

Product Release Notes

Product: PONEMAH Physiology Platform
Model: P3 Plus
Version: 4.60-SP1 (Service Pack 1 for version 4.60)
Build: J03263 (CD Build)
Date: June, 2007

Product Release Notes for PONEMAH Physiology Platform (P3 Plus) Version 4.60-SP1 indicate revisions made to the P3 Plus core application since release of P3 Plus Version 4.60. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the Version 4.60 CD. Product Release Notes indicate only revisions to application contents that are part of CD Part #J03263 – Build Version 4.60.

Product Release Notes for P3 Plus do not include information regarding revisions of the P3 Plus Analysis Modules.

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>
Data Review		
2593	F	<p>When a Review file is opened and data is loading, right clicking the mouse on a graph page may result in the Ponemah program shutting down. This was an issue with tracking the correct location of the mouse pointer. This has been corrected.</p>
JET (Jacketed External Telemetry)		
2595	F	<p>Running greater than seven JET devices could result in the Ponemah program closing. This issue was found while verifying the system architecture. This issue revolves around allocating sufficient space to perform necessary system operations. The possibility exists where the space allocated could be exceeded. This has been corrected to avoid this potential situation.</p>
7700 Series Signal Conditioners		
2583	F	<p>Internal testing isolated an issue with the 7700 platform which resulted in information from one channel in the calibration menu switching to another channel. If a user clicked on a cell to change the value of that cell, a situation could occur where the values being reported (in the Value column) are not for that channel.</p> <p>If calibrating two distinct signals such as Blood Pressure (BP) and ECG, the incorrect values would be readily seen. For example, the calibrated value for BP (calibration values of 0 for Low Unit and 100 for High unit) would switch to another channel. When data would be acquired, values for the ECG signal would be based off of the BP calibrated value.</p> <p>Additionally, accessing and changing values in the 7700 Calibration dialog during an acquisition increases the probability of this issue occurring. Increasing the aggregate sample rate also increases the probability of this issue occurring.</p> <p>Internal testing showed that this occurrence was infrequent and it was not reproduced on computers with single core processors (only dual-core). Even though testing with single core processors did not reveal this issue, it cannot be confirmed that channel swapping would not occur on these systems.</p> <p>It has been determined that this problem has existed from the inception of the 7700 platform.</p>

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ACQ16 USB Acquisition Interface		
2581	F	<p>With the introduction of the ACQ16 USB, an updated GUI (graphical user interface) was utilized for the calibration of signals. The GUI currently supported in the ACQ7700 platform was expanded to encompass the ACQ16 USB unit.</p> <p>Several options were made available in this GUI that did not pertain to the ACQ16 USB unit and should not have been listed. In the General Tab, the ability to switch between Bi-polar and Uni-polar measurements has been removed from the GUI along with the ability to select +/-20V for the Span. Additionally, the ability to switch between Single-ended or Differential measurements has been removed from the Configuration Tab.</p>
DSI OpenART		
2604	F	<p>Support for OpenART 3.1 was available with version 4.40. A subsequent release, OpenART3.11, was developed providing support for the DSI Repeater. Ponemah version 4.60 supported the Repeater but did not provide Activity to the user. Support for Activity from the Repeater has been added. 4.60 may still be used with OpenART 3.1 if the Repeater is not used or Activity data from the Repeater is not needed.</p>