Product Release Notes

Product: Ponemah Physiology Platform
Model: Ponemah Analysis Modules
Version: 5.20
Build: 006870-001 (CD Build)
Date: May, 2013

Product Release Notes for the Ponemah Version 5.20 indicate revisions made to the modules since release of Ponemah Physiology Platform Version 5.10. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Ponemah Physiology Platform Version 5.20 CD. Product release notes indicate only revisions to application contents that are part of a specific build or version.

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 Ponemah, 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 Ponemah. 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.

DSI ▪ 119 14th St. NW ▪ Suite 100 ▪ St. Paul, MN 55112
T:+1 (651) 481 7400 ▪ F:+1 (651) 481 7404 ▪ Toll free: 1 (800) 262 9687
www.datasci.com ▪ information@datasci.com

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
GENERAL NOTE:			
*Several new features were implemented in more than one analysis module. These features are listed under **Features Implemented in Multiple Analysis Modules**. For clarity, the analysis modules affected by the change are listed in each of the entries in this section. These features will not be logged under the individual analysis module sections.*			
Features Implemented in Multiple Analysis Modules			
See Description	N	N/A	Added functionality to permit marking data as bad that contains artifact including dropouts or samples that fall outside an expected range, to prevent analyzing and reporting on this data. Affected Modules: • BP (14163) • ECG (14169) • EMG (14175) • LVP (14160) • PVO (14184) • PCR (14181) • PCRP (14199) • RAW, ACT, TEMP, BARO (14157)
See Description	N	N/A	Added a Count derived parameter which will report the number of cycles within a logging interval or a Data Reduction interval. Affected Modules: • BP (14203) • ECG (14221) • LVP (14233)

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
16766/ 17290	N/A	N/A	The derived parameters reported by the current and prior versions of the following analysis modules may show minor differences. This is due to the use of newer development tools namely, Microsoft Visual Studio 2012 (VS2012), which has been updated to optimize floating point arithmetic. • BP • ECG • EMG • LVP • PCR • PCRP • PVO • RAW, ACT, TEMP, BARO • URP
Blood Pressure (BP)			
			*Please refer to the **Features Implemented in Multiple Analysis Modules** section for a list of additional new features pertaining to this analysis module.*
14262	N	N/A	Added the following **Inter-Beat Interval** (IBI) derived parameters allowing frequency domain **Heart Rate Variability** (HRV) to be calculated from blood pressure signals. • **IBIs**: time interval between the current and previous cycles' systolic marks • **IBIms**: time interval between the current and previous cycles' maximum slope marks • **IBIed** – time interval between the current and previous cycles' end diastolic marks In order to report the IBIms, the **Max Slope** mark was added and can be used to aid in the visualization and validation of the IBIms calculation.

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
17850	N/A	N/A	Due to the addition of the **Max Slope** mark, **v5.20** of the **BP** module is not compatible with **v4.3 and prior** of the **BPR** module. A warning was added to the **BP** module to notify the user if an incompatible **BPR** module is trying to be used with **v5.20** of the **BP** module.
17506	F	N/A	Removed the **BP Epoch Channel** checkbox from the AdvAttrib1 tab. This was removed since the functionality was no longer present due to splitting out the respiration from blood pressure component from the blood pressure analysis module and into its own analysis module.
Diaphragmatic EMG (dEMG)			
17853	F	N/A	The **dEMG** analysis module would repeatedly display the following message when the **Rectified** presentation signal is not included in a **Primary** graph page. "Invalid Presentation Signal" This has been corrected in v1.10 of the dEMG module. A **Workaround**: Include the **Rectified** presentation signal in the **Primary** graph prior to opening the data in **Review**. If a **Rectified** signal was not part of the **Protocol** during acquisition, the protocol would need to be updated and the **RAW** data would need to be **Replayed** in order to generate a **Review** file that does not exhibit the issue.

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
17928	F	N/A	When collecting **dEMG** data, an **ECG** signal may be seen in the dEMG waveform as signal artifact. The dEMG module allows the user to select an **ECG channel** to filter the **ECG artifact** out of the dEMG signal via the **Analysis Attributes** dialog. If an ECG channel is selected within the module during acquisition, but is not present during the Review session, **Ponemah** will shutdown unexpectedly. Instances where an ECG signal has been selected in the dEMG module, but is not present in Review are: • Unchecking the ECG channel upon entering Review. • Opening the Review file on a system that does not have ECG enabled in the license file. This has been corrected.
Electromyogram (EMG)			
			*Please refer to the **Features Implemented in Multiple Analysis Modules** section for a list of additional new features pertaining to this analysis module.*
Electrocardiogram (ECG)			
			*Please refer to the **Features Implemented in Multiple Analysis Modules** section for a list of additional new features pertaining to this analysis module.*
15308	E	N/A	Upon selecting the ECG Analysis Attributes' Advanced Attributes 2 tab, there is a "Check for Inverted R" checkbox that is used to flag as invalid any cycles that have inverted R waves. In some occasions, having this feature enabled would mismark valid cycles that were not inverted as invalid. The default setting for this check box has been adjusted to be disabled.
Left Ventricle Pressure (LVP)			
			*Please refer to the **Features Implemented in Multiple Analysis Modules** section for a list of additional new features pertaining to this analysis module.*

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
14263	N	N/A	Added **Electromechanical Window** (EMw) parameter which reports the time in milliseconds between the LVP's **End Diastolic** mark and ECG's **Twave End** mark. In order to report the **EMw**, the **Twave End** mark was added and can be used to aid in the visualization and validation of the IBIms calculation.
15146	E	N/A	If the LVP and ECG channels are sampled at different sampling rates, the QA derived parameter would not be calculated. This has been updated to allow the QA derived parameter to be calculated when the LVP and ECG sampling rates are different.
17852/ 17856	N/A	N/A	Due to the addition of the **Twave End** mark, v5.20 of the **LVP** module is not compatible with v4.3 or prior of the **CVOL** and **CBF** modules. A warning was added to the **LVP** module to notify the user if an incompatible **CVOL/CBF** module is trying to be used with v5.20 of the **LVP** module.
13908	F	N/A	The QA derived parameter would not automatically update under the following conditions: After manually: • Deleting an Rwave validation mark. • Inserting QRS validation marks (inserting an ECG cycle). This has been corrected.
15064	F	N/A	The LVP analysis module's "ECG Channel" drop down list box height was too short making it difficult to see and select all of the available options. This has been corrected.
RAW Electrical Mean (RAW, ACT, TEMP, BARO)			
			*Please refer to the **Features Implemented in Multiple Analysis Modules** section for a list of additional new features pertaining to this analysis module.*
Pulmonary Volume (PVO)			

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
			*Please refer to the **Features Implemented in Multiple Analysis Modules** section for a list of additional new features pertaining to this analysis module.*
16522	F	N/A	When impedance data are Replayed with a protocol that has does not have activity enabled, the Pulmonary Volume channels' bad data marks are not placed properly during the Replay. This issue can be avoided by selecting an activity channel. If activity based noise detection is not desired, the activity threshold can be raised to avoid triggering on activity This has been corrected.
Pulmonary Compliance and Resistance (PCR/PCRP)			
			*Please refer to the **Features Implemented in Multiple Analysis Modules** section for a list of additional new features pertaining to this analysis module.*
Unrestrained Plethysmography (URP)			
			*Please refer to the **Features Implemented in Multiple Analysis Modules** section for a list of additional new features pertaining to this analysis module.*
14202	N	N/A	The URP analysis attribute's "Advanced Attribute 2 tab" provides users the ability to account for animal body temperature, chamber temperature, relative humidity, and atmospheric pressure for more accurate derived parameter calculations. The chamber temperature, relative humidity, and atmospheric pressure values can all be entered manually for a static compensation, or by checking a check box, the user can assign a channel to be used to dynamically monitor and apply values from that channel. In the previous version, the body temperature compensation only allowed users to enter a static value; however, users are allowed to monitor body temperature dynamically with a PhysioTel Implant. The option has been added for the user to assign the implant temperature channel to the body temperature compensation for a more dynamic, accurate measurement.

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
14202	N	N/A	Added Apneic Count (ApCt) derived parameter which reports the number of cycles in the logging period or Data Reduction period whose inter-breath duration exceeds a user defined interval to signify an apneic event.
16781	N	N/A	Added inspiratory flow at 50% tidal volume (IF50) and expiratory flow at 50% tidal volume (EF50) derived parameters.
17297	N	N/A	Added a derived parameter to report the ratio of expiratory flow to the inspiratory flow at 50% tidal volume (E/IF50).

Additionally, this document identifies the individual software components and versions for the analysis modules used in the Ponemah Analysis Modules release. Due to the fact that the build may contain 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 within the enclosed build.

DSI ▪ 119 14th St. NW ▪ Suite 100 ▪ St. Paul, MN 55112
T:+1 (651) 481 7400 ▪ F:+1 (651) 481 7404 ▪ Toll free: 1 (800) 262 9687
www.datasci.com ▪ information@datasci.com

Contents of CD Build #006870-001: Ponemah Version 5.20

Model	Description	Version
PNM-BP100W	Blood Pressure Analysis Module	V5.20
PNM-BPR100W	Blood Pressure Respiration Analysis Module	V4.40
PNM-CVOL100W	Cardiac Volume Analysis Module	V2.60
PNM-CBF-100W	Coronary Blood Flow Analysis Module	V4.40
PNM-CYS100W	Cystometry Analysis Module	V4.40
PNM-dEMG100W	Diaphragmatic EMG Analysis Module	V1.10
PNM-ECG100W	Electrocardiogram Analysis Module* *NOTE: Multiple Lead is embedded in the PNM-ECG100W analysis module	V5.20
PNM-ERO100W	ECG Rate Only Analysis Module	V4.00
PNM-EMG100W	Electromyogram Analysis Module	V5.20
PNM-LVP100W	Left Ventricular Pressure Analysis Module	V5.20
PNM-MAP100W	Monophasic Action Potential Analysis Module	V4.30
PNM-PAF/AWR100W	Pulmonary Air Flow / *Airway Resistance Analysis Modules *NOTE: This option is embedded in the PNM-PAF100W analysis module	V5.40
PNM-PCR/PCRP100W	Pulmonary Compliance & Resistance Analysis Module / Pulmonary Compliance & Resistance Pressure Analysis Module	V5.20/V5.20
PNM-PT100W	Pulsatile Tissue & Gut Motility Analysis Module	V4.40
PNM-PVO100W	Pulmonary Volume Analysis Module	V5.20
PNM-SBF100W	Systemic Blood Flow Analysis Module	V4.20
PNM-URP100W	Unrestrained Plethysmography Analysis Module	V5.20
	Raw Electrical Mean (TEMP, BARO, ACT)	V5.20

DSI ▪ 119 14th St. NW ▪ Suite 100 ▪ St. Paul, MN 55112
T:+1 (651) 481 7400 ▪ F:+1 (651) 481 7404 ▪ Toll free: 1 (800) 262 9687
www.datasci.com ▪ information@datasci.com