## **Vision Software**



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#### 1 Purpose

This document describes new features and fixed bugs in the following new software version in comparison with the previous version.

New version: 4.1.1.156Old version: 4.1.1.130

#### 2 New features

| Topic                          | Description   |
|--------------------------------|---|
| Leverage calculation           | Leverage calculation with Vision is now available. This allows to detect outliers during routine analysis on a component level. |
| B&W Tek – Drivers              | Drivers for B&W Tek portable Raman instruments have been added. The following instruments are now supported:                    |
|                                | <ul><li>i-Raman® Plus 532S</li><li>i-Raman® Plus 532H</li></ul>   |
| NIRS PRO v2 – Integration      | Vision supports the PRO FOSS v2.  |
| NIRS PRO v2 – Integration time | The integration time can now be changed in the status dialog windows. This improves the usability.                              |

#### 3 Improvements

| Торіс                                    | Description   |
|--|---|
| Content uniformity test report           | Empty pages have been removed.  |
| DCM selection during import of xml files | Vision asks the user to define the DCM for each sample group in Vision Air XML files. This ensures that the user sets the correct DCM for all spectra he imports. |

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| Topic                                   | Description   |
|---|---|
| SmartProbes – Low flux test description | During a noise test with external standards, Vision displayed misleading information about the reference scan measurement. This could lead to wrong sample handling by the user. This text has been adjusted. |
| Single fiber XDS – Perform-<br>ace test | The ranges and values for performance tests have been changed according to new specifications. The Peak observed from the filter sliders are removed from the evaluation.                                     |
| B&W Tek – auto-integration              | The determination of the auto-integration time is better and faster.  |
| B&W Tek – auto-integration              | The default value is a more realistic value.  |

# 4 Fixed bugs

| Topic   | Description  |
|---|--|
| Content uniformity test report                              | The time display for the last measurement of a content uniformity test was not identical between the test report and the <b>Recall result</b> functionality in Vision. This has been fixed.  |
| Content uniformity test report                              | The report did not display the correct number of analyzed samples. This has been fixed.  |
| SPC Export/Import   | Files exported via SPC format in Vision could not be imported again by using the SPC import. This has been fixed.  |
| NIRS XDS MasterLab Analyzer reflection mode – Low flux test | When performing a photometric test with external standard with<br>an XDS MasterLab, the measurement lid did not open. Therefore,<br>the internal standard was measured. This has been fixed. |
| NIRS XDS MasterLab Analyzer reflection mode – Low flux test | When performing a photometric test with internal standards with an XDS MasterLab, the test report indicated <b>Reference: external</b> . This has been corrected.                            |
| DS2500 Solid Analyzer –<br>Test report                      | The test report for the DS2500 Solid Analyzer displayed as <b>Sampling System: RCM, Rapid Content Module</b> . This has been changed to <b>DS2500 Solid Analyzer</b> .                       |
| DS2500 Solid Analyzer –<br>Open lid                         | When selecting <b>every sample</b> in the timer settings in the operation method configuration, Vision opened the lid too soon. This caused false results. This has been fixed               |
| Hellma MUX – Driver   | The driver for Hellma MUX applied window correction to 1 channel only. This has been fixed.  |
| B&W Tek – Portable spec-<br>trometer                        | The displayed CCD temperature reading was not correct for all instrument models. This has been fixed.  |

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Known bugs

| Торіс                | Description  |
|----------------------|--|
| B&W Tek – Dark scans | When performing a dark scan, the laser was not switched off completely. This has been fixed. |

### **5 Known bugs**

| Topic  | Description  |
|--|--|
| Tray selection   | In seldom cases, the tray sample position selection window does<br>not display the correct tray setup. Selecting the tray again can<br>solve this issue.             |
| Content uniformity test report                                 | The report for content uniformity tests does not display the whole serial number of the instrument but only the first 4 digits.                                      |
| DS2500 Solid Analyzer –<br>Operation method configu-<br>ration | The timer settings in the operation method configuration has been deactivated for the DS2500 Solid Analyzer restricting changes to the frequency of reference scans. |
| XDS spectra – DCM sample properties                            | In seldom cases, Vision crashes when opening DCM sample properties for XDS spectra if the configuration is not set to XDS Analyzer.                                  |

## **6** Compliance

The current software version does not contain any modifications that affect conformity of Vision regarding GAMP.

Requirements of 21 CFR Part 11 can only be activated when a Vision Pharma License has been used for the installation of Vision.

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