

Product Release Notes

Product: PONEMAH Physiology Platform
Model: P3 Analysis Modules (all modules)
Version: P3 4.80
Build: J02910 (CD Build)
Date: April, 2008

Product Release Notes for PONEMAH Physiology Platform version 4.80 Analysis Modules indicate revisions made to the Analysis Modules since release of Ponemah version 4.70.

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
Monophasic Action Potential (MAP)		
N/A	N	Updated the current capabilities for the MAP (PNM-MAP100W) algorithm to support the Review capabilities in version 4.80.
Pulmonary Air Flow (PAF)		
N/A	N	Added analysis support for JET RIP (Respiratory Inductive Plethysmography). This provides flow and volume measurements collected from JET transmitters (see 4.80 Release Notes for more information).
N/A	N	Added the Presentation signal, Input, which will display an individual band (chest or abdomen) for the RIP configuration.
N/A	N	Added a Noise tab for rejection of unwanted data. The user has the ability to select criteria used to determine a noise threshold. Once established, Bad Data Marks will be placed on the waveform data that exceed this threshold and the derived information will be removed from the spreadsheets.
2736	F	If acquisition hardware was not connected to the system, the Secondary Channel for PAF was disabled. T

Additionally, this document identifies the individual software components and versions contained on CD Build J02910, Ponemah version 4.80. Due to the fact that the CD contains many individual software components, each having its own version number, the CD 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 CD.

Contents of CD Part # J02910 – Build Version 4.80

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>	V4.60
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	V4.40
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>	V4.50
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	V2.10
PNM-URP100W	Unrestrained Plethysmography Analysis Module	V4.30
	Raw Electrical Mean	V4.40