

Product Release Notes

Product: PONEMAH Physiology Platform
Model: P3 Analysis Modules (all modules)
Version: 4.80-SP2 (Service Pack 2 for version 4.80)
Build: J03263 (CD Build)
Date: October, 2008

Product Release Notes for PONEMAH Physiology Platform version 4.80-SP2 Analysis Modules indicate revisions made to the Analysis Modules since release of Ponemah version 4.80. Please note that 4.80-SP1 was not formally released and, in addition, there were no changes to analysis modules in SP1.

For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 4.80-SP2 CD. Product Release Notes indicate only revisions to application contents that are part of CD Part #J02910 – Build Version 4.80

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
Cardiac Volume (CVOL)		
2974	F	Changing the trigger channel in the attributes menu for CVOL and reanalyzing the channel did not update the derived data appropriately. The data had to be reanalyzed a second time before utilizing the new trigger channel.
2903	F	Post processing of a data file may have caused Ponemah to close if the ppp3.ini file had been modified after the protocol was saved. In the ppp3.ini file, users have the option to add cuvettes and associated well values. If a protocol was saved after calibrating, the position of the cuvette in the .ini file was also saved. If a user changed the position of this cuvette by adding or deleting cuvettes, the saved position in the protocol was no longer valid and would cause Ponemah to close.
2735	F	The possibility existed where a validation mark (i.e., End Systole Mark) could be placed after the End Cycle Mark. This resulted in Ponemah closing when the review file was opened. Error checking has been added to ensure that no marks exist outside of the End Cycle Mark.
2732	F	Ponemah would occasionally close when reanalyzing a CVOL channel in Review. This was due to how the software would mark the Minimum Value point relative to the End Cycle point. On occasion, the software would mark the Minimum Value point past the End Cycle point.
Pulmonary Air Flow (PAF)		
3000	F	The Min Good Data Time attribute (Noise tab) for PAF did not have a character limit. This has been corrected to limit the number of characters to six.
2999	F	A remote possibility existed where Ponemah would unexpectedly close if PAF was selected as one of the analysis modules and the selected sample rates for the channels were 750Hz and 50Hz. This combination, using 750Hz as the primary rate, had the possibility to cause issues with how PAF processed the sample data.
3078	F	The averaging of the Minute Volume parameter (MV) was incorrect in Review. The formula now implemented is $\text{avg TV} * \text{avg BPM} = \text{MV}$. Previously, MV was calculated as the sum of individual products for each breath divided by the number of breaths in the logging period.
RAW Electrical Mean (RAW)		
3001	F	A remote possibility exists where Ponemah would unexpectedly close if RAW was selected as one of the analysis modules and the selected sample rates for the channels were 750Hz and 50Hz. This combination, using 750Hz as the primary rate, had the possibility to cause issues with how RAW processed the sample data.
Electrocardiogram (ECG)		

Key: N = New Feature; E = Enhancement; F = Fix		
Reference #	Type of Change	Description
3052	F	Invalid characters were reported for the Noise derived parameter instead of the expected numerical values. Note: If "ECG Multilead Analysis" (MLE) was enabled in the license file, this issue would not be seen.
2986	F	Acquiring data using a large number of JET devices may have resulted in a periodic Data Buffer Overflow error. This error occurred when long RR-Intervals were detected. The unusually long RR-Interval resulted in an extended period over which Noise was being calculated. As a result of the long period over which Noise was calculated, the software would stop acquisition unexpectedly and post the above error message.
Left Ventricular Pressure (LVP)		
3069	F	When analyzing LVP data, an occasional cycle would not be analyzed and no validation marks would be present on the cycle. This issue was due to a slower than expected sample rate for the channel relative to the rate of the LVP signal. This slow sample rate resulted in derivative values for the signal not staying above the expected threshold value for a predetermined number of samples.

Additionally, this document identifies the individual software components and versions for Ponemah version 4.80-SP2. 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 # J03263 – Build Version 4.80-SP2

Model	Description	Version
PNM-BP100W	Blood Pressure Analysis Module	V4.40
PNM-CBF100W	Coronary Blood Flow Analysis Module	V4.00
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>	V4.80
PNM-ERO100W	ECG Rate Only Analysis Module	V4.00
PNM-EMG100W	Electromyogram Analysis Module	V4.00
PNM-IBP/IBPS100W	Indirect Blood Pressure / Indirect Blood Pressure Sound Analysis Modules	V4.00
PNM-LVP100W	Left Ventricular Pressure Analysis Module	V4.50
PNM-MAP100W	Monophasic Action Potential Analysis Module	V4.10
PNM-PAF/AWR100W	Pulmonary Air Flow / *Airway Resistance Analysis Modules <i>*NOTE: This option is embedded in the PNM-PAF100W analysis module</i>	V4.80
PNM-PCR/PCRP100W	Pulmonary Compliance & Resistance Analysis Module / Pulmonary Compliance & Resistance Pressure Analysis Module	V4.30 / V4.30
PNM-PT100W	Pulsatile Tissue & Gut Motility Analysis Module	V4.30
PNM-SBF100W	Systemic Blood Flow Analysis Module	V4.00
PNM-CVOL100W	Cardiac Volume Analysis Module	V2.20
PNM-URP100W	Unrestrained Plethysmography Analysis Module	V4.30
	Raw Electrical Mean	V4.50

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