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1.0 Purpose

The purpose of this operating instructions is to offer a general instruction on how to set-up and use the Kaye Validator AVS(Advanced Validation System), Temperature reference and thermocouples or other compatible sensors.

2.0 Scope

This SOP applies to all Biopharmaceutical Development Program (BDP) personnel, as well as offsite facility personnel, using the Kaye Validator AVS platform.

3.0 Authority and Responsibility

- 3.1 The Quality Engineering and Validation Manager, Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.
- 3.2 BQA is responsible for assignment of this procedure, training personnel in this procedure, and for documenting training.
- 3.3 Personnel using the validation system to capture temperature or other parameters (i.e. Kaye Validator®, Kaye Validator® AVS, E-Val™, or equivalent) are responsible for complying with this procedure.

4.0 Equipment

4.1 Kaye Validator AVS

- 4.1.1 Self-contained thermal validation device with high accuracy sensor measurement hardware and secure data recording capability.
- 4.1.2 Standalone functionality when calibrating sensors, running qualification studies, and verifying sensor calibration.
- 4.1.3 Accepts up to 48 inputs in any combination of thermocouple, voltage, and current inputs.
- 4.1.4 The Internal memory is 4 GB which provides a location for qualification data to be maintained. Qualification data resides in internal memory. A Lithium ion backup



battery provides short-term power in case of AC power loss. A fully charged battery will provide approximately 4 hours of reserve power to perform an orderly shutdown of the system.

4.2 Kaye Validator AVS Software (Version 1.5 or higher)

- 4.2.1 Create user accounts and assign user IDs, passwords and permission levels.
- 4.2.2 Create validation study setups that can be run standalone or Console-controlled. When calibrating sensors and running qualification studies from the Console, the Kaye Validator AVS software features expanded tools for viewing and displaying data.
- 4.2.3 Generate reports from secure data files that contain original calibration and qualification data recorded during the study.
- 4.2.4 Access the Kaye Validator AVS Audit Trail, which provides a complete listing of events that affect the integrity of the Kaye Validator AVS software and the Kaye Validator AVS instrument.

4.3 Sensor Input Modules (SIMs)

- 4.3.1 Sensor input module to which thermocouples or other measuring devices are connected.
 - X2600: Sensor Input Module (SIM) without thermocouple probes & wiring. Provides up to 12 inputs
 - X2601: 4/20 Sensor input module without sensor wiring, easily connect 4/20 mA transducers to AVS. Includes sense resistor and separate power connector. Provides up to 12 inputs
 - X2602: RTD Input Module (100Ω RTD). Provides up to 6 inputs
- 4.3.2 Each SIM has a memory chip to store calibration offsets, SIM serial number, slot location, and the serial number of the Kaye Validator AVS measurement board on which calibration is performed.
- 4.3.3 SIMs can be wired by the user or purchased pre-wired.

4.4 Temperature Reference

Temperature references provide the stable temperature required for sensor calibration. Amphenol Advanced Sensors has five temperature reference models. They are designed to provide different temperature ranges and are compatible with the Kaye Validator AVS.

CTR -80 (setpoint range -80°C to -30°C)

This bath is recommended for calibration of sensors used in freeze dryers, freezers, and cryogenic units. The CTR -80 accepts up to 36 TCs



LTR –90 (setpoint range –95°C to 140°C at 23°C ambient)

This bath is recommended for calibration of sensors used in freeze dryers, freezers, cryogenic units, cold rooms, incubators, and steam autoclaves. The LTR –90 accepts up to 12 thermocouples 7 stranded.

LTR –25/140 (setpoint range –25°C to 140°C at 25°C ambient)

This bath is recommended for calibration of sensors used in freezers, cold rooms, incubators, and steam autoclaves. The LTR –25/140 accepts up to 18 thermocouples.

LTR –40/140 (setpoint range –40°C to 140°C at 25°C ambient)

This bath is recommended for calibration of sensors used in freezers, cold rooms, incubators, and steam autoclaves. The LTR –40/140 accepts up to 18 thermocouples.

LTR-150 (setpoint range -30°C to 150°C at 20°C ambient)

This bath is recommended for calibration of sensors used in freezers, cold rooms, incubators, and steam autoclaves. The LTR –150 accepts up to 48 thermocouples.

HTR 400 (setpoint range 25°C above ambient to 400°C)

This bath is recommended for calibration of sensors used in steam autoclaves, dry heat ovens, and tunnel sterilizers. The HTR 400 accepts up to 24 thermocouples. For stability chambers and steam sterilizers, PTFE-insulated Type T thermocouples are used. For dry heat and tunnel sterilizers, Kapton-insulated Type T thermocouples are used.

HTR 420 (setpoint range 30°C above ambient to 420°C)

This bath is recommended for calibration of sensors used in steam autoclaves, dry heat ovens, and tunnel sterilizers. The HTR 420 accepts up to 48 thermocouples. For stability chambers and steam sterilizers, PTFE-insulated Type T thermocouples are used. For dry heat and tunnel sterilizers, Kapton-insulated Type T thermocouples are used.

IRTD 400 The Kaye IRTD 400 (M2801) temperature measurement standard is required for fully automatic sensor calibration and calibration verification. The IRTD 400 has a measurement accuracy of $\pm 0.025^\circ\text{C}$ within a temperature range of -195°C to 420°C .

5.0 Procedure

5.1 Wiring SIMs

There are two methods for wiring SIMs. You can assign sensor locations in the Setup file and then wire the sensors according to the Setup Report, or you can buy pre-wired SIMs or wire the SIMs yourself and then create a Setup that reflects the sensor locations. The steps below provide instruction for how to wire SIMs yourself.



- 5.1.1 Loosen the two screws in the top of the SIM and open the cover.
- 5.1.2 Using appropriate thermocouple wire, cut lengthwise through the outer insulation to separate the red and blue wires, remove the resulting excess exterior sheathing, and then strip back each wire approximately ½ inch in order to make the connection with the SIM connectors. Connect the positive (+) lead to the positive (+) connector and the negative (-) lead to the negative (-) connector. The negative thermocouple lead is normally red, in conformance with ANSI standards. For Type T thermocouples, the positive lead is blue.
- 5.1.3 When validating moist heat processes, thermocouples with a sealed PTFE tip should be used with a drip cut through the outer insulation close to the SIM module to reduce the possibility of drawing moisture into the SIM. To add a drip cut, remove 4 inches (10 cm) of the outer insulation from each thermocouple at a point where natural drainage can take place to prevent water reaching the terminal screws.
- 5.1.4 Amphenol Advanced Sensors also recommend shaving open about 1/4 inch from each of the red and blue inner wire jackets at opposite ends of the outer insulation drip cut to allow condensate drainage from within the individual wires. If moisture does collect in the SIM, remove the SIM from the instrument, open, and allow to air dry before storage.
- 5.1.5 Connect dry contact inputs directly to the SIM connectors.
- 5.1.6 Connect voltage inputs (up to 10 VDC) to the SIM connectors. Connect the positive (+) lead to the positive (+) connector and the negative (-) lead to the negative (-) connector.
- 5.1.7 For current applications using the Thermocouple SIM, connect a 250Ω precision shunt resistor to the SIM connector in parallel with the input leads. The 250Ω resistor converts a 4-20 mA signal to 1-5 volts. Connect the positive (+) lead from the power supply to the positive (+) SIM connector, the positive (+) lead from the device to the negative (-) SIM connector, and the negative (-) lead from the device to the negative (-) power supply connector.
- 5.1.8 Using the 4/20 mA SIM connect the positive (+) lead from the device to the positive (+) SIM connector, the positive (-) lead from the device to the negative (-) SIM connector. Place the shunts on the module to internal or external power. Internal power (J26) means the device will be powered by the AVS. External power (J26) means the power will be supplied from a remote source. Maximum draw for this module is 240mA.
- 5.1.9 Using the RTD SIM connect the 100Ω device to the module. Connect the two red wires to (+), Connect the white wires to (-) to the channel you will be using.
- 5.1.10 Once all sensors are connected, route the wire harness around the terminal connectors and out the drain hole. Secure the wire harness with tie wraps.
- 5.1.11 Close the SIM cover and tighten the screws.

5.2 Connecting the System

All system connections are on the back of the Kaye Validator AVS. Each connection port is labeled with an icon representing its function.



- 5.2.1 Make sure the Kaye Validator AVS and the temperature reference are powered off before connecting the system.
- 5.2.2 Inspect the IRTD 400 for physical damage. Do not use the IRTD 400 if it is bent or damaged in any way. Insert the IRTD 400 into the temperature reference bath/well.
- 5.2.3 Connect the IRTD 400 to one of the appropriate (4 pin DIN connector) sockets, using the cable supplied with the IRTD.
- 5.2.4 Connect the temperature reference to its appropriate (4 pin DIN connector) socket, using the cable supplied with the temperature reference.
- 5.2.5 Connect the Console to AVS Dock.
- 5.2.6 Connect the temperature reference and Kaye Validator AVS power cable to a grounded power source.
- 5.2.7 Insert the wired SIMs into the SIM slots. Label each SIM with the associated slot number.
- 5.2.8 Turn the temperature reference power switch to the ON position.
- 5.2.9 Turn the Kaye Validator AVS power switch to the ON position.



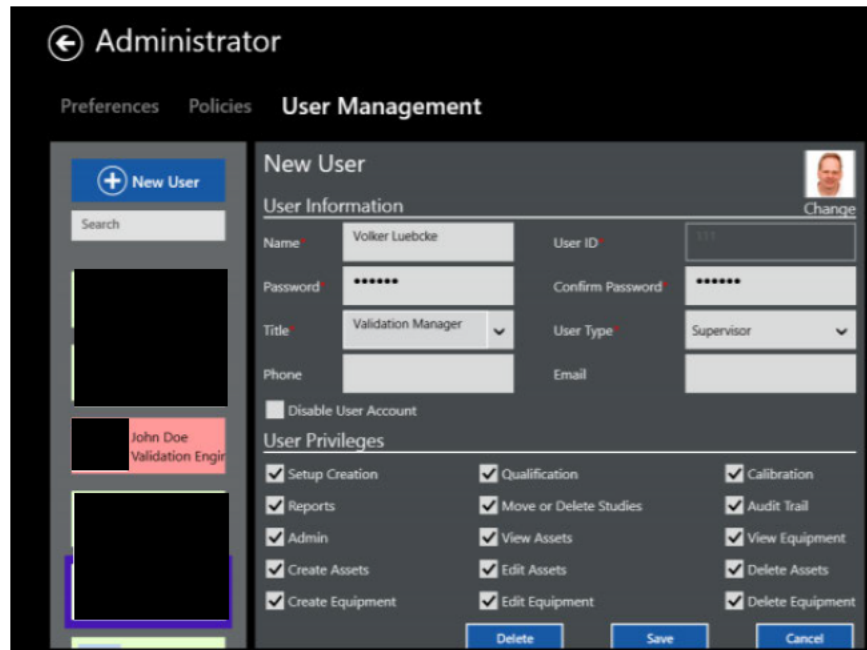
5.3 AVS Console Power Settings

NOTE: If AVS tablet console has multiple power plans then each plan should be configured as defined below.

- 5.3.1 Go to Windows CONTROL PANEL and select SYSTEM AND SECURITY.
- 5.3.2 Select POWER OPTIONS then select CHANGE PLAN SETTINGS.
- 5.3.3 Set power settings for BATTERY and PLUGGED IN to NEVER for both TURNOFF DISPLAY AND PUT THE COMPUTER TO SLEEP.
- 5.3.4 Select CHANGE ADVANCED POWER SETTINGS and expand list under SLEEP. For SLEEP AFTER set BATTERY and PLUGGED IN to NEVER. For ALLOW HYBRID SLEEP set BATTERY and PLUGGED IN to OFF. For HIBERNATE AFTER set BATTERY and PLUGGED IN to NEVER.
- 5.3.5 Next Go to Windows DEVICE MANAGER and expand the list under NETWORK ADAPTORS.
- 5.3.6 Check this is the latest version of the document before use Effective Date:
- 5.3.7 Right click on LAN9500A USB 2.0 TO ETHERNET 10/100 ADAPTOR and select PROPERTIES.
- 5.3.8 Select the POWER MANAGEMENT tab.
- 5.3.9 Uncheck the box ALLOW THE COMPUTER TO TURN OFF THIS DEVICE TO SAVE POWER and click OK.

5.4 Creating User Accounts

- 5.4.1 The Validator AVS software has designed user level specific permissions that define system access. Permissions can also be customized for each user. In general, there are two levels of user type; System administrator and Operator.
- 5.4.2 System Administrator – Responsible for the security of the program. The System Administrator has privileges to creates and maintains user accounts, sets site options, delete equipment, access to Audit trail, move or delete studies and back ups and restores user information.
- 5.4.3 Operator- Create, modify, or move a setup, Change the setup stored in the Validator AVS, calibrate sensors or verify sensor calibration, manually start or stop a qualification study and Generate reports.
- 5.4.4 Each user is assigned two distinct levels of identification, user ID and password, which are used to uniquely identify an authorized Validator AVS user. Each user ID is associated with a unique user name to provide traceability during the validation process.



User Management Tab

5.5 Starting the Kaye Validator AVS Software

- 5.5.1 Verify that the communication connections between all equipment is established per Section 5.2.
- 5.5.2 To start the AVS software, navigate to the Console homepage.
- 5.5.3 Select on the KAYE VALIDATOR AVS tile. The Kaye Validator AVS user login screen appears.
- 5.5.4 Log in to the AVS console. The Hub page appears.

NOTE: The Hub page provides access to the major functions of the Kaye Validator AVS software.

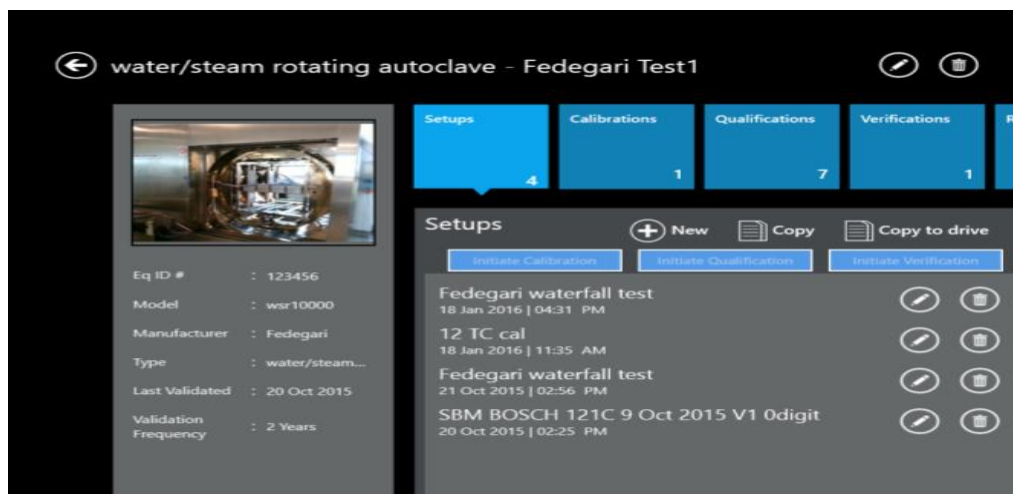
- 5.5.5 Select the Hardware tab.
- 5.5.6 Each hardware item is shown with a communication link. A Device Not Found symbol (Grey color line) indicates a communication problem. If the hardware is greyed out and not communicating, troubleshoot using the user's manual or contact the area supervisor.

5.6 Creating/Modifying a Setup

NOTE: The Setup defines everything required to calibrate sensors, run qualification studies, and verify sensor calibration. The Setup is created/modified using the

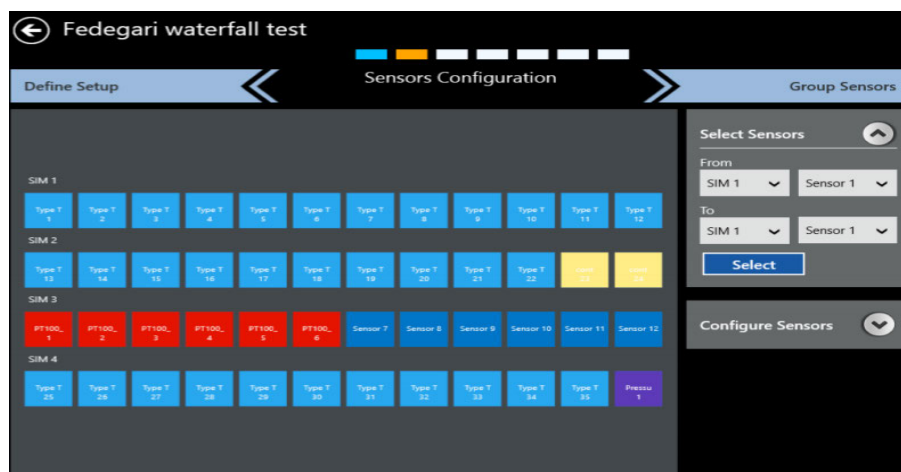


Kaye Validator AVS software. The Console does not have to be connected to the Kaye Validator AVS to create/modify Setups.



Asset Details

- 5.6.1 On the Activity page, select Assets tile, then on Asset Details page select Setups tab.
- 5.6.2 Existing Setups are listed by the date and time the files were saved.
- 5.6.3 To create a new Setup, select New, enter up to 35 characters to describe the Setup, and select Sensor Configuration.
- 5.6.4 To modify an existing Setup, select the Setup from the file list and select edit icon.
- 5.6.5 The Sensors screen appears.



- 5.6.6 Add, modify, or delete sensor configurations as necessary.
- 5.6.7 Select sensors by selecting a sensor tiles in the SIM.



- 5.6.8 To add or modify a sensor definition, enter/modify the sensor label and sensor description, and select a sensor type. Specify scale factors as required. To automatically number multiple sensor definitions, select Auto Numbering both check boxes to append 2 digits in sequence to the sensor label and description label. Select OK for the Descriptions and then Assign.
- 5.6.9 To remove sensor location(s), select the sensor tile again to deselect it.
- 5.6.10 Select the GROUP SENSORS tab.
- 5.6.11 Change group titles or add groups as necessary (up to 25 groups, 35 characters) in the group list box.
- 5.6.12 To assign sensors to the groups:
- 5.6.13 Select the study group from the list box.
- 5.6.14 Assign the sensor locations as necessary by clicking on the applicable tiles.
- 5.6.15 Repeat for all groups as needed.
 - NOTE:** Sensors of different types should not be mixed in a group. The Group Sensors screen also offers the wiring overlay features. In the wiring overlay one of the pictures predefined in the asset details can be chosen as a background while the sensors per group can be dragged into the picture to reflect the position during the study. The sensor positions are stored in the setup. The printer button enables the export of the wiring overly to a pdf file that can be uploaded to the asset with the upload document function in the asset details. Save the changes.
- 5.6.16 Select the CALCULATIONS tab.
- 5.6.17 Select STATISTICAL CALCULATION and ensure all calculations are selected.
 - NOTE:** For Temperature Mapping (CTU) Studies, select 'Undefined' for Calculate Lethality option.
- 5.6.18 Select the CAL/VER PARAMETERS tab.
- 5.6.19 Set the temperature set points, stability criteria, and deviation criteria as necessary as per SOP **21558** "*Guidelines for using Temperature Recording Devices for Validation*".
- 5.6.20 Enter the Calibration Temperature setpoints.
- 5.6.21 Enter the same setpoints as the Verification Temperature setpoints.
- 5.6.22 For the Calibration and Verification Temperature setpoints, ensure Low, High, and Check are selected.
- 5.6.23 Select the QUALIFICATION PARAMETERS tab.
- 5.6.24 Set the START STOP CONDITIONS.
- 5.6.25 Set the DATA STORAGE SAMPLING RATE as directed by the validation protocol.



- 5.6.26 Set the CLOCK ADJUSTMENT MANUAL ADJUSTMENT to At Qualification Start.
- 5.6.27 Leave the RELAY parameter set at the default value.
- 5.6.28 Select the REVIEW tab and ensure the setup is correct.
- 5.6.29 Select SAVE to save the setup file.
- 5.6.30 Enter username and password, then select OK. A message will appear indicating that the setup has been saved.
- 5.6.31 In the bottom left of the screen, select AVS SOFTWARE to return to the review page. Select the back arrow until you have returned to the Hub page.

5.7 Sensor Calibration

- 5.7.1 Calibrate sensors before running the qualification study.
- 5.7.2 Place the Kaye Validator AVS (with temperature reference and IRTD connected) in a location with stable and even temperature, not exposed to any local heating or cooling sources (i.e., close to a sterilizer, an open door causing a draft, etc.).
- 5.7.3 Insert the TCs to be used into the temperature reference bath, ensuring that all TC tips are touching the bottom of each well. For liquid nitrogen (LN2) bath, carefully insert the TCs and IRTD into the LN2 Dewar and ensure the tips are dipped inside the liquid nitrogen at an appropriate level.

NOTE: Temperature reference baths have three-hole well inserts, which only allow for three TCs per well. If more than three TCs need to be placed in the well, remove the inserts.

- 5.7.4 Load the setup from the AVS console onto the AVS as follows:
 - 5.7.4.1 From the Hub page, select the ASSETS tile.
 - 5.7.4.2 Select the asset's tile created for the study.
 - 5.7.4.3 On the SETUPS tab, select the setup file created for the study.
 - 5.7.4.4 Select INITIATE CALIBRATION.
 - 5.7.4.5 Select individual sensors by clicking on each one individually or by clicking SELECT ALL.
 - 5.7.4.6 Select INITIATE CALIBRATION.
- 5.7.5 To begin sensor calibration, press START. Select YES on the Warning popup screen to Initiate Calibration. The AVS automatically performs sensor calibration at the specified set points.

NOTE: For TC calibration using LN2, since the Dewar (Temperature Reference Bath) does not get connected to Kaye AVS, an error message indicating "No Bath Detected" will be displayed when attempting to start calibration. Select "Yes" to initiate manual calibration.



5.7.6 When calibration is complete, select SAVE to save the file.

5.7.7 Generate and print the sensor calibration report

5.8 Qualification Study

5.8.1 Ensure sensor calibration has been performed per Section 5.6.

5.8.2 Position sensors in vessel or chamber being tested.

5.8.3 Insert a new (or freshly formatted) memory card into the USB card port.

5.8.4 Load the setup from the AVS console onto the AVS as follows:

5.8.4.1 From the Hub page, select the ASSETS tile.

5.8.4.2 Select the asset's tile.

5.8.4.3 On the SETUPS tab, select the setup file created for the study.

5.8.4.4 Select INITIATE QUALIFICATION.

5.8.4.5 Enter the protocol and run numbers.

5.8.4.6 Select individual sensors by clicking on each one individually or by clicking SELECT ALL.

5.8.5 Select START QUAL to begin the qualification study.

NOTE: The qualification study data can be viewed in either List view which displays all the real-time data of the sensors in the groups or in graph view which displays real time data on a line graph for the selected group.

5.8.6 To stop the qualification study at any time, select the STOP QUALIFICATION.

5.9 Calibration Verification

5.9.1 Perform post qualification verification on all sensors used following completion of the qualification study.

5.9.2 Insert the thermocouple sensors into the temperature reference.

5.9.3 Load the setup from the AVS console onto the AVS as follows:

5.9.3.1 From the Hub page, select the ASSETS tile.

5.9.3.2 Select the asset's tile.

5.9.3.3 On the SETUPS tab, select the setup file created for the study.

5.9.3.4 Select INITIATE VERIFICATION.

NOTE: If the USB/Docking Screen appears, highlight the USB/Docking Tile and select Connect.

5.9.3.5 Select individual sensors by clicking on each one individually or by clicking SELECT ALL.



5.9.3.6 Select INITIATE VERIFICATION.

5.9.4 To begin sensor verification, press START. The AVS automatically performs sensor verification at the specified set point.

5.9.5 If the lower port of the block is not connected, a popup will appear. Select YES, enter your credentials, select YES, and select DONE.

5.9.6 When verification is complete, press SAVE STUDY to save the file. Enter your credentials and select OK for the study file name popup.

5.9.7 Back out to the Hub page. Select NO for the continue with Sensor Verification pop-up.

5.9.8 Generate and print the sensor calibration/verification report

5.10 **Generating Reports**

5.10.1 **Generating Setup Reports**

5.10.1.1 Setup Reports can be generated from Setup file.

5.10.1.2 On the Console, go to Setups tab of Asset details screen of Kaye Validator AVS application.

5.10.1.3 Select Setup and select edit icon.

5.10.1.4 Step through the screen and to the review pane and select Create Setup Report, enter user ID & password generate Report in PDF.

5.10.2 **Generating Calibration Reports**

5.10.2.1 On the Console, open Kaye Validator AVS application, select Asset pane, and select an Asset

5.10.2.2 Select Calibrations pane, select a Calibration Study file and select Generate Reports.

5.10.2.3 Select Standard Reporting,

5.10.2.4 The File Selection screen appears, listing all Calibration files stored in the default data path.

5.10.2.5 Select a Calibration file, select Adobe icon. Select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF.

5.10.2.6 Return to the AVS software, select ← on left top to go back to the Activities screen.

5.10.3 **Generating Qualification Reports: Procedure for Qualification Report Generation Using the Kaye Validator AVS**

5.10.3.1 On the Console, open Kaye Validator AVS application, select Asset pane, and select an Asset.



- 5.10.3.2 Select Qualifications pane, select a Qualification Study file and select Generate Reports
- 5.10.3.3 Select Standard Reporting.
- 5.10.3.4 The File Selection screen appears, listing all Qualification files stored in the default data path.
- 5.10.3.5 Select Qualification file icon.
- 5.10.3.6 On the Select Sensor(s) Type screen, select Temperature and select OK.
- 5.10.3.7 The Select Cycles graph appears. On the Mark Qualification Start and End window, select Accept to accept the defaults. If applicable, on the Marking Exposure window, select Accept to accept the defaults.
- 5.10.3.8 Select Next on the top right of the screen. If applicable, on the Edit Cycle Name Alert window select No when asked to edit the cycle names.
- 5.10.3.9 Edit new groups or calculations if applicable. Select → on the top right.
- 5.10.3.10 Select Graph Report Tile, select Generate Report, enter a graph name, and select Apply. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF. Return to the AVS software, select ← on left top to go back to previous screen.
- 5.10.3.11 Choose Custom Report. Enter all required information and Select Generate Report. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF. Return to the AVS software, select ← on left top to go back to previous screen.
- 5.10.3.12 Select Standard Reporting Tile. By default, Detailed Report is selected. To change the settings for Report Content and Header / Footer select the appropriate button.
- 5.10.3.13 Select Generate Report, select View Report. Select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF. Return to the AVS software.
- 5.10.3.14 On Report Generation screen select Close.
- 5.10.3.15 Choose "Summary Report". To change the settings for Report Content and Header / Footer select the appropriate button and select Save after changes are made.



- 5.10.3.16 Select Generate Report select View Report, select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF. Return to the AVS software.
- 5.10.3.17 On Report Generation screen select Close.
- 5.10.3.18 Choose Interval Calculations Report. To change the settings for Report Content and Header / Footer select the appropriate button and select Save after changes are made. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save.
- 5.10.3.19 On Report Generation screen select Close.
- 5.10.3.20 Choose Pass-Fail Criteria Report. Define a new template or use an existing. Select the → on the top right. Mark the template and select Generate Report. Select View Report. Select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF. Return to the AVS software.
- 5.10.3.21 On Report Generation screen select Close. Select ← on left top to go back to the Activities screen.
- 5.10.4 Generating Qualification Reports: Procedure for Qualification Report Generation Using the AVS Reporting Tool
 - 5.10.4.1 On the Console, open AVS Reporting Tool application, select an Asset.
 - 5.10.4.2 Select Standard Reporting Tile
 - 5.10.4.3 The File Selection screen appears, listing all the Qualification files stored in the default data path.
 - 5.10.4.4 To create a CSV file, select box for the Qualification file, select Export CSV. Select the data options that are to be exported, select OK. Identify the destination for the exported file, select Choose this folder. Select OK. Message will display CSV file has been generated.
 - 5.10.4.5 Select Qualification Icon.
 - 5.10.4.6 On the Select Sensor(s) Type screen, select Temperature and select OK.
 - 5.10.4.7 The Select Cycles graph appears. On the Mark Qualification Start and End window, select Accept to accept the defaults. If applicable, on the Marking Exposure window, select Accept to accept the defaults.
 - 5.10.4.8 Edit new groups or calculations if applicable. Select → on the top right.



- 5.10.4.9 Select Next on the top right of the screen. If applicable, on the Edit Cycle Name Alert window select No when asked to edit the cycle names.
- 5.10.4.10 Select Graph Report Tile, select Generate Report, enter a graph name, and select Apply. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF. Return to the Reporting Tool software, select ← on left top to go back to previous screen.
- 5.10.4.11 Choose Custom Report. Enter all required information and Select Generate Report. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF.
- 5.10.4.12 Select Generate Report, select View Report. Select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF.
- 5.10.4.13 On Report Generation screen select Close.
- 5.10.4.14 Choose "Summary Report". To change the settings for Report Content and Header / Footer select the appropriate button and select Save after changes are made.
- 5.10.4.15 Select Generate Report select View Report, select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF.
- 5.10.4.16 On Report Generation screen select Close.
- 5.10.4.17 Choose Interval Calculations Report. To change the settings for Report Content and Header / Footer select the appropriate button and select Save after changes are made.
- 5.10.4.18 Select Generate Report select View Report, select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF.
- 5.10.4.19 On Report Generation screen select Close.
- 5.10.4.20 Choose Pass-Fail Criteria Report. Define a new template or use an existing. Select the → on the top right. Mark the Pass Fail Report and select Generate Report. Select View Report. Select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF.



- 5.10.4.21 On Report Generation screen select Close. Select ← on left top to go back to previous screen.
- 5.10.5 Generating Verification Reports
 - 5.10.5.1 On the Console, open Kaye Validator AVS application, select Assets pane, and select an Asset.
 - 5.10.5.2 Select Verifications pane, select a Verifications Study file and select Generate Reports.
 - 5.10.5.3 Select Standard Reporting.
 - 5.10.5.4 The File Selection screen appears, listing all Verification files stored in the default data path.
 - 5.10.5.5 Select a Verification file, select Adobe icon. Select to open the file with Xodo. Once report appears, swipe your finger from the top of the screen, then Save As, enter a File name and location and save. Close the PDF.
 - 5.10.5.6 Return to the AVS software, select ← on left top to go back to the Activities screen.

5.11 Using the Kaye Validator AVS Audit Trail

- 5.11.1 Within the Kaye Validator AVS program, select the AUDIT tile.
- 5.11.2 When the Audit Trail window opens, click on the Filter icon for the Date column.
- 5.11.3 Select the start date of the audit trail by choosing IS GREATER THAN OR EQUAL TO, then select the desired start date.

NOTE: The start date should be the day that the AVS was first used for the study (e.g. thermocouple calibration) or when the AVS was first used for each individual equipment validation within the study.
- 5.11.4 Select the end date of the audit trail by choosing IS LESS THAN OR EQUAL TO, then select the desired end date.

NOTE: The end date should be the last day the AVS was used for the study (e.g. thermocouple verification,) or when the AVS was last used for each individual equipment validation within the study.
- 5.11.5 Select FILTER.
- 5.11.6 After filtering the Audit Trail with the appropriate dates, the Audit Trail can be filtered by User ID, User Name, and/or Device Name as applicable to the validation study.
- 5.11.7 Select GENERATE REPORT.
- 5.11.8 Enter User ID and Password, then click OK.
- 5.11.9 Export a PDF file as follows:



- 5.11.9.1 Select EXPORT.
- 5.11.9.2 Select
- 5.11.9.3 When the Export Settings screen appears, ensure All is selected under Page Range.
- 5.11.9.4 Select.
- 5.11.9.5 Enter the PDF file name.
- 5.11.9.6 Specify the folder to save the file in.
- 5.11.9.7 Select SAVE. Check this is the latest version of the document before use Effective Date:
- 5.11.10 Print the file as follows:
 - 5.11.10.1 Select on the printer icon or select File à Print.
 - 5.11.10.2 Select a printer in the Print dialog box.

6.0 References and Related Documents

Kaye Validator AVS User's Manual, Document M5100

SOP 21558 Guidelines for using Temperature Recording Devices for Validation

7.0 Change Summary

