

Product Release Notes

Product: PONEMAH Physiology Platform
Model: P3 Analysis Modules (all modules)
Version: P3 4.70
Build: J02910 (CD Build)
Date: September, 2007

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 4.70
Analysis Modules indicate revisions made to the Analysis Modules since release of P3 Plus Version 4.60.

For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 4.70 CD. Product Release Notes indicate only revisions to application contents that are part of CD Part #J02910 – Build Version 4.70.

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.

Key: N = New Feature; E = Enhancement; F = Fix		
Reference #	Type of Change	Description
Electrocardiogram (ECG)		
N/A	N	Added the R Direction attribute. This drop down list box allows the user to specify the direction of the R wave. The selections are Positive and Negative. With the implementation of the R Direction attribute, the dV/dt Threshold attribute has been removed.
N/A	N	Added support for Template Analysis to the ECG algorithm.
N/A	N	Added the attribute Min R Height. This attribute is used to ensure that the analysis does not false trigger on small noise spikes during periods of inactivity. If the peak of a potential R wave, measured from the Iso-electric level, does not exceed this value, it will not be marked as an R wave.
N/A	N	A tab for Noise has been added to the ECG attribute dialog. This tab contains attributes that are used to identify noisy data. These attributes include Bad Data Threshold, Minimum Heart Rate and Minimum Good Data Time. On identifying noisy data, Bad Data Marks will be placed to span the noisy sections.
N/A	E	Updated the Typical Values Tab in the Attributes dialog. Species information has been added which is defined in the Groups information dialog. After selecting the desired species in the Groups dialog, Typical Values will update accordingly in the Attributes tab. This will provide information based on species as well as default the values for Maximum Heart Rate, Minimum Heart Rate and Minimum Good Data Time, accordingly.
N/A	N	Added the QRS Detection Threshold. This attribute is used to predict the derivative level used to determine R waves and is expressed as a percentage of the derivatives of prior QRS complexes.
N/A	N	<p>Added new derived parameters Match, PMatch, QMatch, SMatch and TMatch. These parameters are used exclusively in conjunction with Template analysis and report the percentage of cycles within a logging interval that are matched (Match parameter) or report the average degree of match for the desired region within the logging period.</p> <p>Additionally, added the derived parameter, Noise. This parameter provides an estimate of the level of noise on the ECG signal and is a useful tool for sorting data.</p>
N/A	E	Modified the End of Cycle criteria. The end of an ECG cycle follows the R wave by 66.7% of the interval between the current cycles R wave and the following R wave. It was previously 75%.
N/A	E	<p>Removed the following PPP3.INI dependencies. These features have been formally released in previous versions but were manually enabled. These features are now available without manual intervention:</p> <ul style="list-style-type: none"> • Alternate End of T • Peak Sensitivity • S Recovery Threshold • Enable Spike Detection <p>In addition to removing the dependency, Base Recovery Threshold has been defaulted to 50% (S Recovery Threshold is the PPP3.INI listing).</p>

Key: N = New Feature; E = Enhancement; F = Fix		
Reference #	Type of Change	Description
N/A	E	Increased the cycle number display in Review from three digits to five digits for ECG. Cycle numbers previously reset after 999. Cycle numbers will now reset to one after 99999.
2550	F	The possibility existed where two arrhythmic R marks could occur at the same time point. In order for this to occur, the Max R Height was lowered so that only arrhythmic R waves would appear. This scenario is unlikely to be encountered during normal analysis. This issue has been corrected to eliminate the possibility of two R marks occurring at the same time point.
2619	F	The default setting for the High ST Segment Attribute (Adv Attrib 2 Tab) was enabled while the Typical Value column stated that this attribute should default to disabled. This has been corrected so that the default status for the High ST Segment is disabled.

Additionally, this document identifies the individual software components and versions contained on CD Build J02910, P3 Plus Version 4.70. 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 4.70

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	V4.00
PNM-PAF/AWR100W	Pulmonary Air Flow / *Airway Resistance Analysis Modules <i>*NOTE: This option is embedded in the PNM-PAF100W analysis module</i>	V4.40
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-URP100W	Unrestrained Plethysmography Analysis Module	V4.30
PNM-CVOL100W	Cardiac Volume Analysis Module	V2.10
	Raw Electrical Mean	V4.40