

## Product Release Notes

**Product:** PONEMAH Physiology Platform  
**Model:** P3 Plus  
**Version:** 4.90-SP4 (Service Pack 4 for version 4.90)  
**Build:** 005198-004 (CD Build)  
**Date:** February, 2010

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 4.90-SP4 indicate revisions made to the P3 Plus core application since release of P3 Plus Version 4.90-SP3 (limited release, not distributed) as well as the V10.09 Analysis Modules release. 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 subsequent Service Pack CDs. Release Notes for 4.90-SP3 have been included in the SP4 release since the SP3 release was not distributed. 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>		
3288	F	<p>Railed data could result in an offset in the data signal. If incoming data exceeded the span (low and high limits set by the hardware) resulting in the signal railing, an offset from baseline would occur if a <b>Low Pass</b> filter was enabled in the software for that channel. If no filter was enabled, the signal would return to the expected baseline once it recovered from the over range condition.</p> <p><b>Work-around:</b> Disable the <b>Low Pass</b> filter in Ponemah.</p>
<b>Jacketed External Telemetry (JET)</b>		
3466	F	<p>A communication issue existed where data could be discarded or displayed on an incorrect channel. The likelihood of this issue occurring was extremely remote since a number of specific conditions needed to be met in order to create this issue. Additionally, this issue is theoretically not plausible in any system configuration other than version 4.90-SP2 (Service Pack 2).</p> <p>The triggers for this issue to occur are as follows:</p> <ul style="list-style-type: none"> <li>• A noisy Bluetooth environment where disconnects would be vastly increased resulting in greater amounts of data needing to be buffered.</li> <li>• A disconnect of a JET device followed by a reconnect of the device in a very short period of time.</li> <li>• 4.90 SP2: With Service Pack 2, the identified period for reconnects would be within 1-4 seconds. All other versions are in the magnitude of microseconds, thereby eliminating the possibility of this happening in any other version.</li> </ul> <p>If the above conditions are met, the data would be affected in the following manner:</p> <ul style="list-style-type: none"> <li>• If multiple sample rates exist, the channels sampled at the <b>Primary</b> A/D rate will display invalid data every 20ms. Channels sampled at the <b>Secondary</b> A/D rate will display data from another channel.</li> <li>• If all channels are sampled at the Primary sample rate, 100ms of data will be discarded which would result in lost time and would compromise alignment of data if the <b>Sync</b> feature was being utilized.</li> </ul>

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Study Protocol Option		
3469	F	Previously, the ability to verify a Study configuration prior to acquiring data was not possible through the Study Log files. This Log information was only displayed after the first acquisition was performed on a workstation. An Export button has been added to the Manage Studies dialog. This will allow the Study setup information to be exported to Excel (not Access) for review prior to any data being collected.
3475	F	If a <b>Sync</b> was performed and one of the files that was to be copied was not present in the specified location (for example, .EVT or .SIG file), a message was posted alerting the user to that fact that the file(s) did not exist. However, the message did not inform the user that no files would be copied. The message has been expanded to notify the user that no data will be copied as a result of not finding all files.
3478	F	If a Network Study was configured, and one of the workstations configured had not run an acquisition, the study directory (folder structure created in Windows) was not created. If <b>Synchronize Entire Study</b> was performed by that workstation, no data would be copied to the workstation. However, when a Review was performed, the directory would be created and the appropriate files copied for that Run. After a Review, a <b>Synchronize Entire Study</b> could be performed and would function as expected.
Review		
3490	F	Ponemah would close unexpectedly when exiting Review due to graph pages being configured to a size not recognized by the system. If graph pages were sized such that only the title bar or a portion of the title bar was visible (scaled to minimum size possible), Ponemah would close upon exiting Review.
3515	F	<p>Older versions of Ponemah created a <b>.JMP</b> file (Jump file) which was separate from other files. In recent versions of the software, the Jump file has been appended to the <b>.RAW</b> file. An issue was reported where Ponemah would post a “PPP3.exe” error alerting the user that Ponemah must shut down when the Review file was opened. This was due to the corruption of the separate <b>.JMP</b> file from the older version of Ponemah. A message has been added to notify the user that the <b>.JMP</b> file has been corrupted.</p> <p>To correct the corrupted <b>.JMP</b> file, delete or rename the <b>.JMP</b> file in the directory and reopen the Review file. Review will create a new <b>.JMP</b> file if no file exists and the Review file will open as expected.</p>

Reference #	Type of Change	Key: N = New Feature; E = Enhancement; F = Fix Description
OpenART		
3516	F	Data could rail (positive or negative) when a card reset occurs on the PCI or PCIe card. This rail would occur at one second boundaries after a reset on any channel set to a <b>Secondary</b> A/D sample rate.
ACQ 7700 Signal Conditioners		
3480	F	Setting the <b>High Pass</b> filter in the signal conditioner to <b>Probe</b> should have defaulted to DC. However, a 0.05Hz High Pass filter was enabled when selecting the <b>Probe</b> setting. This has been corrected to default to DC.
3481	F	When <b>Probe</b> was set for the <b>High Pass</b> filter, an incorrect value of 300Hz was placed in the log file. This has been corrected.
3502	F	Changing <b>High Pass</b> filter settings would result in an offset. To create the issue, a <b>High Pass</b> filter must be selected (something other than <b>DC</b> or <b>Probe</b> ). If the filter setting was then changed to <b>DC</b> , an offset from zero could be seen on the signal.
Open/Miscellaneous Issues		
3470	F	If logged on to Windows as a User under the DSO environment (Data Security Option), Ponemah will close if using the <b>Copy Previous Study</b> option. A Windows C++ Runtime Error is posted and Ponemah will close upon clearing the message.

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3196	F	<p>XP Service Pack 3 has been tested and approved for use with Ponemah. However, an issue with registry key permissions may result in errors when working with Ponemah as a result of loading XP Service Pack 3 when logged on to the workstation as a User to Windows.</p> <p>Multiple errors may be presented when trying to start Ponemah or when working with DSI Reporting:</p> <p>Version 4.80</p> <ul style="list-style-type: none"> <li>• Error 29:5 has occurred. 3502 Protocol.c</li> <li>• No license file available, please select a license file</li> <li>• Error 1:29 has occurred. 1643 Protocol.c</li> <li>• Possible errors reported for MSDE not running properly</li> </ul> <p>Version 4.90</p> <ul style="list-style-type: none"> <li>• No registry entries found. Cannot open P3 Mail Slot</li> <li>• Unable to create registry entry, verify user is a member of the Power Users group. Exiting 5 - Access is denied</li> </ul> <p>DSI Reporting</p> <ul style="list-style-type: none"> <li>• Message: Requested registry access is not allowed</li> </ul> <p><b>Work-around:</b> If the User or User Group is granted Read/Write access to the “<b>Ponemah Physiology Platform</b>” key in the registry, Ponemah will start without errors and DSI Reporting will be able to access necessary tables. Note that these permissions should propagate to Child Objects within the <b>Ponemah Physiology Platform</b> key.</p>
2881	F	<p>If an acquisition is run and the generated files are copied to another location upon completion, running a new acquisition with the same name will overwrite the files in the directory where data were copied. For example, files created were defaulted to LSS_Data. Upon completion of collection, files are moved to another directory. If an additional acquisition is performed, data will not be written to the default LSS_Data directory but will overwrite data in the new location where copied. No error message is presented to the user alerting them that files are being overwritten.</p>