

Product Release Notes

Product: PONEMAH Physiology Platform
Model: P3 Analysis Modules (all modules)
Version: 4.80-SP4 (Service Pack 4 for version 4.80)
Build: J03263 (CD Build)
Date: November, 2008

Product Release Notes for PONEMAH Physiology Platform version 4.80-SP4 Analysis Modules indicate revisions made to the Analysis Modules since release of Ponemah version 4.80-SP2. Please note that 4.80-SP3 was not formally released and, in addition, there were no changes to analysis modules.

For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 4.80 CD. Product Release Notes indicate only revisions to application contents that are part of CD Part #J03263 – Build Version 4.80-SP4.

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)		
3076	F	Performing inverted calibrations affected data analysis in review (see 3076 in the v48-SP4 Release Notes document). The analysis module was modified to handle changes made in review to support the inverted calibration.
3137	F	When Ponemah was started, no new information (for example, new catheter information for the cuvette calibration in CVOL version 2.30) was added to the PPP3.INI file if CVOL was not automatically loaded as part of the default protocol being opened. Simply selecting CVOL as an analysis module in the Input Setup menu, or loading a protocol with CVOL already enabled, will load the new cuvette information into the PPP3.INI file.
N/A	E	Added the ability to perform Parallel Volume in review. Previously, this function was limited to acquisition and replay. Users are presented with a dialog where they may set parser bars to define the region (cycles) to be used for the Parallel Volume calibration.
N/A	E	Added standard Scisense catheters to the Cuvette Cal tab in the CVOL analysis attributes dialog. This allows users to select a specific catheter to use when performing a cuvette calibration. If the specific Scisense catheter is not listed, users may add this catheter model to the list of available catheters by opening and editing the appropriate section in the PPP3.INI file located in the run time directory.
N/A	E	Added Heart Rate (HR) and Cardiac Output (CO) to the list of available derived parameters.
N/A	E	Added the ability to collect up to five individual segment volumes which will be used to calculate the total segment volume. This feature has been added to the Standard Attributes tab.
N/A	E	Incorporated the Alpha correction factor. This will correct for volume measurements obtained by other devices outside of the conductance measurement.

Key: N = New Feature; E = Enhancement; F = Fix		
Reference #	Type of Change	Description
2764	F	The ability to reanalyze data in a secured system existed without a card being present in the card reader (Data Security Option). If an analysis was performed and the Effects and Scope of Changes dialog was left open when a card was removed, a user was able to click on the OK button and perform a reanalysis of the channel. This has been corrected to appropriately disable the OK button on this dialog if no card is present and prompt a user to insert their access card before any changes can be made.
Pulmonary Air Flow (PAF)		
3076	F	Performing inverted calibrations affected data analysis in review (see 3076 in the v48-SP4 Release Notes document). The analysis module was modified to handle changes made in review to support the inverted calibration.
2994	F	Opening a file in review would result in Ponemah closing if multiple PAF channels were selected and analyzed simultaneously using the Additional Channels tab when abdominal channels existed (RIP setup). The software would change the abdominal channel settings when batch analyzed ultimately resulting in the abdominal channel being set to its own channel (abdominal channel). This resulted in Ponemah closing.
2966	F	When opening a protocol from an earlier version of the software (previous version of the PAF module), the derived parameters NUM, PEnh, RT and TVe were not selected in the derived parameter list even though the earlier version had these parameters selected. This has been corrected.
171	E	In order to perform a Least Square calibration, a valid pneumotach channel needed to be specified. If no channel was specified in the RIP tab, the software did not warn the user. A check has been implemented to warn the user if no valid pneumotach channel is selected in the RIP tab.
2764	F	The ability to reanalyze data in a secured system existed without a card being present in the card reader (Data Security Option). If an analysis was performed and the Effects and Scope of Changes dialog was left open when a card was removed, a user was able to click on the OK button and perform a reanalysis of the channel. This has been corrected to appropriately disable the OK button on this dialog if no card is present and prompt a user to insert their access card before any changes can be made.
RAW Electrical Mean (RAW)		

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3076	F	Performing inverted calibrations affected data analysis in review (see 3076 in the v48-SP4 Release Notes document). The analysis module was modified to handle changes made in review to support the inverted calibration.
N/A	E	Enhanced the RAW analysis to provide more appropriate information to users. The analysis module has been expanded to provide 4 separate selections. These selections are TEMP (Temperature), ACT (Activity), BARO (Barometric), and RAW. Functionality is equivalent for each module. However, providing different types eases setup by clarifying inputs in various menus. When using the Study Protocol Option, selecting BARO will eliminate error messages previously seen with inconsistent setups across groups (see v48-SP4 Release Notes, Study Protocol Option section).
N/A	E	Changed the default trigger direction to “Disable” in the Standard Attributes tab. This is the desired setting for signals such as temperature, activity and other signals that do not have a cyclic component.
3133	F	If the Trigger Direction was set to “Disable”, the Threshold mark placed at one second boundaries would progressively move based on sample rate and file length in review. The Threshold mark did not affect calculated/derived data when analyzing non-pulsatile signals (trigger direction is disabled). Only mark placement was affected.
2764	F	The ability to reanalyze data in a secured system existed without a card being present in the card reader (Data Security Option). If an analysis was performed and the Effects and Scope of Changes dialog was left open when a card was removed, a user was able to click on the OK button and perform a reanalysis of the channel. This has been corrected to appropriately disable the OK button on this dialog if no card is present and prompt a user to insert their access card before any changes can be made.
Electrocardiogram (ECG)		
3076	F	Performing inverted calibrations affected data analysis in review (see 3076 in the v48-SP4 Release Notes document). The analysis module was modified to handle changes made in review to support the inverted calibration.

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Reference #	Type of Change	Description
2764	F	The ability to reanalyze data in a secured system existed without a card being present in the card reader (Data Security Option). If an analysis was performed and the Effects and Scope of Changes dialog was left open when a card was removed, a user was able to click on the OK button and perform a reanalysis of the channel. This has been corrected to appropriately disable the OK button on this dialog if no card is present and prompt a user to insert their access card before any changes can be made.
Left Ventricular Pressure (LVP)		
3076	F	Performing inverted calibrations affected data analysis in review (see 3076 in the v48-SP4 Release Notes document). The analysis module was modified to handle changes made in review to support the inverted calibration.
3156	F	When opening the attributes dialog, a predetermined amount of time (data) is brought into the dialog for analysis. Instances where high heart rates existed, Ponemah would close if greater than 100 cycles were brought in for analysis by the software. This has been corrected to account for high cycle counts. Work-around: when in review, scroll to the end of the dataset to ensure that less than 100 cycles exist. This will prevent more than 100 cycles to be brought into the attributes dialog.
2764	F	The ability to reanalyze data in a secured system existed without a card being present in the card reader (Data Security Option). If an analysis was performed and the Effects and Scope of Changes dialog was left open when a card was removed, a user was able to click on the OK button and perform a reanalysis of the channel. This has been corrected to appropriately disable the OK button on this dialog if no card is present and prompt a user to insert their access card before any changes can be made.
Monophasic Action Potential (MAP)		
3076	F	Performing inverted calibrations affected data analysis in review (see 3076 in the v48-SP4 Release Notes document). The analysis module was modified to handle changes made in review to support the inverted calibration.

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Reference #	Type of Change	Description
2764	F	The ability to reanalyze data in a secured system existed without a card being present in the card reader (Data Security Option). If an analysis was performed and the Effects and Scope of Changes dialog was left open when a card was removed, a user was able to click on the OK button and perform a reanalysis of the channel. This has been corrected to appropriately disable the OK button on this dialog if no card is present and prompt a user to insert their access card before any changes can be made.

Additionally, this document identifies the individual software components and versions for Ponemah version 4.80-SP4. 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-SP4

Model	Description	Version
PNM-ECG100W	Electrocardiogram Analysis Module <i>*NOTE: *Multiple Lead is embedded in the PNM-ECG100W analysis module</i>	V4.90
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-CVOL100W	Cardiac Volume Analysis Module	V2.30
	Raw Electrical Mean	V4.60