

Product Release Notes

Product: PONEMAH Physiology Platform
Model: Ponemah Analysis Modules (all modules)
Version: 4.80-SP5 (Service Pack 5 for version 4.80)
Build: 004939-004 (CD Build)
Date: March, 2009

Product Release Notes for PONEMAH Physiology Platform version 4.80-SP5 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 4.80 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
Pulmonary Compliance and Resistance (PCR)		
N/A	E	Added the ability to convert the pressure signal into different user units. The transmitters have a default unit of mmHg. Functionality has been added to allow the user to convert the pressure signal from mmHg to cmH ₂ O. Since this has been added to the analysis, previously collected data may be reanalyzed to convert the data to cmH ₂ O.
3241	F	Issues existed with PCR/PCRP (versions 4.40 and 4.30, respectively) when the sample rates for the two channels differed. This could result in the system closing unexpectedly while in Review or erroneous values calculated for derived parameters that relied on the PCRP signal. This has been corrected by only allowing the user to select PCRP channels that have the same sample rate as the PCR channel. If the sample rates differ, the user will not see those PCRP channels in the attributes dialog.
Left Ventricular Pressure (LVP)		
3232	F	Moving a Q mark in Review on an ECG channel could result in Ponemah closing if reporting the Q-A derived parameter. The Q-A derived parameter is a cross channel calculation utilizing an ECG and a pressure channel. If no data existed for the pressure channel in the region where modifications were made to the Q wave, the program would close. Examples where no data would exist for a pressure channel would include incorrect analysis attribute settings and Bad Data Marks.
3247	F	The RAW analysis module was previously 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 as well as eliminating errors seen during Study setup. The LVP analysis module was not updated to permit BARO channels to be selected and used as the Barometric Channel in the Advanced Attributes 1 tab. It only recognized channels designated as RAW.

Key: N = New Feature; E = Enhancement; F = Fix		
Reference #	Type of Change	Description
3249	F	<p>An issue existed in LVP which could result in the system closing unexpectedly while in Review or erroneous values calculated for derived parameters. This was a result of the LVP channel and the Barometric Channel having different sample rates.</p> <p>This has been corrected by only allowing the user to select BARO channels that have the same sample rate as the LVP channel. If the sample rates differ, the user will not see those BARO channels in the attributes dialog.</p>

Additionally, this document identifies the individual software components and versions for the analysis modules used with Ponemah version 4.80-SP5. 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 # 004939-004 – Version 4.80-SP5

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	V4.80
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	V4.50 / V4.40
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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