

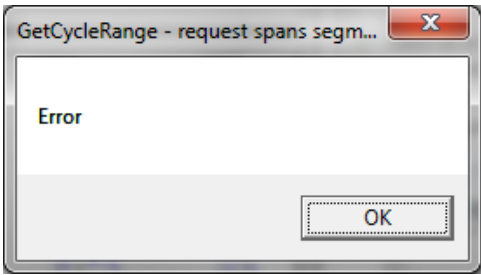
Product Release Notes

Product: Ponemah Physiology Platform
Model: Ponemah
Version: 5.10-SP3
Build: 006802-003 (CD Build)
Date: January, 2014

Product Release Notes for Ponemah Physiology Platform version 5.10 Service Pack 3 (SP3) indicate revisions made to the Ponemah core application since release of version 5.10. Since the v5.10-SP3 install also includes the revisions from previous v5.10 service packs, those revisions are also listed with associated Previously Fixed Version distinctions for reference. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the version 5.10 CD. Product Release Notes indicate only revisions to application contents that are part of a specific CD build.

Product Release Notes for Ponemah do not include information regarding revisions of the Ponemah Analysis Modules. Information regarding revisions to the Analysis Modules is detailed in separate Product Release Notes. Version 5.10 SP3 does not include any revision to the version 5.10 analysis modules.

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 DSI Technical Support Group – support@datasci.com.

Reference #	Type of Change	Previously Fixed	Description
Key: N = New Feature; E = Enhancement; F = Fix			
Ponemah Core - General			
T18987	F	N/A	<p>The Auto Configure feature will adjust certain settings within the Setup P3 Setup dialog to help reduce the time configuring a system prior to starting an acquisition. However, when using the OpenART acquisition interface and configuring an Ambient Pressure Reference (APR-1) with an Implant that has pressure as its first channel (e.g. PA-C10), selecting Auto Configure Protocol will incorrectly display channel labels.</p> <p>This has been corrected to function as expected.</p>
T19098	F	N/A	<p>When using the Scatter Graph, the user can draw a free form drawing around specific points of interest using the Free Form Select icon. Two methods are available for the user to determine how selected and unselected points are handle: Delete Cycles or Add Bad Data Marks. Once points are selected, the user can right-click to display options for either applying the method to the selected or unselected points. When using the Delete Cycles method, the user may see the following error:</p>  <p>When this error occurs, this message will repeat for each point selected/unselected upon hitting OK.</p> <p>This has been corrected.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
T18094	F	5.10-SP2	<p>In previous versions of Ponemah (5.0 and lower) , the A/D Sample rate, Channel Input Setup, and Channel Mapping dialogs would display channel letters in front of the channel name for each separate implant. In 5.1 and above, those letters have disappeared.</p> <p>For Example: Previous Version of Ponemah A1: Pressure A2: Biopotential A3: Temperature B1: Pressure B2: Biopotential B3: Temperature. Ponemah 5.1+ 1: Pressure 2: Biopotential 3: Temperature 4: Pressure 5: Biopotential 6: Temperature</p> <p>This has been corrected to display the Subject ID (OpenART), Implant ID (PhysioTel Digital, Device ID (JET), and channel letters (ACQ-7700/ACQ-16).</p>
T18244	F	5.10-SP2	<p>An Ambient Pressure Reference (APR-1) is required for data acquisitions from DSI pressure implants (e.g. HD-S21) and must be configured within the OpenART interface to account for ambient pressure changes. When an APR-1 is not present in the configuration, which is typical when acquiring from implants that do not contain a pressure sensor (e.g. biopotential only devices, such as ETA-F10), the Auto Configuration feature will still assign the last channel within P3 Setup's Channel Input Setup as an Ambient channel by configuring the BARO analysis module and assigning the associated label and units.</p> <p>This has been corrected to configure the last channel appropriately regardless of the presense an APR-1.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3767	F	5.10-SP1	<p>Ponemah validates a protocol upon loading a previously saved protocol and upon saving modified settings. This validation process checks for any conflicts and incorrect setting entries to ensure successful acquisition and Data Reduction. During the protocol loading validation process, Ponemah would attempt to validate Disabled channels/groups within the Data Reduction setup, which are ignored during the settings saving validation. This would result in a protocol loading validation failure with no notification displayed to the user. When this loading validation failed, the previously loaded protocol's Data Reduction configuration would remain present and roll over into the newly loaded protocol.</p> <p>This has been corrected such that the protocol loading validation will ignore disabled groups. Additionally, if the load validation fails, the default Data Reduction settings will be loaded and a notification has been added to alert the user of the issue.</p>
3726	F	5.10-SP1	<p>When creating a freeform event (click Functions Events and type in an event) with an apostrophe character, the resulting XLS spreadsheet generated after acquisition does not contain the event or any events created after the offending event.</p> <p>This has been fixed.</p>
T14008	F	5.10-SP1	<p>While using the Data Security Option of Ponemah, a user is unable to delete files on a secure system.</p> <p>This has been fixed.</p>
T14503	F	5.10-SP1	<p>Auto Protocol Configuration was updated to correctly configure the new PhysioTel Digital L00 temperature only implant. All enabled L00 channels will be set to the Primary sampling rate of 10 Hz.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
T15043	F	5.10-SP1	<p>RAW files cannot be concatenated on a secure system. When trying to combine RAW files on a secure system, an error would occur indicating that the new RAW file could not be written.</p> <p>This has been fixed.</p>
T15156	F	5.10-SP1	<p>Occasionally, an error message could be seen stating that the refresh time associated XY-Loop and Scatter graphs is less than 0.01 second despite these graph pages being disabled.</p> <p>This has been fixed.</p>
T15922	F	5.10-SP1	<p>Using a Ponemah, Post system to Review data the application crashes when the user enters P3 Setup and then exits using the OK or Cancel buttons within Ponemah's Idle mode. This issue does not occur while in Replay or Review..</p> <p>This has been fixed.</p>
			Data Review

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
T18759	F	N/A	<p>While in Review, users can enter the Setup P3 Setup Channel Input Setup to enable and disable the derived parameters desired to be displayed in the derived data spreadsheets for the channels loaded within the Review session. When successive channels within a single group have analysis modules defined such that the preceding channel's analysis module has more available derive parameters than the analysis module of the next channel, disabling or enabling a derived parameter in the preceding channel may also automatically remove the next channel's derived parameters from the derived data spreadsheet.</p> <p>For example: Assume the following conditions: Channel 1 and Channel 2 are defined to Group A Channel 1 is defined to a BP analysis module (25 derived parameters) Channel 2 is defined to RAW analysis module (10 derived parameters) Channel 1 has the following parameters enabled: Num, Sys, Dia, Mean Channel 2 has only the NPMN derived parameter enabled</p> <p>Then, disabling Channel 1's Num parameter will also remove Channel 2's NPMN parameter from the derived data spreadsheet, but would remained enabled within the Derived Parameter selection dialog.</p> <p>Saving a mark section in this state would result the following error message and the mark section not being saved:</p> <p><i>“ODBC Database error: Number of query values and desitination fields are not the same.”</i></p> <p>This has been corrected to update the derived data spreadsheet and save mark section as expected.</p>

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
3764	F	5.10-SP1	<p>When Saving a Mark Section within Ponemah Review on a Windows XP SP3 machine, the following error message may be seen under certain conditions due to memory fragmentation.</p> <p>GouldServer-1</p> <p>This would result in the ODBC interface file (MS Excel® or Access®) not being created.</p> <p>This was not seen when using a Windows 7® computer and has been corrected to better manage the Windows XP® memory. Additionally, the displayed message has been updated to indicate that insufficient resources are available.</p>
3768	F	5.10-SP1	<p>Starting in Ponemah v4.90, Ponemah required a T0 (time zero) event to trigger Data Reduction to start when using Parser Segments as the Reduction Type. However, a T0 event may not be necessary if the user wishes to use the first parser segment. This situation would result in empty Data Reduction tables and would require a T0 event to be placed at the beginning of the recording in order for the tables to populate appropriately.</p> <p>This has been corrected to allow Data Reduction tables to populate when the Reduction Type is set to Data Parser and no T0 event is entered. In this case, the first parser segment will be used to reduce data.</p>
Data Security Option (DSO)			

Reference #	Type of Change	Previously Fixed	Description
Key: N = New Feature; E = Enhancement; F = Fix			
T18793	F	N/A	<p>An Ambient Pressure Reference (APR-1) is required when collecting from a telemetry pressure channel. When using the network-based JET and PhysioTel Digital interfaces to perform these pressure collections, the APR-1 is connected to the system using the E2S-1 converter to allow the pressure reference to be found across the network. On a system secured with DSO, users were unable to access the APR-1 configuration window from the Hardware button within the Run Study dialog. This was due to the APR-1 configuration being incorrectly defined to the access level feature setting AppConfig - Directories within the Ponemah Admin program.</p> <p>This has been fixed by correctly reassociating the APR-1 configuration with the XXX access level setting.</p>
T18968	F	N/A	<p>When DSO is enabled, the Tools menu becomes available within which users can define Audit Reason Codes match their Standard Operating Procedures for changes made to the application. However, when adding these user-defined reasons, random characters may be added to the end of the string that were not entered by the user. These characters may be illegal and cause an error when closing the Audit Reason Codes dialog.</p> <p>This has been corrected and unintended characters will no longer be added to the end of the user-defined reason.</p>
PhysioTel Digital (PTD)			
N/A	N	5.10-SP1	Added support for the new L00 Large Animal temperature only implant.
N/A	N	5.10-SP1	Added support for the new PhysioTel Digital Simulator (PTD-Sim).
T1684	E	5.10-SP1	Externalized the product definition databases to allow for the addition of new implantmodels with minimal software impact.

Reference #	Type of Change	Previously Fixed	Description
			Key: N = New Feature; E = Enhancement; F = Fix
T14045	E	5.10-SP1	<p>Ponemah would encounter some issues that would result in a “Safe handle has been closed” exception error if the latest Microsoft.NET Framework 4.5 is installed on the workstation.</p> <p>This has been fixed by allowing Ponemah compatibility with .NET Framework 4.5.</p>
T15607	E	5.10-SP1	<p>Firefox has been included on the SP CD in the utilities folder. It was included to facilitate easy download and installation for troubleshooting support issues. Installing Firefox is not required for Ponemah to be to operate.</p>
T14007 T3155	F	5.10-SP1	<p>The real start time used by Ponemah did not correctly represent the time of the first data point collected. This resulted in the Implant Status countdown not accurately communicating when data would start displaying on the Primary Graph pages. The Implant Status would change to “Acquiring” but there would still be approximately 8 seconds before the data was seen. Additionally, this led to a several second differential between the acquisition start time and the start time displayed in Review.</p> <p>This has been fixed such that the Implant Status dialog would accurately change to “Acquiring” upon data appearing on the graph page and the start time shown in the Review file matching the time of the first sample acquired by the PTD Hardware.</p>
T1679	F	5.10-SP1	<p>When selecting multiple CLCs with the same frequency, the configuration wizard would be unable to complete.</p> <p>This has been fixed.</p>
T1701	F	5.10-SP1	<p>Ponemah would crash when trying to start Diagnostics. A third-party component was upgraded that caused a compatibility problem.</p> <p>This has been fixed.</p>

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
T13971	F	5.10-SP1	<p>When disabling an implant in the Hardware Configuration dialog, the channels in the Implant's tree view would not gray out and the properties under the implant details page were still editable.</p> <p>This has been fixed to show all channels and their associated properties are disabled (gray) when an implant is disabled.</p>
T14401	F	5.10-SP1	<p>The check box for calculated input channels, such as Activity, would be unchecked even when the channel was enabled.</p> <p>This has been fixed.</p>
Jacketed External Telemetry (JET)			
T18175	F	5.10-SP2	<p>During acquisition from JET devices, the Activity signal was displayed incorrectly and derived measurements from this signal were incorrect. Movement of the device did not correlate to the activity being reported to the software.</p> <p>This has been corrected.</p>

Reference #	Type of Change	Previously Fixed	Description
			Key: N = New Feature; E = Enhancement; F = Fix
3699	F	5.10-SP1	<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
3758	E	5.10-SP1	JET log files have been improved to provide a more comprehensive picture of JET activity.
3759	F	5.10-SP1	<p>Minor resource leak discovered while acquiring from JET. This would not have impacted operation and system performance during the acquisition.</p> <p>This was fixed for proper coding procedures and practices.</p>
3761	F	5.10-SP1	<p>Bluetooth commands were originally sequenced per JET receiver/WRAP. This could have led to multiple, simultaneous commands being sent across all Bluetooth frequencies and contribute to system instability.</p> <p>This has been corrected to sequence commands across all JET receivers/WRAPs associated with the PC.</p>

Reference #	Type of Change	Previously Fixed	Description
			Key: N = New Feature; E = Enhancement; F = Fix
3762	F	5.10-SP1	<p>JET receivers/WRAPs may lose the Windows® port connection with one of its Bluetooth radios which will prevent searching for lost JET device. For example, if the radio port connection drops and a JET device goes out of range and then comes back into range, the JET receiver would not search for the missing device.</p> <p>This has been corrected.</p>
3763	F	5.10-SP1	<p>When stopping a JET acquisition, the Quality of Service dialog takes some additional time to close. When quickly restarting an acquisition, messages from the earlier acquisition may be seen in the JET logs.</p> <p>This has been corrected.</p>
3772	F	5.10-SP1	<p>When searching for JET receivers/WRAPs within the JET Device Configuration, Ponemah would occasionally close unexpectedly.</p> <p>This has been corrected.</p>
3773	F	5.10-SP1	<p>When JET devices were located at the edge of the JET receiver reception range, JET device buffers may have rapidly risen to 99%. This could result in system instability, device timeout/drop out, and JET device data buffer overflow messages.</p> <p>This has been corrected to better handle JET device activity when operating at the edge of the JET receiver reception range, as well as to safe guard against high buffer activity.</p>

Reference #	Type of Change	Previously Fixed	Description
			Key: N = New Feature; E = Enhancement; F = Fix
T13940	F	5.10-SP1	<p>When multiple JET devices are timed out and the connection attempts fail, Ponemah may not cycle through all the disconnected devices before reattempting a device that failed. This occurs when three or more devices are disconnected and two or more of the devices are in range but have difficulty reconnecting.</p> <p>This has been corrected.</p>
OpenART			
N/A	N	5.10-SP1	<p>Added support for the new HD-S11 small animal transmitter. This small animal device offers digital transmission of:</p> <ul style="list-style-type: none"> • Animal ID - This prevents data being incorrectly recorded if an animal is placed in the incorrect cage. • Battery Odometer – Keeps track of the time the transmitter has been on. • Battery Voltage – Monitors the status of the battery. • Calibration – Stored within the device and loaded automatically. Removes entry errors by eliminating the need to hand enter values.
3756	F	5.10-SP1	<p>If using a transmitter module configured with a BPR definition to derive respiration from blood pressure, the input channel order of pressure and respiration from blood pressure may switch. This switch can be seen in the OpenART Configuration window and the order listed will persist into Ponemah's Channel Input Setup.</p> <p>This has been fixed to always list the BP and BPR channels in the same order.</p>
ACQ-OpenART			

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
T3048	E	N/A	<p>When using an OpenART and ACQ-7700/16 sync system to acquire data from DSI Implantable Telemetry together with hardwired signals, the 7700/16 calibration dialog required that the configured implants from OpenART be on and in range of the receivers in order to proceed with the calibration process.</p> <p>This has been updated to no longer require the presence of the OpenART source since calibration of the 7700/16 hardware would occur prior to the subjects being placed on or near their associated receivers.</p>
BMDS Wand			
T18282	F	5.10-SP2	<p>When using the BMDS SP-6004 Smart Probe to read from IMI-1000 RFID chips, invalid characters would be appended to the ID and cause the Ponemah to be unable to select the subject for acquisition within Study.</p> <p>This has been corrected to accurately read the RFID chips.</p>