

vLog 4.5 Installation and Operational Qualification Protocol Errata

The following document describes known issues with the vLog 4.5 IQOQ.

1 Error in Acceptance Criteria of Section 6.4

Use of Windows 10 with vLog 4.5 will result in a discrepancy in section 6.4 of the vLog Installation and Operational Qualification Protocol, as it is written.

Section 6.4 captures the specifications of the hardware used with the Vaisala Veriteq vLog System and compares them against the published hardware requirements, listed in the acceptance criteria. Any mismatch results in failure to meet the acceptance criteria.

Windows 10 was not available at the time of vLog 4.5's release and was therefore not one of the originally approved operating systems. vLog 4.5 was thoroughly tested with Windows 10 in 2016 and the operating system was subsequently approved for use with vLog 4.5, as described in the software validation certificate: M211804EN-C.

This is a Deviation as defined in section 5.10: "A discrepancy or exception that prevents meeting the acceptance criteria". Section 5.10 goes on to state:

Discrepancies, exceptions, and deviations to approved protocols may occur. It is the responsibility of the qualification group to document each discrepancy, exception, or deviation and to provide an explanation of the circumstances that led to said discrepancy, exception, or deviation. They should be documented in the space provided in each test section.

Discrepancies, exceptions, and deviations must be approved by the Quality Assurance group according to current standard operating procedures, prior to any further execution of the protocol.

This document may be used to support the justification for approval of this deviation, and if so, should be appended to the protocol.

2 Error in Section 7.2.11

An error has been discovered in section 7.2.11 of the vLog 4.5 validation protocol. With default settings in the vLog application the test in section 7.2.11.8 will fail. The application will list the maximum temperature value as 25.84°C and the printed graph in Appendix A will list it as 25.86°C.

This is the result of missing steps in the instructions. Section 7.2.11 should be updated as follows.

Replace steps 7.2.11.1 to 7.2.11.3 with the following steps (adjusting the numbering of the rest of the procedure as appropriate).

| Step | Procedure | Expected Results | Are actual results as expected? Initials/Date |
|----------|---|---|---|
| 7.2.11.1 | Select Tools > Options > Insert from the menu bar. | The Insert tab of the Options page appears. | |
| 7.2.11.2 | Set Sample Smoothing to Zero . Click the OK button. | Sample smoothing is set to Zero . | |
| 7.2.11.3 | Select File > Insert Logger Files from the menu bar. | The File Open dialog box appears. | |
| 7.2.11.4 | Select the SPL file Sample1 , located on the <i>Protocol CD</i> in the <i>\Samples\</i> sub-directory. | The Sample1 file is selected. | |
| 7.2.11.5 | Click the Open button. | The Select Channels dialog box appears. | |
| 7.2.11.6 | Ensure all available channels are selected. | All channels are selected. | |
| 7.2.11.7 | Click the OK button. | The Confirm Relative Humidity Channel dialog box appears. | |
| 7.2.11.8 | Select the Relative Humidity radio button. | The Relative Humidity radio button is selected. | |
| 7.2.11.9 | Click the OK button. | A graph is generated based on the data in the file Sample1.spl . | |

All following steps (7.2.11.4 and beyond in the original protocol) can be completed as written.

This is an Exception as defined in section 5.10: "A difference between the approved protocol procedure and the procedure followed in testing". Section 5.10 goes on to state:

Discrepancies, exceptions, and deviations to approved protocols may occur. It is the responsibility of the qualification group to document each discrepancy, exception, or deviation and to provide an explanation of the circumstances that led to said discrepancy, exception, or deviation. They should be documented in the space provided in each test section.

Discrepancies, exceptions, and deviations must be approved by the Quality Assurance group according to current standard operating procedures, prior to any further execution of the protocol.

This document may be used to support the justification for change to the approved procedure, and if so, should be appended to the protocol.

Steven Bell
 Product Manager
steven.bell@vaisala.com