

## Product Release Notes

**Product:** PONEMAH Physiology Platform  
**Model:** P3 Plus  
**Version:** 4.80-SP4 (Service Pack 4 for version 4.80)  
**Build:** J03263 (CD Build)  
**Date:** November, 2008

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 4.80-SP4 indicate revisions made to the P3 Plus core application since release of P3 Plus Version 4.80-SP3. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 4.80 CD. Product Release Notes indicate only revisions to application contents that are part of CD Part #J03263 – Build Version 4.80-SP4.

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>		
3099	F	<p>When using OpenART as the acquisition interface, serial number information is placed in the log file for each receiver. However, if using the DRA arrangement (Distributed Receiver Array-multiple receivers) for one animal, only one receiver was logged in the file. This has been corrected to place information from all receivers into the log file.</p>
3130	F	<p>If Bad Data Marks were placed during an acquisition or replay using Noise analysis, running subsequent acquisitions/replays would result in incorrect Bad Data Mark placement regardless if Noise was used in the subsequent sessions. The issue resulted in Bad Data Marks from the first acquisition/replay being added to the second acquisition/replay session and this issue would present itself when entering review mode. Review was not clearing the Bad Data Marks between acquisition/replay sessions.</p> <p><b>Work-around:</b> Close Ponemah prior to entering review mode after an acquisition/replay.</p>
3135	F	<p>Viewing Data Reduction output in Access files may have resulted in the data not appearing to be sorted by a specific column. This is normal database functionality and this file is simply a repository for data. Output is typically dependent on structured queries to mine information of interest. However, a Primary Key was added to Ponemah to force a sort on Column ID. This will provide a more logical ordering of the data and not force users to sort data if only using the Access output directly from Ponemah.</p>
3092	F	<p>&lt;Alt&gt;&lt;O&gt; is a function used in traditional TOX ECG applications where a small number of complexes are collected. This feature allows the user to turn on and off the saving of data based on a predefined amount of time (or cycles) desired. This feature also prints the waveforms of interest to a writer along with the data reduction output.</p> <p>This feature can be initiated multiple times within an acquisition. However, if no writer was attached, subsequent attempts to trigger &lt;Alt&gt;&lt;O&gt;, after the initial attempt would not launch the functionality. The user would need to stop the acquisition and restart. This has been corrected to allow for multiple triggers to occur independent of having the writer present.</p>

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Study Protocol Option		
NA	E	<p>When creating a study, the software automatically verifies the configuration to alert users to any potential issues that might result from their setup. Examples include groups that do not have data reduction enabled or derived parameters that don't match across groups.</p> <p>If using OpenART, the barometric channel would prompt Study to flag this channel as a potential issue since it is typically configured differently than other groups based on the Data Reduction and derived output not being enabled.</p> <p>Enhancements have been made to the RAW analysis module (see v48-SP4_Analysis Modules_Release Notes) to make it more identifiable to the intended application. With this enhancement, the user may select "BARO" (Barometric) as the RAW analysis type. Study will then recognize the BARO channel when attempting to verify the Study will not trigger an error when encountered. However, the BARO channel must be included as a channel within the last group (animal) and not reside in a group by itself. If the BARO channel is placed in a group by itself, the error will be reported.</p>
3089	F	<p>Using the Load External Data option would not allow P3D files (Access files) to be added with the current file extension. Also, when loading the files, they had to reside in a directory that was not secured using the Data Security Option. This has been corrected to allow P3D files to be loaded without changing file extensions and from secured directories.]</p> <p><b>Work-around:</b> To load P3D files with an existing system, place the P3D files in a location that is not secured using the Data Security Option. Next, change the file extension from .p3d to .mdb. This will allow the files to be loaded through Study using the Load External Data option.</p>
Data Review		
3093	F	<p>A potential for Ponemah to close during a redraw existed if many Bad Data Marks were placed during acquisition and subsequent reviews. The issue centered on how the buffer was handling marks placed during review when Bad Data Marks existed from the acquisition/replay session. This has been corrected to properly handle additional Bad Data Marks placed during review.</p> <p><b>Work-around:</b> Using the current version (without SP4), it would be recommended not to add Bad Data Marks during acquisition/replay and only add them during review. This would alleviate the potential for the buffering issues.</p>

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3076	F	<p>Performing inverted calibrations affected data analysis in review. The software expects the High Cal/High Unit to be greater than the Low Cal/Low Unit. For example, expected High calibration fields would have values greater than the Low information; High Cal/Unit = 2.5mV/100 units and the Low = -2.5mV/-100 units. If these were switched such that the High Cal/Units = -2.5mV/-100 units and Low Cal/Unit = 2.5mV/100 units, review would treat the data as railed data and would not apply High Pass filters. This has been corrected to allow for inverted calibrations.</p> <p>This calibration process does not affect data in acquisition or replay modes, only review mode.</p> <p><b>Work-around:</b> Change calibration process so that the High Cal/Units values are always greater than the Low Cal/Units values.</p>
3144	F	<p>Under a secured system (Data Security Option), the log file was updated when saving a marks section with the current user's information. Since only one card could be present in the card reader when saving, the individual performing the save was credited with all changes. This has been expanded to track all users that make changes during a marks section and place the activity for each user in the log file regardless of which user saves the marks section.</p>
3149	F	<p>The option exists to remove all unmatched cycles after performing template analysis using ECG Pro. Previously, this was not placed in the log file. This deletion of unmatched cycles is now placed in the log file with the associated time range (start time to end time of deleted cycles).</p>
3139	F	<p>Saving a parsed review file would result in Ponemah closing if a channel with template bindings and match information was excluded from the review file upon initial opening. This would occur when first opening the review, the user is prompted to open all channels or select only the channels of interest.</p>
3145	F	<p>The dates contained in the log file for a marks section were the dates associated with the acquisition of the data and not the review of the data. This has been changed to reflect the date of the review (post processing). Dates and times are now placed in the log file based on when the post processing of the data occurred.</p>

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3134, 2877	F	<p>Analyzing multiple channels with the same analysis is possible through the Analyze dialog (Additional Channels Tab). Upon selecting multiple channels, the software correctly analyzes all channels. However, the graph page did not automatically update with changes from the analysis. This has been corrected to automatically update the graph page upon completion of analysis.</p> <p><b>Work-around:</b> Minimize the graph page or force a redraw by resizing the graph window.</p>
3138	F	<p>Reanalyzing channels whose analysis modules contain calculated marks (validation marks placed based on another mark's location) could result in Ponemah closing. An example of calculated marks would be the % Recovery marks from the LVP analysis module. Several factors contribute to this error including reanalyzing when previous calculations have not finished as well as computer resources available to Ponemah.</p>
3148	F	<p>Overwriting a marks section name would result in an incorrect name being placed in the log file. For example, if a marks section was saved (example, Test1), changes made, and a new marks section saved (example, Test2), file names are logged as expected. This information would be listed in the log file under "Reference" and "Review". However, if a third marks section is saved with the same name as the first marks section (Test1), the input in the log file would not update appropriately. This has been corrected to appropriately update marks sections.</p> <p>Additionally, the Review and Reference input names in the log file have been expanded for clarity. These have been updated to "Review Mark Section Saved" and "Reference Section".</p>
3154	F	<p>Performance issues were linked to the Change Notes feature. To increase speed, Change Notes were removed (see #3082, 4.80-SP2). For systems using the Data Security Option, the ability to add a note to a channel that has been modified was added. Prior to saving a marks section, a user is required to select a reason from the Audit Reason Codes list or provide user entered information. A dialog will be presented to the user for each channel that has been modified. The ability to apply a signal note to all channels is also available. If a reason is not entered, the Marks section will not be saved. Additionally, this information is added to the log file.</p>

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3151	F	<p>The Advanced Options tab in the Data Parser dialog allows channels to be disabled. This allows users to exclude a channel(s) when parsing data.</p> <p>An issue existed where channels 32, 64, 96, and 128 were disabled by default. These channels could be selected for purposes of parsing but when saving the file, the option would default back to disabled (for these channels). This issue extends to any protocol file saved in 4.80, prior to service pack 4 (including FullDemo.pro and Default.pro). Any review file created from an incorrect protocol file will have those channels disabled.</p> <p>To fix protocols from within a review file (non-Study), make the changes to the channel selection for Parser and export the protocol. The protocol will now be correct for future reviews using this protocol. A new review may be created by performing a replay of the data. If using the Study Protocol Option, this will not fix previously collected data.</p>
3157	F	<p>There was a potential for Ponemah to close unexpectedly if saving a marks section for a large file immediately after opening the Review file.</p> <p><b>Work-around:</b> Allow all calculations to complete before saving a marks section.</p>
<b>Summary Report Option</b>		
3111	F	<p><b>Note:</b> This issue was fixed in 4.80-SP3. However, SP3 was not distributed. Instead, this single fix was added to SP4 for distribution.</p> <p>The following defect was fixed in the Summary Report Option: Operation of Summary using data generated through review can result in errors in the sequence of data in the Summary Report and in any exported Group Summaries.</p> <p>The factor that increases the likelihood of encountering this error is the use of multiple Data Reduction Intervals. If a single Data Reduction interval is used, as may be the case in a Tox Study, this error will not be encountered.</p> <p>This error will not be encountered when using data generated through acquisition or replay, only review data is suspect.</p>