

## Product Release Notes

**Product:** Ponemah Physiology Platform  
**Model:** Ponemah  
**Version:** 4.90-SP5  
**Build:** 005198-006 (CD Build)  
**Date:** October, 2012

Product Release Notes for Ponemah Physiology Platform version 4.90 Service Pack 5 (SP5) indicate revisions made to the Ponemah core application since release of version 4.9-SP4. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the version 4.90 CD and subsequent Service Pack CDs. 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](mailto:support@datasci.com).

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix Description
<b>Ponemah Core - General</b>			
3767	F	N/A	<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>
<b>Data Review</b>			
3764	F	N/A	<p>When <b>Saving a Mark Section</b> within Ponemah <b>Review</b> on a <b>Windows XP SP3</b> machine, the following error message may be seen under certain conditions due to memory fragmentation.</p> <p><b>GouldServer-1</b></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>

Reference #	Type of Change	Previously Fixed	Key: N = New Feature; E = Enhancement; F = Fix
			Description
3768	F	N/A	<p>Starting in Ponemah v4.90, Ponemah required a <b>T0</b> (time zero) <b>event</b> to trigger Data Reduction to start when using <b>Parser Segments</b> as the <b>Reduction Type</b>. 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	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></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"> <li>1) An incorrect, eight character password is entered when Ponemah is first started.</li> <li>2) The correct password is then entered.</li> <li>3) One of the following acquisition engines is used               <ol style="list-style-type: none"> <li>a. Versions 4.70-4.90: OpenART, ACQ16-USB-OpenART, ACQ7700USB-OpenART or JET.</li> <li>b. Version 5.00: Any interface except ACQ-16EPP.</li> </ol> </li> </ol> <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><b>Work-around:</b> 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>

Reference #	Type of Change	Previously Fixed	<b>Key: N = New Feature; E = Enhancement; F = Fix</b>  <b>Description</b>
N/A	E	4.90- DSOSP1	<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 4.90 with 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 4.90 software configuration to support the new cards include an update to the P3Security.dll file for 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 5.00 for the Windows XP and Windows 7 (version 5.00 only) Operating Systems. 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 4.90 is needed, please contact Technical Support at <a href="mailto:Support@datasci.com">Support@datasci.com</a>.</p> <p>Downloads for all service packs may also be obtained by visiting our secured website at <a href="https://www.datasci.com/portal/users/">https://www.datasci.com/portal/users/</a>. Please see the v490-DSOSP1_Install.pdf (or appropriate service pack version) for more information.</p> <p><b>NOTE:</b> Windows XP Service Pack 3 is the recommended configuration for Ponemah version 4.90-SP4. Windows XP Service Pack 2 is the recommended configuration for Ponemah versions 4.90 through 4.90-SP3.</p>
<b>Jacketed External Telemetry (JET)</b>			



Reference #	Type of Change	Previously Fixed	<p><b>Key: N = New Feature; E = Enhancement; F = Fix</b></p> <p><b>Description</b></p>
3719	F	N/A	<p>During <b>JET</b> acquisitions, a ‘y-event’ may have been randomly marked without user action or desire. Y-events are used to mark external triggers collected from the ACQ-16 or ACQ-7700 hardware devices.</p> <p>This has been corrected.</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 <b>JET Device Configuration</b> 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><b>Work-around:</b> 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"> <li>1. Power cycle all equipment</li> <li>2. Run the <b>JET Bluetooth System Optimizer</b></li> <li>3. Close and Open Ponemah prior to starting an acquisition</li> </ol>
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>

Reference #	Type of Change	Previously Fixed	<b>Key: N = New Feature; E = Enhancement; F = Fix</b>  <b>Description</b>
3758	E	N/A	JET log files have been improved to provide a more comprehensive picture of JET activity.
3759	F	N/A	Minor resource leak discovered while acquiring from JET. This would not have impacted operation and system performance during the acquisition.  This was fixed for proper coding procedures and practices.
3761	F	N/A	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.  This has been corrected to sequence commands across all JET receivers/WRAPs associated with the PC.
3762	F	N/A	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.  This has been corrected.
3763	F	N/A	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.  This has been corrected.
3772	F	N/A	When searching for JET receivers/WRAPs within the JET Device Configuration, Ponemah would occasionally close unexpectedly.  This has been corrected.

Reference #	Type of Change	Previously Fixed	<b>Key: N = New Feature; E = Enhancement; F = Fix</b>  <b>Description</b>
3773	F	N/A	<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>
<b>Study Protocol Option</b>			
3725	F	N/A	<p>If the <b>Enable Day 0</b> function was not enabled and <b>Export Study Setup</b> was selected from the <b>Manage Studies</b> 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><b>Note:</b> If <b>Enable Day 0</b> was selected as part of the study configuration, the exported data would be represented correctly.</p>