Product Release Notes

Product: Ponemah Physiology Platform

Model: Ponemah Analysis Modules

Version: 5.20-SP11

Build: 006920-014 (CD Build)

Date: April, 2018

Product Release Notes for the Ponemah Version 5.20 Service Pack 11 (SP11) indicate revisions made to the Analysis Modules since release of Ponemah Version 5.20. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Ponemah v5.20 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	Key: N = New Feature; E = Enhancement; F = Fix Description
**Electrocardiogram (ECG)  ** **Note: The following details revisions made to the v5.3x ECG Module since the release of v5.30. ECG v5.34 is now available any researcher who is licensed for ECG Analysis. A license file update is required to use ECG Module v5.34 if upgrading from ECG v5.20. Contact DSI Technical Support to obtain an updated license file.**
38939	N	N/A	Added derived parameter for JTp-I.
33675	N	v5.20-SP8	Added the Derived Parameter TQ-I to report the time, in milliseconds, between the end of T mark from the previous cycle and the Q mark of the current cycle.
33573	N	v5.20-SP8	Added the Derived Parameter TP-I to report the time, in milliseconds, between the end of T mark from the previous cycle to the start of P mark of the current cycle.
32752	N	v5.20-SP8	Added the Derived Parameter PP-I to report the time, in milliseconds, between the start of P mark from the previous cycle to the start of P mark of the current cycle.
32863	E	v5.20-SP8	Added the ability to add all validation marks to a cycle by selecting the Insert PQRST from the right-click menu within Review.
36320	F	v5.20-SP8	R mark may not be placed for cycles containing a prominent negative QRS component with a marked difference between the negative and positive derivatives.
32734	F	v5.20-SP8	Corrected an 'x' being reported to the Derived List Views for noise calculations associated with slow heart rate (HR) cycles when Noise Detection is enabled and the Minimum HR attribute setting is higher than the slowest heart rate.
32748	F	v5.20-SP8	Prevented Noise from reporting an erroneous large value for successive fast beats; such as couplets.
32741	F	v5.20-SP8	When a Merge Bad Data Marks is performed in Review after adding new Bad Data Marks, any preexisting Bad Data Marks would be ignored during the Merge. This was corrected.
32711	F	v5.20-SP8	Correct the Num (cycle number) parameter from occasionally reporting an 'x' to the Derived List View while using the Epoch Logging Rate within Review.
31431	F	v5.20-SP7.1 (ECG v5.32)	Occasionally, Ponemah would shut down unexpectedly during an Acquisition or Replay when the analysis does not trigger (mark the R wave). For example, when triggering is disabled by setting an attribute to an out of range value or when long (>9 seconds) instances of dropout occur. This was corrected.

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
30328	F	v5.20-SP7.1 (ECG v5.32)	When analyzing data with the ECG module and selecting to only analyze the "Visible Region in the Graph Page," additional cycles would be marked which are outside of the visible region. This has been corrected.
27872	E	v5.20-SP7 (ECG v5.31)	The Twave count (TCnt) and Pwave count (PCnt) Derived Parameters would report an 'X' to the Derived Parameter and Data Reduction List Views if no T or Pwave was found. This has been updated to report a '0' in the Derived Parameter and Data Reduction List Views.
N/A	E	v5.30	Improved the ECG Analysis Module Rwave detection to more reliably mark Rwaves and ultimately locate more cycles using the attribute based analysis. The following are some of the advantages of the ECG v5.30 module: • More accurate Rmark placement. • Improved immunity to Rwave polarity changes. • Improved noise tolerance permitting identification of Rwaves in noisier sections of data. • Fewer attribute modification necessary when analyzing large dataset. *Note*: Changes in the Rwave detection resulted in the QA interval and Electromechanical window (EMw) derived parameters no longer being available in Acquisition/Replay. These parameters are still available within Review. For more information on the ECG v5.30 Analysis Module and specific descriptions of the new attributes and how they impact ECG analysis, please see the user manual.
17635	E	v5.30	The ECG Analysis Module attributes have been reorganized to group attributes according to the ECG cycle mark (e.g. Rmark, Tmark, etc.) they are associated with to make analysis more intuitive.
14352	E	v5.30	The Ponemah v5.20 install includes the ECG and ECG Rate Only (ECGRO) as two separate modules and the license file supports both ECG and ECGRO simultaneously. ECGRO provides a subset of ECG functionality, marking only the R marks to provide Heart Rate only. To provide the benefits of the updated R identification in the ECGRO module, the ECG module was updated to provide ECGRO functionality via license file control.

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N/A	N/A	v5.30	Small differences in the Noise calculation may be seen within Replay due to the updates made to improve R detection. Potential differences in calculations relative to ECG 5.20 may vary from 0 to 5%.
Blood Pressure (BP)			
39446	F	N/A	Fix added for a rare crash at the start of acquisition. The crash can occur when the BP Analysis module is unable to detect the first BP cycle for an extended duration.
33560	F	v5.20-SP8	Only BP channels within a Group will be displayed in the BP Analysis Module Diff Pressure Chan. dropdown selection. BP channels from other Groups will no longer be displayed.
18636	F	v5.20-SP2	When using the Blood Pressure analysis module, the recalculation of derived parameters would trigger a memory leak within the module. This issue would present itself by updating the derived data spreadsheets (.drx) abnormally slow and may result in an application freeze or crash. This issue has been corrected.
18138	E	v5.20-SP2	When processing Blood Pressure data using multiple BP channels within a single Group (e.g. Pulse Wave Velocity studies), recalculation of parameter data would be performed at an unacceptable rate. This has been improved to more quickly recalculate parameter data.
Blood Pressure Respiration (BPR)			
31507	F	V5.20-SP7.1	Occasionally, a crash would be seen when viewing the data at the end of a data segment from a Primary or Page View graph containing a BPR signal. This has been corrected.
Cystometry (CYS)			
35480	F	v5.20-SP8	A crash may be observed during analysis. The crash occurs when the end of a cycle does not fit in the Base Time/Height attributes and the subsequent cycle is not a close follower. This has been corrected.
Left Ventricular Pressure (LVP)			
40540	F	N/A	When LVP End and End Diastolic marks coincide, DiaD was reported incorrectly. This has been corrected.

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40537	F	N/A	If a cycle that reported an 'x' for DiaD was averaged, the result was an 'x'. This has been corrected.
39475	F	V5.20-SP10	When running Acquisition or Replay, the value entered in the LVP Offset attribute is not added to the Left Ventricle End Diastolic Pressure (LVEDP) parameter. This has been corrected.
32243	N	v5.20-SP8	Added a Derived Parameter for Systolic Duration (SysD) and Diastolic Duration (DiaD). SysD reports the time, in milliseconds, between the LVEDP mark and the following LVP end mark. DiaD reports the time, in milliseconds, between the LVP end mark and the following LVEDP mark.
32585	F	v5.20-SP8	Only LVP channels within a Group will be displayed in the LVP Analysis Module Diff Pressure Chan. dropdown selection. LVP channels from other Groups will no longer be displayed.
31423	F	v5.20-SP8	Ponemah will enter a Not Responding state when reanalyzing the LVP signal if the Derivative Window analysis attribute is changed. This has been corrected.
28688	F	V5.20-SP7.1	Bad Data Marks can be automatically placed by the analysis module to account for signal noise and dropout by enabling Noise detection from the Noise tab. When Bad Data Marks were placed around a large signal change, subsequent valid LVP cycles would not be marked for a short period of time. This has been corrected to mark the valid cycles immediately after the Bad Data Mark range. With this correction, small variations in the End Diastolic Mark placements may be seen if comparing the previous BP version (v5.20) to the new (v5.21). This may also result in the Derived Parameters that depend on the End Diastolic Mark for their calculation having small variations.
32019/ 22403	F	V5.20-SP7.1/ v5.20-SP3	The LVP analysis module would intermittently report a "1.$" to the derived data spreadsheet (DRx). This issue occurred when LVP cycles mis-triggered such that the minimum slope validation mark from one cycle was superimposed on the End Diastolic mark of the following cycle. This issue was only encountered with noisy datasets and would not occur with typical LVP waveform morphology. Note: This issue was originally fixed in v5.20-SP3, but has since manifested itself in subsequent data sets. As a result, DSI has made additional improvements to solve this issue as part of the LVP v5.23/Analysis Modules v10.19 release. This issue has been corrected.

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
31276	F	v5.20-SP7	Occasionally the LVP calculations within the Derived Data List View would not complete after Saving a Mark Section. This would result in the Derived Data List View display a calculation completion percentage of 99% and the resultant Excel file generated being incomplete; e.g. Excel would only contain the Event, Log, and Message tabs. This has been corrected.
31370	F	v5.20-SP7	Reanalyzing data with the LVP analysis module would intermittently cause Ponemah to freeze and require the user to close the application from the Task Manager. This has been corrected.
Pulmonary Air Flow (PAF)			
32398	F	v5.20-SP8	Only channels assigned to RAW could be selected as Activity channels in the Noise tab. This has been corrected to allow channels defined as ACT (activity) to also be selected. Workaround is to define it to the RAW Analysis Module.
Pulmonary Volume (PVO)			
18760	F	v5.20-SP2	The PVO analysis module includes an automated Noise elimination feature that will automatically place bad data marks throughout the dataset based on user defined criteria to help accelerate the analysis process. Upon initiating analysis using the PVO module with Noise detection enabled, users were experiencing the analysis module becoming unresponsive requiring them to close the application using the task manager. This has been correct to allow analysis with Noise detection to function as expected.
Pulmonary Compliance Resistance (PCR)			
30894	F	v5.20-SP8	Corrected a display issue where the Analysis Attribute dialog's Recalculate button was unable to be selected, as it was displayed behind the Expand/Compress arrow buttons.
Unrestrained Plethysmography (URP)			
34677	F	v5.20-SP8	Fix for an unexpected shutdown of Ponemah upon launching the Data Insights dialog when a URP channel is present within Review.

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31699	E	V5.20-SP7.1	The URP analysis modules allows an implant temperature channel to be selected for the animal body temperature measurement. When accounting for animal body temperature in this manner, the data from the channel is interpreted as being in kelvin. This resulted in users being required to enter implant temperature calibration values in kelvin instead of their standard Celsius units. This has been corrected such that implant calibration values can be entered based on their standard Celsius units allowing the Temperature Derived Parameters to report values in unit Celsius, while the software accounts for the unit conversion necessary for the body temperature compensation algorithm. When not using a telemetry implant for body temperature compensation, the manual edit field should still be entered in kelvin.
Raw Electrical Mean (RAW, TEMP, BARO, ACT)			
32800	F	v5.20-SP8	Fix for adjustments made in the Noise tab during Acquisition not persisting in Review, resulting in Bad Data Marks not being placed.
20771	F	v5.20-SP2	This issue is an extension of the Scatter Plot issue as described in the Ponemah v5.20-SP2 Release Notes Reference #19098. When using the free form drawing tool to either Add Bad Data Marks around or Delete Cycles from the selected or unselected points two consecutive times, the application would unexpectedly shut down upon the second time. This has been corrected.

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Additionally, this document identifies the individual software components and versions for the analysis modules used in the Ponemah Analysis Modules release. Since the build may contain many individual software components, each having their 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 #006920-014: Ponemah Version 5.20-SP11
Analysis Module Version 10.21

Model	Description	Version
PNM-BP100W	Blood Pressure Analysis Module	v5.23
PNM-BPR100W	Blood Pressure Respiration Analysis Module	v4.41
PNM-CVOL100W	Cardiac Volume Analysis Module	v2.60
PNM-CBF-100W	Coronary Blood Flow Analysis Module	v4.40
PNM-CYS100W	Cystometry Analysis Module	v4.50
PNM-dEMG100W	Diaphragmatic EMG Analysis Module	v1.10
PNM-ECG100W-V530	Updated Electrocardiogram Analysis Module* *NOTE: • The Analysis Module install for Ponemah v5.20-SP10 contains PNM-ECG100W-V530 (ECG Module v5.33), which is available to anyone licensed for ECG analysis. • A license file update is required to use ECG Module v5.33 if upgrading from ECG v5.20. Contact DSI Technical Support to obtain an updated license file. • Multiple Lead and ECGRO are embedded in the PNM-ECG100W-V530 Analysis Module.	v5.34
PNM-EMG100W	Electromyogram Analysis Module	v5.20
PNM-LVP100W	Left Ventricular Pressure Analysis Module	v5.32
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	v5.41
PNM-PCR/PCRP100W	Pulmonary Compliance & Resistance Analysis Module / Pulmonary Compliance & Resistance Pressure Analysis Module	v5.21/v5.20
PNM-PT100W	Pulsatile Tissue & Gut Motility Analysis Module	v4.40
PNM-PVO100W	Pulmonary Volume Analysis Module	v5.21
PNM-SBF100W	Systemic Blood Flow Analysis Module	v4.20
PNM-URP100W	Unrestrained Plethysmography Analysis Module	v5.22
	Raw Electrical Mean (TEMP, BARO, ACT)	v5.31