood Pressure Respiration cycle is inserted, it is assigned a sequential cycle number and subsequent cycle numbers are incremented. |
| **Deleting Marks** | **Marks** are deleted by positioning the mouse cursor on the mark to be deleted and bringing up the right click menu. When deleting these marks, the entire cycle will be deleted; the cursor is positioned on the **Max Volume Mark** and the right mouse button is clicked to delete the mark. |
| **Moving Marks** | Moving the **Max Volume Marks** follow the standard rules used in Data Review. A **Max Volume Mark** cannot be dragged past another Max Volume Mark. |

| | |
|---|---|
| **Calculations** | The calculations of derived parameters are identical to those performed during acquisition, with the exception of **RBpm** as it uses a Harmonic Mean. For non-pulsatile parameters, the start point is the point after the previous log time. The end point is the point at which the line is logged. |
| **Logging Mark** | The **Logging Mark** for a **Blood Pressure Respiration cycle** is the **Max Volume Mark**. The time at the L**ogging** M**ark** is the time used to report a cycle's derived data. |
| **End of Cycle** | The end of a **Blood Pressure Respiration cycle** occurs one sample prior to the next cycle's **Max Volume Mark**. |

### ATTRIBUTE TYPES

The following table describes the effects of changing BPR attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| **Attribute** | **Effect On Review** |
|---|---|
| Minimum Pulse Height | Signal Conditioning, Calculation, Signal Interpretation, and Redraw |
| Pressure Drop | Signal Conditioning, Calculation, Signal Interpretation, and Redraw |
| Respiration Smoothing | Signal Conditioning, Calculation, and Redraw |
| BP Channel | Signal Conditioning, Calculation, Signal Interpretation, and Redraw |
| Marks and Cycles | Signal Conditioning, Calculation, and Redraw |
| Precision | Signal Conditioning, Calculation, Redraw, and Precision |
| Reanalyze only – No attribute change | Signal Conditioning, Calculation, and Redraw |

## Troubleshooting

Use the following table to assist in troubleshooting the analysis. This includes issues that may exist in the BP analysis module which may affect the BPR module:

| Issue | Solution |
|---|---|
| Heart Rate is doubled | The analysis is triggering on the dicrotic notch. This can be rectified by lengthening the **Systolic Validation Time** and **Non-Detection Time** values. Refer to the chart of **Typical Values** for a specific heart rate range. |
| Heart Rate is halved | The analysis is pausing too long for the specified heart rate. The problem can be rectified by shortening the **Systolic Validation Time** and **Non-Detection Time** values. Refer to the chart of **Typical** Values for a specific heart rate. |
| All Derived Parameters are reporting zero | The **Minimum Pulse Height** may be set too high for the specified signal. Lower the **Minimum Pulse Height**. |
| Heart Rate is out of range (very high) | The analysis may be triggering on noise. The two solutions for this are:<br>1. Increase the **Minimum Pulse Height** to a value of 10% of pulse pressure.<br>2. Increase the **Low Pass Filter** (in the **Adv Attrib** tab) to remove the noise or artifact. Select a lower value in the list box. |
| "x" in **Derived Parameter List View** window instead of a number | The **Derived Parameter** value is too large for the field. An "x" was placed here, so that a truncated number would not be displayed. |
| Cannot find the analysis module in the **Subject Setup \| Subject Details** dialog | The analysis module is likely not enabled in the Ponemah License. Check License options via **Help \| View License**. |
| Analysis does not trigger (No marks) | Reduce the sample rate to 250-1000Hz (Sample Rate within the Acquisition Interface dialog). |

## Left Ventricular Pressure (LVP)

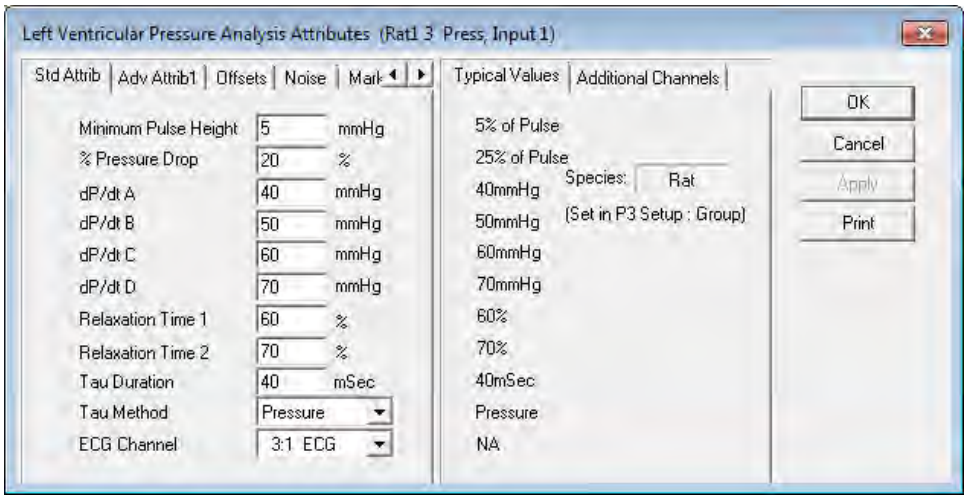
The **Left Ventricular Pressure** analysis module analyzes the left ventricular pressure from the heart. The analysis calculates the common parameters that are associated with left ventricular pressure on a beat-to-beat basis.

### Attributes Dialog

The **Left Ventricular Pressure Analysis Attributes** dialog allows you to modify the signal analysis for different types of left ventricular pressure signals and signal conditions. If an analysis change in the **Attributes** dialog is performed mid-cycle, then the attribute change will not take effect until the following cycle.

## STANDARD ATTRIBUTES TAB

The **Standard** attributes allow setting the most common attributes that would need to be changed during Acquisition or Review.




*Standard Attributes tab*

The standard attributes allow setting the most common attributes that would need to be changed during Acquisition or Review.

**Minimum Pulse Height** — Sets the minimum developed pressure that the signal must achieve before the analysis will detect and validate a cardiac cycle. The **Minimum Pulse Height** prevents the analysis from triggering on artifacts.

**% Pressure Drop** — Defines how far the ***Systolic*** pressure must drop before the cardiac cycle will terminate. The pressure used in determining the percentage is the difference from the ***Systolic*** pressure to the ***Minimum*** pressure.

**dP/dt (A, B, C, and D)**

Defines four pressure levels that the dP/dt will be reported from during the systolic period.

**Relaxation Time 1, 2**

Defines levels in the derivative signal at which relaxation times will be reported. A relaxation period begins when -dP/dtMAX occurs, and ends when the derivative signal reads zero. For example, if **Relaxation Time** is set to 60%, then the system will report how long it took (in milliseconds) for the derivative to rise by 60% of -dP/dtMAX.

**Tau Duration**

Defines the duration over which **Tau** is to be calculated, starting at -dP/dtMAX. **Tau Duration** is measured in milliseconds. Three methods are used for calculating Tau: **Pressure**, **dP/dt**, and **DevPressure**.

**Pressure:**

Tau is calculated as the negative inverse of the slope of the regression line of the natural logarithm of Left Ventricular Pressure versus time.

**dP/dt:**

Tau is calculated as the negative inverse of the slope of the regression line of the natural logarithm of -dP/dt versus time.

**DevPressure:**

Tau is calculated as the negative inverse of the slope of the regression line of the natural log of left ventricular pressure - the previous end diastolic level versus time.

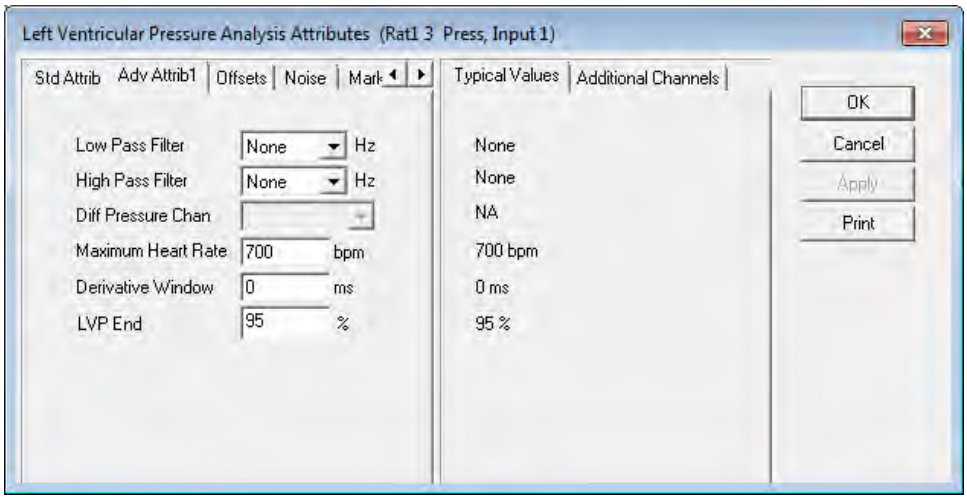
**Tau Method**

Defines which two values are used in the calculation of **Tau**. Use different methods for different conditions. Each method passes the data into the formula that calculates the linear line equation using the least square method. The three available methods are: Pressure, dP/dt, and DevPressure.

**ECG Channel** Permits the selection of an ECG channel for the calculation of the Q-A Interval. If no ECG channels are set up, this control is inactivated. ECG channels must be set up prior to using this attribute.

## ADVANCED ATTRIBUTES TAB

The Advanced attributes allow selection of attributes which are not commonly changed during Acquisition or Review.




*Advanced Attributes tab*

**Low Pass Filter** Selection of Low Pass filter in hertz.

**High Pass Filter** Selection of High Pass filter in hertz.

**Diff Pressure Chan** This list box allows the selection of a channel that can be used to subtract another channel from the input. The only effect that this has is for display. To display the difference, the **Presentation** field in a **Primary** graph must be set to **Diff**.

**Maximum Heart Rate** This attribute is used to assist the analysis in the rejection of noise, to ensure that large rapid signal fluctuations due to noise are not marked as cardiac cycles. Maximum Heart Rate should be set higher than the highest expected heart rate.

**Derivative Window**

The Derivative Window defines the range of samples over which the LVP's derivative signal is calculated. This window acts as a smoothing function for the derivative by calculating across a larger range. Using a value of 0ms will provide the derivative between two consecutive points, whereas entering a larger value may provide the derivative across non-consecutive points.

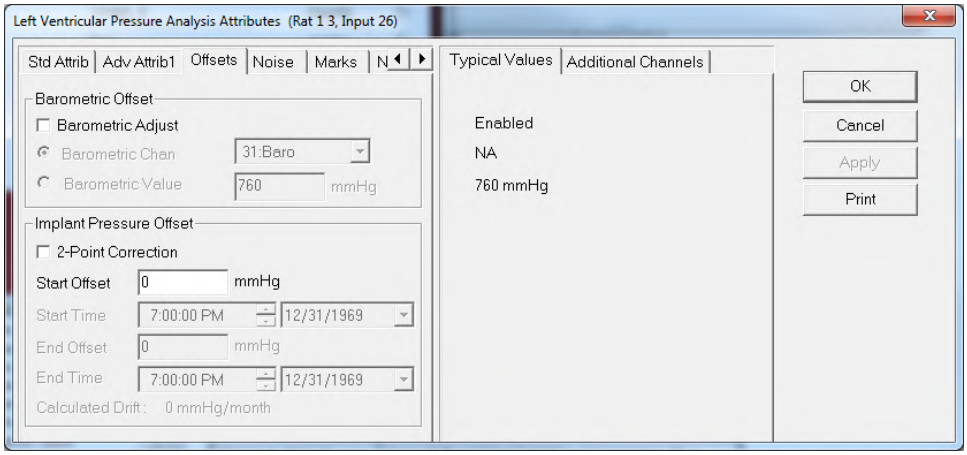
Ex: If sampling at 1000 Hz, the time between consecutive points is 1ms. By choosing a Derivative Window of 2ms, the derivative will be calculated across every other point.

**LVP End**

The LVP End attribute controls the placement of the LVP End Mark. The mark is placed at the point where the derivative signal rises by "LVP End" % of –dP/dtMAX.

## OFFSET TAB

The Offsets tab allows the designation of barometric channels, barometric values and implant offset values to be used for compensating pressures from the LVP analysis.




*Offsets tab*

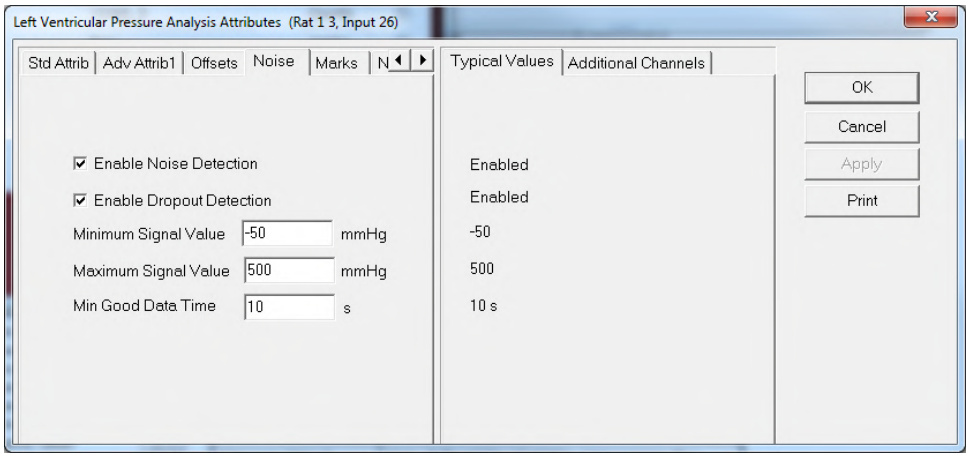
**Barometric Adjust**

This check box enables the correction for barometric pressure. This is used for certain telemetry systems that do not compensate for barometric pressure internally. The correction factor is applied by using a RAW channel as the input. The pressure offset is in kilopascals.

| | |
|---|---|
| **Barometric Chan** | This list box will display the available RAW inputs that could be used for the offset adjustment and is only used when the **Barometric Adjust** check box is enabled. |
| **Barometric Value** | User defined value that can be used to account for pressure offset when not continuously monitoring barometric pressure using the APR. |
| **2-Point Correction** | This check box allows for the correction of transmitter drift over a user defined period of time. |
| **Start Offset** | Allows the entry of an implant offset that will be used to adjust the pressure output of the analysis. This value is manually typed in by the user and can be used independently as a constant, static value over time or used in conjunction with the 2-Point Correction attributes. |
| **Start Time** | Start time and date that the 2-point correction for drift will be applied. |
| **End Offset** | Allows the entry of an end implant offset that will be used to adjust the pressure output of the analysis over a user specified range of time. 2-Point Pressure Offset is calculated as (End Offset – Start Offset)((End Date/Time – Start Date/Time).months) |
| **End Time** | End time and date that the 2-point correction for drift will be applied. |

## NOISE TAB

The **Noise Tab** contains attributes that are used to identify noisy data. On identifying "noisy" data, as defined by the user, **Bad Data Marks** will be placed to span the noisy sections.




*Noise tab*

**Enable Noise Detection** — Enables the **Noise Detection** attributes for the automatic placement of **Bad Data Marks**.

**Enable Dropout Detection** — If **Dropout Detection** is enabled, any negative dropout data encountered when analyzing data shall be bracketed **by Bad Data Marks** such that the dropout data falls within the **Bad Data Start** and **End** marks. The dropout check shall be performed on unfiltered samples.

**Minimum Signal Value** — User defined threshold for determining the minimum value for acceptable data. Data that falls below this threshold will be considered noise and bracketed by **Bad Data Marks**.

**Maximum Signal Value** — User defined threshold for determining the maximum value for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks**.

| | |
|---|---|
| **Minimum Good Data Time** | Provides the user the ability to mark data as bad between two **Bad Data Mark** regions. If the time between the regions is less than the value specified. If the time is less than what is specified, the **Bad Data Mark** region will appear as one contiguous segment. |

## MARKS (VALIDATION) TAB

The **Left Ventricular Pressure** analysis displays validation tick marks for each cardiac cycle. Each cardiac cycle should have only one set of validation marks. These marks verify that the system is analyzing the left ventricular pressure signal correctly. If there is more than one set of validation marks per cardiac cycle, correct the problem by changing the analysis attributes.

The validation marks and their meanings are listed below:

| Color | | Meaning |
|---|---|---|
| Black | | End Diastolic Point |
| Magenta | | +dP/dt |
| Blue | | Systolic Point |
| Green | | -dP/dt |
| Cyan | | % Recovery 1 |
| Red | | % Recovery 2 |
| Yellow | | LVP End |
| | | Mark Cycle Numbers |

## TYPICAL VALUES

Use these values as guidelines for a first time setup. Under different situations, values above or below the typical values will have to be used.

| Attribute | Setting | Units |
|---|---|---|
| Minimum Pulse Height | 5% of Pulse | mmHg |
| % Pressure Drop | 25% of Pulse | % |
| dP/dt A | 40 | mmHg |
| dP/dt B | 50 | mmHg |
| dP/dt C | 60 | mmHg |

| | | |
|---|---|---|
| dP/dt D | 70 | mmHg |
| Relaxation Time 1 | 60 | % |
| Relaxation Time 2 | 70 | % |
| Tau Duration | 40 | mSec |
| Tau Method | Pressure | NA |
| QA Trigger Channel | NA | NA |

## Derived Parameters

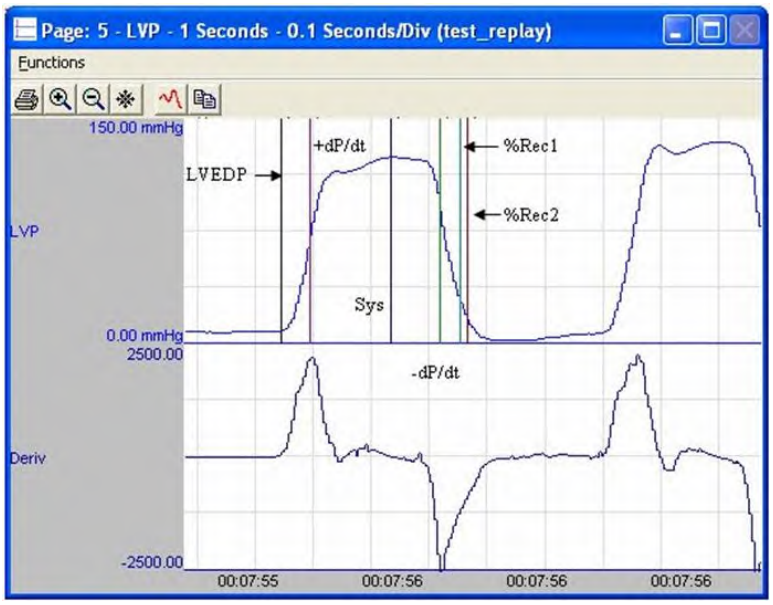
**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The derived parameters selected in this dialog box will be calculated, and the results will be placed in the **Derived Parameter List View(s)**. The following details the available **Derived Parameters** from the Left Ventricular Pressure module and the averaging method used within Review.

| Name | Definition | Averaging Method in Review |
|---|---|---|
| **Num** | The number of the cardiac cycle. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. | Recent |
| **Sys** | The systolic pressure is the maximum pressure that occurs during the cardiac cycle. | Mean |
| **LVEDP** | The left ventricular end diastolic pressure is the pressure at the last zero crossing of the differentiated pressure during the rise to the systolic period. | Mean |
| **Min** | The minimum pressure during the cardiac cycle. Not defined over a specific cycle. Min is calculated over the period of time that the logging period takes place. | Mean |
| **TTI** | Tension-Time Index is the area under the left ventricular pressure during the ejection phase of the contraction. This is the integration between the LVEDP point and -dP/dtMAX. | Mean |
| **DP** | Developed pressure is the difference between the systolic pressure and the left ventricular end diastolic pressure (SYS-LVEDP). | Mean |
| **HR** | The heart rate is computed in beats-per-minute. It is calculated by taking the reciprocal of the time interval for the cardiac cycle multiplied by 60. Note: When running in a logging rate other than 1 epoch, sum the cycles in seconds in the logging period, divide by the number of cycles, take the reciprocal, and multiply the value by 60. | Harmonic Mean |
| **+dP/dt** | +dP/dt is the maximum positive value of the first derivative of the pressure that occurs during the cardiac cycle. | Mean |
| **-dP/dt** | -dP/dt is the maximum negative value of the first derivative of the pressure that occurs during the cardiac cycle. | Mean |

| Name | Definition | Averaging Method in Review |
|---|---|---|
| **CI** | Contractility index is +dP/dt divided by the pressure at that point. | Mean |
| **RT1, RT2** | The Relaxation Time is the time period from -dP/dt to the time specified by the Relaxation Time attribute.<br>The time is reported in milliseconds. | Mean |
| **dP (A, B, C, and D)** | These parameters report the value of dP/dt at the pressure levels specified in dP/dt A, dP/dt B, dP/dt C, and dP/dt D (in the attributes window). These values will not be reported accurately if these pressure values are set too close to the Pressure Threshold Value (Minimum Pulse Height). The dP/dt (A, B, C, and D) pressure settings in the attribute dialog under the Std Attributes tab should at least be set to a value 20 units above that of the Minimum Pulse Height value. | Mean |
| **NPMN** | The non-pulsatile mean pressure reported for a logging period. This parameter is still reported even if no pulse pressure exists. | Mean |
| **Q-A** | The Q-A Interval is the time in milliseconds from the start of the Q-wave, in the ECG trigger channel, to the start of the systolic pressure rise (LVEDP) | Mean |
| **IVT** | The time in milliseconds from the start of the systolic pressure rise (LVEDP) to the maximum slope of the systolic pressure rise (+dP/dt) | Mean |
| **TTI-T** | LVEDP to -dP/dt. The time is in milliseconds. | Mean |
| **Tau** | Tau is the time constant isovolumic left ventricular pressure decay. It is reported in milliseconds, and can be defined as described in the Attributes window section. | Analysis |
| **Period** | The duration of the current cycle time, in milliseconds. | Mean |
| **EMw** | Time difference between the end of Systole and the end of ventricular relaxation and is calculated as QLVPend Interval - QT Interval | Mean |
| **Count** | This parameter will provide a total of the number of marked cycles within the defined logging period. This is different from the Num parameter which will simply list the last cycle within the logging period. | Sum |
| **SysD** | Systolic Duration. The time, in milliseconds, between the End Diastolic and the following LVP End validation marks. | Mean |
| **DiaD** | Diastolic Duration. The time, in milliseconds, between the LVP End validation mark and the following End Diastolic validation marks. | Mean |

## Online Screens and Functions

Below is a **Primary** graph displaying a typical left ventricular pressure signal with its digitally generated differential. The **Validation M**arks also are displayed on the waveform.




*Labeled LVP waveform*

## Presentation Signals

Below is a list of presentation signals that are available for the LVP Analysis Module:

| Signal | Description |
|---|---|
| **Pressure** | This is the original pressure signal after applying any software filters. |
| **Derivative** | This will display the derivative of the pressure signal. |
| **Heart Rate** | This will display the heart rate updated at every cardiac cycle. |
| **Difference** | This will display the difference between this input signal, and an input signal selected in the Advanced Attributes tab (other available pressure signals). The analysis module will subtract the current pressure signal from the signal selected from the list box and make the resulting signal available to be graphed. |

## Data Review

This is a list of the Data Review related features of the Left Ventricular Pressure Analysis Module. The analysis specific portion of Data Review centers on the marks that the user is permitted to display, insert, and delete and how the user is permitted to move them.

**Displaying Marks and Cycle Numbers**

The marks and cycle numbers displayed in a Review window channel are controlled through the Marks Tab in the attribute dialog accessed via the Analyze selection in the Right click menu.

**Mark Operations**

Left Ventricular Pressure marks are divided into two types, marks that always exist when a valid cycle is found (End Diastolic, Systolic, Max Slope, Min Slope) and marks that may or may not exist, depending on the signal morphology (Recovery 1, Recovery 2).

**Inserting Marks**

Marks are inserted by right clicking at the point of insertion in the Review window. The pop-up menu that is displayed will provide the option to insert marks as appropriate. The list of marks available for insertion will depend on the marks adjacent to the point of insertion; signal morphology is not considered.

**Insert LVP Cycle**

Inserts an entire Left Ventricular Pressure cycle: End Diastolic, Systolic, Max Slope, Min Slope, LVP End, and Recoveries, if applicable. This set of marks may be inserted between the second Recovery Mark and an End Diastolic Mark. If a Recovery Mark is not present, the cycle may be inserted between a Min Slope Mark and an End Diastolic Mark. When a Left Ventricular Pressure cycle is inserted, it is assigned a sequential cycle number and subsequent cycle numbers are incremented.

**Deleting Marks**

Marks are deleted by positioning the mouse cursor on the mark to be deleted and bringing up the right click menu. A Left Ventricular Pressure cycle's marks cannot be deleted individually. They are linked to the Systolic Mark. To delete these marks, the entire cycle must be deleted; the cursor is positioned on the Systolic Mark and the right mouse button is clicked to delete the marks. One of the selections in the pop-up menu will permit deletion of all the marks in the cycle.

**Moving Marks**

Moving of the End Diastolic, Systolic, Max Slope, Min Slope, and LVP End marks follow the standard rules used in Data Review. The Recovery marks are calculated marks; their positions are dependent on the Min Slope value and cannot be adjusted by the user. If the user changes the position of the Min Slope Mark, the Recovery marks will be recalculated.

The Min Slope Mark may be moved past the Recovery marks.

**Calculations**

The calculations of derived parameters are identical to those performed during acquisition, with the exception of Min. For non-pulsatile parameters, the start point is the point after the previous log time. The end point is the point at which the line is logged.

In Review the Min parameter is calculated between the Min Slope mark and the following cycle's LVEDP mark.

**Logging Mark**

The logging mark for a Left Ventricular Pressure cycle is the Systolic Mark. The time at the logging mark is the time used to report a cycle's derived data. If an LVP cycle's logging mark falls within a logging interval, the LVP cycle's data will be included in the logging interval.

**End of Cycle**

The end of an LVP cycle occurs one nanosecond prior to the next cycles LVEDP mark. For the last cycle in a data segment, the logging time +1 nanosecond is used.

When LVP and ECG data are brought into Review, the ECG channel should be used as the epoch channel to ensure that related cycles are kept together.

## ATTRIBUTES IN REVIEW

The following table describes the effects of changing LVP attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| **Attribute** | **Effect On Review** |
|---|---|
| Minimum Pulse Height | Signal Interpretation |
| % Pressure Drop | Signal Interpretation |
| Relaxation Time 1 | Calculation, Redraw |
| Relaxation Time 2 | Calculation, Redraw |
| dP/dt A | Calculation |
| dP/dt B | Calculation |
| dP/dt C | Calculation |
| dP/dt D | Calculation |
| QA Trigger Channel | Calculation |
| Tau Duration | Calculation |
| Tau Method | Calculation |
| High Pass Filter | Signal Conditioning, Calculation, Redraw |

| | |
|---|---|
| Low Pass Filter | Signal Conditioning, Calculation, Redraw |
| Diff Pressure Chan | Signal Conditioning, Calculation, Redraw |
| Maximum Heart Rate | Signal Interpretation |
| Derivative Window | Signal Conditioning, Calculation, Redraw |
| LVP End | Signal Interpretation |
| Barometric Adjust | Signal Conditioning, Calculation, Redraw |
| Barometric Channel | Signal Conditioning, Calculation, Redraw |
| Barometric Value | Signal Conditioning, Calculation, Redraw |
| 2-Point Correction | Signal Conditioning, Calculation, Redraw |
| Start Offset | Signal Conditioning, Calculation, Redraw |
| Start Time | Signal Conditioning, Calculation, Redraw |
| End Offset | Signal Conditioning, Calculation, Redraw |
| End Time | Signal Conditioning, Calculation, Redraw |
| Marks and cycle numbers | Redraw |
| Precision | Precision |

## Troubleshooting

Use the following table to assist in troubleshooting the analysis:

| **Problem** | **Solution** |
|---|---|
| Heart Rate is doubled | The analysis is triggering on an artifact. Increase the Minimum Pulse Height and/or the % Pressure Drop. Refer to the chart of Typical Analysis Attribute Settings for typical values. |
| All Derived Parameters are reporting zero | The Minimum Pulse Height may be set too high for the specified signal. Lower the Minimum Pulse Height. |
| Heart Rate is out of range (very high) | The analysis may be triggering on noise. The two solutions for this are:<br><br>Increase the Minimum Pulse Height to a value of 10% of pulse pressure.<br><br>Increase the Low Pass Filter (in the Adv Attrib1 tab) to eliminate noise on the signal. Select a lower value in the list box. |

| | |
|---|---|
| Tau is negative or very large | The method being used to calculate Tau influences the values that are reported. When the **Pressure vs. Time** method is used, this field may report values that do not exist. This occurs when the pressure goes to zero, because the natural log of zero is undefined and the system will return an infinite value for this reading. If this occurs, use another method for Tau. |
| "x" in **Derived Parameter List View** window instead of a number | The derived number is too large for the field. An "x" was placed here, so that a truncated number would not be displayed. |
| Cannot find the analysis module in the Input Setup dialog | The analysis module is likely not enabled in the Ponemah License. Check License options via **Help \| View License**. |
| Algorithm does not trigger (No marks) | Reduce the sample rate to 250Hz, or increase the **Low Pass Filter** in the **Adv Attrib1** tab. Select a lower value in the list box. |

## Electrocardiogram (ECG)

The **Electrocardiogram** analysis module analyzes ECG complexes. The analysis calculates **Derived Parameters** from the input signal on a beat-to-beat basis.

### COMPATIBILITY

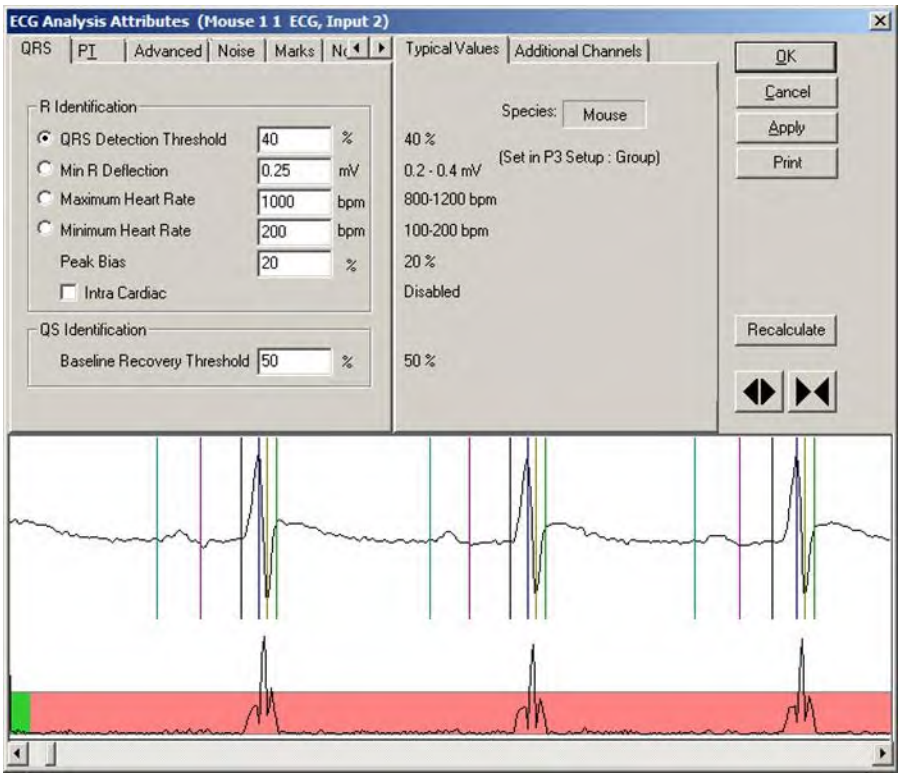
- Cross-channel calculations for QA-Interval and Electromechanical window (EMw) are only available in Review**.**

### SEGMENT BASED ANALYSIS

- The ECG signal is divided into discrete QRS Segments for the purpose of analysis. The use of segments when analyzing an ECG signal permits establishing a context for QRS identification based on adjacent data. Use of segments also ensures uniformity between results displayed in the Attribute Dialog box and results in the primary graph page
- QRS Segment boundaries may be observed in the attribute dialog box when graphically modifying the QRS Detection Threshold Attribute.
- Noise spikes in the ECG signal may affect the identification of cycles within the affected segment, but adjacent segments will not be affected.

## Attributes Dialog

The **ECG Analysis Attributes** dialog allows you to modify the signal analysis for different types of ECG signals and signal conditions. If an analysis change in the **Attributes** dialog is performed mid-cycle, then the attribute change will not take effect until the following cycle.



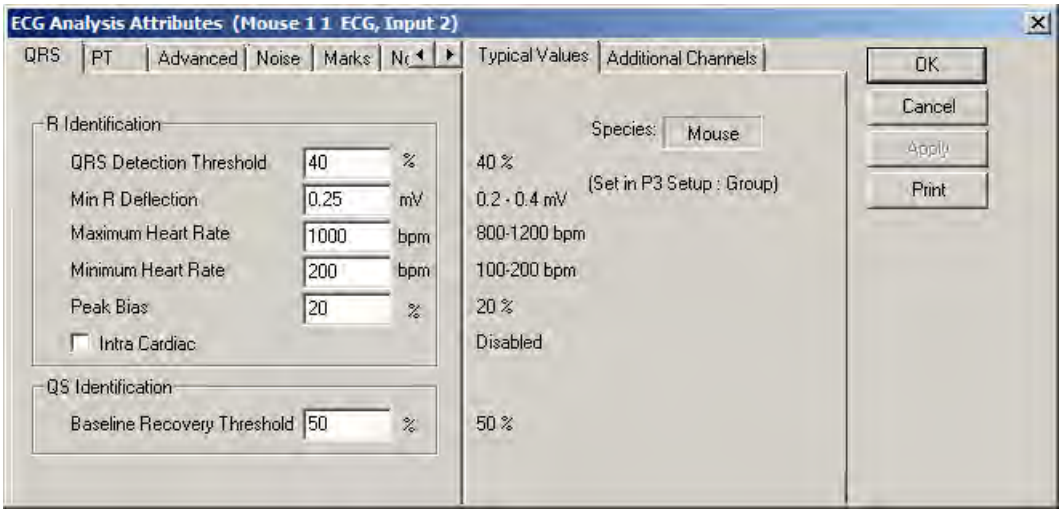

*Attributes Dialog Window. The first complex is displayed in gray, the second complex is displayed in black.*

## WAVEFORM WINDOW

- The Waveform Window contains a portion of the ECG signal with validations marks visible to indicate the analysis module is triggering properly. This window is only present during an active Acquisition or Review session and is not present during Experiment configuration while in Configuration mode.
- If the data point located at the left edge of the Waveform Window coincides with a QRS Segment boundary, the time point at the left edge of the signal will match the time point at the left edge of the Primary graph page from which the ECG Analysis Attribute dialog was invoked.
- If this data does not coincide with a QRS or Data Segment boundary, additional data will be pulled into the Waveform Window prior to the time associated with the left edge of the Primary graph page to complete the partial QRS segment and provide the full context for analysis of that segment. This additional data is displayed in gray to distinguish it from the visible portion of the waveform as seen in the Primary graph page which is displayed in black. This section may be seen by scrolling the Waveform Window to the left.

## QRS ATTRIBUTES TAB

The QRS attributes allow setting the most common attributes used to detect the QRS complex.




*QRS Attributes Tab*

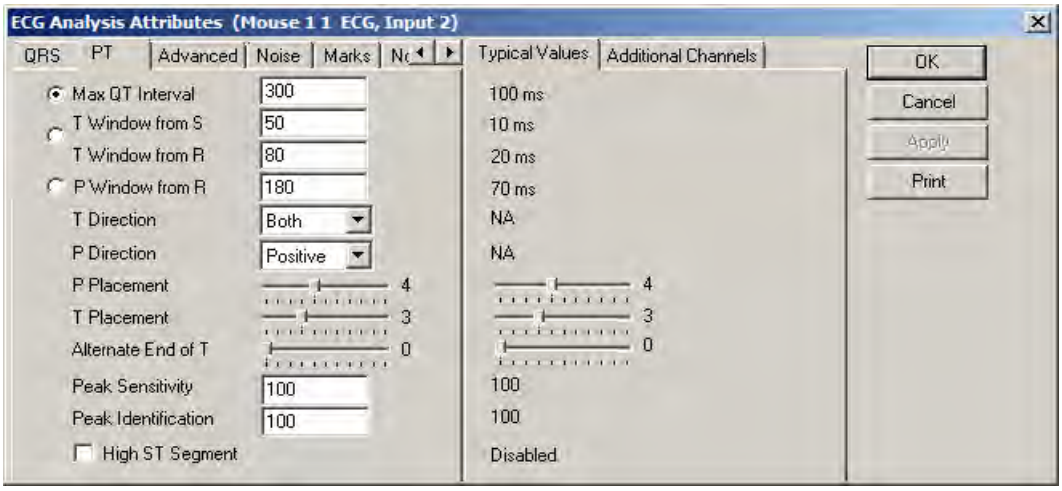
| | |
|---|---|
| **QRS Detection Threshold** | A. The QRS detection threshold is used to calculate the threshold for identifying potential Rs from the rectified derivative signal<br>B. The % entered is applied to the largest derivative peak in a QRS segment that results in potential Rs that satisfy Minimum Heart rate criteria.<br>C. A high minimum heart rate may result in the analysis unnecessarily searching for potential Rs<br>D. Decreasing the minimum heart rate attribute to cover the longest anticipated RR will prevent unexpected lowering<br>E. Attribute Dialog<br>o Two signals are displayed, the ECG signal and the rectified derivative of the smoothed ECG.<br>o The derivative peak used to calculate the height of the pink region is marked in green. There will be one green cycle per QRS segment<br>o When adjusting the pink region, the attribute is set relative to the height of the green derivative peak<br>o The goal is to place the top of the pink box such that it only intersects valid derivative peaks.<br>F. **Tip:** Setting the QRS Detection Threshold<br>o **Too Low** – analysis will be inefficient, investigating more derivative peaks than necessary. It is likely that some erroneous peaks will be identified<br>o **Too High** – Some QRSs will be missed especially in the case of higher heart rate data (i.e. HR > Min HR |
| **Min R Deflection** | • The QRS amplitude change in the smoothed ECG* must exceed this value for the complex to be recognized. This is based on max/min signal value, and does not depend on the iso-electric level<br>• Attribute Dialog |

| | |
|---|---|
| | ○ The displayed signal is the smoothed ECG signal<br>○ The pink adjustment boxes will be anchored to the lowest point for positive complexes and vice versa<br>○ This attribute should be set above the noise level but lower than the smallest anticipated QRS<br>• Tip: Setting the Min R Deflection<br>○ **Too Low** – The analysis may mark noise<br>○ **Too high** – The analysis may miss valid Rs<br><br>* The QRS Smoothing Filter attribute is used to decrease the influence of noise when searching for ECG complexes. The resultant smoothed signal is used internally for QRS identification, not for reporting of derived data. |
| **Maximum Heart Rate** | The Maximum Heart Rate attribute should be set higher than the maximum expected heart rate. The analysis will disregard Rs that result in a heart rate higher than the Max Heart Rate attribute.<br><br>• The value for Maximum Heart Rate must be greater than value entered for the Minimum Heart Rate<br>• Attribute Dialog<br>○ The displayed signal is the ECG signal<br>○ The pink region represents the time interval corresponding to the max heart rate<br>• **Tip:** Setting the Maximum Heart Rate<br>○ **Too Low** – QRSs will be missed<br>○ **Too high** – Noisy cycles have a greater chance of getting marked. |
| **Minimum Heart Rate** | This attribute is used by the analysis to determine when it should search for missing QRS complexes. The Minimum Heart Rate attribute does not represent a hard cutoff like the Maximum Heart Rate attribute and there may be situations where it should be set higher than the lowest heart rate.<br><br>• The Minimum Heart Rate attribute should be set close to the lowest anticipated heart rate.<br>• **Tip:** Setting the Minimum Heart Rate<br>○ **Too Low** – Rs may be missed in noisy areas<br>○ **Too high** – Analysis efficiency will decrease due to unnecessary searches for QRS. |

| | |
|---|---|
| **Peak Bias** | The Peak Bias is used to influence the marking positive or negative Rs. A positive Peak Bias favors positive Rs, a negative Peak Bias favors negative Rs. |
| **Intra Cardiac** | This checkbox is used to enable processing of ECG signals which exhibit rapid changes in the P wave such that the derivative of the P wave exceeds the QRS derivative. Enabling this check box prevents the analysis from marking the P wave as the R wave.<br><br>When enabled, potential QRSs that are followed by potential QRSs within the interval specified by the P window from R attribute, will not be marked as a QRS, instead the following QRS will be marked.<br><br>*WARNING*: If the Intra Cardiac setting is enabled, it is important to correctly set the P Window from R setting. If the P Window from R is set too large or too small, the analysis may mis-trigger. For example, if the P Window from R is too small, the analysis may mark some of the P waves as R waves. If the P Window from R is too large, the P wave may be marked where the T wave of the previous cycle is located. |
| **Baseline Recovery Threshold** | When a disturbance is seen on the leading or lagging edge of the R wave, the analysis may mark the Q or S wave at the point of the disturbance. This attribute may be used to prevent the analysis from looking for the Q or S wave until after the disturbance.<br><br>The number in the edit field represents the percentage of the leading edge of the R wave by which the signal must return (from the R peak) before the analysis will look for the Q or S wave.<br>• If this value is set to 0 (default), the analysis will start looking for the Q or S wave from the level of the R peak.<br>• If this value is set to 70, the signal will have to recover by 70% of the R height before the analysis starts looking for the Q or S wave. |

## PT ATTRIBUTES TAB

This tab contains attributes that affect affecting the detection of the P & T waves.




*PT Attributes Tab*

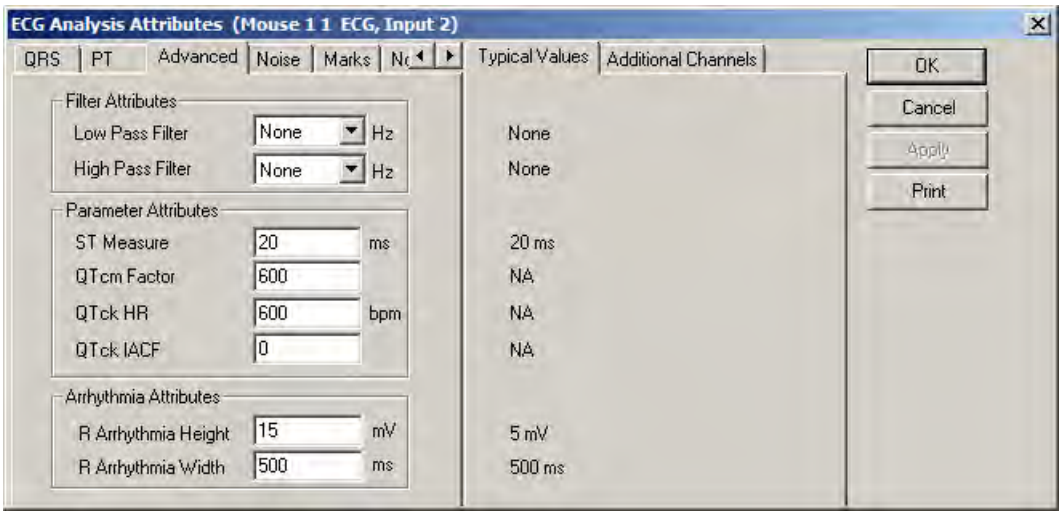
| | |
|---|---|
| **Max QT Interval** | After the analysis has determined the location of the end of the T wave, it will accept it as a valid end of T provided the QT interval (measured from the beginning of the Q wave to the end of the T wave) does not exceed the Max QT Interval. |
| **T Window from S \ T Window from R** | These two parameters define the region in which the analysis will look for an end of T. The analysis will scan the portion of the signal to the right of the T Window from S and to the left of the T window from R. T Window from S uses S end. |
| **P Window from R** | Defines the region where the analysis will look for the beginning of the P wave. |
| **T Direction** | This attribute directs the analysis to look for a T wave that is either "exclusively":<br>• Positive<br>• Negative<br>• Both (either positive, negative, or bi-directional). |

| | |
|---|---|
| | In most cases a setting of **Both** should work, and the analysis will determine the nature of the T wave. Positive and Negative settings may be used to help the analysis along when dealing with troublesome data. |
| **P Direction** | This attribute directs the analysis to look for a P wave that is either "exclusively":<br>• Positive<br>• Negative<br>• Both (either positive, negative, or bi-directional).<br><br>In most cases a setting of **Both** should work, and the analysis will determine the nature of the P wave. Positive and Negative settings may be used to help the analysis along when dealing with troublesome data. |
| **P Placement** | This attribute permits the user to shift the P mark towards the peak or away from the peak of the P wave.<br><br>A lower value (slider towards the left) moves the P mark away from the peak. The effect of this attribute is more pronounced on P waves that exhibit a gradual rise from the baseline. |
| **T Placement** | This attribute permits the user to shift the T mark towards the peak or away from the peak of the T wave.<br><br>A lower value (slider towards the left) moves the T mark away from the peak. The effect of this attribute is more pronounced on T waves that exhibit a gradual return to the baseline. |
| **Alternate End of T** | The alternate end of T attribute permits the algorithm to search beyond the first potential end of T for another end of T further in the complex.<br>• A lower value (slider towards the left) causes the analysis to select the first end of T that it finds.<br>• A higher value (slider towards the right), utilizes a more aggressive search for an alternate end of T.<br><br>This attribute is useful when dealing with complexes in which the T wave, after the peak, does not return to the baseline smoothly, but shows a second peak. |
| **Peak Sensitivity** | Peak Sensitivity controls the elimination of small peaks when identifying T and P peaks. This parameter should be used in conjunction with **Peak Identification.** |

| | |
|---|---|
| | When dealing with extremely small P or T waves, the analysis may not identify the end of T or beginning of P, in such cases, the Peak Sensitivity attribute may help in correctly validating the signal.<br><br>The default sensitivity level is 100:<br>• Reducing this attribute permits greater sensitivity with 0 being maximum sensitivity<br>• Adjust this parameter in steps of 25. |
| **Peak Identification** | Peak Identification controls the thresholds used to identify potential T and P peaks. If small peaks are not identified, **Peak Sensitivity** should be lowered. If the problem persists after Peak Sensitivity is lowered to 0, Peak Identification should be lowered as well. |
| **High ST Segment** | This attribute may be used in the case of a signal in which the T wave runs into the QRS complex resulting in a high ST segment. This attribute should be enabled only if the analysis is incorrectly marking the T wave.<br><br>The default sensitivity level is 100:<br>• Reducing this attribute permits greater sensitivity with 0 being maximum sensitivity<br>• Adjust this parameter in steps of 25. |

## ADVANCED ATTRIBUTES TAB

The Advanced tab allows the selection of attributes that would less likely need to be changed during Acquisition or Review.



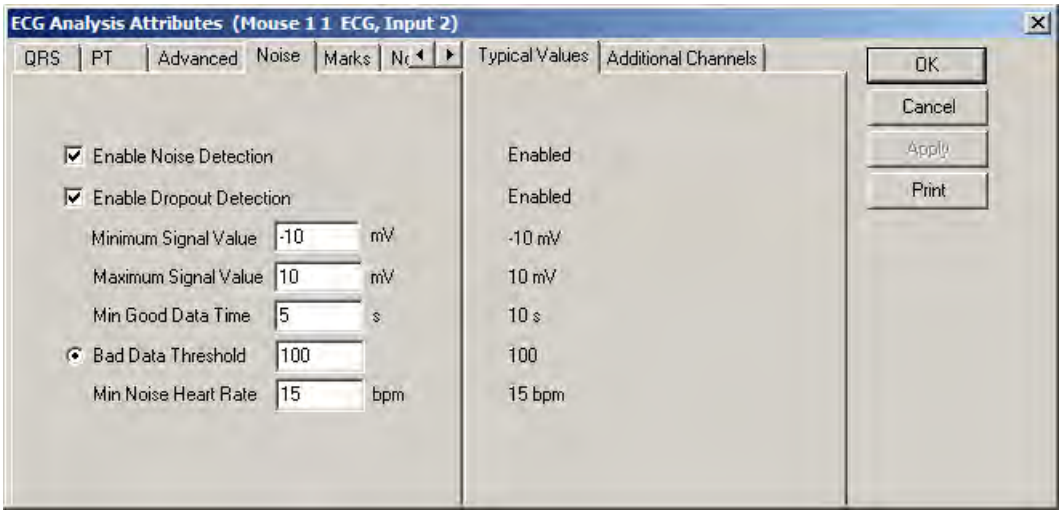

*Advanced Tab*

| | |
|---|---|
| **Filter Attributes** | **Low Pass Filter**: Selection of Low Pass filter in hertz. |

| | |
|---|---|
| | **High Pass Filter**: Selection of High pass filter in hertz.<br>1. Click on the drop-down button to access the filter choices<br>2. Select a value for the filter<br>3. Click **Apply** |
| **Parameter Attributes** | **ST Measure**: The number of milliseconds after the end of the S wave, at which the ST elevation is measured. The default value is 10.<br><br>**QT cm Factor**: Matsunaga correction factor. This sets the RR value in ms. used in the correction factor. This default value is based on a HR of 100 beats per minute.<br><br>**QTck HR**: King correction factor for HR. Used in the calculation of QTck.<br><br>**QTck IACF**: Individual animal correction factor (King) used in calculating QTck. |
| **Arrhythmia Attributes** | **R Arrhythmia Height:** If the peak of the R wave, measured from the Iso-electric level, exceeds this value, this beat will be marked invalid.<br><br>**R Arrhythmia Width:** If the width of the signal from the beginning of the Q wave to the beginning of the S wave exceeds the R Arrhythmia Width, the associated beat will be marked invalid. |

## NOISE TAB

The **Noise Tab** contains attributes that are used to identify noisy data. On identifying "noisy" data, as defined by the user, **Bad Data Marks** will be placed to span the noisy sections.

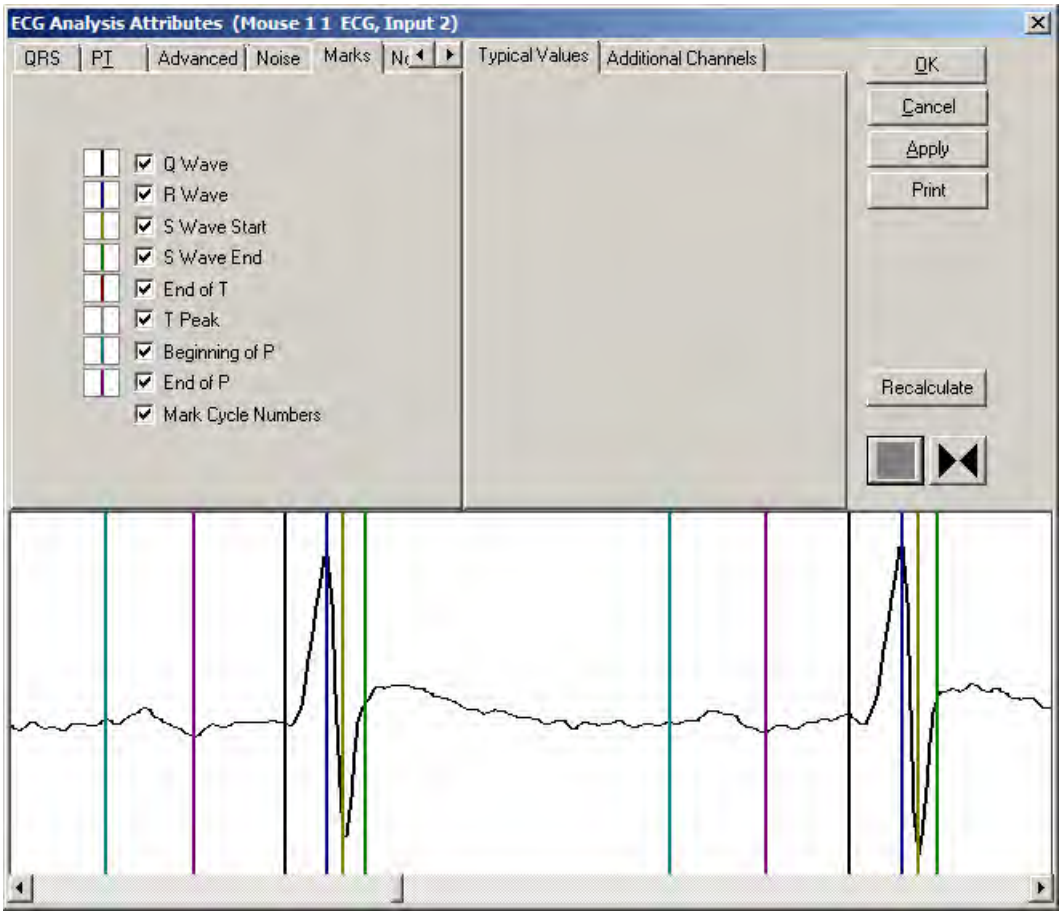



*Noise tab*

| | |
|---|---|
| **Enable Noise Detection** | Enables the **Noise Detection** attributes for the automatic placement of **Bad Data Marks**. |
| **Enable Dropout Detection** | Enabling this function places **Bad Data Marks** around data that is defined as dropout. |
| **Minimum Signal Value** | User defined threshold for determining the minimum value for acceptable data. Data that falls below this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Maximum Signal Value** | User defined threshold for determining the maximum value for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Min Good Data Time** | Provides the user the ability to mark data as bad between two **Bad Data Mark** regions. If the time between the regions is less than the value specified. If the time is less than what is specified, the **Bad Data Mark** region will appear as one contiguous segment. |
| **Bad Data Threshold** | This edit box specifies a noise level. When the level set in this box is exceeded, the data will be interpreted as noise and **Bad Data Marks** will be inserted to remove the section of data from analysis. |
| **Min Noise Heart Rate** | Heart rates detected by the analysis that fall below the level specified will be treated as noise and **Bad Data Marks** will be inserted to remove the data from analysis. |

### MARKS (VALIDATION) TAB

The **ECG** analysis displays validation tick marks for each cardiac cycle. Each cardiac cycle should have only one set of validation marks. These marks verify that the system is analyzing the left ventricular pressure signal correctly. If there is more than one set of validation marks per cardiac cycle, correct the problem by changing the analysis attributes.




*Marks tab*

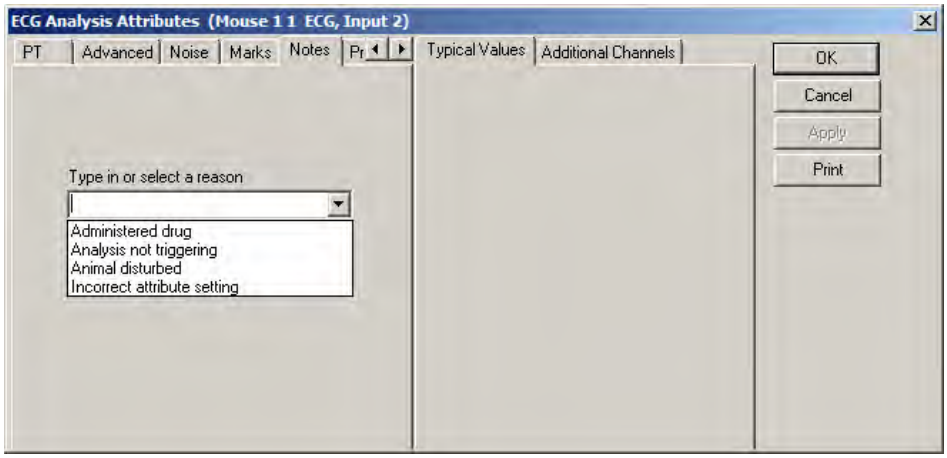
The validation marks and their meanings are listed below:

| **Color** | | **Meaning** |
|---|---|---|
| Black | | Q Wave |
| Blue | | R Wave |
| Yellow | | S Wave Start |
| Green | | S Wave End |
| Red | | End of T |
| Gray | | T Peak |
| Cyan | | Beginning of P |
| Magenta | | End of P |
| | | Mark Cycle Numbers |

## NOTES TAB

The Notes tab allows the user to enter a note for the change that has occurred.

The user can either select one of the predefined reasons or enter a text message. This entry is then inserted into the experimental log file along with the user who made the change and the time that the note was entered.




*Notes tab*

## PRECISION TAB

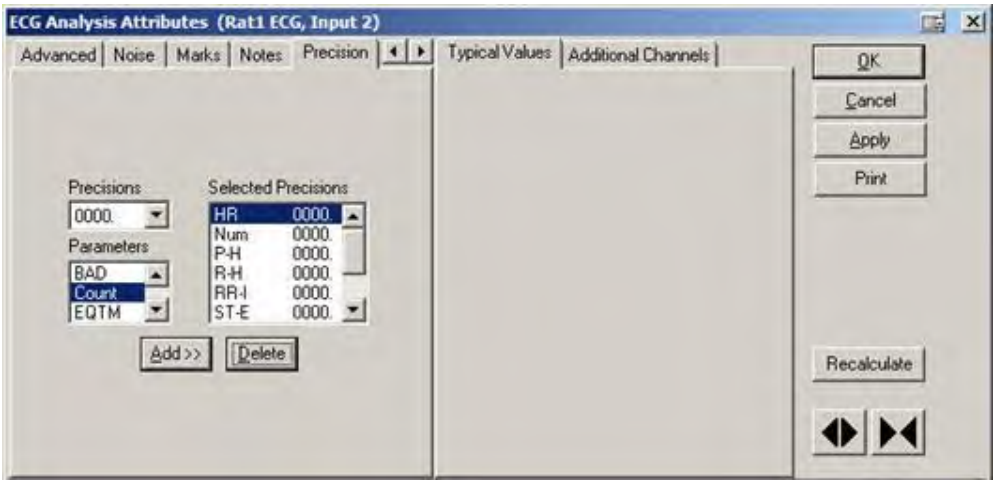
The Precision tab allows the user to define the precision at which each derived parameters will be reported.

Add items to the list of Selected Precisions:

1. Select the parameter from the Parameters list
2. Select the precision from the dropdown list for that particular parameter
3. Click the Add button to have that parameter added to the list of Selected Precisions

Delete items from the list of Selected Precisions:

1. Select a line item from the **Selected Precisions** list
2. Click **Delete**



### TYPICAL VALUES

The table contains typical values for different heart rates based on species selection in the PONEMAH Setup Group Tab. Selection of a species will automatically update these values in the attributes dialog. When using a species other than those listed, choose a species designation based on similar HR. Use these values as guidelines for a first time setup. Under different situations, values above or below the typical values will have to be used.

| **Attributes tab** | **Typical Value-Dog, Minipig, Sheep, Swine**<br><br>**HR=40-200** | **Typical Value-Monkey**<br><br>**HR=120-180** | **Typical Value-Ferret, Guinea Pig, Rabbit, Rat**<br><br>**HR=300-480** | **Typical Value-Hamster, Mouse**<br><br>**HR=400-600** |
|---|---|---|---|---|
| **QRS tab** | | | | |
| QRS Detection Threshold | 40% | 40% | 40% | 40% |
| Min R Deflection | 0.2-0.4 mV | 0.2-0.4 mV | 0.2-0.4 mV | 0.2-0.4 mV |
| Maximum Heart Rate | 200-400 bpm | 200-400 bpm | 800-1200 bpm | 800-1200 bpm |
| Minimum Heart Rate | 10-30 bpm | 30-100 bpm | 50-150 bpm | 100–200 bpm |
| Peak Bias | 20% | 20% | 20% | 20% |
| Baseline Recovery Threshold | 50% | 50% | 50% | 50% |
| **PT tab** | | | | |
| Max QT Interval | 300mSec | 300mSec | 150mSec | 100mSec |
| T Window from S | 50mSec | 50mSec | 25mSec | 10mSec |
| P Window from R | 180mSec | 180mSec | 100mSec | 70mSec |
| **Advanced tab** | | | | |
| ST Measure | 20mSec | 20mSec | 20mSec | 20mSec |

## Derived Parameters

**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The derived parameters selected in this dialog box will be calculated, and the results will be placed in the **Derived Parameter List View(s)**. The following details the available **Derived Parameters** from the ECG module and the averaging method used within Review.

| Name | Definition | Averaging in Review |
|---|---|---|
| **Num** | The number of the cardiac cycle. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. The cycle number may be used to correlate a line of derived data to the graphical display of numbered ECG cycles. | Recent |
| **RR-I** | Time interval in milliseconds from one R wave to the next R wave. | Mean |
| **HR** | The heart rate is computed in beats-per-minute and is the reciprocal of the RR-I for the cardiac cycle multiplied by 60. Note: When running in a logging rate other than 1 epoch, sum the cycles in seconds in the logging period, divide by the number of cycles, take the reciprocal, and multiply the value by 60. | Harmonic Mean |
| **R-H** | Height of the R wave from the Iso-electric level, in millivolts. | Mean |
| **P-H** | Height of the P wave from the Iso-electric level, in millivolts. | Mean |
| **T-H** | Highest point between the end of the S wave and the end of the T wave relative to the Iso-electric point. | Mean |
| **T-HN** | Lowest point between the end of the S wave and the end of the T wave relative to the Iso-electric point. | Mean |
| **ST-I** | Time interval in milliseconds from the S wave to end of the following T wave. | Mean |
| **ST-E** | The ST elevation, measured “ST Measure” milliseconds after the S wave, from the Iso-electric level. | Mean |
| **QRS** | Time interval of the QRS complex, from the Q wave to the S wave, measured in milliseconds. | Mean |
| **PR-I** | PR interval measured from the start of the P wave to the beginning of the Q wave, in milliseconds. | Mean |
| **QT-I** | QT interval measured from the Q wave to the end of the following T wave, in milliseconds | Mean |
| **QAT** | Q Alpha T is the time interval from the Q wave to the peak of the following T wave in milliseconds. | Mean |
| **QTcb** | The corrected QT interval, using Bazett’s method. Computed as the QT interval divided by the square root of the RR-I in seconds. The corrected QT is reported in milliseconds.<br><br>When running in a multiple epoch logging rate, or second logging rate, the averaged value will be calculated off of the averaged RR-I value | Analysis |
| **QTcf** | The corrected QT interval, using Fridericia’s method. Computed as the QT interval divided by the cube root of the RR-I in seconds. The corrected QT is reported in milliseconds. | Analysis |

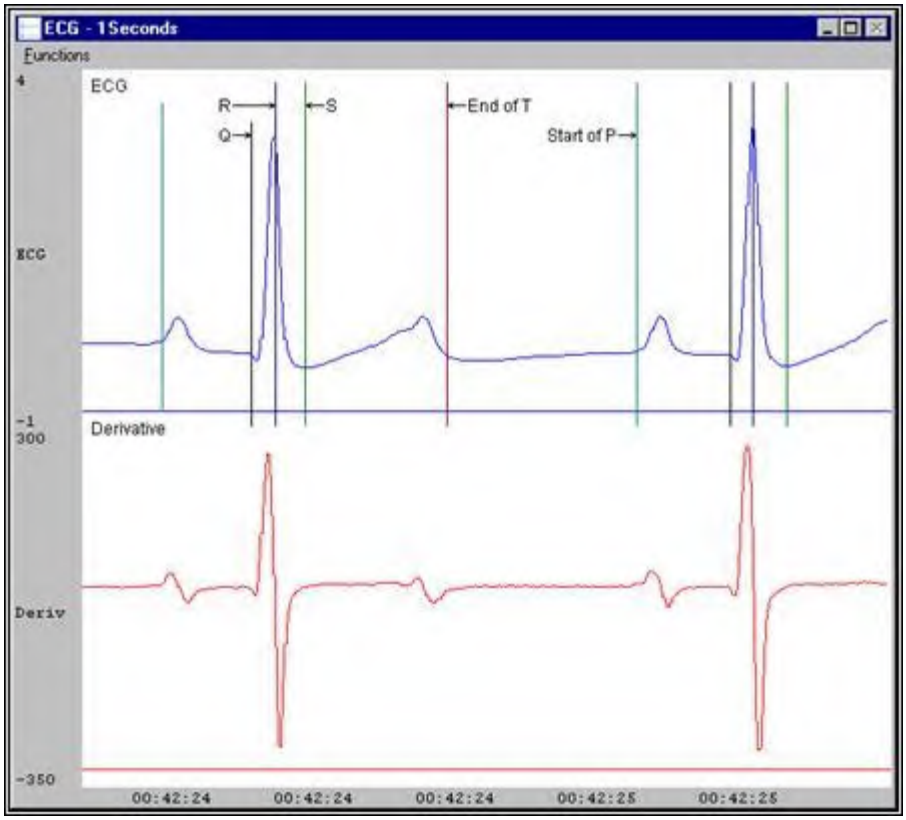
| Name | Definition | Averaging in Review |
|---|---|---|
| | When running in a multiple epoch logging rate, or second logging rate, the averaged value will be calculated off of the averaged RR-I value. | |
| **QTcv** | The corrected QT interval, using Van de Water's method. Computed as: QT Interval – 0.087 (RR Interval – 1)Where the RR Interval and the QT Interval are in seconds. The resultant corrected QT is reported in milliseconds.<br><br>When running in a multiple epoch logging rate, or second logging rate, the averaged value will be calculated off of the averaged RR-I value. | Analysis |
| **EQTS** | Extended QT in a single lead. The longest QT interval in any of the recorded leads in a single group. | Mean |
| **EQTSc** | The channel from which the longest QT Interval was obtained, in the current group. This is the channel from which the EQTS parameter was reported. Note: When running in a logging mode other than 1 epoch, the averaged value will be reported as the channel that was reported most in the logging period. A 'tie' of two or more channels will report the lowest numbered channel. | Max Times |
| **EQTM** | Extended QT for multileads. The QT Interval measured from the first occurrence of the Q wave to the last occurrence of the T wave across all recorded leads in a single group. | Mean |
| **EQTMcs** | The channel from which the first Q was found, in the current group. This is the Q used to report the EQTM parameter. Note: When running in a logging mode other than 1 epoch, the averaged value will be reported as the channel that was reported most in the logging period. A 'tie' of two or more channels will report the lowest numbered channel. | Max Times |
| **EQTMce** | The channel from which the last T was found, in the current group. This is the T used to report the EQTM parameter. Note: When running in a logging mode other than 1 epoch, the averaged value will be reported as the channel that was reported most in the logging period. A 'tie' of two or more channels will report the lowest numbered channel. | Max Times |
| **QTD** | QT Dispersion, which is the longest QT interval measured in any recorded lead minus the shortest QT measure in any recorded lead in a single group. | Mean |
| **QTMc** | The channel from which the shortest QT interval was found, in the current group. Note: When running in a logging mode other than 1 epoch, the averaged value will be reported as the channel that was reported most in the logging period. A 'tie' of two or more channels will report the lowest numbered channel. | Max Times |
| **QR-I** | QR interval measured from the Q wave to the following R wave, in milliseconds | Mean |
| **QRSA** | QR amplitude in the lowest point on the Q wave to the peak of the R wave. This is calculated as R wave value minus the lowest point between the Q and R marks. | Mean |
| **MxdV** | Maximum derivative of the R wave. | Mean |
| **T-A** | Area of the T wave from the Iso-electric level calculated from the S end mark to the point prior to the T end mark. | Mean |

| Name | Definition | Averaging in Review |
|---|---|---|
| | | |
| **PCt** | The number of valid P waves encountered in the logging period. Note: When running in a logging mode other than 1 epoch, the averaged value will be the number of counts over the logging period. | Sum |
| **TCt** | The number of valid T waves encountered in the logging period.<br><br>Note: When running in a logging mode other than 1 epoch, the averaged value will be the number of counts over the logging period. | Sum |
| **QTCt** | QT count, the number of channels in a group from which the EQTS, EQTM, and QTD parameters are calculated. Note: When running in a logging mode other than 1 epoch, the averaged value will be the smallest number obtained from the lines of data that are used. | Min |
| **BAD** | The number of arrhythmic beats detected during a specified logging period. This counter does not count missing T waves as BAD. Note: When running in a logging mode other than 1 epoch, the averaged value will be the number of counts over the logging period. | Sum |
| **GW** | The Good Wave counter counts the total number of complete complexes detected during the logging period. A complex is considered to be complete when the Q, P, and T waves are detected. Note: When running in a logging mode other than 1 epoch, the averaged value will be the number of counts over the logging period. | Sum |
| **TW** | The total number of good and bad complexes that were detected during a logging period. The sum of the BAD and GW does not necessarily equal the TW, since the system can analyze a complex even if there are no end of T waves detected. Note: When running in a logging mode other than 1 epoch, the averaged value will be the number of counts over the logging period. | Sum |
| **QATN** | Reports the time, in milliseconds, between the Q wave and the lowest point between the end of S and the end of T wave. | Mean |
| **PWdth (Pwidth)** | Reports the time, in milliseconds, between the start and end of the P wave. | Mean |
| **Tpe-I** | This parameter reports the time in milliseconds between the peak of the T wave and the end of the T wave. The peak of the T is identified as the greatest deflection from the Iso-electric level between the end of S and the End of T and is marked with the T peak mark. | Mean |
| **T-P** | his parameter reports the time in milliseconds between the peak of the T wave and the end of the T wave. The peak of the T is identified as the greatest deflection from the Iso-electric level between the end of S and the End of T and is marked with the T peak mark. | Mean |
| **Match** | Used specifically with Template Analysis. Reports the percentage of cycles that match a template in a given logging period | Mean |
| **Pmatch** | Used specifically with Template Analysis. Reports the average degree of match for the P Region for cycles within the logging interval. | Mean |

| Name | Definition | Averaging in Review |
|---|---|---|
| **Qmatch** | Used specifically with Template Analysis. Reports the average degree of match for the Q Region for cycles within the logging interval. | Mean |
| **Smatch** | Used specifically with Template Analysis. Reports the average degree of match for the S Region for cycles within the logging interval. | Mean |
| **Tmatch** | Used specifically with Template Analysis. Reports the average degree of match for the T Region for cycles within the logging interval. | Mean |
| **Noise** | This parameter reports an approximation of the noise level in the ECG cycle. The value reported is the RMS value of the derivative between the 2 R marks after excluding the following regions:<br>• 10% of the signal following the start R mark<br>• 10% of the signal prior to the end R mark<br>• 10% of the signal around the 2 largest derivative peaks<br><br>If a derivative greater than 3 times the largest QRS derivative is encountered, T and P regions will not be removed. | Mean |
| **QT cm** | The corrected QT interval, using Matsunaga's method. Computed as QTcm = log (QTcm Factor) * QT/ log (RR) (where RR is expressed in mSec). | Analysis |
| **Qtck** | The corrected QT interval using King's method. Computed as QT + Beta * (HR – "QTck HR"). | Analysis |
| **Count** | This parameter will provide a total of the number of marked cycles within the defined logging period. This is different from the Num parameter which will simply list the last cycle within the logging period. | Sum |
| **PP-I** | Reports the time, in milliseconds, between 2 continuous cardiac cycles' P start marks. If the preceding cycle has been removed due to bad data marks, a value "x" is reported. | Mean |
| **TP-I** | Reports the time, in milliseconds, from a preceding T end mark to the current P start mark. The 2 cycles need to be continuous cardiac cycles and have the T mark on the preceding T wave and a P start mark on the current cycle. If the required validation marks are not placed or the data is not continuous, a value "x" is reported. | Mean |
| **TQ-I** | Reports the time, in milliseconds, from a preceding T end mark to the current Q mark. The 2 cycles need to be continuous cardiac cycles and have the T mark on the preceding T wave and a Q mark on the current cycle. If the required validation marks are not placed or the data is not continuous, a value "x" is reported. | Mean |
| **JTp-I** | Reports the time, in milliseconds, between the S end and the T peak of a cycle. | Analysis |

## Online Screens and Functions

The following is an example of a **Primary** graph displaying an ECG signal and its derivative.




*ECG Key Marks*

In the above figure, the Electrocardiogram signal is displayed along with its validation tick marks. The validation marks identify Q, R, End of S, End of T, and Beginning of P.

## Presentation Signals

Below is a list of presentation signals that are available for the ECG Analysis Module:

| Signal | Description |
|---|---|
| **ECG** | This is the original ECG waveform after applying any software filters and spike removal algorithms (if spike detection is enabled) |
| **Derivative** | This will display the derivative of the ECG signal. |

## Data Review

The analysis specific portion of Data Review centers around the marks that the User is permitted to display, insert, and delete and how the User is permitted to move them.

| | |
|---|---|
| **Displaying Marks and Cycle Numbers** | The marks and cycle numbers displayed in a Review Graph Page Display Pane are controlled through the Marks Tab in the Analysis Attributes dialog. The Analysis Attributes dialog is accessed through the right click menu – Analyze. |
| **Mark Operations** | ECG marks are divided into two types, marks that always exist when a valid cycle is found (Q, R, Sstart, Send) and marks that may or may not exist, depending on the signal quality and morphology (Pstart, Pend, Tend, and Tpeak). The R mark may exist by itself (Arrhythmic R mark) to indicate a bad cycle. |
| **Inserting Marks** | Marks are inserted by right clicking at the point of insertion in the Review window. The popup menu that is displayed will provide the option to insert marks as appropriate. The list of marks available for insertion will depend on the marks adjacent to the point of insertion, signal morphology is not considered. |
| **Insert QRS** | Inserts QRSsSe. This set of marks may be inserted at any location except between a Ps, Pe, and anywhere within a set of QRSsSe marks. When a QRS is inserted, it is assigned a sequential cycle number and subsequent cycle numbers are incremented. |
| **Insert Arrhythmic R** | An Arrhythmic R may be inserted between two ECG cycles, but not within a cycle. An ECG cycle is composed of PsPeQRSsSeTe. The PsPe and Te marks may not be present. The first and last marks present in a cycle represent the limits prior to and after which the Arrhythmic R may be inserted. |
| **Insert T End** | This selection will be available if an insert is attempted to the right of an S End mark and a T End is not present for the current cycle. Tp is added along with Te. |
| **Insert S End** | This selection will be available if an insert is attempted to the right of an S Start mark and an S End mark is not present for the current cycle. The only location where an S Start is present without an S End, may be at the end of the review file depending on how much of the next cycle is available. |
| **Insert Pse** | This selection will be available if an insert is attempted at the start of a cycle and P marks are not present for the cycle. |

**Deleting Marks**

Marks are deleted by positioning the mouse cursor on the mark to be deleted and bringing up the right click menu. Ps, Pe, Tp and Te may be deleted in this fashion. Q, Ss, and Se marks cannot be deleted individually. They are linked to an R wave. To delete these marks, the entire cycle must be deleted; the cursor is positioned on the R wave and the right mouse button is clicked to delete the marks. One of the selections in the popup menu will permit deletion of all the marks in the cycle, including any Ps, Pe, Tp, and Te marks associated with the R wave.

Deleting either of the P wave marks will delete both P wave marks. Deleting T end will delete the T peak mark as well.

**Moving Marks**

Moving Ps, Pe, Q, R, Ss, Se, Tp and Te marks follow the standard rules used in Data Review. One exception is the interaction between the T marks and the subsequent cycles P marks. The T marks can be moved past the P and vice versa.

## ATTRIBUTE TYPES IN REVIEW

The following table describes the effects of changing ECG attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| Attribute | Effect on Review |
|---|---|
| QRS Detection Threshold | Signal Interpretation |
| Min R Deflection | Signal Interpretation |
| Maximum Heart Rate | Signal Interpretation |
| Minimum Heart Rate | Signal Interpretation |
| Peak Bias | Signal Interpretation |
| Baseline Recovery Threshold | Signal Interpretation |
| QRS Smoothing Filter | Signal Interpretation |
| QRS Segment Length | Signal Interpretation |
| QRS Width | Signal Interpretation |
| QRS Baseline Deriv Threshold | Signal Interpretation |
| Peak Baseline Window | Signal Interpretation |
| Peak Width Similarity | Signal Interpretation |

| | |
|---|---|
| Valid Peak Threshold | Signal Interpretation |
| Alternate Peak Threshold | Signal Interpretation |
| Wide Q Wave | Signal Interpretation |
| Intracardiac | Signal Interpretation |
| R Width Max | Signal Interpretation |
| R Width Min | Signal Interpretation |
| Average HR | Calculation |
| R Arrhythmia Height | Signal Interpretation |
| R Arrhythmia Width | Signal Interpretation |
| Max QT Interval | Signal Interpretation |
| T Window from S | Signal Interpretation |
| T Window from R | Signal Interpretation |
| P Window from R | Signal Interpretation |
| P Placement | Signal Interpretation |
| T Placement | Signal Interpretation |
| Alternate End of T | Signal Interpretation |
| Peak Sensitivity | Signal Interpretation |
| Peak Identification | Signal Interpretation |
| T Direction | Signal Interpretation |
| P Direction | Signal Interpretation |
| High ST Segment | Signal Interpretation |
| ST Measure | Calculation |
| QTcm Factor | Calculation |
| QTck HR | Calculation |
| QTck IACF | Calculation |
| Low Pass | Signal Conditioning, Calculation, Redraw |
| High Pass | Signal Conditioning, Calculation, Redraw |

## Troubleshooting

Use the following table to assist in troubleshooting the analysis:

| Problem | Solution |
|---|---|
| A complex is incorrectly marked as an arrhythmia | Verify **R Arrhythmia Width** is wide enough to accommodate the QRS complex. Ensure that **R Arrhythmia Height** setting is large enough to accommodate the R wave. |
| Start of P wave not marked | Ensure that **P Window from R** extends beyond the P wave. |
| End of T wave not marked correctly | Ensure that the **T Window from S** and the **T Window from R** correctly define the region in which the end of T is expected. Ensure that **Max QT Interval** extends beyond the T wave. |
| Algorithm does not trigger (No marks) | Reduce the sample rate to 250-1000Hz. |
| The R waves are marked with a single mark, and nothing else is marked | Is **Max R Deflection** too low?<br>Is **R Arrhythmia Width** too small? |
| T mark is not displayed | Ensure that the **Max QT Interval** extends beyond the end of the T wave. The **T window from R** should encompass the P wave. The **T window from S** should end prior to the start of the T wave and be close to the Iso electric level. |
| T mark is not displayed even though the T windows are set correctly | Check **T Direction**. |
| P mark is not displayed | Verify that **the P window from R** extends beyond the beginning of the P wave. If the P mark does not appear, check the **P Direction** attribute. |
| Cannot find the analysis module in the Input Setup dialog | The analysis module is likely not enabled in the Ponemah License. Check License options via **Help \| View License**. |

## ECG Pattern Recognition Option (ECG PRO)

The purpose of **ECG PRO Analysis** is post-acquisition pattern recognition option (PRO) analysis.

It allow users to modify attribute analysis mark placements based on user-defined ECG cycle mark placement. Template analysis uses these templates to compare like regions of ECG signals within the data set and updates the marks on matched cycles. ECG PRO analysis is a **Review** only feature.

Briefly, the process for analyzing using ECG PRO analysis is:

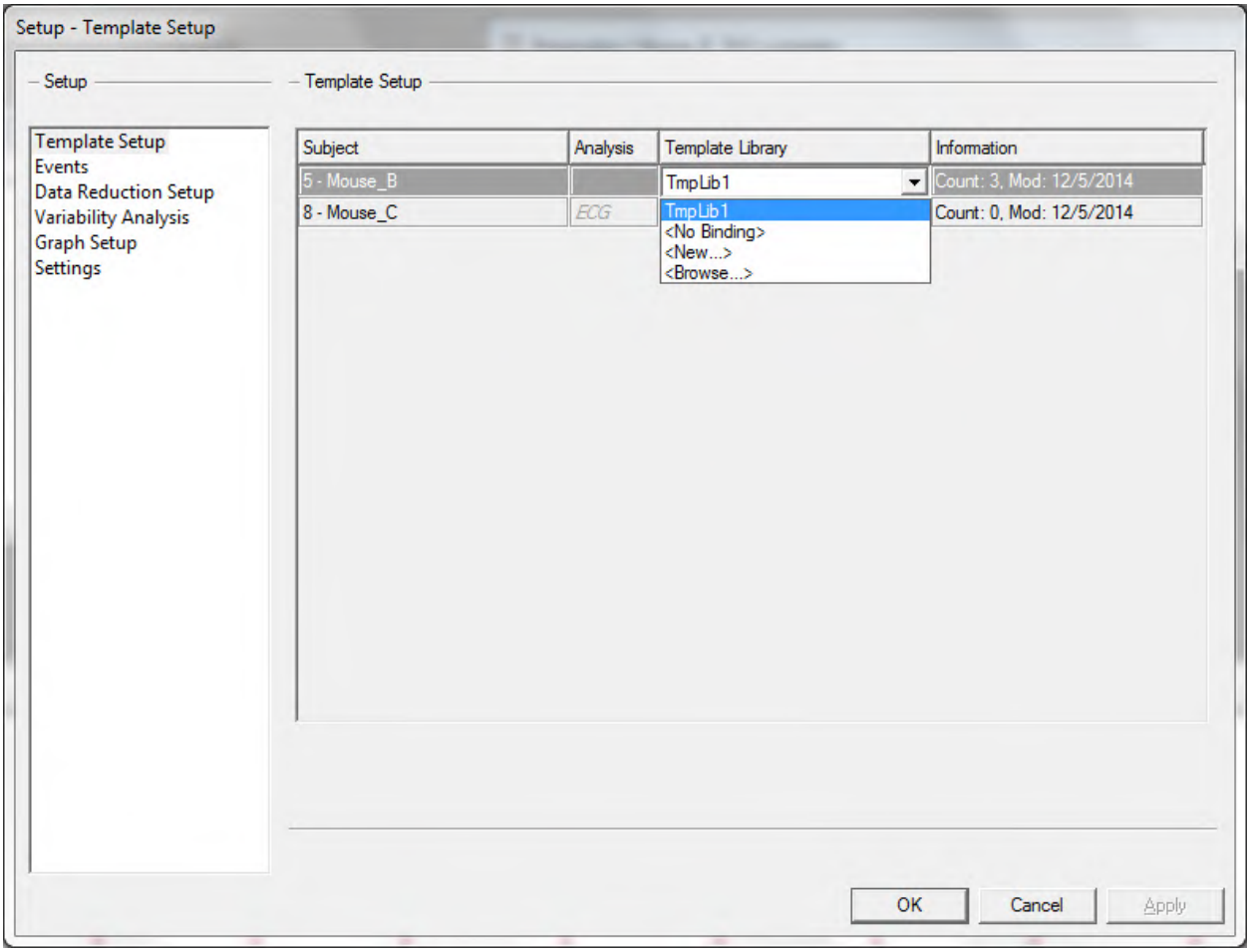
- User selects ECG cycles for inclusion in the **Template Library.**
- User defines the **Match Criteria.**
- PRO Analysis evaluates the match.
- **Marks** and **Derived Parameters** are updated.

## Template Library Setup

ECG PRO Analysis is Review only feature; therefore, **Template Setup** can only be done while in Review.

To setup ECG PRO Analysis:

1. Select **Setup | Experiment Setup.**
2. Select the **Template Setup** configuration and select a **Template Library**.
   **Template Library** is a file in which **Templates** are stored. Template Libraries may contain Templates from different waveform files.
   **Templates** are ECG cycles with accurately placed **Marks** that will be used as the representative ECG cycles for patter recognition analysis.
3. Select **<New…>** from the dropdown to create a new **Template Library**.
   The user has a few options from the dropdown:
   a. **<No Binding>** disassociates any previous configured **Template Library** from the Subject.
   b. **<Browse…>** - associates an existing **Template Library** that was configured during a previous Review session.




*Note*: The sample rate used to collect the data in the **Template Library** must match the sample rate of the data being analyzed by that library.

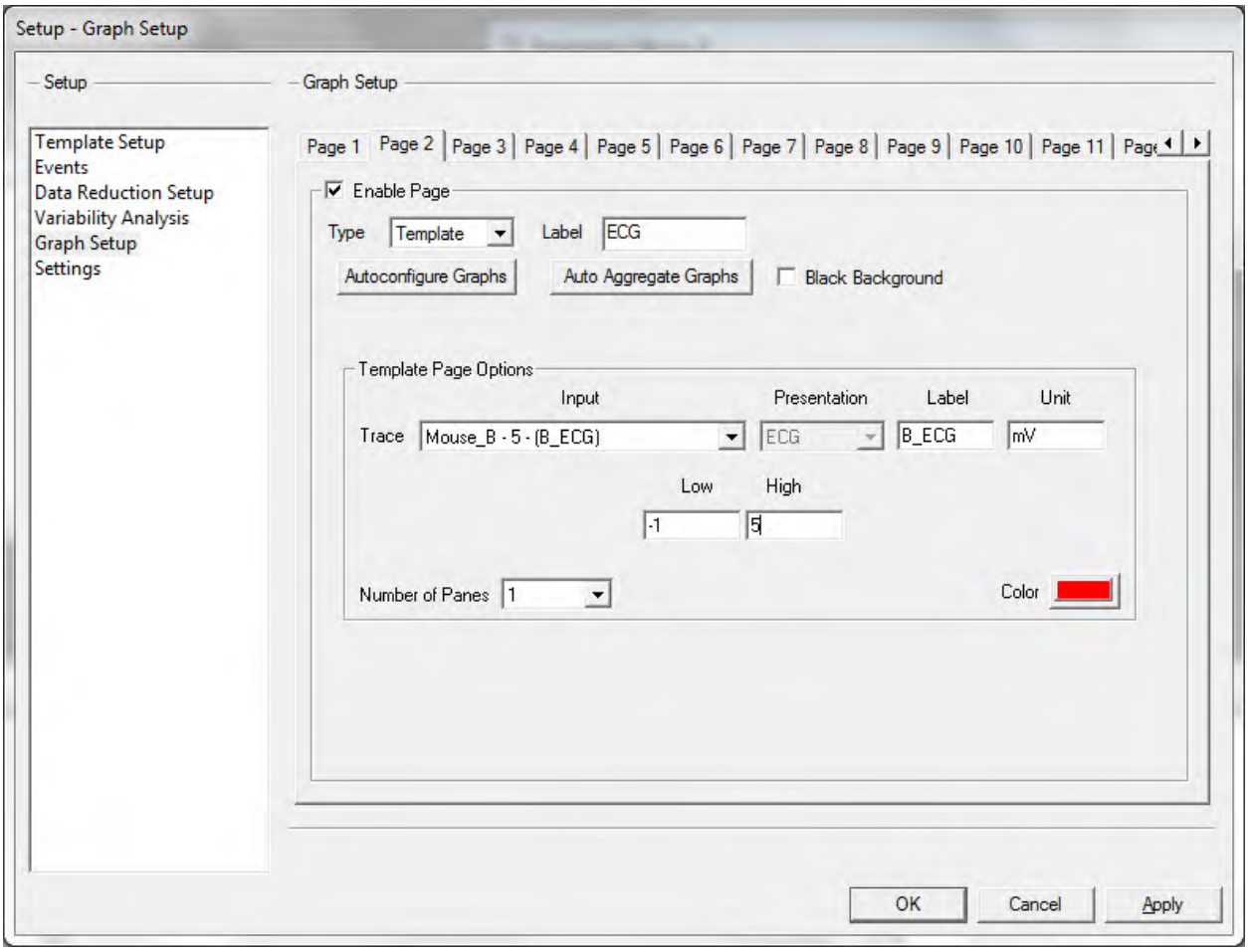
## Graph Page Setup

A **Template** graph is used to aggregate **Template** cycles defined by the user. Within this **Template** graph, the user can update cycle **Marks** and view match criteria.

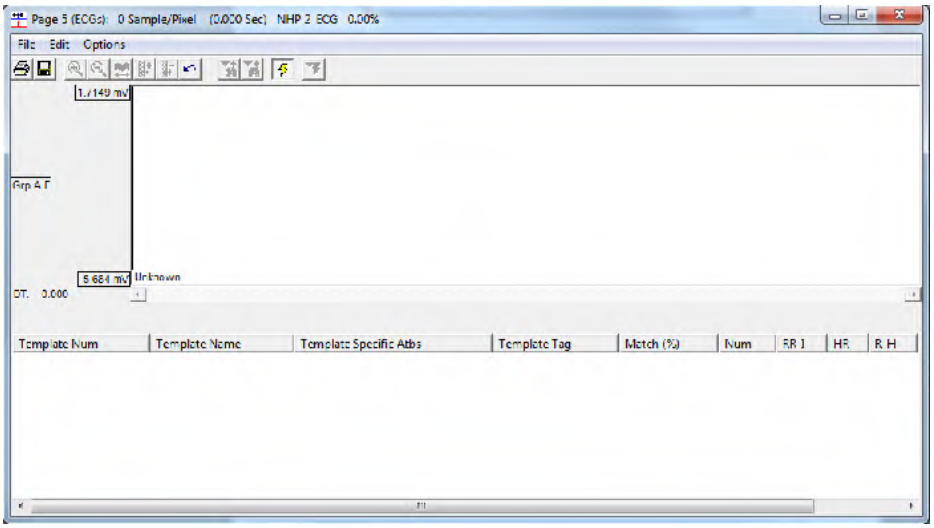
To configure a **Template** graph:

1. Select **Setup | Experiment Setup**.
2. Select the **Graph Setup** configuration.
3. Select a page to use as a **Template** graph page.
4. Check the **Enable Page** check box.
5. Select **Template** for the **Type**.
6. **Input** should reflect the users Subject/Channel selection.
7. Type the appropriate information in the **Label**, **Unit**, **Low** and **High** text boxes.
   *Note*: The user can also select a **Black Background** and trace **Color**.

8. Select the **OK** button.




A graph page similar to the one below will appear. When starting from scratch, the **Template** graph will be empty. The next step is to add **Templates** to the **Template Library**.




## Adding Templates to the Template Library

Any ECG cycle with accurately placed **Validation Marks** can be used as a **Template**. To learn more about Validation Marks and how to alter their positions, please see the **Validation Marks** section within the **Data Review | Using Review** portion of this manual.

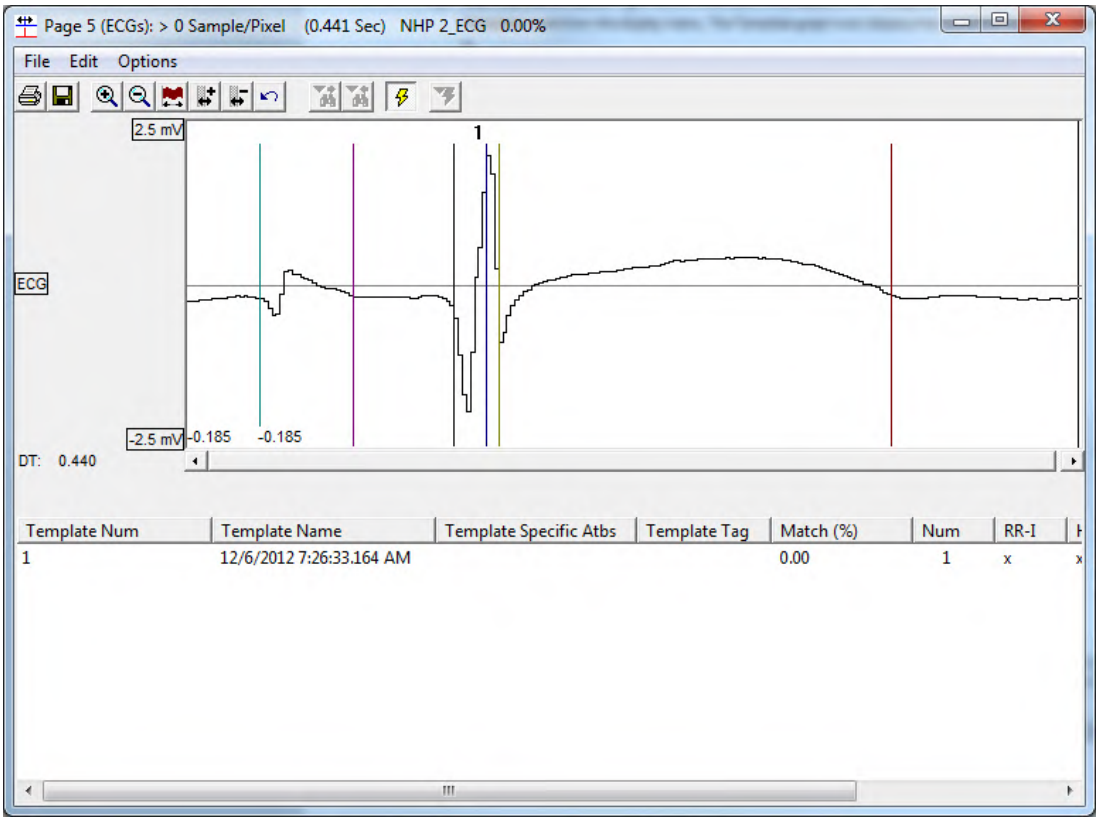
**IMPORTANT - R marks** must be identified for cycles prior to analyzing with ECG PRO. This requires that either the **R marks** be preserved from Acquisition or the attribute based analysis must be executed prior to performing ECG PRO analysis. The other marks (**P, Q, S** and **T**) need not be present in order to perform ECG PRO analysis.

To add **Templates** to the **Template Library**:

1. Locate an ECG cycle from the **Primary** graph.
2. If necessary, adjust the **Validation Marks** to accurately reflect the appropriate positions of the **ECG Marks** of interest.

   *Note*: **ECG Marks** may be moved within the **Template** graph page.
3. From the **Primary** graph, right-click on the cycle to be added to the **Template Library** and select **Add Template Cycle** from the display menu. The Template graph now displays the cycle that was just added to it.

   *Note:* An **Autoscale** may need to be performed for both the X and Y axes to see the full Cycle.




The list view displays the following:

**Template Number** The **Cycle Number** displayed in the waveform area.

**Template Name** Defaults to the time associated with the **Template** cycle.

**Template Specific Attribute** Indicates whether **Template Specific Attributes** are enabled for the **Template** cycle. Template Specific Attributes permit specific attributes to be used for the Template cycle, overriding the global attribute settings used when Template Analysis is executed.

The current use case for enabling these is to mark Isolated P waves when searching for Second Degree Atrioventricular (AV) Block using **Data Insights**.

For more information, see **Data Insights | Finding Second Degree AV Block using Template Specific Attributes** within the **Tutorial** section of this manual.

| | |
|---|---|
| **Template Tag** | Indicates the applied Template Tag(s) associated with the Template cycle.<br><br>Once a Template Tag is associated with a Template cycle, the Tag is also associated with any cycles within the waveform that are matched to the Template cycle. This is useful to identify unique waveform morphologies. Data Insights may then be used to search, visualize, and report on these cycles.<br><br>For more information, see **Data Insights \| Finding Unique Cycle Morphologies using Template Tags** within the **Tutorial** section of this manual. |
| **Match %** | Indicates the percent match of the **Template** within the matched cycles. The **Match %** will always add up to 100%. |
| **Derived Parameters** | Derived parameters for the Template cycle. |
| **Dialog Match %** | After the analysis is complete a percentage will appear in the **Template** graph page after the title (in the title bar). This indicates the percentage of cycles that the **Template Library** matched within the data set. |

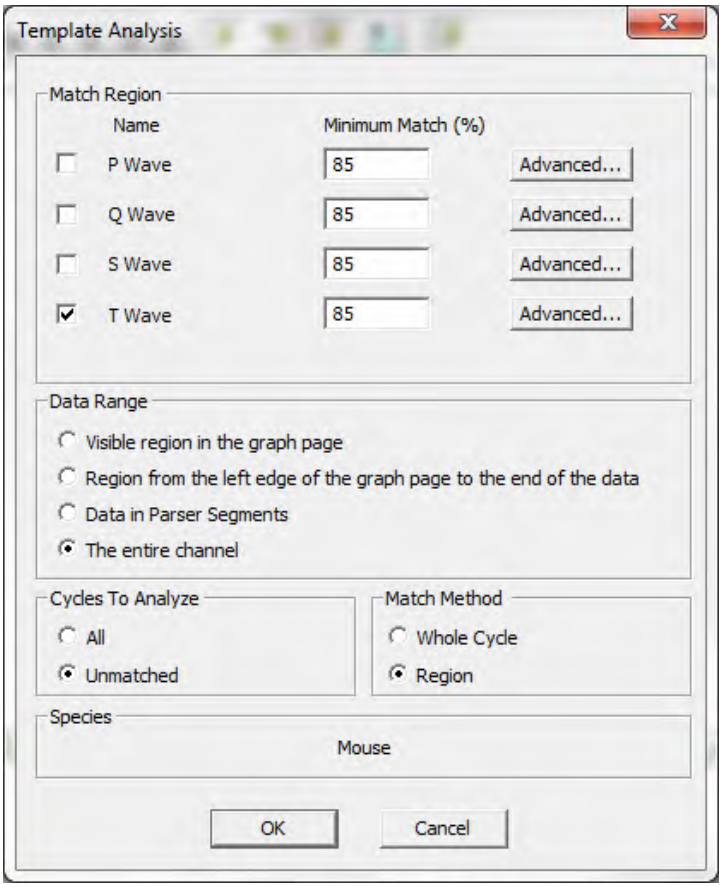
The next step is to analyze the data using the **Template** that was added.

## Analyzing with the Template Library

The following section outlines the process to execute ECG PRO analysis and describes the various dialogs.

To analyze using the current **Template Library**:

1. Right-click the **Display Pane** associated with the Subject's Channel you wish you analyze from the **Primary** graph and select **Analyze [Entire Library]**. This will launch the **Template Analysis** dialog shown below.




2. Select the desired **Template Match Region** to which all other ECG cycles will be compared.
   In this example, the T Wave is selected as the **Match Region** for analysis with a **Minimum Match** of 85%. This means that if the T Region does not match with at least 85% confidence, the cycle will not be marked as matched.

   If needed, change the advanced settings for the desired Match Region. See the **Advanced Setup** section below.

   *Note*: Multiple **Match Regions** may be selected depending on the desired output from the analysis (the **Derived Parameters** of interest).

3. Select a **Data Range** on which to perform the analysis.
   The **Data Range** allows you to reanalyze the data visible in the graph, the data from the left edge of the visible region from the primary graph forward to the end of the loaded data set, the data within the

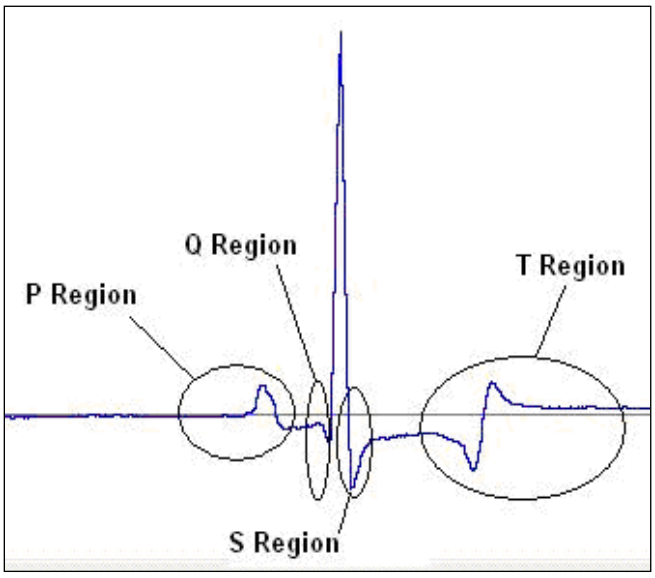
**Parser Segments**, or the entire channel.

*Note*: When on the first analysis pass using ECG PRO, the entire channel is typically used. However, there may be value to setting up regular **Parser Segments** when working with large (24 hour or more) data sets. This can be used to focus on a representative subset of the data while setting up the **Template Library**. When the **Template Library** is complete the entire data set can be analyzed using the **Template Library**. This can speed up the Analysis process significantly. See the **Data Parser** section of this manual to learn how to set up rule based **Parser Segments**.

4. Select the type of **Cycles to Analyze**
    a. **All** will compare the Template Library to All cycles with a valid R mark.
    b. **Unmatched** will skip previously matched cycles and compare the **Template Library** to only the unmatched cycles. This is useful when adding additional **Templates** to the **Template Library** for greater match coverage, as the processing time is quicker.

5. Select the desired **Match Method**.
   When multiple **Match Regions** are selected and **Whole Cycle** is chosen, the **Template** that, on average, matches the cycle best will be used to place the marks. When **Region** is used, the best match for each **Match Region** will be used to place the marks, possibly from different **Templates**.

   For the different match regions please refer to the image below:



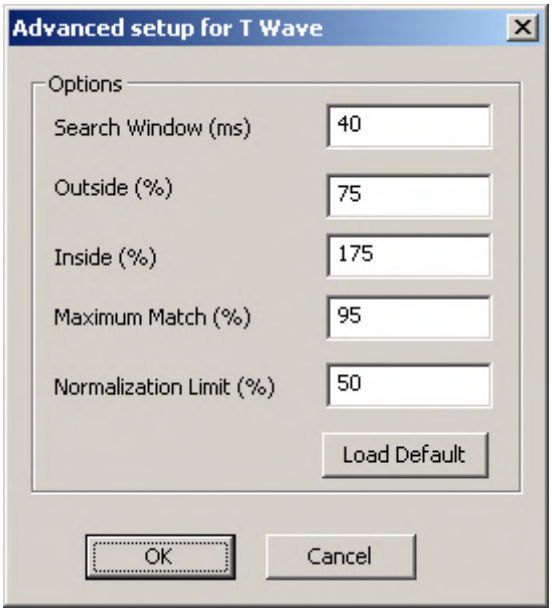

6. Select **OK** to execute the analysis.

7. Add additional **Template Cycles** to the **Template Library** and re-run the **Template** analysis until your desired **Dialog Match %** is achieved.

8. **Template Libraries** are saved through **Templates | Save** when the Review Session is closed.

## ADVANCED SETUP

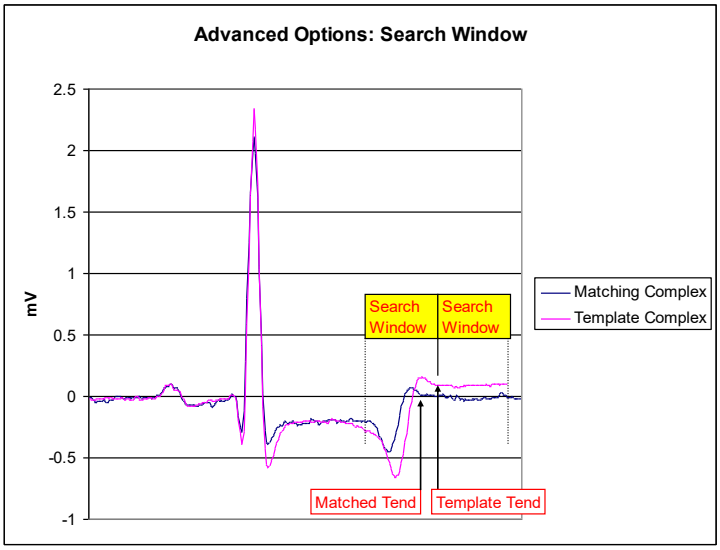
From the **Template Analysis** dialog select the **Advanced** button for a specific **Match Region**. The dialog is shown below. It is unlikely that users will need to modify the **Advanced** settings.



The available options are:

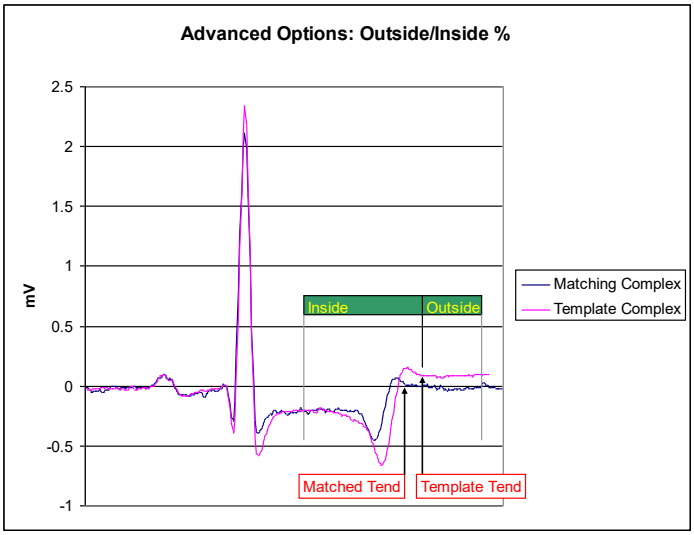
**Search Window**

Template analysis will search for the best match for a Match Region, being P, Q, S, or T over the range of data specified by the Search Window. Each region has a specific mark that the search window is centered around. The example below displays the search window for Tend. The 40 millisecond window, displayed in yellow below, is applied to the Trend data from the template to locate a match within the unmatched data that is being analyzed. Below are graphical representations of a template and data that is being analyzed.




**Inside and Outside %**

Specifies the range of template data for the selected region used in the comparison. Once a candidate complex has been located, the template analysis will search the specified percentage on each side of the mark. In the case below the Outside % follows the mark and the Inside % precedes the mark. Displayed below is the range for the Trend windows.




**Further explanation of Inside and Outside percentages:**

The Inside and Outside percentages relate to how much data around a mark is used for matching purposes. The specifics for each mark follow:

**P Wave**

The percentages relate to the region between the **P Start** and **P End**.

When matching against the **P Start mark**, an inside % of 80% and outside % of 35% corresponds to:

- **Inside time** = 80% of the time between P start and P end
- **Outside time** = 35% of the time between P start and P end
- **Inside time is to the right** of the P start mark
- **Outside time to the left** of the P start mark

When matching against the **P End** mark, an inside % of 80% and outside % of 35% corresponds to:

- **Inside time** = 80% of the time between P start and P end
- **Outside time** = 35% of the time between P start and P end
- **Inside time is to the left** of the P end mark
- **Outside time to the right** of the P end mark

**Q Wave**

The percentages relate to the region between the **Q mark** and the **R mark**.

An inside % of 120% and outside % of 30% corresponds to:

- **Inside time** = 120% of the time between Q and R
- **Outside time** = 30% of the time between Q and R
- **Inside time is to the right** of the Q mark (this will extend past the R mark)
- **Outside time to the left** of the Q mark

Similarly for the **S** and **T** marks, where:

For the **S** mark, the region is between the **S end and the R** mark

For **T** marks, the region is between the **T peak and T end** marks

- **Maximum Match (%)** - Once a template matches the data at or above the maximum match, no further match attempts are made for the cycle.
- **Normalization Limit (%)** - is used to control how much of a change in amplitude between a template and data will still be regarded as a match. If a user is interested in amplitude changes this parameter should be kept small.

The **Load Default** button will add the species specific default values.

### BATCH TEMPLATE ANALYSIS

**Batch Template Analysis** (analysis across multiple channels at once) may be performed by selecting this option via the **Actions** menu located in the main Ponemah window. This is typically used after **the Template Libraries** have been configured for each Subjects' ECG Channels.

**Batch Template Analysis** can be applied to the entire data set or across the defined **Parser Segments** of the data set. From **Actions** within a Review session, select **Batch Template Analysis.** Once started**, Batch Template Analysis** will analyze all valid channels without requiring any user interaction, and is capable of being started immediately after the Review file has been loaded. Prior to starting a **Template Batch Analysis**, the user has the option of using each individual channel's **Match Range** settings or overriding all settings with global **Match Range** settings. The **Data Range**, **Cycles to Analyze** and **Match Method** will be selectable and applied globally to each channel, these settings will not use the settings saved within each channel. The **Settings Override** option, along with the global settings themselves, will be saved within Review.

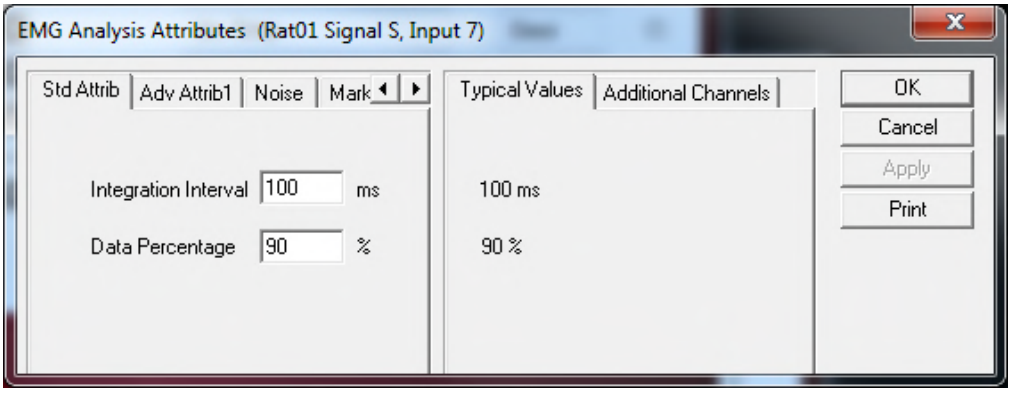
## Electromyogram (EMG)

The Electromyogram Analysis Module analyzes electromyogram signals. The analysis calculates derived parameters from the input signal over a user specified logging period.

## Attribute Window

The **EMG Analysis** attributes dialog allows you to modify the signal analysis for different types of EMG signals and signal conditions. If an analysis change in the **Attributes** dialog is performed mid-cycle, then the attribute change will not take effect until the following cycle.

### STANDARD ATTRIBUTES TAB




*EMG Standard Attribute Tab*

**Integration Interval**

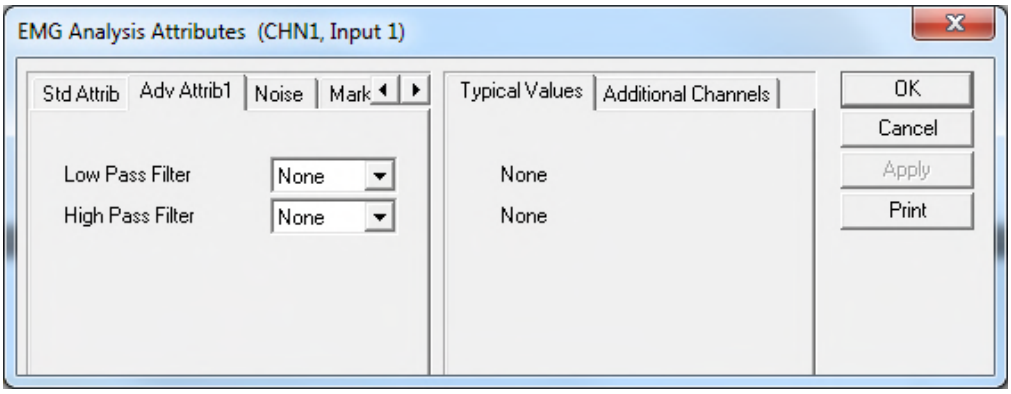
The period over which the EMG signal is integrated before resetting. The result of the previous integration is displayed over this period.

**Data Percentage**

The quantity of valid samples that must be present for derived parameter calculation, expressed as a percentage of the logging interval. All parameters will display Nan if insufficient data samples are available.

## ADVANCED ATTRIBUTES TAB

The **Advanced** attributes allow selection of attributes which are not commonly changed during Acquisition or Review.

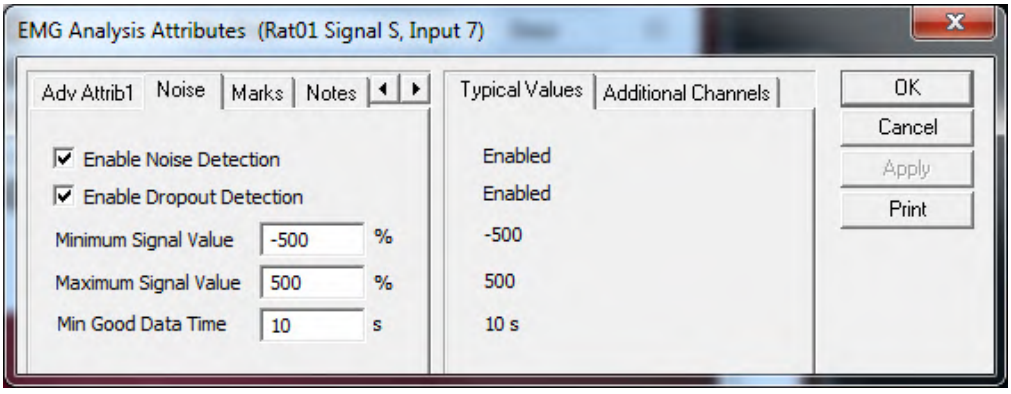



*EMG Advanced Attribute Tab*

| | |
|---|---|
| **Low Pass Filter** | Selection of Low Pass filter in hertz. |
| **High Pass Filter** | Selection of High Pass filter in hertz. |

## NOISE TAB

The **Noise Tab** contains attributes that are used to identify noisy data. On identifying "noisy" data, as defined by the user, **Bad Data Marks** will be placed to span the noisy sections.




*EMG Noise Tab*

| | |
|---|---|
| **Enable Noise Detection** | Enables the **Noise Detection** attributes for the automatic placement of **Bad Data Marks**. |
| **Enable Dropout Detection** | If **Dropout Detection** is enabled, any negative dropout data encountered when analyzing data shall be bracketed **by Bad Data Marks** such that the dropout data falls within the **Bad Data Start** and **End** marks. The dropout check shall be performed on unfiltered samples. |
| **Minimum Signal Value** | User defined threshold for determining the **minimum value** for acceptable data. Data that falls below this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Maximum Signal Value** | User defined threshold for determining the **maximum value** for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Minimum Good Data Time** | Provides the user the ability to mark data as bad between two **Bad Data Mark** regions. If the time between the regions is less than the value specified. If the time is less than what is specified, the **Bad Data Mark** region will appear as one contiguous segment. |

## MARKS (VALIDATION) TAB

The **EMG** analysis displays a validation tick mark at the end of each Integration Interval. This mark is used to denote the logging mark of the cycle (interval) as well as used to determine the cycle number.

The validation marks and their meanings are listed below:

| **Color** | | **Meaning** |
|---|---|---|
| Black | | Integration Interval |
| | | Mark Cycle Numbers |

## TYPICAL VALUES

Use this value as a guideline for a first-time setup. Under different situations, a value above or below the typical value should be used.

| Attribute | Setting | Units |
|---|---|---|
| Integration Interval | 100 | ms |

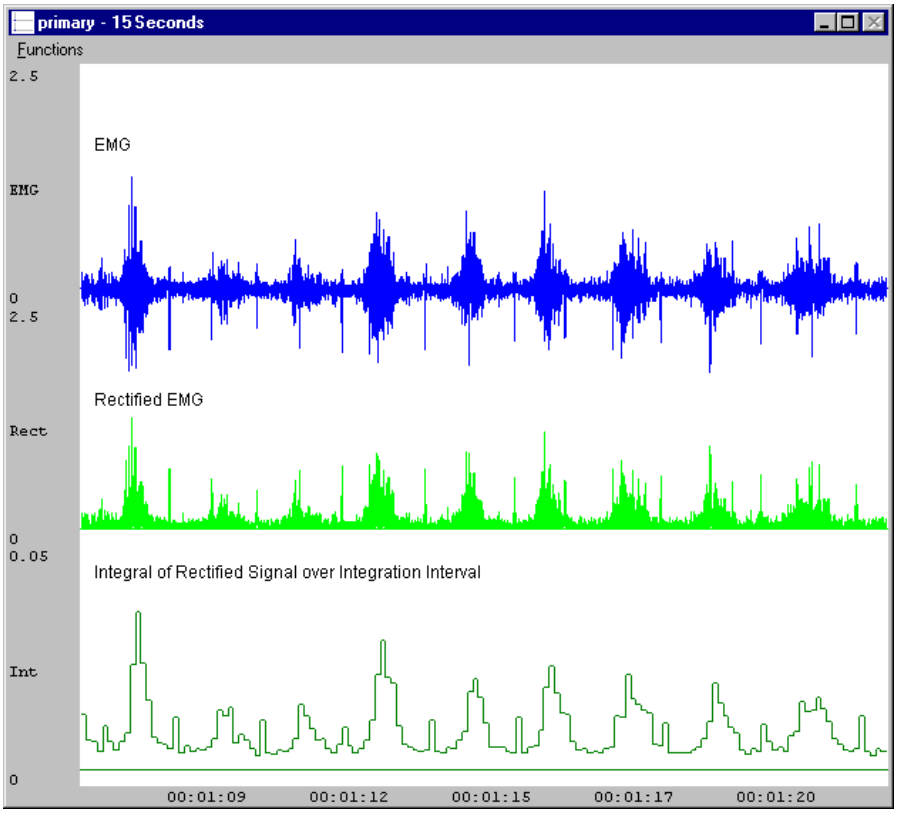
## Derived Parameters

**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The **Derived Parameters** selected in this dialog will be calculated, and the results will be placed in the Derived Parameter List View(s). The following details the available **Derived Parameters** from the Electromyogram module and the averaging method used within Review.

| Name | Definition | Review Averaging Method |
|---|---|---|
| **Num** | The number of the cardiac cycle. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. | Recent |
| **INT** | The integral of the rectified signal over the integration interval. | Mean |
| **PEAK** | The maximum interval over the logging period. | Max |
| **INT2** | The integral of rectified input signal over the logging rate. | Mean |

## Online Screens and Functions

The following is an example of a Primary graph displaying an EMG signal.




*EMG, Rectified EMG and EMG Integration*

In the above figure, the Electromyogram signal is displayed along with the rectified signal and its integral over the **Integration Interval**.

## Presentation Signals

Below is a list of presentation signals that are available for the EMG Analysis Module:

| **Signal** | **Description** |
|---|---|
| EMG | This is the original EMG input signal after applying any software filters. |
| Rectified | This will display the rectified EMG signal. |
| Integral | This will display the integral of the rectified signal over the integration Interval. |

## Data Review

This is a list of the Data Review related features of the EMG Analysis Module. The analysis specific portion of Data Review centers on the marks that the user is permitted to display, insert, and delete and how the User is permitted to move them.

| | |
|---|---|
| **Displaying Marks and Cycle Numbers** | The marks and cycle numbers displayed in a Review **Primary** graph page **Display Pane** are controlled through the **Marks** Tab in the **Analysis Attributes** dialog. The **Analysis Attributes** dialog is accessed through the right click menu – **Analyze [Attributes]**. |
| **Mark Operations** | EMG only supports the **Integration Interval** mark. |
| **Inserting Marks** | **Marks** may be inserted by right clicking at the point of insertion in the **Primary Graph Display Pane** of the Channel of interest. The pop-up menu that is displayed will provide the option to insert marks as appropriate. The list of marks available for insertion will depend on the marks adjacent to the point of insertion; signal morphology is not considered. |
| **Insert EMG Cycle** | Inserting EMG cycles is not permitted as the mark placement is based on the time specified for the Integration Interval. |
| **Deleting Marks** | Deleting EMG cycles is not permitted. |
| **Moving Marks** | Moving EMG cycles is not permitted. |
| **Calculations** | The calculations of derived parameters are identical to those performed during acquisition. |
| **Logging Mark** | The **Logging Mark** for an **EMG cycle** is the **Integration Interval.** The time at the L**ogging** M**ark** is the time used to report a cycle's derived data. |
| **End of Cycle** | The end of an **EMG cycle** occurs one sample prior to the next cycle's **Integration Interval** mark. |

### ATTRIBUTES IN REVIEW

The following table describes the effects of changing EMG attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| Attribute | Effect On Review |
|---|---|
| Integration Interval | Signal Interpretation |
| High Pass Filter | Signal Conditioning, Calculation, Redraw |
| Low Pass Filter | Signal Conditioning, Calculation, Redraw |
| Marks and cycle numbers | Redraw |
| Precision | Precision |
| Enable Noise Detection | Signal Interpretation |
| Minimum Signal Value | Signal Interpretation |
| Maximum Signal Value | Signal Interpretation |
| Maximum Heart Rate | Signal Interpretation |
| Minimum Good Data Time | Signal Interpretation |

### Troubleshooting

There is no troubleshooting for this analysis module.

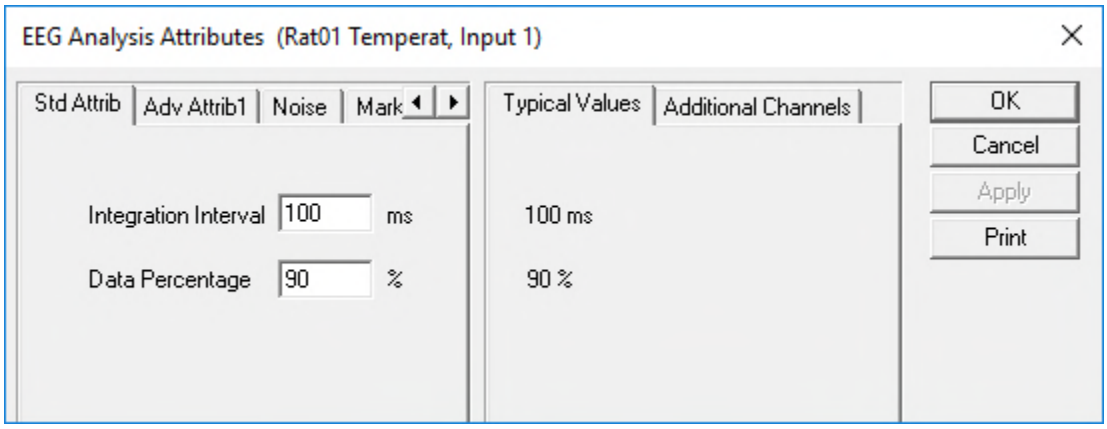
## Electroencephalogram (EEG)

The Electroencephalogram Analysis Module analyzes electrical activity signals from the brain. The analysis calculates derived parameters from the input signal over a user specified logging period.

### Attribute Window

The **EEG Analysis** attributes dialog allows you to modify the signal analysis for different types of EEG signals and signal conditions. If an analysis change in the **Attributes** dialog is performed mid-cycle, then the attribute change will not take effect until the following cycle.

#### STANDARD ATTRIBUTES TAB

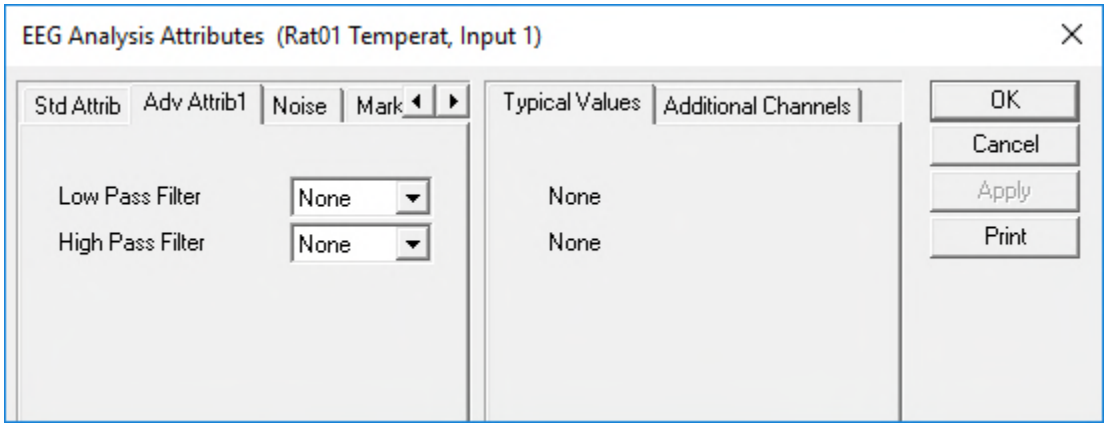


*EEG Standard Attribute Tab*

| | |
|---|---|
| **Integration Interval** | The period over which the EEG signal is integrated before resetting. The result of the previous integration is displayed over this period. |
| **Data Percentage** | |

## ADVANCED ATTRIBUTES TAB

The **Advanced** attributes allow selection of attributes which are not commonly changed during Acquisition or Review.

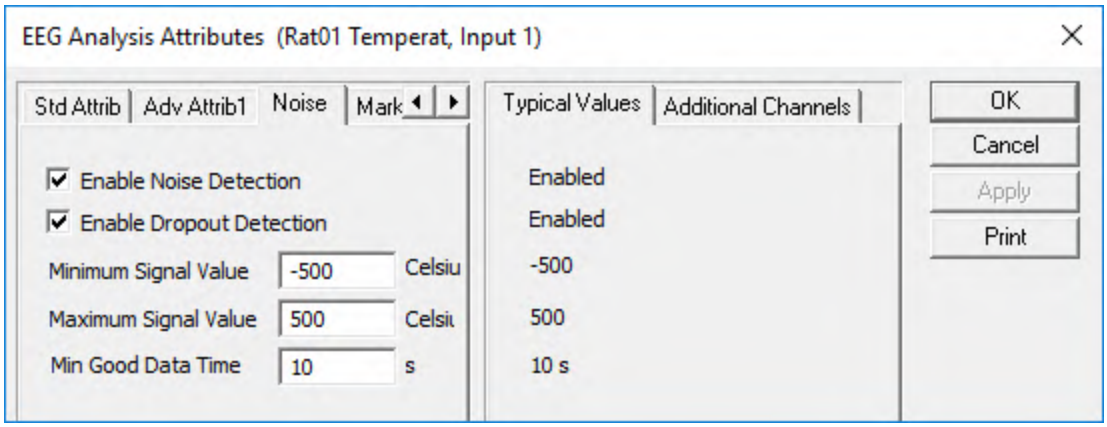



*EEG Advanced Attribute Tab*

| | |
|---|---|
| **Low Pass Filter** | Selection of Low Pass filter in hertz. |
| **High Pass Filter** | Selection of High Pass filter in hertz. |

## NOISE TAB

The **Noise Tab** contains attributes that are used to identify noisy data. On identifying "noisy" data, as defined by the user, **Bad Data Marks** will be placed to span the noisy sections.




*EEG Noise Tab*

**Enable Noise Detection** — Enables the **Noise Detection** attributes for the automatic placement of **Bad Data Marks**.

**Enable Dropout Detection** — If **Dropout Detection** is enabled, any negative dropout data encountered when analyzing data shall be bracketed **by Bad Data Marks** such that the dropout data falls within the **Bad Data Start** and **End** marks. The dropout check shall be performed on unfiltered samples.

**Minimum Signal Value** — User defined threshold for determining the **minimum value** for acceptable data. Data that falls below this threshold will be considered noise and bracketed by **Bad Data Marks**.

**Maximum Signal Value** — User defined threshold for determining the **maximum value** for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks**.

**Minimum Good Data Time** — Provides the user the ability to mark data as bad between two **Bad Data Mark** regions. If the time between the regions is less than the value specified. If the time is less than what is specified, the **Bad Data Mark** region will appear as one contiguous segment.

## MARKS (VALIDATION) TAB

The **EEG** analysis displays a validation tick mark at the end of each Integration Interval. This mark is used to denote the logging mark of the cycle (interval) as well as used to determine the cycle number.

The validation marks and their meanings are listed below:

| Color | | Meaning |
|---|---|---|
| Black | | Integration Interval |
| | | Mark Cycle Numbers |

### TYPICAL VALUES

Use this value as a guideline for a first-time setup. Under different situations, a value above or below the typical value should be used.

| Attribute | Setting | Units |
|---|---|---|
| Integration Interval | 100 | ms |

## Derived Parameters

**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The **Derived Parameters** selected in this dialog will be calculated, and the results will be placed in the Derived Parameter List View(s). The following details the available **Derived Parameters** from the Electromyogram module and the averaging method used within Review.

| Name | Definition | Review Averaging Method |
|---|---|---|
| **Num** | The number of the cardiac cycle. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. | Recent |
| **INT** | The integral of the rectified input signal over the integration interval. | Mean |
| **PEAK** | The maximum interval over the logging period. | Max |
| **INT2** | The integral of rectified input signal over the logging rate. | Mean |

## Presentation Signals

Below is a list of presentation signals that are available for the EEG Analysis Module:

| Signal | Description |
|---|---|
| **EEG** | This is the original EEG input signal after applying any software filters. |

| Signal | Description |
|---|---|
| **Rectified** | This will display the rectified EEG signal. |
| **Integral** | This will display the integral of the rectified signal over the integration Interval. |

## Data Review

This is a list of the Data Review related features of the EEG Analysis Module. The analysis specific portion of Data Review centers on the marks that the user is permitted to display, insert, and delete and how the User is permitted to move them.

| Action | Description |
|---|---|
| **Displaying Marks and Cycle Numbers** | The marks and cycle numbers displayed in a Review **Primary** graph page **Display Pane** are controlled through the **Marks** Tab in the **Analysis Attributes** dialog. The **Analysis Attributes** dialog is accessed through the right click menu – **Analyze [Attributes]**. |
| **Mark Operations** | EEG only supports the **Integration Interval** mark. |
| **Inserting Marks** | **Marks** may be inserted by right clicking at the point of insertion in the **Primary Graph Display Pane** of the Channel of interest. The pop-up menu that is displayed will provide the option to insert marks as appropriate. The list of marks available for insertion will depend on the marks adjacent to the point of insertion; signal morphology is not considered. |
| **Insert EEG Cycle** | Inserting EEG cycles is not permitted as the mark placement is based on the time specified for the Integration Interval. |
| **Deleting Marks** | Deleting EEG cycles is not permitted. |
| **Moving Marks** | Moving EEG cycles is not permitted. |
| **Calculations** | The calculations of derived parameters are identical to those performed during acquisition. |
| **Logging Mark** | The **Logging Mark** for an **EEG cycle** is the **Integration Interval.** The time at the L**ogging** M**ark** is the time used to report a cycle's derived data. |
| **End of Cycle** | The end of an **EEG cycle** occurs one sample prior to the next cycle's **Integration Interval** mark. |

### ATTRIBUTES IN REVIEW

The following table describes the effects of changing EEG attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| Attribute | Effect On Review |
|---|---|
| **Integration Interval** | Signal Interpretation |

| | |
|---|---|
| **High Pass Filter** | Signal Conditioning, Calculation, Redraw |
| **Low Pass Filter** | Signal Conditioning, Calculation, Redraw |
| **Marks and cycle numbers** | Redraw |
| **Precision** | Precision |
| **Enable Noise Detection** | Signal Interpretation |
| **Minimum Signal Value** | Signal Interpretation |
| **Maximum Signal Value** | Signal Interpretation |
| **Maximum Heart Rate** | Signal Interpretation |
| **Minimum Good Data Time** | Signal Interpretation |

## Troubleshooting

There is no troubleshooting for this analysis module.

## Glucose (GLU)

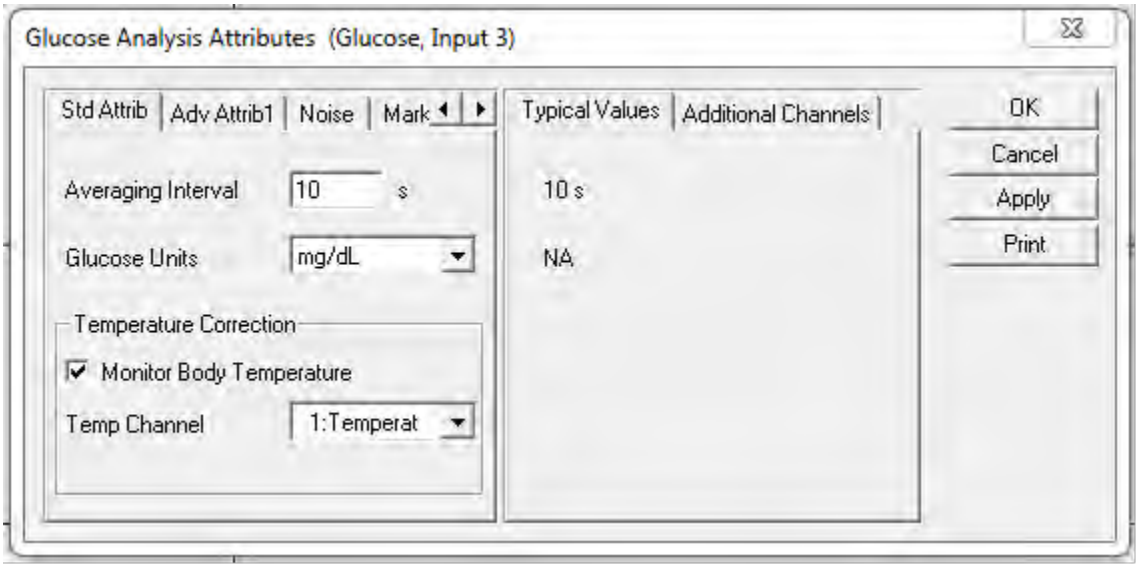
The **Glucose** analysis module analyzes the blood glucose signal obtained from the HD-XG implant. The analysis calculates the common parameters that are associated with glucose after the signal has been calibrated.

### Attributes Window

The **Glucose Analysis Attributes** dialog allows you to modify the signal analysis for different types of glucose signals and signal conditions. If an analysis change in the **Attributes** dialog is performed **Averaging Interval**, then the attribute change will not take effect until the following cycle.

#### STANDARD ATTRIBUTES

The **Standard** attributes allow setting the most common attributes that would need to be changed during Acquisition or Review.



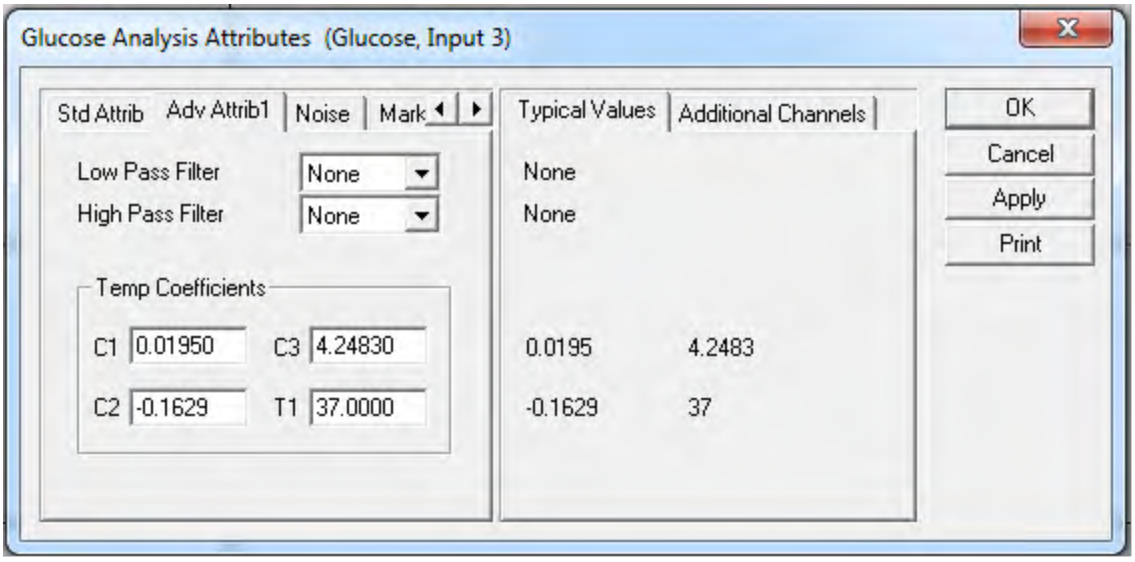

*Glucose Standard Attributes Tab*

| | |
|---|---|
| **Averaging Interval** | Interval at which glucose "cycles" will be reported by the analysis module. This represents the finest granularity at which data are reported. Data may be further averaged depending on the **Logging Rate** or **Data Reduction** settings. |

| | |
|---|---|
| | A **Mark** will be placed every **Averaging Interval**, referenced from the start of the acquisition i.e. elapsed time 0. |
| **Glucose Units** | Allows the user to select either **mg/dL** or **mmol/L.** This selection is used to set the **Units** for other attributes and to update the "**Min Calibration Range**" value and units within the **Glucose Calibrations \| Calibration Settings** dialog. |
| **Monitor Body Temperature** | Checking this box will enable the selection of the **Temp Channel**. |
| **Temperature Channel** | The channel from which temperature values are retrieved for calculating corrected nA. This will default to the temperature channel from the HD-XG device associated with the Subject. |

## ADVANCED ATTRIBUTES TAB

The **Advanced** attributes allow selection of attributes which are not commonly changed during Acquisition or Review.

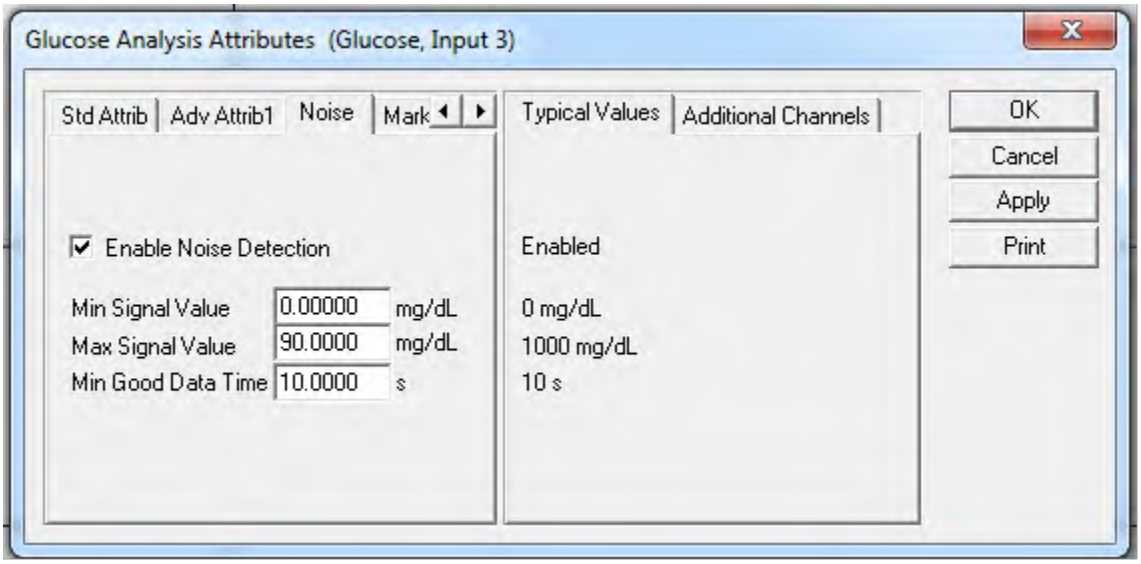



*Glucose Advanced Attribute Tab*

| | |
|---|---|
| **Low Pass Filter** | Selection of Low Pass filter in hertz. |
| **High Pass Filter** | Selection of High Pass filter in hertz. |
| **Temp Coefficients** | Coefficients used to apply temperature correction to the input nA signal. Four coefficients are required.<br><br>**DSI recommends not changing these values.** |

## NOISE TAB

The **Noise Tab** contains attributes that are used to identify noisy data. On identifying "noisy" data, as defined by the user, **Bad Data Marks** will be placed to span the noisy sections.



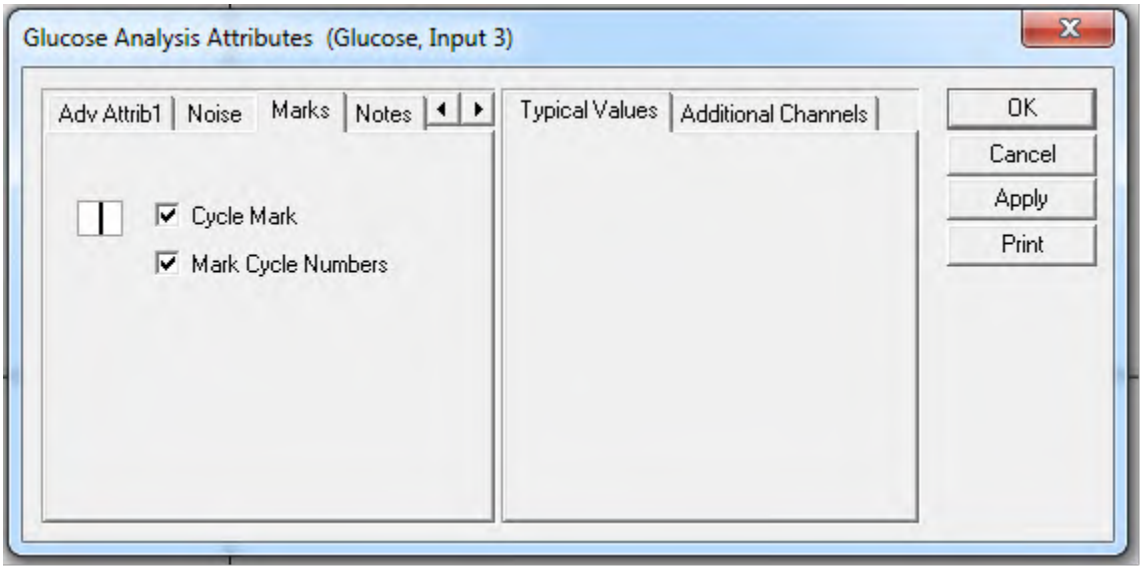

*Glucose Noise Tab*

| | |
|---|---|
| **Enable Noise Detection** | Enables the **Noise Detection** attributes for the automatic placement of **Bad Data Marks**. Enabling this function will also places **Bad Data Marks** around data that is defined as **Dropout**. |
| **Minimum Signal Value** | User defined threshold for determining the minimum value for acceptable data. Data that falls below this threshold will be considered noise and bracketed by **Bad Data Marks**. |

| | |
|---|---|
| **Maximum Signal Value** | User defined threshold for determining the maximum value for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Min Good Data Time** | If multiple **Bad Data Marks** exist in the file and are separated by less than the time specified in the window, the analysis will combine the sections to create one contiguous **Bad Data Mark** section. |

## MARKS (VALIDATION) TAB

The **Glucose** analysis displays validation tick marks for each cardiac cycle. Each cardiac cycle should have only one set of validation marks. These marks verify that the system is analyzing the glucose signal correctly.




*Glucose Marks Tab*

The validation marks and their meanings are listed below:

| **Color** | | **Meaning** |
|---|---|---|
| Black | | Cycle Mark |

## TYPICAL VALUES

Use these values as guidelines for a first time setup. Under different situations, values above or below the typical values will have to be used.

| Attribute | Setting | Units |
|---|---|---|
| **Averaging Interval** | 10 | s |
| **Glucose Units** | mg/dL or mmol/L | N/A |
| **Monitor Body Temperature** | Enabled | N/A |
| **Temperature Channel** | Enabled | Input channel associated with same Subject |
| **Low Pass Filter** | None | Hz |
| **High Pass Filter** | None | Hz |
| **Temp Coefficients** | C1=0.0195<br>C2=-0.1629<br>C3=4.2483<br>T1=37 | N/A |

## Derived Parameters

**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The derived parameters selected in this dialog box will be calculated, and the results will be placed in the **Derived Parameter List View(s)**. The following details the available **Derived Parameters** from the ECG module and the averaging method used within Review.

| Name | Definition | Review Averaging Method |
|---|---|---|
| **Num** | The number of the averaging interval since start of Acquisition. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. | Recent |
| **nAavg** | Average of nA samples within the averaging interval.<br><br>All samples within a cycle are included in the calculation, with the following exceptions:<br>• Railed samples<br>• Samples within bad data marks | Mean |
| **nAmax** | Maximum of nA samples within the averaging interval.<br><br>All samples within a cycle are included in the calculation, with the following exceptions:<br>• Railed samples<br>• Samples within bad data marks | Mean |
| **nAmin** | Minimum of nA samples within the averaging interval.<br><br>All samples within a cycle are included in the calculation, with the following exceptions:<br>• Railed samples | Mean |

| Name | Definition | Review Averaging Method |
|---|---|---|
| | • Samples within bad data marks | |
| **Gavg** | Average of calibrated Glucose signal samples within the averaging interval.<br><br>All samples within a cycle are included in the calculation, with the following exceptions:<br>• Railed samples<br>• Samples within bad data marks | Mean |
| **Gmax** | Maximum of calibrated Glucose signal samples within the averaging interval.<br><br>All samples within a cycle are included in the calculation, with the following exceptions:<br>• Railed samples<br>• Samples within bad data marks | Mean |
| **Gmin** | Minimum of calibrated Glucose signal samples within the averaging interval.<br><br>All samples within a cycle are included in the calculation, with the following exceptions:<br>• Railed samples<br>• Samples within bad data marks | Mean |
| **Samp** | The number of samples used in reporting nAxxx and Gxxx derived parameters. | Minimum |
| **Ref-Ds** | The averaged Reference values of all disabled calibration points during the logging interval. | Mean |
| **Ref-En** | The averaged Reference values of all enabled calibration points during the logging interval. | Mean |
| **Slope** | The averaged interpolated Slope during the logging period. | Mean |
| **Offset** | The averaged interpolated Offset during the logging period. | Mean |

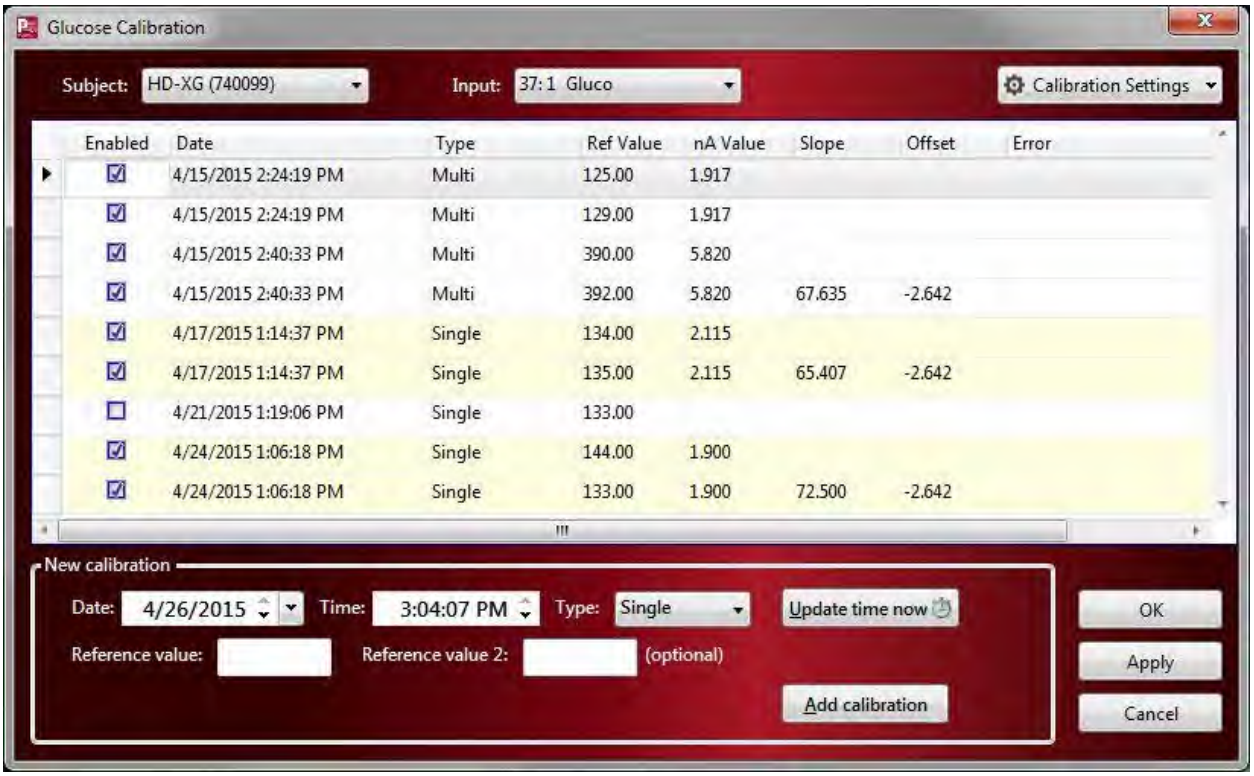
## Calibration – In Vivo

It is necessary to perform an initial multi-point calibration and to collect periodic calibration points at least twice per week throughout the duration of a glucose study. Calibration data is collected using blood samples from the tail or other appropriate sampling point with analysis performed by the StatStrip Xpress glucose meter or an equivalent analytical method. Calibration reference points should always be collected while the Ponemah Acquisition program is actively collecting data, and ideally, while the Subject is on or within range of the telemetry receiver (typically within about 25 cm of the receiver).

Ponemah Acquisition provides a dialog to facilitate entry of the calibration values that will later be used during Review. This can be accessed from the **Toolbar** menu by clicking on the **Glucose Calibration** icon. This provides several important features to facilitate the process:

- Automated or manual entry of date/time stamps associated with each sample point

- Entry of individual or duplicate samples for each time point
- Designation of calibration as single-point or multi-point calibration (this can be changed later)
- Ability to add multiple calibration values without dismissing the dialog
- Ability to switch between available subjects without dismissing the dialog




Each subject will have its own list of Glucose calibration reference values. If the dialog provided in Ponemah doesn't meet your particular needs, it is also possible to add these calibration reference values to an Excel file and import them during a Review session.

## CALIBRATION FREQUENCY RECOMMENDATION

The glucose sensor is affected over the implant duration by the presence of fibrin, tissue, and glucose levels. For optimal performance, the HD-XG must be calibrated using reference measurements over the course of a study:

- Initial multi-point calibration
- Twice weekly single-point calibration
- End-of-study multi-point calibration

Raw telemetry data is recorded in nanoamperes (nA) and calibration reference values are recorded in milligrams per deciliter (mg/dL) or millimoles per liter (mmol/L). The calibration algorithm converts the telemetry (nA) data to values that are equivalent to the appropriate mg/dL or mmol/L values.

## SELECTING A CALIBRATION REFERENCE

Several calibration reference options exist, including glucose analyzers, reagents and diagnostics equipment, and glucometers with test strips. DSI recommends the Nova StatStrip Xpress meter and test strips, as it provides comparable results to other laboratory analytics with the advantage and convenience of requiring smaller blood samples (1.2 µL) and providing immediate results. The StatStrip Xpress provides measurement and correction for hematocrit and other common interferents, as well as a higher level of accuracy than most alternative hand-held glucometers. See the DSI website www.datasci.com/glucose for more information on the StatStrip Xpress.

## MULTI-POINT CALIBRATION

A multi-point calibration establishes a linear relationship between the sensor output and blood glucose levels. DSI typically recommend using two points (baseline and slightly post-peak) for calibration purposes, but can support multiple points over the course of the challenge, such as an Oral Glucose Tolerance Test (OGTT). The blood glucose levels should differ by at least 200 mg/dL (11 mmol/L) to minimize calibration error caused by inaccuracies of the glucose reference. DSI recommends using an OGTT for multi-point calibration; however, an Intraperitoneal Glucose Tolerance Test (IPGTT) may also be used.

DSI recommends that at least two people are involved in the calibration process. One person is responsible for recording the calibration values on the Ponemah system and providing direction on the appropriate sample times. The second person handles the subjects, collects the samples, and reports the measurements. Additional personnel can be leveraged to streamline the process and increase throughput.

In a normal rat, the baseline blood glucose level might be approximately 100 mg/dL (5.5 mmol/L); while the peak value after an OGTT might be at least 300 mg/dL (16.7 mmol/L). Peak glucose values will typically occur 12-16 minutes post-dose during an OGTT in a healthy animal. DSI recommends taking a reading 5 to 10 minutes after this peak for an OGTT or 3 to 5 minutes after this peak for an IPGTT. If telemetry data cannot be viewed in real-time, such as when the computer is not physically located in the procedure room, please characterize the animal prior to collecting calibration values to estimate an appropriate post-dose time for the appropriate post peak blood glucose sample.

To learn how to perform a multi-point calibration, please see the **Glucose Calibration Process** section within the **Tutorials** section.

## SINGLE-POINT CALIBRATION

Single-point calibrations help account for non-physiologic changes in the baseline glucose value over time. Examples of non-physiologic changes include sensor drift due to enzyme instability or fibrin and tissue growth on the sensor. Single-point calibrations should be performed at least twice per week at the same time of day, and during a time period when the animal's blood glucose is relatively stable.

To learn how to perform a single-point calibration, please see the **Glucose Calibration Process** section within the **Tutorials** section.

## BEST PRACTICES

### LEAVE TELEMETRY DEVICE ON DURING THE ENTIRE STUDY

Leave the HD-XG implant in **ON** mode throughout the entire study to improve glucose sensor stability. Turning the device **ON** after extended time in **OFF** mode will result in a positive spike and it will take 1-5 hours for the glucose values to return to normal. If an implant is turned **OFF** mid-study, a single-point calibration should be performed at least 5 hours after turning **ON**. If there is a notable change in the baseline from the previous on time, it is advisable to perform a new multi-point calibration.

### TAKE DUPLICATE SAMPLES FOR EACH REFERENCE VALUE

- Duplicate samples should be used to minimize error and establish the most reliable calibration of the implantable glucose sensor. If duplicate samples vary by >10%, one or more additional samples are recommended to establish a more accurate reference value.
- Take duplicate glucose samples from a single point in time by drawing blood from the animal and testing the blood glucose level twice (e.g. using two different test strips). Enter the two reference values in the **Glucose Calibration** dialog in the **Reference value** and **Reference value 2** text fields, the software will average them.

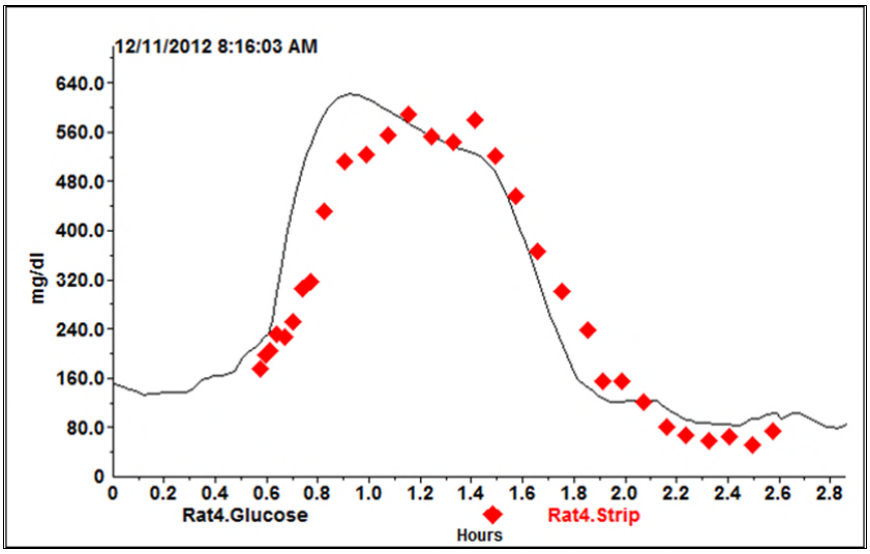
### MINIMIZE STRESS, ANESTHESIA ARTIFACTS

- Taking blood samples too frequently from animals that are stressed (due to restraint) can cause significant bias and variability in reference samples.
- Taking samples from anesthetized animals is discouraged as isoflurane has been demonstrated to impact the glucose sensor reading in some cases, particularly at later points in the study period.

### CONSIDERATIONS & ALTERNATIVES

In order to optimize implant calibration, there are several factors to consider.

- **Potential lag time between the glucose values** taken by the implanted sensor and the calibration reference. In a normal, healthy rat the peak glucose value is typically observed 4-7 minutes post dose for an intraperitoneal glucose tolerance test (IPGTT) and 12-16 minutes post dose for an OGTT. These durations will vary based on the glucose dose, whether or not the animal was fasted, and the animal strain. A blood sample taken from the tip of a rat's tail may have a 2-5 minute (or more) delayed response to the glucose dose due to stress artifact and the hemodynamics of the tail. Figure 23 below demonstrates the glucose measurement lag between the descending abdominal aorta and tail. The tail sample has a peak glucose value that occurs later than the peak value detected by the sensor in the descending aorta, which could result in errors during the calibration process. By sampling a few minutes after the peak is observed in the telemetry signal, the stable periods for the implant and reference signal can be more closely aligned and the theoretical calibration error can be reduced. This has a similar effect to shifting the tail samples backwards in time to better align with the telemetry signal. Data illustrated below is an example of the blood glucose measurement lag in the tail (Rat4.Strip) vs. descending aorta (Rat4.Glucose). This lag is variable and can last as little as a few seconds or greater than 10 minutes depending on animal stress, tail blood hemodynamics.



- **The method used to increase glucose levels to record baseline and peak values**. Several methods can be used to increase blood glucose levels if an increase of at least 200 mg/dL (11 mmol/L) needs to be achieved. Oral or IP glucose tolerance tests can be used and the method chosen depends on your study needs. IPGTTs typically result in faster and higher glucose peaks, which can expedite the calibration process and aid in achieving the desired glucose difference of 200 mg/dL (11 mmol/L), however, glucose is metabolized more quickly and the peak glucose value lasts for a shorter period of time. OGTTs require a large bolus of glucose to achieve the target 200 mg/dL (11 mmol/L) difference. However, peak glucose levels typically remain stable for a longer period of time, resulting in an easier and more accurate calibration process.

  When using Type 1 or Type 2 diabetic animals, an IP insulin tolerance test can be substituted for the glucose tolerance test.

## GLUCOSE CALIBRATION DIALOG

The **Glucose Calibration** dialog is used during Acquisition and Review to enter **Glucose Calibration Reference** values obtained by your Glucose Reference during Multi- and Single-point calibrations. The following describes dialog in detail. For instructions on how to use while performing a Multi- or Single-point calibration, please see the **Glucose Calibration Process Tutorial**.

The following describes the components of the dialog:

**A. Subject**

Dropdown box used to select the **Subject** whose calibrations information is desired to be displayed. Ensure the correct Subject is chosen before entering calibration values.

**B. Input**

Dropdown box used to designate which implant **Input** channel is displayed within the dialog. Since the HD-XG only has one glucose input channel, it will automatically be displayed and cannot be changed.

**C. Calibration List View**

This is an interactive **List View**, displaying information on all calibration values recorded for the selected **Subject** and **Input**.

*Note*: Visual cues (row highlights) are provided to indicate when **Calibration Reference** values are used together to calculate the calibration **Slope** and **Offset**. Information on when these are grouped together is provided in the **Slope/Offset** section below.

Each column is explained below:

- **Enabled**

  Allows the user to enable (**checked**) or disabled (**unchecked**) calibration values without losing the record. This permits the researcher to view the Glucose signal with certain calibration values disabled in order to improve the quality of the resultant signal.

- **Date**

  Displays the **Date** and **Time** the Glucose Reference value was taken, as recorded when entering the calibration value. If necessary, this may be updated directly in the List View by left-clicking the associated **Date/Time** text.

- **Type**

  Displays the **Type** of calibration to which the associated Glucose Reference value was defined; e.g. **Mult-** or **Single-point**.

- **Ref Value**

  Displays the recorded **Reference Value** measured by the **Glucose Reference** during the **Multi-** or **Single-point** calibration process. This can be augmented directly in the List View by left-clicking the **Ref Value** text.

- **nA Value**

  Displays the corresponding averaged nano Ampere (nA) value recorded by the implant at the time the **Ref Value** was recorded.

- **Slope/Offset**

  The **Slope** and **Offset** values are calculated by Ponemah based on the recorded calibration information and are used to generate the **Glucose** signal from the **nA** signal. These cannot be modified directly, as they are calculations.

  Only the last entry in a set of **Multi-point** calibrations will report a **Slope** and **Offset**. Each set of **Single-points** will report a **Slope** and **Offset**. A set of **Single-points** meaning those recorded with the same date/time point; e.g. Reference value and Reference value 2.

  In the case of a set of **Multi-point**, the **Slope** and **Offset** are obtained calculating a regression line through the **Reference** (y axis) and **nA** (x axis) values. All consecutive **Multi-points** within one hour of the last **Multi-point** will be grouped as part of the same challenge, yielding a single **Slope** and **Offset** value. The resultant **Slope** and **Offset** values will be applied from the start of the **Multi-point** sequence.

  In the case of each **Single-point** calibration, the **Offset** remains unchanged from the previous time point and the **Slope** is adjusted by **Calibration Damping %** of the difference between the previous **Slope** and the **Slope** that would yield a 100% correction.

- **Error**

  This will list any validation errors associated with the record. These must be corrected prior to closing the **Glucose Calibration** dialog.

**D. New Calibration**

Permits the user to add additional **Glucose Calibration Reference** values to the selected **Subject**. The user can enter the **Date** and **Time** at the time of the blood draw or simply select Update Time now to automatically update these fields with the current computer time. The user would also choose the calibration **Type** from the dropdown box and then enter the blood glucose **Reference values** measured by the **Glucose Reference**. Once all information is entered, select the **Add Calibration** button to add the reference information to the **Calibration List View**.

**E. Calibration Settings**

Provides access to advanced calibration settings. These settings are **Subject** specific; i.e. changes made are only applied to the currently selected **Subject**.


The following describes the settings listed within this dialog

- **Min Cal Range**

  Used to ensure the **Reference values** entered for a **Multi-point** calibration span at least the specified range to be valid. In this example, the **Multi-point** calibration **Reference values** must span at least 50 mg/dL to be a valid **Multi-point** calibration.

- **Calibration Interval**

  Used to define the range of data averaged when retrieving the **nA value** that corresponds to the recorded glucose **Reference value** reading.

- **Calibration Damping**

  Used to adjust the aggressiveness of the linear scaling during the calibration process.

  - Can be set to a value of **0-50%,** defaults to **20%**.
  - Is only applied to the **Single-point** calibration values and does not affect **Multi-point** calibration.
  - If the **Damping Factor** is set to **0%** the interpolation will be undamped and scale factor will be adjusted to compensate completely for each enabled single-point calibration value. The resulting calibrated telemetry data will pass directly through the single-point calibration value (or the average value of duplicate calibration samples).
  - If the **Damping Factor** is set to **20%** the applied scale factor will compensate for all but 20% of the difference between the previously used scale factor and the scale factor calculated for this point if 0% damping were used. The resulting calibrated telemetry data will not pass directly through the single-point calibration value unless 0% damping is used.
  - If the **Damping Factor** is set to **50%** the applied scale factor will compensate for all but 50% of the difference between the previously used scale factor and the scale factor calculated for this point if 0% damping were used. The resulting calibrated

telemetry data will not pass directly through the single-point calibration value unless 0% damping is used.
- Use of a **damping factor** greater than zero will minimize the amount that the glucose signal "bounces" between **Single-point** calibrations based on potential error in the **Calibration Reference** values. It may also under correct for a signal which is drifting due to loss of sensitivity.

- **Use Initial Slope and Offset**

Used during the calibration process to define a slope and offset to use until such time as reference values are available. The use of the initial slope and offset are not typically required, as the Ponemah calibration algorithms apply the first multipoint calibration both forward and backward in time.

Below are some examples of when using this feature may prove beneficial:

- User desires to have estimates of blood glucose levels reported during acquisition and prior to a multipoint calibration.
- User suspects the validity of a multipoint calibration and deems not to use it in the calibration process. (reference values lost, reference values suspect, timing of reference measurements concerning, …)
- A valid multipoint calibration is not available (was not performed)
- Animal applied to another experiment and data directory changed.
    - In this case even if a valid multipoint calibration were previously performed, the data from that portion of the study is in a different directory and would not be available for calibration purposes. As such, one would obtain the slope and offset by performing a calibration in the other experiment and then could apply that slope and offset in this new experiment using the initial slope and offset feature.

Note that in the examples above it is up to the user to define the slope and offset based upon their expert opinion and/or available data.

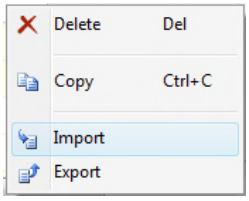
## IMPORT/EXPORT CALIBRATION DATA

### IMPORT

Calibration data can be recorded using Excel during the blood draw and glucose reference measurement periods and imported into the Glucose Calibration dialog at a later time. To import Glucose Calibration Reference values:

1. Start a Review session by selecting **Actions | Start Review**
2. Select the **Glucose Calibration** toolbar icon for a **Primary** graph page.
3. Select the **Subject** to which the calibration values will be imported.

4. Right-click the **List View** within the **Glucose Calibration** dialog.
5. Select **Import**.




6. Select the file to import.
    a. **.csv files**: allows the user to import calibration values from Excel, when saved as a CSV.
    b. **.glu files**: allows the user to import calibration data previously entered using Dataquest A.R.T.

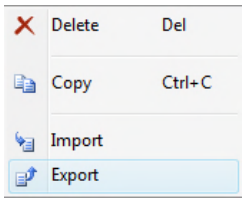
    *Note*: **.csv files** should be in the following format to properly import **Glucose Calibration Reference values**.

| | A | B | C | D |
|---|---|---|---|---|
| 1 | #DateTime | RefValue | CalType | Enabled |
| 2 | 2/17/2014 9:42 | 101 | 1 | 1 |
| 3 | 2/17/2014 9:42 | 95 | 1 | 1 |
| 4 | 2/17/2014 9:52 | 180 | 1 | 1 |
| 5 | 2/17/2014 9:52 | 222 | 1 | 1 |
| 6 | 2/24/2014 8:21 | 95 | 0 | 1 |

### EXPORT

Calibration data can be exported from the Calibration dialog to a .csv file, permitting the user to view these in Excel. To export Glucose Calibration Reference values:

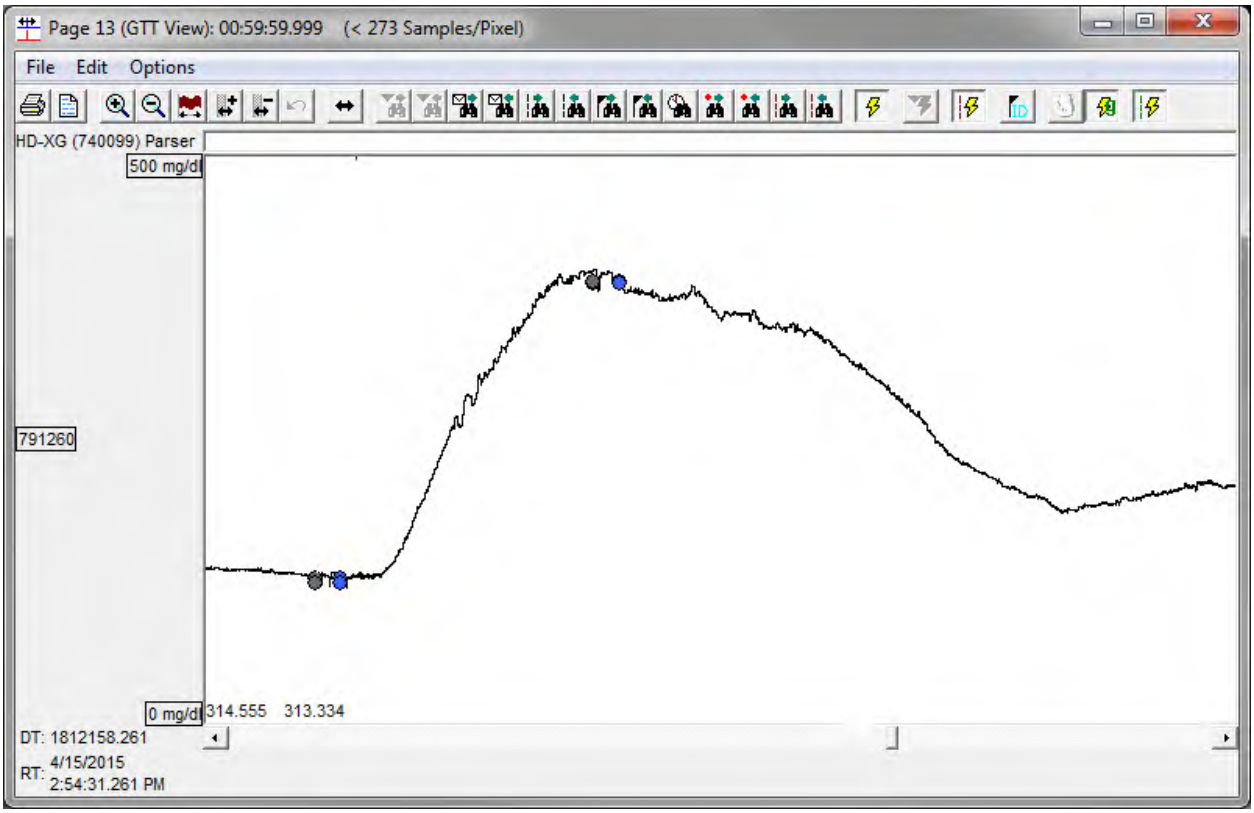
1. Within a Review session, select the **Glucose Calibration** toolbar icon for a **Primary** graph page.
2. Right-click the **List View** within the **Glucose Calibration** dialog.
3. Select **Export**.




4. Enter a **File name** and browse to the folder location desired to save the file.
5. Select **Save**.

## Online Screens and Functions

The following is an example of a **Primary** graph displaying a Glucose signal during a **Glucose Tolerance Test (GTT).**

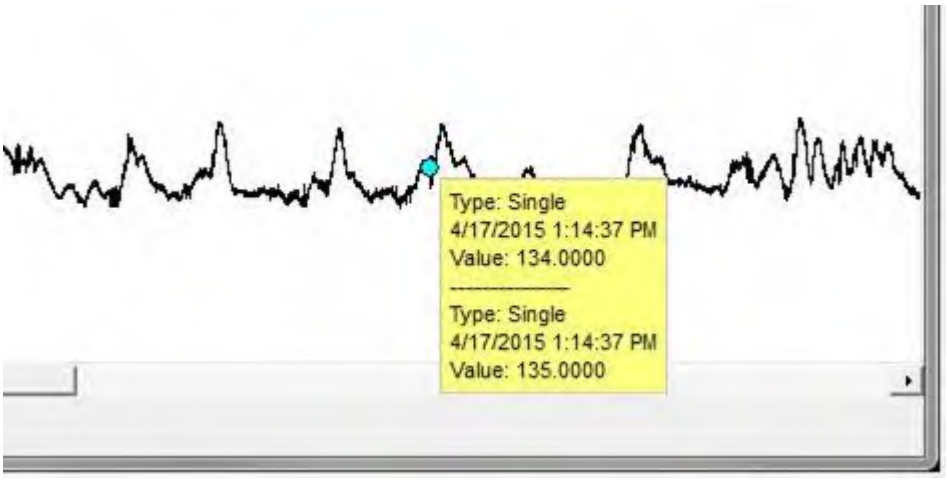



The **Validation Mark** for Glucose is the **Cycle** mark, is currently not displayed to provide a full view of the signal. The circular, colored marks displayed on the waveform are **Calibration Reference Points**. These points were entered in the **Glucose Calibration** dialog and correspond to glucose measurements taken manually using a **Glucose Reference**; e.g. glucometer.

The mark color indicators are described below:

| **Reference Mark Color** | | **State** |
|---|---|---|
| Blue | | Enabled Single-point Reference Value |
| Cyan | | Enabled Multi-point Reference Value |
| Gray | | Disabled Reference Value |
| Red | | Error with recorded Reference Value |

Hovering over these marks will provide information on the reference value, as shown below:




*Note*: **Calibration Reference Value** marks can be toggled **ON/OFF** using the **Glucose Reference Value Toggle** toolbar icon. 

## Presentation Signals

Below is a list of presentation signals that are available for the Glucose Analysis Module:

| Signal | Description |
|---|---|
| **nA_uc** | This will display the nA input signal without temperature correction applied. |
| **nA** | This will display the nA input signal with temperature correction applied. |
| **Glucose** | This will display the nA input signal converted to glucose readings using slope(s) and offset(s) from the **Glucose Calibration** dialog. The resultant units will depend on the units of the reference values entered during calibration. |

## Data Review

The analysis specific portion of Data Review centers around the marks that the User is permitted to display, insert, and delete and how the User is permitted to move them.

| | |
|---|---|
| **Displaying Marks and Cycle Numbers** | The marks and cycle numbers displayed in a Review **Primary** graph page **Display Pane** are controlled through the **Marks** Tab in the **Analysis Attributes** dialog. The **Analysis Attributes** dialog is accessed through the right click menu – **Analyze [Attributes]**. |
| **Mark Operations** | The **Cycle** mark is the only mark supported by Glucose and defines a glucose cycle. |
| **Inserting Marks** | A **Cycle** mark may be inserted by right clicking at the point of insertion in the **Primary** graph's **Display Pane** of the Channel of interest. The pop-up menu that is displayed will provide the option to insert a **Cycle** mark. |
| **Insert Glucose Cycle** | Inserts a **Glucose** "cycle". When a **Glucose** cycle is inserted, it is assigned a sequential cycle number and subsequent cycle numbers are incremented. |
| **Deleting Marks** | Marks are deleted by positioning the mouse cursor on the mark to be deleted and bringing up the right click menu. |
| **Moving Marks** | Moving the **Cycle** mark is permitted between the previous **Cycle** mark/**Data Break**/**Bad Data Mark** and the following **Cycle** mark/**Data Break**/**Bad Data Mark** |
| **Calculations** | The calculations of **Derived Parameters** are identical to those performed during Acquisition. |
| **Logging Mark** | The **Logging Mark** for a **Glucose** "cycle" is the **Cycle Mark**. The time at the logging mark is the time used to report a "cycle's" derived data. If a **Glucose** "cycle's" logging mark falls within a logging interval, the **Glucose** "cycle's" data will be included in the Logging interval. |
| **End of Cycle** | The start of a **Glucose** "cycle" is at the **Cycle** mark. The end of a "cycle" depends on what follows its **Logging Mark**:<br>• If the **Logging Mark** is not followed by a data break or another **Logging Mark** within 600s, the "cycle" will end at the last sample within 600s of the **Logging Mark**. |

- If the logging mark is followed by a **Data Break** with no intervening logging marks, the “cycle” will end on the sample that coincides with the **Data Break**.
- If the **Logging Mark** is followed by a **Logging Mark** with no intervening **Data Breaks**, the “cycle” will end on the sample that precedes the **Logging Mark**.

## ATTRIBUTE TYPES IN REVIEW

The following table describes the effects of changing Glucose attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| **Attribute** | **Effect on Review** |
|---|---|
| Averaging Interval | Signal Interpretation |
| Glucose Units | None |
| Monitor Body Temperature | None |
| Temperature Channel | Signal Conditioning |
| Low Pass Filter | Signal Conditioning |
| High Pass Filter | Signal Conditioning |
| Temp Coefficients | Signal Conditioning |
| Enable Noise Detection | Signal Interpretation |
| Minimum Signal Value | Signal Interpretation |
| Maximum Signal Value | Signal Interpretation |
| Min Good Data Time | Signal Interpretation |

## Pulmonary Air Flow (PAF)

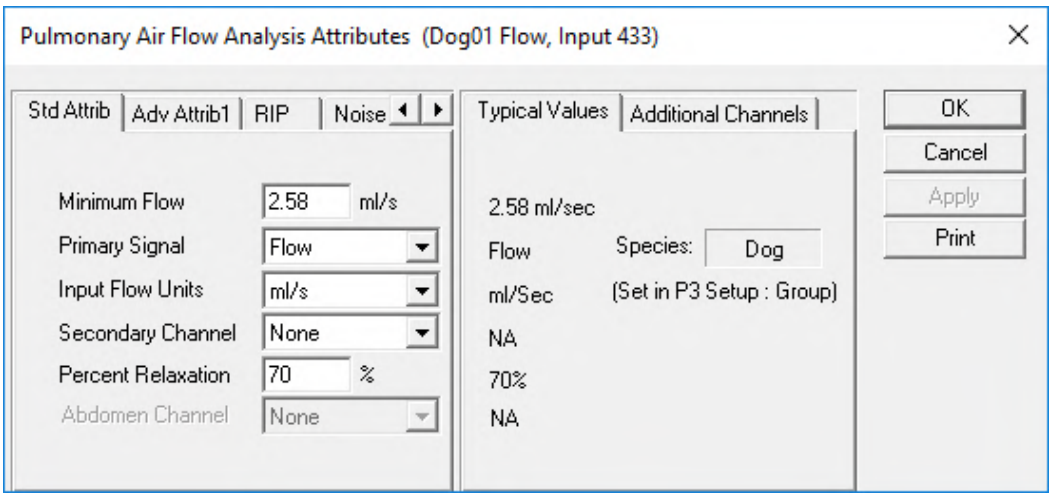
The **Pulmonary Air Flow** analyzes pulmonary airflow signals obtained from a plethysmograph box, a pneumotachograph, or via respiratory inductive plethysmography (RIP). It also calculates values for the respiratory cycle on a breath-to-breath basis.

### Attributes Dialog

The **Pulmonary Air Flow Analysis Attributes** dialog allows you to modify the signal analysis for different types of air flow signals and signal conditions. If an analysis change in the **Attributes** dialog is performed mid-cycle, then the attribute change will not take effect until the following cycle.

#### STANDARD ATTRIBUTES TAB

The **Standard** attributes allow setting the most common attributes that would need to be changed during Acquisition or Review.




*Pulmonary Air Flow Standard Attributes Tab*

**Minimum Flow**

Sets the minimum flow that the analysis must achieve before the analysis will detect and validate a pulmonary cycle. The Minimum Flow stops the analysis from triggering on artifacts such as cardiac noise.

**Primary Signal**

Sets the system for either a Flow input signal or a Volume input signal or RIP input signals. If Volume is selected as the primary signal, you can display the digitally derived flow signal on a primary graphic page by selecting Flow as the Presentation in the Primary Graph Page Setup window. If Flow is selected as the primary signal, you can display the digitally derived volume signal on the primary graph page by selecting Volume as the Presentation in the Primary Graph Page Setup window.

**Input Flow Units**

Input Flow Units is active when Flow is selected as the Primary Signal. Input Flow Units specifies the units of flow being measured so that the system calculates the volume correctly.

Calculated Flow Units is active when Volume or Vol-RIPChest is selected as the Primary Signal. Calculated Flow Units specifies the volume units used so that the system calculates the flow values correctly.

**mL/Sec** (milliliters per second)

**mL/Min** (milliliters per minute)

**L/Sec** (liters per second)

**L/Min** (liters per minute)

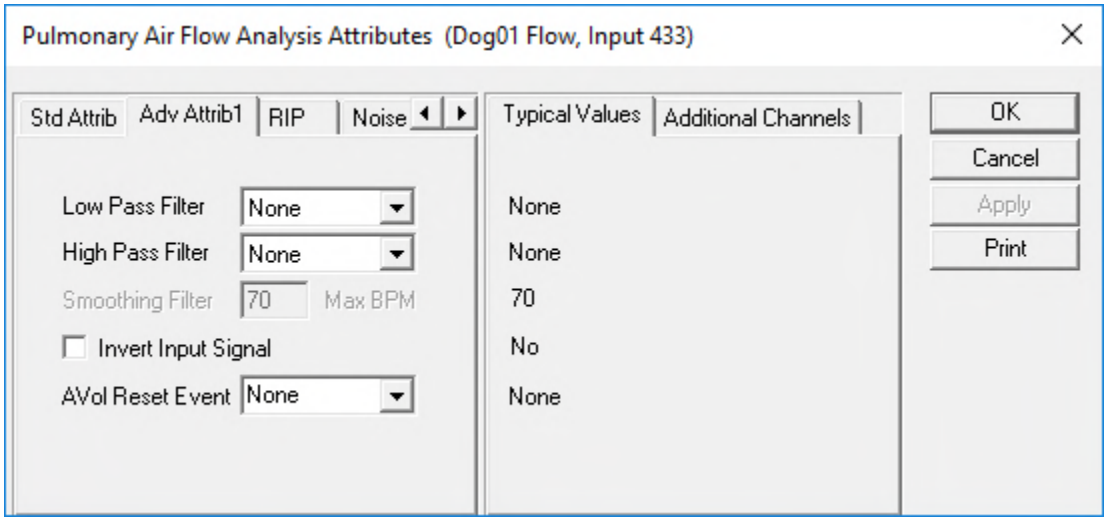
**Secondary Channel** Not Applicable.

**Percent Relaxation** Used to draw the percent relaxation mark and to calculate Penh and RT. The Percent Relaxation Mark is drawn when the volume signal drops from its maximum value by the specified percentage.

**Abdomen Channel** Not Applicable.

## ADVANCED ATTRIBUTES TAB

The **Advanced** attributes allow selection of attributes which are not commonly changed during Acquisition or Review.




*Pulmonary Air Flow Advanced Attribute Tab*

**Low Pass Filter** Selection of Low Pass filter in hertz.

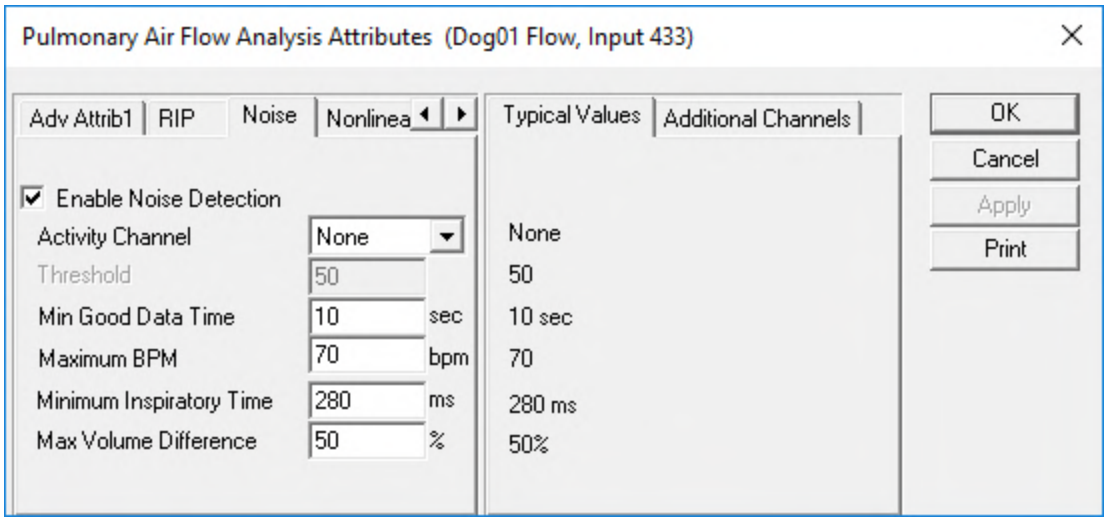
| | |
|---|---|
| **High Pass Filter** | Selection of High Pass filter in hertz. |
| **Smoothing Filter** | Defines a smoothing function by specifying the maximum breaths per minute that will not experience signal loss due to the filter. This filter is only applied when the Primary Signal is a volume signal, either Volume or Vol-RIP-chest. If Flow is selected as the Primary Signal, this attribute will be disabled, and a smoothing filter will not be applied.<br><br>Setting the Smoothing Filter to a high value (e.g. 999) will effectively disable this filter. |
| **Invert Input Signal** | This check box should be enabled if the respiration signal is acquired such that inspiration is negative. The PAF Analysis Module requires that inspiration is positive. Selecting the check box will reverse the polarity of the acquired signal. |
| **AVol Reset Event** | Used to determine the start point for the Accumulated Volume derived parameter (AVol). The selection of an event, “a” through “J”, will determine the start point for the calculation of AVol. If “None” is selected, the AVol derived parameter will report zero (acquisition and replay) or “x” (Review).<br><br>The start of an acquisition, a break in the data, or subsequent entries of the event to trigger the start point for the AVol calculation will result in the derived parameter being reset. |

### RESPIRATORY INDUCTIVE IMPEDANCE (RIP) TAB

This tab is used with DSI Jacketed External Telemetry (JET) for calibration of its RIP module. This is not applicable for Ponemah v6.x, as it is not compatible with DSI JET.

### NOISE TAB

The **Noise Tab** contains attributes that are used to identify noisy data. On identifying “noisy” data, as defined by the user, **Bad Data Marks** will be placed to span the noisy sections.




*Noise Tab*

**Enable Noise Detection** — Enables the **Noise Detection** attributes for the automatic placement of **Bad Data Marks**.

**Activity Channel** — Not applicable.

**Threshold** — Not applicable.

**Minimum Good Data Time** — Provides the user the ability to mark data as bad between two **Bad Data Mark** regions. If the time between the regions is less than the value specified. If the time is less than what is specified, the **Bad Data Mark** region will appear as one contiguous segment. This is a Review only feature.

**Maximum Breaths per minute (BPM)** — User defined threshold for determining the **maximum BPM** for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks** for removal from analysis.

**Minimum Inspiratory Time** — This sets the minimum allowable value for **Minimum Inspiratory Time**.

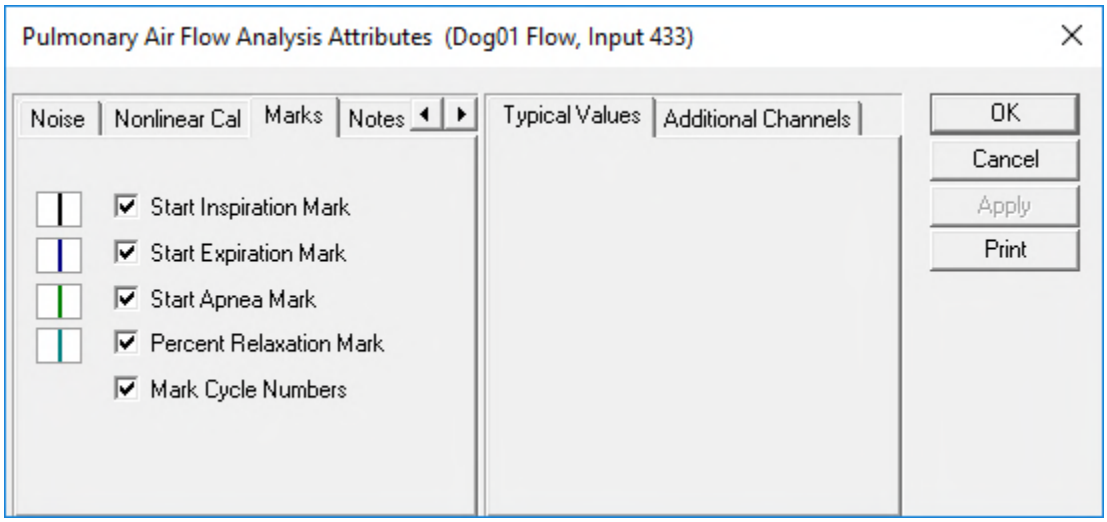
**Maximum Volume Difference** — The difference between inspiration and expiration volumes greater than this percentage will be considered noise and bracketed by **Bad Data Marks**.

## NONLINEAR CALIBRATION TAB

This tab is not applicable for Ponemah v6.x.

## MARKS (VALIDATION) TAB

The **Pulmonary Air Flow** analysis displays validation tick marks for each respiratory cycle. Each respiratory cycle should have only one set of validation marks. These marks verify that the system is analyzing the PAF signal correctly. If there is more than one set of validation marks per respiratory cycle, correct the problem by changing the analysis attributes.




*Marks Tab*

The validation marks and their meanings are listed below:

| **Color** | | **Meaning** |
|---|---|---|
| Black | | Start of Inspiration |
| Blue | | Start of Expiration |
| Green | | Start of Apnea |
| Cyan | | Percent Relaxation |
| | | Mark Cycle Numbers |

## TYPICAL VALUES

The table contains typical values for different heart rates. Use these values as guidelines for a first-time setup. Under different situations, values above or below the typical values may need to be used.

| **Attribute** | **Setting** | **Units** |
|---|---|---|
| Minimum Flow | Dog 2.58 | mL/Sec |

| | | |
|---|---|---|
| | Monkey 0.65<br>Rat 0.18<br>Mouse 0.02 | |
| Primary Signal | Flow | NA |
| Input Flow Units | User Defined | |
| Percent Relaxation | 70 | % |

## Derived Parameters

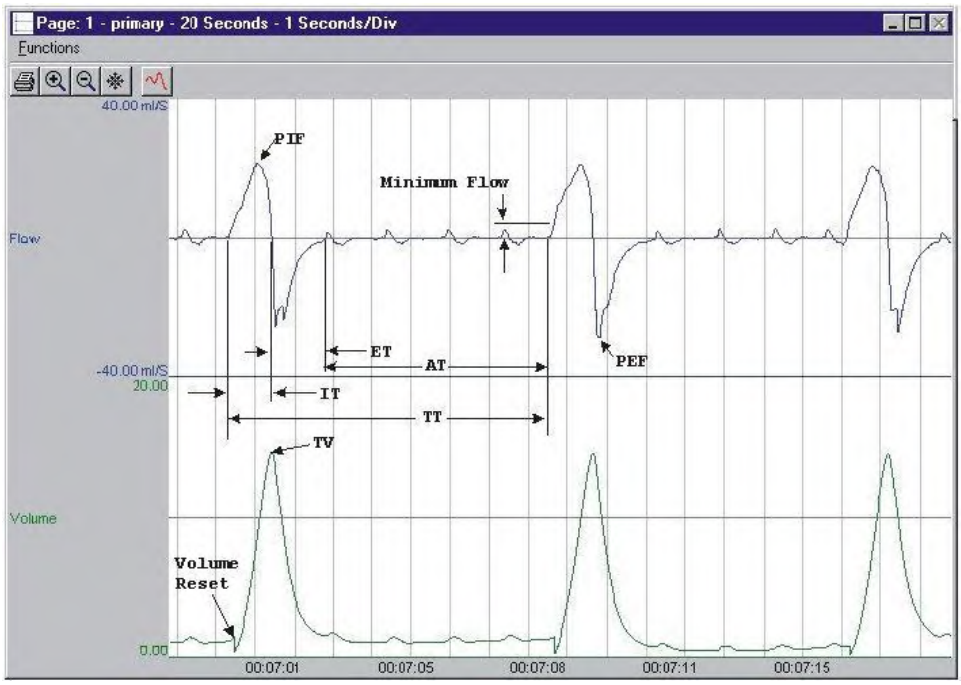
**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The **Derived Parameters** selected in this dialog will be calculated, and the results will be placed in the Derived Parameter List View(s). The following details the available **Derived Parameters** from the Pulmonary Air Flow module and the averaging method used within Review.

| Name | Definition | Review Averaging Method |
|---|---|---|
| **Num** | The number of the respiratory cycle. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. | Recent |
| **PIF** | Peak Inspiratory Flow is the maximum inspiratory flow that occurs during a valid breath. | Mean |
| **PEF** | Peak Expiratory Flow is the maximum expiratory flow that occurs during a valid breath. | Mean |
| **TV** | The Tidal Volume is the total volume of air that was inspired during a breath and is always reported in milliliters. | Mean |
| **MV** | The Minute Volume is the product of the tidal volume and the number of breaths-per-minute. The equation is: MV = TV * BPM.<br><br>Note: When running in a logging mode other than 1 epoch, the averaged value will be calculated off of the averaged TV and averaged BPM values. | Mean |
| **BPM** | The number of breaths-per-minute is calculated on a breath-to-breath basis. It is computed as the reciprocal of the total time for a respiratory cycle * 60.<br><br>Note: When running in a logging rate other than 1 epoch, sum the cycles in seconds in the logging period, divide by the number of cycles, take the reciprocal, and multiply the value by 60. | Harmonic Mean |
| **IT** | The Inspiratory Time is calculated from the first zero crossing of the flow in the inspiratory direction to the zero crossing of the flow in the expiratory direction. The time value is reported in milliseconds. | Mean |
| **ET** | The Expiratory Time is calculated from the zero crossing of the flow in the expiratory direction until flow reaches zero again. The time value is reported in milliseconds. | Mean |
| **TT** | The Total Time is the time period, in milliseconds, from one valid breath to the next valid breath. | Mean |
| **AT** | The Apnea Time is computed as follows: | Mean |

| Name | Definition | Review Averaging Method |
|---|---|---|
| | AT = TT − (IT + ET) | |
| **CaRaw** | Not Applicable | |
| **Phase** | Not Applicable | |
| **dT** | Not Applicable | |
| **Penh** | Enhanced Pause. Calculated as:<br>((ET+AT)/RT-1) * (PEF/PIF)<br><br>Formula from Noninvasive Measurement of Airway Responsiveness in Allergic Mice Using Barometric Plethysmography Hamelmann et al. | Mean |
| **RT** | Relaxation Time. This is the time from the start of expiration to the point where the volume signal drops by the Percent Relaxation value from its maximum value for the cycle. | Mean |
| **TVe** | This is the difference between the volume at the start expiration mark and the volume at the point prior to the next cycles start inspiration mark. It is always reported in milliliters. | Mean |
| **IF50** | IF50 reports the inspiratory flow value at the point where the volume signal rises to 50% of the tidal volume. | Mean |
| **EF50** | EF50 reports the expiratory flow value at the point where the volume signal drops to 50% of the tidal volume. | Mean |
| **AVol** | Accumulated Volume is the summed total of the Tidal Volume (TV) from a reset point forward and is reported in milliliters. Reset points include the start of data collection, break in the data or the selection of the event associated with the AVol Reset Event attribute. | Recent |

## Online Screens and Functions

The following is an example of a **Primary** graph displaying a typical Pulmonary Air Flow signal along with its digitally integrated volume signal. Key derived parameters are also indicated.




*Pulmonary Air Flow Key Parameters*

## Presentation Signals

Below is a list of presentation signals that are available for the PAF Analysis Module:

| Signal | Description |
|---|---|
| **Flow** | When Primary Signal = Flow, this will be the original flow signal.<br>When Primary Signal = Volume, this will display the differential of the signal, and it is generated as a two-point differential. |
| **Volume** | When Primary Signal = Flow, this will display the integration of the flow signal over the entire breath and reset at the start of the next valid breath.<br>When Primary Signal = Volume, this will display the original volume signal. |
| **CaRaw** | Not Applicable |
| **Phase** | Not Applicable |

## Data Review

This is a list of the Data Review related features of the Pulmonary Air Flow Analysis Module. The analysis specific portion of Data Review centers on the marks that the user is permitted to display, insert, and delete and how the User is permitted to move them.

| Action | **Description** |
|---|---|
| Displaying Marks and Cycle Numbers | The marks and cycle numbers displayed in a Review **Primary** graph page **Display Pane** are controlled through the **Marks** Tab in the **Analysis Attributes** dialog. The |

| Action | Description |
|---|---|
| | **Analysis Attributes** dialog is accessed through the right click menu – **Analyze [Attributes]**. |
| Mark Operations | PAF marks are divided into two types, marks that always exist when a valid cycle is found (**Start Inspiration** and **Start Expiration**) and marks that may or may not exist, depending on the signal morphology (**Percent Recovery** and **Start Apnea**). |
| Inserting Marks | **Marks** may be inserted by right clicking at the point of insertion in the **Primary Graph Display Pane** of the Channel of interest. The pop-up menu that is displayed will provide the option to insert marks as appropriate. The list of marks available for insertion will depend on the marks adjacent to the point of insertion; signal morphology is not considered. |
| Insert PAF Cycle | Inserts an entire **PAF cycle**, **Start Inspiration, Start Expiration,** and **Percent Relaxation**, if applicable. **Start Apnea** is not inserted; if Apnea exists this must be inserted manually. This set of marks may be inserted between a **Start Inspiration** mark and the last mark of the preceding cycle. Cycles may also be inserted prior to the first cycle and after the last cycle. When a PAF cycle is inserted, it is assigned a sequential cycle number and subsequent cycle numbers are incremented. |
| Insert Start Apnea | Inserts a **Start Apnea** mark. This mark may be inserted prior to a **Start Inspiration** mark or after the last cycle, as long as the preceding mark is not a **Start Apnea** mark. |
| Deleting Marks | **Marks** are deleted by positioning the mouse cursor on the mark to be deleted and bringing up the right click menu. Only the **Start Apnea** mark may be deleted in this fashion. The rest of the marks cannot be deleted individually. An entire cycle may be deleted. A cycle is deleted by positioning the cursor on the **Start Inspiration** mark,<br>bringing up the right mouse menu, and selecting **Delete Cycle**. |
| Moving Marks | Moving of the **Start Inspiration**, **Start Expiration** and **Start Apnea** marks follow the standard rules used in Data Review. There are special considerations when dealing with the **Percent Relaxation** mark. The **Percent Relaxation** mark is a calculated mark; its position is dependent on the Tidal Volume and cannot be adjusted by the user. If the user changes the position of the **Start Inspiration**, **Start Expiration**, or **Start Apnea** marks, the **Percent Relaxation** mark will be recalculated. When the **Percent Relaxation** mark is moved the derived parameter RT may change and will not be marked as a grayed cell unless a reanalyze is performed. This is also the case when the Secondary Channel is changed for the derived parameters CaRaw, Phase, and dT. |
| Calculations | The calculations of derived parameters are identical to those performed during acquisition and replay. Review reports the volume at the start of expiration as the Tidal Volume. Replay reports the maximum volume over the entire cycle. In most cases the values reported from Review and Replay are identical.<br><br>When a Review file is opened, the trace data may not be identical to the acquired data. The difference arises because of the scaling involved in the storage and reconstitution of the data. The difference for a point, on average, is less than 0.05%.<br><br>One of the consequences of this difference is seen with Calculated Marks. If, after opening a Review file, Review is prompted to recalculate a Calculated Mark, the mark may move with no change to the marks on which it depends. This is because |

| Action | Description |
|---|---|
| | the original placement of the Calculated Mark was based on the Replay data values whereas, recalculation uses the data values present in Review. |
| Logging Mark | The **Logging Mark** for a **PAF cycle** is the **Start Inspiration Mark**. The time at the **Logging Mark** is the time used to report a cycle's derived data. |
| End of Cycle | The end of a **PAF cycle** occurs one sample prior to the next cycle's **Start Inspiration** mark. When a PAF channel is the epoch channel, all review channels that display their cycle's logging mark prior to the end of the epoch channel's cycle will be included in the derived output. |

### ATTRIBUTE TYPES IN REVIEW

The following table describes the effects of changing PAF attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| Attribute | Effect On Review |
|---|---|
| **Minimum Flow** | Signal Interpretation |
| **Primary Signal** | Signal Conditioning, Calculation, Redraw |
| **Input Flow Units and Calculated Flow Units** | Signal Conditioning, Calculation, Redraw |
| **Secondary Channel** | Calculation |
| **Percent Relaxation** | Calculation, Redraw |
| **High Pass Filter** | Signal Conditioning, Calculation, Redraw |
| **Low Pass Filter** | Signal Conditioning, Calculation, Redraw |
| **Smoothing Filter** | Signal Conditioning, Calculation, Redraw |
| **Maximum BPM** | Signal Interpretation |
| **Minimum Inspiratory Time** | Signal Interpretation |
| **Invert Input Signal** | Signal Conditioning, Calculation, Redraw |
| **Max Volume Difference** | Signal Interpretation |
| **AVol Reset Event** | Calculation |
| **Marks and Cycle Numbers** | Redraw |
| **Precision** | Precision |

## Troubleshooting

Use the following table to assist in troubleshooting the analysis:

| Issue | Solution |
|---|---|
| **Breaths-per-Minute is doubled, halved, etc.** | This usually occurs when the analysis triggers on noise or artifacts. It can be corrected by changing the **Minimum Flow** to a higher or lower value to eliminate rates higher or lower than normal. If the signal has a lot of baseline noise, change the Low Pass Filter (in the Adv Attrib1 tab) to a higher value to remove the noise. Select a lower value in the list box. |
| **All Derived Parameters are reporting zero** | The **Minimum Flow** may be set too high for the specified signal. Lower the **Minimum Flow** value. |
| **Tidal Volume incorrect** | 1. This can be caused by the flow signal drifting above or below the zero line. Enable a High Pass Filter at 3Hz (in the Adv Attrib1 tab) if the flow signal is drifting. |

| | |
|---|---|
| | 2. The wrong Input Flow Units are being used. Since the volume is derived mathematically, the system must know the real units of flow being measured.<br>3. If the Tidal Volume is low, there could be a problem with the experimental setup. If the animal is in a plethysmograph, verify that there are no air leaks. This also pertains to any other setup. There can be no air leaks. |
| **"x" in** Derived Parameter List View **window instead of a number** | The **Derived Parameter** value is too large for the field. An "x" was placed here, so that a truncated number would not be displayed. |
| **Cannot find the analysis module in the** Subject Setup \| Subject Details **dialog** | The analysis module is likely not enabled in the Ponemah License. Check License options via **Help \| View License**. |

## Pulmonary Volume (PVO)

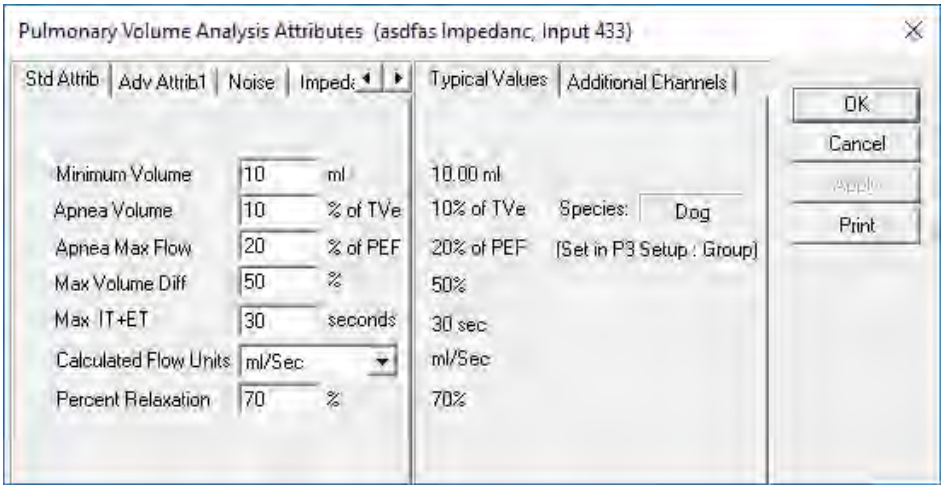
The **Pulmonary Volume** analyzes pulmonary volume signals obtained from a respiratory impedance implant. It also calculates values for the respiratory cycle using volume-based attributes on a breath-to-breath basis.

### Attributes Dialog

The **Pulmonary Volume Analysis Attributes** dialog allows you to modify the signal analysis for different types of volume signals and signal conditions. If an analysis change in the **Attributes** dialog is performed mid-cycle, then the attribute change will not take effect until the following cycle.

#### STANDARD ATTRIBUTES TAB

The **Standard** attributes allow setting the most common attributes that would need to be changed during Acquisition or Review.




*Pulmonary Volume Standard Attributes Tab*

**Minimum Volume** — Sets the minimum volume the analysis must achieve before the analysis will detect and validate a pulmonary cycle. The **Minimum Volume** stops the analysis from triggering on artifacts such as cardiac noise.

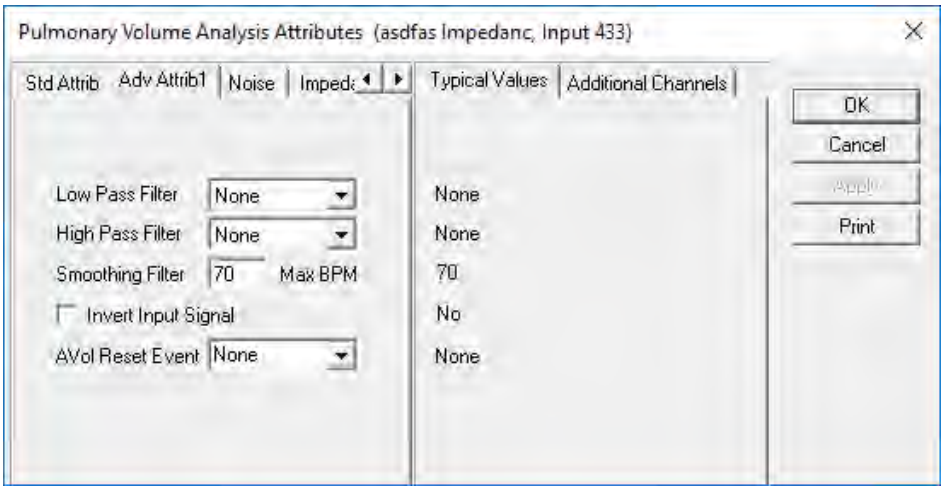
**Apnea Volume** — Sets the maximum volume as a percent of Tidal Volume Expired that could be included within the Apnea Time. If the volume exceeds this value the time prior to this will not be marked as an apnea. This feature is used in combination with **Apnea Max Flow** to determine periods of apnea.

**Apnea Max Flow** — Sets the maximum flow as a percent of Peak Expiratory Flow that could be included within the **Apnea Time**. If the flow exceeds this value the time prior to this may not be marked as an apnea. This feature is used in combination with **Apnea Volume** to determine periods of apnea.

| | |
|---|---|
| **Max IT + ET** | Sets the maximum inspiratory time plus expiratory time for a breath to be considered valid. The total breath time (IT+ET+AT) is used. |
| **Calculated Flow Units** | Calculated Flow Units specifies the volume units used for the system to correctly calculate flow values.<br><br>**mL/Sec** (milliliters per second)<br><br>**mL/Min** (milliliters per minute)<br><br>**L/Sec** (liters per second)<br><br>**L/Min** (liters per minute) |
| **Percent Relaxation** | Used to draw the percent relaxation mark and to calculate Penh and RT. The Percent Relaxation Mark is drawn when the volume signal drops from its maximum value by the specified percentage. |

## ADVANCED ATTRIBUTES TAB

The **Advanced** attributes allow selection of attributes which are not commonly changed during Acquisition or Review.




*Pulmonary Volume Advanced Attribute Tab*

| | |
|---|---|
| **Low Pass Filter** | Selection of Low Pass filter in hertz. |
| **High Pass Filter** | Selection of High Pass filter in hertz. |

**Smoothing Filter**

Defines a smoothing function by specifying the maximum breaths per minute that will not experience signal loss due to the filter. This filter is only applied when the Primary Signal is a volume signal, either Volume or Vol-RIP-chest. If Flow is selected as the Primary Signal, this attribute will be disabled, and a smoothing filter will not be applied.

Setting the Smoothing Filter to a high value (e.g. 999) will effectively disable this filter.

**Invert Input Signal**

This check box should be enabled if the respiration signal is acquired such that inspiration is negative. The PVO Analysis Module requires that inspiration is positive. Selecting the check box will reverse the polarity of the acquired signal.

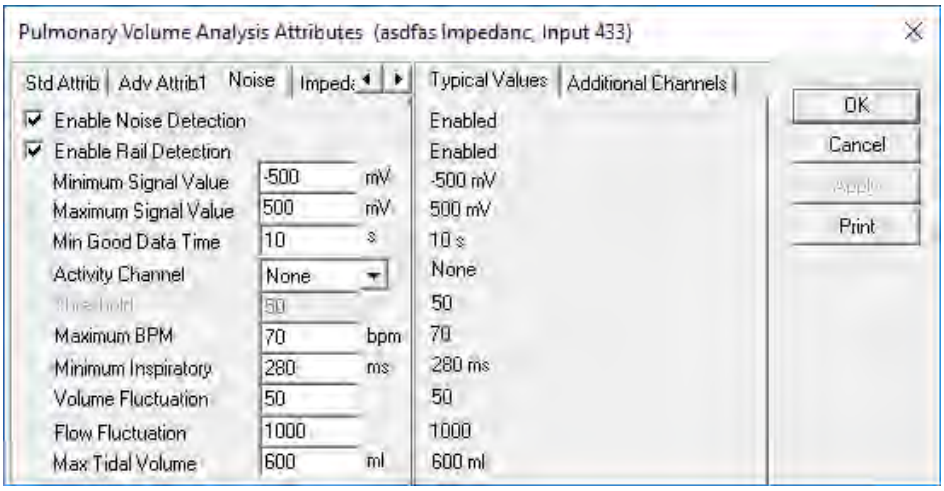
**AVol Reset Event**

Used to determine the start point for the Accumulated Volume derived parameter (AVol). The selection of an event, "a" through "J", will determine the start point for the calculation of AVol. If "None" is selected, the AVol derived parameter will report zero (acquisition and replay) or "x" (Review).

The start of an acquisition, a break in the data, or subsequent entries of the event to trigger the start point for the AVol calculation will result in the derived parameter being reset.

## NOISE TAB

The **Noise Tab** contains attributes that are used to identify noisy data. On identifying "noisy" data, as defined by the user, **Bad Data Marks** will be placed to span the noisy sections.




*Noise Tab*

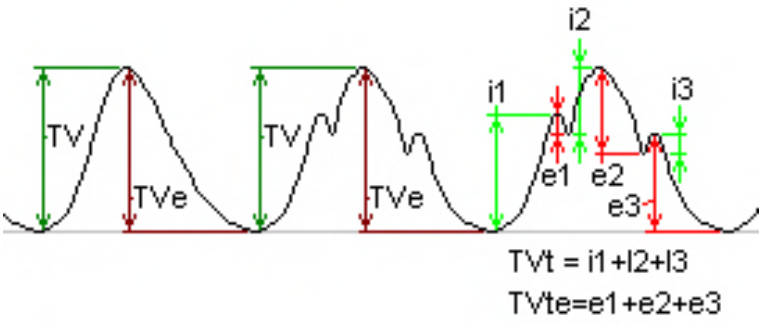
| | |
|---|---|
| **Enable Noise Detection** | Enables the **Noise Detection** attributes for the automatic placement of **Bad Data Marks**. |
| **Enable Rail Detection** | If **Rail Detection** is enabled, any negative telemetry dropout data encountered when analyzing data shall be bracketed **by Bad Data Marks** such that the dropout data falls within the **Bad Data Start** and **End** marks. The dropout check shall be performed on unfiltered samples. |
| **Minimum Signal Value** | User defined threshold for determining the **minimum value** for acceptable data. Data that falls below this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Maximum Signal Value** | User defined threshold for determining the **maximum value** for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks**. |
| **Minimum Good Data Time** | Provides the user the ability to mark data as bad between two **Bad Data Mark** regions. If the time between the regions is less than the value specified. If the time is less than what is specified, the **Bad Data Mark** region will appear as one contiguous segment. This is a Review only feature. |
| **Activity Channel** | Allows user to identify which channel is to be used as the Activity channel. |
| **Threshold** | User defined threshold the signal from the defined **Activity Channel** must exceed to be interpreted as noise. If exceeded Bad Data Marks will be inserted to remove the section of data from analysis. |
| **Maximum Breaths per minute (BPM)** | User defined threshold for determining the **maximum BPM** for acceptable data. Data that exceeds this threshold will be considered noise and bracketed by **Bad Data Marks** for removal from analysis. |
| **Minimum Inspiratory Time** | This sets the minimum allowable value for **Minimum Inspiratory Time**. |
| **Volume Fluctuation** | Volume fluctuation compares all of the inspiratory and expiratory volumes within a breath (TVt and TVte) to the Tidal volume inspired and expired (TV and TVe). |

If the volume fluctuation exceeds this setting it will be treated as noise and Bad Data Marks will be inserted to remove the data from analysis.

The volume fluctuation is calculated as:

$$= 100\left(\frac{TVt + TVte}{TV + TVe} - 1\right)$$

The below graphic shows a cycle with no volume fluctuation and then two cycles with volume fluctuation. For clarity the marks have been placed on different cycles; however, this fluctuation is calculated within a single breath cycle.




**Flow Fluctuation**

Flow fluctuation compares all the inspiratory and expiratory flows in a manner similar to volume fluctuation.

If the flow fluctuation exceeds this setting it will be treated as noise and Bad Data Marks will be inserted to remove the data from analysis.

The flow fluctuation is calculated as:

$$= 100\left(\frac{CumulativeFlow}{2PIF + 2PEF} - 1\right)$$

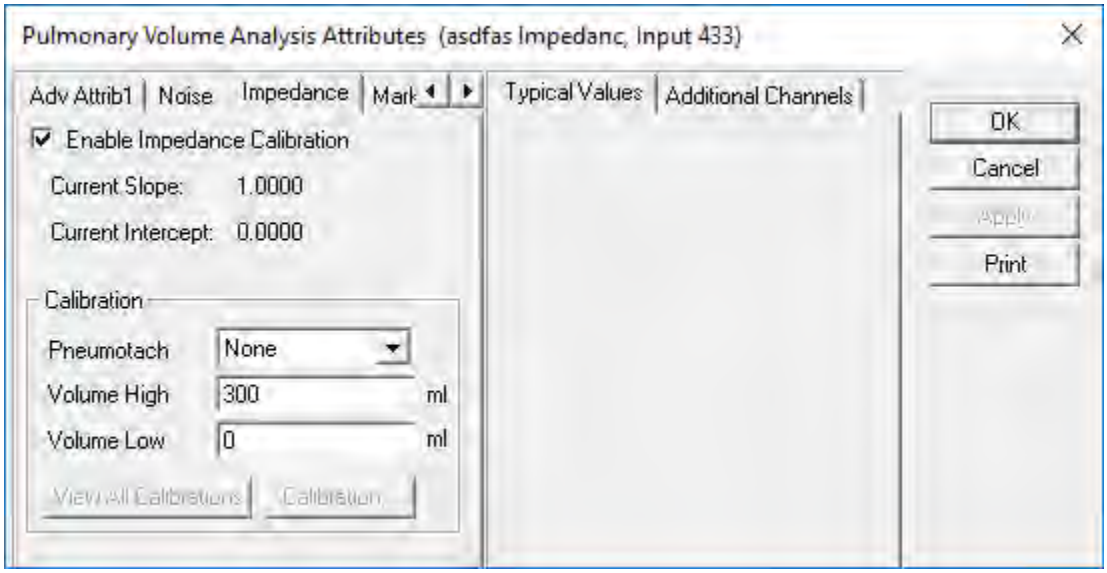
where CumulativeFlow is the sum of the range of flows covered by all continuously increasing or decreasing flows in cycle.

Max Tidal Volume

Sets the maximum allowed tidal volume. Cycles with volumes greater than this will be treated as noise and Bad Data Marks will be inserted to remove the data from analysis.

## IMPEDANCE TAB

The **Impedance Tab** permits users to calibrate the respiratory impedance channel of the implant against a direct measurement from a pneumotach or a Fixed Volume.



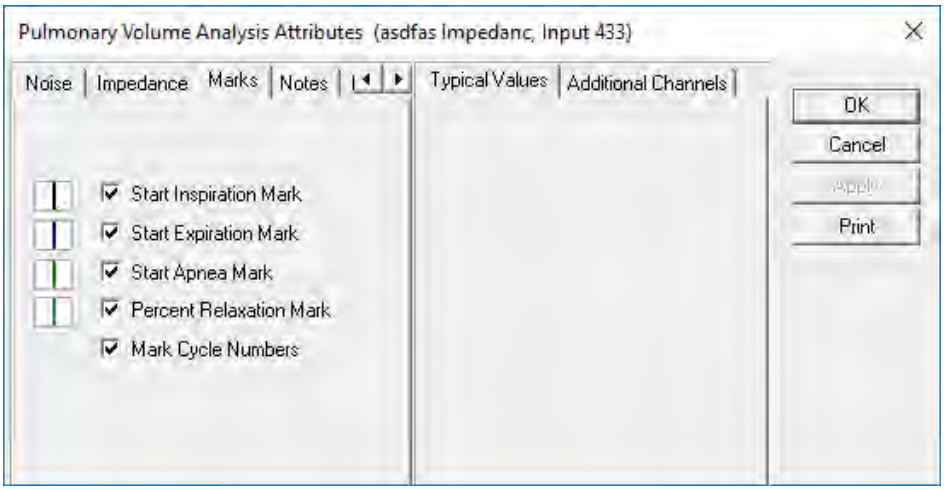

*Impedance Tab*

| | |
|---|---|
| **Enable Impedance Calibration** | Enables the Impedance Calibration attributes to be edited and used by the software. |
| **Current Slope** | Displays the current slope value from the impedance calibration. |
| **Current Intercept** | Displays the current intercept from the impedance calibration. |
| **Pneumotach** | Permits selection of the pneumotach channel. Download list will display all channels with PAF analysis module defined. |
| **Volume High** | The high volume used for impedance calibration when a pneumotach channel is not used. |
| **Volume Low** | The low volume used for impedance calibration when a pneumotach channel is not used. |

## MARKS (VALIDATION) TAB

The **Pulmonary Volume** analysis displays validation tick marks for each respiratory cycle. Each respiratory cycle should have only one set of validation marks. These marks verify that the system is analyzing the PVO signal

correctly. If there is more than one set of validation marks per respiratory cycle, correct the problem by changing the analysis attributes.




*Marks Tab*

The validation marks and their meanings are listed below:

| **Color** | | **Meaning** |
|---|---|---|
| Black | | Start of Inspiration |
| Blue | | Start of Expiration |
| Green | | Start of Apnea |
| Cyan | | Percent Relaxation |
| | | Mark Cycle Numbers |

## TYPICAL VALUES

The table contains typical values for different heart rates. Use these values as guidelines for a first-time setup. Under different situations, values above or below the typical values may need to be used.

| Attribute | Setting | | Units |
|---|---|---|---|
| **Minimum Volume** | Dog | 20.0 | mL |
| | Monkey | 5.0 | |
| **Minimum Volume** | Dog | 2.0 | Ohms |
| | Monkey | 1.0 | |
| **Apnea Volume** | Dog | 10 | % |
| | Monkey | 10 | |
| **Apnea Max Flow** | Dog | 20 | % |
| | Monkey | 20 | |

| | | | |
|---|---|---|---|
| **Max Volume Difference** | Dog | 50 | % |
| | Monkey | 50 | |
| **Max IT + ET** | Dog | 60 | Sec |
| | Monkey | 30 | |
| **Calculated Flow Units** | mL/Sec | | mL/Sec |
| **Percent Relaxation** | 70 | | % |
| **Smoothing Filter*** | Dog | 30-50 | Max BPM |
| | Monkey | 40-60 | |

* A value below the actual breaths per minute is not recommended. Additionally, the user should take caution to set a value which does not significantly alter the amplitude or width of the volume waveform.

## Derived Parameters

**Derived Parameters** are selected within the **Channel Details** of the **Subject Setup** dialog. The **Derived Parameters** selected in this dialog will be calculated, and the results will be placed in the Derived Parameter List View(s). The following details the available **Derived Parameters** from the Pulmonary Volume module and the averaging method used within Review.

| Name | Definition | Review Averaging Method |
|---|---|---|
| **Num** | The number of the respiratory cycle. This number will appear on a primary graph page when validation marks are turned on and the cycle numbers are enabled. When running in a logging mode other than 1 epoch, the last cycle number will be reported. | Recent |
| **PIF** | Peak Inspiratory Flow is the maximum inspiratory flow that occurs during a valid breath. | Mean |
| **PEF** | Peak Expiratory Flow is the maximum expiratory flow that occurs during a valid breath. | Mean |
| **TV** | The Tidal Volume is the total volume of air that was inspired during a breath and is always reported in milliliters. | Mean |
| **MV** | The Minute Volume is the product of the tidal volume and the number of breaths-per-minute. The equation is: MV = TV * BPM.<br><br>Note: When running in a logging mode other than 1 epoch, the averaged value will be calculated off of the averaged TV and averaged BPM values. | Mean |
| **BPM** | The number of breaths-per-minute is calculated on a breath-to-breath basis. It is computed as the reciprocal of the total time for a respiratory cycle * 60.<br><br>Note: When running in a logging rate other than 1 epoch, sum the cycles in seconds in the logging period, divide by the number of cycles, take the reciprocal, and multiply the value by 60. | Harmonic Mean |
| **IT** | The Inspiratory Time is calculated from the first zero crossing of the flow in the inspiratory direction to the zero crossing of the flow in the expiratory direction. The time value is reported in milliseconds. | Mean |
| **ET** | The Expiratory Time is calculated from the zero crossing of the flow in the expiratory direction until flow reaches zero again. The time value is reported in milliseconds. | Mean |
| **TT** | The Total Time is the time period, in milliseconds, from one valid breath to the next valid breath. | Mean |
| **AT** | The Apnea Time is computed as follows:<br>AT = TT − (IT + ET) | Mean |
| **Penh** | Enhanced Pause. Calculated as: | Mean |

| Name | Definition | Review Averaging Method |
|---|---|---|
| | ((ET+AT)/RT-1) * (PEF/PIF)<br><br>Formula from Noninvasive Measurement of Airway Responsiveness in Allergic Mice Using Barometric Plethysmography Hamelmann et al. | |
| **RT** | Relaxation Time. This is the time from the start of expiration to the point where the volume signal drops by the Percent Relaxation value from its maximum value for the cycle. | Mean |
| **TVe** | This is the difference between the volume at the start expiration mark and the volume at the point prior to the next cycles start inspiration mark. It is always reported in milliliters. | Mean |
| **IF50** | IF50 reports the inspiratory flow value at the point where the volume signal rises to 50% of the tidal volume. | Mean |
| **EF50** | EF50 reports the expiratory flow value at the point where the volume signal drops to 50% of the tidal volume. | Mean |
| **AVol** | Accumulated Volume is the summed total of the Tidal Volume (TV) from a reset point forward and is reported in milliliters. Reset points include the start of data collection, break in the data or the selection of the event associated with the AVol Reset Event attribute. | Recent |
| **VolBa** | The Volume Baseline is the volume at start of inspiration. It is reported in the same units as the volume waveform. | Mean |
| **VFluc** | Volume fluctuation compares all the inspiratory and expiratory volumes within a breath (TVt and TVte) to the Tidal volume inspired and expired (TV and TVe). The difference is reported as a percent change. | Mean |
| **FFluc** | Flow fluctuation compares all the inspiratory and expiratory flows in a manner similar to volume fluctuation. | Mean |
| **TVm** | The median tidal volume (TV) – available for trending. | Median |
| **MVm** | The median minute volume (TV) – available for trending. | Median |
| **TVt** | The Tidal Volume Throughout is the total volume of air that was inspired at any time during a breath and is always reported in milliliters.<br>This is the sum of all positive changes in volume from start of inspiration to start of expiration. | Mean |
| **TVte** | The Tidal Volume Expired Throughout is the total volume of air that was expired at any time during a breath and is always reported in milliliters.<br>This is the sum of all negative changes in volume from start of inspiration to start of expiration. | Mean |
| **PZr** | If a pneumotach is available and defined within the calibration dialog this derived data point will output the ratio of pneumotach volume divided by volume signal (calibrated if enabled) for the logging period. | Mean |

## Calibration

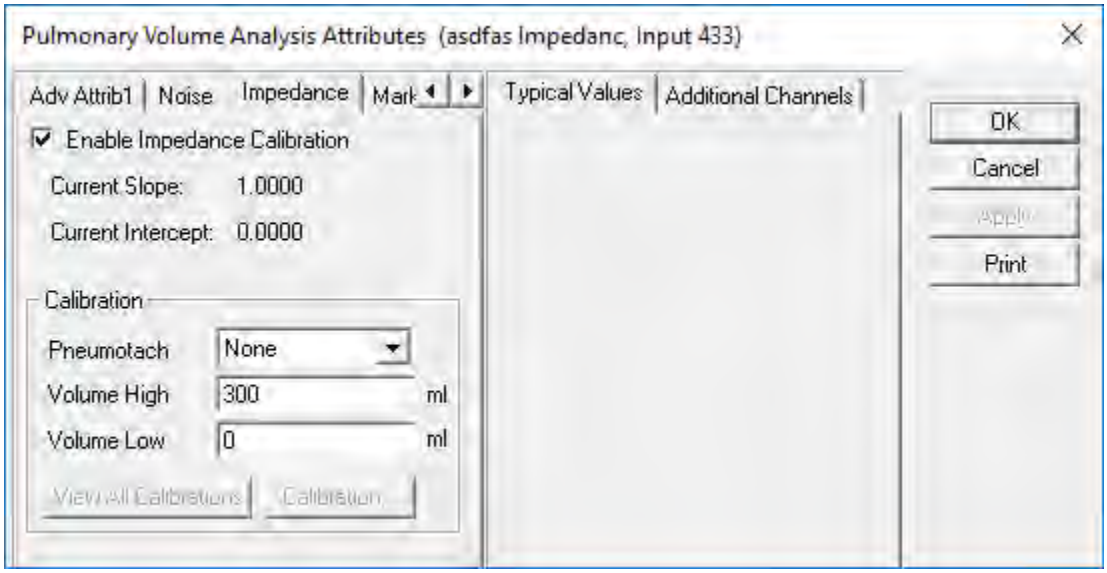
The respiratory impedance signal when uncalibrated reports volumetric changes as impedance (in ohms). In order to transform from impedance into units of volume a calibration is required. The respiratory impedance volume signal may be calibrated versus a pneumotach or versus fixed volume values entered manually.

If calibrating versus a pneumotach, the user is required to have previously set up and calibrated the pneumotach within the software in such a way that it may be used in a synchronized manner with the D70-PCTR or L11R implants; i.e. using a pneumotach interface to the MX2 Signal Interface.

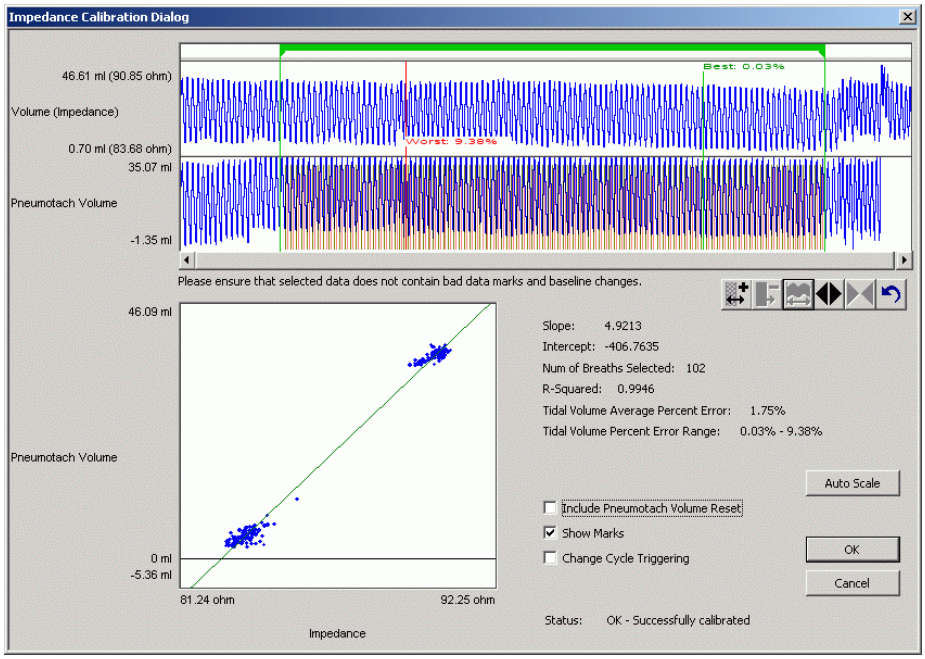
Once the user has the hardware configured correctly and attached to the animal the user must collect data from the pneumotach and the D70-PCTR or L11R. The data will preferably be very clean and with the animal in a posture representative of the posture which the animal will be in during a normal data collection. Data may be collected for as long or short as desired; however, during the calibration process only 5 consecutive minutes may be used. It is strongly recommended to only calibrate during periods when the impedance signal baseline is consistent and bad data marks are not present.

Following data collection:

1. Start Review.
2. Find the start of that "calibration period" and have it within a Primary graph window.
3. Right-click on the impedance waveform and select **Analyze [Attributes]**.
4. Select the **Impedance tab**.




5. Enable the **Impedance Calibration**
6. If calibrating against Pneumotach
    a. Define the **Pneumotach** channel.
    **Note**: The Fixed Volume entry is disabled when using the Pneumotach option.
    b. Select the **Calibration** button.




c. Place Calibration Segment Bar(s).
The green bar located near the top of the dialog is the Calibration Segment Bar. The Calibration Segment Bar allows the user to select which breaths to calibrate versus the pneumotach signal. The bar can be shorted or elongated using the computer mouse. Multiple segments can be added to maximize the number of typical breaths used in the calibration. Additional segments are added by right-clicking in the Calibration Segment Bar portion of the dialog.

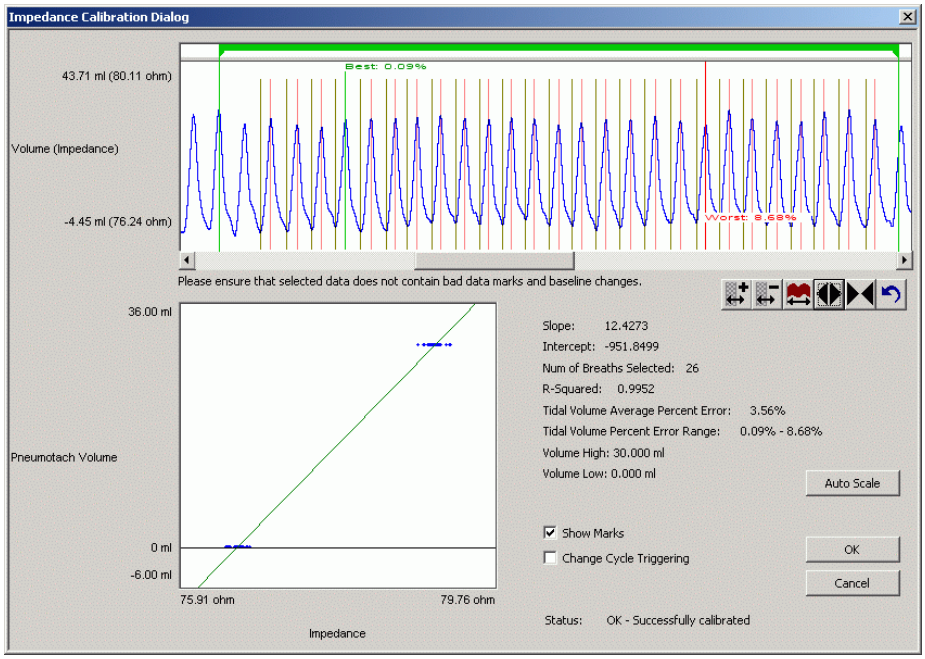
**Note**: The Impedance Calibration Dialog will display up to a five-minute segment of data starting at the left edge of the viewable section of data from the Primary graph page.

7. If calibrating ***WITHOUT*** Pneumotach
   a. Enter in **High Volume** and **Low Volume.**

   Typical values:

| Species | High Volume (mL) | Impedance (ohms) | Slope |
|---|---|---|---|
| Dog | ~150-300 | ~8-10 | ~15-45 |
| Primate | ~10-30 | ~3-5 | ~4-15 |

   b. Select **Calibrate** button.




c. Place Calibration Segment Bar(s).
The green bar located near the top of the dialog is the Calibration Segment Bar. The Calibration Segment Bar allows the user to select which breaths to calibrate versus the pneumotach signal. The bar can be shorted or elongated using the computer mouse. Multiple segments can be added to maximize the number of typical breaths used in the calibration. Additional segments are added by right-clicking in the Calibration Segment Bar portion of the dialog.

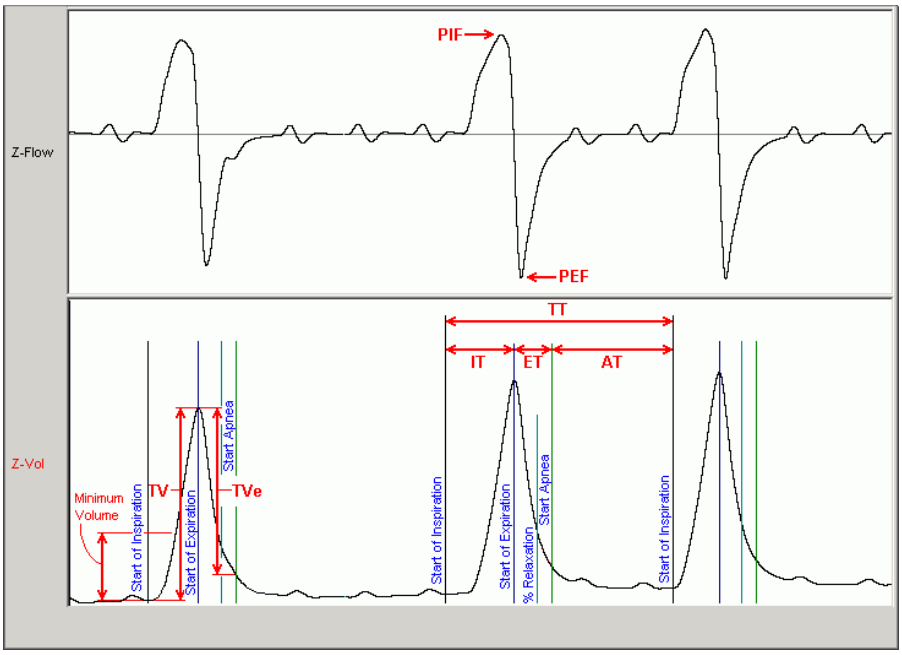
**Note**: The Impedance Calibration Dialog will display up to a five-minute segment of data starting at the left edge of the viewable section of data from the Primary graph page.

8. After placing the Calibration Segment Bar(s) the following with automatically calculated and displayed in the dialog:
    a. Slope and Intercept
    b. Number of Breaths Selected (determined by the placement of the Calibration Segment Bar(s))
    c. Number of Breaths Used in the calibration
    d. $R^2$ value
    e. Average Percent Error [(Vtotal - VPneumo)/VPneumo] of the breaths used in the calibration
    f. Percent Error Range
9. Click **OK** once the calibration is acceptable.

The slope and intercept values will automatically populate the Impedance Calibration dialog. The user may then reanalyze the data set. Scaling of graphs, minimum flows, etc will need to be adjusted to obtain an appropriate analysis.

## Online Screens and Functions

The following is an example of a **Primary** graph displaying a typical Pulmonary Flow and Volume signal. Key derived parameters are indicated, alone with the validation marks: **Start of Inspiration**, **Start of Expiration**, **Percent Relaxation**, and **Start of Apnea**.




*Pulmonary Volume Key Parameters and Marks*

## Presentation Signals

Below is a list of presentation signals that are available for the PAF Analysis Module:

| Signal | Description |
|---|---|
| Flow | This will display the differential of the signal, and it is generated as a two-point differential. |
| Volume | This will display the original volume signal (in ohms if uncalibrated, if mL if calibrated). |
| Input | This will display the original volume signal (in ohms) regardless of calibration. |

## Data Review

This is a list of the Data Review related features of the Pulmonary Volume Analysis Module. The analysis specific portion of Data Review centers on the marks that the user is permitted to display, insert, and delete and how the User is permitted to move them.

| Action | Description |
|---|---|
| Displaying Marks and Cycle Numbers | The marks and cycle numbers displayed in a Review **Primary** graph page **Display Pane** are controlled through the **Marks** Tab in the **Analysis Attributes** dialog. The **Analysis Attributes** dialog is accessed through the right click menu – **Analyze [Attributes]**. |
| Mark Operations | PVO marks are divided into two types, marks that always exist when a valid cycle is found (**Start Inspiration** and **Start Expiration**) and marks that may or may not exist, depending on the signal morphology (**Percent Recovery** and **Start Apnea**). |
| Inserting Marks | **Marks** may be inserted by right clicking at the point of insertion in the **Primary Graph Display Pane** of the Channel of interest. The pop-up menu that is displayed will provide the option to insert marks as appropriate. The list of marks available for insertion will depend on the marks adjacent to the point of insertion; signal morphology is not considered. |
| Insert PVO Cycle | Inserts an entire **PVO cycle**, **Start Inspiration, Start Expiration,** and **Percent Relaxation**, if applicable. **Start Apnea** is not inserted; if Apnea exists this must be inserted manually. This set of marks may be inserted between a **Start Inspiration** mark and the last mark of the preceding cycle. Cycles may also be inserted prior to the first cycle and after the last cycle. When a PVO cycle is inserted, it is assigned a sequential cycle number and subsequent cycle numbers are incremented. |
| Insert Apnea Mark | Inserts a **Start Apnea** mark. This mark may be inserted prior to a **Start Inspiration mark** or after the last cycle, as long as the preceding mark is not a **Start Apnea** mark. In many cases, a start apnea mark will already exist and be overlapped by the subsequent cycle's start of inspiration mark. Movement of these marks may be necessary to differentiate and place them as needed. |
| Deleting Marks | **Marks** are deleted by positioning the mouse cursor on the mark to be deleted and bringing up the right click menu. Only the **Start Apnea** mark may be deleted in this fashion. The rest of the marks cannot be deleted individually. An entire cycle may be deleted. A cycle is deleted by positioning the cursor on the **Start Inspiration** mark,<br>bringing up the right mouse menu and selecting **Delete Cycle**. |
| Moving Marks | Moving of the **Start Inspiration**, **Start Expiration** and **Start Apnea** marks follow the standard rules used in Data Review. There are special considerations when dealing with the **Percent Relaxation** mark. The **Percent Relaxation** mark is a calculated mark; its position is dependent on the Tidal Volume and cannot be adjusted by the user. If the user changes the position of the **Start Inspiration**, **Start Expiration**, or **Start Apnea** marks, the **Percent Relaxation** mark will be recalculated. When the **Percent Relaxation** mark is moved the derived parameter RT may change and will not be marked as a grayed cell unless a reanalyze is performed |
| Calculations | The calculations of derived parameters are identical to those performed during acquisition and replay. Review reports the volume at the start of expiration as the Tidal Volume. Replay reports the maximum volume over the entire cycle. In most cases the values reported from Review and Replay are identical.<br><br>When a Review file is opened, the trace data may not be identical to the acquired data. The difference arises because of the scaling involved in the storage and reconstitution of the data. The difference for a point, on average, is less than 0.05%. |

| Action | Description |
|---|---|
| | One of the consequences of this difference is seen with Calculated Marks. If, after opening a Review file, Review is prompted to recalculate a Calculated Mark, the mark may move with no change to the marks on which it depends. This is because the original placement of the Calculated Mark was based on the Replay data values whereas, recalculation uses the data values present in Review. |
| Logging Mark | The **Logging Mark** for a **PVO cycle** is the **Start Inspiration Mark**. The time at the L**ogging** M**ark** is the time used to report a cycle's derived data. |
| End of Cycle | The end of a **PVO cycle** occurs one sample prior to the next cycle's **Start Inspiration** mark. When a PVO channel is the epoch channel, all review channels that display their cycle's logging mark prior to the end of the epoch channel's cycle will be included in the derived output. |

### ATTRIBUTE TYPES IN REVIEW

The following table describes the effects of changing PVO attributes in Review. Please refer to the **Analysis Attributes Dialog | Attribute Types** section for the meanings of the effects of each attribute type described.

| Attribute | Effect On Review |
|---|---|
| **Minimum Flow** | Signal Interpretation |
| **Apnea Volume** | Signal Conditioning, Calculation, Redraw |
| **Apnea Max Flow** | Signal Conditioning, Calculation, Redraw |
| **Max Volume Difference** | Calculation |
| **Max IT + ET** | |
| **Calculated Flow Units** | |
| **Percent Relaxation** | Calculation, Redraw |
| **High Pass Filter** | Signal Conditioning, Calculation, Redraw |
| **Low Pass Filter** | Signal Conditioning, Calculation, Redraw |
| **Smoothing Filter** | Signal Conditioning, Calculation, Redraw |
| **Invert Input Signal** | Signal Conditioning, Calculation, Redraw |
| **AVol Reset Event** | Calculation |
| **Threshold (Activity)** | |
| **Min Good Data Time** | |
| **Maximum BPM** | Signal Interpretation |
| **Minimum Inspiratory Time** | Signal Interpretation |
| **Volume Fluctuation** | |
| **Flow Fluctuation** | |
| **Max Tidal Volume** | |
| **Slope** | |
| **Intercept** | |
| **Pneumotach** | |
| **Volume High** | |
| **Volume Low** | |
| **Marks and Cycle Numbers** | Redraw |
| **Precision** | Precision |

## Troubleshooting

Use the following table to assist in troubleshooting the analysis:

| Issue | Solution |
|---|---|
| **Breaths-per-Minute is doubled, halved, etc.** | This usually occurs when the analysis triggers on noise or artifacts. It can be corrected by changing the **Minimum Volume** to a higher or lower value to eliminate rates higher or lower than normal. If the signal has a lot of baseline noise, change the Low Pass Filter (in the Adv Attrib1 tab) to a higher value to remove the noise. Select a lower value in the list box. |
| **All Derived Parameters are reporting zero** | The **Minimum Volume** may be set too high for the specified signal. Lower the **Minimum Volume** value. |
| **Tidal Volume incorrect** | Verify the impedance calibration is correct.<br>Ensure the Calculated Flow Units are correct.<br>Adjust noise settings. |
| **"x" in** Derived Parameter List View **window instead of a number** | The **Derived Parameter** value is too large for the field. An "x" was placed here, so that a truncated number would not be displayed. |
| **Cannot find the analysis module in the** Subject Setup \| Subject Details **dialog** | The analysis module is likely not enabled in the Ponemah License. Check License options via **Help \| View License**. |

# Add-on Modules

This section provides detailed information on add-on modules available within Ponemah. If a Ponemah add-on module was purchased, please ensure the license file lists the add-on, as this indicates it is enabled.

## Video

DSI has partnered with Noldus Information Technology, the leading solution provider for human and animal behavioral research for 25 years, to offer scientists a better video experience. By integrating the Noldus Media Recorder and DSI's Ponemah Physiology Platform, scientists now have an easy method for synchronizing physiologic data with video data.

The Noldus Media Recorder enables synchronous video recordings from **up to eight** different video sources. When integrated with Ponemah, you can command the Media Recorder to save and sync video data with the physiologic data recorded from DSI hardware and manage all your data with one application. This combined solution provides greater insights into the physiologic data to better understand your results.

*Note*: Synchronization of video data with physiologic signals will be within +/- 1 second.

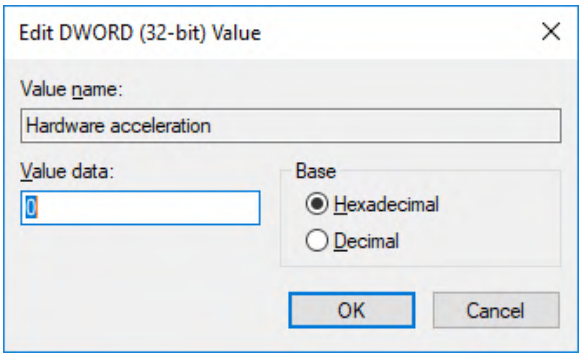
### Installation

In addition to the Ponemah installation, users are required to install the Noldus Media Recorder software. The Noldus Media Recorder software installation is provided on the Ponemah installation USB drive. If the USB drive is not available, the software can be downloaded from support.datasci.com. Run the install.exe from the Ponemah installation USB drive and select the 'Install Media Recorder' option.

Once installed, launch Noldus Media Recorder. The following registry entry should then be updated:

\HKEY_CURRENT_USER\Software\MainConcept\MainConcept AVC/H.264 Video Decoder\MediaRecorder.exe

- Double-click **Hardware Acceleration**
- Change the **Value data** to **0**
- Click **OK.**




- Close the Registry.

## GigE Camera Setup

GigE cameras are high-performance industrial cameras. They can have a higher frame rate and resolution than the other supported cameras. The images are sent unprocessed to the computer using a standard network cable (UTP). Noldus Media Recorder is compatible with certain Basler GigE Cameras.

For GigE camera setup and support, please see the **Noldus Media Recorder Reference Manual**.

Note:

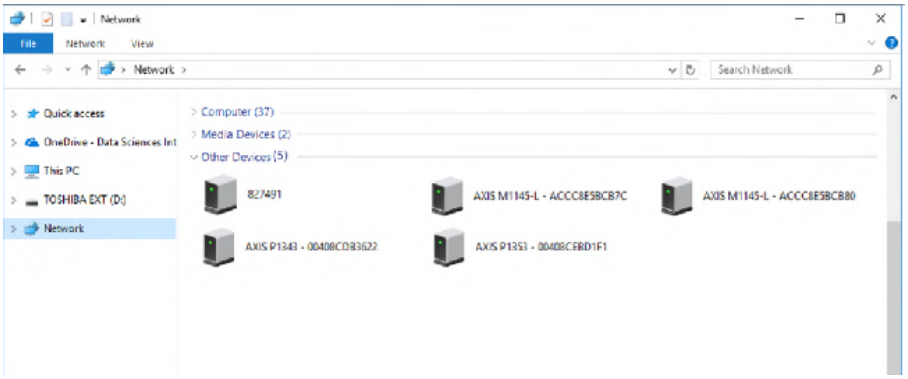
- File size of a 24 hours recording is very large (at least 12 Gb).
- When using multiple GigE cameras, it takes a while before they become visible in Media Recorder. GigE cameras take time to initialize.

## IP Camera Setup

IP cameras are connected directly to a network. IP cameras are especially useful to film remote locations and receive the video files through an ethernet network on your computer. Noldus Media Recorder is compatible with Axis IP Cameras. In order to configure Axis IP Cameras in Noldus Media Recorder a few camera settings are required to be updated.

To Configure:

1. Access the camera's webpage:
    a. Open Windows Explorer.
    b. Select the Network folder.

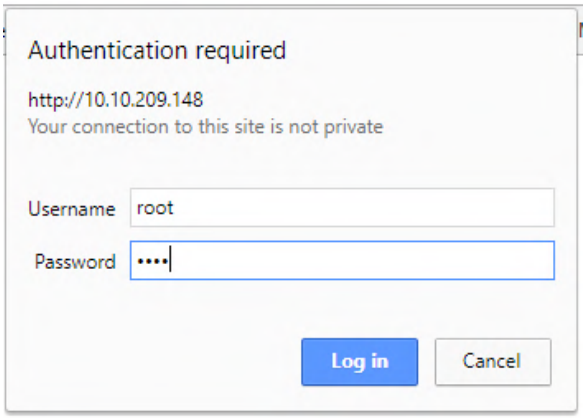



c. Double-click the camera to launch its webpage.

d. When prompted for Authentication, enter the following:

   i. Username: root

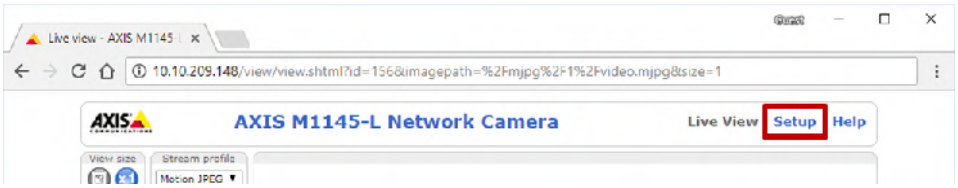
   ii. Password: root




e. Note the IP Address of the camera, as it will be needed later when configuring the cameras in Noldus Media Recorder.

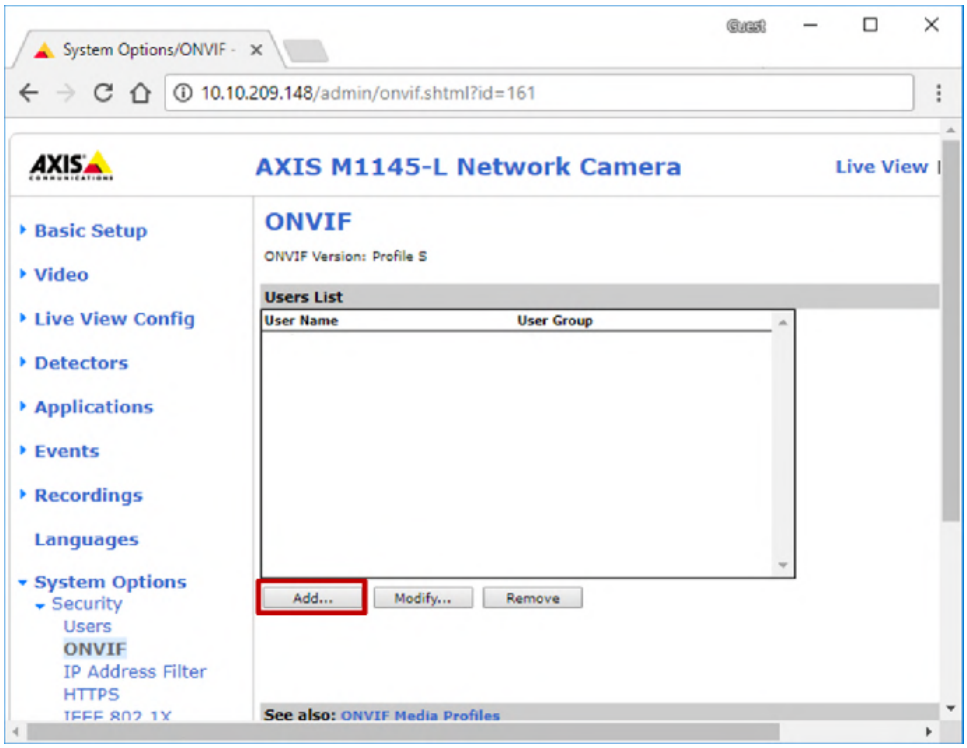
2. Add an ONVIF Admin User:
   ONVIF is a communication standard for network devices. ONVIF Profile S applies video and audio streaming and PTZ control. Most IP cameras nowadays support ONVIF Profile S. For cameras that do so, pan, tilt, and zoom control can be done with Media Recorder and audio from the camera can be recorded. For cameras that do not support ONVIF, pan, tilt, and zoom control must be done with a browser and audio must be recorded with a microphone connected to the sound card of the computer.

   a. Select the **Setup** link in the upper right side of the webpage.

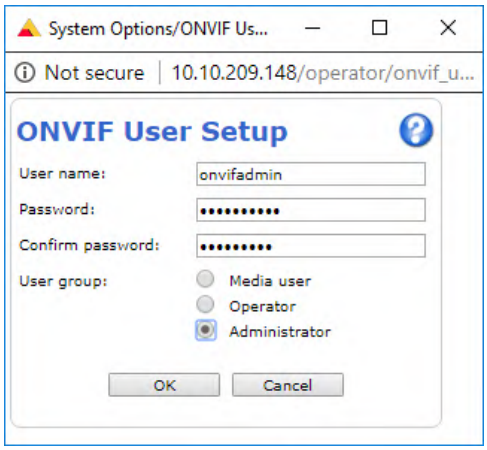



   b. From the menu options on the left side of the webpage, select **System Options | ONVIF**.

c. Click the **Add…** button associated with the *User List*.

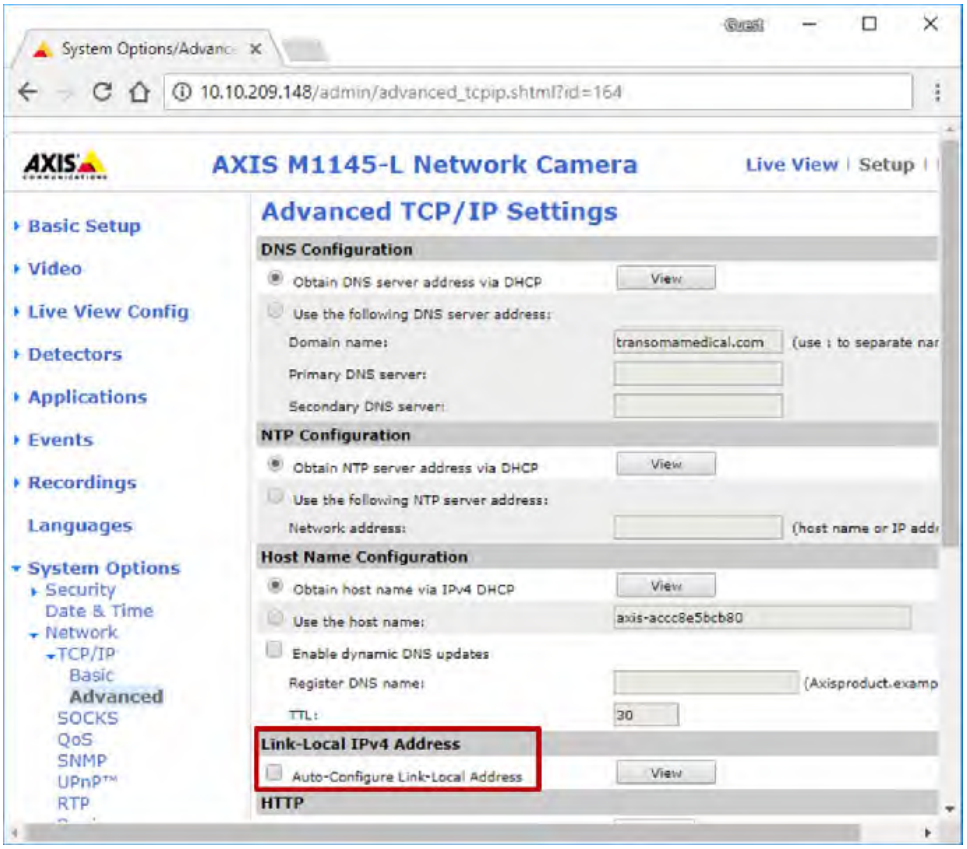



d. When prompted, enter the following:
   i. Username: onvifadmin
   ii. Password: onvifadmin
   iii. User Group: Administrator

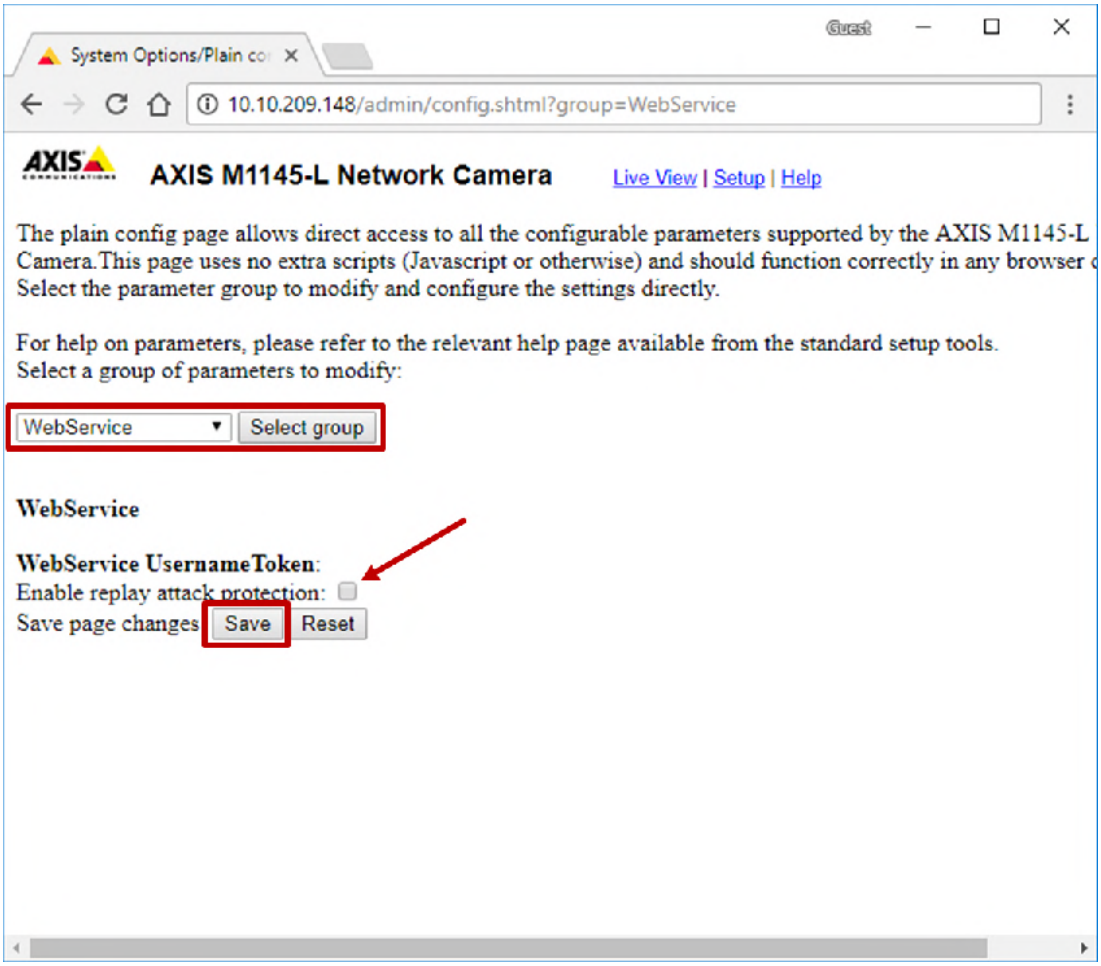



e. Click **OK**.

3. Update TCP/IP Settings:
   a. Still within the **System Options**, select **Network | TCP/IP | Advanced**.
   b. Locate the *Link-Local IPv4 Address* heading.
   c. **Uncheck** *Auto-Configure Link-Local Address*.




4. Update WebService Settings:
    a. Still within the **System Options**, select **Advanced | Plain Config | Advanced.**
    b. Select **WebService** from the dropdown menu, then click **Select Group**.
    c. **Uncheck** the *Enable replay attach protection* setting.
    d. Click **Save.**



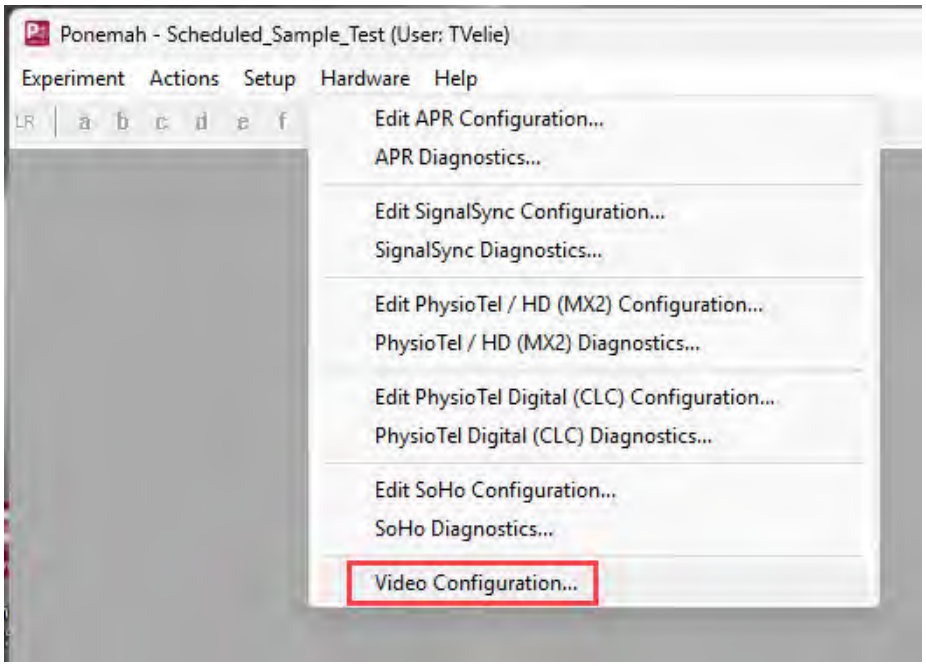

5. **Repeat steps 1-4 above for any additional Axis IP Cameras.**

## Configuring Cameras in Media Recorder

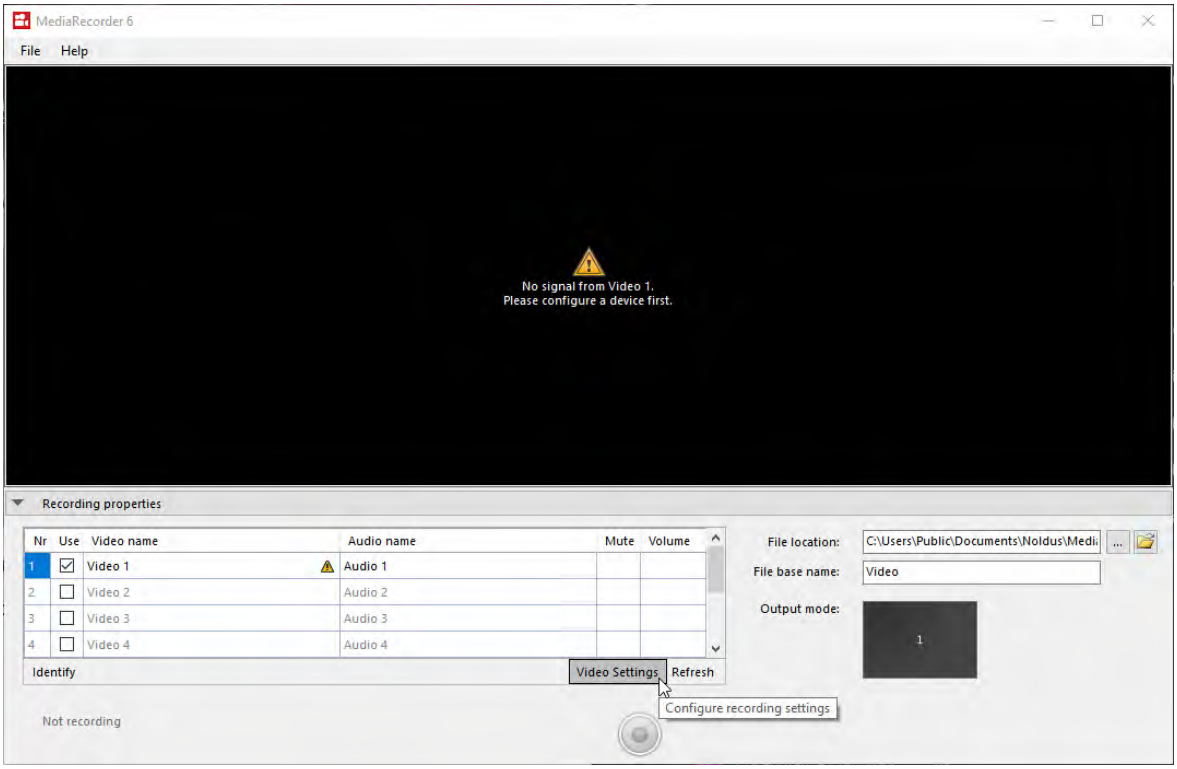
To configure cameras within Noldus Media Recorder:

1. Launch Ponemah.
2. Open the appropriate Experiment.

3. Select the **Hardware menu | Video Configuration** to launch Noldus Media Recorder.

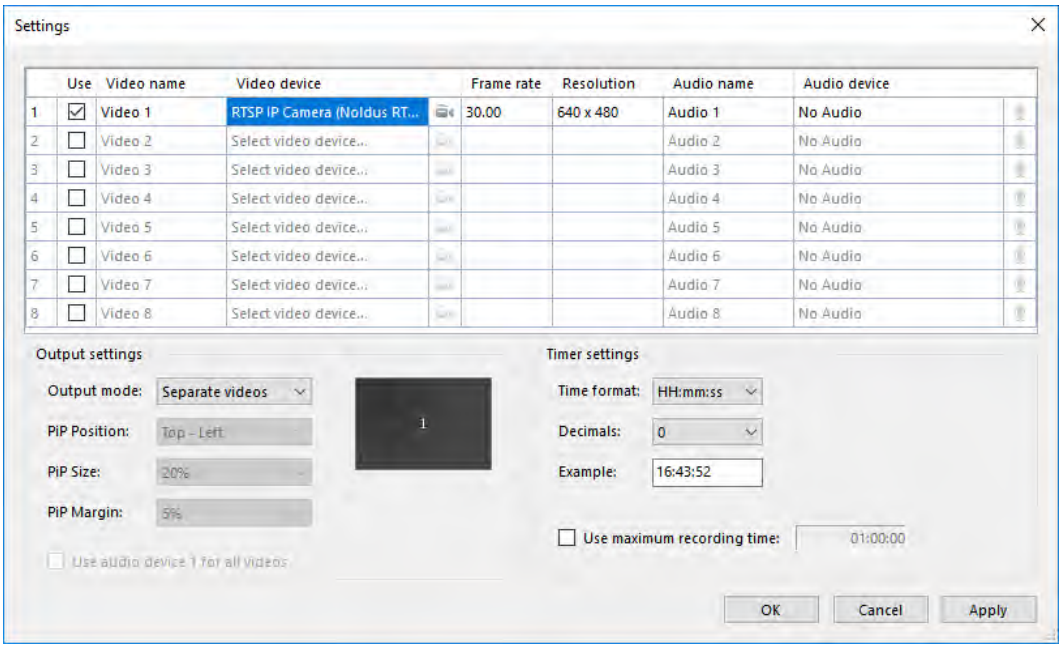



4. Click the **Settings** button or choose the **File menu | Settings**.

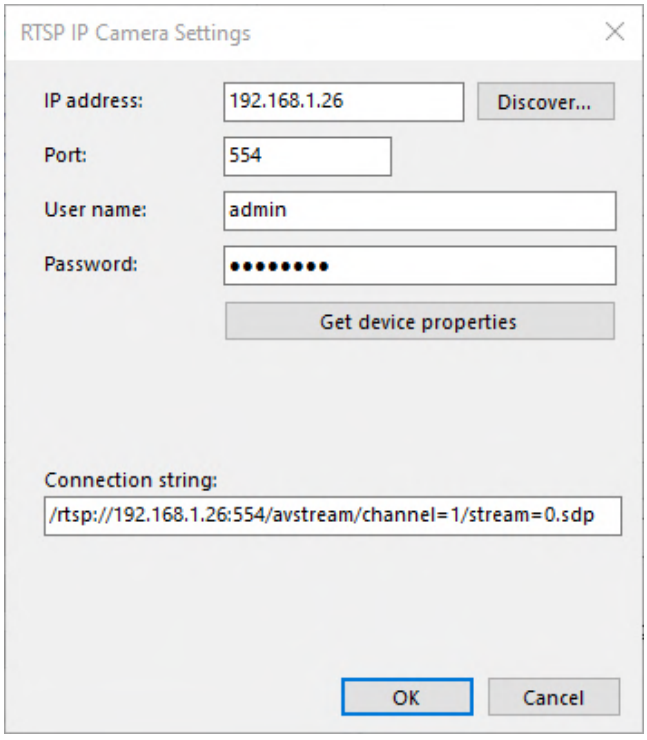



5. (Optional) Update the name of video camera.
   **The name specified here will be displayed within Ponemah during the camera assignment process.**

6. Select **RTSP IP Cameras** from the dropdown list under *Video Device*.




7. Click the **Camera Icon**  to access the advanced settings.
8. Click the **Discover…** button to find cameras on the network to add and settings will be filled automatically. (Optional) Manually fill in the Camera Settings dialog with the camera's IP Address obtained from **IP Camera Setup** section (step 1) and ONVIF username and password from (step 2.d.), then click **Get device properties**.
   If the camera configured is a valid ONVIF camera the device properties will be displayed and **OK** can be selected to close the window. If the camera is not a valid ONVIF camera a warning box will display. In this case the **Cancel** button can be selected and a video stream address can be entered.



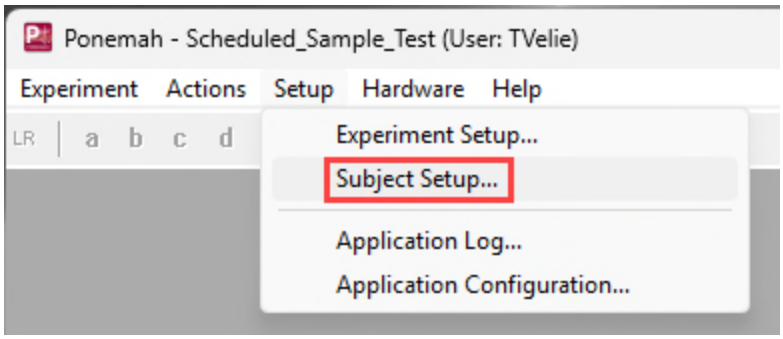

9. Click **OK**.
10. Select the desired **Frame Rate** and **Resolution**.
    The available options will depend on the camera model. By default, the optimal combination of frame rate and resolution for the camera is selected. If you increase the frame rate, the maximum resolution available goes down and vice versa. If you select an impossible combination of frame rate and resolution and format, Media Recorder gives a warning.
11. Add subsequent cameras by enabling the checkbox under the *Use* header.
12. Repeat steps 5-10 for additional cameras.
13. Click **OK** to close the *Medial Recorder Settings* dialog.
14. Once camera setup is complete, choose File | Exit to close Noldus Medial Recorder and return to Ponemah to associate the cameras to the desired subjects.

**Note: Please keep the default settings for Output Settings, Timer Settings, File Location, and File Base Name.**

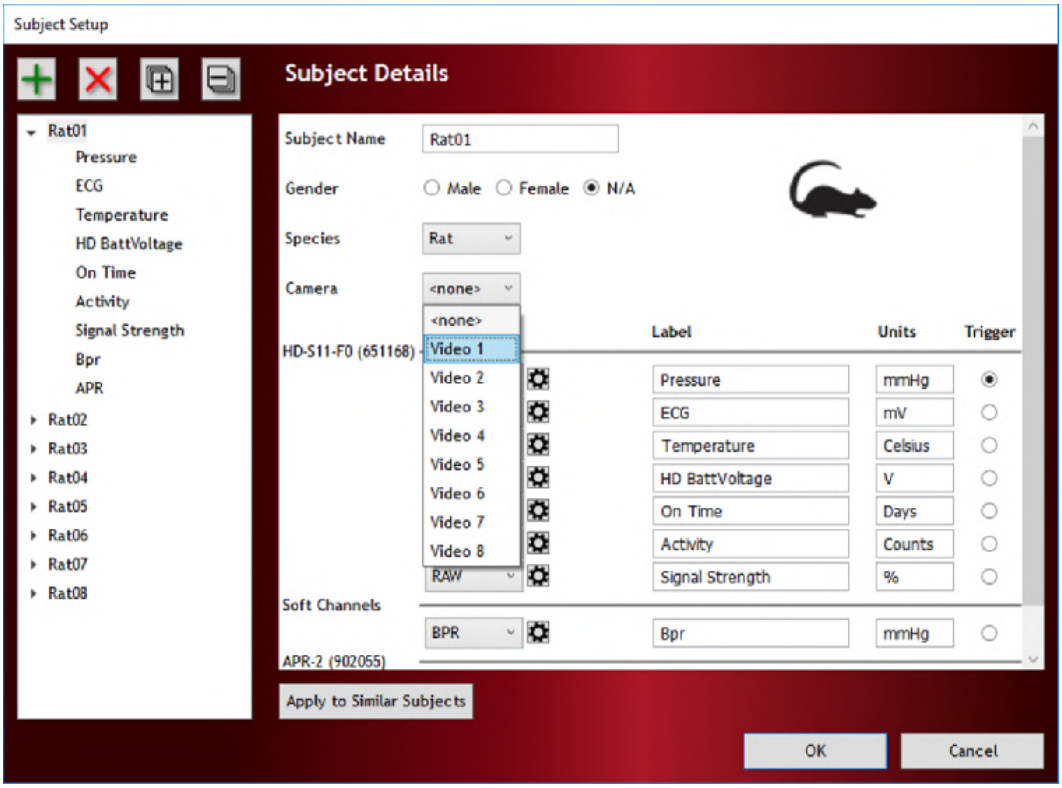
## Associating Cameras to Ponemah Subjects

To assign cameras to the appropriate subject for synchronized physiologic data and video data acquisitions:

1. Select the Ponemah **Setup menu | Subject Setup**.




2. Select a Subject from the tree view on the left to associate the camera.
3. Select the **Camera** dropdown menu in the *Subject Details* section and select the desired camera to pair with the Subject.

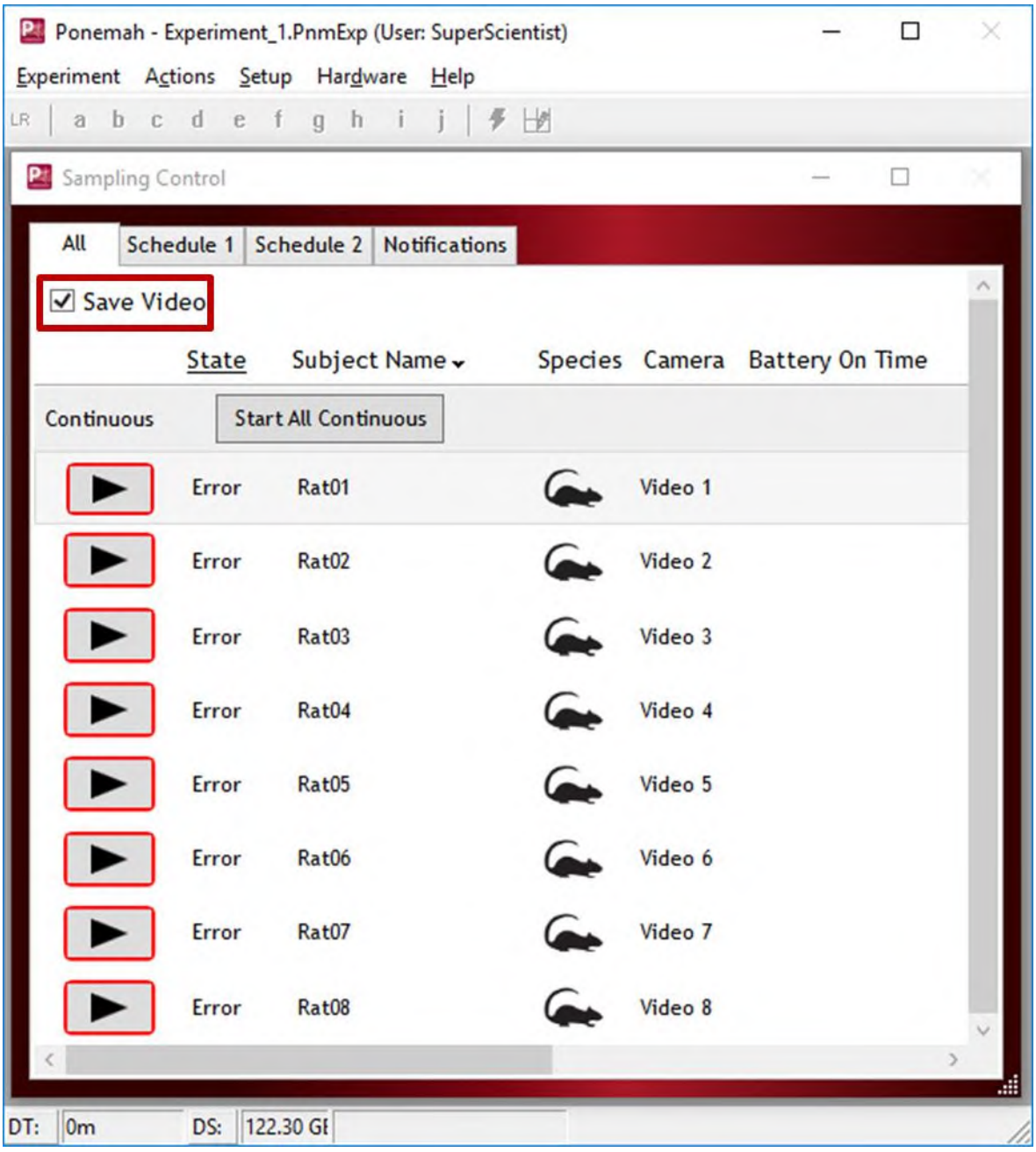



4. Repeat for any addition subjects.
5. Select **OK**.

*Note*: Cameras may be associated with multiple Subjects.

## Acquiring Synchronized Video Data

To acquire synchronized video and save video to disc with the physiologic data, **ensure the Save Video checkbox is checked.**



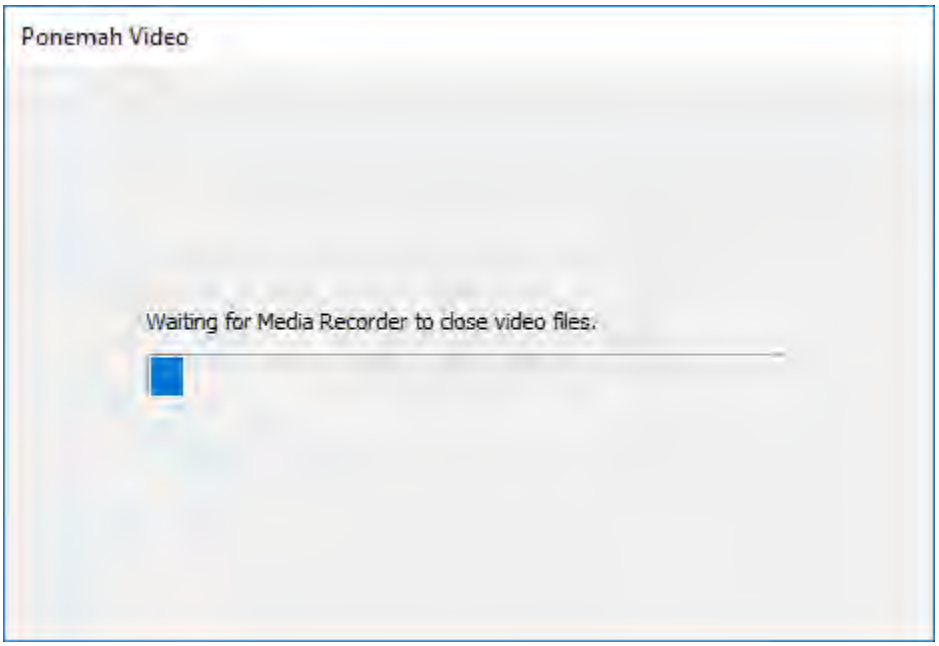

Once **Start All Continuous** is selected, Ponemah will update for acquisition, automatically launch Noldus Media Recorder, and commence video acquisition. Please note, Ponemah will control the start/stop of video recording via Media Recorder.

**Scheduled Sampling does not support video acquisition.** Video recording is only supported with Continuous Sampling.

## Understanding Video File Generation

When acquiring video data, each subject with have its own set of video files. This is includes an .XML file containing pertinent meta data about the video file Ponemah requires for Subject association and video playback in Ponemah Review and the actual video data files.

New video data files are created at the start of each acquisition session. When stopping acquisition, Ponemah will wait (up to one minute) for the Media Recorder to close the video files. The user will be presented with the following progress dialog during the file closing process:




### FILE INCREMENTATION

During acquisition, the video data file will increment every 24 hours **OR** every 500 MBs, whichever is achieved first. This 500 MB file size threshold is user configurable from the **Application Configuration**; however, the 24-hour threshold cannot be altered.

Once either the 24-hour or 500 MB threshold is achieved, video acquisition will automatically stop for up to 1 minute to close the current video file and then automatically restart collection with a new file. The physiologic data will continue collecting during this period, uninterrupted. A pop-up indicator does not exist for when this occurs, but the Noldus Media Player **Record** button will change, the settings will no longer be greyed out, and Media Recorder will say "*Not recording*" in the lower corner of its dialog during this time. Incrementing the video data files in this fashion is done to keep the video file sizes manageable and the synchronization with physiologic data within the +/-1 second specification.

### FILE LOCATIONS

During acquisition, video files are actively saved to the following directory:

C:\Users\Public\Documents\Noldus\Media Recorder\Video Files\

Once acquisition is stopped or the file incrementation threshold discussed above is met, the video files will be closed and automatically transferred to the appropriate Ponemah Experiment folder. Files will also be renamed at this time based on Ponemah's file naming structure. Please see the **Experiment Files** section of this manual for descriptions of the video file types.

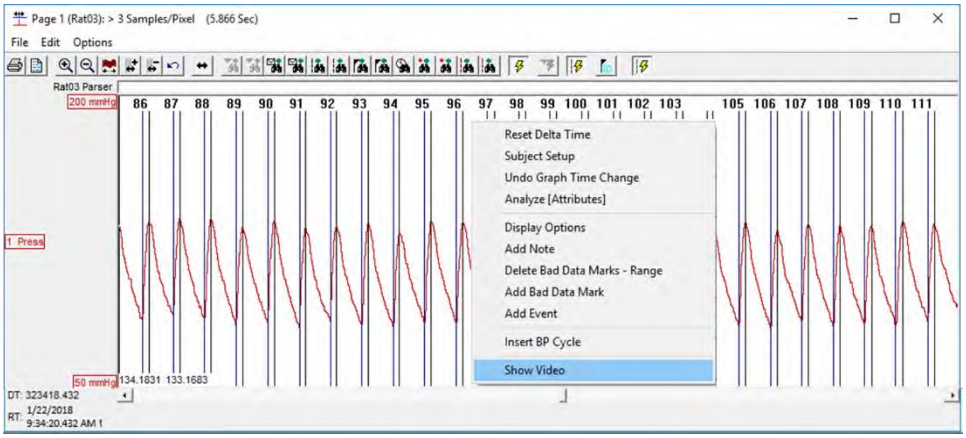
## Video Playback within Ponemah Review

Video Data can be reviewed within Ponemah Review. To do this, start a review session as described in the Loading Data into Review section of this manual. Should any video data be associated with the data loaded into Review, it will automatically be available.

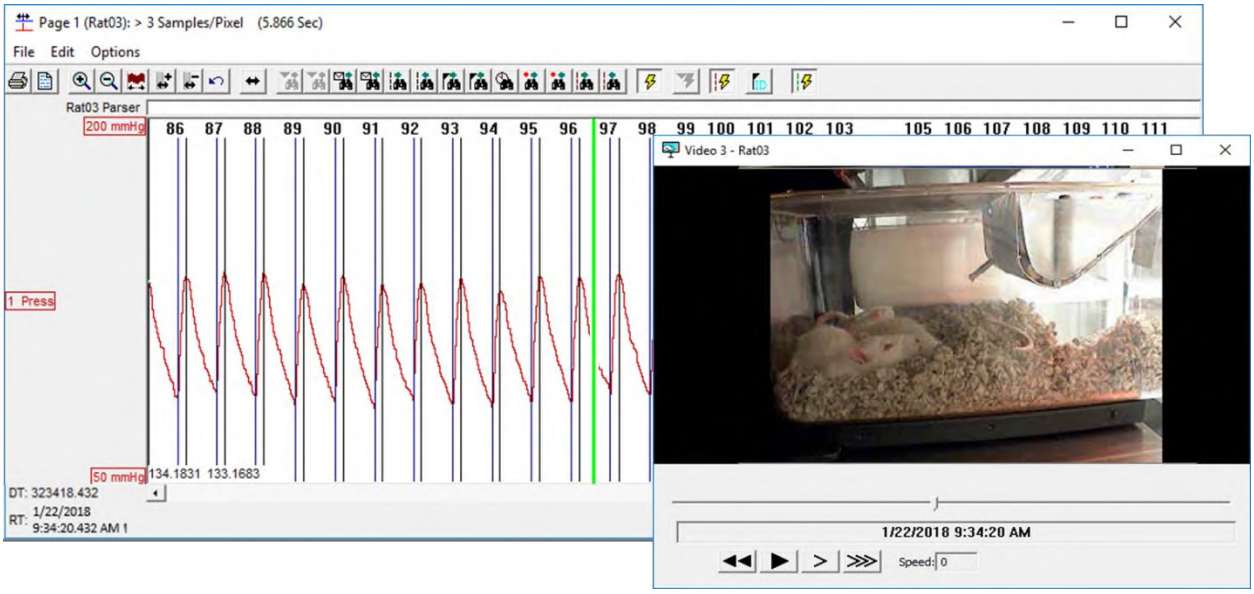
**The Noldus Media Recorder software MUST be installed on the Analysis computer for playback to occur within Ponemah Review. The Analysis computer does NOT require a separate Noldus Media Recorder license nor does the Noldus security dongle need to be used.**

To launch the Video Player:

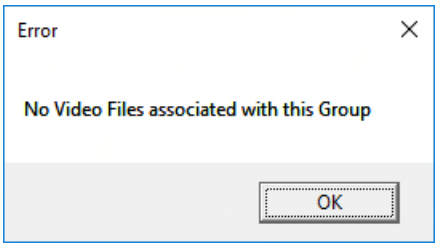
1. Navigate to a Primary or Trend Graph Page.
2. Right-click a graph pane and select **Show Video** from the menu to launch the player.




Once the Video Player is launched, a solid, vertical green line will appear on the graph page to indicate the location of the current frame in relation to the physiologic data. Should this green cursor reach the edge of the graph during video playback, the graph will automatically advance to the next page of data.

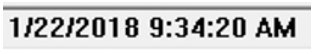



*Note*: if video files are not found for the Subject, the following message will be displayed:



## VIDEO PLAYER CONTROLS

The Video Player offers several control features to navigate through the video file, as outlines below.


The Video Player will display the date and time of the currently displayed image. This date and time corresponds to the solid, vertical green line associated with the physiologic data on the graph page.

Scroll bar for the video data. Scrolling through with this cursor will also advance the physiologic data graphs to keep synchronized with the image displayed in the Video Player.

Rewind button. Used to step through the video file in reverse, two seconds at a time.

Play button. Used to step through images at the frame rate acquired; i.e. real-time playback. When video is playing back, this button turns into a Pause button.

Reduce playback speed by half.
Min: 0.125

Increase playback speed by double.
Max: 2


Playback speed indicator.

Please note, to step forward through the video file frame-by-frame, use the keyboard right arrow key **<→>**. Reversing through the file with the left arrow **<←>** will step back in 0.1 second increments.

## Remote Connection

Ponemah Remote Connection allows an external application either on the same workstation or on a remote workstation to connect to a Ponemah acquisition system and receive parameter data at certain user defined intervals. This is done to create a feedback control mechanism.

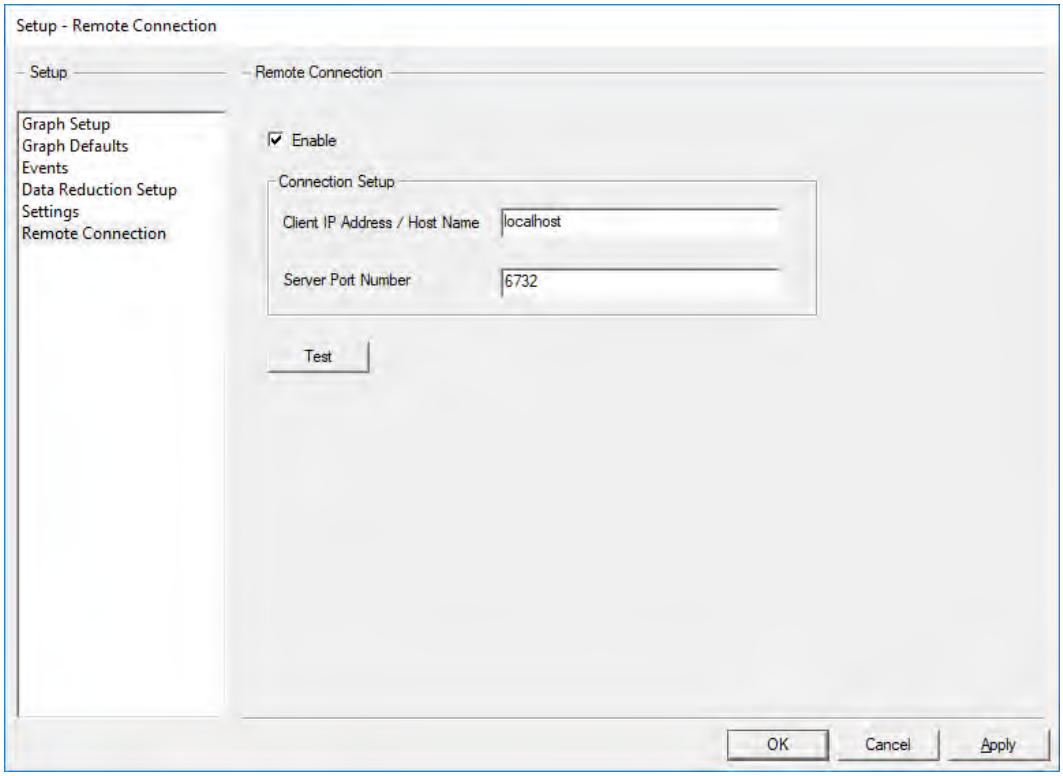
### Configuring the Ponemah Acquisition Workstation

For Remote Connection to send parameter data, Ponemah must be configured appropriately.

*Note*: when using Remote Connection, do not use ‘,’ or ‘;’ in the Implant Name or Subject Name fields.

To configure Ponemah Remote Connection:

1. Select the Ponemah **Setup menu | Experiment Setup**.
2. Select Remote Connection.




3. Check the Enable checkbox and enter the appropriate TCP/IP communication settings.

## Testing Remote Connection

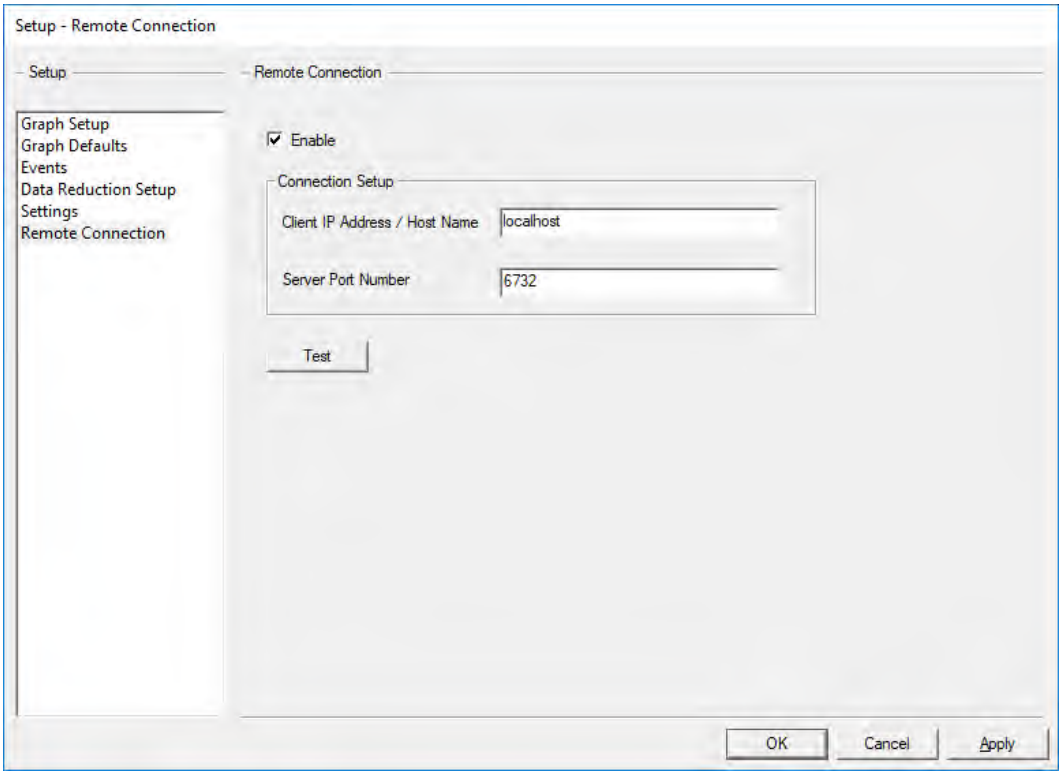
To test Remote Connection and verify Ponemah is logging data through the port, it is recommended to use the open source tool, PuTTY. PuTTY is a simple application that connects to the TPC/IP port to verify operation.

PuTTY is available at: http://www.putty.org/ Select the Windows 64 bit version.

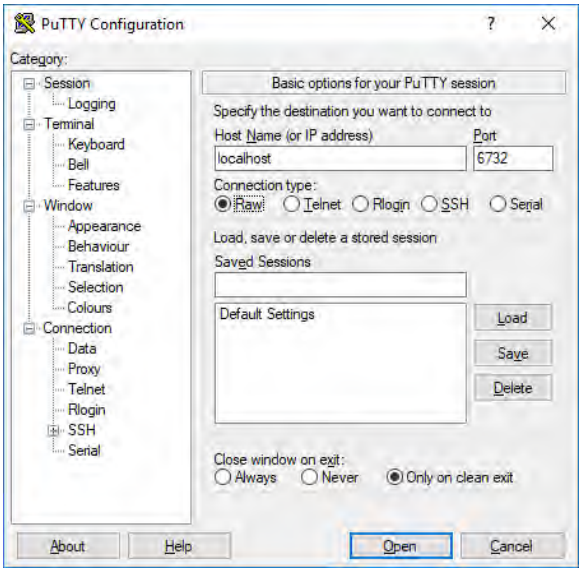
Once PuTTY has been downloaded, run the application on either the same local workstation Ponemah is running on or on the remote workstation the external application will use for the connection. It is important to make sure both workstations can be seen on the network and the appropriate firewall ports are open.

To test the connection:

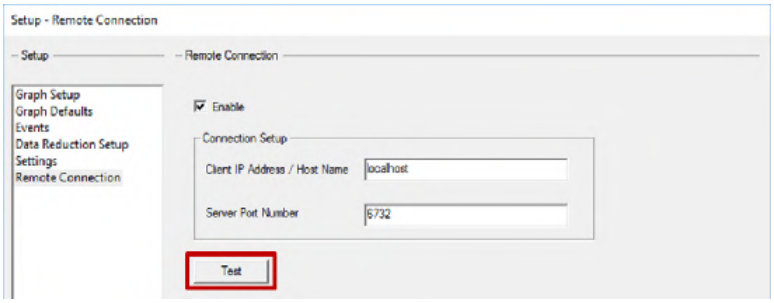
1. Ensure Ponemah and PuTTY are running.
2. Within **Ponemah**, select the Ponemah **Setup menu | Experiment Setup**.
3. Select **Remote Connection**.
    a. Enter the computer name of the Client PC.
    This is the PC name the external application is running on. If it is the external application is running on the same PC as Ponemah, enter **localhost**.
    b. Enter the desired TCP/IP port to be used for the communication.



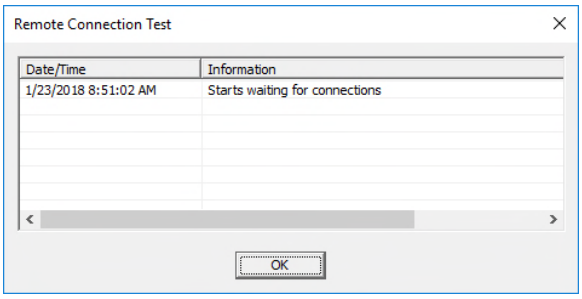

4. Within **PuTTY**, enter the following:
    a. The PC name of the computer running Ponemah.
    b. The desired TCP/IP port number to be used for communication.
    c. Select the **Raw** *Connection type*.



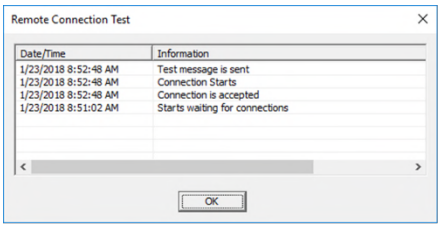

5. Once both applications are configured, click the **Test** button from the Ponemah Remote Connection settings dialog.

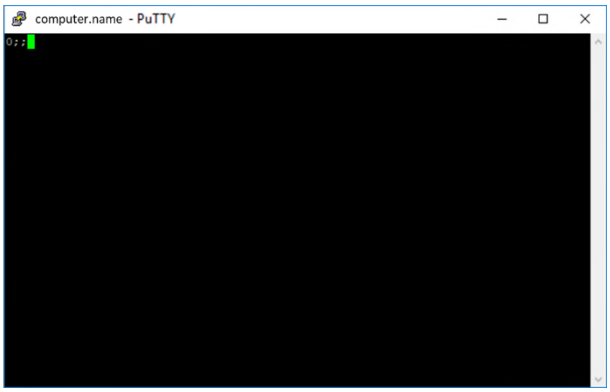



6. A window will appear waiting for a connection to the port to occur.




7. In PuTTy, select **Open**.
   When the Putty response window opens, it will display a response from Ponemah and the Ponemah test window will display the connection status as displayed below.




8. Once a connection has been established, the user can now verify that logged lines of Derived Parameter data from Ponemah can be sent through the connection. Click **OK** to close the *Experiment Setup* dialog.
9. Start an acquisition. (See **Sampling Control — Starting Data Acquisition**)
10. Restart PuTTY and select the connection parameters used in Step 4. and select **Open.**
11. After a logged line of Derived Parameter data is generated by Ponemah, the PuTTY status window will display the information for that logged line of data from the network connection as displayed below.


## Data Output Format

The format of the data output of logged Ponemah Derived Parameter data is outlined below. Please note, all Ponemah Derived Data is output through the connection, not just the selected parameters from the *Channel Details* page of *Subject Setup*.

Each record will start with a 2 byte unsigned integer in big endian order indicating the length of the whole message in bytes after this counter. The max length for each message is 1024.

### DERIVED PARAMETER METADATA (HEADER)

The header data will be in the following format:
[Message length]1; [Instance ID];[Referenced data instance ID];[Subject Name];[Channel Number];[Channel Label];[Channel Analysis];[Elapsed Time, Real Time, Event, Param 1 Name, Param 2 Name…]

*Note*: Referenced data instance ID will be blank for metadata.

**Example:**
Ξ1;0;;HD-S21 (592089);1;LVPressu;LVP;ElapsedTime,RealTime,Event,Num,Sys,LVEDP,Min,TTI,DP,HR,+dP/dt,-dP/dt,CI,RT1,RT2,dP-A,dP-B,dP-C,dP-D,NPMN,Q-A,IVT,TTI-T,Tau,Period,EMw,Count,SysD,DiaDΞ1;1;;HD-S21 (592089);2;Pressure;BP;ElapsedTime,RealTime,Event,Num,Sys,Dia,Mean,PH,HR,TTPK,ET,+dP/dt,-dP/dt,%REC,NPMN,Q-A,RNum,RInt,RBpm,Mean2,PTTs,PWVs,PTTed,PWVed,IBIs,IBIms,IBIed,Count

[2 byte binary data for message length][this is Meta Data for derived parameters];[Data Instance ID is 0];[Reference data instance is not specified];[Subject is 1];[Channel is 1];[Channel Label is LVPressu];[Channel Analysis is LVP];[Parameter sequence: : SubjectID is the first data coming, ElapsedTime is the second, then RealTime, Num, Sys, etc][2 byte binary data for message length][this is Meta Data for derived parameters];[Data Instance ID is 1];[Reference data instance is not

specified];[Subject is 1];[Channel is 2];[Channel Label is Pressure];[Channel Analysis is BP];[Parameter sequence: SubjectID is the first data coming, ElapsedTime is the second, then RealTime, Num, Sys, etc]

## DERIVED PARAMETER DATA

The Derived Parameter data will be in the following format:

[Message length]2;[Instance ID];[Referenced data instance ID];[Elapsed Time, Real Time, Event text, Param 1 value, Param 2 value, etc]

*Note*: Instance ID will be blank for derived parameter data.

**Example:**

Ξ2;;0;0006:14:52.000,1/23/2018,15:45:40.001 (Central Standard Time),(a) event 1,212.00,116.89,5.66,-2.71,87.59,111.23,307.07,8000.16,6837.67,110.79,14.35,17.32,6749.91,7399.18,7818.33,7748.86,47.11,13.88,87.59,6.84,195.40,212.00,116.13,79.31Ξ2;;1;0006:14:52.000,1/23/2018,15:45:40.001 (Central Standard Time),(a) event 1,192.00,125.46,78.00,98.74,47.46,304.24,37.06,65.06,2640.87,1139.93,92.98,98.69,0.00,0.00,0.00,0.00,93.82,0.00,0.00,0.00,0.00,197.22,197.25,197.25,51.00

[2 byte binary data for message length][this is a derived data];[Instance ID is not specified];[It references the data with instance ID 0];[animal ID is HD-S21 (592089), according to Meta Data Instance ID 0 ElapsedTime is 0000:00:03.542, RealTime is 1/23/2018 15:45:40.001 Central Standard Time, event a was marked with description “event 1”, Num value is 212, Sys value is 116.89,etc.][2 byte binary data for message length][this is a derived data];[Instance ID is not specified];[It references the data with instance ID 1]; [animal ID is HD-S21 (592089), according to Meta Data Instance ID 1 ElapsedTime is 0000:00:03.542, RealTime is 1/23/2018 15:45:40.001 Central Standard Time, event a was marked with description “event 1”, Num value is 192, Sys value is 125.46,etc.]

## INSERTING EVENTS IN PONEMAH

To insert events from the external application, send the message with format outlined below to Ponemah via the connection:

[Message length in 2 byte binary Big endian]3;[Instance ID];[Referenced data instance ID];[Subject];[Event Name]

Example:

[Message length]3;;;;Event1

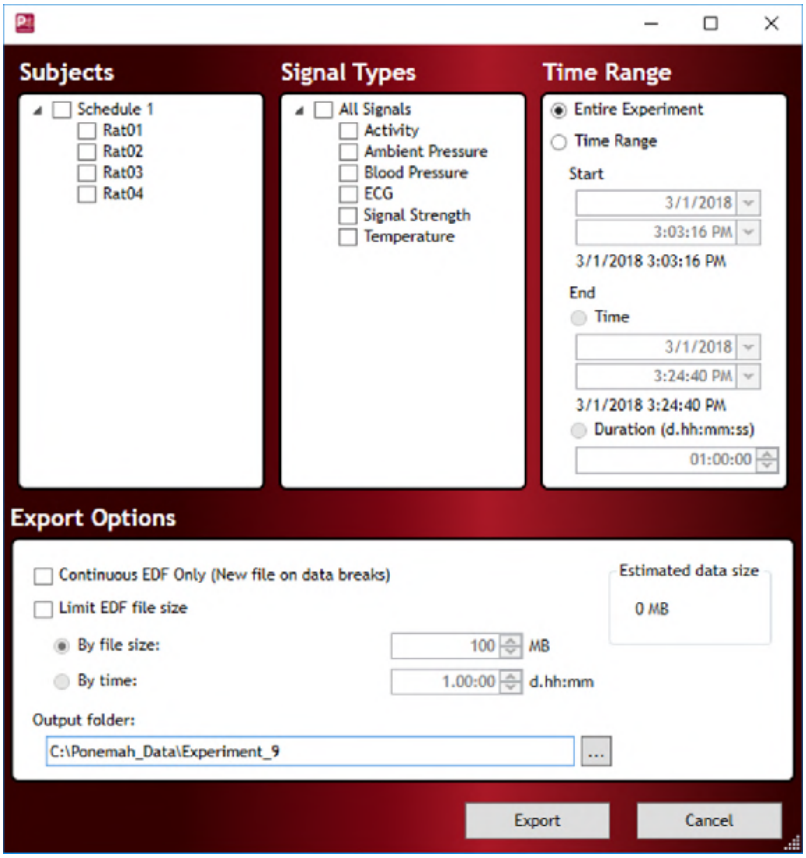
The event will be placed for all Subjects.

## EDF Export

Ponemah European Data Format (EDF) Export permits users to export waveform data to EDF format for further processing of data in third party analysis software. More information about EDF format may be found at the following website: https://www.edfplus.info/

To export waveform data to EDF format:

1. Select **Experiment menu | Export to EDF**.




2. Select the **Subjects**, **Signal Types**, and **Time Range** desired to export.
   *Note*: Ponemah Presentation Signals (e.g. Derivative Presentation) cannot be exported.
3. (Optional) Select **Continuous EDF Only** option.
   This should be used if the third party EDF reader cannot handle time breaks in the data as this will create a new EDF file for each data section between Data Break marks. See **Graph Concepts** to learn more about Data Breaks. Otherwise, new files will be generated based on the selected file size limiter.
4. (Optional) Select to **Limit the EDF file size** by **Size** or **Time** (duration).
   a. Check the associated checkbox to enable the EDF file size limiter.
   b. Use the radio button to select the limiter type.
   c. Enter the size or time threshold required to be achieved to increment the data into a new EDF file.
5. Select an **Output folder** the EDF files will be save to upon Export.

DSI recommends creating a new folder every time EDF files are exported to ensure previous exports are not overwritten.

6. Select **Export**.

EDF Output Files:

- EDF files will be generated by subject and will be named with the subject name. All channels selected for the subject will be contained in the subject EDF file. Example output without a file limiter:
    - Rat01.0001.edf
    - Rat02.0001.edf
    - Rat03.0001.edf
    - Rat04.0001.edf
- Should a file limiter be enabled, Ponemah will automatically increment the file name:
    - Rat01.0001.edf
    - Rat01.0002.edf
    - Rat01.0003.edf
    - Ect.

# Appendices

This appendix provides information about DSI's implant exchange program, tells you how to manage a zero-pressure offset, and describes how to maintain an implant after it has been first implanted.

## Implant Appendix

### Exchange Program

The DSI Exchange program allows you to exchange your used telemetry implants for replacement implants at a fraction of the original purchase price. In addition, we ensure that each implant provided as part of DSI Exchange program will meet or exceed your design expectations for guaranteed performance and quality. By participating in the DSI Exchange program, the overall costs of your study should be considerably reduced. The three key elements to this program are construction, calibration, and certification.


#### CONSTRUCTION

All implants are hand assembled by DSI's highly skilled technicians, and before being shipped to you, each implant is rigorously inspected to ensure that all components meet the highest quality standards.

In addition, we take the following steps to ensure that you receive a biocompatible device that is guaranteed to perform to specifications *in vivo*.

- A new battery is installed, which guarantees the implant will function throughout the warranty period.
- All implants are sterilized and placed in a biocompatible housing before being shipped to you.
- Biopotential leads and catheters are provided to ensure signal fidelity.

#### CALIBRATION

Here's what we do to ensure that all our implants are properly calibrated.

1. Mechanical and electrical testing of all components to guarantee optimal functionality.

2. Full calibration of each physiologic signal, followed by testing to ensure accuracy specifications are met or exceeded, when used as intended. Signals include: temperature, pressure, biopotential, and respiratory impedance.
3. Each implant includes a calibrations label on the sterile package to document that the device has been calibrated for accuracy.

### CERTIFICATION

Every implant shipped from DSI has the same warranty policy, and is guaranteed to operate in exactly the same every time. Implants that are received through the exchange program are like a new product. Exchanged implants are purchased for a fraction of the cost of new devices, which reduces ongoing study costs while maintaining data quality and accuracy.

## Implant Zero Pressure Offset

All DSI implants are carefully calibrated and tested before being shipped to the researcher. However, we strongly recommend that all pressure devices be checked again before surgery and after explant. By checking the zero offset before implantation and after explantation, you can be confident that the data being collected are true and accurate. The following procedure will allow you to verify that the implant is functioning normally prior to surgical placement in an animal.

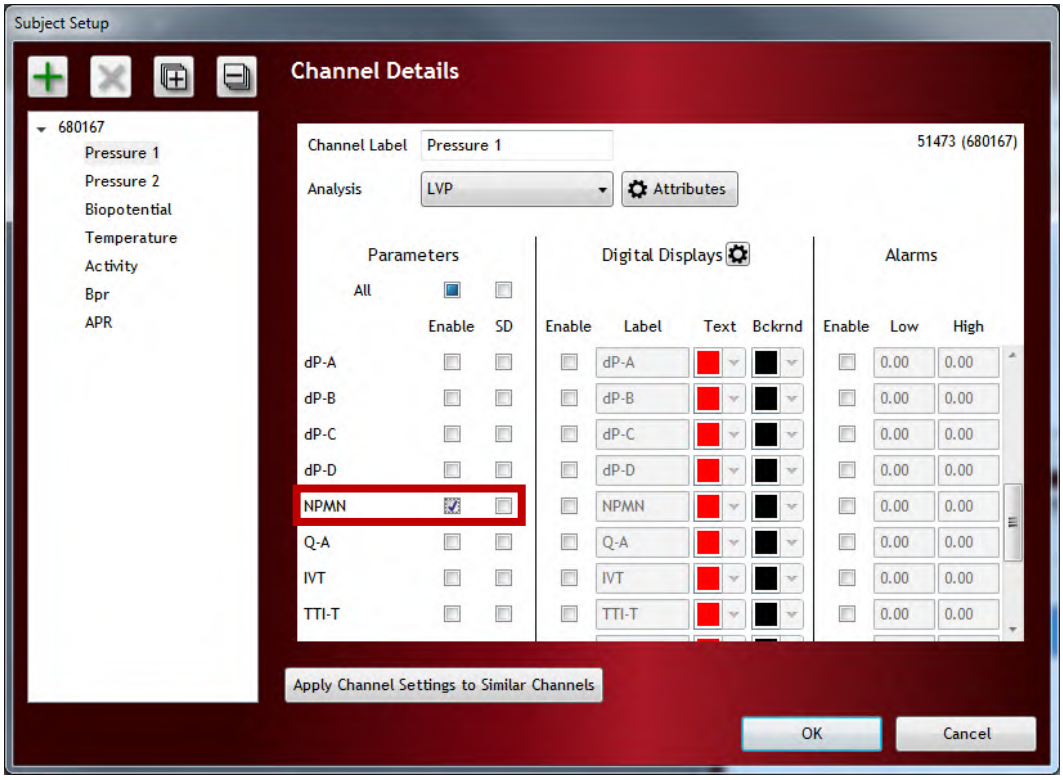
*Notes:*

- Please see the Implant Specifications page of the DSI webpage to determine the initial pressure accuracy for your implants.
- It is important that ambient pressure reference (APR-2) is connected and configured prior to checking the zero offset. (See Hardware Configuration).
- It is very important that the catheter tip(s) be level with the implant body. If the catheters are above or below the level of the implant body, the measured values will be affected by hydrostatic pressure and will not be accurate. Checking the implant while still in its sterile package will help to ensure the catheter is in proper position for the zero offset check.
- Do not immerse the implant into liquid or place in a sealed container during this test as it will also cause “head pressure.”
- Please note that pressure offsets taken at **room** temperature, should not be entered into the software. An offset entered into the analysis attribute should be taken at **body** temperature and with the catheter flat.

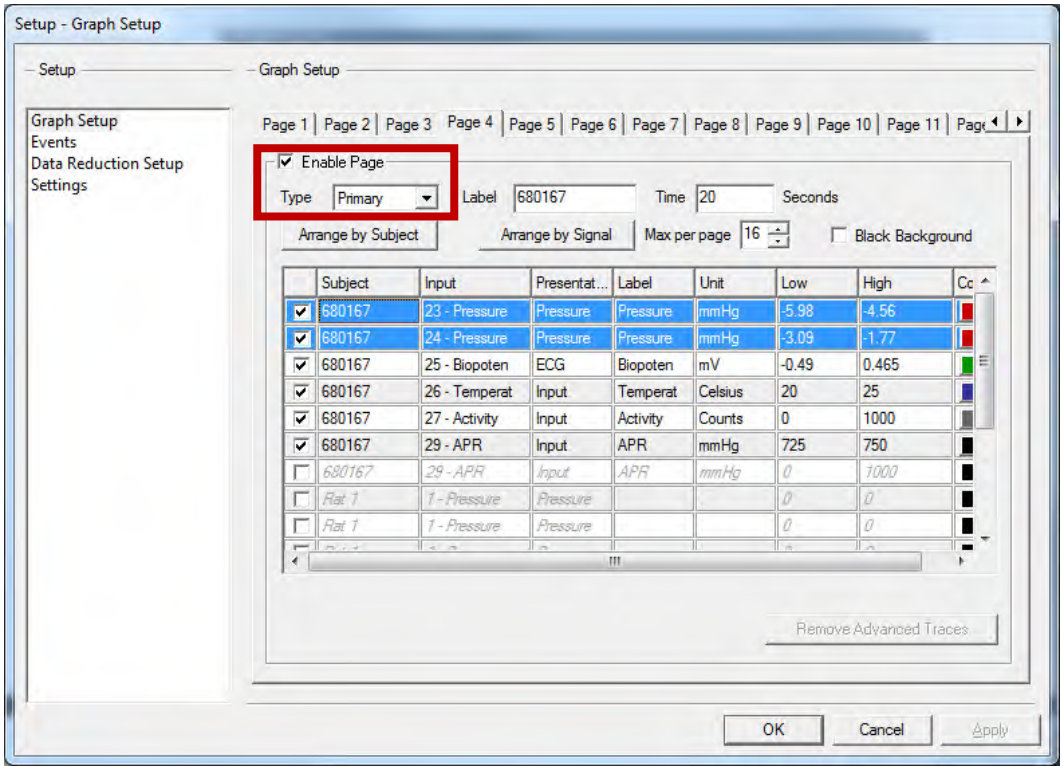
### CHECKING ACCURACY BEFORE IMPLANTATION

1. Activate the devices and ensure each implant is setup and assigned to a CLC (PhysioTel Digital) or MX2 (PhysioTel and PhysioTel HD).
    a. For PhysioTel Digital, please see the *Edit PhysioTel Digital (CLC) Configuration* section of the Ponemah User Manual.
    b. For PhysioTel and PhysioTel HD, please see the *Edit PhysioTel/HD (MX2) Configuration* section of the Ponemah User Manual.

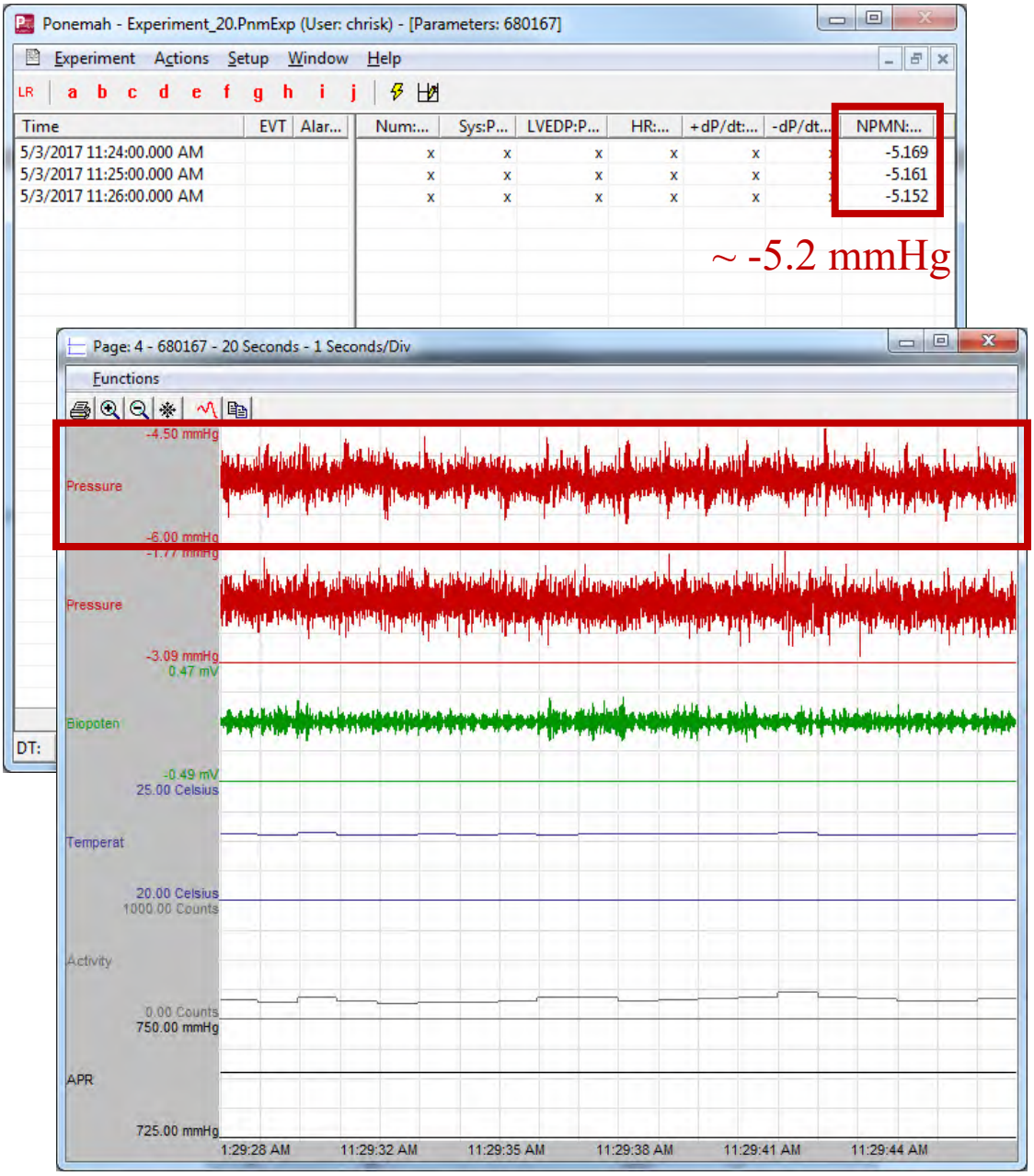
2. In Ponemah, setup the Experiment as described in the **Creating a New Experiment** section of the Ponemah User Manual.
    a. For the Blood Pressure (BP) and/or Left Ventricular Pressure (LVP) channels, add the Non-Pulsatile Mean (NPMN) derived parameter within the **Subject Setup** dialog's **Channel Details**.




    b. Setup a **Primary** graph page for the LVP and/or BP Input Channel from the **Experiment Setup** dialog.

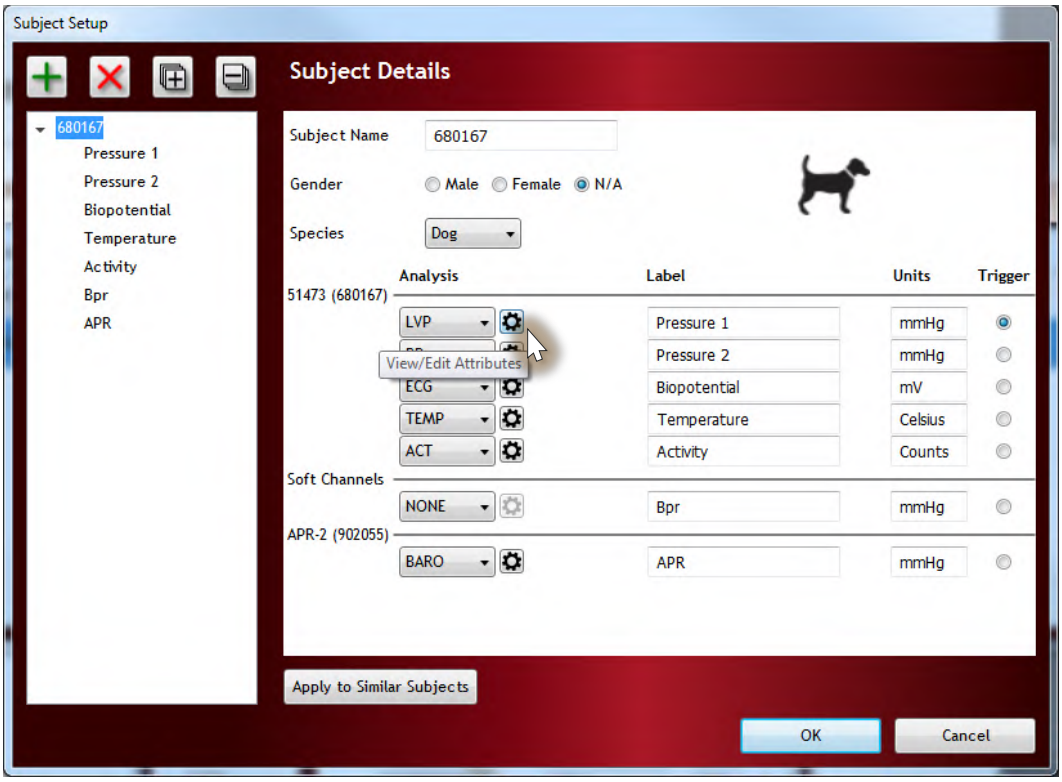



3. Start an acquisition. After a few minutes of collection, assess the NPNM values for the BP and/or LVP channel(s). This is your offset. You may use the Primary Graph(s) to view the real-time recording of the pressure signal to verify it is stable.

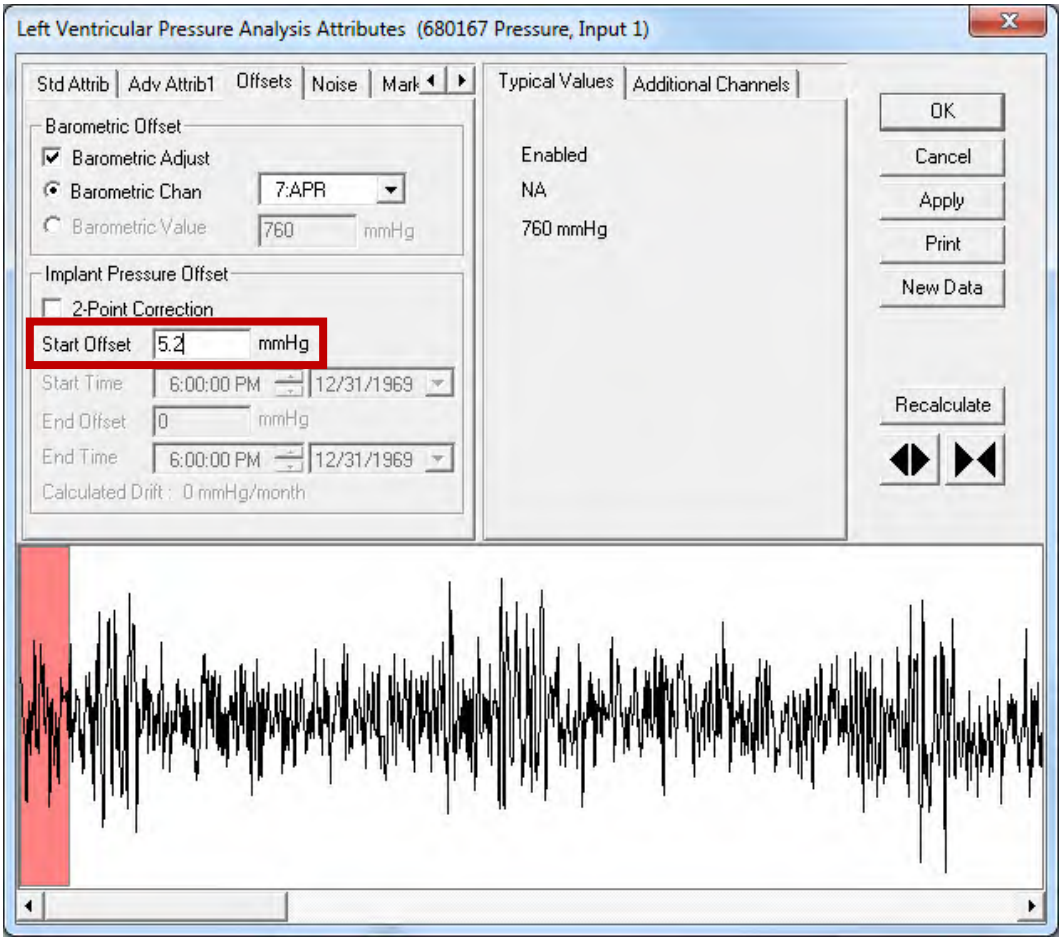



## HOW TO ENTER AN OFFSET

1. While running the offset acquisition, navigate to the **Sampling Control All** tab. Double-click on the Subject whose offset you will be entering. Select the  icon associated with the **Blood Pressure Input Channel** and/or **LVP Input Channel** to bring up the **Analysis Attributes** dialog.

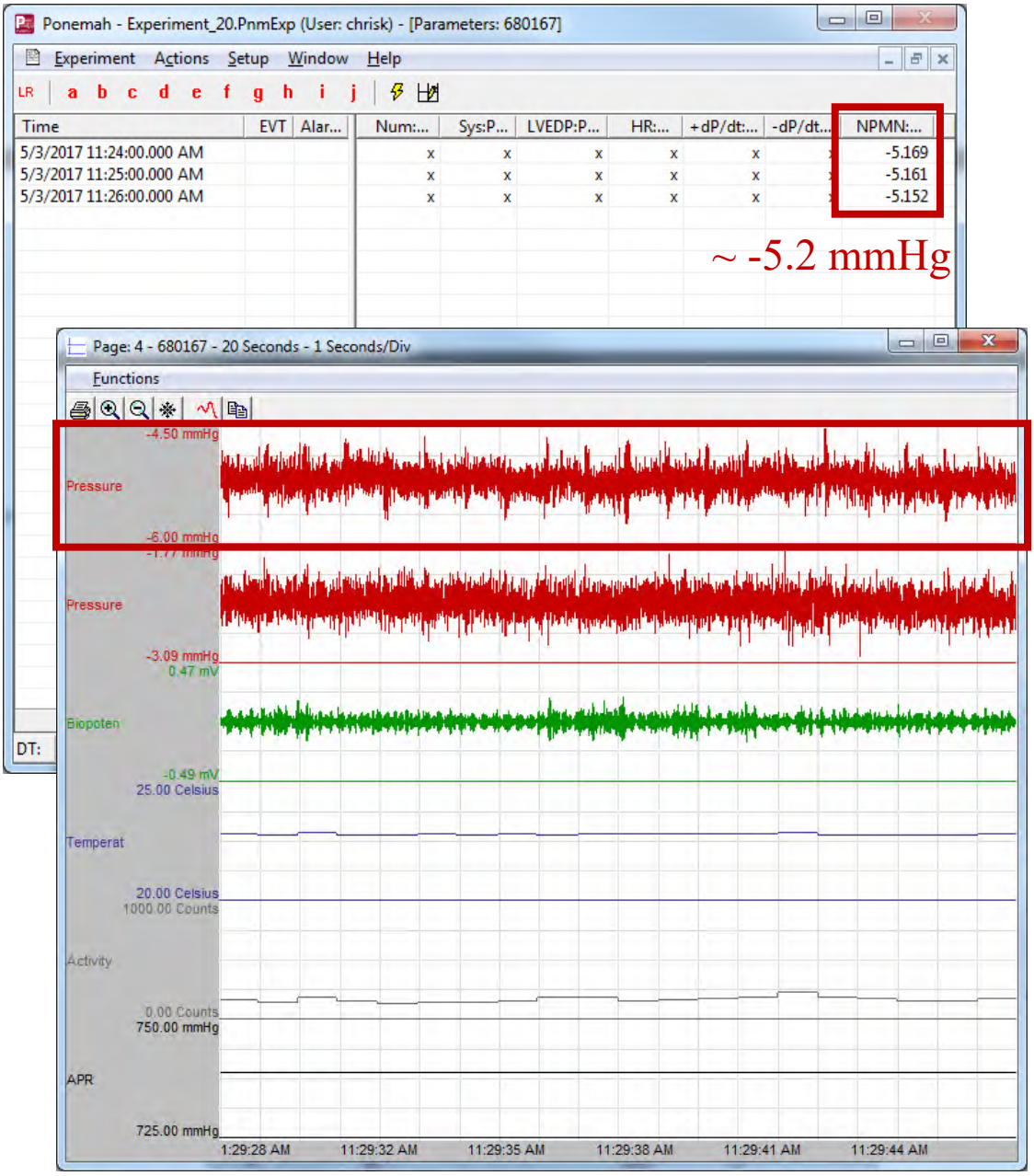



2. Select the **Offsets** tab. At the bottom, located the Offset text box. Enter the value obtained from the NPMN parameter (that was taken at body temperature with the catheter flat and not submerged in a liquid).




*Note:* For the LVP (above) and the BP (not pictured) analysis modules, a negative offset will be corrected by entering a positive value into the Start Offset text box. Example: If the signal is -5.2 mmHg below baseline; enter 5.2 in the text box. A positive offset, therefore, will be corrected by entering a negative value into the Start Offset text box. Example: If the signal is +3.1 mmHg below baseline; enter -3.1 in the text box.

3. Check the **NPMN** values after entering the offset to ensure the new value are approximately 0 mmHg. Notice, the signal on the Primary Graph will also reflect the update (may need to auto scale the channel).




4. Repeat steps 1-3 from the How to Enter an Offset section for any additional pressure channels.

*Note: The 2-point correction checkbox permits the definition of an offset value at the date and time prior to implant and another offset value at the date and time once explanted to apply a linear pressure drift correction over the duration, if desired*

Please contact DSI Technical Support with any questions regarding when and how to take a zero pressure offset.

## Implant Maintenance After First Implantation

### EXPLANTATION

For complete information on products and techniques approved for use with DSI implants, visit www.datasci.com or contact Technical Support (Support@datasci.com). When explanting DSI implants that are implanted intra-peritoneally or subcutaneously, consider the following.

- First carefully detach the implant body.
- Be careful not to drop the implant.
- *Never* cut a catheter, if the intention is to re-use the implant.
    - If cutting the catheter is necessary, use only a new scalpel blade to cut the catheter at a 45-degree angle away from the device body and approximately 3 cm from the implant body.
    - Do not use any instrument other than a scalpel blade to cut the catheter. Cutting the catheter with a pair of scissors or any other instrument could cause damage to the pressure sensor and *void the warranty*.
    - *If the catheter must be cut, the implant cannot be reused in another animal model*. Please send the device back to DSI for participation in the Exchange Program and the standard Exchange discount on a new device will apply.
- Leads can be cut as there are lead coupler kits available for purchase to extend the length of the leads. Lead coupler kits may make the leads less flexible over time so try to save as much length as possible during explantation.
- Clean and sterilize the implant with an approved enzyme detergent and sterilant before returning the implant to DSI or re-using in another animal.
- If the animal should die unexpectedly and the implant cannot be explanted immediately, the animal can be placed in a refrigerator until the explant can take place. The refrigerator will not damage the device, however; storage in a refrigerator will allow for an easier retrieval. Clots may be more difficult to remove from the catheter so it is recommended to heat the catheter to body temperature in a warm water bath to prevent the sensor from being blown. Never cut the tip of the catheter.

### ON-SITE CLEANING AND RE-STERILIZATION

All new and exchanged implants shipped to an investigator are sterile and ready for implantation. In studies where implants are implanted for short periods at a time, significant battery life may remain at the end of the study allowing reuse of the implant. DSI has published specifications on the minimum guaranteed hours of battery life. Record the amount of time the device is on to track use and to calculate the battery life left. The PhysioTel HD platform allows this tracking to be much easier as the battery voltage and approximate on time is transmitted from the implant when it is in the ON mode.

DSI has developed detailed procedures for cleaning and sterilizing telemetry implants. These procedures will increase the number of times you can use each implant before returning it to DSI via the Exchange Program, helping to reduce overall costs per study. Sterilization procedures are available online at www.datasci.com.

### SHELF-LIFE AND STORAGE

The following sections tell you what to do when you receive a new implant, and how to store it.

- New Implants Direct from Manufacturing
  Here's what to do when you receive a new implant from DSI.
  - Carefully examine all implants when they arrive at your facility.
  - Remove the sterile packages containing the implants from the shipping boxes. All implants are sterile upon arrival.
  - Save the shipping boxes to use, when returning used implants for the Exchange Program.
  - Inspect each implant's sterile packaging for signs of damage. If the package remains undamaged, this sterility is warranted according to the information on the package label.
  - Confirm that each implant is turned off before storing.
    - Using the AM radio on the low frequency setting, turn each implant on and off by scanning a magnet across the implant to ensure that none of the implants were damaged during shipping.
    - Although each unit is checked just before shipping, the implant may have been exposed to stray magnetic fields during shipment. This can cause the unit to be turned on unintentionally.
    - Implants in the OFF mode may lose up to 10% of the battery life within 12 months after the manufacture date.

- Storage of Sterilized Implants
  Occasionally there may be a delay between the implant removal from the animal and the beginning of the next study. Proper storage of the on-site sterilized implant is necessary to ensure that the unit will perform normally during the next study.
  - Using the AM radio on the low frequency setting, check each implant to ensure that it is properly turned off.
  - Thoroughly clean and sterilize each implant according to DSI's On-Site Re-sterilization procedure at www.datasci.com/resources/technical-notes.
  - If the original implant sterile package was saved, place the implant into the plastic packaging. This will help to identify the implant and the calibration values associated with it. Do not store implants in saline or other liquid!
  - Sterilization before storage is necessary to prevent the spread of bacteria during handling.
  - Each implant will require sterilization again at the time of use, because there is no effective way of maintaining sterility after the sterile package has been opened.

- Storage Location Requirements
  The implants should be stored in a cool (between 10 and 25 degrees Celsius), dry area away from exposure to static discharge and magnetic fields. *Never* expose them to temperatures above 60 degrees Celsius, as this will void all warranties. It is also important to store them in an area where they will not be accidentally dropped or have items placed on top of them, as the catheter could be crushed and the sensor blown. Battery life is *not*

significantly increased by storing your implant in a refrigerator. By following the proper storage procedures, the implants should perform just as well as the day they were shipped.

## PhysioTel Digital Hexadecimal Conversion

Hexadecimal is base 16. Base 16 is where the 'numbers' you can use are zero through to the letter F (0123456789ABCDEF). i.e. the decimal value for '1' is represented in hexadecimal as '1' but the hexadecimal value of '15' (decimal) is shown as 'F' (hexadecimal) and the value of '17' (decimal) is '11' in Hexadecimal.

| DECIMAL | HEX | DECIMAL | HEX | DECIMAL | HEX |
|---|---|---|---|---|---|
| **1** | 1 | 11 | B | 30 | 1E |
| **2** | 2 | 12 | C | 40 | 28 |
| **3** | 3 | 13 | D | 50 | 32 |
| **4** | 4 | 14 | E | 60 | 3C |
| **5** | 5 | 15 | F | 70 | 46 |
| **6** | 6 | 16 | 10 | 80 | 50 |
| **7** | 7 | 17 | 11 | 90 | 5A |
| **8** | 8 | 18 | 12 | 100 | 64 |
| **9** | 9 | 19 | 13 | 500 | 1F4 |
| **10** | A | 20 | 14 | 1000 | 3E8 |

## SoHo Implant POST result

SoHo implants typically report a POST result of zero when powering up. Refer to the table provided for POST result error values.

```
//------------------------------------------------------------------------------
//
// Name: ImplantPostResults
//
// Description:
//     Enumeration for implant bit-mapped POST results.
//
// PostSuccess                          // 0x00000000 - No self check error encountered.
// PostClocks                           // 0x00000001 - LFCLK vs HFCLK speed compare failed.
// PostWdtReset                         // 0x00000002 - Reset due to watchdog timer.
// PostRfu2                             // 0x00000004 - Reserved for future use.
// PostRfu3                             // 0x00000008 - Reserved for future use.
// PostRfu4                             // 0x00000010 - Reserved for future use.
// PostSdVersion                        // 0x00000020 - Soft Device version is incorrect.
// PostRfu6                             // 0x00000040 - Reserved for future use.
// PostRfu7                             // 0x00000080 - Reserved for future use.
// PostFlashStatic                      // 0x00000100 - Static flash settings have failed CRC check.
// PostFlashDynamic                     // 0x00000200 - Dynamic flash settings have failed CRC check.
// PostRfu10                            // 0x00000400 - Reserved for future use.
// PostRfu11                            // 0x00000800 - Reserved for future use.
// PostRfu12                            // 0x00001000 - Reserved for future use.
// PostRfu13                            // 0x00002000 - Reserved for future use.
// PostRfu14                            // 0x00004000 - Reserved for future use.
// PostRfu15                            // 0x00008000 - Reserved for future use.
// PostSpiAsic                          // 0x00010000 - SPI communication to the AFE ASIC failed.
// PostSpiAccel                         // 0x00020000 - SPI communication to accelerometer failed.
// Posti2Ctemp                          // 0x00040000 - I2C communication to temp IC failed.
// PostRfu19                            // 0x00080000 - Reserved for future use.
// AfeAsicRam                           // 0x00100000 - RAM check failed for read write failure.
// PostRfu21                            // 0x00200000 - Reserved for future use.
// PostRfu22                            // 0x00400000 - Reserved for future use.
// PostRfu23                            // 0x00800000 - Reserved for future use.
// PostRfu24                            // 0x01000000 - Reserved for future use.
// PostRfu25                            // 0x02000000 - Reserved for future use.
// PostRfu26                            // 0x04000000 - Reserved for future use.
// PostRfu27                            // 0x08000000 - Reserved for future use.
// PostRfu28                            // 0x10000000 - Reserved for future use.
// PostRfu29                            // 0x20000000 - Reserved for future use.
// PostRfu30                            // 0x40000000 - Reserved for future use.
//
```

# Hardware Appendix

## PhysioTel and PhysioTel HD Caging and Shielding Recommendations

DSI has experience using the typical shoe box sized cages but more and more customers are finding that lab space is difficult to come by. Many different configurations are possible depending on the animal model and space available. As a rule of thumb, always leave at a minimum the distance of one RPC-1 (~12 inches or 31cm) between cages. The best case situation would be placing each cage two receiver widths (18 inches or 45 cm) away from each other. Excluding pair housing studies, below is an example of the minimum recommended small animal configuration without any shielding:

As shown above, stagger the cages on a shelf to conserve the most space with this single frequency device. This illustration represents one implanted animal in each cage paired with another animal that is not implanted. With the HD-S11-F2 device, it is possible to pair two implanted animals with different frequency implants in the same cage and gather data simultaneously. The RPC-3 receiver is mandatory for pair housing studies and requires the same amount of distance between cages as that of the RSC-1 (~12 inches or 31cm).

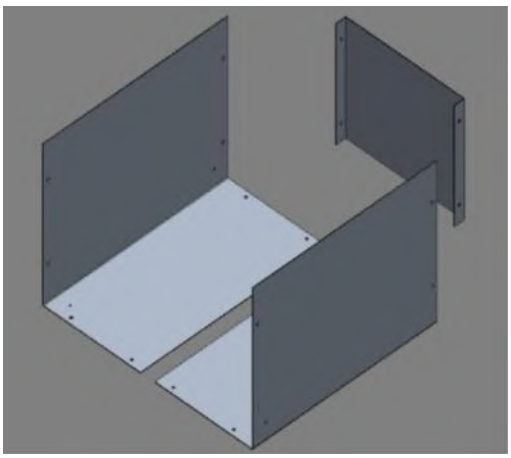
### Shielding Recommendations

If the receivers need to be closer together and data loss is prevalent (>5%) implement electromagnetic shielding. Shielding comes in many forms from sheet metal and chicken wire to high tech clear specifically designed metal mesh. Locate the source of the noise and enclose that with shielding if possible. For example, the MX2 or another implant can be a source of noise if it is placed too close to the receivers. If problems arise or if you require a list of acceptable shielding options, technical support is equipped to help determine the best shielding method either remotely or onsite if necessary.

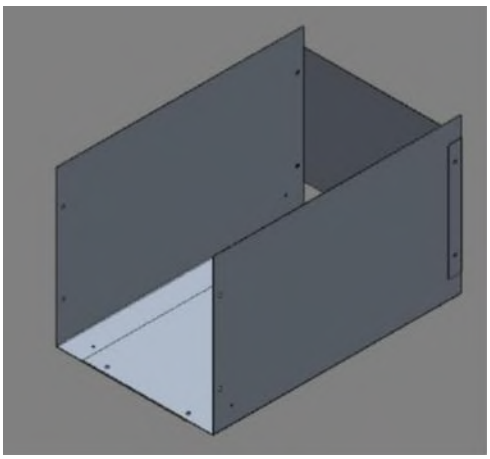
There are a number of ways to shield cages to prevent electromagnetic noise interference in the data. Shielding can be used around individual animal cages and/or MX2s. If possible, additional shielding should be used when configuring the animal room. Shielding is highly recommended when non-metal shelves are used. The shielding material should consist of conductive metal such as copper, stain-less steel, or aluminum. As shown below, shielding allows cages to be placed closer together.

*Note*: The shields can be constructed in such a manner that the following four configurations can be achieved (length x width x height):

- 18 x 12 x 10 inches
- 18 x 12 x 12 inches
- 18 x 18 x 10 inches
- 18 x 18 x 12 inches



Shield components



Shield assembled

## Transceiver Placement Recommendations

This appendix is intended to provide recommendations for placing Transceivers (TRX) in animal cages to minimize any signal drop-out with PhysioTel Digital implants. In general, a single TRX can cover 3-5 meters; however, null points may exist. To be safe, DSI recommends one TRX for every 3 meters, and at least 2 for every CLC. When more than one TRX is used, DSI suggests placing them at right angles to one another to help protect against null points which are small areas of poor signal reception.

It is important to note that there are many different cage and room set-ups and the examples shown below are DSI's suggestions based on customer testing and assessment of the PTD product.

Please contact DSI Technical Support (support@datasci.com) for assistance and recommendations in setting up your specific animal room.

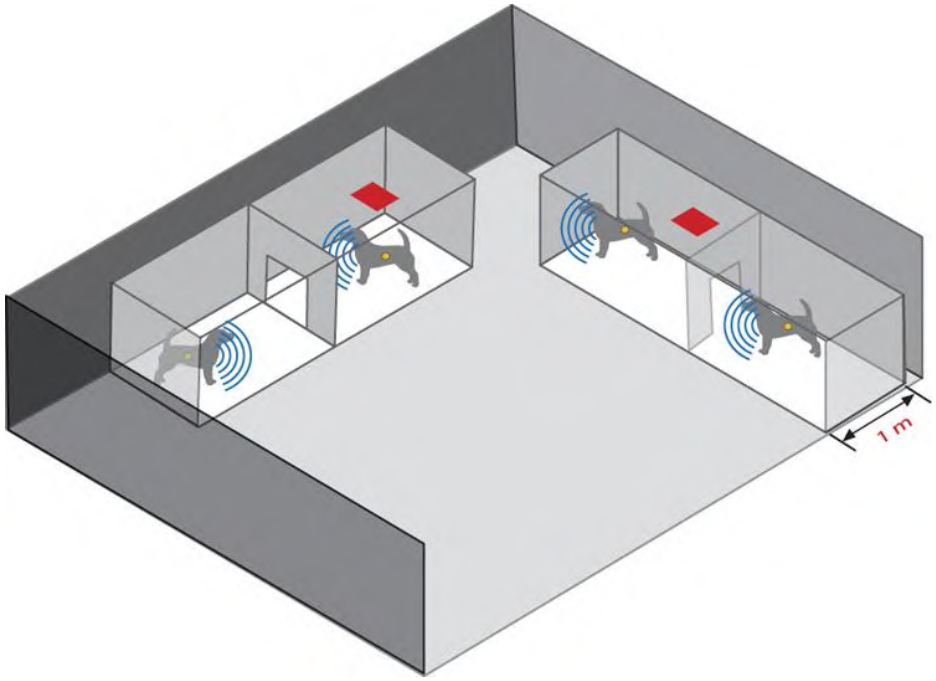
There are several factors that affect the transmission range of the implant.

- Monitoring environment
- Placement of the implant antenna
- Size of the animal

*Regulatory Note: China: Tested to MIIT[2005]423 for short range devices' technical characteristics and test methods (Report No. C170417Z08, C170417Z09, C170417Z10).*

## Dog Cage Example 1

The diagram below illustrates the cage setup with Group Housing and two TRXs. Cage Dimensions are 1 Meter x 1 Meter x 1 Meter. The red square indicates a TRX.



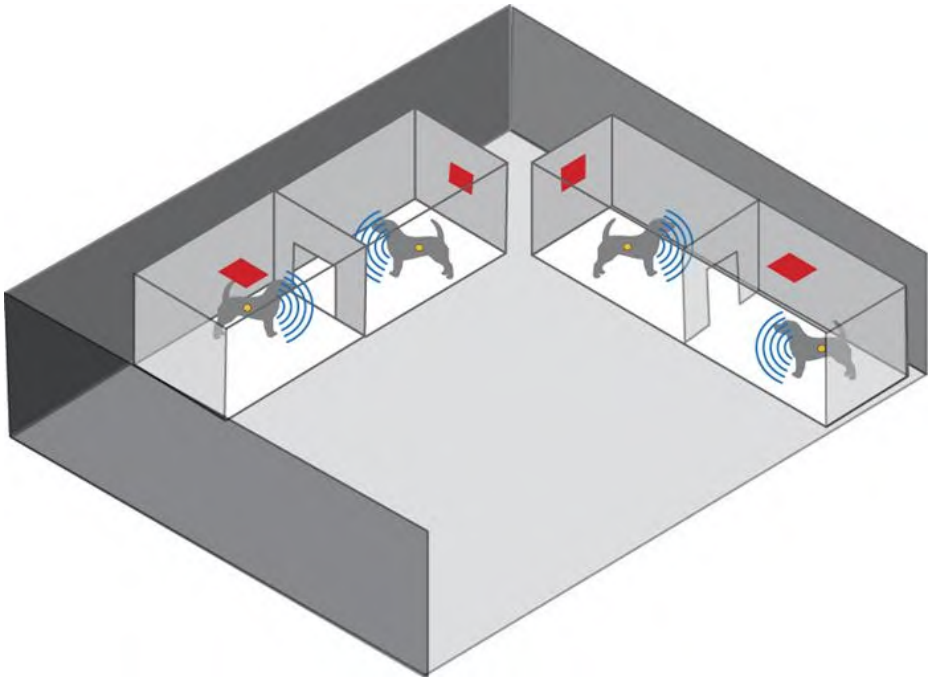

The set-up shown above includes one (1) TRX to cover the two cages on either side of the room. In this scenario the door between the cages is open and animals are able to freely move between cages.

If the door between the cages is closed, an additional TRX may be needed to provide supplemental coverage. DSI suggests testing this scenario to ensure that no drop-out occurs. If drop-out does occur, a second TRX should be used.

The following example illustrates a more ideal setup using four TRXs for increased coverage

## Dog Cage Example 2

The diagram below illustrates the cage setup with Group Housing and four TRXs. Cage Dimensions are 1 Meter x 1 Meter x 1 Meter. The red square indicates a TRX.



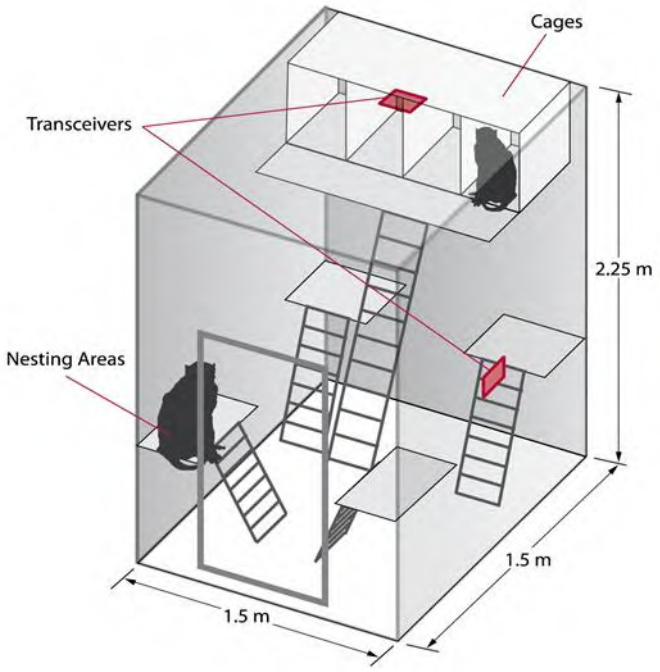
The set-up shown above includes two (2) TRXs to cover the two cages on either side of the room. In this scenario the door between the cages is open and animals are able to freely move between cages.

The TRXs are placed at right angles to one another to provide better coverage of the telemetry signal (having TRXs on different 'planes' helps avoid null areas and reduce the possibility of signal drop-out).

The set-up shown above would work either for the pair-housed or single-housed recordings without modification.

## Primate Cage Example

The diagram below illustrates a primate cage setup with Group Housing and two TRXs.




The set-up shown above includes two (2) TRXs to cover the larger communal primate cage. In the example above, this type of cage can co-house up to four primates at the same time.

Placing the TRXs at right angles to one another will provide better coverage.

## Ambient Pressure Reference (APR-2)

### MAINTAINING PRESSURE ACCURACY

Maintaining accuracy of the APR-2 is a critical element of pressure measurements throughout the Dataquest system. A 1-mmHg error in the measurement of barometric pressure at the APR-2 will result in a 1-mmHg error in pressure measurements recorded by your system. The same level of error will appear on all pressure measurements obtained with the system using the APR-2. Therefore, if absolute accuracy of pressure measurements is important in your research, it is essential that you take the steps necessary to keep the APR-2 accurate.

Extensive qualification testing and calibration prior to shipment assures that under normal use the APR-2 will not drift as a result of temperature changes or shock from shipment. Therefore, the most important part of assuring accuracy is to determine if the APR-2 has drifted over time. The following are three suggestions on how this can be accomplished.

- Comparison with the Weather Service or other barometer
  Compare your APR-2 with the weather, radio or TV station, or another reliable barometer reading at regular intervals (e.g. every 3 months) and when you first receive your APR-2. Perform these comparisons when the weather is relatively calm and avoid comparisons during thunderstorms or when strong weather fronts are moving through your area. To obtain the APR-2 measurement, initiate acquisition from a Subject with a pressure (BP or LVP) input channel. Ambient pressure values will be listed in the Derived List View as NPMN, within the main Ponemah window.

  Keep a record of the comparison measurements you have taken. Keep in mind that it is important to obtain a local reading at the same elevation above sea level as your telemetry system. The APR-2 measures the absolute pressure of the room it is placed in, and does not correct for elevation differences. For further information, contact DSI for the Technical Note 'A Consideration When Comparing DSI's Ambient Pressure Monitor Readings to Other Barometers and the Weather Service.' Any noted difference over time should be constant. If you find that the difference is increasing, then it is likely that the APR-2 has drifted. Contact DSI Technical Services to discuss further action. You can also perform this procedure by comparing the APR-2 with a highly accurate barometer (one with an accuracy of better than 1 mmHg) at your facility or by purchasing a second APR-2.

- Checking the offset of pressure transmitters
  If you are checking the offset of several DSI transmitters that have a manufacture date within the last month, they will provide a good indication of whether your APR-2 has drifted. Check the offset of these transmitters using the procedure outlined in the Implant Appendix | Implant Zero Pressure Offset section of this manual. If you find that all transmitters have an offset that is excessively and consistently biased in one direction (above or below zero mmHg), this may indicate that the APR-2 has drifted. Contact DSI Technical Services to discuss whether you should take further action.

- Recalibration by DSI
  DSI recommends that investigators working under GLP conditions send their APR-2 back to DSI for recalibration every year. For those not working under GLP conditions, DSI recommends recalibration every 3-5 years. The drift specification indicates that, barring failure of the device, it will drift less than 1.0 mmHg per year. Therefore, if you return it for recalibration every year, accuracy will likely remain within +/- 1 mmHg. Contact DSI Technical Services for information regarding recalibration of your APR-2.

*Note: If using the APR-1 with the E2S-1, the same recommendations apply.*

## APR-2 SPECIFICATIONS

| | |
|---|---|
| Barometric pressure range | 0-1000 mmHg (torr) |
| Initial accuracy | +/- 1 mmHg |
| Stability over time | Better than 1.0 mmHg / year at 20ºC to 30ºC. |
| Physical dimensions | 12.5 x 10.5 x 4 cm |
| Weight | 570 g |
| Data output connector | RJ45 (8 pin non-keyed) |
| Power connector | 9VDC |
| Power Input | 9VDC or 12W POE (IEEE 802.3af compliant) |
| Current | 60 mA |
| Standard cable length | 1 meter |
| Maximum cable length | 10 meters |
| Operating temperature range | 0º to 45º C |
| Operating humidity | <70% R.H. non-condensing |
| Storage temperature | -20º to 65º C |
| Storage humidity | <85% R.H. non-condensing |

## APR-1 SPECIFICATIONS

| | |
|---|---|
| Barometric pressure range | 650-800 mmHg (torr) |
| Initial accuracy | +/- 1 mmHg |
| Stability over time | Better than 1.0 mmHg / year at 20ºC to 30ºC. |
| Physical dimensions | 14 x 10.5 x 4 cm |
| Weight | 510 g |
| Data output connector | RJ45 (8 pin non-keyed) |
| Voltage requirement | 6.25 to 12.0 VDC |
| Current | 60 mA |

| | |
|---|---|
| Standard cable length | 1 meter |
| Maximum cable length | 10 meters |
| Operating temperature range | 0º to 50º C |
| Operating humidity | <70% R.H. non-condensing |
| Storage temperature | -20º to 65º C |
| Storage humidity | <85% R.H. non-condensing |

## Ethernet to Serial Converter (E2S-1)

The E2S-1 is only necessary when using an APR-1 with the PhysioTel Implantable Telemetry system. If using the APR-2, the E2S-1 is not required.

The E2S-1 passes data from the APR-1 to the Ponemah system while operating in a network environment. It does not modify the data received from the APR-1.

The E2S-1 uses DHCP by default as a means of being assigned a dynamic IP address. Should the E2S-1 not be discoverable within your network an alternate network configuration may be required (e.g. static IP address). Such configurations are possible but should not be modified unless absolutely necessary. To modify the network configuration please see the **Hardware Appendix: Ethernet to Serial Converter (E2S-1)**. If not set up for static IP addresses, the E2S-1 requires a DHCP server to be active on the network to which it is connected. If you are running the system across your corporate network this service is likely already present. If you are using a dedicated network separate from your corporate network the simplest method of providing this service is through the use of a router with this capability built in (e.g. Cisco Small Business Router RV130). Alternately you could install a DCHP server onto one of the PCs on your dedicated network. An Open Source DHCP server is available from SourceForge at http://sourceforge.net/projects/dhcp-dns-server/.

The front panel contains two indicator lights. The function of these is described below:

- **Ready**
  Constantly lit when the power is on and the E2S-1 is functioning normally. Blinking when the E2S-1 has been located by a software command. Off when the E2S-1 is not powered or a power error exists, the IP Address cannot be found, or there is an IP Address conflict.

- **Power**
  Constantly lit when power is available to the E2S-1 via a network cable that supplies Power over Ethernet (PoE) to J2 or when the external power source is used appropriately. The E2S-1 does not have an on/off switch

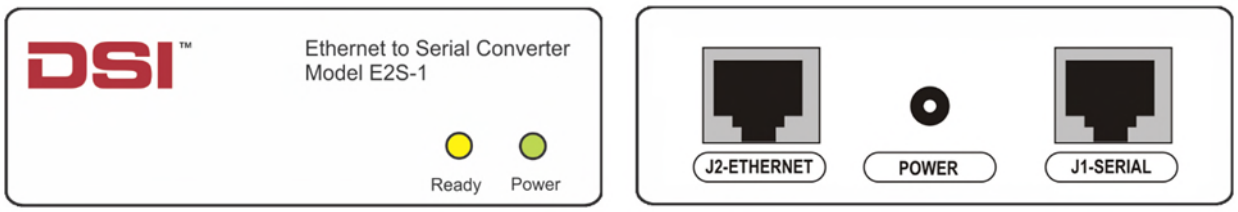
The back panel contains three unique connections:

- J1-Serial
  Plug the cable from the APR-1 into this jack. It provides a path for the barometric pressure signal to pass to the E2S-1 and also for the power from the E2S-1 to the APR-1.

*WARNING: Do Not mistake the "J2 Ethernet" port with "J1 Serial" port. Incorrectly plugging the wrong Ethernet cable into the wrong port may cause serious damage to your network devices. DSI will not replace or repair product or reimburse customers for devices that become damaged due to incorrect installation, nor is DSI liable for any loss of business resulting in the incorrect installation of this product.*

- J2-Ethernet
  Plug the cable from the Ethernet network into this jack. It provides a path for the barometric pressure signal to pass to the Ponemah Computer System from the E2S-1 and also for the power from a PoE capable network (if available) to pass into the E2S-1.

- Power
  Plug the cable from the power supply into this jack to power the E2S-1. This is optional if a PoE capable network is used.




*Front panel of E2S-1 (left), rear panel (right)*

## SPECIFICATIONS

| | |
|---|---|
| Physical dimensions | 14 x 10.5 x 4 cm |
| Weight | <500 g (<18 ounces) |
| J1 Serial connector | RJ45 (8 pin non-keyed) |
| J2 Ethernet connector | RJ45 (8 pin non-keyed) |
| Power connector | 9VDC |
| Voltage requirement | 9VDC or 12V POE (IEEE 802.3af compliant) |
| Standard cable length | 1 meter |
| Maximum cable length | 10 meters |
| Operating temperature range | 0º to 50º C |
| Operating humidity | <70% R.H. non-condensing |
| Storage temperature | -20º to 65º C |
| Storage humidity | <85% R.H. non-condensing |

- Power Indicator on Front Panel Does Not Light
  If using a PoE capable network verify that the Ethernet cable between the network switch and the E2S-1 is plugged in securely at both the E2S-1 and network jack/switch. If this does not resolve the issue try a different cable, try a different network switch, or use the provided power supply.

  If using a non-PoE capable network verify that the power supply is plugged into a functional outlet and securely plugged into the E2S-1. If this does not resolve the issue try a different outlet and/or power supply.

- Ready Indicator on Front Panel Does Not Light
  Power may not be available. Assure the power indicator light is constantly lit. If not, correct per the above troubleshooting.

  If power is available, then the E2S-1 cannot connect to the network and/or an IP Address conflict exists. Reboot the E2S-1 to obtain a new dynamically assigned IP Address.

  If you are unable to solve your problem contact DSI Technical Services.

## Nova Statstrip® Xpress™ Glucometer

The Nova StatStrip Xpress is a hand-held glucometer and test strip system that measures blood glucose levels in laboratory animals. Simply insert a test strip in the Xpress meter, apply 1.2 µL of blood to end of strip, and the glucose value is reported (in mg/dL or mmol/L, depending on the meter model) in just 6 seconds. The measurement range of 10-900 mg/dL (1-50 mmol/L) enables glucose monitoring for various challenge studies.

The StatStrip Xpress meter is one of the most accurate hand-held meters available today. It provides measurement accuracy rivaling that of clinical blood chemistry analyzers. It does this by measuring and correcting for hematocrit and other common interferents such as ascorbic acid, uric acid, acetaminophen, and others.

The hand-held glucometer is used to provide periodic blood glucose levels which are used to calibrate the telemetry readings from the HD-XG implant. Accuracy of these measurements is critically important to the accuracy of the implant data. StatStrip Xpress is the preferred choice for calibrating implantable glucose telemetry.


# Software Appendix

## Installation and Maintenance

This section introduces you to the Ponemah software and covers the following topics.

- The minimum system requirements needed to support your Ponemah system.
- How to install your Ponemah software.
- How to license your Ponemah system.

### System Requirements

- The minimum system requirements are as follows.
- Microsoft® Windows® 11 (64 bit)
- Microsoft Office 2007 or later
- 16GB RAM
- 250GB SATA
- Intel® Core™ i7 or Xeon processor
- Microsoft .NET Framework v4.5*
- 1 Ethernet Network Interface Card+

*Notes*:

*Provided during the Ponemah installation.
+Minimum of 1 Ethernet Network Interface Card is required for telemetry hardware connection. It is recommended to have 2 Ethernet Network Interface Cards to allow for a dedicated telemetry hardware network and connection to corporate/university networks.

### Installation and Maintenance

Installation must occur from a Windows® Administrator account.

1. Begin installation by inserting the Ponemah installation USB drive provided. Open File Explorer, navigate to the USB drive and run the Install.exe to begin installation. If you do not have a USB drive the Ponemah

software installation can be downloaded from support.datasci.com.

2. The Ponemah install screen will appear.Select the Ponemah link to install and follow the onscreen instructions.

   *Note*: If you are updating from a prior Ponemah version, you may retain access to the previous version by installing the new version into a unique Installation Destination folder when prompted.

3. Select Exit once the installation has completed.

*Note*: DSI recommends uninstalling the currently installed version of Ponemah using Add/Remove Programs and deleting the original Ponemah installation folder prior to upgrading to the latest Ponemah version.

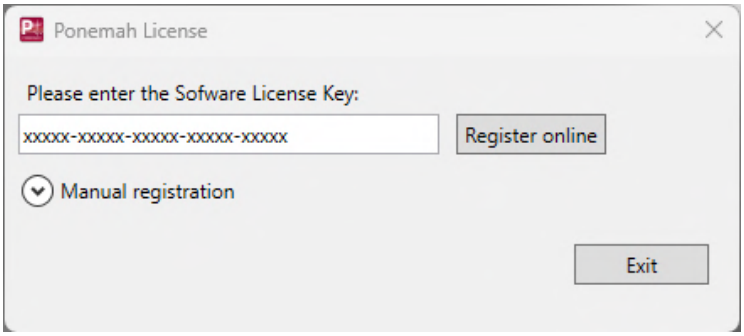
## Activating License

The Ponemah software license is provided as a 25 digit key and is included in a text file on the USB drive with the software installation. If the text file is not available, the software key can be provided by DSI support. The Ponemah software can be activated with a computer that is online or offline.

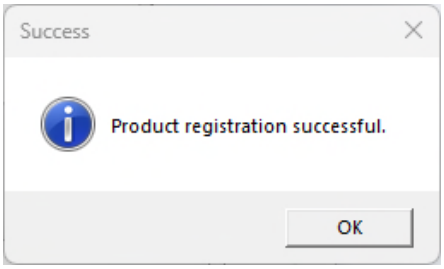
To activate the Ponemah license:

ONLINE ACTIVATION:

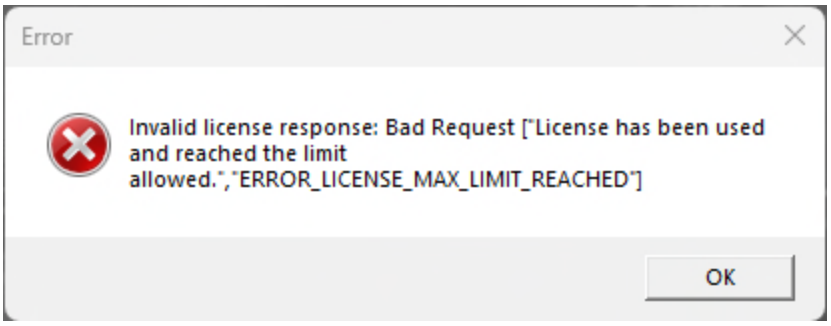
1. Open Ponemah software. The first time Ponemah is launched a key code will need to be entered. Click the 'Register Online' button to activate the license.




2. If the PC is online and the key code is entered correctly there will be a confirmation.

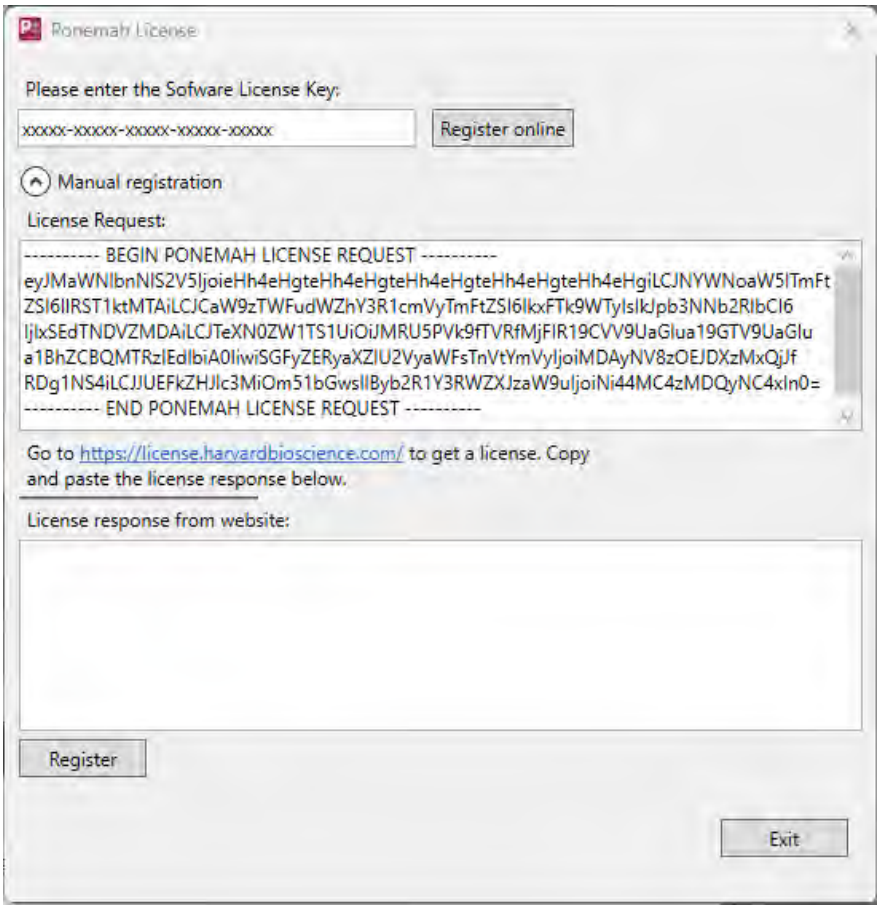



3. An error box will indicate if the license key has been used and is not available. If the Ponemah software needs to be moved to a new PC, contact DSI support to de-activate the license so it can be activated on a different PC.




OFFLINE ACTIVATION:

1. Open Ponemah software. The first time Ponemah is launched a key code will need to be entered. After entering the key, right click in the License Request box and save the contents to a USB drive.




2. Move the USB drive to a PC that is online. Navigate to the license activation site https://license.harvardbioscience.com and paste the text from the USB drive that was copied in step 1.

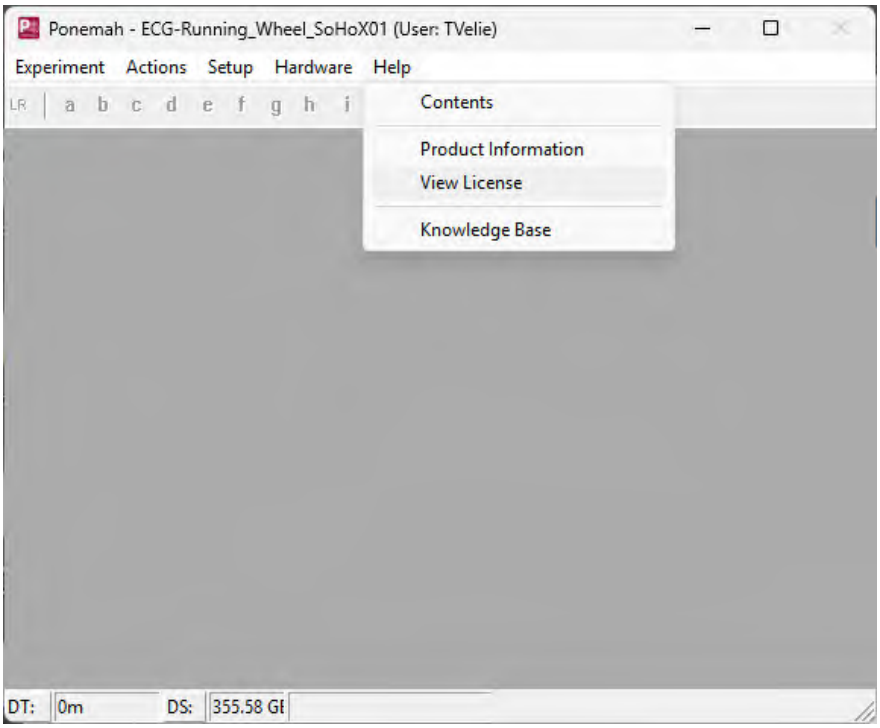

3. A license code will be generated which can be copied to a text file on the USB drive. Bring the USB drive back to the PC and paste in the 'License Response from website' box to activate Ponemah.

*Note*: If this is a subscription license, the Expiration Date will be listed within the View License File dialog accessible by selecting the **Help menu | View License**. A warning message will be displayed when 30 days or less is remaining on the license.

## Updating a License

To update a Ponemah License

1. Launch Ponemah.
2. Select the **Help menu | View License**.




3. Select Load New License.

4. If a new feature has been added to the license, click the 'Register Online' button to update the license. For updating a license offline, see additional steps in the offline activation section above.
5. Restart Ponemah.

## Ponemah Menus

The following outlines the menu structure of Ponemah and provides descriptions of the various menu options.

*Note*: The menu options are called out if they are required to be located and selected to perform the various procedures described throughout this manual.

### Configuration Menus

#### EXPERIMENT

| | |
|---|---|
| **Create…** | Opens the **Create New Experiment** dialog. |
| **Open…** | Opens a **Browse For Folder** selector to allow the user to select a previously created Experiment for further data Acquisition or Review. |
| **Import…** | Opens the **Import Experiment** wizard, allowing the user to create a new Experiment using data imported from Dataquest A.R.T. or Ponemah ≤v5.20. |
| **Experiment Log…** | Opens the **Log Viewer** dialog to allow the user to see time-sequenced hardware and application related events and errors. |
| **Save** | Saves any changes to the current Experiment **Settings**. |
| **Save as…** | Opens the **Save Experiment** dialog to allow the user to create a new Experiment using the Experiment **Settings** from the currently loaded Experiment. |
| **Export Data…** | Opens the **Derived Data Output** dialog to allow the user to choose which Subjects' Derived Output is desired to be exported to Excel. |
| **Load Recent ▶** | Lists the recently loaded Experiments to quickly load a recent Experiment. |

| | |
|---|---|
| **Review Print Setup** | Provides access to signals printing settings to control which data is printed, chart speed, and what information is provided with the printout; e.g. display **Validation Marks**. |
| **Printer Setup…** | Loads **Printer Information and Settings** dialog. |
| **Exit** | Exits the program. |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item

### ACTIONS

| | |
|---|---|
| **Start Sampling \| Continuous – All Subjects** | Start **Continuous** Sampling for all Subjects defined to **Continuous Sampling** within the **Sampling Control** dialog. |
| **Start Sampling \| Continuous – Selected Subjects** | Start **Continuous** Sampling for the highlighted Subjects within the **Sampling Control** dialog. |
| **Start Sampling \| Schedule – 1** | Start sampling using **Scheduled 1.** |
| **Start Sampling \| Schedule – 2** | Start sampling using **Scheduled 2.** |
| **Start Review** | Opens the **Load Review Data** dialog. |
| **Open Parameter Viewer** | Launches the **Parameter View** feature to view derived data across the entire experiment duration. This is accessible during Acquisition, Review, or when in Idle mode (Ponemah is open but not actively acquiring or in Review). |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item

### SETUP

| | |
|---|---|
| **Experiment Setup…** | Opens the master **Setup** dialog where the user can configure **Events**, **Data Reduction**, **Variability Analysis**, **Graphs**, and other Experiment **Settings**. |

| | |
|---|---|
| **Subject Setup…** | Opens the **Subject Setup** dialog where the user can change Subject and Channel settings; such as enable additional **Derived Parameters**. |
| **Application Log…** | Opens the **Application Log** dialog. |
| **Application Configuration…** | Opens the **Application Configuration** dialog where the user can access advanced Ponemah system settings. |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item.

### HARDWARE

| | |
|---|---|
| **Edit APR Configuration…** | Opens the **APR Configuration** dialog. |
| **APR Diagnostics…** | Not Available. |
| **Edit SignalSync Configuration…** | Opens **SignalSync Configuration** dialog to add/remove analog and digital channels from the Experiment. |
| **SignalSync Diagnostics…** | N/A, will be implemented in future update. |
| **Edit MX2 Configuration…** | Opens **MX2 Hardware Configuration** dialog to configure system hardware and add/remove PhysioTel and PhysioTel HD implants from the Experiment. |
| **MX2 Diagnostics…** | Opens **MX2 Diagnostics** web browser. |
| **Edit PhysioTel Digital Telemetry Configuration** | Opens **PhysioTel Digital Telemetry Hardware Configuration** dialog to configure system hardware and add/remove PhysioTel Digital implants from the Experiment. |
| **PhysioTel Digital Telemetry Diagnostics** | Opens **PhysioTel Digital Telemetry Diagnostics** web browser. |

| | |
|---|---|
| **Edit Soho Configuration…** | Opens **SoHub Hardware Configuration** dialog to configure system hardware and add/remove SoHo implants from the Experiment. |
| **Soho Diagnostics…** | Opens the SoHub Diagnostics window. |
| **Video Configuration…** | Opens Noldus Media Recorder software to configure cameras. |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item.

### HELP

| | |
|---|---|
| **Contents** | Opens Ponemah online **Help** (Users' Manual). |
| **Product Information** | Opens the Ponemah **Version Information** dialog that provides the user with information on the installed Ponemah system. |

The following describes the information found in each tab:

- **General Tab**
  - **License Version** - Revision level of the software license.
  - **Permitted Ponemah Version** - The Ponemah version permitted by the license file.
  - **Expiration Date** - The expiration date of the license file (the time-frame permitted to upgrade to a new version).
  - **Available Hardware Channels** - Displays the number of channels currently connected.
  - **Permitted Channels** - Displays the total number of channels that the license file allows.
  - **Windows Version** - Displays the currently loaded version of the Windows operating system.
  - **Current User** - The currently logged on windows user.
- **P3 Options Tab**
  - This tab lists all currently enabled options in the system's license file.
- **Analysis Modules Tab**
  - This tab lists all currently loaded analysis modules in the runtime directory.
- **Application Modules Tab**
  - This tab lists all the .DLLs and .EXEs in the runtime directory.
- **System Modules Tab**
  - This tab lists certain drivers, ActiveX controls, and operating system version numbers.

**Print Button**

This button allows the user to print a hardcopy of the information displayed in the Product Information dialog.

**Email Button**

This button allows the user to email a report of the information displayed in the Product Information dialog to DSI Technical Support. It should be noted that certain attachments are part of the email report. The attachments contain specific information about the configuration of the system. None of the attachments contain any collected data.

**Software License Button**

Displays the **DSI Software License Agreement** as a PDF.

**View License**

This dialog displays the currently loaded options. It also allows the loading of a new license file.

- **License Version** - Revision level of the software license.
- **P3 Version** - The Ponemah version permitted by the license file.
- **Expiration Date mm/dd/yy** - The expiration date of the license file. For perpetual licenses, this is the time-frame the user is permitted to upgrade to a new version if under Software Enhancement Agreement. For subscription licenses, this is the expiration date of the subscription.
- **Serial Numbers** - The software license file number installed on the system.
- **Options** - The Ponemah options that are enabled in the license file.
- **Analysis Modules** - Lists the Analysis Modules that are installed on the system. Note: In order to use the installed Analysis Modules, the Analysis Modules must be enabled in the license file.
- **DLLs and Versions** - Lists the .DLL (Analysis Modules) installed on the system and the permitted version level allowed to be installed.

**Knowledge Base**

## Acquisition menus

### EXPERIMENT

| | |
|---|---|
| **Experiment Log…** | Opens the **Log Viewer** dialog to allow the user to see time-sequenced hardware and application related events and errors. |
| **Review Print Setup** | Launches the **Review Print Setup** dialog, permitting changes to the settings used when printing data from Review using an external printer. See the **Printing** section of this manual located in the **Software Appendix** for more information. |
| **Printer Setup** | Launches the **Printer Setup** dialog, which permits the user to configure an external printer to the system. |

### ACTIONS

| | |
|---|---|
| **Start Sampling \| Continuous – Selected Subjects** | Start **Continuous** Sampling for the highlighted **Subjects** within the **Sampling Control** dialog. |
| **Start Sampling \| Schedule – 1** | Start sampling using **Scheduled Sampling 1.** |
| **Start Sampling \| Schedule – 2** | Start sampling using **Scheduled Sampling 2.** |
| **Stop Sampling \| All** | Stops sampling for all active **Subjects** acquiring on **Continuous**, **Schedule 1**, and **Schedule 2** Acquisition. |
| **Stop Sampling \| Continuous – Selected Subjects** | Stops **Continuous** Sampling for the highlighted **Subjects** within the **Sampling Control** dialog. |
| **Stop Sampling \| Schedule – 1** | Stops **Scheduled 1** sampling**.** |
| **Stop Sampling \| Schedule – 2** | Stops **Scheduled 2** sampling**.** |
| **Logging Rate…** | Launches the **Logging Rate** dialog to permit users to change the way the **Derived Parameter** data is logged to the **Derived Parameter List View**. See the **Data Acquisition \| Logging Rate** section of this manual. |
| **Events…** | Launches the **Events** dialog to apply an **Event** to one or more **Subjects** during acquisition. See the **Marking Events** section for more information on how to add Events. |
| **Validate** | Toggles **ON/OFF** the display of **Validation Marks** on **Primary** graphs. |
| **Toggle Logging Mark** | Toggles **ON/OFF** the display of the **Logging Rate Marks** on **Primary** graphs. These vertical lines represent the start and end of the **Logging Period**. |

| | |
|---|---|
| **Copy Selection** | Permits the user to **Copy** a row or multiple rows of data from the **Derived Parameter** and **Data Reduction List Views** to then **Paste** into another application; e.g. Excel. |
| **Open Parameter Viewer** | Launches the **Parameter View** feature to view derived data across the entire experiment duration. This is accessible during Acquisition, Review, or when in Idle mode (Ponemah is open but not actively acquiring or in Review). |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item

#### SETUP

| | |
|---|---|
| **Experiment Setup…** | Opens the master **Setup** dialog where the user can configure **Events**, **Data Reduction**, **Variability Analysis**, **Graphs**, and other Experiment **Settings**. |
| **Subject Setup…** | Opens the **Subject Setup** dialog where the user can change Subject and Channel settings; such as enable additional **Derived Parameters**. |
| **Application Configuration…** | Opens the **Application Configuration** dialog where the user can access advanced Ponemah system settings. |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item

#### WINDOWS

Standard Windows menu that permits the user to arrange Ponemah windows in various views. Also permits the selection of specific windows from those listed.

#### HELP

Provides the same information as in Experiment Configuration. Please see the **Configuration Menus** section above for more information.

## Review Menus

## EXPERIMENT

| | |
|---|---|
| **Experiment Log…** | Opens the **Log Viewer** dialog to allow the user to see time-sequenced hardware and application related events and errors. |
| **Save Experiment** | This saves any configuration changes that occur, such as graph pages, analysis attributes. |
| **Save Derived Data** | This save the **Derived Parameters** and **Data Reduction** values from the data currently loaded in Review to an Excel (or Access) file only. |
| **Save Mark Sections** | This updates the **Marks** database and saves the **Marks** so they can be loaded in subsequent Review sessions. Saving a **Mark Section** will only save the **Marks** associated with the data loaded into the Review session from which the **Save Marks Section** action is executed. This will also create a new Excel (or Access) file with the **Derived Parameter** and **Data Reduction** outputs from the currently loaded data. |
| **Data Insights** | Launches the **Data Insights** dialog permitting users to find, classify, and report on data patterns and anomalies. See the **Data Insights** section of the manual for more information. |
| **Review Print Setup** | Launches the **Review Print Setup** dialog, permitting changes to the settings used when printing data from Review using an external printer. See the **Printing** section of this manual located in the **Software Appendix** for more information. |

## ACTIONS MENU

| | |
|---|---|
| **Merge Bad Data Marks** | Provides access to the **Bad Data Mark Merge** button, which will merge all **Bad Data Marks** sections within a **Subject**, such that all **Subject Input** channels will have identical **Bad Data Mark** sections. See the **Bad Data Marks** section of this manual for more information on **Merge Bad Data Marks**. |
| **BDM Percentage** | Launches the **Bad Data Mark Percentage** dialog that provides the ability to view the percentage and distribution of data removed by **Bad Data Marks.** See the **Bad Data Marks** section of this manual for more information on **BDM Percentage**. |

| | |
|---|---|
| **Logging Rate** | Launches the **Logging Rate** dialog to permit users to change the way the **Derived Parameter** data is logged to the **Derived Parameter List View**. See the **Data Acquisition \| Logging Rate** section of this manual. |
| **ASCII Output** | Launches the ASCII Output dialog to permit creating ASCII files from the graphically displayed data. See the **ASCII Output** section of this manual located in the **Software Appendix** for more information. |
| **Copy Selection** | Permits the user to **Copy** a row or multiple rows of data from the **Derived Parameter** and **Data Reduction List Views** to then **Paste** into another application; e.g. Excel. |
| **Batch Template Analysis** | This permits the user to perform **ECG PRO**, Template-based, analysis across all Input channels with a valid library binding. Please see the **ECG PRO** section of this manual for more information. |
| **Close Review** | Selecting this will close the current Review section. |
| **Open Parameter Viewer** | Launches the **Parameter View** feature to view derived data across the entire experiment duration. This is accessible during Acquisition, Review, or when in Idle mode (Ponemah is open but not actively acquiring or in Review). |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item

### SETUP

| | |
|---|---|
| **Experiment Setup…** | Opens the master **Setup** dialog where the user can configure **Events**, **Data Reduction**, **Variability Analysis**, **Graphs**, and other Experiment **Settings**. |
| **Subject Setup…** | Opens the **Subject Setup** dialog where the user can change Subject and Channel settings; such as enable additional **Derived Parameters**. |

| | |
|---|---|
| **Variability Analysis…** | Opens the Variability Analysis Editor dialog permitting users to configure Frequency and Time Domain Heart Rate Variability (HRV). See the Variability Analysis section of the Ponemah Software \| Data Review section of this manual. |
| **Manage Frequency Bins** | Permits the user to manage the frequency bin sets used within the Variability Analysis dialog if using Frequency Bins for Frequency Domain HRV. |
| **Application Configuration…** | Opens the **Application Configuration** dialog where the user can access advanced Ponemah system settings. |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item

### GRAPHS

| | |
|---|---|
| **Graph Setup…** | Opens the master **Setup** dialog directly to the **Graph Setup** area to provide quicker access to **Graph Settings**. |
| **Enabled Graph Page List** | Lists all enabled graph pages and permits the user to enable/disable previously configured graphs without having to enter the Experiment Settings \| Graph Setting dialog. Since graphs can be closed using the red 'X' associated with the graph window, this permits a quick, easy way to re-enable the page. |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item

### DATA PARSER

| | |
|---|---|
| **Rules…** | Launches the **Data Parser** dialog directly to the **Parser Rules** setup dialog. Please see the **Data Parser** section of this manual for more information. |
| **Segments…** | Launches the **Data Parser** dialog directly to the **Individual Segments** setup dialog. This provides a list of all defined Parser Segments in the loaded data set. Please see the **Data Parser** section of this manual for more information. |
| **Save Parsed Derived Data** | Outputs an Excel file containing the **Derived Parameter** and **Data Reduction** data for only the sections of data contained within the **Parser Segments**. |

| | |
|---|---|
| **Show Parser Bar in Graphs** | Toggles **ON/OFF** the display of the **Data Parser** bar (white row) located at the top of each **Primary** and **Trend** graph. |

*Note*: Manual sections exist for each of the options above. See the appropriate sections of the manual for more information of the desired menu item

#### WINDOWS

Standard Windows menu that permits the user to arrange Ponemah windows in various views. Also permits the selection of specific windows from those listed.

#### HELP

Provides the same information as in the Experiment Configuration Menus. Please see the **Configuration Menus** section above for more information.

## Experiment Settings Dialog Description

The **Settings** configuration allows the setup default **Experiment Settings** that are saved with the Experiment and are applied during Acquisition and Review.

#### ACQUISITION/REVIEW DEFAULTS

This section allows the defaults **Logging Method and Rate** to be defined for when an Acquisition or Review session is begun. This will define how often data will be logged into the **List Views** and on **Trend** and **Scatter** graphs.

Please see the **Logging Rate** dialog section to learn more about these settings and how to change the **Logging Rate** during Acquisition or Review.

#### DATA SEPARATOR

This section allows the user to select a type of data separator, and therefore, customize how data is displayed in the derivation files. Note: The Data Separator has no effect on ODBC data.

#### GLOBAL SETTINGS

This sections allows the user to change the default method used to display data and other inputs in the Experiment.

| | |
|---|---|
| **Logging Rate Marker** | This check box allows a dashed line to be drawn on the **Primary** graph during data Acquisition indicating the start/end of a line of data is logged to the **Derived Parameter List View**. This will aid in validating which cycles are in a particular **Logging Period**. This is available only if **Logging Method** is set to **Time** mode. |
| **Events Displayed as String** | This check box allows the system to display the complete **Event** message on the graph page. If the check box is not checked, the system displays a character (**a-j**) that represent the **Event** on the graph page. |
| **Validation Marks on at Start** | This check box allows the system to place **Validation Marks** on the **Primary** graph page as soon as Acquisition starts. |
| **Ignore zeros in Data Reduction** | This check box allows **Data Reduction** to ignore zeros when running calculations. If this check box is enabled and **Data Reduction** is attempting to reduce all zeros, the result will be a zero. Control related calculations (Delta, %Delta, and %Chg) will report zeros if the reduced data are all zeros. |
| **Aggregated Parameter Window** | Organizes the **Derived Parameter List View** in an **Aggregate** mode. In **Aggregate** mode, one **Derived Parameter List View** will be available during Acquisition that displays the **Derived Parameters** from all Subjects' **Input Channels** that are being sampled. |
| **Min Good Time** | This provides the user the ability to define the default time frame used to mark data as bad between two **Bad Data Mark** regions. If the time between the regions is less than the value specified. If the time is less than what is specified, the **Bad Data Mark** region will appear as one contiguous segment. |

## Remote Notification – Email Alerts

### Typical Exchange Server Configuration

The following is a list of items to check in Exchange Server in order to use the Email Alert feature in Ponemah.

- E-Mail Server
  The value entered in 'Email Server' is typically the same URL used to access email from a web browser. When you connect to email from a browser, please note if the URL starts with HTTP or HTTPS. If you see

HTTPS you will need to check the box 'Enable SSL', this will ensure the proper authentication is used.

- Port
  Port 25, is the most common port used for email.

- Logon name
  Can be entered one of two ways, Domain\Username or emailaddress@domain.com
  e.g. Company1\Doctor or doctor@company1.com

- Password
  This is the network password for the account you entered in the 'Logon name' field. **Be sure to update this password when you change your network password**, as your alerts will stop working and can result in locking that network account from accessing any other network resources (files, folders, email, intranet, etc.).

- If you are unable to successfully send a Test Alarm email, please contact your IT Administrator to confirm your settings, and that this machine is allowed to relay messages.

## Email to Text

To send the email notification as a text message, add the message recipients' 10 digit mobile phone number followed by their cell phone carrier's domain to **the Email Alarms/Failures To** field.

- AT&T – phonenumber@txt.att.net
- Verizon – phonenumber@vtext.com
- T-Mobile – phonenumber@tmomail.net
- Sprint PCS – phonenumber@messaging.sprintpcs.com
- Virgin Mobile – phonenumber@vmobl.com
- US Cellular – phonenumber@email.uscc.net
- Nextel – phonenumber@messaging.nextel.com
- Boost – phonenumber@myboostmobile.com
- Alltel – phonenumber@message.alltel.com
- Metro PCS – phonenumber@mymetropcs.com
- SunCom – phonenumber@tms.suncom.com

Please contact your specific carrier if not listed. It is recommended to send a Test Email to the phone to confirm messages will be received prior to starting a study.

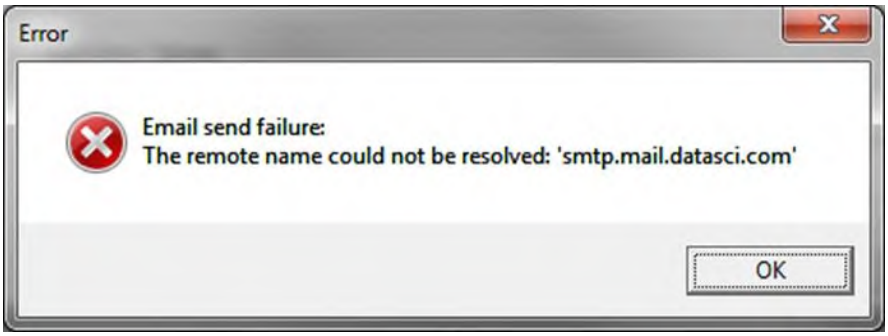
## Troubleshooting

### EMAIL SERVER NAME NOT FOUND

This occurs when the email server that is being used to cannot be located in the network. Possible causes are:

- Server name is not valid.
- No network connection to the server.

- Route to the server cannot be found.



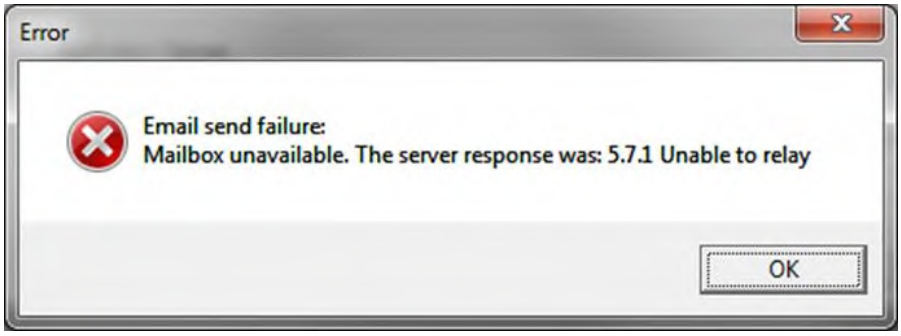

*Recommendation:*

- Ensure you have a network connection.
- Confirm the Email Server with your IT Administrator.

### EMAIL SEND FAILURE

This type of error may occur for the following reasons:

- Bad or invalid email address entered into the **Email To** field(s).
- The outgoing Email server is not allowing an email message to be relayed to another server.

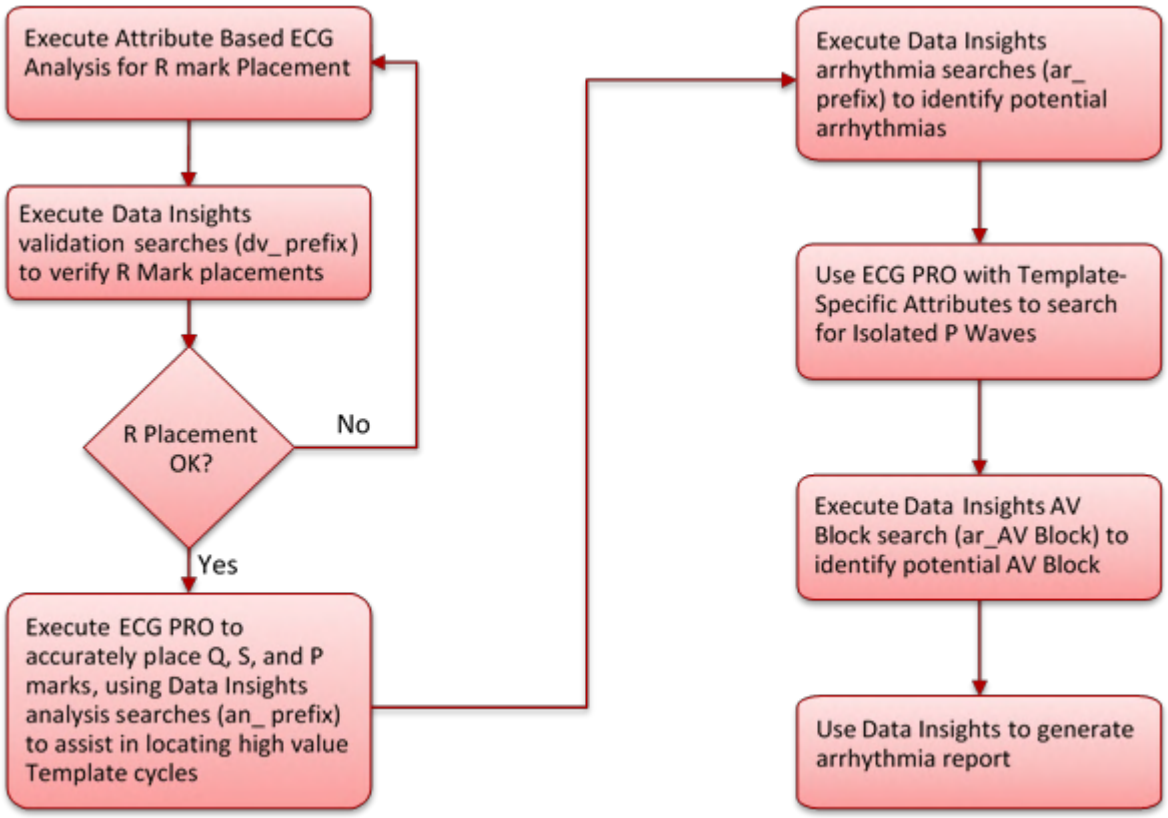



*Recommendation*:

- Ensure all email addresses entered in the **Email To** field(s) are accurate.
- Confirm that you have the correct value entered for **Email Server** in the **Configuration - Email Alerts** dialog.
- Check with your local IT Administrator to ensure the computer configured to send alerts is allowed to relay emails and that the **Email Server** being entered is correct.

## Process Flow Diagram

The following outlines the recommend process for users performing ECG analysis and arrhythmia detection with Data Insights.




## Default Search Definition by Species

Predefined Searches are provided with the installation of Data Insights. The searches can be used immediately for purposes of data validation, arrhythmia detection and other purposes. The following searches are defined below:

### ANALYSIS SEARCHES

Analysis Searches are used to aid in data analysis process. Currently these are used to help construct high value ECG PRO Template Libraries.

- **an_Low P match** (Low P Match - requires ECG PRO):
  Searches for high value P templates by displaying the distribution of P waves with low match percentages. While building a Template Library it is good to use the default Minimum Match % of 85%, this helps keep

matched results well marked. Using the Low P Match Search to look for new templates to add ensures the use of low noise cycles that are significantly different from existing templates, i.e. cycles with a match of 84.9% will not be used.

Select a match result from a region of the waveform with many match results for inclusion as a new template cycle.

| Species | Definition | | | |
|---|---|---|---|---|
| Dog<br>Monkey<br>Rat<br>Mouse | | Value($PMatch_{cyc0}$) | < | 70 |
| | AND | Value($Noise_{cyc0}$) | < | 30 |
| | AND | Value($NUM_{cyc-1}$) | > | 0 |

- **an_Low QS match** (Low QS Match - requires ECG PRO):
  Searches for high value QS templates by displaying the distribution of Q and S waves with low match percentages. While building a Template Library it is good to use the default Minimum Match % of 85%, this helps keep matched results well marked. Using the Low QS Match Search to look for new templates to add ensures the use of low noise cycles that are significantly different from existing templates, i.e. cycles with a match of 84.9% will not be used.

  Select a match result from a region of the waveform with many match results for inclusion as a new template cycle.

| Species | Definition | | | |
|---|---|---|---|---|
| Dog<br>Monkey<br>Rat<br>Mouse | ( | Value($QMatch_{cyc0}$) | < | 70 |
| | OR | Value($SMatch_{cyc0}$) | < | 70) |
| | AND | Value($Noise_{cyc0}$) | < | 30 |

- **an_Unmatched** (Unmatched Cycles - requires ECG PRO):
  Searches for unmatched cycles with low noise to display the distribution of unmatched cycles.

  Select a match result from a region of the waveform with many match results for inclusion as a new template cycle.

| Species | Definition | | | |
|---|---|---|---|---|
| Dog<br>Monkey<br>Rat<br>Mouse | | Value($Match_{cyc0}$) | < | 100 |

- **an_Unmatched Clean** (Clean Unmatched Cycles - requires ECG PRO):
  Searches for unmatched cycles with low noise to display the distribution of clean unmatched cycles.

  Select a match result from a region of the waveform with many match results for inclusion as a new template cycle.

| Species | Definition | | | |
|---|---|---|---|---|
| Dog<br>Monkey<br>Rat<br>Mouse | | Value($Match_{cyc0}$) | < | 100 |
| | AND | Value($Noise_{cyc0}$) | < | 20 |

- **an_Low T Match** (Low T Match - requires ECG PRO):
  Searches for high value T templates by displaying the distribution of T waves with low match percentages. While building a Template Library it is good to use the default Minimum Match % of 85%, this helps keep matched results well marked. Using the Low T Match Search to look for new templates to add ensures the use of low noise cycles that are significantly different from existing templates, i.e. cycles with a match of 84.9% will not be used.

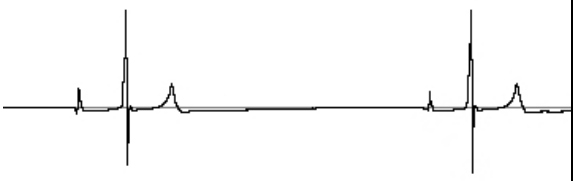
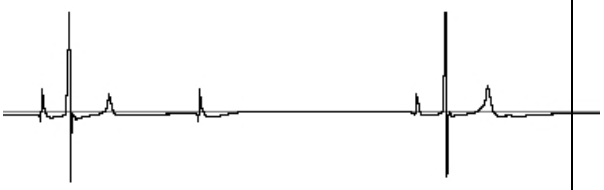
  Select a match result from a region of the waveform with many match results for inclusion as a new template cycle.

| Species | Definition | | | |
|---|---|---|---|---|
| Dog<br>Monkey<br>Rat<br>Mouse | | Value($TMatch_{cyc0}$) | < | 70 |
| | AND | Value($Noise_{cyc0}$) | < | 30 |
| | AND | Value($NUM_{cyc-1}$) | > | 0 |

## ARRHYTHMIA SEARCHES

Arrhythmia Searches are used to aid in arrhythmia detection.

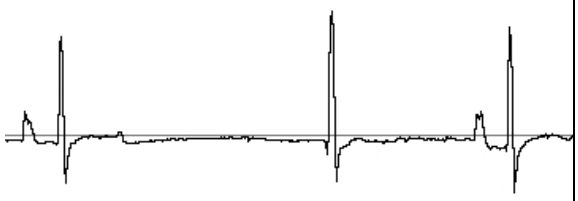
*Note*: If the Species is not specifically called out within the Search Definition, the set of search clauses and the values within are the same for Dog, Monkey, Rat, and Mouse.

| Search Definition | Example Waveform Morphology |
|---|---|
| **First-degree AV block (ar_ AV Block 1st):** Identifies cycles that have a long PR interval that is shorter than the PR interval for a potential isolated P wave<br><br>Dog — Value(PR-$I_{cyc0}$) > 130<br>AND Value(PR-$I_{cyc0}$) < 250<br>AND Value($NUM_{cyc-1}$) > 0<br>AND Value($Noise_{cyc0}$) < 30<br><br>Monkey — Value(PR-$I_{cyc0}$) > 100<br>AND Value(PR-$I_{cyc0}$) < 200<br>AND Value($NUM_{cyc-1}$) > 0<br>AND Value($Noise_{cyc0}$) < 30<br><br>Rat — Not Supported<br><br>Mouse — Not Supported |  |
| **Second-degree AV block (ar_ AV Block 2nd):** Identifies cycles that have a significantly elongated PR intervals. This search is used after marking isolated P waves using ECG PRO's Template Specific Attributes – See the *Data Insights \| Finding Second Degree AV Block using Template Specific Attributes* section of the *Tutorials*.<br><br>Dog — Value(PR-$I_{cyc0}$) > 250<br>AND Value($NUM_{cyc-1}$) > 0 |  |

| | | | | |
|---|---|---|---|---|
| | AND | Value(Noise$_{cyc0}$) | < | 30 |
| Monkey | | Value(PR-I$_{cyc0}$) | > | 200 |
| | AND | Value(NUM$_{cyc-1}$) | > | 0 |
| | AND | Value(Noise$_{cyc0}$) | < | 30 |
| Rat | | Value(PR-I$_{cyc0}$) | > | 100 |
| | AND | Value(NUM$_{cyc-1}$) | > | 0 |
| | AND | Value(Noise$_{cyc0}$) | < | 30 |
| Mouse | | Value(PR-I$_{cyc0}$) | > | 250 |
| | AND | Value(NUM$_{cyc-1}$) | > | 0 |
| | AND | Value(Noise$_{cyc0}$) | < | 30 |

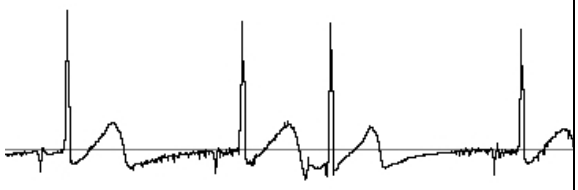
**Junctional Complex (ar_ Junctional):** Identifies cycles that do not have a P or have a P with a short PR interval and are not Ventricular Ectopics

| | | | |
|---|---|---|---|
| ( | Value(PCt$_{cyc0}$) | = | 0 |
| OR | %Decrease(PR-I$_{avg0}$, PR-I$_{cyc0}$) | > | 35 ) |
| AND | Search($_{cyc0}$) | != | ar_V Ectopic |



**Premature Atrial Complexes (ar_ PAC):** Identifies cycles that show a decrease in RR interval relative to the previous cycle, while showing little change in RR interval between the previous and following cycles.

| | | | |
|---|---|---|---|
| | %Decrease(RR-I$_{cyc-1}$, RR-I$_{cyc0}$) | > | 30 |
| AND | %Change(RR-I$_{cyc-1}$, RR-I$_{cyc1}$) | < | 25 |
| AND | Value(Num$_{cyc-2}$) | > | 0 |
| AND | Value(Noise$_{cyc0}$) | < | 100 |

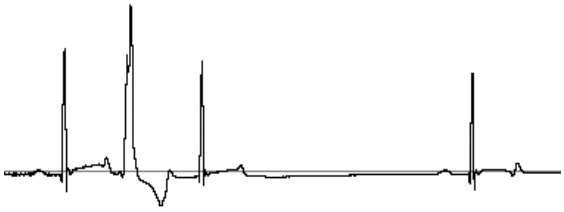


**Sinus Pause (ar_ Sinus Pause):** Identifies cycles with a long RR interval or a marked increase in RR relative to the previous cycle.

| | | | | |
|---|---|---|---|---|
| Dog | ( | Value(RR-$I_{cyc0}$) | > | 3000 |
| | OR | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 200) |
| | AND | Value($Num_{cyc-2}$) | > | 0 |
| Monkey | ( | Value(RR-$I_{cyc0}$) | > | 2000 |
| | OR | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 200) |
| | AND | Value($Num_{cyc-2}$) | > | 0 |
| Rat | ( | Value(RR-$I_{cyc0}$) | > | 500 |
| | OR | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 200) |
| | AND | Value($Num_{cyc-2}$) | > | 0 |
| Mouse | ( | Value(RR-$I_{cyc0}$) | > | 400 |
| | OR | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 200) |
| | AND | Value($Num_{cyc-2}$) | > | 0 |

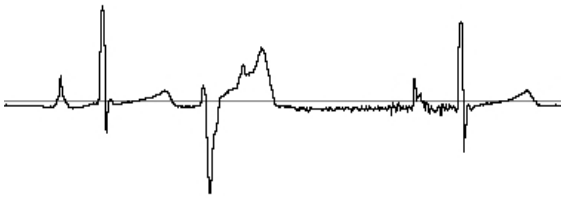
**Ventricular Interpolated (ar_ Interpolated):** Identifies when a ventricular beat is inserted within normal sinus beats.

| | | | |
|---|---|---|---|
| | %Decrease(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 40 |
| AND | %Change(RR-$I_{cyc0}$, RR-$I_{cyc1}$) | < | 35 |
| AND | %Decrease(RR-$I_{cyc2}$, RR-$I_{cyc1}$) | > | 40 |
| AND | Search($_{cyc0}$) | = | ar_ V Ectopic Single |
| AND | Value($Num_{cyc-2}$) | > | 0 |



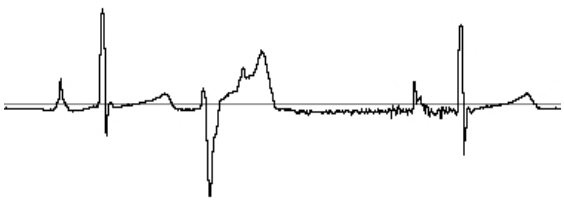
**Ventricular Ectopic (ar_ V Ectopic):** Identifies cycles with a widened QRS.

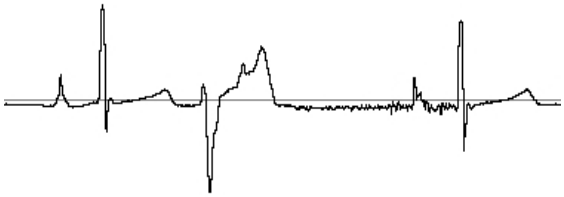
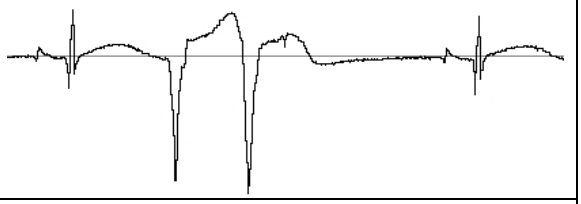
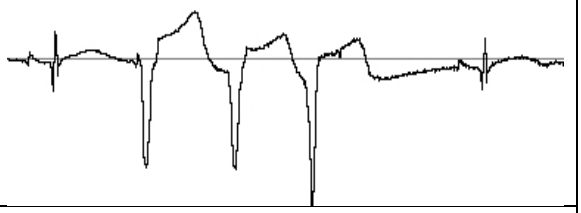
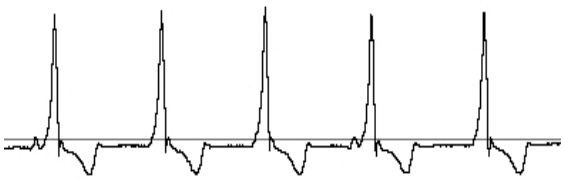
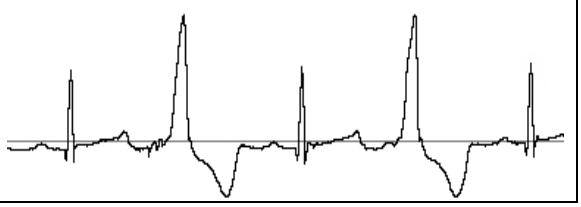
| | | | | |
|---|---|---|---|---|
| Dog | | Value($QRS_{cyc0}$) | > | 54 |
| | AND | Value($Noise_{cyc0}$) | < | 100 |
| Monkey | | Value($QRS_{cyc0}$) | > | 48 |
| | AND | Value($Noise_{cyc0}$) | < | 100 |
| Rat | | Value($QRS_{cyc0}$) | > | 30 |
| | AND | Value($Noise_{cyc0}$) | < | 100 |
| Mouse | | Value($QRS_{cyc0}$) | > | 20 |
| | AND | Value($Noise_{cyc0}$) | < | 100 |

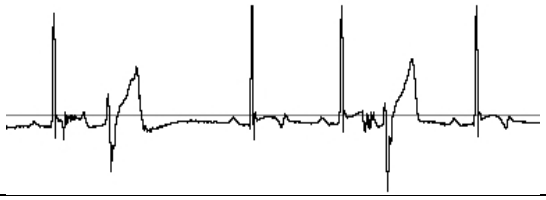


**Ventricular Ectopic Single (ar_ V Ectopic Single):** Identifies isolated Ventricular Ectopics bracketed by two sinus (non-ventricular) beats.

| | | | |
|---|---|---|---|
| | Search($_{cyc-1}$) | != | ar_ V Ectopic |
| AND | Search($_{cyc0}$) | = | ar_ V Ectopic |
| AND | Search($_{cyc1}$) | != | ar_ V Ectopic |



| | |
|---|---|
| **Ventricular Escape Complex (ar_ V Escape Single):** Identifies single Escape beats bracketed by two sinus (non-ventricular) beats.<br><br>%Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) > 40<br>AND Search($_{cyc0}$) = ar_ V Ectopic Single<br>AND Value($Num_{cyc-2}$) > 0 | Example not currently available. |
| **Premature Ventricular Complex (ar_ PVC Single):** Identifies single Premature Ventricular Ectopics bracketed by two sinus (non-ventricular) beats.<br><br>%Decrease(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) > 0<br>AND Search($_{cyc0}$) = ar_ V Ectopic Single<br>AND Value($Num_{cyc-2}$) > 0 |  |
| **Couplet (ar_ Couplet):** Identifies two contiguous Ventricular Ectopic beats that are bracketed by two sinus (non-ventricular) beats.<br><br>Series(ar_ V Ectopic, 1) = 2 |  |
| **Triplet (ar_ V Triplet):** Identifies three contiguous Ventricular Ectopic beats that are bracketed by two sinus (non-ventricular) beats.<br><br>Series(ar_ V Ectopic, 1) = 3 |  |
| **Run (ar_ V Run):** Identifies greater than three contiguous Ventricular Ectopic beats that are bracketed by two sinus (non-ventricular) beats.<br><br>Series(ar_ V Ectopic, 1) > 3 |  |
| **Bigeminy (ar_ V Bigeminy):** Identifies a repeating pattern of two or more Ventricular beats that are separated by one sinus (non-ventricular) beat.<br><br>Series(ar_ V Ectopic Single, 2) >= 2 |  |

| | |
|---|---|
| **Trigeminy (ar_ V Trigeminy):** Identifies a repeating pattern of two or more Ventricular beats that are separated by two sinus (non-ventricular) beats.<br><br>Series(ar_ V Ectopic Single, 3) >= 2 |  |

## DATA VALIDATION SEARCHES

**Data Validation Searches are used** to aid in the data validation process by quickly exposing outliers and potentially mismarked data that may require focused attention.

- **dv_HR Limits** (Heart Rate Limits):
  Searches for cycles that are at HR extremes to help complete the attribute based analysis process to improve the accuracy of R mark placement. The matches may be valid beats, missed beats or incorrectly marked beats, however there is a greater likelihood of mismarked beats.

  Sort the HR column within the **Results Derived View** and step through the extremes until the remaining matches are well mark cycles. Displaying the validation marks in the **Results Wave View** may be helpful. Place Bad Data Marks, Delete Cycles, or reanalyze particular data sections as needed to correct the mismarked data.

| Species | Search Definition | | | |
|---|---|---|---|---|
| Dog | ( | Value($HR_{cyc0}$) | > | 200 |
| | OR | Value($HR_{cyc0}$) | < | 35 ) |
| | AND | Value($Num_{cyc-1}$) | > | 0 |
| Monkey | ( | Value($HR_{cyc0}$) | > | 200 |
| | OR | Value($HR_{cyc0}$) | < | 50 ) |
| | AND | Value($Num_{cyc-1}$) | > | 0 |
| Rat | ( | Value($HR_{cyc0}$) | > | 500 |
| | OR | Value($HR_{cyc0}$) | < | 250 ) |
| | AND | Value($Num_{cyc-1}$) | > | 0 |
| Mouse | ( | Value($HR_{cyc0}$) | > | 550 |
| | OR | Value($HR_{cyc0}$) | < | 300 ) |
| | AND | Value($Num_{cyc-1}$) | > | 0 |

- **dv_HR Change** (Heart Rate Change):
  Searches for a marked increase in RR-I between the current and the following cycle to help complete the attribute based analysis process to improve the accuracy of R mark placement. The matches may be valid beats, missed beats or incorrectly marked beats, however there is a greater likelihood of mismarked

beats.

Sort the RR-I column within the **Results Derived View** and step through the extremes until the remaining matches are well mark cycles. Displaying the validation marks in the **Results Wave View** may be helpful. Place Bad Data Marks, Delete Cycles, or reanalyze particular data sections as needed to correct the mismarked data.

| Species | Search Definition | | | |
|---|---|---|---|---|
| Dog<br>Monkey<br>Rat<br>Mouse | | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 50 |
| | AND | Value($Num_{cyc-1}$) | > | 0 |

- **dv_Missed Beats** (Missed Beats):
  Searches for skipped beats to help complete the attribute based analysis process to improve the accuracy of R mark placement.

  Sort the RR-I column within the **Results Derived View** and step through the extremes until the remaining matches are well mark cycles. Displaying the validation marks in the **Results Wave View** may be helpful. Place Bad Data Marks, Delete Cycles, or reanalyze particular data sections as needed to correct the mismarked data.

| Species | Search Definition | | | |
|---|---|---|---|---|
| Dog | | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 90 |
| | AND | %Change(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | < | 10 |
| | AND | Value($HR_{cyc0}$) | > | 140 |
| | AND | Value($Noise_{cyc0}$) | < | 100 |
| Monkey | | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 90 |
| | AND | %Change(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | < | 10 |
| | AND | Value($HR_{cyc0}$) | > | 150 |
| | AND | Value($Noise_{cyc0}$) | < | 100 |
| Rat | | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 90 |
| | AND | %Change(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | < | 10 |
| | AND | Value($HR_{cyc0}$) | > | 400 |
| | AND | Value($Noise_{cyc0}$) | < | 100 |
| Mouse | | %Increase(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | > | 90 |

| | | | | |
|---|---|---|---|---|
| | AND | %Change(RR-$I_{cyc-1}$, RR-$I_{cyc0}$) | < | 10 |
| | AND | Value($HR_{cyc0}$) | > | 475 |
| | AND | Value($Noise_{cyc0}$) | < | 100 |

## Hints and Troubleshooting

### GENERAL CONFIGURATION

- **OK** button is not available for selection after making changes to edit fields. Ensure that all information within boxes outlined in red have been filled in. If information is absent for any field outlined in red, the OK button will not be available.
- Use of the Average function (**avg**) is based on the current averaging interval defined in the Logging Rate field. This is the same logging rate applied to the derived output (DRx) files.
- Derived data is displayed under the **Results** section within the Data Insights dialog. The number of columns and the information provided in each column will differ based on the search criteria (Search, Series, Template, Real Time, etc.) used. Some examples are below.
- Search: Utilizes existing searches within its search clause and provides Cycle Number as the output.
- Series: Utilizes existing searches within its search clause and provides Cycle Number and the number of cycles found for that data segment or **Series** query.
- **Match Condition Table** displays the specific searches used and the conditions for the searches. In addition this table logs the time the match was found, the duration, and the value for each match. If a number of searches are utilized, this could result in a very large number of entries into the report. An informational message may be posted informing the user that information will be truncated. You can remove the number of items selected for the report to address this. This information is typically reported when doing Series based searches because it provides content of the runs as opposed to only the number of runs encountered.

### SEARCH CONFIGURATION

- It is important to note that Searches are specific to a channel and specie type. For example, searches constructed using ECG parameter information cannot be applied to pressure channels. Searches should be created specific to both specie and signal type. Searches that do not match the signal type will not be allowed to be dragged and dropped on that channel.
- When importing searches, referenced searches must also be present in the.xml file that is being imported. If the referenced search is not contained in the xml file, the search or searches using the missing reference will not be loaded. Additionally, none of the searches in the .xml file being imported should be present in the current Search list. Remove any duplicates before importing. In some cases it may be advisable to remove all searches prior to importing a new list.
- To delete searches, select all that apply. This can be done one at a time or can be done using the Control or Shift keys and selecting multiple Searches at once. Right click the mouse and select **Delete Selected Searches**.
- Selection of Species within the **Search Entry Dialog** is dependent upon the data loaded into Review. If data is loaded that has been specified as dog, selection of a different species cannot be performed. Data with the desired species must be loaded into Review in order to create the species specific search. Additionally, Searches identified as a one species cannot be applied to data from a different species.

- A Series search depends on an embedded search with one or more of it clauses. If the embedded clauses are not applied to a channel, or channels, the Series search will not be able to be dragged and applied to a channel.

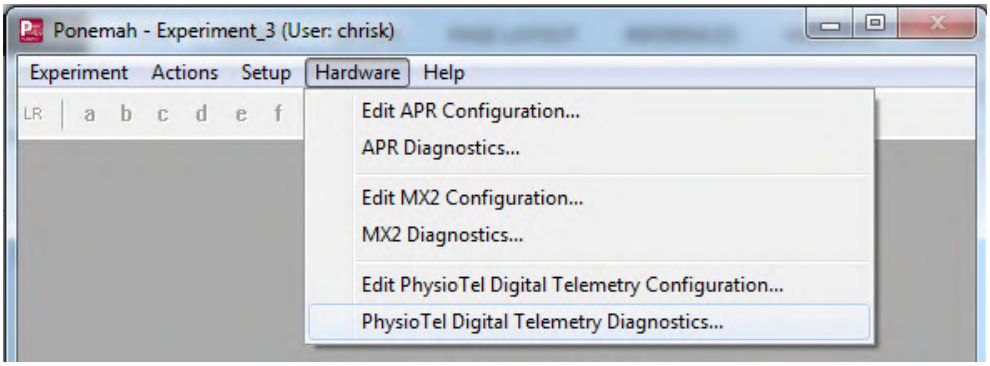
### ANALYSIS

- Templates created in previous versions are not backwards compatible. Contact Technical Support if specific version information is needed. Error messages will be posted stating the adding the Template Library has failed.
- Performing searches looking for increases and decreases greater than a specified value can yield negative results. If only positive results are desired, construct a search clause designating the specific range desired, for example, greater than 0.
- Performing a Search using NUM (cycle number) ensure that the correct channel (algorithm) has been selected. If the incorrect algorithm has not been selected, the Search cannot be applied to the channel. Also, if using NUM as a comparison within a clause, ensure that all clauses using NUM are from the same algorithm. It is possible to apply a Search where NUM has been constructed from different algorithms. However, Match results will equal zero.
- Adding **Bad Data Marks** (BDM) may appear to slow down analysis. Adding BDM at the beginning of the file will update quickly and allow continued analysis or changes within Data Insights. However, adding BDM at the end of the file while parameters are updating will result in the system appearing to slow down. This is due to the fact that BDM placed at the end of the file will wait for the parameters to update before applying the BDM. Removing data in chronological order typically does not show this behavior.
- This may often be seen when sorting on the derived parameters and removing data using BDM. Since the data is no longer in chronological order, removal of data is dependent upon completion of all calculations. Two segments next to each other may be from the opposite ends of the file. Removal of one segment may be performed quickly if it is at the beginning of the dataset. However, removal of the next segment may need to wait for calculations to be completed before applying the BDM updates.
- Adding or removing search clauses will result in all rejected data to be removed. Changing values in the clauses will not affect those results that have been rejected.
- It is useful to include a Noise Clause in searches. This permits the exclusion of noisy data from match results. By default the Noise threshold in the Noise clause should be set high to prevent exclusion and lowered as necessary.

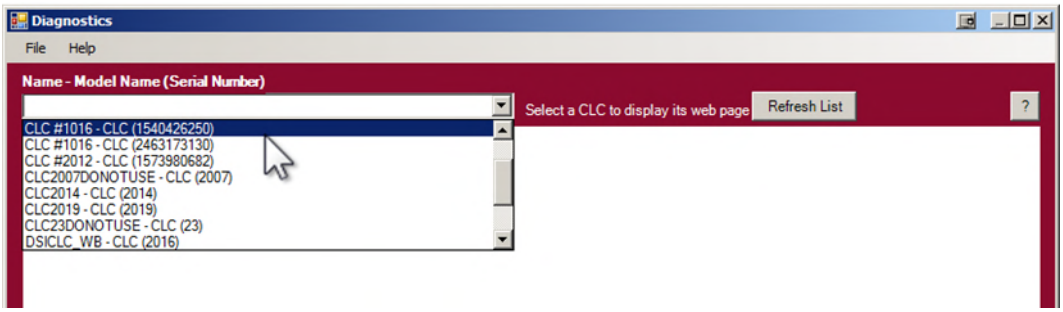
## PhysioTel Digital Diagnostics

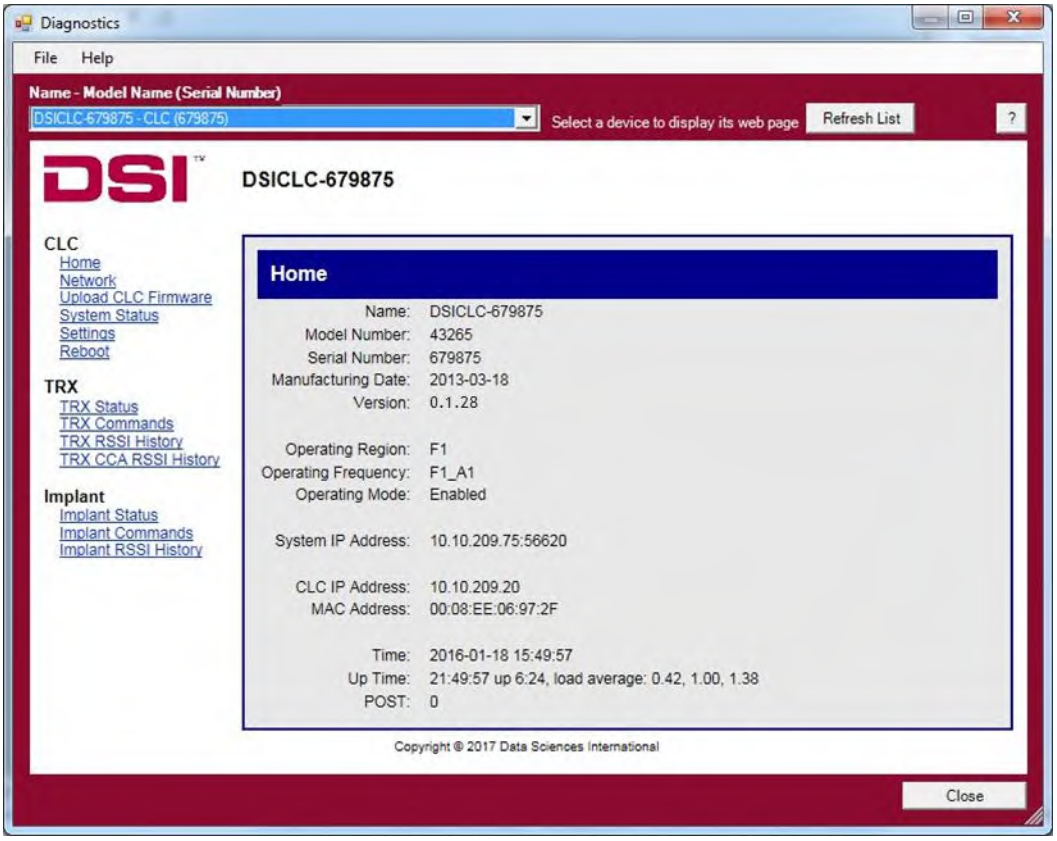
The Diagnostics user interface is a browser based webpage that allows the user to check the status of the PhysioTel Digital hardware components, update firmware, and perform diagnostic tests to optimize the performance of the system components.

The Diagnostic user interface is accessed from the Ponemah Hardware menu.




To select a specific CLC click on the drop-down menu located in the top left corner of the diagnostics window. All of the configured CLCs that are connected to the system will appear in this list.



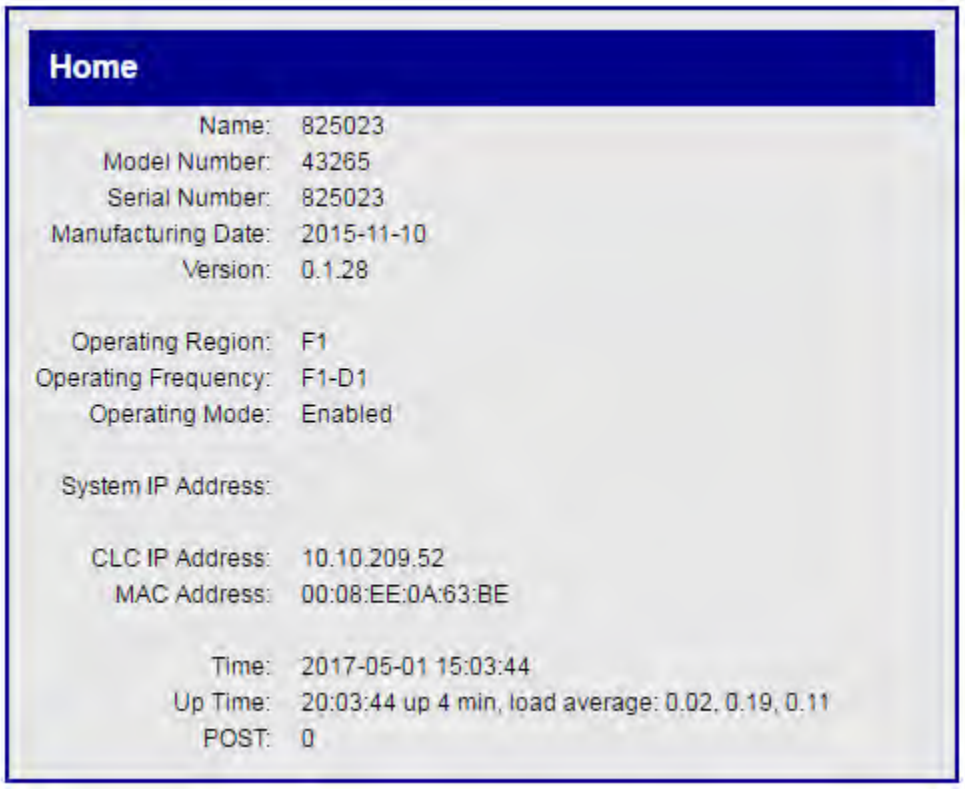



## CLC OPTIONS

The CLC section of the Diagnostics webpage options are describe below.

### Home

The Home page lists general information about the select CLC.




| | |
|---|---|
| **Name** | Displays the user defined name assigned to the CLC. |
| **Model Number** | Displays a numeric value representing the CLC model. |
| **Serial Number** | Displays the CLC serial number. |
| **Manufacturing Date** | Displays the date the CLC was manufactured at DSI. Format is YYYY-MM-DD. |
| **Version** | Displays the firmware version the CLC is currently running. |

**Operating Region** Displays the current Operating Region of the CLC.

| Frequency | Region |
|---|---|
| F1 | US |
| F2 | Europe |
| F3 | Japan |
| F4 | China |

**Operating Frequency** Displays the currently assigned Operating Frequency, based on TRX connection.

*Note*: the Operating Frequency will read “Unknown” if CLC is powered up without a TRX connected.

**Operating Mode** Enabled: Normal operational mode.

Disabled: The CLC sends and receives no RF data.

Assessment: The CLC monitors the RF field and collects RSSI data from attached TRXs.

**System IP Address** IP address of the data acquisition computer.

**CLC IP Address** IP address of this particular CLC.

**MAC Address** Unique identifier for the CLC network interface.

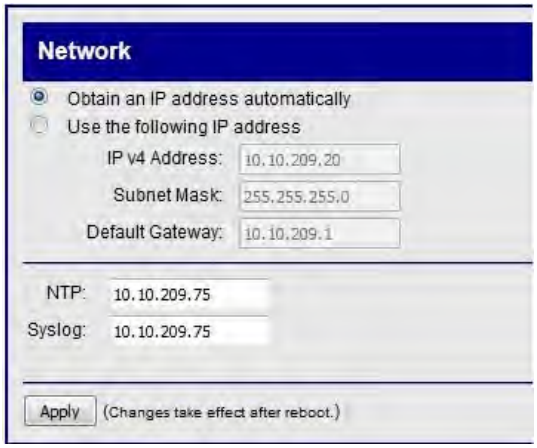
**Time** Current Date & Time (Format = YYYY-MM-DD HR:MN:SC).

**Up Time** Status information since last reboot

**POST** Power On Self-Test (0 = Passed, OK …)

## Network

The Network section allows the user to define how IP addresses are assigned to the CLC.




- **Obtain an IP address automatically**

  This is the normal operating mode for the CLC. With this option selected the CLC is queried and the values that it reports back are displayed in the appropriate text boxes:
  - IP v4 Address:
  - Subnet Mask:
  - Default Gateway:

  *Note*: A new IP address can be generated by performing an "extended" reset: push and hold the reset button on the back of the CLC for 5-15 seconds.

- **Use the following IP address**

  If the user wishes to manually assign a specific IP address to the CLC, click this radio button and type a new IP address in the text box.

  If you wish to perform this operation, follow this procedure:

  1. Click the radio button for Use the following IP address
  2. Enter the desired values in the text boxes labeled:
     - IP v4 Address:
     - Subnet Mask:
     - Default Gateway:
  3. Click Apply.

  *Note*: A reboot of the system will have to be performed in order for the new IP Address to activate.

*Caution*: In the event that the user-assigned IP address is not accessible, this diagnostics tool will lose contact with the CLC. To generate a new IP address, the user will have to perform an "extended" reset: push and hold the reset button on the back of the CLC for 5-15 seconds.

- **NTP**

  The CLC keeps synchronization with the PC using Network Time Protocol (NTP). By default Ponemah will set the NTP IP address to be the IP address of the PC. If it is desired, the NTP IP address can be set manually.

- **Syslog**

  This is an IP address that can be set by DSI personal for on-site troubleshooting. It is not needed for normal operation.

### Upload CLC Firmware

This page allows the user to update the CLC firmware. From time to time it may be advantageous to upgrade the internal read-only program instructions through a firmware upgrade. This often results in improved performance.


To update or change the firmware version in the CLC, follow this procedure:

1. Click on the Browse button and use the file upload window to locate the firmware file.
2. Navigate to the specific filename and click Open
3. Message 1: Uploaded, Validating
4. Message 2: Validated. Upgrade will be applied during reboot.

*Note*: A reboot of the system will have to be performed in order for the update to activate.

### System Status

The System Status is a continuously updating "log" file of the CLC's communication activity. It can be used to monitor communication issues in the event of discontinuities.