



Veriteq vLog

Installation and Operational Qualification Protocol

For Veriteq vLog Version 4.4

Veriteq Instruments, Inc.

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Prepared by: Katie Lowe

Reviewed by: Michael Boetzkes

PROTOCOL PRE-APPROVAL

The Installation / Operational Qualification Protocol for the Veriteq vLog Software Version 4.4 has been reviewed and approved for execution by the following. Signing this protocol indicates that the contents of this document have been reviewed, all test procedures are accurate and the acceptance criteria are applicable for the intended purpose of this study. The following responsible functional areas have approved this Installation/ Operational protocol:

Approved By:

_____	_____
Information Technology	Date
_____	_____
Operations	Date
_____	_____
Quality Assurance	Date

Disclaimers:

1. Prior to execution of this protocol, the following conditions must be met:
 - a. Loggers have been attached to the system either directly via a cable connection or indirectly via a vNet or Digi PortServer device.
 - b. All cables being used that require drivers have been properly installed on the vLog Server.
 - c. All vNet and Digi PortServer devices being used have been setup with static IP addresses and correct network information, and have had their drivers installed on the vLog Server.
 - d. All computers used in the vLog system must meet the minimum requirements as specified in the vLog documentation.
 - e. The Veriteq vLog software has been installed on a computer used in this validation.
2. The logger data cable must not become disconnected during transmission unless specified in the procedure and the logger in test must contain an adequate amount of data.
3. The procedures in this protocol may not leave the system in an ideal configuration for your particular application, especially in the case of an upgrade from a previous version. Review and modification of the system configuration is highly recommended following validation.

Veriteq, a Vaisala company

Unit 100 – 13775 Commerce Parkway
Richmond, BC Canada V6V 2V4
Tel: (604) 273-6850
Fax: (604) 273-2874
Toll Free: 1-800-683-8374
Email: customersupport@veriteq.com
Web Site: <http://www.veriteq.com>

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1 Purpose

The purpose of this IQ/OQ protocol is to provide assurance that the Veriteq vLog Data Logging and Reporting System has been set up properly, is functional, and operates with a high degree of integrity, security and reliability.

The Installation Qualification (IQ) protocol template has been designed to ensure that the system, composed of both the hardware and the software, has been installed correctly at the point of use. The Operation Qualification (OQ) protocol template has been designed to ensure that each component of the system performs as intended.

Veriteq loggers use Coordinated Universal Time (UTC) to create a base time in every logger file. This provides an absolute reference that the Veriteq vLog software uses to display the logger information using the computer's local time zone. Sample files for multiple time zones have been included on the *Veriteq vLog Qualification Protocol CD* in the *\samples<timezone>* directory. When implementing this protocol, use the sample files located in the directory corresponding to the time zone of the computer being used.

The appendices contain printouts of both sample graph files and tabular data listings. For your reference, **Appendix A** lists the passwords for all Veriteq vLog sample files that are supplied on the *Veriteq vLog Qualification Protocol CD*.

2 Responsibilities

2.1 Vendor Responsibilities

Veriteq Instruments, Inc. is responsible for the following:

- IQ/OQ Protocol Template Creation
- Initial Logger Calibration
- Protocol Preparation

2.2 User Responsibilities

_____ is responsible for the following:

- Equipment Maintenance
- Ensuring Calibrated Status of Unit(s)
- Protocol Pre-Approval
- Protocol Implementation and Reporting of Results
- Protocol Execution Deviations, Assessment and Corrective Measures
- Protocol and Report Review
- Protocol and Report Approval

3 System Description

The Veriteq vLog Validatable Data Logging System is a battery-operated, microprocessor-based data collection and PC reporting system for monitoring and recording temperature and relative humidity in FDA-regulated environments.

The system consists of one or more VL-1000, VL-1016, VL-1000LT, VL-1000VLT, (hereafter referred to collectively as VL-1000); V-1400, VL-1416 (hereafter referred to collectively as VL-1400), VL-1700 (thermocouples), VL-4000 and/or VL-2000 data loggers; and the Veriteq vLog Windows-based software. The data loggers are connected to the vLog System using Veriteq serial cables, Veriteq USB cables, Veriteq vNet devices, and/or approved models of Digi PortServer Ethernet devices, and a PC with print capability. Each VL-1000 data logger, except the VLT, can optionally include one or more external temperature probes.

The VL data loggers are self-contained electronic recording instruments that include on-board sensors, non-volatile EEPROM memory, a 10-year lithium battery, and a clock. The system is driven by an on-board microprocessor operating under Veriteq firmware, an unalterable factory-supplied program.

The temperature sensor used in the VL loggers and in the external temperature probes is a NTC thermistor that varies its resistance in relation to temperature. The relative humidity sensor used in the VL-2000 is a capacitive sensor. It works by varying its capacitance in relation to changes in RH. Each VL data logger is factory-calibrated against NIST traceable standards and all calibration information is encrypted and stored digitally in the logger's memory. The onboard sensors are located just inside the lower left corner of the plastic enclosure and are exposed to the ambient environment through ventilation openings in the enclosure.

The external temperature probe for the VL-1000 and VL-1400 data loggers consists of a short length of two-conductor, shielded twisted pair cable, with a plug-in connector at one end, and a thermistor, epoxy-encapsulated in a stainless steel tip or waterproof Teflon tip, at the other end. The probe can be used to provide an additional measurement channel and to allow monitoring in areas not suitable for data loggers.

The VL-1700 series of data loggers, allows thermocouples to be used, particularly in extreme temperature ranges. Completing the series, the VL-4000 series allows external devices, using Voltage or Current analog outputs, to be read and stored.

The VL data loggers work by sampling and storing sensor readings at regular user-programmed sample intervals. In the VL-2000, both temperature and relative humidity readings are taken simultaneously and stored as a set because the response of the RH sensor is temperature-dependent. When the logger data is downloaded to a PC, the Veriteq vLog software package automatically process the raw data and creates an encrypted file for display, analysis, and reporting.

The Veriteq vLog software package is a commercial off-the-shelf program compatible with Veriteq VL and SP data loggers, offering data logger setup, graphing, and reporting functions. The Veriteq vLog software also includes unique file identifiers and password protection for data integrity.

4 Objective

The objective of this protocol is to qualify the installation and operation of the Veriteq vLog software at _____.

This protocol will verify the installation, correct functionality and operation of the Veriteq vLog software according to manufacturer's specifications and the requirements of _____.

5 Documentation Procedures

- 5.1 Data generated during the execution of this protocol will be collected and recorded on the data sheets provided. All supplemental information documents will be attached in the "Attached Exhibits" section of this protocol.
- 5.2 During the execution, the executor's initials and date will be provided at the time of completion for each activity.
- 5.3 Handwritten data is to be neatly printed using a black or blue ball point pen. Corrections are to be crossed out with a single line, initialed, and dated, with an explanation for the correction.
- 5.4 Charts, printout, notes etc. generated during the execution will be dated, signed, and attached to the completed protocol document.
- 5.5 All pages will be reviewed and signed by appropriate _____ personnel to verify document completeness.
- 5.6 Unless specifically required, tests and operational steps may be performed in sequences other than indicated.

- 5.7 Throughout this document, the use of N/A and U/A shall be interpreted as “not applicable” and “unavailable”, respectively. A written explanation must be provided whenever U/A is used.
- 5.8 Pages may be photocopied as needed in order to complete additional testing or perform testing required to resolve deviations/discrepancies. Additional pages must be numbered appropriately to identify them as extra pages and to identify the order in which they appear. Identification shall be applied using alphabetical characters next to the page number and a numeric group annotation to the right of the page number as it appears in the header. For example, if three (3) additional copies of page seven (7) of a forty-one (41) page document are required, the page numbering shall be annotated to read as follows: “Page 7A of 41, Additional page 1 of 3”.
- 5.9 Protocol Deviations

A deviation is defined as:

- A variance between observed conditions and acceptance criteria as stated within an approved protocol.
- A variance between the approved protocol procedure and the procedure followed in the testing.

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

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

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6 INSTALLATION QUALIFICATION

6.1 Test Plan

Testing will be performed to verify installation of the Veriteq vLog System in conformance with manufacturer's specifications and customer requirements. The test plan consists of five sections. These are:

6.1.1 Documentation

This section will verify the presence of all documentation necessary to qualify, maintain, and operate the system properly.

6.1.2 Logger Information

This section will verify that all Data Loggers are properly cataloged and that all configuration information for each logger is recorded.

6.1.3 Computer Hardware Requirements and Configuration

This section will verify that all required equipment is present and properly documented, and that it meets the hardware requirements of the Veriteq vLog system.

6.1.4 Software Installation Verification

This section will verify that the correct version of the Veriteq vLog software is present and properly installed on the PC.

6.1.5 Logger Configuration

This section will verify that the data logger's system configuration has been upgraded to enable the Stop Time feature.

6.2 Documentation

Record the following information for the system. Fill in all applicable information.

Document	Criteria	Storage Location (attach copies as necessary)	Meets Criteria Pass/Fail Initials/date
Purchase Order / Packing Lists	PO matches items received? Yes / No		
vLog installable disks	Back up disks available? Yes / No Location _____		
Calibration Program	Calibration Program has been documented.		
Drawings	<i>Showing installation locations.</i>		
Manuals	Document # / Description	Storage Location (attach copies as necessary)	
Veriteq vLog Software Quick-Start Guide	880-0003-01		
Veriteq vLog User's Guide	880-0206-00		

Comments/Deviations: _____

Acceptance Criteria: Sufficient documentation is in place to allow the user to properly install, operate, and maintain the system. All documentation is correct, current, and has been filed.

Acceptance Criteria Met? Pass/Fail: _____ Initials/Date: _____/_____

Reviewed by: _____ Date: _____

6.4 Computer Hardware Requirements and Configuration

Record the following information for each computer to be used in the Veriteq vLog System. Fill in all information that is applicable.

This form may be duplicated as needed to complete this section.

PC ID / Location	PC Model #	Operating System	Meets Hardware Requirements	Meets Criteria Pass/Fail Initials/date

Comments/Deviations: _____

Acceptance Criteria: Is the Veriteq Interface Cable/Device present? **Yes:** _____ / **No:** _____

Acceptance Criteria: Each computer must be able to connect to a Veriteq data logger using a Veriteq-approved interface cable or device. Approved interface cables and devices include the Veriteq Serial Cable, the Veriteq USB cable (with drivers installed), the Veriteq vNet device, and a selection of Ethernet to Serial devices manufactured by Digi International (with drivers installed). Each computer must be running one of the following approved operating systems: Microsoft Windows 2000, Microsoft Windows XP, Microsoft Windows Server 2003, Windows Vista, Windows Server 2008, or Windows 7.

Acceptance Criteria Met? Pass/Fail: _____ Initials/Date: _____ / _____

Reviewed by: _____ Date: _____

6.5 Software Installation Verification

Follow the steps below to confirm installation of the Veriteq vLog 4.4 software.

Note: *The software must only be installed on a PC that has passed the Hardware Requirements and Configuration qualification (Section 6.4 of the vLog IQ/OQ Protocol).*

Step	Procedure	Acceptance Criteria	Meets Criteria Pass/Fail Initials/date
6.5	Enter the PC ID for the computer used: _____	The PC ID is recorded.	
6.5	Insert the Veriteq vLog 4.4 software CD into the computer's CD-ROM drive.	If this is a new installation, the InstallShield Wizard starts and the Welcome dialog box appears. ¹ Skip to Step 6.5.6. If you are upgrading from a previous version of vLog, you will be asked if you wish to uninstall the previous version. Proceed to step 6.5.3.	
6.5	Click Yes to uninstall the previous version of vLog.	The InstallShield Wizard asks if you wish to completely remove the application and its features.	
6.5	Click Yes .	The InstallShield Wizard confirms that the Uninstall is complete.	
6.5	Click Finish .	The InstallShield Wizard for vLog starts and the Welcome dialog box is shown.	
6.5	Click Next .	The License Agreement is shown.	
6.5	Select " I accept the terms of the license agreement ", and click Next .	The Choose Destination Location dialog box appears.	
6.5	Click Next to accept the default installation location.	The Select Program Folder dialog box appears.	
6.5	Click Next to accept the default Program Folder.	The files are copied and the InstallShield Wizard Complete dialog box appears confirming that "Setup has finished installing vLog on your computer".	
6.5	Click Finish .	Installation is complete and the Wizard closes.	
6.5	From the Start menu, select Programs > Veriteq Instruments > vLog 4.4 > vLog to start the Veriteq vLog program.	For a new installation, a dialog box appears stating that Veriteq vLog is "unable to find the vLog security file", and prompts the user to create a new one.	

Step	Procedure	Acceptance Criteria	Meets Criteria Pass/Fail Initials/date
		If you are upgrading, the message states that the security file was created by a previous version of vLog. You have the option of updating the file or deleting and creating a new one.	
6.5	Click Yes .	The vLog Security Wizard prompts the user to retrieve the software security key, and the user name and password of an existing Windows Account. Note: <i>This user will be granted vLog ADMINISTRATOR status.</i>	
6.5	Click Next .	The vLog Security Wizard page is shown, prompting the user to enter the CD security key.	
6.5	Enter the CD security key, and click Next .	Upon successful security key entry, the vLog Security Wizard administrator account setup page is shown.	
6.5	Enter the Administrator's Windows Authentication User name and Password , and the Full name by which the user is identified. Click Next .	Upon successful entry of administrator's details, the wizard prompts the user to specify the audit trail folder location.	
6.5	Click Next to accept the default file location.	The vLog Security Wizard Security Level page is shown.	
6.5	Select High Security and click Finish .	The vLog program now starts.	
6.5	Click Help > About Veriteq vLog from the menu bar.	The Veriteq vLog box appears, displaying the software version in bold letters.	
6.5	Click the Veriteq vLog box.	The Veriteq vLog box disappears.	
6.5	Click File > Exit .	vLog closes.	

¹If the CD Autorun feature is disabled on your system, the installation must be manually started by double-clicking on the file D:\SETUP.EXE, where D: is the letter of your CD-ROM drive.

Comments/Deviations: _____

Acceptance Criteria: All Acceptance Criteria have been met and the Veriteq vLog Version 4.4 software is installed successfully.

Acceptance Criteria Met? Pass/Fail: _____ Initials/Date: _____/_____

Reviewed by: _____ Date: _____

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6.6 Test User Security Level Information

Using the Administrator account set up in Step 6.5.15, create the local vLog accounts as listed below. If the vLog Administrator account created during software installation is not the “administrator” account you wish to use during the protocol execution, create a second “Admin” account. These accounts will be used during the Operation Qualification testing. All accounts use Windows authentication. The User and Guest accounts must be either 2 existing Domain accounts, or new Local accounts created in advance by the Local Administrator.

Procedure:

1. Login to vLog using the **Administrator’s** Domain user name and password.
2. Go to **Tools > Administrator Options**.
3. Select the **Security** tab and click **Add**. Enter the information as listed in the table below.
4. Click **OK**.
5. Click **Test** and enter the user’s password. Click **OK**. If the setup has been successful, the message “The specified user credentials were successfully authenticated in Windows” appears.
6. Repeat the process for each user listed.
7. When finished, click **OK**.
8. Click **File > Exit**.

Name	Password	User Role	Use Windows Authentication	Meets Criteria
			Local/Domain	Pass/Fail Initials/Date
<Admin> (If applicable)	*****	Administrator	<Domain>	
User1	User1	User	<Local>	
Guest1	Guest1	Guest	<Local>	

Comments/Deviations: _____

Acceptance Criteria: All test users have been configured to have correct access level to the Veriteq vLog software via the vLog user logon.

Acceptance Criteria Met? Pass/Fail: _____ Initials/Date: _____ / _____

Reviewed by: _____ Date: _____

6.7 IQ Final Approval

The procedures in this section have been implemented, reviewed, and approved by the individuals listed below. All results have been documented and all deviations have been identified, documented, reviewed, and approved.

Note: *The Final "Approvers" should be the same as the original protocol approvers when available.*

Upon final approval OQ testing may commence.

Implemented by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Reviewed by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Approved by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

QA Approved by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

7 Operational Qualification Methodology

7.1 Test Plan

Testing will be performed to verify that the operation of the Veriteq vLog System is in conformance with manufacturer's specifications and customer requirements. The Acceptance Criteria for all sections are derived from Veriteq Instruments' recommendations. The test plan will consist of four main sections, as defined below.

7.1.1 Functional Testing

Functional testing will verify the following capabilities of the Veriteq vLog software:

- Veriteq vLog Software Setup
- Logger Communication
- Batch Transfers
- Graph Files
- Graph Titles
- Time Axis Settings
- Scrolling and Zooming
- Logger Files and the Cursor
- Multiple Logger Files
- Axis Units and Range
- Printing of Secure and Non-Secure Logger Files
- Data Integrity and Security

7.1.2 Statistical Testing

Statistical testing will ensure that the data within the files is correctly displayed, and calculated to provide validated results.

- Instantaneous Value Reports
- Channel Minimum, Maximum and Average Reports
- Channel Statistical Deviation Reports
- Group Minimum, Maximum and Average Reports
- Group Statistical Reports
- Channel and Group Mean Kinetic Temperatures
- Lethality

7.1.3 Audit Testing

Uneventful testing will test the Auditing of Veriteq vLog System interaction as a whole, and will consist of the following parts:

- Linking Loggers to an Audit Trail
- Single Logger Processing
- Batch Logger Processing

- User Account Privileges
- Account Security
- Data Accuracy
- Audit File Integrity
- Security File Integrity
- Batch File Integrity

7.1.4 Eventful Testing

Eventful testing is concerned with testing unexpected events. The tests will verify that the Veriteq vLog System can handle these unexpected events with no loss or corruption of data. These events are:

- Logger Disconnection During Transfer
- System Power Loss During Transfer

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7.6 OQ FINAL APPROVAL

The procedures in this section have been implemented, reviewed and approved by the individuals listed below. All results have been documented, all generated reports have been attached to this document and all deviations have been identified, documented, reviewed and approved.

Implemented by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Reviewed by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Approved by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

QA Approved by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

9 IQ/OQ DOCUMENT FINAL APPROVAL

The Veriteq vLog System has passed all tests, and as such, is qualified to be used in the _____ environment:

Reviewed by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

Approved by: _____ Initials: _____ Date: _____

Name (Print): _____

Title: _____

Company: _____

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10 DOCUMENT HISTORY

Note: This section is for internal tracking purposes and may be omitted depending on your procedure for validation document revisions, SOP # _____ .

Document #	Description of changes	Date	By

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