

P/N 012625-001 Rev. 01

## **Product Release Notes**

| Product: | Ponemah <sup>™</sup> Physiology Platform |
|----------|--|
| Model:   | Ponemah                                  |
| Version: | 5.32                                     |
| Build:   | 012627-001                               |
| Date:    | November, 2018                           |

Product Release Notes for Ponemah Physiology Platform version 5.32 indicate revisions made to the Ponemah core application since version 5.30. For information regarding changes to the software from previous versions, please refer to the Release Notes folder located on the version 5.32 install key. 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<br>Change | Previously<br>Fixed | Key:<br>N = New Feature; E = Enhancement; F = Fix<br>Description   |
|-------------|-------------------|---------------------|--|
|             |                   | Pone                | mah Core – General   |
| 43168       | F                 | N/A                 | Leading space removed inTPT variable for SEND csv output where theTPT value does not include hours.  |
| 43158       | F                 | N/A                 | Fix added for issue where "ms" was used as a unit when<br>reporting intervals in a SEND output, versus the CDISC<br>approved unit "msec".  |
| 43121       | F                 | N/A                 | Fix added for issue where Variability Settings were not properly saved after adding and saving a variability definition.   |
| 43120       | F                 | N/A                 | <ul> <li>The following Data Reduction Label issues were addressed.</li> <li>In Data Parser Group Mode, the Control label was incorrect after parser rules were applied.</li> <li>With SEND enabled, the Data Parser dialog did not prevent editing all Groups labels</li> </ul>  |
| 43083       | F                 | N/A                 | <ul> <li>Fix added for issue where various pieces of information were not included in the Experiment Log in Ponemah v5.30 and v5.31, including:</li> <li>Any Algorithm Attribute changes</li> <li>Add/Delete Bad Data Marks</li> <li>Add/Delete Cycles</li> <li>Batch Delete unmatched cycles</li> <li>Merge Bad Data Marks</li> <li>Reanalyze a channel (entire or a region)</li> <li>Update/Add/Delete Event</li> <li>Add Note</li> <li>Mark difference</li> <li>Batch Template Analysis</li> <li>Template Analysis</li> </ul> |
| 43028       | E                 | N/A                 | Added signatures to exported SEND csv files.   |
| 43021       | F                 | N/A                 | Fix added to correctDY andENDY values for predose intervals on the day of dosing.  |
| 42848       | F                 | 5.31                | Fix added for issue where Crash Dump utility did not<br>function properly while operating on Windows 10. A<br>Dump file will now be created automatically in a<br>predetermined folder when a crash occurs.  |



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|-------------|-------------------|---------------------|--|
| 42788       | F                 | 5.31                | Fix added for issue where opening the APR user interface<br>while operating on Windows 10 intermittently caused a<br>system crash.   |
| 42738       | E                 | 5.31                | Fix added to optimize the formatting in Freeform Notes when a note contained multiple lines.   |
| 42603       | F                 | 5.31                | Fix added for User Interface display issues when operating<br>on Windows 10. Icons and windows in the following<br>dialogs could not be viewed or were not sized correctly<br>when Display Settings: Scale and Layout was set to any<br>scale other than 100%:<br>- 7700 Amplifier Setup<br>- Study<br>O Add New Dose<br>O Add New Subject<br>O Add New Workup<br>This has been corrected. |
| 42371       | E                 | 5.30                | DsiTimeSync messages updated to indicate ACQ-7700 sync status with improved clarity.   |
| 42354       | E                 | 5.30                | Update for Security Application for access restriction and<br>Security Application added to the Admin Application<br>within the Ponemah core software.   |
| 42224       | E                 | 5.30                | A user entered Date/Time can be used as T0 to trigger<br>Data Reduction intervals.   |
| 42191       | E                 | 5.30                | Dose information has been added to the Groups tab in<br>Ponemah Setup. This information may be populated from<br>Ponemah's Study Option or may be entered manually   |
| 42184       | E                 | 5.30                | Modified to create a new SQL instance to support SQL 2014 without conflict with earlier versions.  |
| 42112       | E                 | 5.30                | Time Sync Service updated to use latest files for<br>Measurement Computing Components to support the<br>Time Sync Card.  |
| 41904       | F                 | 5.30                | Fix added for issue where the use of ODBC for generating<br>Excel files resulted in a minor memory leak which<br>primarily affected performance when saving at high<br>logging rates (1 sec) over long periods (24 hours) with a<br>large number of subjects (16).<br>Files formerly created in an .xlsb format are now created<br>in an xlsx format.                                      |
| 41777       | E                 | 5.30                | Increased the supported number of graph pages from 8 to 16.  |

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|-------------|-------------------|---------------------|--|
| 41720       | E                 | 5.30                | In the event of a system crash during acquisition, Jump<br>tables were previously not appended to the end of a RAW<br>file. Jump files are now automatically generated and<br>appended to the RAW file if it is detected that a file does<br>not have an associated Jump file during Replay. |
| 41320       | E                 | 5.30                | Increased the number of supported groups from 16 to 32 and number of supported channels from 128 to 256.   |
| 41303       | Е                 | 5.30                | Full build number added to the Log tab in Excel output.  |
| 41166       | F                 | 5.30                | Fix added for issue where adding an Event to All Groups<br>did not trigger Data Reduction calculations for all groups,<br>only the selected group.   |
| 41067       | E                 | 5.30                | Updated to run as native Windows 64-bit application<br>which improves performance and takes advantage of<br>more memory to support large datasets.<br>The installer has been updated to support the Windows<br>64-bit environment.   |
| 40789       | E                 | 5.30                | Subject names from Study may now be displayed in the<br>Groups tab in Ponemah Setup. The user has the option of<br>populating this information from Study or entering it<br>manually   |
| 40576       | E                 | 5.30                | Updated SEND Module compatibility to meet SEND 3.1 requirements.   |
| 40225       | F                 | 5.30                | Fix added for issue where the application would crash if 128 channels were enabled and the Sample Rate dialog was entered, exited, and entered a second time.  |
| 39944       | E                 | 5.30                | Upgraded all Print selections to display the Windows common Print dialog which permits selecting a specific printer.   |
| 39917       | F                 | 5.30                | Removed Email function from Product Information dialog.  |
| 35989       | E                 | 5.30                | Added support for Windows 10, 64-bit operating system.   |
| 33183       | E                 | 5.30                | <ul> <li>Updated the following global default settings:</li> <li>Acquisition Interface to ACQ-DEMO</li> <li>Scatter Graph Delete Data Marks Method to Bad<br/>Data Marks</li> </ul>  |
| 3046        | Е                 | 5.30                | Added the ability to choose how null values are represented in Excel. Users are able to select between 0 and x.  |

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|----------------------------|-------------------|---------------------|--|
|                            |                   |                     | Review   |
| 42187,<br>42188            | F                 | 5.30                | Fix added for issues in Data Insights where Rejected<br>results were not preserved after a mark section was saved<br>and Review/Data Insights was exited. Users were also<br>prompted to Save Marks upon exit from Review whether<br>or not changes were made. |
| 41265                      | F                 | 5.30                | Fix added for issue where right-click updates for Labels<br>and Units in the Channel Input Setup tab would not<br>appear.  |
| 40056                      | F                 | 5.30                | Fix added for issue when exporting and importing a URP search in Data Insights would result in an error.   |
|                            |                   |                     | RAW Analysis   |
| 41590                      | F                 | 5.30                | Fix added for issue where the TA parameter was reported differently between Replay and Review.   |
|                            |                   |                     | ECG PRO  |
|                            |                   |                     | Study  |
| 41371                      | E                 | 5.30                | Workstation name added in audit log when performing a SYNC.  |
| 41264                      | F                 | 5.30                | Fix added for issue where a "save changes" message did<br>not always appear for default.pro within Study when<br>changes were made.  |
| 40828                      | E                 | 5.30                | Modified Manage Study dialog to allow users to define<br>which items are displayed in the study list: All Studies,<br>Active Studies, or Deleted Studies.  |
| Data Security Option (DSO) |                   |                     |  |
| 43178                      | F                 | N/A                 | Fix added for issue where user additions were not displayed in the User log dialog.  |
| 41959 <i>,</i><br>41960    | Ν                 | 5.30                | Smart Card functionality replaced with Windows Account<br>authentication. User names are now listed in the<br>Ponemah logon page by cross-referencing Windows<br>credentials with the P3_Users group.  |

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|-----------------------------------|----------------------------------|---------------------|--|--|
| PhysioTel Digital                 |                                  |                     |  |  |
|                                   | MX2                              |                     |  |  |
|                                   | Ambient Pressure Reference (APR) |                     |  |  |
| OpenART                           |                                  |                     |  |  |
| 40092                             | N/A                              | 5.30                | OpenART support discontinued and removed.                        |  |
|                                   | ACQ-OpenART                      |                     |  |  |
| 40092                             | N/A                              | 5.30                | OpenART support discontinued and removed.                        |  |
| Jacketed External Telemetry (JET) |                                  |                     |  |  |
| Video                             |                                  |                     |  |  |
| BMDS Wand                         |                                  |                     |  |  |

