

Product Release Notes

Product: PONEMAH Physiology Platform
Model: P3 Plus
Version: 4.80-SP5 (Service Pack 5 for version 4.80)
Build: 004939-004 (CD Build)
Date: March, 2009

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 4.80-SP5 indicate revisions made to the P3 Plus core application since release of P3 Plus Version 4.80-SP4. 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 #J02910, Build Version 4.80.

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>
Ponemah Core-General		
3227	F	<p>The Activity signal was collected incorrectly. The value listed would read 512 and, if graphing, the signal would appear as a flat line (railed signal). This issue occurred as Ponemah was collecting the data, not analyzing. Therefore, there is no fix for previously collected data.</p> <p>This occurred in versions 4.80 and 4.90. The issue of saving data incorrectly has been remedied.</p>
3161	F	<p>Modifying the OpenART settings after saving could result in an incorrect setup file. The scenario to create this issue would be to configure the telemetry devices, save the protocol and then reenter the Edit DSI Setup menu and make changes to the configuration. If modifications were made to the transmitter information, the system did not properly handle the new channel configuration. This may have been seen by viewing the Channel Input Setup menu. Incorrect channel information or multiple Ambient pressure channels may have been displayed.</p> <p>NOTE: Incorporating this fix will result in label information or other settings not being recalled from the 7700 Amplifier Setup menu, when loaded. Entering this information after implementing the fix will correctly save this information.</p> <p>Work-around: If this fix is not implemented, the user may delete the associated .amp file and reconfigure the settings if changes are needed or do not make modifications in the Edit DSI Setup menu after saving the protocol. If using the Sync functionality, configure the OpenART sources first.</p>
3253	F	<p>Various error messages are placed in the Application log file, as well as presented to the user, as they occur during system operation. Several messages were placed in the log file but not presented to the user. These messages are as follows:</p> <ul style="list-style-type: none"> • Some DSI sources did not start • No DSI source available • DSI Aquisition Error • DSI Aquisition Error(unknown) <p>The messages have been updated to be presented to the user as well as placed in the log file.</p>

Reference #	Type of Change	Key: N = New Feature; E = Enhancement; F = Fix
		Description
3252	F	Added error messages generated by the system and placed these in the Application log as well as in a dialog that is presented to the user when the error occurs.
3268	F	When synchronizing hardwired and telemetry signals using a Dell 755 PC, the system would ultimately lose its sync. This was a result of an incompatibility between the PC's processing speed, the sync card and the software. The software was requesting information faster than the sync card could answer the request which resulted in the information not propagating through the system as expected. This could be seen by opening Window's Event Viewer. Information would be logged in Event Viewer denoting that 7700 ticks have stopped/started.
3240	F	ECG did not trigger during acquisition, therefore, no derived/calculated data was displayed. Subsequent post processing of the data in Replay or Review performed as expected with no issues. This has been corrected so that ECG analysis triggers during acquisition. This also corrects for a potential issue within the Blood Pressure analysis. When running an acquisition using BP, data had the potential to be marked as noise if Noise detection was enabled. NOTE: This issue occurred in version 4.80 Service Pack 4 only.
Study Protocol Option		
3213	F	Zeros were reported for Data Reduction lines in the Summary/Report Setup box when in the Run Study dialog even though valid data existed. This occurred when Subject IDs began with a number. This issue did not occur if Subject IDs started with an alpha character. This has been corrected to accept Subject IDs beginning with a number.
3224	F	Derived and Data Reduction values would not properly synchronize with other workstations when performing a network study when Subject IDs began with a number (see Tracker #3213). No error would be reported to the user and the user would only be alerted to this issue if attempting subsequent syncs, since this action would fail. This has been corrected.
Data Review		

Reference #	Type of Change	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3191	F	<p>Analyzing data between Parser View Mode and normal view (all data) could potentially result in an error message being posted stating that an issue in allocating memory exists. This unlikely scenario is only recreated by analyzing data in Parser View mode, switching back to normal view and analyzing data and then repeating this process over and over. Eventually, the system will post an error message.</p>
3261	F	<p>Ponemah would close if a cycle with partial validation marks was added to the template library and analyzed. The scenario where partial validation marks existed and Ponemah closed involved Parser Segments. If a Parser Segment was created that intersected a cycle (the full cycle not within the Parser Segment), entering Parser View Mode would remove some or all validation marks from that cycle (depending on where the Parser Segment intersected that cycle) due to insufficient cycle information contained in the segment. If this cycle, with partial marks, was added to the template library, an error was posted stating, "Invalid data to setup up template". The user was allowed to continue and add the cycle to the library. If data was then analyzed using that cycle, the software would close.</p> <p>This has been corrected to not allow cycles to be added to the template library that are affected by the borders of Parser Segments which would result in insufficient cycle information being added.</p>
OpenART		

Reference #	Type of Change	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
N/A	E	<p>New transmitter definitions have been added to allow the configuration of a BPR channel (Respiration from Blood Pressure analysis module, model PNM-BPR100W) from the current pressure transmitters. The following transmitters have been added:</p> <ul style="list-style-type: none"> • TA11PA-C20-BPR • TA11PA-C10-BPR • TA11PA-C40-BPR • TA11PA-D70-BPR • TL10M2-D70-PC-BPR • TL11M2-C50-PT-BPR • TL11M2-C50-PXT-BPR • TL11M2-D70-PCT-BPR • TL11M3-D70-CCP-BPR • TL11M3-D70-CCTP-BPR • TL11M3-D70-PCP-BPR • TL11M3-D70-PCTP-BPR <p>Previous modifications to the BP (Blood Pressure, model PNM-BP100W) and BPR analysis modules have resulted in the BPR analysis being removed from the BP analysis. This change allowed BPR to be available during Review.</p> <p>NOTE: In order to utilize the new transmitter definitions, the .mdb file will need to be copied to the correct location. The default location is C:\Dataquest OpenART. Copy the file from the Service Pack over the existing file that resides in that directory.</p>
ACQ 7700 Signal Conditioners		
N/A	E	<p>The 13-7715-59 Universal XE signal conditioner has been developed and is the latest signal conditioner to be added to the 7700 series line. This signal conditioner replaces the current Universal, model 13-7715-58, and provides all of the features of the previous conditioner as well as enhancements such as four channels per unit and an expanded gain range.</p> <p>The Universal XE signal conditioner will be available in April 2009.</p>
3246	F	<p>If synchronizing OpenART and 7700 hard-wired signals, a potential to have the screen flash and display a part of the 7700 dialog existed. This occurred when the hardware was loaded.</p>
Open Issues		

Reference #	Type of Change	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
N/A	N/A	<p>The Ponemah system may appear unresponsive when saving very large Review files (RVW) while within the Study Protocol Option. The amount of time the system appears to be unresponsive is dependent on a number of factors including the size of the RVW file and the specifications of the workstation.</p> <p>When saving a RVW file, a dialog is posted showing the progress of the save. This dialog eventually disappears and is replaced by an hour glass. At this point the system appears to be unresponsive but is in fact continuing to copy additional information.</p> <p>Work-around: Do not exit out of the program or use Control-Alt-Delete. The system is still performing needed tasks. Allow the save to continue. Once all information has been saved, the system will become responsive.</p>
N/A	N/A	<p>An issue has been discovered when using the Sync functionality (OpenART plus an ACQ USB device) with a Dell 960 workstation. There appears to be a conflict with the PCIe card and the USB host controller. This conflict results in card resets and possible termination of the acquisition. DSI currently sells and tests software using the Dell Optiplex 755 series computers. No issue exists with this configuration.</p> <p>Currently, no solution exists for the Dell 960 and testing all available computer configurations is not feasible. If you have questions regarding the Sync configuration, please contact technical support.</p>