

## Product Release Notes

**Product:** PONEMAH Physiology Platform  
**Model:** P3 Plus  
**Version:** 4.60-SP4 (Service Pack 4 for version 4.60)  
**Build:** 005695-002 (CD Build)  
**Date:** December, 2009

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 4.60-SP4 indicate revisions made to the P3 Plus core application since release of P3 Plus Version 4.60-SP2. Please note that SP3 contained a customer specific request and was therefore not distributed. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 4.60 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><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
<b>Study Protocol Option</b>		
3323	F	<p>A condition existed in which data from separate studies may have been co-mingled in the Study Database when using a common workstation. For the condition to occur, <b>all</b> of the following products and circumstances must be present:</p> <ul style="list-style-type: none"> <li>• Use of Ponemah versions 4.30, 4.40, 4.50 or 4.60 (including any related service pack).</li> <li>• Backing up and restoring <b>Study</b> database as part of your process.</li> <li>• Execution of a Save Run while in <b>Review</b>, <b>Acquisition</b> or a <b>Replay</b> without exiting Ponemah after performing the Restore.</li> <li>• Use of the information in the SQL Server database through any means (<b>Summary Option</b> or directly querying the database).</li> </ul> <p><b>Description of Mechanism Causing the Condition:</b> Consider a workstation that has two studies, <b>Study A</b> and <b>Study B</b>; where <b>Study A</b> is the current study. If <b>Study B</b> is restored, the system will be in a state where the condition could occur. If an <b>Acquisition</b>, <b>Replay</b> or a <b>Review Save Run</b> is performed, derived data from the Run will be incorrectly saved in <b>Study A's</b> database instead of <b>Study B's</b>. When a report is generated from <b>Study A's</b> SQL database, the report will consist of data from <b>Study A</b> with one run or more runs replaced with data from <b>Study B</b>. When a report is generated from <b>Study B's</b> SQL database, it will not contain the data that was written into <b>Study A's</b> database.</p> <p><b>NOTE:</b> If <b>Study B</b> was previously on the workstation but <b>Deleted</b> from <b>Manage Studies</b>, restoring <b>Study B</b> will not affect <b>Study A's</b> database.</p> <p><b>Methods to Confirm the Condition:</b> In addition, presence of the all of the above products and circumstances does not always result in the condition. For definitive determination, study databases may be checked for errors by restoring the databases to be examined and running a Database Scanning Utility (DSU) from DSI. The utility will not modify information, it will only report on the database status. Please contact DSI Technical Support Services to request the Database Scanning Utility.</p> <p><b>Correcting Affected Studies:</b> An affected study can be corrected by the following procedure:</p> <ul style="list-style-type: none"> <li>• Restore the study (if this hasn't already been done).</li> <li>• Use the Data Manager feature in Ponemah to move the Review and RAW file (.rvw and .raw) to the local workstation.</li> <li>• Exit Ponemah, and restart Ponemah (the restored study is now the active study) or reselect the Study in the Manage Studies dialog.</li> <li>• Open a review session on the restored study and save a new Run (this action updates the database table with the correct derived output information).</li> <li>• Generate a new Summary report.</li> </ul> <p><b>Work-Around:</b> The following steps will prevent the condition from occurring in future studies. When restoring a study that is not the current study, close the Ponemah application or reselect the Study in the Manage Studies dialog. The restart of the application refreshes the settings which enable Ponemah to correctly identify the restored study as the active study, ensuring that data will be saved into the correct study database.</p>

Reference #	Type of Change	Key: N = New Feature; E = Enhancement; F = Fix
		Description
Open or Miscellaneous Issues		
3460	F	If a study is created with a protocol that has more channels enabled ( <b>Channel Input Setup</b> ) than hardware channels configured, performing an acquisition will result in no data being written to the database.