

Product Release Notes

Product: PONEMAH Physiology Platform
Model: P3 Plus
Version: 5.00-SP2 (Service Pack 2 for version 5.00)
Build: 006328-002 (CD Build)
Date: April, 2012

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 5.00-SP2 indicate revisions made to the P3 Plus core application since release of P3 Plus Version 5.00. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 5.00 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: Ponemah 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 Ponemah, 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 Ponemah. 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	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
Ponemah Core - General			
3447	F	N/A	<p>Events are manually placed in the data to note points of interest. Depending on the amount of time displayed, multiple events may be viewed in a graph page. If the graph page was resized, the events on the graph may have switched positions. The shift in positions was solely graphical and did not affect how the event was logged in the data or used by other parts of the system.</p> <p>This has been corrected so that resizing the window has no effect on event position in the graph page.</p>
3680	F	N/A	<p>The Combine Raw Files function allows two or more RAW files to be combined. In the event of a catastrophic failure, acquisition is stopped unexpectedly. To continue the acquisition, a user must create a new file name and continue collecting data which creates two sets of files for a single collection period. These two sets of files must be managed when reporting results of the data. This feature allows the files to be combined for purposes of reporting.</p> <p>If data breaks existed in the files that were being combined, the final, combined file would not include all RAW data from the disparate files. This has been updated to include all data when combining files that contain data breaks.</p>
3682	F	N/A	<p>The ability to enter special characters in Ponemah dialogs is often restricted. The special characters ‘.’, ‘-’, and ‘,’ (period, minus sign, and comma) have been added to the Experimental Protocol Header dialog to accommodate common naming and formatting conventions.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3685	F	N/A	<p>If a workstation was connected to the network, loss of that network connection during acquisition would result in a loss of connection to the Ponemah SQL database. A Settings Helper message was posted alerting the user to this issue. Acquisition would continue, however no additional information would be written to the database until acquisition was restarted.</p> <p>Corrections have been made to ensure the connection to the database is preserved and that data continues to be ported into the database.</p> <p>It is recommended that workstations are not connected to the network for protection against network updates (pushes) while acquiring data.</p>
3688	F	N/A	<p>Ponemah Sync functionality allows synchronization between acquisition devices such as OpenART telemetry and ACQ7700. This functionality has not changed. However, the driver installation has been updated to better accommodate Windows 7 Operating Systems.</p>
Data Review			
3683	F	N/A	<p>Bad Data Mark Percentage provides the ability to view the percentage and distribution of data removed by Bad Data Marks. Erroneous values would be calculated if Parser Segments were contained in the Review file and a Parser Segment spanned a section of data that was removed using the Bad Data Mark feature. These values were typically quite obvious and often times were displayed as very large negative values.</p> <p>This has been corrected to properly calculate the values based on the valid data available from the Parser Segments.</p>
Data Security Option (DSO)			

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3724	F	N/A	<p>Logging into Ponemah with an incorrect password could result in an incorrect user name being logged under the following conditions:</p> <ol style="list-style-type: none"> 1) An incorrect, eight character password is entered when Ponemah is first started. 2) The correct password is then entered. 3) One of the following acquisition engines is used <ol style="list-style-type: none"> a. Versions 4.70-4.90: OpenART, ACQ16-USB-OpenART, ACQ7700USB-OpenART or JET. b. Version 5.00: Any interface except ACQ-16EPP. <p>If the above conditions are met, The Data Security Option will record the Windows Login instead of the User login from the Data Security Card. This will result in the Windows login being recorded in the Application log for functions such as opening a protocol file; starting or stopping a Review session; starting or stopping Replay session; and saving files. Additionally, the Experimental log will display all configuration information at startup with the Windows Login.</p> <p>However, the problem corrects itself when a user is forced to enter their PIN for any reason. At the point of entering the PIN, any additional information logged into the log files will have the correct User login information from the Data Security Card.</p> <p>Work-around: After entering the correct PIN (with the above conditions met), remove the card and reinsert the card to prompt the user to enter the PIN again. Entering the PIN correctly a second time will result in correct behavior from the system and all log information will be updated with the correct User information.</p>
ECG Pro			

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
3692	F	N/A	<p>Analyzing data in Review with the ECG Pro option may have resulted in the T Peak mark being placed prior to the S Wave End mark. The frequency of this issue occurring was very low and would lead to the Ponemah program closing unexpectedly during analysis. This issue has been corrected.</p> <p>While this issue exists in ECG Pro, corrective measures have also been placed in the ECG algorithm to prevent the program from closing. See also #3696 in the Analysis Modules Release Notes.</p>
DSI OpenART			
N/A	N/A	N/A	<p>OpenART has been updated with several fixes and enhancements. See the separate OpenART release notes for details (document 392-0040-007).</p>
3701	F	N/A	<p>The Ponemah system may have experienced an infrequent shutdown when using the HD series transmitters. The error “DSI0897: Time error too large” would be posted and acquisition would stop.</p> <p>Changes have been made to correct for this error condition in order to preserve acquisition. If this error is encountered, a gap of up to 20 seconds may occur before data is again being collected and saved to disk. However, acquisition will not stop.</p>
Jacketed External Telemetry (JET)			

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3077	F	N/A	<p>The Pressure Transmitter Calibration dialog allows the calibration values for the blood pressure transmitters to be entered and used by the system. The text box allows two decimal places to be entered. When saving the values and reentering the dialog, only one decimal place is saved. This is expected behavior and values are rounded properly to the tenths decimal place which matches the precision specified on the transmitter packages.</p> <p>An issue did exist that may have prohibited the user from entering the entire transmitter calibration value. The text box saved two “spaces” which were not visible to the user. Left clicking the mouse in this text box did not select these “spaces” which were then included in the calibration string, limiting the number of values that could be entered. This issue was not seen if a user Tabbed into the text box or double-clicked into the text box. These actions selected the entire contents of the text box and the “spaces” would have been highlighted and overwritten by the user entered calibration value.</p> <p>The spaces have been removed to allow consistency when typing in calibration values.</p>

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
3687	F	N/A	<p>A series of warnings have been added to ensure that users are aware of the implications when performing acquisitions or review sessions without properly using the eAPR source. A warning will be posted when attempting to start an acquisition if:</p> <ol style="list-style-type: none"> 1) No eAPR channels are defined 2) An eAPR is not assigned to BARO (Barometric Analysis Module) 3) One or more Blood Pressure (BP) channels are not associated with an eAPR channel <p>When opening a Review file, a warning will be posted if a BARO channel exists for the Review file but the BARO channel is deselected and not brought into the Review session.</p> <p>In all cases above, not using the eAPR will result in values (derived parameters) that have not been properly compensated for differences in barometric pressure.</p> <p>The version of the BP analysis module contained within this Service Pack (SP2) is version 5.00. If prior versions of the BP module are used in conjunction with this Service Pack, a message will be posted alerting the user that the earlier version of the BP module does not permit verification of the ambient pressure configuration but prompts the user to review the current setup.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3699	F	N/A	<p>Devices lost during acquisition (signal out of range) have been designed to reconnect and join the acquisition when found. It was reported that devices occasionally would not reconnect after connection had been lost.</p> <p>“Search connections” are created after closing the JET Device Configuration dialog. These are the connections used to search for and bring lost JET devices back online. After investigation, it was discovered that every time the configuration dialog was opened and closed, new “search connections” were created. The system supports a maximum number of “search connections”. Opening and closing the dialog could create more connections than are supported by the software resulting in lost JET devices not being able to reconnect. Modifications have been made to prevent the number of “search connections” to exceed the maximum limit to ensure devices are reconnected.</p> <p>Work-around: This issue can be prevented by configuring the system and closing down between each acquisition. This will ensure that the above issue does not occur if the fix is not implemented.</p> <ol style="list-style-type: none"> 1. Power cycle all equipment 2. Run the JET Bluetooth System Optimizer 3. Close and Open Ponemah prior to starting an acquisition
3700	F	N/A	<p>All TCP/IP functionality could be lost on the host workstation but only in the presence of #3699. If the issues described in #3699 occurred, further errors may have occurred resulting in all search connections being shut down and complete loss of reconnect functionality.</p> <p>Changes to correct #3699 prevent these further issues from occurring.</p>
ACQ 7700 Signal Conditioners			

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3684	F	N/A	<p>The Universal XE Signal Conditioner, model 13-7715-59, did not reset the High Pass filter to DC when using the Reset Channel Settings. This function is intended to return the channel to the default setting which includes disabling the High Pass filter. This issue could be easily seen when performing a calibration since the difference between the High Cal and Low Cal values would be minimal and may have resulted in an invalid calibration message.</p> <p>This has been corrected to properly reset the High Pass filter settings to DC when using Reset Channel Settings functionality.</p>
Study Protocol Option			
3679	F	N/A	<p>Clicking on the Automate button to initiate a script, while in the Study Automation dialog, resulted in the following error being posted:</p> <p>Scripting Error: ActiveX component can't create object:'Useraccounts.Commondialog'</p> <p>This has been corrected to allow the Automation scripts to be utilized as expected.</p>
3725	F	N/A	<p>If the Enable Day 0 function was not enabled and Export Study Setup was selected from the Manage Studies dialog, all positive study days would be listed as one less than they should have been in the exported data. This has been corrected.</p> <p>Note: If Enable Day 0 was selected as part of the study configuration, the exported data would be represented correctly.</p>
DSIReporting (DSIR)			
3702	F	N/A	<p>DSIReporting, version 2.1 (2.0.1.5 listed in Help – About DSI Reporting), has been tested and approved for use with Microsoft Windows 7 operating system. Changes to the install were performed to account for Windows 7 security.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3703	F	N/A	<p>DSIReporting, version 2.1, has been tested and approved for use with Microsoft Word (Microsoft Office 2010). Changes to the install were performed to support Office 2010, in addition to the previously supported version of Word.</p>
3705	F	N/A	<p>The last label used for segment identification may have been truncated. An error with the margin calculation may have resulted in the last label being truncated on the X axis when a graph was plotted or a report was generated.</p> <p>The margin calculation has been updated to prevent labels from being truncated.</p>
3704	F	N/A	<p>An error in ordering data existed which may have led to column headers and data not aligning properly in the generated report. Column order was not explicitly ordered by the software which could cause entire columns of data to shift to incorrect column headers. This error was not consistent and occurred very infrequently (see also 3715 and 3716).</p> <p>The software has been changed to explicitly order columns to remove this risk.</p>
3707	F	N/A	<p>The Export to .txt and Export to Excel functions (Tools pull-down menu) may have reported errors when selected, ultimately preventing access to this functionality. This issue has been corrected and users may now select and use the export options as expected.</p>
3708	F	N/A	<p>Additional graphing options were added with version 2.0. To enable or disable these advanced features, users must select Basic or Advanced graphing capabilities from the Graphing Library menu (Options pull-down menu).</p> <p>When selecting Basic mode, Standard Deviation and Standard Error bars were not always present when the report was generated or when using the Plot to Document function. Corrections have been made to ensure that these bars are present on the graph when outputted to a document.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3713	F	N/A	<p>The option Include Date/Time Footer is available under the General Options header. This function places the date and time that the report was generated in the footer of the pages in the report.</p> <p>When this option was selected in version 2.0, the date and time were only placed in the footer of pages containing tables. The date and time were not included on pages containing graphs. This has been corrected to place the date and time in the footer of pages containing both graphs and table information.</p>
3714	F	N/A	<p>Data may be exported using one of the export functions listed under the Tools menu. This sort order for the output was fixed but the sort order may have appeared to be random when performing the export function. This was due to the previously defined sort order for this function.</p> <p>The sort order has been updated to be more user friendly when reviewing the exported data. The updated order is as follows: Subject Name, Gender, Group ID, Dose Order, Test Day, Workup Order, Column ID</p>
3715	F	N/A	<p>The Summary Style 3 Report Element had a very small potential to result in ordering issues for parameters. The ordering of the data may not have been ordered properly which could be easily seen in the graphics presentation for that parameter (see also 3704 and 3716).</p> <p>This has been resolved to ensure proper ordering of parameter information.</p>
3716	F	N/A	<p>The graphical presentation for a given parameter may have been incorrect based on parameter ordering. This issue is related to 3715. If the incorrect ordering was passed from the Summary Style 3 element (issue 3715), the graph output would be noticeably incorrect. The fix implemented for 3715 corrects for this issue (see also 3704). However, additional filtering to ensure proper ordering of the data has been added to the graphical component.</p>

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix
			Description
3730	F	N/A	Double left-clicking the mouse on a Template to open the Manage Templates dialog would result in an error if the dialog was closed without making any changes. An error message would be posted stating that an unhandled exception had occurred. This has been corrected.
3731	F	N/A	If Subjects were deleted from the Gender filter such that no Subjects were available, an error message stating that an unhandled exception occurred would be posted after subsequent actions. This has been corrected.

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3733	F	N/A	<p>Entering DSIR for the first time to report data would correctly report information for all Runs selected within Study. If no changes were made to existing runs after the initial report, no issue would exist.</p> <p>If users exited DSIR and manually changed Runs that were previously reported (through Ponemah Study Protocol Option), entering back into DSIR would not result in the new Runs being properly updated and reported. The previously selected Run would still be used for reporting (unless new Runs were created-see below).</p> <p>However, if new Runs were created, such as collecting data on a new Study Day, entering DSIR and reporting for all Runs would update properly. This issue only occurred if different Runs were selected for reporting, after a report was generated, and no additional Runs created for that Study.</p> <p>This issue has been corrected to properly update Report Runs within DSIR if changes to the Runs are made within Study (Ponemah). Queries for updates to the currently selected Runs are now performed every time DSIR is opened. This will result in a refresh and pull in all current Run information. Also, when working with a Study within DSIR, selecting a different Study from the Study pull-down list and reverting back to the initial Study will also result in queries for any changes to Run information. Finally, the Refresh button (added next to the Study pull-down list in DSIR) will allow the user to pull in any changes to Run information without the need to close DSIR or select other studies.</p> <p>Work-around: Support Tools, under the Help pull-down menu, can be used to clear all information currently held within DSIR. By using the Clear All Study Level Data function, all currently held Run information will be cleared which will automatically reset all Run information when a Study is selected. However, this will also result in all previously saved Profile information being removed from the system permanently. Any previously stored Profile would then need to be recreated.</p>

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
Open Issues and Miscellaneous Items			

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
N/A	E	V50-SP1	<p>Updates have been added to support Gemalto .NET v2+ Data Security Access cards. The previously supported cards, Cryptoflex32K cards, are no longer available. All shipments that include Data Security Access Cards after May 1, 2011 will contain the new .NET v2+ access cards.</p> <p>Functionality of the .NET v2+ cards is identical to the previous cards; no differences in user interaction will be seen. Both cards are still supported within Ponemah and may be used on the same secured Ponemah system.</p> <p>This service pack is intended for use with Ponemah version 5.00 with Windows 7 and Windows XP (Service Pack 2 or 3) 32 Bit Operating Systems only. Windows XP, Windows XP Service Pack 1, and Windows 2000 Operating System are not supported.</p> <p>Changes to the 5.00 software configuration to support the new cards include an update to the P3Security.dll file for Windows 7 and Windows XP Service Pack 3 Operating Systems. For Windows XP Service Pack 2, additional drivers are needed to support the .NET v2+ cards.</p> <p>Support for the .NET v2+ cards is also available for Ponemah versions 4.60, 4.70, 4.80, and 4.90 for the Windows XP Operating System. Please consult the version specific Release Notes for more information. All updates are available on version specific CDs or in downloadable Zip files. If a version prior to 5.00 is needed, please contact Technical Support at Support@datasci.com.</p> <p>Downloads for all service packs may also be obtained by visiting our secured website at https://www.datasci.com/portal/users/. Please see the v50-SP1_Install.pdf (or appropriate service pack version) for more information.</p> <p>NOTE: Windows 7 or Windows XP Service Pack 3 is the recommended configuration for Ponemah version 5.00.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
N/A	N/A	N/A	<p>Scaling graphs, moving graphs and performing other similar activities while acquiring data using Windows 7 may have resulted in the program becoming unresponsive. This issue was found internally and was linked to Window's Themes. This issue was only found to occur on several, specific laptop configurations containing specific BIOS versions.</p> <p>Changing the Theme back to Window's Classic resolved this issue. It was found that upgrading a combination of the BIOS and video drivers also corrected this issue.</p>
N/A	N/A	N/A	<p>Service Pack 1 for version 5.00 added supports for the Gemalto .NET v2+ Data Security Access cards (see above). This update slightly limited user interaction with access cards that had not been previously configured in the system.</p> <p>After making the system secure through the P3 Plus Admin program, inserting an access card <i>after</i> entering the Setup Access Card menu posts the error message, "authorization failed 57004 security.C". This prevents the access card from being initialized and assigned to a user but does not affect the card or system in any way.</p> <p>This issue may be avoided by following the steps below for cards that have not been initialized:</p> <ol style="list-style-type: none"> 1. Run the P3 Plus Admin program and secure the system (or once secured, simply log into the P3 Plus Admin functionality) 2. <u>Insert access card prior to entering the Access Card Setup dialog</u> 3. Enter the default PIN number provided in the manual in the login screen 4. Select the Tools pull-down menu and Access Card Setup dialog.

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
3732	F	N/A	<p>From the Options pull-down menu, attempting to change the Graphing Library to a new state (Basic or Advanced) would result in an error message being posted stating that an unhandled exception had occurred.</p> <p>This issue has not been corrected but a work-around exists. If Microsoft Word is run as an Administrator, users may toggle between Basic or Advanced with no issues.</p>