

## Product Release Notes

**Product:** PONEMAH Physiology Platform  
**Model:** Ponemah Analysis Modules (all modules)  
**Version:** 4.90  
**Build:** 004866-002 (CD Build)  
**Date:** January, 2009

Product Release Notes for PONEMAH Physiology Platform version 4.90 Analysis Modules indicate revisions made to the Analysis Modules since release of Ponemah version 4.80-SP4.

For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 4.90 CD. Product Release Notes indicate only revisions to application contents that are part of CD Part #004866-001 – Build Version 4.90.

**Notice for organizations that must comply with FDA's Good Laboratory Practices (GLP) and 21 CFR Part 11 Electronic Records; Electronic Signatures:** Ponemah versions may contain **Preview Features**. These **Preview Features** are listed in the Product Release Notes table under the column, "Type of Change". A **Preview Feature** indicates that enhancements have been made to the program, but have not been validated. Instead, Data Sciences International (DSI) has opted to delay complete validation until receiving comments from customers regarding use of these features. Further validation of these features will be performed in later releases of the platform. There may be additional **Preview Features** that had been documented in previously released versions that are not documented here. These features are not available unless manually enabled by the user. If documentation is needed regarding these features, please contact the Technical Support Group at DSI.

Key: N = New Feature; E = Enhancement; F = Fix		
Reference #	Type of Change	Description
<b>Cardiac Volume (CVOL)</b>		
3040	F	The option to add Cuvette information is possible by adding this information to the PPP3.INI file. Previously, if more than 30 cuvette entries were added, Ponemah would close upon starting the program. This has been corrected and updated to handle 100 entries. If more than 100 entries are added, only the first 100 will be displayed.
3105	F	Typical values in CVOL were missing for the following attributes <ul style="list-style-type: none"> <li>• Segments 2, 3, 4, and 5</li> <li>• Cal Slope</li> <li>• Cal Intercept</li> <li>• Parallel Volume</li> <li>• Alpha Correction Factor</li> </ul>
3109	F	Settings for Segment x Channel, where x equals an input, in the Standard Attribute settings were not being saved as part of the protocol. After saving a protocol and exiting Ponemah, opening the protocol file again would display “None” in the Segment x Channel boxes.
3119	F	Values for the SW derived parameter were incorrect in acquisition and replay but correctly displayed during review. This has been corrected.
2736	F	If hardware (acquisition interfaces) was not connected to the system, trigger channels would not be available for the analysis module. This pertains primarily to Post systems since no hardware is connected to a Post analysis system.  <b>Work-around:</b> One potential work-around for a post system would be to set the acquisition interface (Application Configuration dialog) to ACQ-DEMO.
3110	F	Precision settings were not saved in the protocol. This has been corrected to save precision settings.
<b>Pulmonary Compliance and Resistance (PCR)</b>		
N/A	E	Added the Accumulated Volume derived parameter to the PCR analysis module. This provides the total volume inspired for a given animal during an acquisition.
3165	F	The Volume signal associated with the PCR channel did not properly update if the Flow signal was inverted and then inverted again, back to its original state.

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<b>Reference #</b>	<b>Type of Change</b>	<b>Description</b>
3166	F	A possibility existed where a reset of the Volume channel could occur at random points in the data. This was random and did not always occur in the same data set. This has been corrected.
3167	F	After reanalyzing a PCR channel, the associated PCR channel must also be reanalyzed. However, this was not obvious to the user. A message has been added to the PCR attributes dialog to alert the user that the PCR channel needs to be reanalyzed after a change has been made to the PCR channel.
<b>Blood Pressure (BP)</b>		
N/A	E	Added the derived parameters Pulse Wave Velocity (PWV) and Pulse Transit Time (PTT). Added additional attributes; Upstream Pressure Channel, Pulse Wave Distance, and Pulse Wave Velocity Units to the Blood Pressure Advanced Attributes 1 dialog.
N/A	E	Added an Offsets tab to the BP analysis attributes. This combines previous functionality as well as new functionality implemented for JET BP (Implant Pressure Offset). This tab is dedicated to offsets that can be applied to the BP signal.
N/A	E	Added a Noise tab to the BP analysis attributes. This provides a means to mark data that exceeds user defined values as bad data and will bracket this data with Bad Data Marks.
N/A	E	Removed the Blood Pressure Respiration attributes (Resp Attrib tab) from the BP analysis. A new analysis module, Blood Pressure Respiration (BPR), has been created to allow respiration from blood pressure to be review capable.  Due to the database structure of the Study Protocol Option, the derived parameters for BPR will still be present in the Derived Parameters list for BP. However, these will report zeros during acquisition/replay and x's when in review. These parameters will remain simply to maintain the structure of the database for studies that were collected using these parameters. It is recommended to load the new BPR analysis module once current studies, using the respiration derived parameters from BP, have been completed.

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Reference #	Type of Change	Description
3211	F	<p>When in acquisition/replay or review, clicking in the area on either side of the slider bar, in the Attributes dialog, to move the graphics display would cause the system to close unexpectedly.</p> <p>This error was found in version 4.60 of the BP analysis module. This version was released after Ponemah version 4.90 and was not present on the 4.90 DVD (4.50 was the version of BP released with the Ponemah 4.90 DVD).</p>
3170	F	<p>When configuring and using a sensor to adjust for barometric changes, the Blood Pressure analysis did not properly handle data if the Barometric Channel was sampled at a different rate than the blood pressure channel.</p>
2736	F	<p>If hardware (acquisition interfaces) was not connected to the system, trigger channels would not be available for the analysis module. This pertains primarily to Post systems since no hardware is connected to a Post analysis system.</p> <p><b>Work-around:</b> One potential work-around for a post system would be to set the acquisition interface (Application Configuration dialog) to ACQ-DEMO.</p>
<b>Blood Pressure Respiration (BPR)</b>		
N/A	N	<p>Added the new Blood Pressure Respiration (BPR) analysis module, part number PNM-BPR100W, to the list of modules. This functionality was previously available within the BP analysis module. However, the BPR functionality was not available in review. The separate BPR module has been created to allow the signal to be review capable.</p>
3212	F	<p>Sampling a BP channel at a high rate (faster than the BPR channel) could have resulted in sharp changes to the morphology of the respiration signal (BPR channel). The fast rate coupled by a noisy signal would result in sharp changes to the BPR signal that could not be smoothed out using the filter. Changes have been made to account for this situation.</p> <p>This error was found in version 4.60 of the BP analysis module. This version was released after Ponemah version 4.90 and was not present on the 4.90 DVD (4.50 was the version of BP released with the Ponemah 4.90 DVD).</p>

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Reference #	Type of Change	Description
3215	F	<p>If the BP channel that BPR referenced was disabled prior to entering review, opening the review file would result in Ponemah closing.</p> <p>This error was found in version 4.60 of the BP analysis module. This version was released after Ponemah version 4.90 and was not present on the 4.90 DVD (4.50 was the version of BP released with the Ponemah 4.90 DVD).</p>
<b>Electrocardiogram (ECG)</b>		
N/A	E	Added the Matsunaga QT correction factor. An additional attribute in the Advanced Attributes 2 tab has been added to define the number of milliseconds for this calculation.
2893	F	If the Noise feature was enabled in the ECG attributes dialog, the PC screen flashed. This has been updated to remove this occurrence.
2894	F	A radio button was located next to the Bad Data Threshold feature in the Noise attribute tab of the ECG analysis module. This was not needed and has been removed for clarification.
<b>Left Ventricular Pressure (LVP)</b>		
2736	F	<p>If hardware (acquisition interfaces) was not connected to the system, trigger channels would not be available for the analysis module. This pertains primarily to Post systems since no hardware is connected to a Post analysis system.</p> <p><b>Work-around:</b> One potential work-around for a post system would be to set the acquisition interface (Application Configuration dialog) to ACQ-DEMO.</p>
<b>Systemic Blood Flow (SBF)</b>		
N/A	E	Added support for SBF in Review. Previously, this analysis module was not review capable.
N/A	E	Added the derived parameter Total Peripheral Resistance (TPR) which is calculated as $TPR = (P1 - P2)/CO$ . Added attributes Systemic Pressure Channel, Monitor Venous Pressure and Venous Pressure which are used in the calculation of TPR.
2987	F	If an SBF channel was analyzed after reanalyzing an LVP channel, Ponemah would close or no marks would be displayed on the waveform data.

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Reference #	Type of Change	Description
<b>Coronary Blood Flow (CBF)</b>		
N/A	E	Added support for CBF in Review. Previously, this analysis module was not review capable.
2736	F	<p>If hardware (acquisition interfaces) was not connected to the system, trigger channels would not be available for the analysis module. This pertains primarily to Post systems since no hardware is connected to a Post analysis system.</p> <p><b>Work-around:</b> One potential work-around for a post system would be to set the acquisition interface (Application Configuration dialog) to ACQ-DEMO.</p>
<b>Pulmonary Air Flow (PAF)</b>		
2736	F	<p>If hardware (acquisition interfaces) was not connected to the system, trigger channels would not be available for the analysis module. This pertains primarily to Post systems since no hardware is connected to a Post analysis system.</p> <p><b>Work-around:</b> One potential work-around for a post system would be to set the acquisition interface (Application Configuration dialog) to ACQ-DEMO.</p>
<b>Electromyogram (EMG)</b>		
N/A	E	Added support for EMG in Review. Previously, this analysis module was not review capable.

Additionally, this document identifies the individual software components and versions for Ponemah version 4.90. Due to the fact that the build contains many individual software components, each having its own version number, the build itself carries a version number that refers to a manufacturing build version. Please refer to the table below for an itemized list of the software contained on the enclosed build.

## Contents of CD Part # 004866-001 – Build Version 4.90

Model	Description	Version
PNM-BP100W	Blood Pressure Analysis Module	V4.70
PNM-BPR100W	Blood Pressure Respiration Analysis Module	V4.10
PNM-CBF100W	Coronary Blood Flow Analysis Module	V4.10
PNM-CYS100W	Cystometry Analysis Module	V4.30
PNM-ECG100W	Electrocardiogram Analysis Module <i>*NOTE: *Multiple Lead is embedded in the PNM-ECG100W analysis module</i>	V5.00
PNM-ERO100W	ECG Rate Only Analysis Module	V4.00
PNM-EMG100W	Electromyogram Analysis Module	V4.10
PNM-IBP/IBPS100W	Indirect Blood Pressure / Indirect Blood Pressure Sound Analysis Modules	V4.00
PNM-LVP100W	Left Ventricular Pressure Analysis Module	V4.60
PNM-MAP100W	Monophasic Action Potential Analysis Module	V4.20
PNM-PAF/AWR100W	Pulmonary Air Flow / *Airway Resistance Analysis Modules <i>*NOTE: This option is embedded in the PNM-PAF100W analysis module</i>	V4.90
PNM-PCR/PCRP100W	Pulmonary Compliance & Resistance Analysis Module / Pulmonary Compliance & Resistance Pressure Analysis Module	V4.40 / V4.30
PNM-PT100W	Pulsatile Tissue & Gut Motility Analysis Module	V4.30
PNM-SBF100W	Systemic Blood Flow Analysis Module	V4.10
PNM-CVOL100W	Cardiac Volume Analysis Module	V2.30
PNM-URP100W	Unrestrained Plethysmography Analysis Module	V4.30
	Raw Electrical Mean	V4.60

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