

## Product Release Notes

**Product:** PONEMAH Physiology Platform  
**Model:** P3 Plus  
**Version:** 4.90-SP2 (Service Pack 2 for version 4.90)  
**Build:** 005198-002 (CD Build)  
**Date:** September, 2009

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 4.90-SP2 indicate revisions made to the P3 Plus core application since release of P3 Plus Version 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 4.90-SP1 CD. Product Release Notes indicate only revisions to application contents that are part of a specific CD build.

Product Release Notes for P3 Plus do not include information regarding revisions of the P3 Plus Analysis Modules. Information regarding revisions of the P3 Plus Analysis Modules is indicated in separate Product Release Notes.

**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>Ponemah Core-General</b>		
3270	F	<p>When using the sync feature to synchronize the USB-OpenART acquisition units (ACQ7700/ACQ16 and OpenART), the Event Viewer log was not updated if the service was stopped.</p> <p>If the time sync service was stopped during acquisition and then restarted, the dsiTimeSync log (Event Viewer) was not updated with any information stating that the 7700 ticks had stopped. This has been corrected to post a message when the service is stopped during acquisition.</p> <p>This issue does not exist when synchronizing JET and OpenART.</p>
3272	F	<p>If the Measurement Computing PCI card (used to sync two acquisition units) was removed from the workstation, no information was placed into the log file indicating that the card was not found.</p> <p>Two new error messages have been added to the dsiTimeSync log to indicate that the PCI card was not found and the 7700 counter could not be read.</p>
3277	F	<p>If an acquisition was stopped unexpectedly (for example, power loss), the possibility of not having the <b>Jump</b> table information properly written to the end of the RAW file was possible. This could result in an error message when the file was replayed or reviewed stating that the Jump table is missing or corrupt. Replaying the file and performing a <b>Jump to Event/Time</b> from the toolbar menu (or <b>Functions</b> menu) would recreate the needed information and correct the issue. However, the mechanism to correct for this issue did not always function as expected. A correction has been made to allow the user to fix missing or corrupt jump information in these rare instances by performing a <b>Jump to Event/Time</b> in replay as intended.</p>
3285	F	<p>Default synchronization timing for the JET-OpenART interface is +/-100ms. However, the synchronization for these two acquisition engines can be set as low as +/-20ms. It was found that after acquiring data for several hours, the tolerance could have been greater than the user defined +/-20ms. Updates have been made to ensure that the level of synchronization for this setting does not exceed the +/-20ms.</p>

Reference #	Type of Change	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
3287	F	<p><b>Channel Mapping</b> (Channel Configuration menu) allows users to move and group channels together that do not follow each other in a consecutive fashion in the <b>Channel Input Setup</b> menu. This is utilized primarily with the sync feature when synchronizing two acquisition units. The order in which the channels appear may be modified using mapping but the sample rates for the channel stay with the input from the <b>Channel Input Setup</b> menu.</p> <p>For example, the <b>Channel Input Setup</b> dialog has channels 1-3 enabled which are assigned to the BP, ECG, and Temp analysis, respectively. Additionally, BP and ECG are assigned to a primary sample rate of 1000Hz and Temp is assigned to a secondary sample rate of 50Hz. Using the mapping feature, input 3 (Temp) is moved above input 2 (1, 3, and 2). While the order has changed, the sample rate defined for input 3 remains in that position and therefore channel 2 (BP) will be sampled at 50Hz (and Temp at 1000Hz).</p> <p>The software now posts a message when changes are made to this menu alerting users to the fact that the A/D sample rates may need to be modified due to changes in the channel mapping.</p>
3380	F	<p>Ponemah Version 4.90 did not function properly on the French Windows operating system. For new installations, this issue would present itself when selecting a license file (after installing the software program) which would result in Ponemah closing unexpectedly.</p>
3383	F	<p>When running long acquisitions or acquisitions that had a very short logging rate such as 1 epoch, raw data would become corrupt when Excel reached the line limit (for example 65,535 lines) and posted the warning message alerting the user to this condition. The corruption of data would continue until the warning message was cleared and then acquisition would return to normal. This has been corrected.</p>
<b>Jacketed External Telemetry (JET)</b>		
2529	F	<p>No message was posted in the Log file if a WRAP server lost connection during an acquisition. The Log file now displays a message that connection has failed.</p>
<b>Study Protocol Option</b>		

Reference #	Type of Change	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
3132	F	<p>Ponemah would appear to be unresponsive when saving a very large <b>Marks Section</b> (Save Run) within Study.</p> <p>A progress dialog is displayed when a save is performed. However, after the dialog closes additional processing is still taking place making it appear to the user that the system is not responding. The system could still process data for up to 20 minutes after the progress dialog has disappeared depending on the workstation specifications and file size. However, if the system was not stopped and allowed to continue processing, the saving of data completed as expected.</p> <p>Changes have been made to how the data is processed and ordered to optimize saving. For very large files, some additional processing may take place after the progress dialog has disappeared. However, this time should be minimal.</p>
3275	F	<p>Within Study, saving a <b>Marks Section</b> during Review would create an .xlsb file (Microsoft Excel 2007) with no dot prior to the file extension. This has been corrected to create the file extension appropriately.</p>
3282	F	<p>An incorrect permissions setting resulted in an error message being posted when performing the <b>Backup Study</b> function that did not adequately identify the issue.</p> <p>The error message was posted when the account used by SQL Server (by default, the SYSTEM account) did not have write access to the P3PlusTempDirectory which caused the backup to fail. The following message was posted:</p> <p>"Cannot open backup device'C:\LSS\P3PlusTempDir\TmpBackupFile.sdybkup'. Device error or device off-line. See the SQL Server error log for more details. BACKUP DATABASE is terminating abnormally."</p> <p>The following hint was added to help users better understand why the issue occurred and allow them to correct the issue internally:</p> <p>"This can be caused by permission problems for directory &lt;'C:\LSS\P3PlusTempDir'&gt; . SQL Server service needs to be run under an account that has full access to the directory."</p>

Reference #	Type of Change	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
3296	F	<p>Version 4.90 utilized Microsoft SQL Server 2005 Express Edition which was an updated version of the database. The previous version was Microsoft SQL Server 2000 (MSDE). Data generated using the <b>Study Protocol Option</b> is placed into the database as well as the ODBC generated files (Access and Excel). It is not possible to back up a study using 2005 and restore the backup file to a workstation running 2000. When an attempt is made to perform a back up to a previous version of the database, the following message is posted alerting the user to an error condition:</p> <p>"Too many backup devices specified for backup or restore; only 64 are allowed. RESTORE DATABASE is terminating abnormally."</p> <p>This error does not adequately alert the user to the potential issue. The following information was added to the message for clarity:</p> <p>"This can be caused by invalid backup devices or restoring a database created by a newer version of SQL server."</p>
3361	F	<p>If a <b>Saved Parsed Run</b> was performed during Review, an error was generated after Study was shut down and reopened. The error upon reopening the Study stated that the system was unable to read the <b>RAW</b> file (the specific file was listed) and that another file should be selected. The ability to select the same file and open the file as expected is permitted. However, this error occurred every time the Study was closed, reopened and the Review file selected.</p>
3391	F	<p>The Study <b>Data Log</b> records information such as calibration values, setup information and changes to analysis when using the Study Protocol Option. This information is also recorded in the individual <b>Experimental Logs</b> through the ODBC interface. However, if the <b>ODBC Interface (Application Configuration menu)</b> was disabled and no Excel or Access files were generated, information for the <b>Data Log</b> did not update. This has been corrected to allow the <b>ODBC Interface</b> to be disabled while still maintaining updates to the <b>Data Log</b>.</p>
<b>Data Review</b>		

Reference #	Type of Change	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
2534	F	<p>The <b>Snap Zoom In</b> feature in Review has a limit as to how far the ratio of samples per pixel may be expanded in order to preserve signal resolution by requiring a fixed number of samples be visible at all times in the graph.</p> <p>An issue occurred that did not allow the user to fully utilize the zoom feature if two sample rates were used during data collection and the secondary channels were configured but not graphed when in Review. If all channels sampled at the slower rate were configured in the <b>Graph Setup</b> dialog but were disabled, it would be expected that the limit would be based only on those channels being displayed in the graph page (enabled graph channels only). However, this was not the case. If a channel with a secondary sample rate was configured but disabled, Ponemah used this information to determine the minimum number of samples to be displayed in the graph at any one time.</p> <p>Therefore, if data were acquired with two sample rates, when in Review the <b>Snap Zoom In</b> feature was limited by any channel configured in the <b>Graph Setup</b> dialog (even when disabled) with a secondary sample rate. This has been updated to calculate the minimum number of samples based on currently enabled channels.</p> <p><b>Work-around:</b> Change any disabled channels with a secondary rate to a channel with a primary sample rate and disable again.</p>

Reference #	Type of Change	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
3266	F	<p>The ability to move a validation mark from one parser segment to another existed resulting in two cycles within one Parser segment with the same cycle number. This could ultimately lead to Ponemah closing. However, this issue is not easily recreated and multiple steps are needed to move a validation mark into another Parser segment.</p> <p>This issue occurred when a validation mark from the first cycle in a Parser segment is dragged to the left edge of the Parser segment. Once the validation mark was placed at the left edge of the segment, the user could not drag the mark any further. At that point, zooming in on the signal to a very high resolution would allow the validation mark to be moved to the parser segment on the left. Zooming in on the signal typically had to be performed multiple times in order to recreate this issue and the parser segments had to be contiguous (no gaps between segments). The software now guards against this situation and does not permit the validation mark to move across Parser segments.</p>
3280	F	Opening a Review file with an XY presentation enabled could have resulted in Ponemah closing unexpectedly. This has been corrected.
3305	F	When working with very large Review files, analyzing multiple channels before the file was fully loaded may have resulted in Ponemah closing unexpectedly. A change has been implemented to allow the user to analyze large data Review files, prior to the file being fully loaded, without incidence.
3358	F	<p>Review calculates data based on beat information. This resulted in an inconsistency in how the <b>Line</b> parameter (<b>Data Reduction</b>) was calculated and reported between acquisition and Review. When <b>Line</b> was specified in Review, the last cycle (not the last logged line of data) was pulled into the Data Reduction sheet.</p> <p>An update to the <b>Line</b> parameter calculation provides consistency with the calculation during acquisition (or replay). When in Review, the data for the <b>Line</b> parameter will match the last logged line of data in the DRx list view for a given Data Reduction interval.</p>
3370	F	If a Review file was opened using <b>Open Review File</b> and then Review was closed, the protocol listed in the title bar while in idle mode would still list the protocol name that was loaded prior to loading the review file but the settings would be that of the Review file. If the review file is loaded using Recent Review Files, this problem did not occur. This has been corrected.

**DSI Corporate Headquarters**119 14<sup>th</sup> Street NW Suite 100

St. Paul, MN 55112

P: +1 (651) 481.7400 • F: +1 (651) 481.7404

www.datasci.com

**Ponemah Operations**

5525 Cloverleaf Parkway

Valley View, OH 44125

P: +1 (216) 328.7000 • F: +1 (216) 328.7400

www.ponemah.com

Reference #	Type of Change	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
<b>Data Security Option (DSO)</b>		
3316	F	Event files (.EVT) were inadvertently not signed after an acquisition. The .EVT files were marked with a question mark instead of a green check mark when a verification of the files was performed.
3364	F	<p><b>Data Manager</b> had a single security permission which either permitted the user to access the dialog or restricted the user from entering the dialog. If the user had access, the ability to Move, Copy, and Delete files were available. Greater control was needed since deletion of data is generally restricted in typical user environments. The security permissions have been updated to allow individual control over Moving, Copying and Deleting data. The original security permission has been removed.</p> <p><b>NOTE:</b> This change requires an update to <b>Access Levels</b> on all workstations. Each <b>Access Level</b> must be reconfigured to support this update. By default, loading the service pack will disable access to the <b>Data Manager</b> dialog.</p>
2996	F	When attempting to open a review file from a mapped network drive on a secured system, an error message appeared stating that the review file was unable to be opened and that the access permissions should be checked. An update has been made to address how review files are recognized when using mapped drives to browse for the files.
3382	F	Microsoft Excel files (.xls) may not have appeared in the Verify dialog under a secured system. If .xls and .xlsb files were both present in the Verify Files dialog, when .xlsb files were found alphabetically in the dialog no subsequent .xls files would be listed.
<b>CRS 800 Recorder</b>		
3347	F	<b>Configuration</b> and <b>Offsets/Scales</b> were not properly recalled when replaying data which prohibited the user from changing <b>Configurations</b> and using the <b>Offsets</b> and <b>Scaling</b> functions. It may have also led to incorrect signals being printed. This issue occurred if the software did not recognize the acquisition hardware device upon starting Ponemah (device was not attached or the device was not powered). If the acquisition unit was recognized, this issue did not occur. This has been corrected to allow the <b>Configuration</b> and <b>Offsets/Scales</b> functionality to be utilized without hardware being recognized.