

## Product Release Notes

**Product:** Ponemah Physiology Platform  
**Model:** Ponemah Analysis Modules  
**Version:** 4.90-SP4 (Service Pack 4 for version 4.90)  
**Build:** 005198-004 (CD Build)  
**Date:** February, 2010

Product Release Notes for Ponemah Physiology Platform version 4.90-SP4 Analysis Modules indicate revisions made to the modules since release of Version V10.09 of the analysis modules. Version V10.09 was an Analysis Modules only release and contained the last changes to these modules since the release of 4.90-SP1.

For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 4.90 CD and subsequent Service Pack CDs including V10.09. Product Release Notes indicate only revisions to application contents that are part of CD Part #004866-002 – Build Version 4.90.

**Notice for organizations that must comply with FDA's Good Laboratory Practices (GLP) and 21 CFR Part 11 Electronic Records; Electronic Signatures:** P3 Plus 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 P3 Plus, 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 P3 Plus. 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	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
<b>Electromyogram (EMG)</b>		
3504	F	<p>Ponemah had the potential to close if a series of events were carried out. After analyzing the EMG channel while in Review, creating a graph with the integral displayed and moving the graph page around on the desktop would cause Ponemah to close.</p> <p>This issue would not occur on the first channel (input 1) or any other channel that had the same sample rate as channel one. This has been corrected.</p> <p><b>Work-around:</b> If installing the updated module is not desired, set all channels to the same sample rate as channel one.</p>
3510	F	<p>Auto scaling the integral signal could cause Ponemah to shut down unexpectedly. This has only been found to happen if a large spike in the data occurred and an auto scale of the graph was performed while the spike was visible in the graph page. This only occurred during Acquisition or Replay, not Review.</p> <p><b>Work-around:</b> Do not use the auto scale feature while a large spike is visible in the graph page during Acquisition or Replay.</p>

Additionally, this document identifies the individual software components and versions for the analysis modules used in the Ponemah 4.90-SP4 Analysis Modules release. 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 # 005198-004 – Version 4.90-SP4

Model	Description	Version
PNM-BP100W	Blood Pressure Analysis Module	V4.80
PNM-BPR100W	Blood Pressure Respiration Analysis Module	V4.20
PNM-CBF100W	Coronary Blood Flow Analysis Module	V4.20
PNM-CYS100W	Cystometry Analysis Module	V4.40
PNM-ECG100W	Electrocardiogram Analysis Module <i>*NOTE: *Multiple Lead is embedded in the PNM-ECG100W analysis module</i>	V5.10
PNM-ERO100W	ECG Rate Only Analysis Module	V4.00
PNM-EMG100W	Electromyogram Analysis Module	V4.30
PNM-IBP/IBPS100W	Indirect Blood Pressure / Indirect Blood Pressure Sound Analysis Modules	V4.00
PNM-LVP100W	Left Ventricular Pressure Analysis Module	V4.90
PNM-MAP100W	Monophasic Action Potential Analysis Module	V4.30
PNM-PAF/AWR100W	Pulmonary Air Flow / *Airway Resistance Analysis Modules <i>*NOTE: This option is embedded in the PNM-PAF100W analysis module</i>	V5.10
PNM-PCR/PCRP100W	Pulmonary Compliance & Resistance Analysis Module / Pulmonary Compliance & Resistance Pressure Analysis Module	V4.60 / V4.50
PNM-PT100W	Pulsatile Tissue & Gut Motility Analysis Module	V4.40
PNM-SBF100W	Systemic Blood Flow Analysis Module	V4.20
PNM-CVOL100W	Cardiac Volume Analysis Module	V2.40
PNM-URP100W	Unrestrained Plethysmography Analysis Module	V4.40
	Raw Electrical Mean (TEMP, BARO, ACT)	V4.70