

Product Release Notes

Product: Ponemah Physiology Platform
Model: Ponemah Analysis Modules
Version: 5.10
Build: 006663-001 (CD Build)
Date: July, 2012

Product Release Notes for the Ponemah Version 5.10 indicate revisions made to the modules since release of Ponemah Physiology Platform Version 5.00. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Ponemah Physiology Platform Version 5.10 CD. Product release notes indicate only revisions to application contents that are part of a specific build or version.

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 Ponemah, 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 Ponemah. 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.

Reference #	Type of Change	Previously Fixed	Description
Key: N = New Feature; E = Enhancement; F = Fix			
Blood Pressure (BP)			
N/A	E	5.00-SP2	Added Pulse Transit Time-End Diastolic (PTTed) and Pulse Wave Velocity-End Diastolic (PWVed) to the list of available parameters. The addition of these two parameters compliment the currently available PTTs and PWVs calculations that use the Systolic point as the reference.
N/A	E	N/A	A popup warning has been added to the BP Offset tab to help guide users as to when the Barometric Adjust attributes should be used. Upon checking or unchecking the Barometric Adjust checkbox, the following message will popup: <i>“Do not check this box if pressure signal is from DSI PhysioTel, HD, or Digital implantable telemetry. If pressure signal is from JET BP, this box must be checked and the barometric channel should be defined to the eAPR-1.”</i>
N/A	E	N/A	Added support for Auto Configure Protocol . Upon selecting P3 Setup – Auto Configure Protocol , the BP analysis module will correctly configure the Barometric Adjust attributes for BP automatically as follows: PhysioTel Digital and OpenART – Barometric Adjust checkbox is unchecked . JET BP channel – Barometric Adjust check is checked and Barometric Channel is set to the channel that has its analysis module defined to BARO .

Reference #	Type of Change	Previously Fixed	Description
Key: N = New Feature; E = Enhancement; F = Fix			
3710	F	N/A	<p>Bad Data Marks will be periodically placed, along with correctly placed marks under the following conditions: BP Noise Detection is enabled and either the Minimum Signal Value is set to a value greater than 0 or the signal span within the ACQ-7700 dialog does not encompass 0 mmHg. By default the spans for JET and OpenART acquisition interfaces include 0mmHg.</p> <p>The periodicity of Bad Data Mark placement will depend on the sample rate being used: Sample Rate (Hz)/Repetition Time (s)</p> <p>250/400 500/200 1000/100</p> <p>This issue has been corrected.</p>
3711	F	N/A	<p>Bad Data Marks may have resulted in incorrect placement if BP Noise Detection is enabled and the signal Heart Rate approaches the Minimum Heart Rate Noise attribute. This would result in Bad Data Marks being placed prior to the heart rate crossing the Minimum Heart Rate Threshold.</p> <p>This has been corrected.</p>
Diaphragmatic EMG (dEMG)			
N/A	N	N/A	<p>A new analysis module, Diaphragmatic EMG (dEMG), has been developed to analysis data from EMG signals collected from the Diaphragm.</p> <p>Available derived parameters include:</p> <ul style="list-style-type: none"> • Tidal Volume • Minute Ventilation • Breaths per Minute • Inspiration Time • Total Time • Expiration Time
Electrocardiogram (ECG)			

Reference #	Type of Change	Previously Fixed	<p style="text-align: center;">Key: N = New Feature; E = Enhancement; F = Fix</p> <p style="text-align: center;">Description</p>
3689	F	5.00-SP2	<p>Reanalyzing ECG signals in Review may have resulted in Ponemah stopping unexpectedly. This was due to a potential memory issue when analyzing the last block of data in each analysis segment within the file. If the last block of data read by the program was smaller than expected, an error may have been posted forcing the program to be shut down and restarted. However, this issue was not consistent and analysis may have behaved as expected during subsequent reanalysis.</p> <p>This error has been corrected to properly interpret the last block of data in each segment.</p>
3691	F	5.00-SP2	<p>The Minimum Heart Rate attribute in the Noise Tab is used to place Bad Data Marks which remove data from analysis that falls below the user specified value. However, Bad Data Marks were not always placed and data below the user specified value were not always removed from analysis.</p> <p>Expected results of the Minimum Heart Rate attribute should be within -5% of the user defined value. This has been corrected to remove data within -5% of the user defined value for correctly marked R waves.</p>
3696	F	5.00-SP2	<p>Analyzing data in Review with the ECG Pro option may have resulted in the T Peak mark being placed prior to the S Wave End mark. The frequency of this issue occurring was very low and would lead to the Ponemah program closing unexpectedly during analysis. While this issue exists in ECG Pro, corrective measures have been placed in the ECG algorithm to prevent the program from closing.</p> <p>Changes to the ECG algorithm will prevent the application from closing. The validation marks, if placed incorrectly, will not be corrected. However, all parameters related to the T mark will not be calculated (“x”s will be displayed in the grid view). In order to update the marks information and derived output, manually remove T wave information by mousing over either T End or T Peak and selecting Delete Tpe (T Peak and End). After the marks are removed, manually place the end of T mark by selecting Insert T End from the right click menu and inserting the mark in the correct location.</p>

Reference #	Type of Change	Previously Fixed	Description
			Key: N = New Feature; E = Enhancement; F = Fix
3697	F	5.00-SP2	<p>Bad Data Marks (BDM) may not have been placed on the data, even though the Bad Data Threshold Attribute had been exceeded, when dealing with noisy data. Values for the Noise parameter may have been greater than the Bad Data Threshold but the BDM was not placed on the graph and data not removed from the grid.</p> <p>This has been corrected.</p>
Left Ventricle Pressure (LVP)			
N/A	E	N/A	<p>A popup warning has been added to the LVP Adv Attrib1 tab to help guide users as to when the Barometric Adjust attributes should be used. Upon checking or unchecking the Barometric Adjust checkbox, the following message will popup:</p> <p><i>“Do not check this box if pressure signal is from DSI PhysioTel, HD, or Digital implantable telemetry.</i></p> <p><i>If pressure signal is from JET BP, this box must be checked and the barometric channel should be defined to the eAPR-1.”</i></p>
N/A	E	N/A	<p>Added support for Auto Configure Protocol. Upon selecting P3 Setup – Auto Configure Protocol, the LVP analysis module will correctly configure the Barometric Adjust attributes for LVP automatically as follows:</p> <p>PhysioTel Digital and OpenART – Barometric Adjust checkbox is unchecked.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
N/A	E	N/A	<p>Added Derivative Window attribute setting to LVP Adv Attrib1 tab. 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.</p> <p>Ex: If sampling at 1000Hz, the time between consecutive points is 1ms. By choosing a Derivative Window of 2ms, the derivative will be calculated across every other point.</p> <p>NOTE: The default value of 0ms will provide the derivative functionality seen in previous versions.</p>
3728	F	N/A	<p>Analyzing data in Acquisition, Replay, or Review with the LVP module may not have marked valid LVP cycles for species with heart rates greater than 500bpm and with a rapid systolic rise. This was due to an algorithm duration setting being too long for certain species.</p> <p>The frequency of this issue occurring was very low and would lead to these missed cycles not being marked and thus they would not be included in the DRx/Data Reduction spreadsheet derived parameter averages.</p> <p>This has been corrected by making this duration setting species specific.</p>
3729	F	N/A	<p>When analyzing flat line data with LVP, the Non-Pulsatile Mean (NPMN) derived parameter may have reported 0's to the DRx spreadsheet instead of the expected average between logging intervals. This occurred when the Logging Rate matched the LVP Reset Time (defined in PPP3.INI file) and the start points for these two attributes coincide.</p> <p>This has been corrected.</p>
Pulmonary Airflow (PAF)			

Reference #	Type of Change	Previously Fixed	<p style="text-align: center;">Key: N = New Feature; E = Enhancement; F = Fix</p> <p style="text-align: center;">Description</p>
N/A	E	N/A	<p>Added support for Auto Configure Protocol. Upon selecting P3 Setup – Auto Configure Protocol, the PAF analysis module will correctly configure the following attribute settings for data collection with JET RIP as follows:</p> <p>Chest Channel: Primary Signal – Vol-RIP-chest Input Flow Units – L/min Secondary Channel – Second PAF channel in Group (Abdomen Channel)</p> <p>Abdomen Channel: Primary Signal – Volume Input Flow Units – L/min Secondary Channel – None</p>
3676	F	N/A	<p>When analyzing data in Acquisition and Replay, PAF cycle marks may be placed incorrectly when no cycle is detected for 5 minutes. If this occurs, the Start Apnea mark would precede the Start Expiration mark, which could cause the application to unexpectedly shutdown during Review of the data.</p> <p>This has been corrected by in Acquisition and Replay by preventing marks from being placed out of sequence. In Review, the calculations of derived parameters will skip cycles whose marks are out of sequence to prevent the application from shutting down.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3678	F	5.00-SP2	<p>Ponemah may fail to respond when analyzing data using the PAF analysis module under the following conditions:</p> <ul style="list-style-type: none"> • Analyzing respiratory data (PAF module) in Review • Data set is greater than 22 hours long • Sample rate set to 750Hz <p>If all three of the conditions above are met, Ponemah may become unresponsive. The analysis module has been updated to correct for this error condition.</p> <p>Work-around: Several options exist to prevent this issue from occurring or to allow most of the data to be analyzed without loading the updated PAF module, if desired.</p> <ul style="list-style-type: none"> • Do not sample the channel at 750Hz. This issue only exists using this sample rate. • If data is greater than 22 hours, place Bad Data Marks after the 22 hour point (elapsed time). This will allow data prior to 22 hours to be analyzed. If the review file is not able to be opened, replay the data for a second to create a new review file. Prior to analyzing, place Bad Data Marks at the 22 hour point for the remainder of the file. <p>NOTE: This version of the PAF dll file (PAF dll version 5.20-SP1) is intended to be used with Ponemah version 5.00.</p>

Additionally, this document identifies the individual software components and versions for the analysis modules used in the Ponemah Analysis Modules release. Due to the fact that the build may contain 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 within the enclosed build.

Contents of CD Build #006328-002: Ponemah Version 5.10

Model	Description	Version
PNM-BP100W	Blood Pressure Analysis Module	V5.10
PNM-BPR100W	Blood Pressure Respiration Analysis Module	V4.30
PNM-CVOL100W	Cardiac Volume Analysis Module	V2.50
PNM-CBF-100W	Coronary Blood Flow Analysis Module	V4.30
PNM-CYS100W	Cystometry Analysis Module	V4.40
PNM-dEMG100W	Diaphragmatic EMG Analysis Module	V1.00
PNM-ECG100W	Electrocardiogram Analysis Module *NOTE: *Multiple Lead is embedded in the PNMECG100W analysis module	V5.20
PNM-ERO100W	ECG Rate Only Analysis Module	V4.00
PNM-EMG100W	Electromyogram Analysis Module	V4.30
PNM-IBP/IBPS100W	Indirect Blood Pressure / Indirect Blood Pressure Sound Analysis Modules	V4.00
PNM-LVP100W	Left Ventricular Pressure Analysis Module	V5.10
PNM-MAP100W	Monophasic Action Potential Analysis Module	V4.30
PNM-PAF/AWR100W	Pulmonary Air Flow / *Airway Resistance Analysis Modules *NOTE: This option is embedded in the PNM-PAF100W analysis module	V5.40
PNM-PCR/PCRP100W	Pulmonary Compliance & Resistance Analysis Module / Pulmonary Compliance & Resistance Pressure Analysis Module	V4.60/V4.50
PNM-PT100W	Pulsatile Tissue & Gut Motility Analysis Module	V4.40
PNM-PVO100W	Pulmonary Volume Analysis Module	V1.00
PNM-SBF100W	Systemic Blood Flow Analysis Module	V4.20
PNM-URP100W	Unrestrained Plethysmography Analysis Module	V4.40
	Raw Electrical Mean (TEMP, BARO, ACT)	V4.70