

Product Release Notes

Product: Ponemah Physiology Platform
Model: Ponemah Analysis Modules
Version: PNM-PAF480-SP1 (Service Pack 1 for PAF DLL version 4.80-SP1)
Build: 006215-001 (CD Build)
Date: December, 2010

Product Release Notes for the Ponemah Analysis Module, PNM-PAF480-SP1, indicate revisions made to the Pulmonary Airflow modules (PAF) since its original release. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Ponemah Physiology Platform Version 5.00 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.

Defect Reference #	Type of Change	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
<p align="center"><i>GENERAL NOTE:</i></p>		
<p>This analysis module is for use with Ponemah core versions 4.80 to 5.00 and includes all fixes to date. However, this module does not contain added features implemented after release of version 4.80.</p>		
<p align="center">Pulmonary Airflow (PAF)</p>		
3678	F	<p>Ponemah may fail to respond when analyzing data using the PAF analysis module under the following conditions:</p> <ul style="list-style-type: none"> Analyzing respiratory data (PAF module) in Review Data set is greater than 22 hours long Sample rate set to 750Hz <p>If all three of the conditions above are met, Ponemah may become unresponsive. The analysis module has been updated to correct for this error condition.</p> <p>Work-around: Several work-arounds exist to prevent this issue from occurring or to allow most of the data to be analyzed without loading the updated PAF module, if desired.</p> <ul style="list-style-type: none"> Do not sample the channel at 750Hz. This issue only exists using this sample rate. <p>NOTE: This version of the PAF dll file (4.80-SP1) is intended to be used with Ponemah versions 4.80 to 5.00.</p>
3327	F	<p>Ponemah would close during Acquisition if an Abdomen Channel was selected as one of the channels in the Additional Channels list.</p>
3543	F	<p>The Avol Reset Event should have reported zeros during acquisition when set to None. However, if set to None, acquisition was reporting values for the Avol derived parameter. This only affected acquisition. Review correctly reported X's when set to None.</p>
3311	F	<p>If the Abdomen Channel was disabled prior to opening a Review file, Ponemah would close. This has been corrected to set the Abdomen Channel to "None" if the channel is disabled.</p>

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3331	F	<p>Entering a value of 0 for the Fixed Volume and selecting QDC in the RIP Calibration dialog would result in erroneous values being listed for Average Percent Error and Percent Error Range. A volume of 0 is not a valid calibration value and no longer allowed. Entering this value will now display an error message alerting the user to an incorrect calibration value.</p>
3325	F	<p>Ponemah would close unexpectedly if an analysis was performed on multiple PAF channels in Review using the Additional Channels feature. This would occur if different sample rates existed between the PAF channels being analyzed.</p>
3549	F	<p>Using the Additional Channels tab could cause Ponemah to close unexpectedly if a channel (or channels) selected had different sample rates. This pertains to channels that are dependent on other channels (Trigger Channels). If one or more channels had different sample rates, Ponemah would close upon analyzing the data. Changes were added to all analysis modules to prevent this issue from occurring in the future by not applying attribute changes to these dependent channels.</p>
3303	F	<p>The Noise detection attribute may not have correctly placed Bad Data Marks when an analysis was performed. If the Bad Data Mark was placed just prior to the end of a data block, only the start would be marked and not the entire period that is expected.</p>

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.

Contents of CD Build #006215-001: PNM- PAF480-SP1

Model	Description	Version
PNM-PAF/AWR100W	Pulmonary Air Flow / *Airway Resistance Analysis Modules <i>*NOTE: This option is embedded in the PNM-PAF100W analysis module</i>	V4.80-SP1