

Product Release Notes

Product: PONEMAH Physiology Platform
Model: P3 Plus
Version: 4.80-SP6 (Service Pack 6 for version 4.80)
Build: 004939-005 (CD Build)
Date: December, 2009

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 4.80-SP6 indicate revisions made to the P3 Plus core application since release of P3 Plus Version 4.80-SP5 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 4.80 CD and subsequent Service Pack CDs. 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>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
Study Protocol Option		
3288	F	<p>Analyzing a signal that contained railed data may have resulted in a shift in the signals baseline. If a section of data was railed (flat line at the top or bottom of the scale), applying a Low Pass filter could have resulted in the signal not returning to its original baseline after the signal came back on line from the railed position. This shift in baseline could have been both positive and negative. This issue occurred randomly only in Review when a Low Pass filter was enabled.</p> <p>IMPACT: This would affect presentation signals, trend graphs and derived (calculated) data where the derived data was dependent on a baseline reference as opposed to a reference on the signal itself (for example, Q wave for ECG analysis is considered the iso-electric point).</p>
3391	F	<p>The Study Data Log 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 Experimental Logs through the ODBC interface. However, if the ODBC Interface (Application Configuration menu) was disabled and no Excel or Access files were generated, information for the Data Log did not update. This has been corrected to allow the ODBC Interface to be disabled while still maintaining updates to the Data Log.</p> <p>IMPACT: Only affects data placed into the Data Log. This does not impact any other section of the software.</p>
3461	F	<p>If a user performed the Synchronize Entire Study function while logged on as a User to Windows, the sync would not be performed resulting in no data being copied over due to incorrect impersonation for the User accounts. However, if logged on as an Administrator, the synchronization occurred as expected.</p> <p>IMPACT: Files are copied to the temporary directory, P3PlusTempDir, impersonation is performed and files are copied to the desired directory under the P3 Administrator account.</p>

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3463	F	<p>When synchronizing study data, the Study Data Logs were not synchronized and combined with other Data Logs from other workstations. The Data Log was originally designed to reside locally. This has been updated to include the Study Data Log information when synchronizing data from workstations.</p> <p>IMPACT: Study Data Log information will now be combined in a single database table and include information from all workstations when sync is performed.</p>
3467	F	<p>If mapped drives were configured in the Study Search Paths dialog and these mapped drives later removed from Windows, performing a Synchronize Entire Study would result in Ponemah closing since it no longer had access to the mapped drives.</p> <p>IMPACT: No impact on functionality. This is limited to an error check when searching for the missing drives.</p>
3448	F	<p>A “?” was displayed next to files in the Verify Files dialog (if using the Data Security Option) after performing a Synchronize Entire Study when a check mark indicating that the files have not been modified should have been displayed. This was a result of the signature files not being copied over.</p> <p>IMPACT: No impact on functionality. This corrects for broken call to copy signature files when the security option is enabled.</p>