

Product Release Notes

Product: Ponemah Physiology Platform
Model: Ponemah
Version: 5.20
Build: 006780-001 (CD Build)
Date: May, 2013

Product Release Notes for Ponemah Physiology Platform version 5.20 indicate revisions made to the Ponemah core application since release of version 5.10. 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.

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			
3088	E	N/A	<p>Added compatibility for 64 bit Windows 7 SP1 operating system. Ponemah v5.20 is compatible with 32 and 64 bit Windows 7 SP1 operating systems.</p> <p>Microsoft® Office 2003, 2007, 2010, and 2013 are supported by Ponemah v5.20. If using 64 bit Office, Excel 2003 should be selected under Options Application Configuration ODBC Interface to appropriately generate Excel files.</p>
14056	E	N/A	<p>Microsoft SQL Server was updated to the 2008 Express Edition to support running the application on a 32 bit and 64 bit computer. If a previous version of SQL is already installed on the computer, it will not be overwritten by the new version. The previous version used for Ponemah v4.90-v5.10 was Microsoft SQL Server 2005.</p> <p>Impact of SQL change: Data generated using the Study Protocol Option is placed into the database as well as the ODBC generated files (Access and Excel). It is not possible to back up a study using 2008 and restore the backup file to a workstation running 2005. When an attempt is made to perform a backup to a previous version of the database, the following message is posted alerting the user to an error condition:</p> <p>“This can be caused by invalid backup devices or restoring a database created by a newer version of SQL server.”</p>
3042	E	N/A	<p>The Logging Rate time entry interface has been improved to allow users to easily distinguish between hours, minutes, and seconds.</p>
15085	F	N/A	<p>When selecting Auto Configure Protocol without having the Ponemah Analysis Modules installed, issues were seen in Analysis Module/Channel association and labeling.</p> <p>These have been corrected.</p>

Reference #	Type of Change	Previously Fixed	Description
			Key: N = New Feature; E = Enhancement; F = Fix
12932	F	N/A	<p>During acquisition, if the Zoom(+) function was pressed on the primary graph until the span on the graph was less than 1 second, Ponemah would become unresponsive to any other commands and need to be closed through task manager.</p> <p>This has been corrected.</p>
3009	F	N/A	<p>Occasionally, Ponemah would become unresponsive upon startup. The Ponemah icon would become available in the in the task bar, but the startup dialog would not display. Hovering the mouse over the Ponemah icon would result in the following message:</p> <p>“Waiting for MSDE (Not Responding)”</p> <p>This has been corrected.</p>
3172	F	N/A	<p>If a license file is loaded without the currently select Acquisition Interface enabled, the user is not notified and is unable to select a valid interface. For example, if OpenART is the currently selected Acquisition Interface and a license file is loaded that does not include OpenART, the user would be unable to change to a valid interface.</p> <p>This has been corrected to allow the user to select a valid interface.</p>
16636	F	N/A	<p>When using multiple Digital Displays, the user can separate, rearrange, and reorder them as desired. However, the application would occasionally become unresponsive upon moving additional windows after reattaching the displays during an acquisition.</p> <p>This has been corrected to prevent the application from becoming unresponsive.</p>

Reference #	Type of Change	Previously Fixed	Description
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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 using Data Manager.</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>
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>

Reference #	Type of Change	Previously Fixed	Description
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T15156	F	5.10-SP1	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. This has been fixed.
T15922	F	5.10-SP1	Using a Ponemah Post system to Review data, the application would crash if the user entered the P3 Setup and then exited using the OK or Cancel buttons within Ponemah's Idle mode . This issue does not occur while in Replay or Review . This has been fixed.
Data Review			
17282	E	N/A	When printing waveforms to a PDF with previous versions of Ponemah, a separate PDF file would be created per page if the waveform duration spanned multiple pages. This has been modified to print one aggregate PDF file per executed print when the waveform duration spans multiple pages.
17293	E	N/A	The Group Mode for Bad Data Marks feature merges all bad data mark sections within a group, such that all group channels will have identical bad data mark sections. Originally, this was implemented as a checkbox to allow users to run a Review session in a Group Mode such that placing bad data marks on one channel would automatically apply bad data marks at the same locations to all additional channels within that group. This could result in performance issues when executing automated analysis modules, which in turn would take an abnormally excessive amount of time to complete. To prevent the user from unknowingly running in this state, the Group Mode for Bad Data Marks checkbox was removed. It is replaced with a Bad Data Mark Merge option located under the Functions menu. Upon selecting the option, the bad data marks merge action will execute to result in desired outcome of having consistent bad data mark placement across all channels within the group.

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17145	F	N/A	<p>When a subset of channels are parsed to create a new parsed Review file, the protocol file associated with the new Review file was not adjusted to disable the channels that do not have data. This would result in Ponemah shutting down unexpectedly upon closing the parsed Review file.</p> <p>Similarly, if a single subject with HRV setup had been parsed out of a multi-subject file, the HRV setup would be incorrect. Attempting to edit the HRV setup would cause Ponemah to unexpectedly shutdown. However, if the Review Protocol was saved prior to entering the HRV setup dialog, the HRV setup would be corrected and the application would work as expected.</p> <p>These have been corrected.</p>
13875	F	N/A	<p>When using the Page View graph, the application would shut down unexpectedly under the following conditions:</p> <ul style="list-style-type: none"> • Press Page Up, then press Ctrl key • Press Page Up, then press Ctrl+P <p>This has been corrected.</p>
17816	F	N/A	<p>Upon entering Parser View Mode, Ponemah would enter a “Not Responding” state under the following conditions:</p> <ul style="list-style-type: none"> • Group mode for Data Parser is enabled • Only a subset of the groups have parser segments defined • Derived parameter calculations are not complete when Parser View is entered <p>The issue occurs because if parser view mode is entered while channels are still calculating data, Review continues trying to calculate results while in Parser View Mode. This is fine if the channel exists in Parser View Mode (i.e. it has a parser segment associated with it). If a channel does not exist in Parser View Mode, the system does not have a means of marking the calculations done, and as a result keeps attempting to do so, resulting in the “Not Responding” state.</p>

Reference #	Type of Change	Previously Fixed	Description
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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)			
17739	F	N/A	<p>Within Review mode, the user can choose to run with Difference Marks enabled or disabled. If automated analysis was executed after modifying analysis modules attribute settings with the Difference Marks disabled, Ponemah would not prompt the user to enter an Audit Reason upon saving a Marks Section when the system is secured. If the Difference Marks on enabled, the user is prompted appropriately.</p> <p>This has been corrected to prompt the user for an Audit Reason regardless of having the Difference Marks enabled/disabled.</p>

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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 implant models with minimal software impact.
T14045	E	5.10-SP1	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. This has been fixed by allowing Ponemah compatibility with .NET Framework 4.5.
T15607	E	5.10-SP1	Firefox has been included on the installation DVD 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.
T14007 T3155	F	5.10-SP1	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 . 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 .
T1679	F	5.10-SP1	When selecting multiple CLCs with the same frequency, the configuration wizard would be unable to complete. This has been fixed.

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T1701	F	5.10-SP1	Ponemah would crash when trying to start Diagnostics . A third-party component was upgraded that caused a compatibility problem. This has been fixed.
T13971	F	5.10-SP1	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. This has been fixed to show all channels and their associated properties are disabled (gray) when an implant is disabled.
T14401	F	5.10-SP1	The check box for calculated input channels, such as Activity, would be unchecked even when the channel was enabled. This has been fixed.
Jacketed External Telemetry (JET)			
16497	F	N/A	When JET-OpenART is being used as the Acquisition Interface, users can perform a time synchronization calibration to ensure JET and OpenART data is synchronized. During this calibration of the time synchronization between JET and OpenART, the Time Calibration dialog would not close as expected. The user would be required to close Ponemah from the Task Manager. This has been corrected.

Reference #	Type of Change	Previously Fixed	Description
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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
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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>
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>

Reference #	Type of Change	Previously Fixed	Description
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OpenART			
14055	E	N/A	The OpenART PCIe card driver was updated for operation on 64 bit Windows 7.
2983	N	5.10-SP1	Added support for the new HD-S11 small animal transmitter. This small animal device offers digital transmission of: <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	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. This has been fixed to always list the BP and BPR channels in the same order.
ACQ-7700/ACQ-16 Signal Conditioners			
3073	E	N/A	Updated the ACQ-7700 and ACQ-16 USB drivers for compatibility with 64 bit Windows 7.

Reference #	Type of Change	Previously Fixed	<p>Key: N = New Feature; E = Enhancement; F = Fix</p> <p>Description</p>
2976	N/A	N/A	<p>Removed support for the following hardware:</p> <ul style="list-style-type: none"> • EPP (parallel port) ACQ-7700 and ACQ-16 interfaces. It is recommended to upgrade EPP versions of the ACQ-7700 and ACQ-16 to USB interfaces for use with Ponemah v5.20. • 12-Lead ECG EPP. Users can upgrade to the multi-lead biopod with ACQ-7700 USB interface. • USB-Writers • Recorders (CRS800W/DC800W) • ACQ-7700 Bridge Module • ACQ-7700 Digital I/O Module