Validation

Kaye Validator® AVS

User Manual

M5100-EN Rev. K
September 2020

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Kaye Validator ® AVS

Thermal Process Validation System

User Manual

M5100-EN Rev. K
September 2020

967 Windfall Road
St. Marys, PA 15857-3333, USA
Web: www.kayeinstruments.com

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Chapter 1. Kaye Validator AVS

1.1. Introduction

Figure 1: Kaye Validator AVS

The Kaye Validator® AVS system is a validation system designed for thermal process validation in the pharmaceutical and biotechnology industries. It features automated and manual sensor calibration / verification, qualification studies and reporting.

A complete Kaye validation package includes:

- A Kaye Validator AVS.
- A Kaye Validation Console for programming and control.
- Up to four Kaye Sensor Input Modules (SIMs) per Validator.
- A Kaye Temperature Reference; (Low Temperature LTR-90, LTR-40/140, LTR150, CTR-40, CTR-80) or (High Temperature HTR400, HTR 420).
- A Kaye IRTD Traceable Intelligent Temperature Standard.
- Premium grade thermocouples. Additional temperature and non-temperature sensors for qualification studies (optional).

1.2. Validator AVS Benefits

A Kaye Validator AVS system consists of the Validator AVS and the Validation Console. The console can be docked directly to the Validator AVS and used as the operator interface to the Validator AVS. Selectable input capacity (1 to 4 SIMs) up to 48 total inputs.

1.2.1. Validator AVS Hardware

- Standalone operation for running Qualification, and Calibration/ Verification studies
- Expanded Sensor Capacity: 48 inputs T/C, RTD, Volts, and Current inputs
- Improved SIM design and sensor connectivity
- Improved scan time 36 channels / sec (DAQ 1), 48 channels / sec (DAQ 2)
- Ethernet/ Wi-Fi/ Docking Station connectivity with AVS Console
- Battery Backup with field replaceable battery pack (three hours)
- Internal memory for data storage of last ten studies
- Improved connectivity with Kaye IRTD and Kaye Temperature References
- Backward compatible with Kaye IRTD, Kaye Dry Wells, and Baths
- IP55 rated, chemical resistant ABS housing with carry handles

1.2.2. Validator AVS Console / Software

- Hardened, rugged Console (Windows 10 LTSC) dedicated to validation tasks pre-loaded with all Kaye AVS software
- Easy-to-operate / state-of-the art intuitive user interface
- Ethernet/ Wi-Fi/ Docking Station connections to AVS hardware
- Asset centric concept for process equipment and Kaye hardware
- Improved Reporting Tool –including Pass / Fail Report
- Core Load and Software designed to address Data Integrity and 21 CFR Part 11 requirements
- Sync functionality for data back and storage
- Reduces Validation effort and provides enhanced reliability
- Console includes hot swappable battery and onboard camera

1.3. About this Manual

The first section of this manual provides an overview of the Validator AVS hardware, instructions for creating user accounts, entering asset and equipment information, and an overview on using the Validator AVS software. The second section of this manual covers, using the Validator AVS, including calibrating sensors, running qualification studies, and verifying sensor calibrations.

The following is a brief description of each Chapter of this user's guide:

- *Chapter 1* provides an overview of the Validator AVS system.
- *Chapter 2* explains the Validator AVS hardware and provides instructions to connect the system.
- *Chapter 3* provides instructions for creating user accounts and privileges.
- *Chapter 4* provides instructions for entering Kaye equipment into the system.
- *Chapter 5* provides instructions for entering assets into the system.
- *Chapter 6* provides instructions for creating setups.
- *Chapter 7* provides instructions for performing calibration or verification.
- *Chapter 8* provides instructions for performing a qualification study.
- *Chapter 9* provides instructions for displaying live data on the Console.
- *Chapter 10* provides instructions for creating reports.

1.4. The Validator AVS System

The Validator AVS system integrates hardware and software and provides unparalleled accuracy and flexibility to configure studies, calibrate and verify sensors, run qualification studies, and generate reports to evaluate the performance of your processes.

The Validator AVS system has two main components the Validator AVS hardware and the Validator AVS Console.

1.4.1. Validator AVS Hardware

The Validator AVS is the heart of the Validator AVS system and it can run as a standalone unit.

All connectivity to sensors, calibration equipment, as well as the AVS console is done through the AVS. The AVS performs all sensor measurement, calculations, and generation of raw encrypted data files. Once a configuration / setup is downloaded from the console, the AVS hardware controls the complete Qualification as well as Calibration / Verification process. The AVS then creates and stores encrypted data files to its internal storage and sends those files to the Console for reporting and analysis.

Figure 2: Validator AVS Hardware

1.5. The Validator AVS Console / Software

Figure 3: Validator AVS Console

The Validator AVS system includes a portable, hardened dedicated validation Console running on Windows 10 LTSC. There are two different designs of the console, but each have the same functionality. The AVS Console is pre-loaded with a customized Kaye core-load designed to meet data integrity requirements and limit applications to only those necessary for validation needs.

The AVS Console can be docked directly into the AVS hardware or connected via a WIFI or LAN connection. The AVS Console / Software provides an interface for the AVS to configure and control the AVS hardware during validation processes. It also provides real-time display, data storage, and a powerful reporting tool for post analysis of Qualification data.

AVS software contains features to do the following:

- Create Assets
- Create Setups
- Perform Sensor Calibration
- Run Qualification Studies
- Perform Sensor Verification
- Create Qualification Reports

1.5.1. Study Setup

The study setup defines everything required to calibrate sensors and run a qualification study. When you create a setup, you:

- Define the number and type of sensors to be used in a Qualification Study
- Assign sensors to groups (Distribution / Penetration) for reporting and calculations purposes
- Define group events to be monitored during the qualification study
- Specify calibration setpoints, temperature stability, and deviation criteria for sensor calibration and verification
- Specify start and stop conditions for the qualification cycle and the exposure cycle
- Specify data storage rate. All calculations are based on storage rate
- Define the output relays

After you have created and saved your setup, you run the study by loading the setup via connection from your Console to the Validator AVS. See also the Validator AVS online help for instructions on setting up a study.

1.5.2. Sensor Calibration

The Validator AVS provides both pre-qualification sensor calibration and post-qualification calibration verification.

Before you perform a qualification study, you should calibrate the temperature sensors to correct raw temperature readings to a traceable temperature standard. You can perform a two-point calibration, or a two-point calibration with an additional checkpoint. Sensors which pass the calibration process will have their offsets loaded into the SIM memory and can be utilized during the Qualification study. Sensors that do not meet the pre-qualification calibration test criteria are marked as failed and are not calibrated. Sensors that fail calibration are marked red in the live data screens and cannot be used in a qualification study.

After the qualification study, you can perform a post-qualification verification to verify that the sensor readings are still within the required criteria. You can perform a one-point, two-point or three-point post-qualification verification or even change the criteria before running the verification. If a sensor fails post-qualification verification, the sensor is noted as failed, but the readings are still reported. Calibration offsets are not changed during post-qualification verification.

If your validation system includes a Kaye temperature reference and a Kaye IRTD, you can perform fully automatic pre-qualification and post-qualification calibrations. If you do not have a Kaye temperature reference you can manually set the reference.

For sensor calibration instructions, see Chapter 7. *Calibrating and Verifying Sensors.*

1.5.3. Qualification Study

During a qualification study, the Validator AVS performs calculations and compiles data for your reports. For details on how to run the qualification study using the Validator AVS software, see Chapter 9, *Qualification Study* and the Validator AVS online Help.

1.5.4. Report Generation

The Validator AVS software includes a comprehensive reporting utility that allows you to access original study data to generate easy-to-read reports to document the specifics of your validation study. All reports are generated from secure data files that can only be read by the Validator AVS software. You can create four different report types:

- Setup Report
- Calibration Report
- Qualification Report
    - Detailed Report
    - Summary Report
    - Interval Report
    - Pass / Fail Criteria Report
    - CSV Export
- Calibration Verification Report
- Audit Trail Report

Once reports have been created, they are automatically generated as .pdf files and stored with the appropriate Asset under "Reports".

For a more complete description of report generation, see the Validator AVS online help.

Chapter 2. The Validator AVS Hardware

2.1. Introduction

The Validator AVS comes equipped with a universal power supply, a power cord for 115 VAC or 230 VAC, 32 GB of internal storage memory, and an USB flash drive interface. This chapter describes the Validator hardware and provides instructions for connecting the system. Included are sections describing:

- The back of the Validator AVS hardware has connection ports for all system devices and an emergency backup USB flash drive interface on the left side.
- AVS docking mechanism
- AVS LED Panel
- Internal memory
- Backup battery
- Sensor Input Modules (SIMs), used to connect sensors to the Validator AVS
- The Kaye temperature reference, which provides the stable temperature required for sensor calibration
- The Kaye IRTD, a self-contained temperature standard
- Connecting the AVS hardware to the AVS Console
- Preventive maintenance
- Transporting and shipping

2.1.1. Connection Ports

The Validator AVS has connectors on the back of the unit for easy plug-in of SIMs, temperature standards, and temperature references. It also provides connection ports for USB and Ethernet for the Console and the AVS Validator. Another separate USB port is utilized for the yearly device calibration USB with ICAL software. The USB memory card port on the left side of the instrument can be used to move raw encrypted saved studies from the AVS directly to a thumb drive. An icon indicating the type of device identifies each connector.

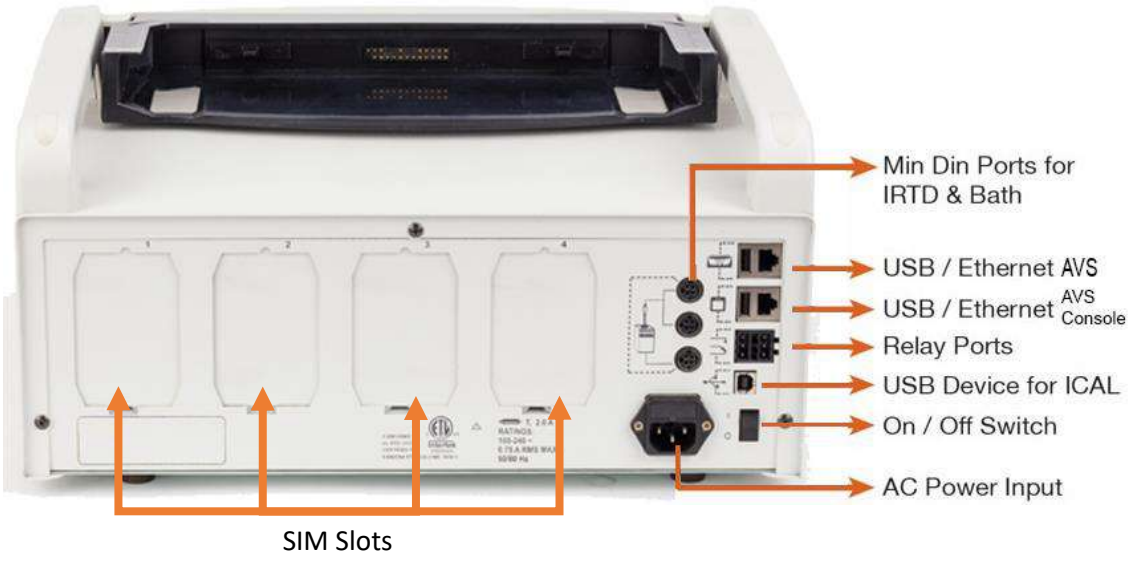


Figure 4: Validator AVS Connections

2.2.1 Connection Ports (cont.)

Table 1: Connection Port Explanation

Icon	Connection Port
	4 Pin Din Connector There are three 4-pin DIN connectors, two for the IRTD and one for the Temperature Reference. (**Note:** The Validator AVS can accept data from only one IRTD at any given time. For calibrations, only the upper port is active!)
	**Output Relay Ports** There are two NO/NC relay outputs, labeled with a contact switch icon, to provide a dry contact to an external device. The contact can be programmed in the Setup as to what action trigger the contact. Relay port 1 is second from the icon at the housing's edge Relay port 2 is near the icon. **Relay Rating**: 110 VAC ½ amp resistive load 24 VDC 2 amp resistive load
	**USB Connector** One USB connector, labeled with a USB icon, is available to connect an ICAL device. The ICAL port is for service use only.
	**USB/ Ethernet Connector** The AVS and Console icon offer both USB and Ethernet connections. The AVS USB can be used as extension of the Console for USB data transfer or USB hub for keyboard etc. The Ethernet can connect the Console to the network. The AVS Ethernet, can set up a connection to the network.

2.1.2. LED Panel

When the AVS is running in Standalone mode without the AVS Console connected, the AVS LED panel can provide key status indications for the user. The front panel of the Validator AVS displays the machine status with four LEDs. These LEDs display red, green, or both colors, steady or blinking.

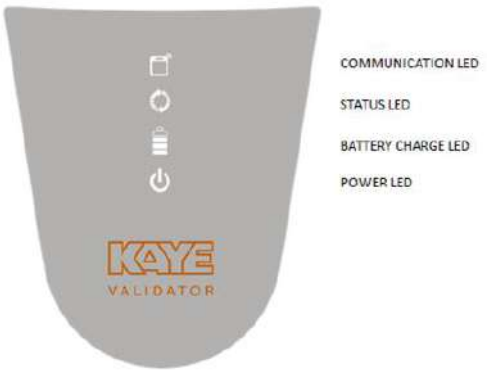


Figure 5: Validator AVS Front Panel

The LEDs indicate whether a console is connected to the Validator, if a study is running and the status of the battery, and AC power status. Details are described within Figure 6 below:

PWR Switch	POWER	CONDITION	LEDs			
			COMMUNICATION LED	STATUS LED	BATTERY CHARGE LED	POWER LED
ON	AC or BATT	System boot up - Initial				
		System booting up				
		System shutting down				
		System error				
		Study in progress				
		Console connected to Validator AVS				
	BATT	Battery capacity > 75%				
		Battery capacity < 75%				
		Faulty/Not-responding Battery				
		Low Battery < 25%				
	AC	Charging in progress				
		Charging complete				
		Faulty/Not-responding Battery				
		Battery not detected				
OFF						

All LEDs are lit RED/Green once
Depends on machine state
OFF
Steady
Blinking

Figure 6: Validator AVS LED Status Messages

2.1.3. Side Port for Data Transfer

On its left side, the Validator AVS offers a side port with a USB port (to accommodate an emergency backup USB flash drive) and a data transfer button, as displayed in Figure 7 below.

The Validator AVS writes the study data into the internal memory. If there is an unread study available on the Validator AVS there is a message when connecting the console and the study data is transferred to the console directly. Alternatively, the study data can be dumped to the USB side port. After connecting an USB flash drive and pressing the button, the last ten studies are written to the flash drive. The files can then be reimported into the console through the AVS software. To provide data security, data is stored in encrypted secure data files that can only be read by the Validator AVS software. Files that have been tampered with are no longer readable by the software. This port is only used for emergency backup, not for normal use during the Qualification studies.

The AVS software also has a software utility in the Hardware section of Live monitoring which allows you to view the last 10 studies stored in the AVS. From this screen you can also transfer the files to the console. Use the AVS convert function (see 3.7 Handling Data Files) to import the files into the Validation console.

Figure 7: Data Transfers Side Port

2.1.4. AVS Docking Mechanism

The AVS hardware also contains a patented docking mechanism to connect the AVS Console to the AVS hardware.

Figure 8 below displays the procedure for docking the AVS Console to a Validator AVS via its docking station.

Figure 8: Docking and Releasing Console

Note: *The AVS Console can be docked to the AVS hardware with or without power applied to the AVS hardware or AVS Console. The AVS Console can be undocked from the AVS hardware with power off.*

If Power is applied to Console and to AVS hardware, ensure that you first navigate to Main screen in the AVS software and press "Disconnect" (upper right side of the screen). Failure to do so could cause connection problems for the next connection.

2.1.5. Internal Memory

The AVS hardware contains 4 GB of internal solid-state memory for storage of Qualification and Calibration / Verification raw data files. At the completion of a study, data files are automatically stored to the internal memory as well as transferred to the AVS Console.

The internal memory always contains the last ten studies as a backup. These files can be downloaded to a USB via the AVS side port or transferred via the AVS software from the Live screen using the **Hardware** button.

2.1.6. Backup Battery

The Validator AVS is equipped with a rechargeable lithium ion backup battery to provide short-term power in case of AC power loss. The intent of the battery is to provide sufficient time (approximately three hours) to complete your study or address the power failure. When the Validator AVS detects that the AC power has failed and the system is running from battery, the power icon on the front panel changes from green to red while the battery LED show the current battery state. Valid battery states are:

- Solid green = more than 75%
- Solid yellow = less than 75%
- Blinking red = less than 25%. Battery capacity is near depletion and device shut down within the next 15 minutes.
- Solid red = a battery defect
- Blinking green = AC Power connected, and battery is charging

If AVS switches to battery backup or back to AC power during the study event, messages appear on the live screen and are posted in the Audit Trail.

CAUTION! **Power is still supplied to the unit via the backup battery after the AC power cord is unplugged. Remove battery from the battery pack before servicing the instrument. Use the Power Switch located at the rear of the unit, do not cut the AC power only.**

When servicing the unit, first ensure that the backup battery is removed. To access the battery, remove the two screws from the battery compartment on the bottom of the AVS hardware.

The Validator AVS monitors its own battery voltage. When the battery has approximately six minutes of power remaining, the Validator AVS stops collecting data and closes its data files. The unit is equipped with rechargeable, field replaceable, battery pack. A replacement battery pack is available (Type RRC2040-2, Kaye Art. Nr. 200-163).

Figure 9: Battery Replacement

CAUTION! **Batteries must be disposed of in accordance with local, state and federal regulations.**

2.1.7. Sensor Input Modules (SIMs)

The Validator AVS accepts up to 48 inputs in any combination of thermocouple, voltage, current inputs, or 24 RTD inputs. The AVS uses Sensor Input Modules to provide secure connections for sensors to the Validator AVS, while also protecting the electronics from draft, dust, humidity, electrical noise, and mechanical shock. SIMs are designed to be wired once and used repeatedly. Once the SIMs are wired, you can calibrate multiple harnesses at the same time and store them for later use.

Figure 10: Sensor Input Module

The Validator AVS can accommodate up to four SIMs. Each SIM has:

- Sensor inputs: TC-SIMs have 12 sensor input connections, RTD SIMs can connect six RTD sensors, 4-20mA SIMs can connect 12 sensors, and one connection for using an external power supply if needed or local power. Refer to Z2612 for reference.
- A memory chip to store calibration offsets, SIM serial number, slot location, and the serial number of the Validator AVS measurement board where calibration was performed.
- A cold junction reference RTD to maintain measurement accuracy in different environmental conditions.

Since calibration of thermocouples requires compensation for errors measured in fractions of microvolts, making these offsets specific to this instrument and SIM location, it is recommended that you use the supplied erasable labels to record:

- SIM serial number
- SIM slot number
- Serial number of the Validator AVS where the sensors were calibrated and the date they were calibrated

When you want to use these SIMs, just pull them off the shelf and plug them in. The calibration offsets are stored in the SIM's internal memory. To prevent you from using the wrong instrument or SIM slot, the system alerts you during the qualification run that the SIM is plugged into the wrong instrument or SIM slot. The SIMs are made of high impact materials that will withstand 5000 insertions and are designed with a tilt and a drain hole to minimize the effects of condensation.

IMPORTANT: *SIMs are recognized by the system when you power up the Validator AVS. Ensure that all SIMs are connected prior to powering up the Validator AVS, or you should power down, insert your SIMs, and power up again. If a SIM is disconnected after power up, calibrated offsets or SIM data might not be read correctly. To rectify this, power down, reconnect the SIM, and power back up.*

2.1.8. Wiring SIMs

There are two methods for wiring SIMs. You can assign sensor locations in your 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. This section shows you how to wire SIMs yourself.

IMPORTANT: *The SIM contains a static sensitive component that stores calibration information. Use caution when connecting sensors. It is recommended that you wear an anti-static ground strap when connecting sensors and routing wires.*

To connect sensors to SIM locations:

1. Loosen the two screws in the top of the module to open a SIM. Figure 11 below displays the inside of a thermocouple SIM.

Figure 11: SIM Wiring

Components:

- Tie wrap mounts
- Connector (locations 1 - 6)
- Sensing RTD
- Connector (locations 7 - 12)

Sensor location number. There are 12 connection locations, labeled 1 - 12, with a positive and negative connector for each input.

2. Press the two press-keys to open connectors where the sensor is to be inserted.

1. Connect your inputs. Valid inputs are the following:
    - Thermocouples T, J, B, S, R, N and K
      (see *Connecting a Thermocouple* in this chapter)
    - Contacts (see *Connecting a Contact* in this chapter)
    - Voltage (see *Connecting a Voltage Input* in this chapter)
    - Current (see Connecting a Current Transmitter in this chapter)

2. Release the two keys.

3. Repeat Steps 2 through 4 for all remaining sensors.

4. Once all sensors are connected, route the wire harness around the connectors and out the drain hole. Secure the harness with the tie wraps provided. Follow Figure 12 below to maintain peak module thermal accuracy.

Figure 12: SIM Wiring

Legend:

1 = Tie wraps (provided)
2 = Tie wraps (optional - user-supplied)
3 = Drain hole

5. Tighten the two screws at the top of the module to close the SIM.

6. Label the SIM with SIM slot number, SIM serial number, the Validator AVS serial number, and the calibration date.

Note: *To wire the dedicated 4-20 mA SIM, see document Z2612, "4 to 20 mA Sensor Input Module".*

2.3.1a Connecting a Thermocouple

Connect thermocouples to the connectors as shown in Figure 13 below. Cut through the outer insulation to separate the wires, and then strip back each wire approximately ½ inch to make the connection with the connector.

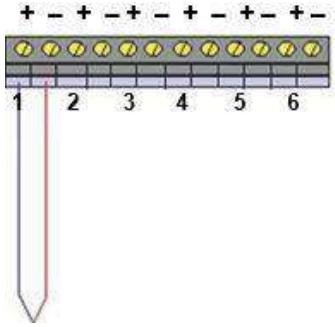


Figure 13: Thermocouple Connections

Always connect the positive (+) lead to the positive (+) connector and the negative (-) lead to the negative (-) connector. In conformance with ANSI standards The negative thermocouple lead is normally red.

Moist Heat Environments

When validating moist heat processes, a sealed PTFE tip thermocouple should be used with a drip cut (shown in Figure 14 below) on the outer insulation close to the SIM module to reduce the possibility of drawing moisture into the SIM.

Note: *The design of Kaye AUTOBOND wires eliminates any moisture seeping, making a drip cut unnecessary. Contact customer care for more information regarding Kaye AUTOBOND wire.*

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 without water reaching the terminal screws.

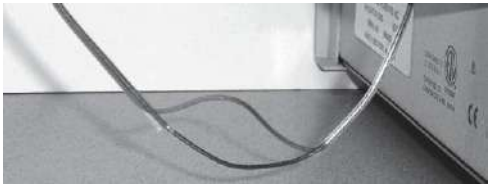


Figure 14: Drip Cut

Also, it is recommended to shave open approximately 1/4 inch from each of the inner wire jackets at opposite ends of the outer insulation drip cut. This permits condensation drainage from within the individual wires, as shown in Figure 15 below. If Autobond thermocouples are used, this is not necessary.

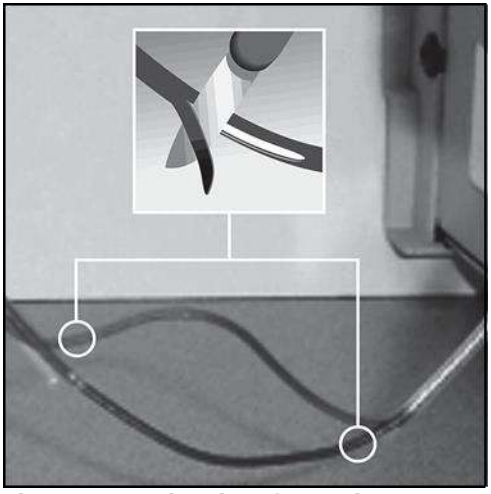


Figure 15: Shaving from the Inner Wire

If moisture does collect in the SIM, remove the SIM from the instrument, open it, and let it air dry before storage.

2.3.1b Connecting a Contact

You can connect dry contact inputs directly to the TC-SIM, as shown in Figure 16 below. Dry contact inputs can be used to make a time notation in the data file (to mark start exposure, stop exposure, start of qualification, end of qualification) and to mark any events that occur during the qualification study. You can also wire a dry contact to your vessel's PLC to detect status output and use it to automatically mark the start and end of the exposure cycle during the qualification study.

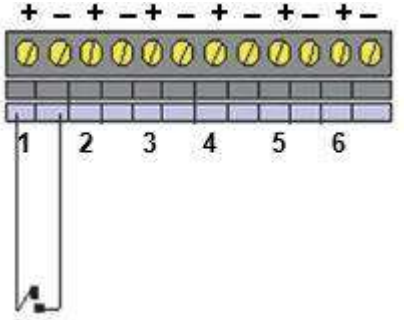


Figure 16: Connecting Dry Contact Inputs

2.3.1c Connecting a Voltage Input

Connect a voltage input (up to 10 VDC) to the connectors, as shown in Figure 17 below. Always connect the positive (+) lead to the positive (+) connector and the negative (-) lead to the negative (-) connector.

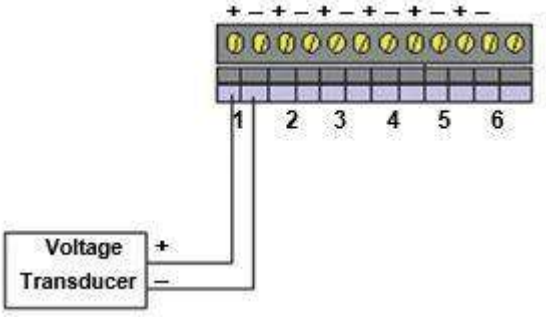


Figure 17: Voltage Input Connection

2.3.1d Connecting a Current Transmitter

A dedicated 4-20 mA SIM is available that provides 12 current inputs and a connection for an external power supply.

However, a current transmitter can also be connected to the standard TC-SIM. Connect a precision shunt resistor to the connectors to convert the current to a measurable voltage, as displayed in Figure 18 below. A 250 □ resistor converts a 4-20 mA signal to a Voltage signal. The 62.5 □ resistor converts a 4-20 mA signal to 0.25-1.25 V. These voltages can be defined in the TC setup as voltages accordingly. For easier handling, we recommend using the dedicated 4-20 mA SIMs in the first place.

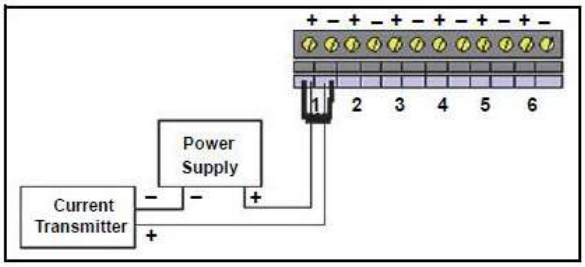


Figure 18: Current Transmitter Connection

The 4-20 mA SIM can be configured in two ways based on the power connections. You can switch between external or local power, based on the placement of the jumper blocks as displayed in Figure 19 and Figure 20. Please refer to instructions on the SIM for current jumper placement and orientation.

Sensors using 4-20 mA outputs can be attached in several different ways.

If the sensor requires less than 4 mA to operate:

- Connect the positive lead to the positive input channel and the negative lead to the negative input channel, as displayed in Figure 19 below.
- Configure the jumper block for local power and attach 24V supply to J4.

Figure 19: Configuration for Sensor with < 4 mA Power

If the sensor requires more than 4 mA, it normally has a second set of terminals to supply power:

- Connect the transmitter output to the input channel (+ to + and - to -), as displayed in Figure 20.
- Configure the jumper block for external power.

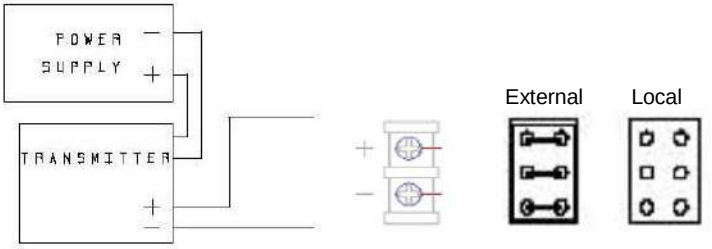


Figure 20: Configuration for Sensor with More than 4 mA Power

If a sensor requires less than 4 mA to operate and is loop powered remotely, see options 1 or 2 below for connection. Configure jumper block for same channel as External Power.

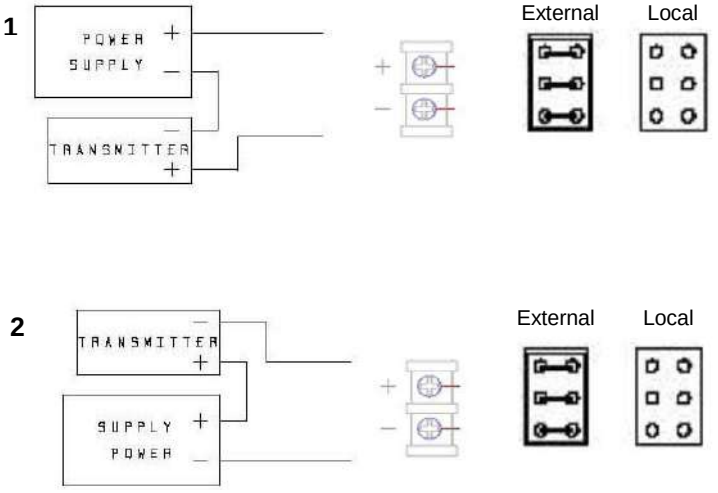


Figure 21: Configuration for Sensor with Less than 4 mA Power (Loop Powered Remotely)

The red LED on the SIM is powered from the AVS and lights when the AVS is on and a SIM is plugged in. The green LED is lit if the sensor is powered via the external power source connector.

2.2. Kaye IRTD

The Kaye IRTD temperature measurement standard is a traceable highly accurate standard used by the AVS system to calibrate and or verify an AVS system accuracy before a Qualification study. The measurement accuracy is traceable to the national standard to 0.025ºC, with a range of -196ºC to 420ºC.

The IRTD provides a traceable standard that is used to correct the temperature readings of your thermocouples. During the calibration process, the Validator AVS automatically reads and monitors the value of the temperature reference and the IRTD probe.

For Calibration or Verification, only one IRTD can be connected at a time to the AVS hardware. Always connect the supplied IRTD cable to the upper IRTD icon DIN connector.

2.3. Temperature Reference

Temperature references provide the stable temperature required for sensor calibration. Six temperature reference models are available. They are designed to provide different temperature ranges and are compatible with the Validator AVS. Utilizing the supplied AVS to Temp Reference cable, attach it to the Temperature Reference icon located on the back of the AVS hardware.

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

Recommended for calibration of sensors used in freeze dryers, freezers, cryogenic units, incubators, and steam autoclaves. The LTR-90 accepts up to 12 thermocouples.

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

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)

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 25°C ambient)

The Kaye LTR-150 is a multi-purpose calibrator specifically designed to calibrate 48 thermocouples at once and function as a Dry Block, Liquid Bath, or Surface calibrator.

HTR 400 (setpoint range 50°C above ambient to 400°C)

Recommended for calibration of sensors used in steam autoclaves, dry heat ovens and tunnel sterilizers. The HTR 400 accepts up to 24 thermocouples.

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

Recommended for calibration of sensors used in steam autoclaves, dry heat ovens, and tunnel sterilizers. The HTR 420 accepts up to 48 thermocouples.

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

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

CTR -40 (setpoint range -40°C to 150°C)

Liquid bath recommended for calibration of sensors used in freezers, cold rooms, incubators, and steam autoclaves. The CTR -40 accepts up to 36 thermocouples.

CTR -25 (setpoint range -25°C to 140°C)

Liquid bath recommended for calibration of sensors used in freezers, cold rooms, incubators, and steam autoclaves. The CTR -40 accepts up to 36 thermocouples.

2.3.1. Sensor and IRTD Installation

The Kaye LTR-150, LTR-90, LTR -25/140, LTR -40/140, and the HTR 400 temperature references have inserts for thermocouples and two Kaye IRTDs. Failure to use these inserts to achieve proper thermocouple placement in the temperature reference results in reduced accuracy during calibration.

The Kaye CTR -80 temperature reference has three thermocouple wells and two 12-inch nylon spacers to allow you to properly position your thermocouples and Kaye IRTDs.

LTR-150, LTR-90, LTR -25/140, LTR -40/140, HTR 400, and HTR 420

To insert thermocouple sensors into the LTR-150 LTR-90, LTR -25/140, LTR -40/140, HTR 400, and HTR 420:

- For the LTR-90, insert the thermocouple sensors through the rubber insulator first.

IMPORTANT: *The LTR-90 comes with a rubber insulator. This rubber insulator must always be used. If it is not used, specifications are not guaranteed. Also, at cold temperatures, there is significant ice buildup, which can affect accuracy and uniformity.*

Insert the thermocouple sensors into the inserts and push all the way down into the well.

For 22-gauge wire, three Type T PTFE or Kapton thermocouples fit into each well.

For 28-gauge wire, six Type T PTFE thermocouples fit into each well.

To install the IRTD into the LTR-150 LTR-90, LTR -25/140, LTR -40/140, and HTR 400:

- For the LTR-90, insert the IRTD through the rubber insulator first.
- **Slowly** insert the IRTD into one of the two reference wells (the two small wells) in the LTR-90, LTR -25/140, LTR -40/140, or HTR 400. Do not drop it from the top of the well. To prevent mechanical shock to the IRTD when immersing it in a new temperature environment, ensure that the immersion process takes place over a 30-second interval. The IRTD should fit snugly, but still be easily removed.

CTR -80/-40/-25

To insert thermocouple sensors into the CTR -80:

- Loosen the sliding clamp mechanism on a thermocouple well, insert the thermocouple sensors 7.5 inches into the well, slide the clamp into place, and tighten the clamp to hold the sensors in place. When properly installed, the sensors will protrude approximately 0.5 inches beyond the end of the thermocouple wells. For 22-gauge wire, 12 PTFE thermocouples fit into each well.

Note: *The 7.5 inches wide access cover can be used as a measuring device when positioning the sensors.*

To install the IRTD into the CTR -80:

- Insert the IRTD into one of the two 12-inch nylon spacers. An IRTD with the standard 18-inch stem fits properly. If you have an older model IRTD with a 15-inch stem, shorten the length of the nylon spacers accordingly.

2.4. Connecting the AVS Console to the AVS Hardware

The communication between the AVS Console and the AVS Hardware is based on TCPIP protocol. The Validator AVS and the Kaye Validation Console typically connect through the integrated docking station, but both components can utilize any kind of TCPIP based network to interconnect using a wired Ethernet or a wireless Wi-Fi connection.

To connect through TCPIP, an infrastructure (company network, router, or even smartphone hotspot) providing a DHCP-server is required.

There are different ways to establish a connection between the console and hardware:

- Docking port of the Validator AVS
- Wired connection via Ethernet infrastructure (LAN)
- Wireless connection via an access point (Guest WiFi, Mobile Hot Spot etc.)

Docking Port

Using the docking port is the simplest way to establish a connection between the console and hardware. As illustrated in Figure 8 on page 13, insert the console into the docking port of the AVS. The TCPIP based connection has the fixed IP address of 192.168.1.2 for the Validator AVS.

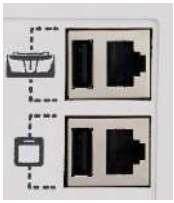
Note: *The IP address 192.168.1.2 is fixed in the system and cannot be changed. To avoid IP address conflicts please ensure this IP is not used in any connected hardware (e.g. local networks).*

For connection through the docking port simply select **USB/Docking** and press **Connect**. The Console begins connecting with the Validator AVS.

Connecting the AVS Hardware to Ethernet

Two Ethernet ports are located on the back of the Validator AVS. The icons alongside the ports indicate the device the port is connecting to. Simply connect the Validator AVS to a LAN network with an Ethernet cable. An IP address provided by a DHCP server is required.

Any console connected to the same network (either wired or connected via Wi-Fi) can discover the AVS in the hardware screen and connect remotely. For a wired connection, the Ethernet port for the console can be used while docked. For office use, there is a separate docking station available.



Connecting the AVS Console to Wi-Fi

Establishing a Wi-Fi connection of the console is very simple:

In the Startup screen, swipe from the right side or press the **Pin** button (see the arrows in Figure 22 below) to open the Windows Action Center. Inside the Windows Action Center choose **Network**. It is not necessary to log in as “Kaye Admin”.

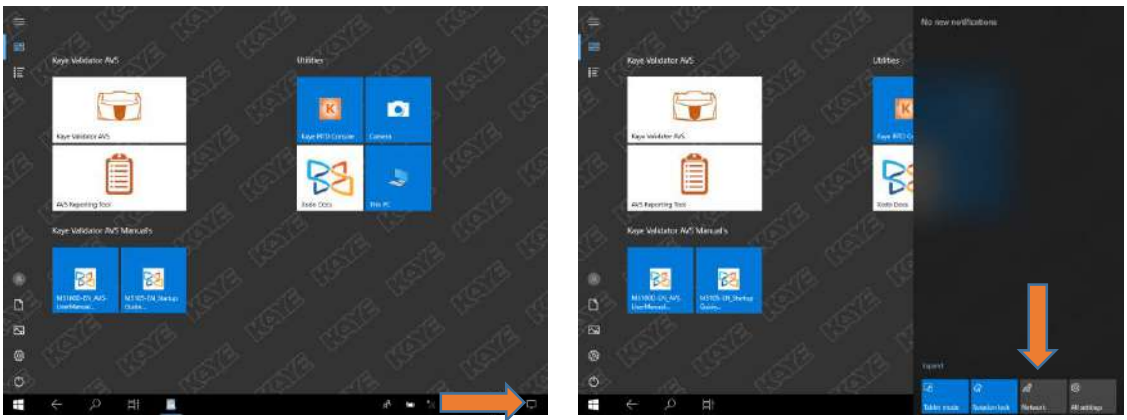


Figure 22: Startup Screen with Windows Action Center and Network

Inside **Network** a list of available network connections display. Ensure that the Wi-Fi tile is blue and switched on, otherwise press the Wi-Fi tile. In the example below, multiple networks are available:

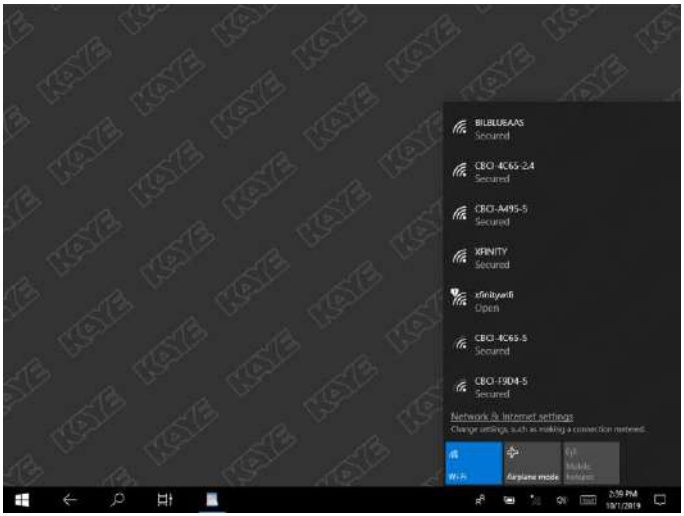


Figure 23: Startup Screen and Network Connections

After choosing a network, connect by pressing **Connect**. If **Connect Automatically** is checked, the console automatically connects to this network if it is in range.

To establish a connection, a Wi-Fi password may be required. You can get any required information from your Wi-Fi administrator. When using the hotspot function for a mobile phone, the password is listed in the configuration of the hotspot.

For first initial network connection, Windows prompts if you would like to identify and connect to any other devices on the network. It is recommended to choose **Yes** for unrestricted access inside the network (please contact your IT administration for details).

Once connected to the network, the console is listed as connected to the Wi-Fi.

Connecting the AVS Hardware to Wi-Fi

The AVS hardware contains an onboard Wi-Fi card which must also be configured and pointed to the same Wi-Fi network as the AVS Console.

After docking the console, choose **Hardware/Discover** on the Homepage of the Kaye AVS software.

In the Select AVS window, choose the AVS you want to configure for Wi-Fi. As mentioned, it is necessary to have an established connection. It is recommended to dock the console with the AVS and choose **USB/Docking**.

Figure 24: Select AVS Screen

After selecting the required AVS, press **Configure Wi-Fi**. A new dialog box opens.

7. Enter the Network name (or SSID) of the network manually or use the **Network** button to prepopulate the available SSIDs automatically into a drop-down menu for selection.

Note: *The SSIDs in the drop-down are copied from the console's discovered Wi-Fi list. If you connect remotely to the Validator AVS via Ethernet, these networks may not be available in the remote location.*

8. Set the security and encryption type for the network. If you do not know these values use automatic and the Wi-Fi card will try to ask these parameters from the Wi-Fi network. If that information is not retrievable, please ask your Wi-Fi administrator.

Note: *Most modern Wi-Fi networks use WPA2-PSK and AES as listed in the example. Use that option for the best chance for a successful connection.*

9. Enter the Wi-Fi password: In the example above the password is generated by the mobile hotspot of the smartphone. Please ask your Wi-Fi administrator if you do not know the password.

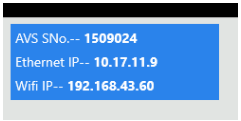
Note: *The Validator AVS requires an encrypted Wi-Fi network. Open networks without password are not supported.*

10. Press **Ok** to transfer the new Wi-Fi setup to the Validator AVS. After a short time, the message “Wi-Fi configured successfully” displays.

Note: *If an error message (Wi-Fi Configuration failed) appears, please ensure that the Validator AVS and Wi-Fi network are available, and all information was entered correctly.*

If “Automatic” was selected to configure the network security and encryption, it is possible the network did not provide the required information and it is necessary to choose the correct values from the drop-down menus. The Validator AVS is limited to 2.4GHz networks and the channels 1 to 11. 5Ghz networks and channels 12 to 16 are not supported.

11. Press **Discover**, to ensure that the Wi-Fi IP address of the Validator AVS is displayed.



Connecting via Wi-Fi:

Select the AVS and press **Connect**. In the small popup choose **Wi-Fi** as the connection type.

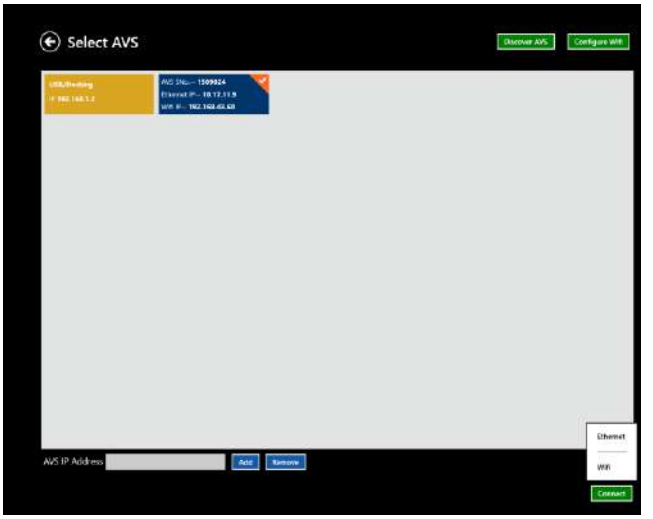


Figure 25: Select AVS Screen with Discovered AVS

It is now possible to undock the console from the AVS and still receive live data from the Validator AVS via Wi-Fi.

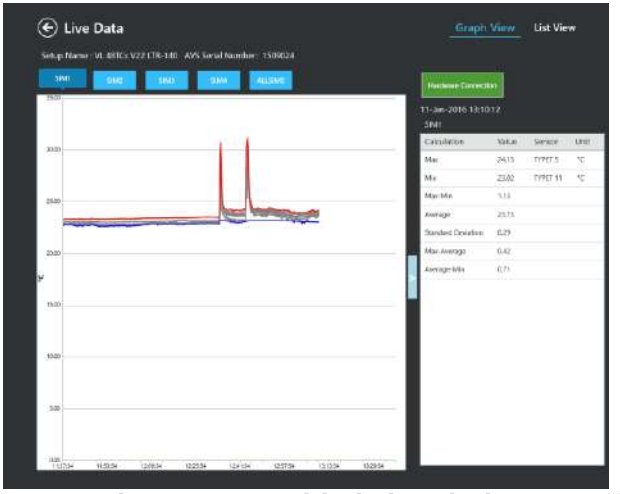


Figure 26: Live Data Provided via Wi-Fi Connection

Note: *In Validator AVS machines without Wi-Fi modules any attempt to configure Wi-Fi results in the message "Wi-Fi configuration failed!".*

If the discovered Validator AVS has valid IP addresses for Ethernet and Wi-Fi, an option appears when pressing **Connect**.

If only one IP address is available, the connection is established to this address only.

Note: *Occasionally, invalid IP addresses (starting with 169.x.x.x) are displayed but not functionable.*

2.5. Preventive Maintenance

2.5.1. Fuse Replacement

The Validator AVS is equipped with a 250V T 4A fuse. The fuse is in the line filter along with the power cord. To replace the fuse:

1. Turn the power off.
2. Disconnect the power cord from the line filter.
3. Using a small, slotted screwdriver (provided with the SIMs), pry open the fuse holder from the bottom tab.
4. Slide the fuse holder out and replace the fuse with a 250V T 4A replacement fuse.

2.5.2. Calibration

Each Validator AVS is fully calibrated before shipment. The equipment normally requires no further adjustment or calibration during installation. Under normal operating conditions, it is recommended you calibrate the Validator AVS once a year to maintain peak system accuracy. If you use a Validator AVS for high accuracy measurements, or circuit boards are replaced or added, you may need to recertify calibration.

2.6. Transporting and Shipping

The Validator AVS is designed to be easily transportable from one place to another within a plant. The unit weighs approximately 26.5 pounds (lbs.) or 12 kg, including the Validation console (without SIMs) and comes with two robust handles for carrying.

For shipping the Validator AVS, you need a safe and durable container. A rugged, foam-fitted hard case equipped with wheels and a collapsible handle is delivered together with your Validator AVS. It includes secure space for the Validator AVS, the Console, and accessories (SIMs, cables, etc.).

We encourage you to use this hard case for transport, storage, and shipping. If you use another type of container, ensure that the Validator AVS is padded with four inches of cushioning filler on all sides.

If you need to return the Validator AVS for service, contact the Customer Service Department for a Return Materials Authorization Number before you ship. Include the number with the instrument.

Chapter 3. Initial AVS Console/Software Setup

3.1. Introduction

Before using the Validator AVS software to run Qualification studies, various initial administrative settings need to be defined.

In this chapter the following Administrative functions are covered:

- Start the AVS program and log in to the User Management utility using the default System Administrator account.
- Create your System Administrator account.
- Set policies and preferences.
- Create other user accounts.
- Upgrade the AVS firmware.
- Handling of files through file management
- Access the Validator AVS online help.

3.2. Logging in as a Default System Administrator

The Kaye validation console boots automatically into the Kaye Operator windows account on startup. In the Startup menu, start the Validator AVS software by double pressing the AVS icon.

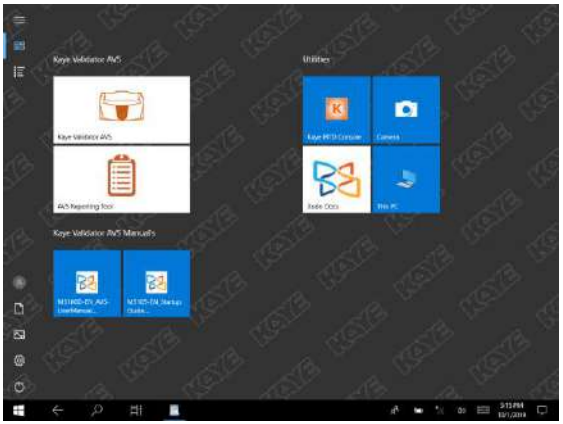


Figure 27: Desktop Screen

Once you have started the Validator AVS software, the Login screen appears as displayed below:

Figure 28: Login Screen

1. Enter “Kaye” in the **User ID** textbox.

2. “Kaye” is the default System Administrator user ID. The **User ID** textbox is case sensitive. Ensure that you enter the default user ID *exactly* as it appears here.

3. Enter “411” in the **Password** textbox, as the one-time default System Administrator password.

4. Press **Login**.

After the initial Login, you start directly with the creation of a new system administrator in the user management screen.

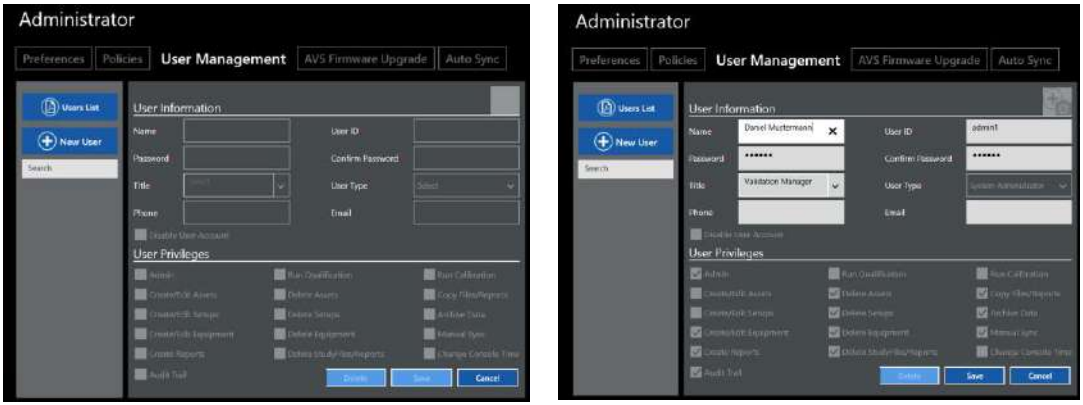


Figure 29: New User Screen - Create Initial System Administrator

1. Press **New User** and create a system administrator. The fields with red asterisks are mandatory: User IDs are unique, and the password is following the default rules for passwords (minimum of six characters).
   Enter your new System Administrator identification into the **User ID** textbox. Your user ID can be any combination of numbers and characters, up to a maximum of 16. A user ID cannot be used by more than one active account.

2. Enter your new System Administrator password in the **Password** textbox. Your password can be any combination of numbers and characters, up to a maximum of 16. For security reasons, it is preferable to use more than six characters or numbers.

3. Enter your password again in the **Confirm Password Field** and press **OK**.

At this point, you should record your user ID and password for future reference. You need both to log in to the Validator AVS. If you do not enter the correct user ID/password combination, you will be denied access.

For the initial system administrator, the User Type and User privileges are preset. You can enter a title, phone and email and even associate a picture by using the build in camera.

After creating the new system administrator, by pressing **Save** the software automatically logs out. From now on the initial Kaye/411 user is not available anymore. The next time you log in to the Validator AVS Software, you will need to enter your own System Administrator user ID and password. The system can identify you by name using your unique user ID and password combination.

The Main screen appears (see below). You are now ready to create other admin and user accounts and set the preferences and policies as required.

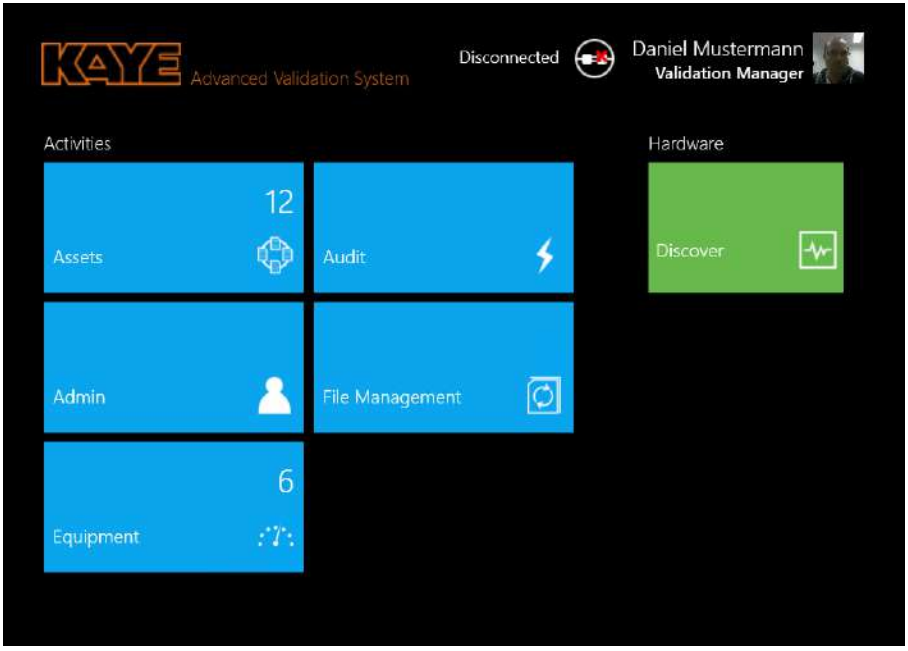


Figure 30: Main Screen

3.2.1. Creating New System Administrator Accounts

Once you are logged in with the new system administrator account, you can add admin and user accounts to the system and set site options.

Note: *A good practice is to establish more than one individual with Administrative functions. This way the Administrative functions can still be accessed even if one of the System Administrators is unavailable.*

To create a new System Administrator account:

1. Press the **Admin** tile on the Main screen. The Admin Settings window opens at the Preferences tab.
2. From the Admin Settings window, press **User Management**.
3. On the User Management screen, press **New User**, and enter your name in the Name textbox.

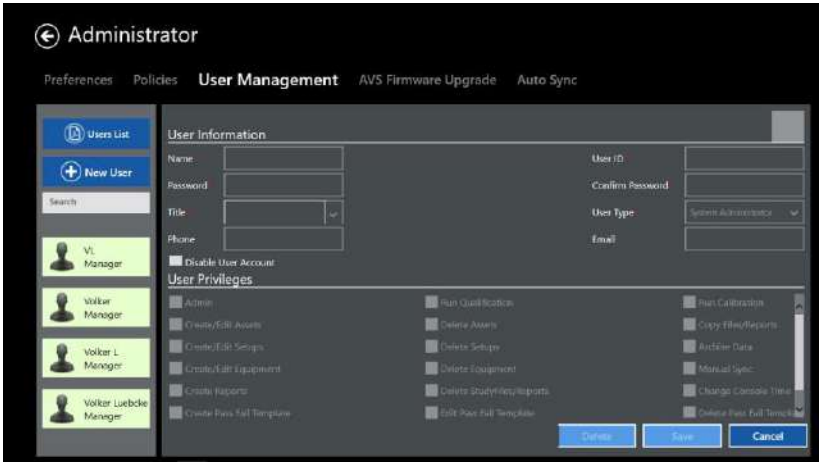


Figure 31: User Management Tab

The name you enter here displays later in the active user list on the left side of the screen. In contrast to User IDs, usernames are not unique. Once you have added your name to the active user list, you can enter the same name again. Your name is associated with the user ID/password combination that you entered. You use this user ID/password combination to log into the Validator AVS.

4. Enter your new System Administrator identification in the **User ID** textbox. Your user ID can be any combination of numbers and characters, up to a maximum of 16. A user ID may not be used by more than one active account.

5. Enter your new System Administrator password in the **Password** textbox. Your password can be any combination of numbers and characters, up to a maximum of 16. For security reasons, it is preferable to use more than six characters or numbers.

6. Enter your password again in the **Confirm password field** and press **OK**.

   At this point, you should record your user ID and password for future reference. You need both to log in to the Validator AVS. If you do not enter the correct user ID/password combination, you will be denied access.

7. Enter your designation and your contact names. Press **Save** to save your information.

The User Management screen displays the list of active users. The System Administrator accounts you just created is the only name on the list (the default System Administrator account Kaye has been deleted). Now you are ready to add new users to the system.

3.3. Creating New User Accounts

When you create a new user account, the username is added to the active user list. You assign a unique user ID for each user and a temporary password. The user has to change the password on their first login. To create a user account:

1. From the Admin menu, press **User Management** and then press **New User**. The New User screen becomes active.
2. Enter the new username in the **Name** textbox.

   A user's name is associated with the user ID that you enter in Step 3. The name you enter here appears in the active user list.

Note: *User IDs must be unique. Once a User ID name has been used, it cannot be used again.*

3. Enter the new account's user identification in the **User ID** textbox.

   The user ID can be any combination of numbers and characters. The user ID and password are case sensitive. A user ID may not be used by more than one active account.

4. Enter a temporary password for the user in the **Password** textbox.

   The temporary password can be any combination of numbers and characters. The user is required to change this password when they first log in to the program.

5. Enter the temporary password again in the **Confirm Password** textbox.

Note: *A user account is not active until the user changes the temporary password when logging into the Console for the first time.*

6. Select the desired Title from the dropdown list.
7. Select the User Type from the drop-down, default User privileges are set based on the User Type selected.

8. Select any specific permissions you wish to give to a user. These permissions can include for example:
    - Create setup
    - Stop study
    - View or edit reports
9. Press **Save**.

    The User Management screen displays with the newly added username in the user list.

3.3.1. Deleting and Disabling User Accounts

Other than active users (marked with green color in the user management screen), there are two possible states for a user:

Disabled User
A user can be disabled by an Administrator or automatically disabled after three consecutive login failures if enabled in the Policies (see 3.5 Setting Policies for details). A disabled user's account is marked in red in the user list. Users are listed in alphabetic order. The disabled state is set with the checkbox **Disabled User Account** in User Information. An Administrator can re-enable the user account by unchecking **Disabled User Account**. Note, all actions are logged to the Audit Trail.

Deleted User
If a user's account is no longer required an Administrator can delete the account by pressing **Delete** at the bottom of the screen. To prevent discrepancies in the audit trail, the deleted user's ID is blocked for further usage. A deleted User does not appear in the Users list however, the User's ID and password are retained in memory so that combination can never be reused. Note, all actions are logged to the Audit Trail.

Users List
Users List generates a pdf report that lists all active, disabled, and deleted user information, along with their privileges, along with their assigned privileges.

User Search
For quick access, there is a search field that automatically filters for username. Please not the field filters for the complete username as one expression. As an example, if you enter "B" all usernames starting with a "B" are listed. If you would like to search for "Bob Smith", entering just "Smith" does not work.

3.3.2. One Time Emergency Access

It is good practice to establish more than one active Administrator account. In case one system administrator is not available anymore the system can still be maintained. If Administrator access is no longer possible Kaye can provide one-time Emergency access with the sole purpose of modifying an Administrator account. For this procedure, direct support from Kaye service is required.

At the login screen, enter “Ctrl+e” into the password field to start the emergency login. Please contact Kaye Support directly to receive required information. Emergency access is logged in the audit trail.

3.4. Setting Preferences

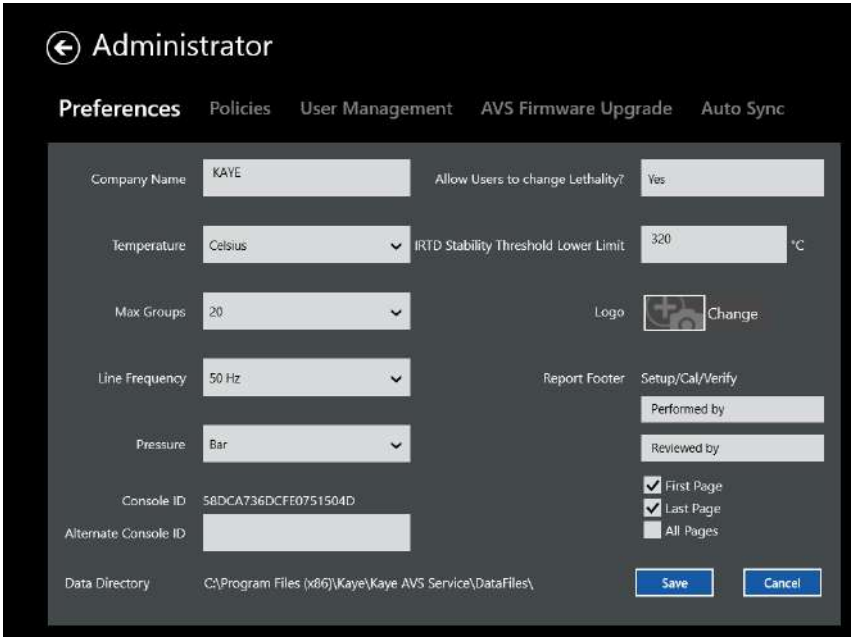


Figure 32: Preferences Tab in the Admin Menu

The Validator AVS software installs with default system settings. You can change the settings on the Preferences screen.

The company name as entered, is displayed in all report headers.

1. Use the drop-down list to set the temperature units to Celsius or Fahrenheit. All calculations are performed in the temperature units specified here. The IRTD and the temperature reference (Kaye LTR, HTR or CTR product line) are also programmed to operate in these units.

IMPORTANT: *If a setup was created before changing units on the Preferences screen, the software will prompt to change to the new settings the next time the setup is saved. However, only the label will be changed, not the temperature value. It is required to convert the temperature units manually to the new temperature units. For example, if you created a setup using °C, you may have entered 100.0°C as a calibration setpoint. If you change the temperature units to °F, the software will*

change the calibration setpoint to 100.0°F, not 212.0°F, changing the label from C to F but not the numeric value. If you want the setpoint to be 212.0°F, go to the Calibration screen and change the temperature value accordingly.

2. Select the absolute pressure units for saturated steam calculations from the Pressure Units list box. If you selected “Other”, enter the value of 1 Atmosphere in the absolute pressure units you are using.

3. Select 60 Hertz or 50 Hertz from the drop-down menu to set the line frequency. Choose the setting that matches your environment.

IMPORTANT: *The Validator AVS filters noise induced by the AC Power to achieve its high accuracy performance. If the line frequency is not set correctly, the filter is not working correctly, resulting in a higher signal noise level.*

4. If necessary, you can enter an alternate machine identification number. The machine ID appears in the audit trail for identification of the console.

5. Press **Yes** or **No** to indicate if you want to enable a user to change lethality calculations parameters.

6. Enter the lower limit for IRTD stability (From 250 to 400°C or 482 to 750°F). The IRTD stability is fixed to 0.012°C but for high temperatures which threshold limit is set with this value, or temperatures below 0°C, the IRTD stability value becomes editable in the setup, from 0.012 C to a maximum of 0.10 C.

7. Logo: Import of a custom logo that will be displayed in the report headers. It can be any kind of bitmap and the preferable size is 90 x 30 pixel. Other formats will be downsized.

8. Report Footer: Configuration if signature fields should be applied on first/last/every page for setup, calibration and verification reports. For detailed and summary reports, this is set in the report tool directly.

9. The path and folder holding the Data Directory is displayed.

3.5. Setting Policies

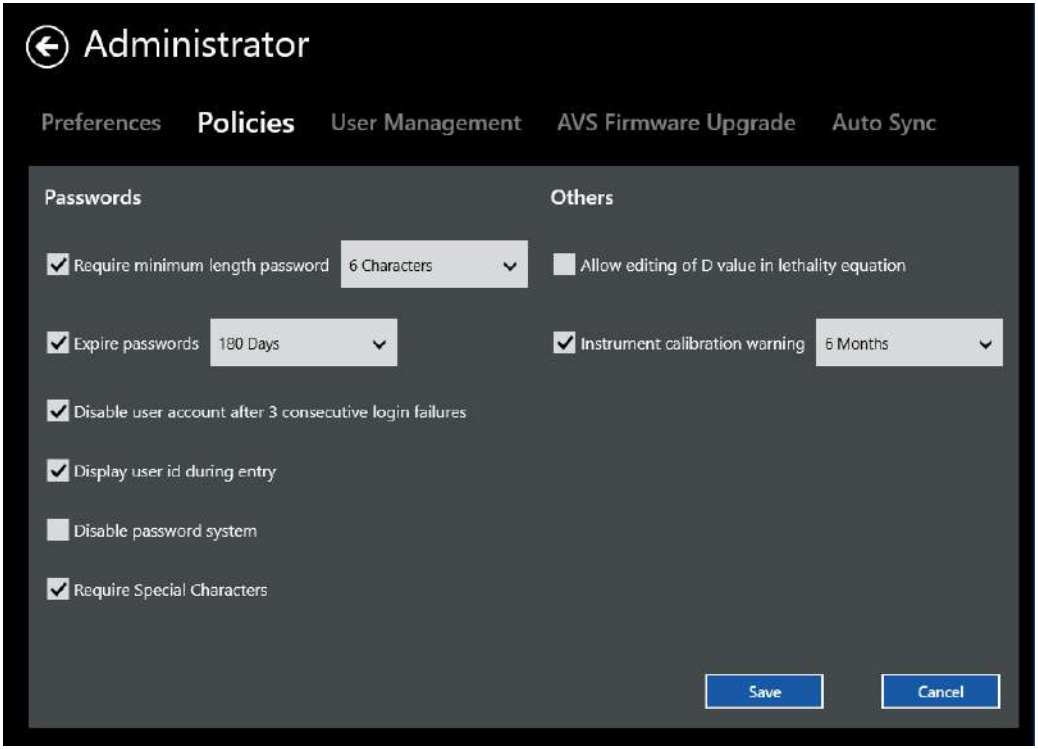


Figure 33: Policies Tab

The Validator AVS software allows you to set security policies in order to comply with company policies and/or 21 CFR Part 11 regulations. Allowing users more flexibility on how to handle the password system, lethality D-Value and the calibration warning.

As the System Administrator, you can adjust policies that:

- Require minimum length passwords for all user accounts.
- Set passwords to expire after a defined number of days. The user will be prompted to change their password once their current password has expired. By default, passwords are set to expire after 180 days. The software will display the password expiration date to the user at login when there are five days or less until their password expires. Expired passwords will not be accepted as new password again.

- Disable user accounts after three unsuccessful login attempts. This option will disable a user account if there are three consecutive login failures at the PC for the same user ID. If a user account is disabled, only a System Administrator can enable the account again and assign a new temporary password.
- Disable User IDs during entry masks the User ID entry like the password entry with dots in the login screen.
- Disable the password system. User IDs and passwords will not be required to use the software. If disabled, all Users in Audit Trail are marked as "Unknown".
- Require Special Characters will enforce a password with increased strength by requesting at least one capital letter, a special character, and a numeric character in the password. This feature is only available if minimum number of characters criteria is set as well.
- Allow editing the D value in the lethality calculation. When this option is enabled, the D value field on the Lethality Calculations screen is editable in the setup. If this option is not enabled, the D value field does display to the default value of “1”, but is not editable when creating a new setup.
- The instrument calibration warning sets a pre-warning interval for Kaye Equipment populated under the Equipment tile (see Chapter 4 Defining Equipment).
- The Audit Sync In Users Before Sync Out feature, if enabled, it allows automatic Sync-In for users prior to executing a manual or automatic Sync-Out. Ensuring to Administrators that all Users on all AVS Consoles are consistent and maintained.

3.6. Updating the Validator AVS Firmware

Figure 34: Firmware Upgrade Tab

A new firmware release upgrade release for the Validator AVS can be applied using the AVS Firmware Upgrade tool from the Admin functions. For upgrading the Firmware please follow the steps exactly as outlined in the software:

1. Dock the console to the Validator AVS that is supposed to get upgraded.

Note: *A remote upgrade using Ethernet or Wi-Fi is not supported!*

2. Press the **Get AVS SN** number to establish a connection to the Validator AVS. This assures the connectivity and retrieves the serial number for the audit trail entry.
3. Insert a USB thumb drive with the firmware provided by Kaye into the USB port of the Kaye console on the backside of the Validator AVS. You can easily identify the correct USB port by referring to the displayed picture.
4. The firmware is ready to be upgraded, ensure that the Validator AVS is properly powered and not powered off during the upgrade process. Failure to do so can cause system damage and then restoration at a Kaye Service Center.
   Press **Upgrade Firmware** and wait until a message displays to restart the Validator AVS.

Note: *Upgrading the AVS Operating system can take up to 15 minutes depending on the amount of copied data. Please be patient and do not switch the Validator AVS off before the corresponding message is displayed.*

3.7. Handling Data Files

High quality Document Management policies and Data Integrity guidelines require that companies have the proper controls and procedures to backup and protect critical GxP data.

The AVS system, under the File Management tile on the Main screen, has several critical features that allow manual and automatic backup of critical Qualification data files, reports, audit trail, and users. These features allow the backup, restoration, and archiving of critical data to user define paths such as Mapped drives on the Network, etc. Using these features creates the flexibility to define what data gets stored, where it's stored, and the frequency.

If you have multiple AVS Consoles or systems, utilizing these features you can setup a common location where all Validation data from multiple Consoles can be merged.

The following rules apply to the Sync function when merging data:

Preferences and Policies are not synchronized

If two items with the same name exists, the item is updated with the latest version (depending on the modified date) in case for users and assets.

If two items have the same name but different dates (reports, study files), both are retained.

The sync operations are started from the File Management tile on the Main screen. When starting a sync operation, the software firstly asks for the sync folder location.

- **Sync Out**

  The Sync out function is used to copy the data content of the console to another file location. If the content of one console is copied to a dedicated folder, it serves as a backup function.

  If the data of two or more consoles synchronizes to the same folder, the data is merged together to build up a pool of shared data for a work group.

  You can select data to be copied. If an asset is selected, the asset with all the information (setups, study files, reports, documents) is copied. It is possible to select only one or a few assets to transfer these from one console to another,

but also possible to make a complete transfer with user, audit, equipment, templates, and asset data, depending on the setup.

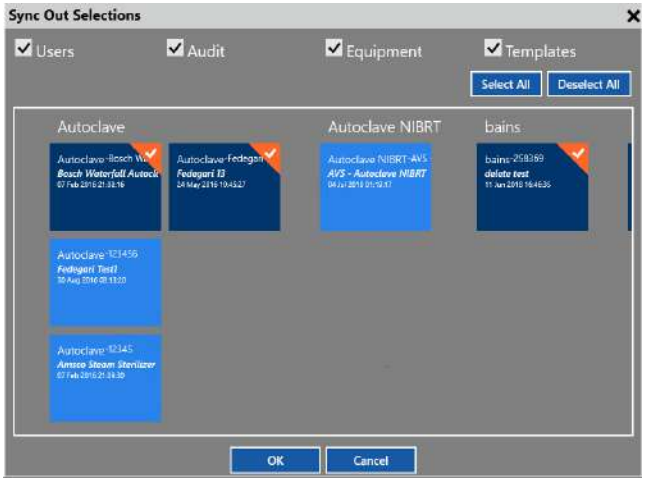


Figure 35: Sync Out Selection Box

- **Sync In**

The sync in function copies data from a file location to the console. It can be used to restore data of a backup generated with the Sync out or Archive function. Like in the sync out function the user can select which data and which assets are copied to the console. In addition to the Data selection there's a date filter to prevent old data to be copied to the console. The date filter specifies a time frame with simple drop-down selection.

The copied data is merged with the existing console data.

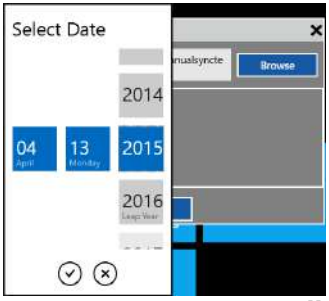


Figure 36: Sync In - Date Filter

- **Archive**

The Archive function works like the Sync out function except it will not copy but move files to a file location for archiving purpose, removing the files from the console.

Therefore, in addition to the Sync out function there is an archive date. All files that are older than the specified date is moved. Like in Sync out the assets can be selected individually.

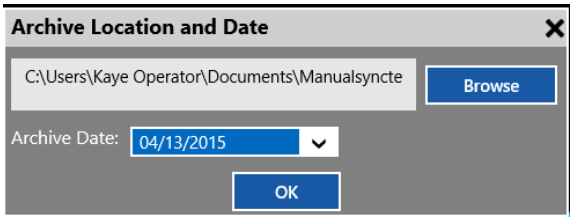


Figure 37: Archive Date Filter

- **AVS Convert**

The AVS Convert function imports single study files into the Asset system of the console. Single raw encrypted study files can be copied out of Asset Details for importing into another console or sent by email. Study files copied using the USB side port, copy the files in a single file format that requires importing into the AVS software. The AVS Convert function is primarily used by Kaye Technical Support. It allows customers to copy and send raw encrypted study files via e-mail to Kaye for analysis or review.

To import a copied study file, select a single data file in the browser (if desired, add a comment for easier identification). If the corresponding asset is not currently in the system, the software creates a new asset and setup file from the information stored in the study file.

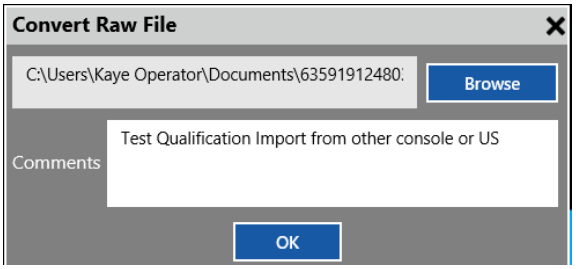


Figure 38: AVS Convert – Import Comments

- **Using Mapped Drives for Synchronization**

The synchronization function can be used to share data via a mapped drive to a server. Ensure that the mapped drive is correctly mapped in the Windows console. Please note the following to ensure that synchronization performs properly:

It is recommended to enter the server address as plain IP address; a server name may not work.

It is possible to use subfolders inside the mapped drive.

The system requires the service *MappedDriveHost* running in the background for sync operations.

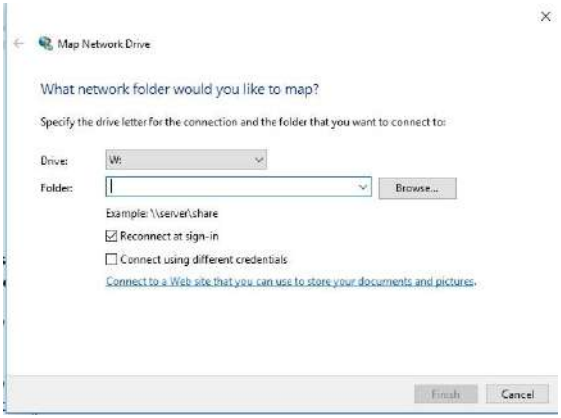


Figure 39: Windows – Mapping a Drive

When syncing from the software to a mapped location from the Validator AVS software:

Browse to the mapped drive. It is may be required to open the drive through the file explorer and the entering windows credentials for access.

If credentials are required to login to the mapped drive, they are automatically requested.

Enter your credentials for accessing the drive. If you are using a domain for security, you can add the domain information after the username with an @ extension as displayed in Figure 40 (alternatively the domain\user format is accepted as well).

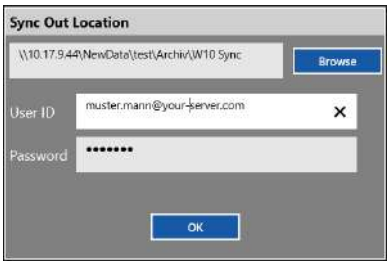


Figure 40: Mapped Drive Login Credentials

The security setup to access a shared folder is dependent on your network environment. There are several scenarios:

The folder can be accessed without any restriction. If so, enter a random user and password, as empty fields are not accepted. The random user and password are not used and discarded.

If the folder has user restrictions, enter your user credentials to access the folder.

If the folder has a domain security policy. Enter the domain after the username with an @ separating the username and password. Some domains do not accept this type of authentication and may require joining the console to the domain which copies all domain security policies and users to the console. Please contact your IT department for further support.

- **Auto Sync Function**

The Validator AVS software can automatically data sync to a remote network folder in a defined time interval. The setup for the sync location follows the same rules as described in manual sync out.

The setup for Auto Sync is located under the **Admin** tile in “Auto Sync”.

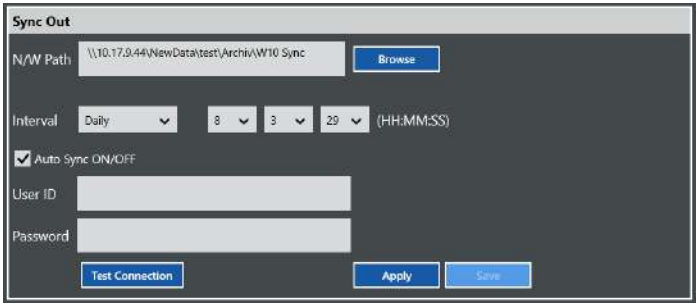


Figure 41: Auto Sync Details

The Validator AVS software can sync data automatically to a remote network folder in a defined time interval. The setup for the sync location follows the same rules described for manual sync out and using a mapped network drive detailed on previous pages. Please note, Auto Sync expects a mapped drive on the network as the remote folder. Local drives or USB drives cannot be used for automatic synchronization.

N/W Path: Browse to the mapped drive and folder to sync to. It may be required to open through the file explorer and then enter your windows credentials for access.

User ID / Password: Enter your credentials to access the drive. If you are in a domain security, you can add the domain information after the username with an @ extension as shown below. Please use **Test Connection** to check if the user/password combination works with the path.

Interval: That the interval and time the automatic sync out is set to start.

Auto Sync ON/OFF: Enable or disable the Auto Sync Function.

Test Connection: Pressing this button, the software checks if the entered path and user credentials permit access, displaying a message accordingly.

Apply/Save: Once settings changes are complete, you can apply and test the connection. For permanent use of the setup press **Save**. If you exit without saving the old credentials are valid and any new credentials are lost.

The results of the Auto Sync function are logged in the audit trail. If the automatic sync fails, a message with required user verification appears to ensure that operators are notified.

Note: *For the daily sync, it is only possible to save a sync time later than the current time on the same day. As example if you want to auto sync at 6:00h in the morning, you need to set it before 6:00h.*

3.8. Online Help

For online help, utilize the AVS Console Pen and right click inside any screen or swipe down from the upper right corner of the display. There are two icons with a question mark, labeled as “Windows Help” and “Help”. **Windows Help** displays the help screen of the operating system; **Help** displays context-specific help for the open AVS application screen.

Chapter 4. Equipment

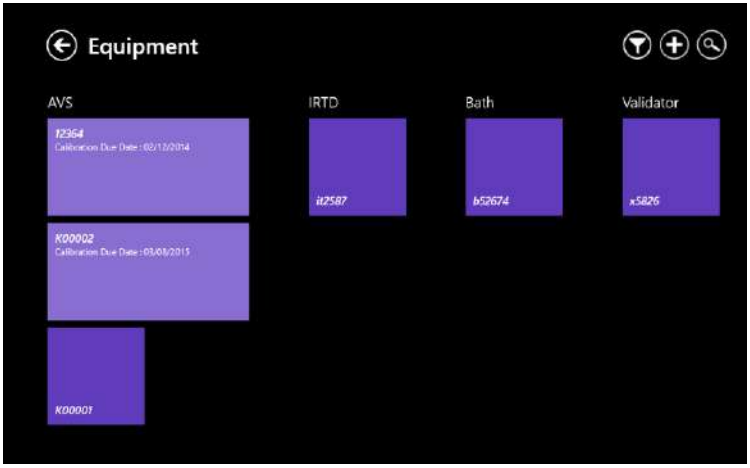


Figure 42: Equipment Hub

The AVS software includes a unique feature called "Equipment" which allows users to create an asset for each piece of Kaye equipment in their validation fleet.

Once entered, the AVS software alerts users with upcoming or overdue calibrations, as well as automatically providing the name of each study where that piece of equipment was used for a Qualification, Calibration or Verification.

Note: *This feature can be valuable when experiencing "As Found" failures on any yearly calibrations, as you no longer need to search through large amounts of data to find where each piece of equipment was used.*

Functional details:

A database of all used Kaye Equipment identified by serial number, calibration information, and an optional picture.

Calibration reminders are based on the calibration reminder setting in preferences and the calibration due date.

Search study files where certain Kaye equipment were used. The search is based off the entered Kaye equipment serial ID and automatically retrieved serial numbers saved within the study files. For temperature baths, no serial number is retrieved.

4.1. Adding New Equipment

To add a new piece of Kaye equipment to your Equipment assets, press the **Plus** (+) icon on Equipment screen. The New Equipment screen opens.

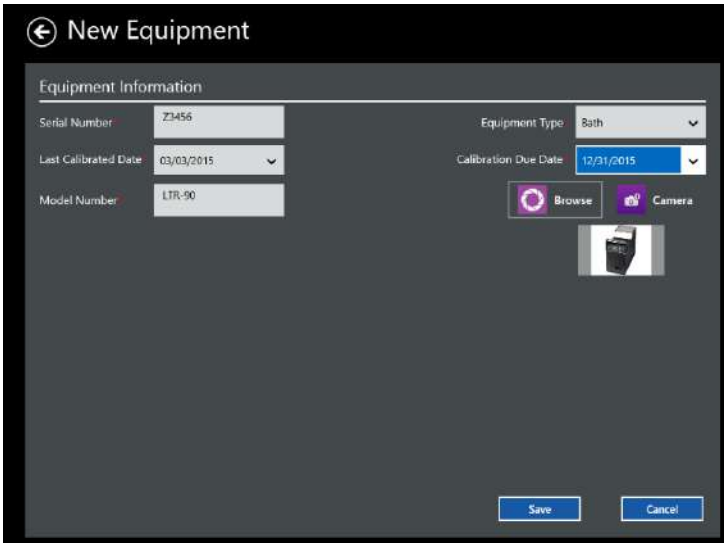


Figure 43: New Equipment Screen

Use the textboxes and drop-down menus to enter the following:

- The equipment serial number as a unique identifier
- Last calibrated date
- Model number
- Equipment type
- Calibration due date

You can also upload an image of the equipment as a bmp or jpeg or access the camera to take a picture directly.

When you have finished, press **Save** to save the entry and return to the Equipment screen or **Cancel** to reset entries on the screen.

4.2. Checking Details / Studies for Existing Equipment

To review the details and studies for a piece of Kaye equipment press the tile for that item on the Equipment screen. The Equipment Details screen opens (it may take several minutes to populate fully).

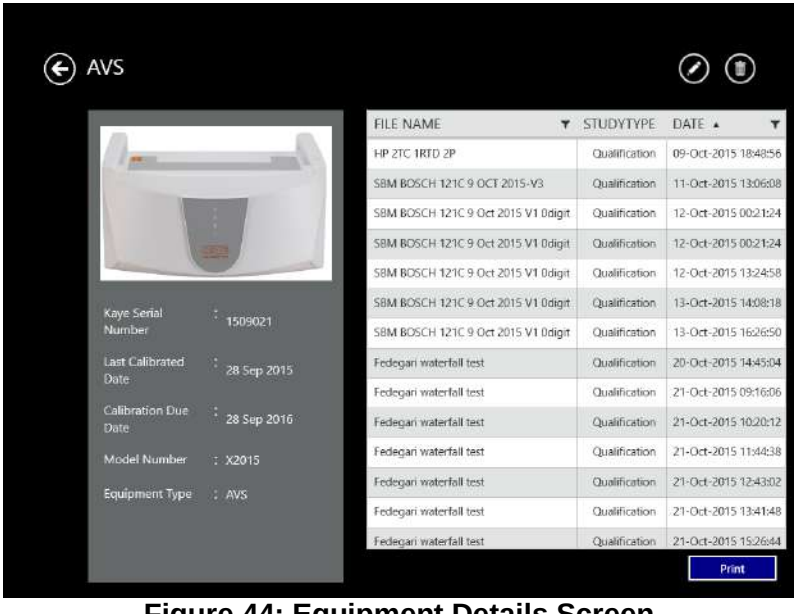


Figure 44: Equipment Details Screen

On the left side of the screen the listed details are as follows:

- Serial number
- Date of last calibration
- Due date for calibration
- Model number
- Equipment type

Press the **Pen** icon to change any of these parameters. The left side of the screen displays study files associated to this equipment.

On the left side of the screen, a list of where the equipment was used for Qualifications, Calibrations, or Verifications is displayed. The list can be sorted by study name or date and printed.

Note: *When a study is run, the AVS software obtains the serial numbers of the equipment used and posts them to the Equipment Assets. Studies run before the Equipment asset is created cannot be listed. Thus, it is important to list your Equipment assets as soon as any new equipment is acquired.*

In the funnel view, accessible from the equipment screen, it is possible to filter a list of available studies by simply selecting the tile of the equipment.

4.3. Equipment - Calibration Reminder

The Equipment functionality provides a calibration reminder and visual alert to assist users with the maintenance of their Kaye equipment.

When adding a new Equipment asset, the Calibration Due Date is manually defined. Inside User Preferences the Administrator can define the number of months from the due date to alert the Users. The number of equipment due for calibration is displayed inside the Equipment tile on the Main screen.

Opening Equipment, the tiles for any equipment due for calibration are enlarged in light blue and display the calibration due date directly within the tile.

When equipment is recalibrated, the user is required to manually update the calibration data and due date.

Chapter 5. Defining Assets

The Validator AVS includes an intuitive Asset Centric Data Management concept (patent pending) where you can store and access your data faster and more efficiently.

Each individual process that you validate, whether an autoclave or freezer etc. can be setup and defined as an asset. All files and data related to this asset, like setups, calibrations, or study files are organized and accessed in one single screen around the basic asset data. It is possible to upload additional documents like standard operation procedures or certificates and associate it with the asset. Assets can be sorted and searched by type, location, or manufacturer for easier access.

To open the Assets Hub, press **Assets** on the Main Menu. The Assets Hub displays, as in Figure 45 below:

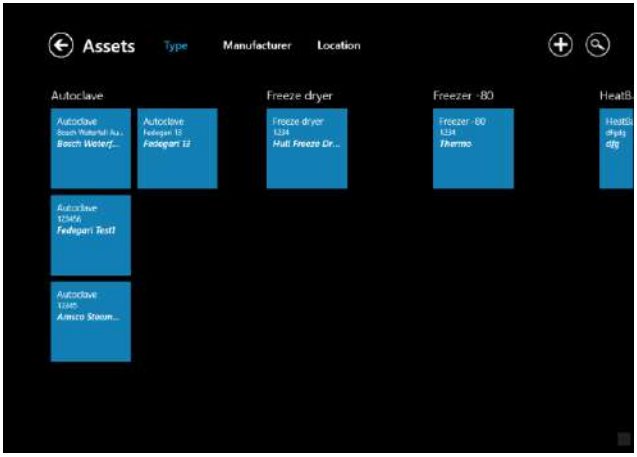


Figure 45: Assets Hub

The Asset Hub lists the various assets validated by your Validator AVS system. On the top text line, you can press the category to display the assets by:

- Type (sterilizer, dry heat oven, controlled temperature, etc.) up to 20 user-designated types
- Manufacturer
- Location

The asset tiles display each asset with type and model number. If the number of assets exceeds the screen size, scrolling and zooming enables viewing additional assets.

To search for an asset, press the **Search** (magnifying glass) icon, and enter the search criteria / data.

For further details about a particular asset, press the tile for that asset to open its corresponding Asset Details window.

To add one or more assets to the list, press the **Plus** icon (+) to open the New Asset creation window. Press the **Back** icon (the left arrow) to return to the Main screen.

5.1. New Asset Screen

To enter a new asset into the Validator AVS system, go to the Asset Hub screen and press the **Plus** (+) icon. The New Asset screen opens.

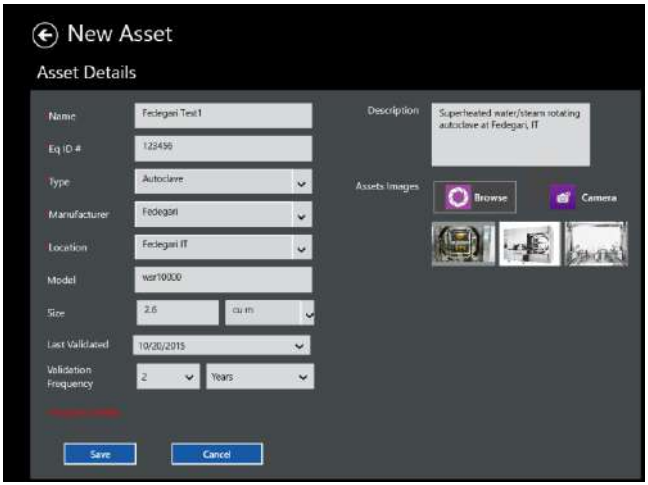


Figure 46: New Asset Screen

Enter each new asset details separately, use the textboxes and drop-down menus to enter:

- The Asset Name: Asset names must be unique. Before synchronizing several asset data sets, it is recommended to ensure there are no duplicate asset names utilized. This field is mandatory and required for unique identification.
- The Equipment ID: Equipment IDs must be unique. This field is mandatory and required for unique identification.
- The type of asset: Any new type definition will be available in the drop-down in the future. Please be careful as also test types or wrong spelled types will be available in the drop-down. This field is mandatory and required for sorting.
- Manufacturer: Specify the manufacturers name of the asset. This field is mandatory and required for sorting.
- Location: Specify the location of the asset. This field is mandatory and required for sorting.
- Model: Specifies the model number of the asset. This field is optional.
- Size: Specifies the volume of the asset in cubic units. In the drop-down, it is possible to select the appropriate units or enter custom units. This field is optional.
- Last Validated: Specifies the date of the last validation of the asset. This field is optional.
- Validation frequency: Specify the required validation frequency. This field is optional.

At the right, you can enter an optional Description of the asset. You can also upload up to three images of the unit to appear on the Asset Details screen, as well as a wiring overlay images that provides users of sensor placement on the asset.

When you have finished, press **Save** to save the entry and return to the Asset Hub or **Cancel** to leave the screen without changes.

5.1. Asset Details Screen

To learn more about a particular asset, select the tile for that asset on the Assets screen. The Asset Details screen (shown below) opens:

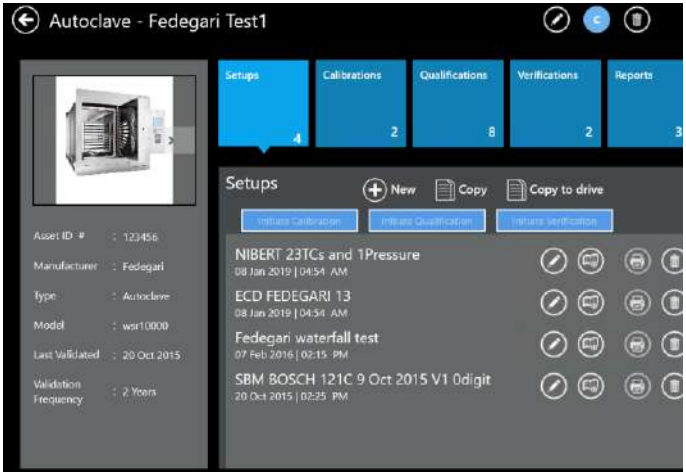


Figure 47: Asset Details

In the upper left, the title is the asset type and name. The pane on the left displays a picture and asset information defined during asset creation, details include:

- Asset ID: The internal asset number or serial number for unique identification of this asset.
- Manufacturer: Asset manufacturer name
- Type: Categorization of the asset
- Model: A model name or subtype can be specified
- Last validated: Date of the last validation as manually entered in the Edit Asset screen.
- Validation frequency.

In the right pane, tiles list the following categories associated with this asset:

- Setups
- Calibrations
- Qualifications

- Verifications
- Reports
- Documents

A number on each tile represents the number of available files under this specific tile. Selecting a tile highlights that tile and displays any associated files.

If more setup files are available, “Other" displays the number of additional setups. Pressing the downward arrow opens the Setup List. On the list page, users can apply predefined filter options (Status, Activity, Setup Name, Date, Comments, and Actions) to sort the files.

The Setup tile displays the latest setup files. If more setup files are in the database, the option, “Other Setups” displays the number of additional associated setups. Press the downward arrow to open Setup List. On the list page, users can apply predefined filter options (Status, Activity, Setup Name, Date, Comments, and Actions) to sort the files.

The **New (+)** button creates a new setup.

The **Copy** button permits the selected Setup to be copied to another Asset.

Pressing **Copy** opens a list of all available setups on the machine. Depending on the number of assets and setups, the population of this list may take some time.

Assets are listed with names and with the setup name, number of sensors, comments, and last modification date. Using the last column, you can select setups to copy to the asset.

Use the **Copy to Drive** icon to copy a Setup to a USB to E-mail for service analysis.

For every setup the following action buttons are available:

- **Pencil**: Permits editing an existing setup and saving under the same or new name (the created date is different).
- **Wiring Map**: Allows reviewing of the sensors wiring diagram and exporting them to a pdf. Wiring diagrams are created inside the setup when defining the groups.
- **Print**: Permits exporting a setup report including the wire diagram to a pdf file.
- **Delete**: Allows deletion of a setup (requires proper privilege assignment).

The **Setup** tile is used to initiate Calibrations, Qualifications, and Verifications studies. Simply select the Setup file and then the desired action to initiate.

The **Calibration** / **Verification** tiles lists all raw encrypted calibration / verification study files. The file names include, the setup name, date, run number, and comments. After selecting a Calibration / Verification study file, you can select **Generate Reports** to open the report tool and create a report. Similar to the Setup files, the Calibration / Verification raw encrypted data files can be deleted or copied to a drive provided proper privileges.

The **Qualification** tiles lists all raw encrypted Qualification study files. The Qualification tile has the same functionality options as the Calibration / Verification tiles.

The **Reports** tile lists all .pdf copies of the Setup, Calibration / Verification, Qualification, and Pass/Fail reports generated in the reporting tool. The AVS software automatically stores the reports in the Asset /Reports tile. Available reports can be sorted by type for ease evaluation of year to year reports.

The **Documents** tile provides options to upload any pdf documents related to the asset, e.g. wiring diagrams, SOPs, or calibration certificates.

The action buttons in the right corner allow editing the asset details (pencil) and to delete the asset from the system (trash bin). In that case all associated files needs to be deleted manually before the system allows deleting the asset.

The existing asset can also serve as a template for a new asset. Use the blue **C** button to open the Copy Asset screen. It is required to enter a new name and ID for the asset. Select certain available setups to be automatically copied to the new asset.

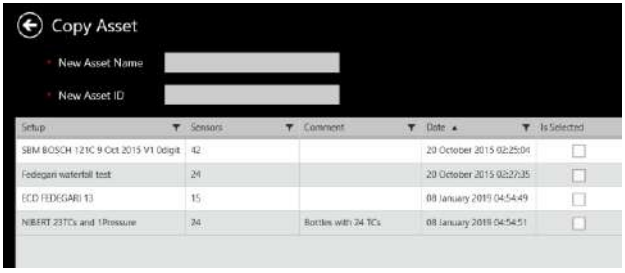


Figure 48: Copy Asset Screen

Chapter 6. Defining Study Setups

Before you can run a qualification study, you must use the Validator AVS software to create or modify a setup. A setup defines everything required to calibrate sensors and run a qualification study.

Note: *To create or modify a setup, you must have permissions established by your System Administrator in the Admin menu (User Management tab).*

The setup is accessed from the Asset Details screen, through the Setup pane. When creating a setup:

- Define the number and type of sensors to be used in the Qualification study
- Assign sensors to groups and generate a wiring diagram
- Specify calculations and define group events to be monitored during the qualification study
- Specify calibration and verification setpoints
- Specify temperature stability and deviation criteria for sensor calibration and verification
- Specify start and stop conditions for qualification and exposure cycle
- Define output relays

6.1. Create a Setup File

A setup defines everything required to calibrate sensors and run a qualification study for a specific asset. Setup files are created in the Setup screens. To create setups, permissions must be assigned by your System Administrator.

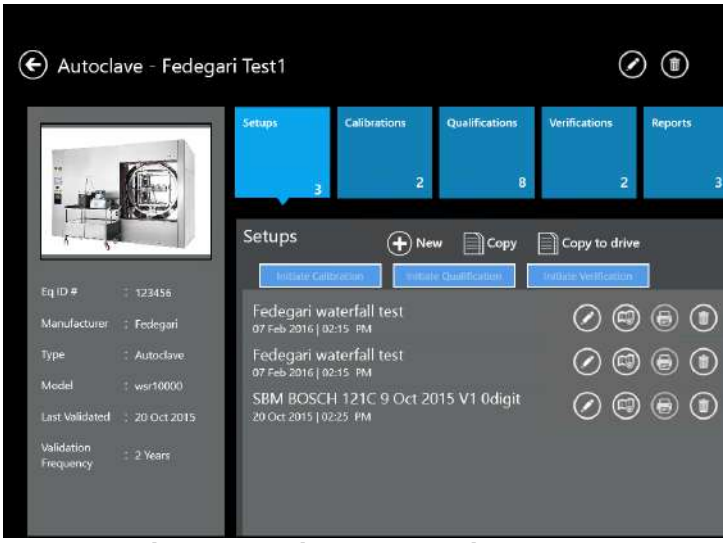


Figure 49: The Setup Hub Screen

To create a setup file:

From the Asset Details screen, press **Setups**. In the Setup Pane Hub, press **New Setup** to enter the Study Details screen.

You can now define sensors, assign sensors to calculation groups, set calibration parameters and criteria, specify the qualification cycle, and save your setup.

6.2. Modify an Existing Setup

Setup files for a specific asset are listed on the Setup screen. To modify an existing setup file:

Select the setup file you wish to edit and press the **Pen** icon.

Note: *You must have user permissions to modify a setup.*

6.3. Define Setup Screen

On the Asset Details Screen Setup Hub, select the Setup tile and then press **New Setup (+)**.

Figure 50: Define Setup Screen

On this screen, you define descriptive information to detail a Setup. Use the textboxes or drop-down lists to enter:

- The Setup Name
- The Number of Sensors to be used in the Qualification study
- The EQ ID
- The SOP (Standard Operating Procedure) Protocol Number
- The Load Description
- Any Comments you wish to add.

Note: *The Setup name, Study type, and Number of sensors fields are mandatory.*

The Setup Name and Comment fields can accept alphanumeric characters and blanks; the EQ ID, Load Description, and SOP fields can also accept special characters (hyphen, underscore, forward and backward slashes.)

When all asset data is entered, press **Sensors Configuration** to continue.

6.4. Sensors Configuration Screen

From the Study Details screen, press **Sensors Configuration** to open the Sensors Configuration screen. Below the current Setup name, are rectangular boxes displaying the seven Setup process steps. The box highlighted in orange displays the current position in the process.

The Sensor Configuration process is broken down into two steps:

- Select Sensors
- Configure Sensors

Note: *Sensor Configuration must match the actual wiring of the sensors to the SIMS. The Sensor selection and configuration process must be repeated for each type of sensor (T/C, RTD, Current, etc.).*

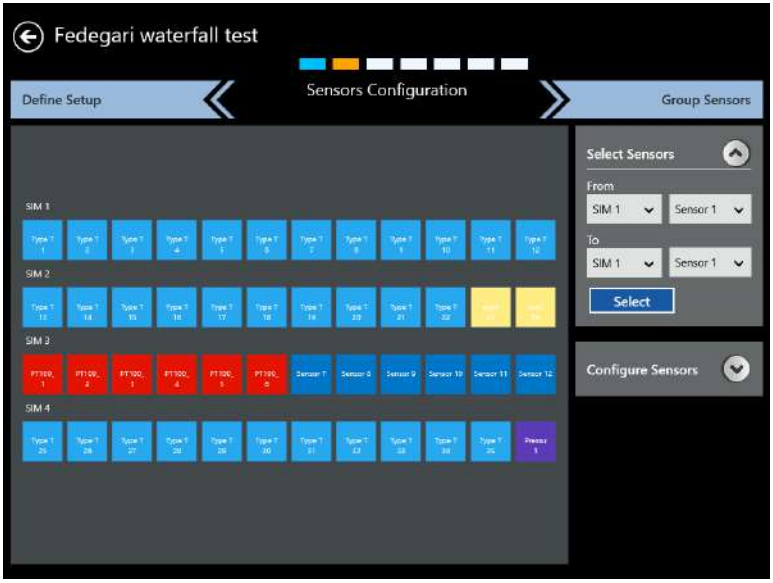


Figure 51: Sensors Configuration Screen

The Sensors Configuration screen graphically represents the four Sensor Input Modules labeled SIM 1, SIM 2, SIM 3, and SIM 4.

To configure, for example 24 thermocouples from SIM 1 and Sim 2, they must first be selected. If the sensors are not in consecutive channels, you can select each channel tile individually. As you do this the channels are marked with a checkmark indicating they are selected.

If the 24 sensors are in consecutive channels, an easier method is to define the range of channels using the Select Sensors drop down. Simply, select the channel of the first sensor and the channel of the last sensor and press **Select**. All channel in the range are selected.

Now that you have selected the sensors, you must configure them for the appropriate input type.

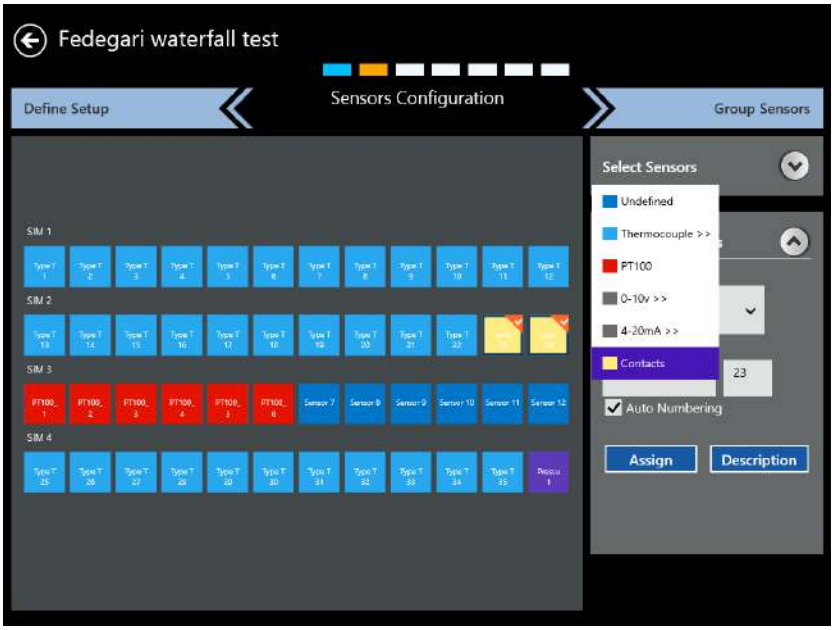


Figure 52: Configuring Sensors

Open the Configure Sensors drop-down list, and assign the selected sensors to one of the following color-coded sensor types:

- Thermocouples (T,J,K,E,B,R,S,N)

For most validation processes in the Pharmaceutical industry, Type T thermocouples provide the best accuracy within the range of -200C to 350C.

It is recommended to utilize Type T (0.01C) resolution to maximize accuracy during calibration and qualification.

- Voltage - the AVS system can accept inputs from other linear voltage transducers (i.e. humidity, CO2, etc.). Refer to the calibration cert. provided with the transducer and enter the input and output scaling range. The acceptable input range is from -1V to 12V.
- Current - the AVS system can accept inputs from other linear current transducers (i.e. humidity, CO2, etc.) Refer to the calibration cert. provided with the transducer and enter the input and output scaling range. The acceptable input range is from 1 to 25ma. A 4-20ma SIM is required for current inputs.
- Pressure - the AVS system can accept inputs from a Kaye or other pressure transducers. Select Voltage or Current, then select pressure for pressure sensors and the units of pressure assigned in the Preferences are utilized.
- Contacts - the AVS system accept can dry contact inputs (no voltage applied) inputs (switches, PLC's etc.). Calculations such as Lethality and Start/ Stop Cycles such as Qualification and Exposure can be triggered by Contacts inputs.
- RTD - The AVS system accepts three and four wire 100-ohm platinum RTD's utilizing the RTD SIM.

For pressure:

Once the sensor type has been selected, you can assign up to an 8-character label to define the sensors and automatically numbered.

When that is completed press **Assign** to lock the sensor type. The SIM channels update with the configuration and the channel tiles display the sensor type color.

Once the sensor type has been configured, you can press **Description** and enter up to 32 characters to provide a more detailed description. These can be used to define sensor placement (i.e. top shelf, back left).

After sensor configuration, for each type of sensor type configured in your Setup, press the **Group Sensor**s tab to advance to the next screen.

6.5. Understanding Groups

Grouping sensors is a powerful analysis and time saving tool that can be utilized for your Validation studies.

The following rules apply when assigning groups:

There must be at least one group defined in a setup. Each group must have a unique name.

Groups should be homogeneous (similar sensor types) since calculations are performed on all the sensors.

Sensors do not have to be in consecutive locations. You can assign any sensor from any SIM to a group.

You must assign a sensor to a group to record data from that sensor. Any sensor not assigned to a group is considered unused and no data is recorded for that sensor.

- Each group can have unique header information.
- Each group can have a separate sensor overlay image.
- Assigned calculations are applied for each group of sensors
- Qualification reports include unique pages for each group.

Grouping Examples:

- Using separate Distribution and Penetration sensor groups to analyze a sterilizer study.
- Using separate groups for each shelf of a Freeze Dryer to determine temp variance and then having all sensors from all shelfs in separate group for analysis.
- Utilize groups to perform validation of four separate freezers at the same time each containing 12 sensors.

These are but a few ways groups can enhance analysis and save time.

6.6. Assigning Sensors to Groups

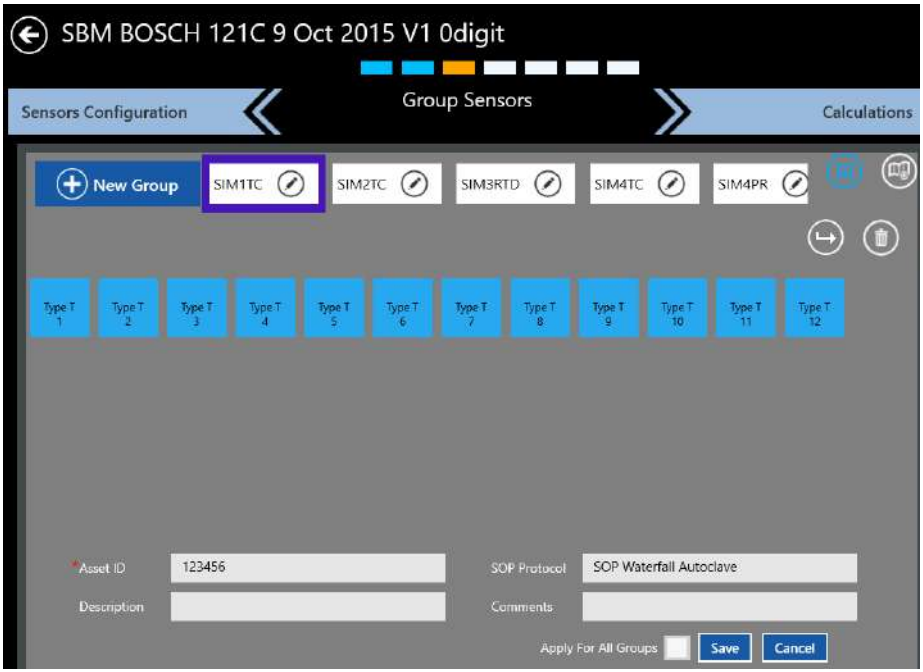


Figure 53: Group Sensors Screen

After the configuration of the sensors, the next step is to group them by pressing **Group Sensors**. The Group Sensors screen displays a scrollable listing of existing groups, as well as the **New Group** button.

As long there is no group defined, the **Default Group** button automatically generates groups for sensors with the same measured variable, like temperature, voltage, and Current etc.

To assign sensors to groups:

- Select individual sensors to select them for the group. These sensors now appear deep blue with an orange checkbox.
- Press the **New Group** button, and the Group Name textbox appears on the screen. The **Group Name** textbox accepts characters that can be upper and lower case, numeric, special characters like hyphen, underscore, slashes (forward and backward) and, blanks.
- Enter a name and toggle the **Save** button to save the group.

This screen also offers the following options:

- Delete - permits deletion of a group of sensors
- Move Sensors - permits moving sensors to another sensor group (specified in drop-down list)
- Customized Header for each group: The group specific header fields are pre-populated with the information from the asset. The header can be customized for each group. Any new information needs to be saved using the **Save** button before switching to another group.
- Add Sensors - add further sensors to a group
- A Wiring Overlay – accessible via the **Book** icon - enables wiring overlay configuration.

Figure 54: Wiring Overlay Diagram

Using the wiring diagram, you can define up to five pictures as background for placing the sensor positions. After selecting a picture frame on the left side, a picture can be loaded from a disk or taken with the built-in camera.

Note: *When opening the camera, ensure that the software can access the camera. The picture can be taken by double tapping the screen.*

Sensor tags can be moved via drag and drop to the position reflecting the desired or actual position on the asset. Wiring diagrams can be exported to a pdf using the **Printer** button.

For every group, it is possible to select a picture and a sensor position, then save it together with the setup. The wiring diagram can be printed from the Wiring Overlay screen or as a part of the setup report directly from the Asset Details screen. The wiring diagram is used as the basis for the live mode layout view.

When you have finished, and saved your changes, press **Calculations** to proceed to the Calculations screen.

6.7. Specifying Calculations

Figure 55: Calculations

Once you have defined sensors and assigned them to one or more groups, the next step is to specify calculations to be performed during the qualification study. Calculations include statistical, lethality, interval, saturation pressure of steam, and saturation temperature of steam calculations.

Calculations for Statistical Lethality and Saturation are performed for all groups, interval calculations can be specific for each group.

Note: *If lethality is selected in the setup, the report tool requires the definition of an exposure cycle as mandatory.*

It is also possible during report generation, to define events to monitor during the study. These events are listed in the reports and can be used to define reporting tool cycles.

When finished, press **Calibration Parameters** to enter the qualification parameters.

6.8. Specifying Calibration Parameters

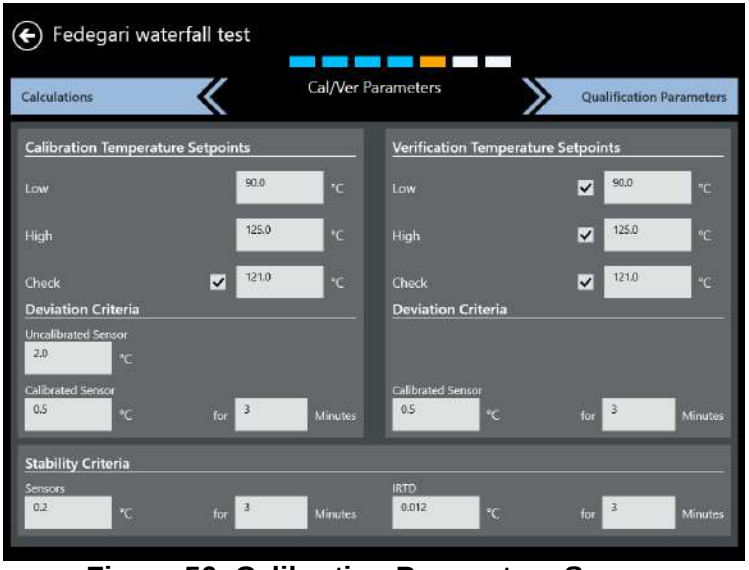


Figure 56: Calibration Parameters Screen

The Validator AVS provides both sensor calibration and verification.

Before running a qualification study, regulations require performing sensor calibration to maximize accuracy and ensure that the system meets required uncertainty criteria. During sensor calibration, the Validator AVS automatically compares each sensor to the IRTD (NIST-traceable temperature standard). The variation for each sensor at the low and high calibration point is stored in the SIM as an offset. Offsets are then applied to each sensor reading during the Qualification study. You can specify a two-point calibration, or a two-point calibration with one check point.

Sensors that do not meet the User defined uncalibrated sensor criteria are marked as failed and are not calibrated. Calibration and verification temperatures, chosen set points, stability criteria, and deviation criteria all constitute a calibration signature.

After the qualification study, it is recommended to perform a calibration verification to verify that the sensor readings are still within the process criteria. You can specify a one-point, two-point, or three-point verification independently from the calibration criteria.

If a sensor fails verification, the sensor is noted as failed, but the readings are still reported. Calibration offsets are not changed during calibration verification.

Set calibration parameters by specifying:

- Temperature setpoints for calibration. You must specify a low setpoint and a high setpoint and optionally, a check setpoint. If you specify low setpoint and high setpoint, the high setpoint must be at least 2° higher than the low setpoint.
- Temperature setpoints for calibration verification to verify that each sensor is still within your process criteria. You must select at least one verification point during verification. Additional check points may be defined during the actual Verification process.
- Sensor and IRTD stability in terms of temperature variation over a fixed time period. Stability is the amount of change that is acceptable over the fixed time period.
- Deviation criteria for uncalibrated temperature sensors, and deviation criteria for calibrated temperature sensors over a fixed time period. Deviation is the difference in temperature between the sensor values and the temperature standard.

6.9. Specifying Qualification Study Conditions

Specify the conditions that control your qualification study on the **Qualification Parameter**s screen. From this screen, you specify:

Qualification start/stop conditions - used to start and stop the qualification cycle manually or automatically.

Exposure start/stop conditions - used to start and stop the exposure cycle manually or automatically. Only applicable if Lethality calculation is defined.

Data storage options - the rates at which data is written to the disk during a qualification run. Data is stored in the AVS hardware as a raw encrypted data file. All calculations are based on the Storage rate. It is possible to have a faster storage rate to enhance calculations and graphing and then also have a separate print rate when you define the report.

Clock adjustment on qualification start – This feature aids in synchronizing the study time with another device (i.e. PLC or controller of sterilizer). It allows a change of +/- 15 console time minutes to adapt e.g. to the time of an autoclave for parallel protocols in sync. Please note, after the study start you should reset the time manually or use an NTP server connection for automatic time setup. To utilize this feature, users must be assigned this privilege by an Administrator.

Output relay - the events that activate the two independent output relays.

When you have finished, press **Review** to check your entries and save the setup.

6.10. Reviewing and Changing the Setup

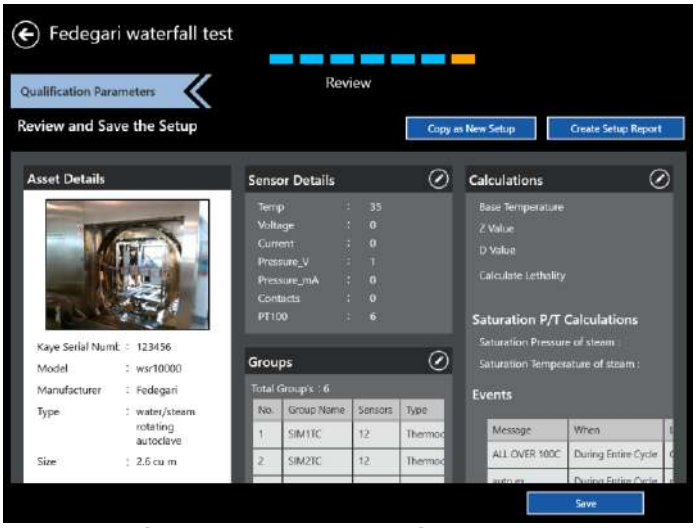


Figure 57: Setup Review Screen

After pressing **Review**, the Review screen opens, listing all the pertinent details about the setup you have just created. The Review screen provides following actions:

- Copy as New Setup —copy the current setup as a new setup and save it under a different name.
- Create Setup Report — creates a setup report as pdf file for saving and printing.

This screen also displays the following sections, each with an **Edit** icon to permit rapid changes:

- Asset Details
- Sensor Details
- Calculation
- Groups
- Report Header
- Calibration Parameters
- Qualification Parameters

Press **Save** to save the setup or use **Back** to exit the Setup menu without changes.

Chapter 7. Calibrating and Verifying Sensors

7.1. Introduction

Before you perform a qualification study, you should calibrate your temperature sensors to correct raw temperature readings to a traceable temperature measurement standard. You may also need to perform verification of the calibration to confirm the accuracy of a qualification study.

You can perform automatic calibration only if your validation system includes a Kaye temperature reference (Kaye temperature bath) and a Kaye temperature standard (IRTD). The IRTD, a self-contained precision measurement standard that provides data directly to the Validator AVS, accurately measures the temperature of the standard. The IRTD provides a traceable standard that is used to correct the temperature readings of your thermocouples. The Validator AVS automatically sets the temperature reference to the specified setpoint (low, high, check), and automatically reads the value of the IRTD at that setpoint.

In this chapter, you will be able to:

- Load a setup into the Validator AVS
- Select sensors to calibrate
- Run calibration

The Validator AVS uses the calibration parameters defined in your setup to perform sensor calibration. Calibration parameters specify the temperature reference setpoints at which calibration is performed, and the stability and deviation criteria for the temperature sensors and the temperature standard.

With the Validator AVS, you calibrate sensors at a low setpoint and a high setpoint. When you start calibration, the Validator AVS computes the stability of the temperature sensors and the temperature standard at the specified setpoint, according to the parameters defined in your setup. When the temperature standard and all sensors pass the stability criteria, the Validator AVS logs the stability readings to the calibration report file. The Validator AVS then computes and logs deviation on the uncalibrated sensors and calibrates all sensors that passed the deviation criteria. Finally, the Validator AVS computes and logs deviation on the calibrated sensors for a specified time.

The Validator AVS repeats this process for both setpoints. You can also specify a check point in your setup. During the check point, the Validator AVS calculates and logs deviation on the calibrated sensors.

When calibration is complete, the Validator AVS writes the calibration offsets, the serial number of the Validator AVS used for calibration, and the SIM slot number to the SIMs. If a sensor fails at the low, high, or check setpoint, it is marked as failed in the SIM and in the calibration report file.

Before you begin the calibration process:

- Place the Validator AVS in a location with a stable and even temperature and not exposed to any local heat sources (i.e. close to a sterilizer, an open door causing a draft, etc.). Temperature variations and/or exposure to external heat sources during calibration may cause temporary temperature measurement errors.
- To provide maximum accuracy during the calibration process, power up the Validator AVS and let it run for approximately 30 minutes in the operating calibration environment for the Validator AVS to acclimate to the ambient temperature.
- Using the IRTD cable, connect the IRTD to the AVS using the top slot of the IRTD icon, located on the back of the AVS. To utilize the Temp Reference, use the Temperature Reference cable to connect the Temp Reference to the back of the AVS slot marked with a Temp Reference icon.

Before you begin the calibration or calibration verification process, you must load your setup into the Validator AVS. If a Kaye IRTD is used, connect the Kaye IRTD to the upper port of the Validator AVS.

IMPORTANT: *Connecting the Kaye IRTD to the lower connection port can result in distorted data in the calibration reports. Ensure that you always use the upper connection port!*

7.2. Loading a Setup into the Validator AVS

IMPORTANT: *When you load a setup with a different calibration signature (calibration parameters and/or temperature units) than the setup currently in memory, any sensors already calibrated are marked as uncalibrated. If you reload the original setup, and you have not calibrated sensors using the new setup, the offsets are restored, and the sensors marked as calibrated.*

To load a setup:

From the Main Menu go to Asset Details and then select a setup to be used for your Qualification study, from the list of available setups. Buttons for initiating a study are active and pressing **Initiate Calibration** or **Initiate Verification** starts the corresponding process.

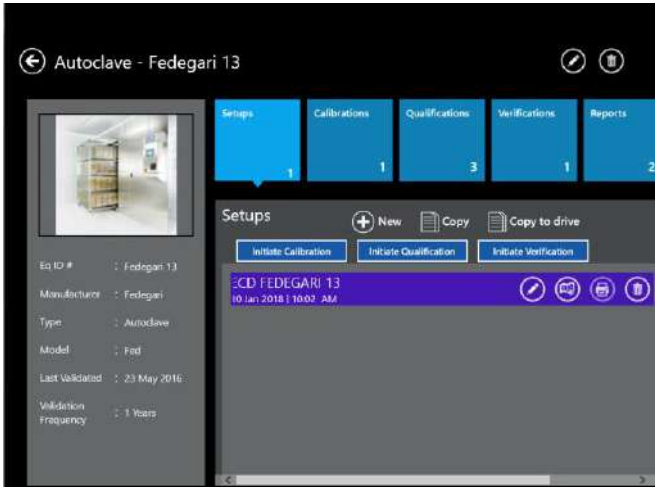


Figure 58: Initiate a Calibration from Asset Setups

After pressing **Discover**, available devices are displayed. Select the Validator AVS to be used for your Qualification study. Docking mode is preselected (highlighted in orange), but it is possible to select any Kaye Validators AVS that is currently available through a network connection.

Select the desired Validator AVS and press **Connect**. The Validator AVS then loads the setup and reads sensor information. This process may take a few seconds to complete. When completed, the Start Calibration screen displays.

7.3. Selecting Sensors

You can select sensors to be calibrated or verified on the Select Sensors screen. This screen (Figure 59 below) lists all thermocouple sensors defined in the setup. Sensors that are not selected appear as plain blue, while selected sensors appear in their SIM row in deep blue with an orange triangle. For each SIM, you can select sensors individually or select all sensors in one step.

Figure 59: Sensor Selection Screen

To select sensors individually, press the individual sensor tile. The icon color changes to deep blue and the checkbox is enabled.

After you have selected and confirmed your sensors, press **Initiate Calibration** to start a new calibration, or **Initiate Verification** to perform a verification (press **Cancel** to discard all sensor selections. Press **Return** in the upper left to exit.).

Note: *Once you begin a new calibration, any offsets from previous calibrations are lost*.

7.4. Calibrating or Verifying Sensors

Press **Start** on the Sensor Calibration screen to start a calibration study. The Validator AVS automatically calibrates (or verifies) sensors at the setpoints defined in your setup. In case of a verification, it is possible to change the checkpoint settings via the **Criteria** button before starting a run to accommodate for any changes in requirements.

Hardware connections and criteria, as defined in the setup, can be reviewed any time by pressing the corresponding buttons.

Note: *It is recommended to ensure live data is displayed from connected sensors and IRTD before starting a study.*

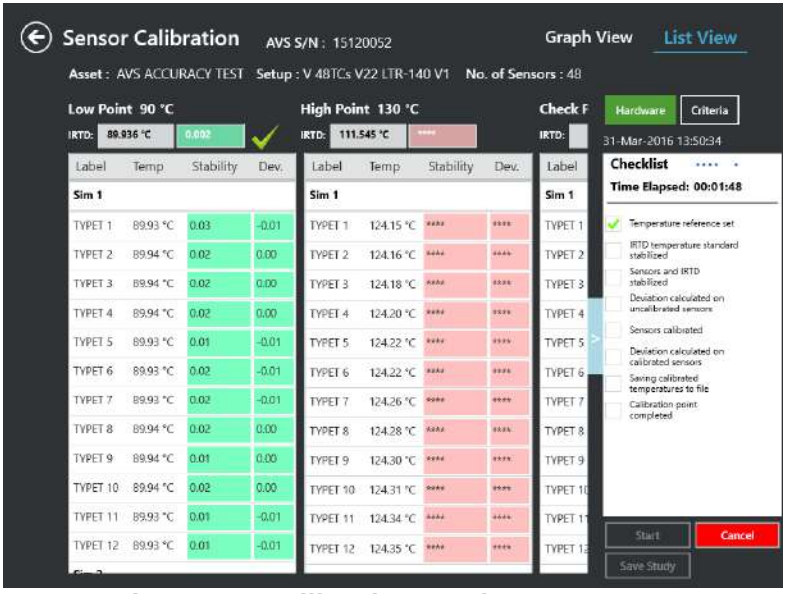


Figure 60: Calibration Study Screen

When starting a calibration run the Validator AVS deletes all existing calibration offsets stored in the SIMs for the selected sensors. Next, the AVS establishes communication between the temperature reference and IRTD. The Calibration screen during the calibration process displays temperature readings and stability readings for each sensor being calibrated, IRTD temperature and stability readings, and the required setpoint.

The header includes the study name, temperature point (high, low, or checkpoint), and the **Graph** and **List View** icons. Under the header, three blocks correspond to the low,

high, and check points, with temperature set points displayed at the top of the blocks. Each block has an interior header, temperature, stability, and deviation. On the first block, an additional header label lists the relevant data for a particular label (IRTD set point, SIM number, sensor label) for each row. If the list exceeds the screen size, you can scroll vertically through the remaining data. Use the **Stop Calibration** button to stop calibration.

If the stability point for any sensor is reached, that point is replaced with a green checkmark. However, if the deviation of any sensor is not within the specified limit, the deviation appears in red.

Note: *All calibration offsets are deleted from the SIMs if the calibration parameters or temperature units of the new setup are different than the calibration parameters or temperature units of the setup currently in memory.*

Calibration offsets for sensors at each setpoint are written to the SIM when the calibration process is complete. If you stop a calibration, calibration offsets already calculated are not written to the SIMs, and the calibration report file is deleted.

7.4.1. Automatic, Semi-Automatic or Manual Mode

When you start a calibration, the Validator AVS software detects whether a Kaye temperature reference and an IRTD are connected. The Kaye IRTD is required for automatic or manual calibration. If the Temp reference is not detected, automatic calibration is not possible, and the system automatically switches to semi-automatic mode.

7.4.2. Calculate Stability

The first step in the calibration process is to ensure that the IRTD and sensors are stable before we calibrate the sensors. Stability is the maximum allowable change in temperature for each sensor and the temperature standard over a specified time interval. The maximum allowable change in temperature for the IRTD is fixed at 0.012°C (0.022°F) if all temperature setpoints are equal to or greater than 0.0°C (32.0°F). If any temperature setpoint is less than 0.0°C (32.0°F), it is possible to change the IRTD stability value manually in your setup, the allowable range is from 0.012 to 0.10° C .

The stability calculation begins once the temperature reference is within five degrees of the setpoint. Sensor and IRTD readings are displayed on the Data screen with a red

background until they reach stability. To achieve stability, the IRTD and all sensors must meet the stability criteria defined in the setup.

All sensors and the IRTD must be stable (green) before the calibration process will continue.

To terminate the calibration process, press **Cancel**.

7.4.3. Calculate Deviation of Uncalibrated Sensors

When the IRTD and all sensors reach stability, the Validator AVS calculates deviation by comparing each uncalibrated sensor to the IRTD, and then logs the stability and uncalibrated deviation data to the calibration report file. The Validator AVS marks any sensor outside the deviation criteria as failed and those sensors should not be utilized for the Qualification study. On the Qualification live screen this sensor label appears in red. When uncalibrated deviation is complete, the Validator AVS calibrates all sensors that passed uncalibrated deviation at the low setpoint.

7.4.4. Calculate Deviation of Calibrated Sensors

The Validator AVS then calculates calibrated deviation. Corrected results for each sensor are compared to the IRTD, then logged, and displayed on the Data screen. Sensors that fail the calibrated deviation evaluation display with a red background and marked failed in the calibration report file.

7.4.5. Data Logging Complete at Setpoint

When the Validator AVS finishes logging the corrected results, it automatically sets the Kaye temperature reference to the high setpoint and repeats the calibration process. When the high setpoint calibration process is complete, the Validator AVS automatically sets the Kaye temperature reference to the check setpoint. The only difference between the low and high setpoint calibration and check setpoint is during check setpoint calibration, offsets are not changed.

7.4.6. Graph View

In the calibration study Graph View, the header consists of icons representing four SIMs, along with a summary. A drop-down list below these icons displays the setpoint.

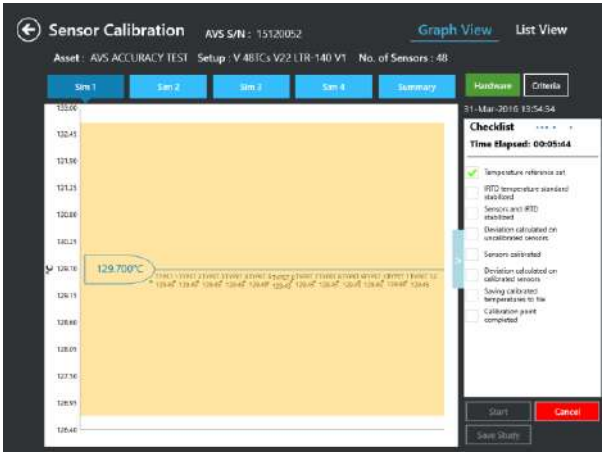


Figure 61: Calibration Study -- Graph View

On the graph, temperature appears on the Y-axis, while the highlighted X-axis displays the stabilized IRTD temperature. All sample points that lie within the deviation specified are displayed as green dots along with the label and the temperature point of the sensor. Samples that deviate from specification are displayed as red dots along with a sensor label, temperature point, and a value indicating how much the sensor is off.

On the Summary tab, outliers of all SIMs are displayed, along with the SIM number, sensor label, temperature point, and a value indicating how much the sensor is off. The graph view is an efficient way to identify sensors that are not fully down the Temp Reference wells.

7.5. Current Calibration and Hardware Connections

Both List and Graph views display essential data:

- Bath serial number
- Hardware connection status
- Preview stability criteria
- Calibration checklist - keeps track of each particular step in the calibration:

- Temperature reference set
- Sensors stabilized
- IRTD temperature standard stabilized
- Deviation calculated on uncalibrated sensors
- Sensors calibrated
- Deviation calculated on calibrated sensors
- Saving calibrated temperature to files
- Calibration point complete

A green check mark appears next to each step in the process when it is completed.

7.5.1. Calibration / Verification Study File

At the completion of the Calibration or Verification process a message appears at the bottom of the screen alerting the user that the Calibration or Verification process is complete.

The **Save Study** button on the bottom right of the screen can be pressed and the raw encrypted Calibration / Verification file is copied from the AVS hardware to the AVS console and automatically placed in the Asset under the Calibration or Verification tile.

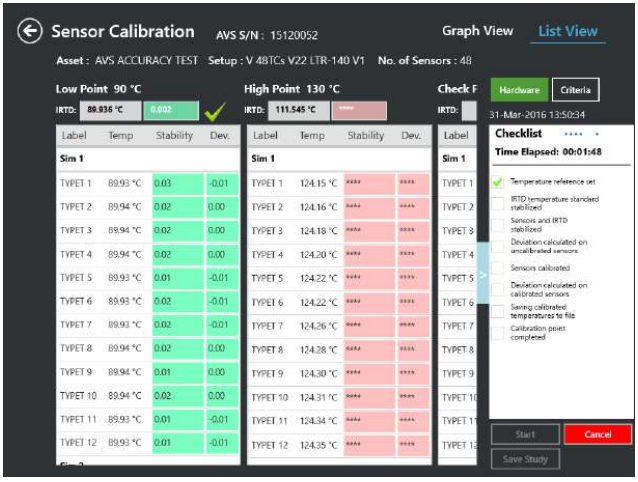


Figure 62: Calibration Study Screen

Chapter 8. Qualification Study

8.1. Introduction

Once the setup is defined and the sensors are calibrated, you are ready to run a qualification study. The Validator AVS uses the qualification parameters defined in the setup to perform the qualification study. Depending on the start and stop qualification conditions and the start and stop exposure conditions defined the study performs a fully automatic qualification, a fully manual qualification, or a mixture of automatic and manual. For example, the setup could be specified that the qualification study starts manually, exposure starts automatically when a contact closes, exposure ends automatically when the contact opens, and qualification ends manually.

During the qualification study, the Validator AVS measures sensor inputs, performs calculations, and stores data at the Data Storage rate defined in the Setup. At the end of the study the User selects **Save**, encrypted raw data is stored to the AVS hardware internal memory as well as transferred to the Console. Qualification data is always written to the Validator AVS internal memory.

The Validator AVS is also equipped with a lithium ion backup battery to provide short-term power in case of AC power loss during the run. The intent of the battery is to provide sufficient time (approximately 180 minutes) to allow you to complete the study. When the battery has approximately six minutes of power remaining, the Kaye Validator AVS stops collecting data and closes its data files.

When the qualification study is complete, reports can be generated to document the specifics of the study using the Validator AVS report generator (see Chapter 10).

Before beginning the qualification study:

- To ensure Validator AVS measurement accuracy, place the AVS far enough away from the process to avoid any large temperature gradients or drafts.
- To provide maximum accuracy during the qualification study, power up the Validator AVS and let it run for approximately 30 minutes in the operating environment where qualification is to be performed for the Validator AVS to acclimate to the ambient temperature.
- Position the sensors in the vessel or chamber (the asset) being tested.

8.2. Loading a Qualification Setup

To begin a Qualification, from the Main Menu press **Assets**, then select the Asset to be Qualified. With the proper Asset screen displayed, press the **Setups** tile and select the name of the Setup to be used for the Qualification. Ensure that the **Setup** is highlighted and press the **Initiate Qualification** button.

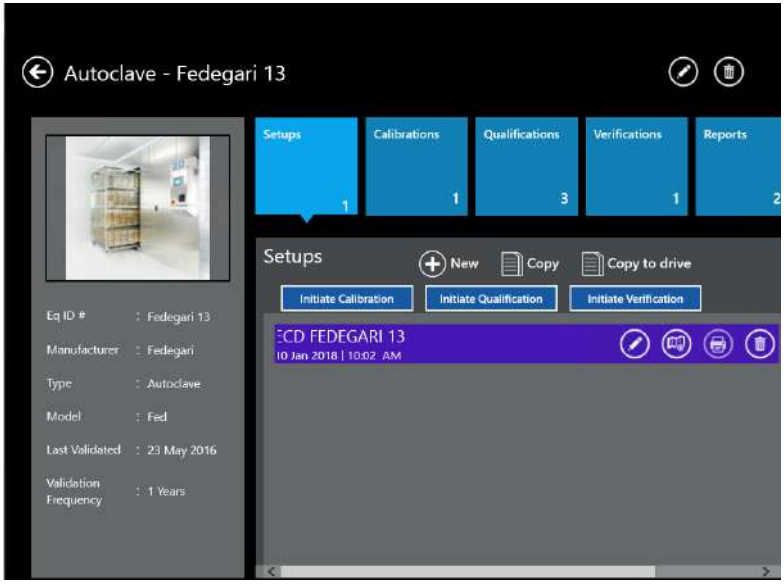


Figure 63: Initiate a Qualification from Asset Setup

A window opens prompting you to change the SOP Protocol Number and display the run number if desired. The run number is counted automatically but it is editable if required. Pres **Ok** to open the Select AVS screen.

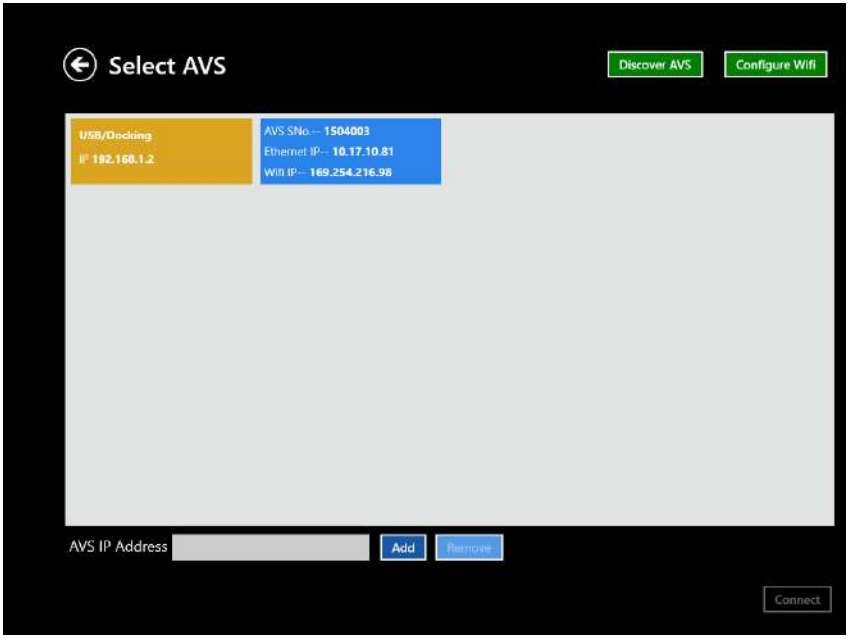


Figure 64: Select AVS

Press **Discover** to display all the Validator AVS'. By default, this screen highlights the Validator AVS that was last used with the Console.

Select the Validator AVS to run the Qualification study and then press **Connect** to start the setup transfer for the qualification study.

IMPORTANT: *Before loading the Setup, the AVS software compares the calibration signature defined in the Setup with what is contained in the SIMs; this is done to ensure the signatures match and the SIMS are in the same AVS and slot as they were initially calibrated.*

If they do not match, a message displays notifying the User to correct the situation or proceed. If the issue is not corrected, the offsets in the SIM are not used during Qualification.

8.3. Qualification Start / Stop Conditions

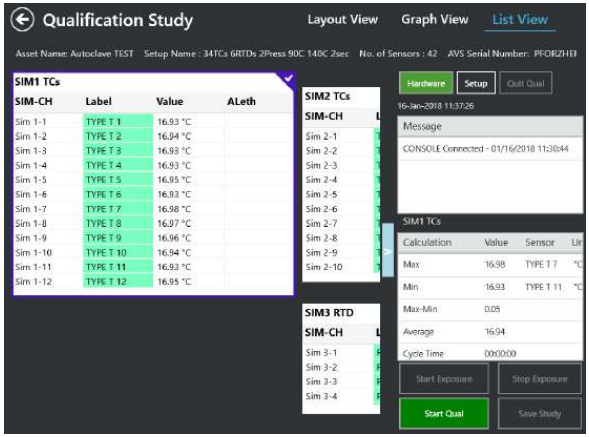


Figure 65: List View - Real-Time Readings

When the Setup is loaded the Qualification Study screen displays. The bottom right of the screen contains all the Start / Stop command buttons for Qualification and Exposure as defined within the Setup. Start / Stop conditions are programmed in the Setup and can be configured individually to either, occur manually, by pressing the appropriate button, or automatically by a specified condition (i.e. Start Exposure when Min Temp >100C).

The AVS controls the proper sequencing of buttons to ensure the correct order is followed (i.e. you cannot press Stop Exposure before Start Exposure is initiated etc.).

If a condition is defined to be Started / Stopped manually, then the proper sequence of that button is highlighted a color and does not occur until the button is pressed. If the condition is defined in the Setup to occur automatically based on an event, then the button is grayed out and occurs automatically when the condition occurs.

At the end of the Qualification study, press the **Save Study** button to save the study. The Qualification file gets added to the Asset under Qualifications.

All actions are documented in the Messages pane and Audit Trail. The **Quit Qual** button in the upper right of the display, allows a user to quit a study in progress. The user is prompted to save the study. The Qualification file contains all data up to the time the study was aborted.

8.4. Qualification Real-Time Displays

During the Qualification Study the Validator AVS software offers numerous real-time and historical displays to enable the User to easily evaluate and analyze the performance of the Qualification study. The displays include List, Graph, Overlay, and Interval Calculations.

List View

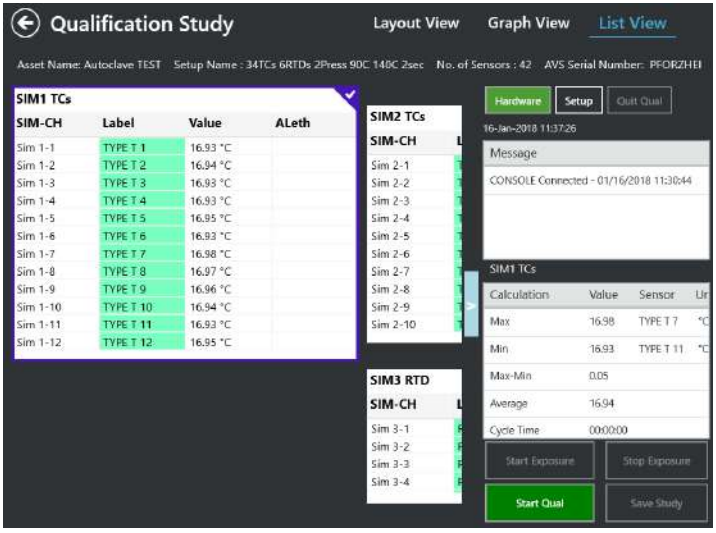


Figure 66: Qualification Study in List View

The List view displays the live readings of sensor values of a group in a table for all groups in a Qualification study. The first column shows the SIM number and channel, representing the physical connection of the sensor. In the second column, the label as assigned in the setup is displayed, followed by the sensor value in the third column.

The fourth column is available if lethality is defined in the setup and displays an ALeth value for accumulating lethality. The calculation of the displayed ALeth value follows the definition for the lethality calculation in the setup. The message window and button controls can be moved aside by pressing the small light blue arrow between them to have more area to display the data views.

The color of the sensor label field indicates the calibration status of sensor.

Green	Sensor is calibrated (with the same setup in the same AVS in the same SIM slot).
White	Sensor is not calibrated but can be used.
Red	Sensor failed calibration and is automatically excluded from calculations.

The List View shows the sensor values in groups as defined in the setup. If you select a group, the calculations for the group are displayed in the corresponding window.

Graph View

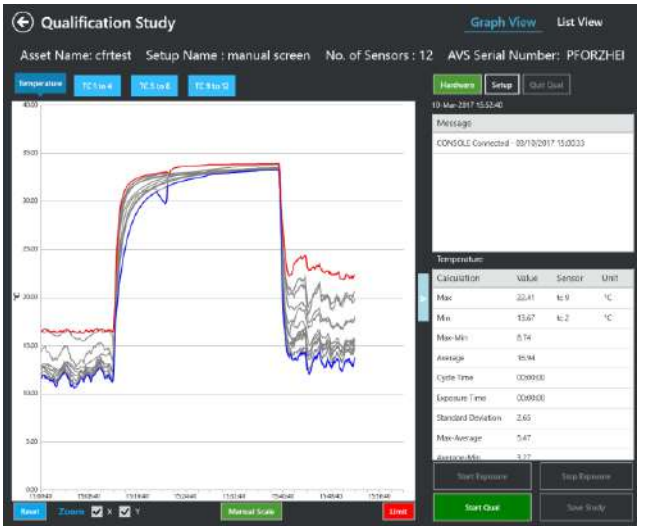


Figure 67: Qualification Study in Graph View

Pressing **Graph View** switches to the real-time graphing of sensor readings. Sensors are organized in groups defined in the setup. The different groups can be selected by pressing the buttons above the graph.

The Graph View is controlled with the buttons below the Graph. Zooming can be performed via touch screen controls. For easier operation, it is possible to zoom only by the X- or Y-axis by selecting the corresponding checkbox. The Y-axis can be scaled manually by entering min and max-values and then reset anytime to automatic scaling again. For better visualization of the process specification two limit lines can be set.

Inside the graph, current max and min values are highlighted with red and blue line colors respectively and the sensor label, timestamp, and values are displayed. The current max and min value are also listed in the calculations pane.

The graph can also show the accumulating lethality as line or bar graph series by pressing the **Lethality** button, activating the checkbox and selecting the desired option. Deactivate the checkbox to return to the values graph view.

Historical Data View

Figure 68: Historical Data in Graph View

The Validator AVS stores the data of the current study in its internal memory. In addition to the real-time data view it is possible to review this historical data at any time during a study.

This view is extremely valuable. For example, in cases where a study is started with a docked AVS but the AVS Console is needed outside the dock requiring a disconnect from the hardware; you can reconnect the Console with the hardware several hours later and press **Discover** and the AVS immediately returns to the Qualification real-time screens. The messages and Audit Trail document any disconnect and reconnect of the Console during Qualification.

When you press the **Graph** view the AVS Console automatically retrieves historical data from the AVS hardware. After the download is finished, below the graph, additional controls are available to access historical data.

Historical data is represented by data packages with the timestamp the data was recorded. The size of the data packages can be set in the drop-down to display 1, 2, 4, 6, 12, and 24 hours duration. If a data packages is selected, the graph automatically switches to the Historical mode.

The following functions are available in historical mode:

- The headline of the graph changes from Real-Time data to Historical data.
- Use Zoom to zoom and navigate inside the displayed data package.
- The groups selection functionality is identical to the real-time view, only the selected group and corresponding calculations are displayed.
- Use **Manual Scale** to extend the scale of the X-axis to a set displayed time.
- Select a data package to directly display it.
- A line in the Graph can be used to navigate to any timestamp in the graph and see the time and calculation data displayed for that specific timestamp.
- When selecting the **Sensor Value in Table** checkbox the calculation window is replaced by the sensor readings for the timestamp selected with the selection line.
- With the **Arrows**, it is possible to navigate between data chunks.
- The **Double Arrow** on the left navigates directly to the first data chunk.
- The **Double Arrow** on the right navigates to the live data screen and the headline of the graph displays real-time data.

Pressing **List View** switches back to a sensor reading table view.

Layout View

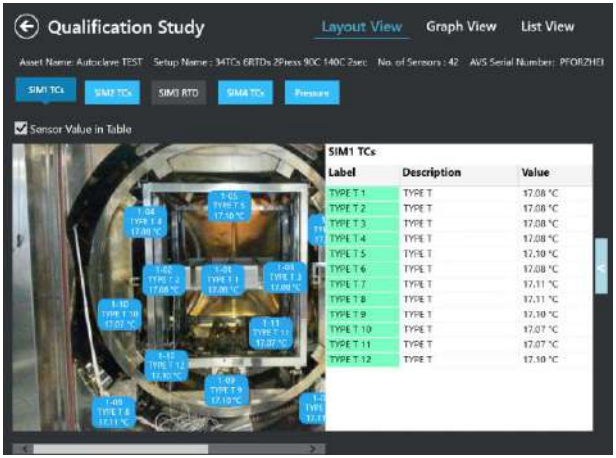


Figure 69: Layout View Qualification Study with Value Table

To improve your understanding, it is possible to view the distribution of live readings data in Layout view. The background picture and sensor positions are defined in the setup group configuration as a “wiring diagram”. You can take pictures using the built-in camera or add existing pictures and then position sensor tags via drag and drop. Real-time values are displayed inside the tags.

Layout view is only available if a wiring diagram is defined in the setup.

When activating **Sensor Value in Table**, a table of live reading values are displayed in parallel with sensor labels and descriptions.

Interval Calculations View

The Interval calculations are available as a live screen if group specific interval calculations are specified in the setup.

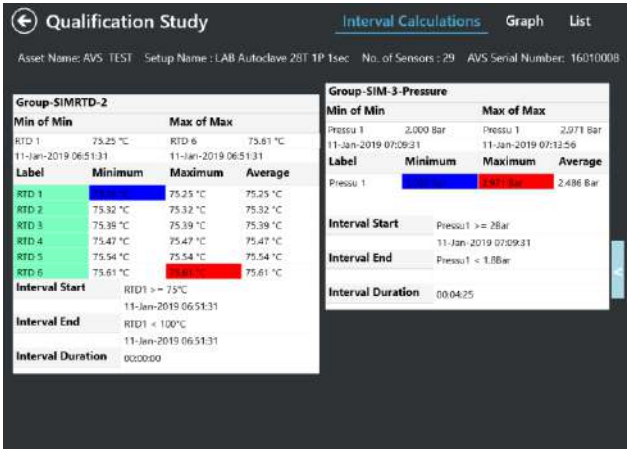


Figure 70: Interval Calculations Live View Screen

The live screen data for the interval calculations is calculated on the display rate. The display rate is a fixed update rate for the refresh of all live screens. It is five seconds for SIM slots 1-3 and six seconds if SIM slot 4 is used in the setup.

Interval reports are generated on the storage data rate, which can be specified in the setup separately.

Note: *Live screen interval calculations and the interval calculations report may show discrepancies if the storage rate is different from the display rate. To avoid such discrepancies, it is required to set the storage rate to the display rate.*

Chapter 9. Monitor Mode

The Validator AVS software has a Monitor mode which allows you to connect to a selected AVS hardware and view live data from an existing Setup on the AVS. Unlike Qualification or Calibration / Verification, no data is being collected/ stored, only displayed in real time. The monitor mode provides a useful tool to:

- Verify connection to AVS hardware
- Verify connectivity with the SIMs
- Verify sensors connections and readings
- View current calibration offsets of SIMs
- View, transfer, or manage data files stored in AVS hardware
- Check connectivity with calibration standard and or references

9.1. Select Validator AVS

From the Main Menu, press the **Discover** tile, located under *Hardware*, to open the Select Validator AVS window.

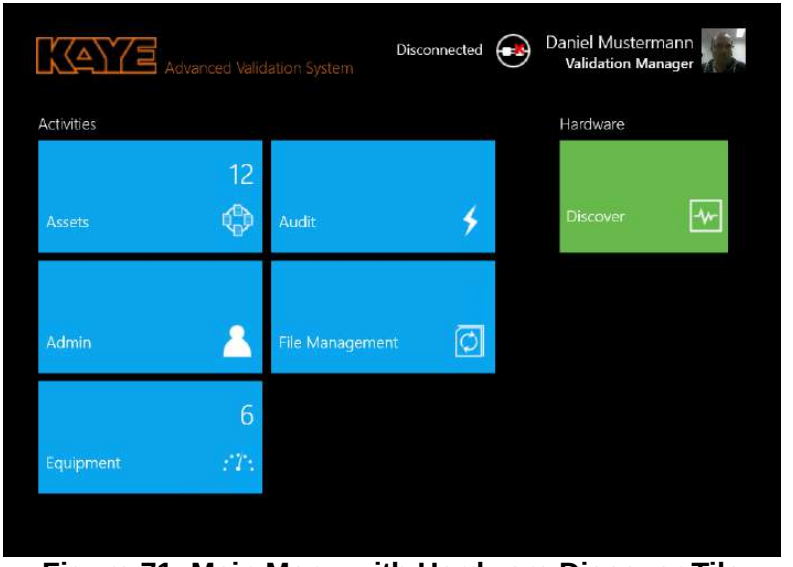


Figure 71: Main Menu with Hardware Discover Tile

Press **Discover** to view a list of all available AVS connections. If your AVS Console is docked with the AVS, select the orange box and press **Connect**

If you wish to connect to an AVS Wi-Fi or LAN connections (blue), select the desired AVS and press **Connect**.

Figure 72: Select AVS Screen: Selecting a Validator

Please see Section 2.4 (Connecting the AVS Console to the AVS Hardware) for detailed information on how to connect the Kaye Validation console to the Validator AVS.

9.2. Monitoring Live Data

The Monitoring screen displays live data, pressing **Back** (←) returns to the Main Menu, which now displays, under hardware the green tile, as **Monitoring**. The hardware tile in the Main Menu always displays the current status of the AVS. If the AVS is running a Calibration, Verification, or Qualification the hardware tile displays accordingly. If the AVS is idle and not connected to the AVS Console the hardware tile displays **Discover**.

Live Data During Monitoring

The Monitoring mode displays live data in List or Graphing views. The List and Graph Views have primarily the same functionality as provided in the Qualification screens. (See section 9 for more details). In the Monitoring of Live Data mode, if no study is running the data collection structure (sensor and groups definition) follows the last transferred setup (to transfer a setup you need to start a study). If the Validator AVS is in monitoring status, you can switch between List and Graph View to see live data from the Validator AVS on the screen.

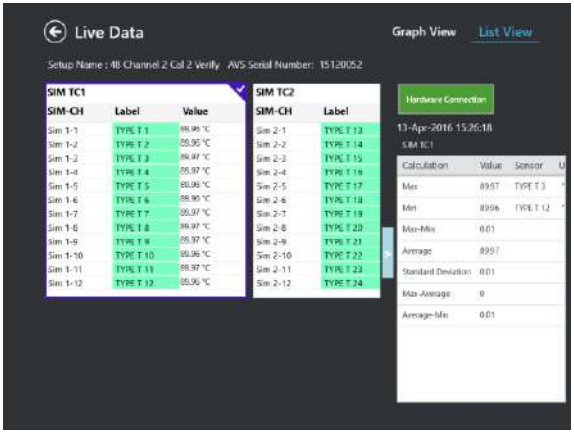


Figure 73: Monitoring in List View

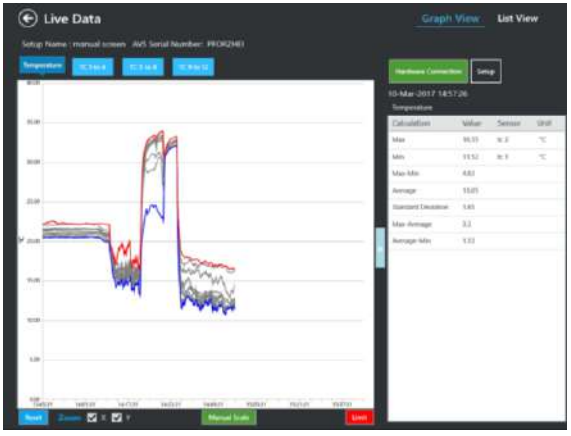


Figure 74: Monitoring in Graph View

In addition, by swiping down from the top right-side of the screen opens commands (see Figure 75) on the lower left-side of the screen. Press About, to view all detailed information about the system including connected devices IP and MAC addresses, software, and firmware versions.

It is possible to review (but not change) the current setup parameters by pressing **Setup**.

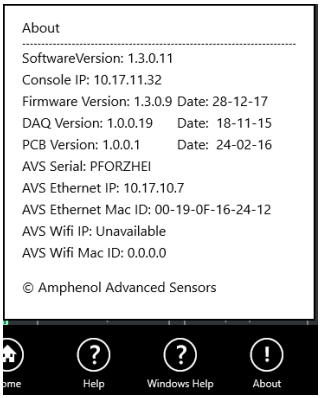


Figure 75: About

9.3. Check Communications Connections

On any of the live data monitoring screens, you can check your communications connections by pressing **Hardware**. On the Hardware screen, each hardware item (Kaye equipment) is displayed with a communications link.

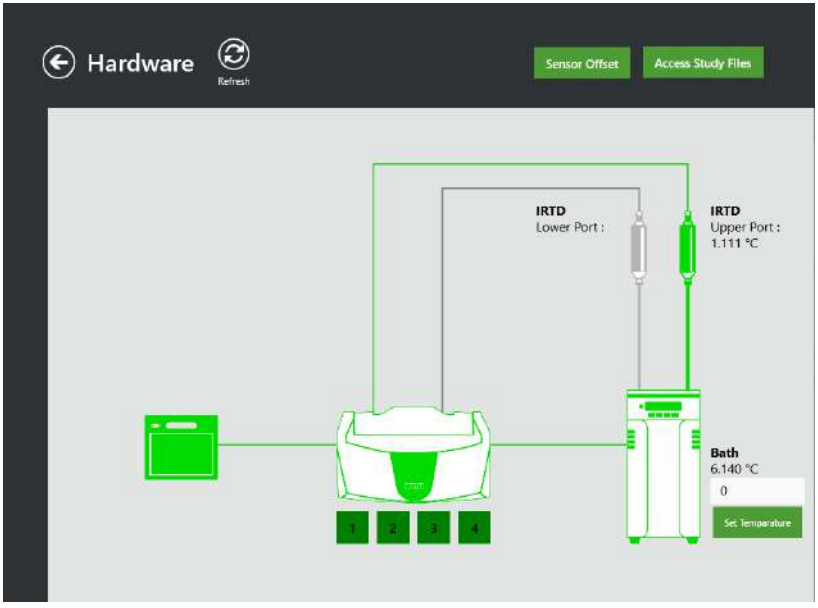


Figure 76: Hardware Screen

A Device Not Found status indicates that the hardware is not communicating and may not be connected properly.

Note: *When changing SIMs, it is recommended to switch off the Validator AVS before changing the SIM configuration. During the startup the SIM parameters like serial number, sensor offsets and setup information are updated.*

Each hardware item has equipment-specific information which is displayed by pressing the respective icons.

Select the AVS unit graphic to display physical information about the Validator. The information displayed includes the Validator serial number, the date the Validator was last calibrated, the setup that is currently loaded into the Validator, and the version number of the Validator firmware.

For each SIM, the SIM serial number, SIM Type, and the SIM calibration date are displayed.

Select the temperature reference graphic to view the model and version.

Note: *The current temperature reading of the reference is displayed. By entering a value into the set field and pressing* ***Set Temperature*** *you can set a bath to a new target temperature.*

Select the **IRTD1** or **IRTD2** graphic to view information on the address, probe ID, label (including the serial number), calibration date, user label, and temperature scale. Connecting 2 IRTD's can be used to compare IRTD's.

Note: *During Calibration / Verification the IRTD lower port is not used. Only the IRTD attached to the upper port is utilized.*

If the link to the Validator AVS is not responding, all links are marked with a gray image of device.

9.4. Sensor Offsets

Calibration offsets are stored in each SIM's memory. You can view the calibration offsets on the Sensor Offsets screen. Press **Sensor Offsets** on the hardware screen. The calibration current SIMs offsets display on the Sensor Offsets screen.

Sensor Offsets displays a table with the sensor offsets for each SIM and for the different sensor inputs with (InputMin, OutputMin, InputMax, OutpitMax). If the values are displayed it indicates that the SIM and the sensors are calibrated correctly for the current SIM slot. If there are no values but INVALID entries it indicates that the SIM and sensors are not calibrated, or the SIM is not in the same slot as during the calibration. When reviewing the offsets, ensure that the system is calibrated correctly and ready for use in a study.

9.5. Access Study Files

The Validator AVS hardware automatically stores the last ten executed studies in backup memory. If the study file was not saved at the completion of the study from the AVS console, it is possible using the Access Study Files to view and or retrieve these to the console. Press **Access Study Files** in the hardware screen to display a table of the last ten studies.

The table displays the name of the setup together with study type and date as well as the user who started the study. Backup study files can be imported or deleted from the AVS memory provided the User has the appropriate privileges. Select the files to delete the files from the AVS memory or import to the connected console. When retrieving the corresponding asset and it is not available, it is then automatically created as a new asset tile with the setup used for this study.

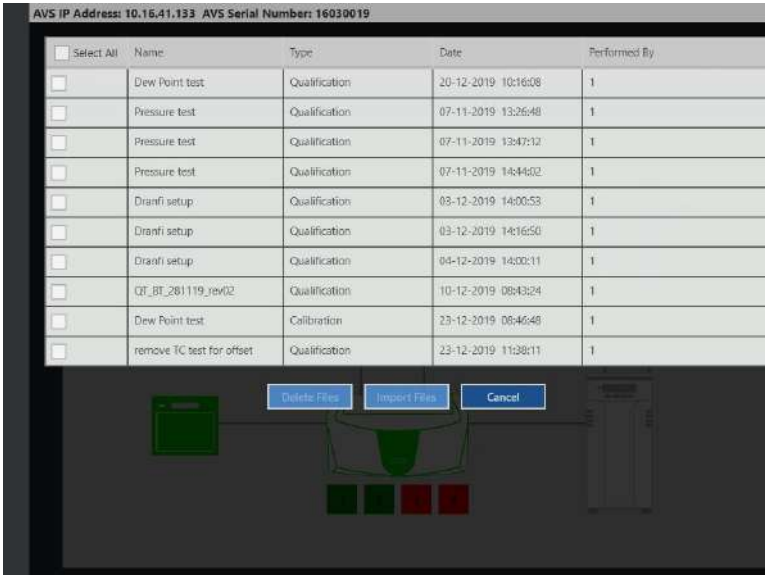


Figure 77: Study Files

Chapter 10. AVS Reports

Reports Overview

The Validator AVS software includes a comprehensive reporting tool which allows the documentation of all aspects of your Validation efforts. These reports give the flexibility to perform a thorough analysis of process performance, while meeting regulatory guidelines for 21 CFR Part 11 and Data Integrity guidelines.

Available reports include:

- Setup
- Sensor Calibration / Verification
- Qualification
    - Detailed report
    - Summary report
    - Interval report
    - Graph reports
    - CSV Export (Excel)
    - Pass / Fail report
    - Custom Reports (CEI 60068)
- CSV Export (Excel format)
- Audit Trail

All reports are created from raw encrypted study files generated during the validation processes. Raw file content cannot be modified or tampered with.

All qualification reports are arranged in groups. A user can select which groups and calculations are included in each report. Individual groups can have specific headers.

Reports are created in .pdf format. They are stored with the appropriate asset under **Reports** for future access and analysis.

The following sections provide an overview of each report as well as the methods to generate them.

You can edit calculations, events, cycles, and define Pass/Fail criteria. Any edits are documented inside the reports to provide traceability. The raw encrypted stored data can never be modified or edited.

Reports can always be recreated from the raw encrypted file.

Note: *Although the AVS software does not have Electronic signature capability within the reporting tool, you can easily import the report.pdf files into your company's Document Management System for applying electronic signatures.*

10.1. Setup Report

The Setup Report documents all details and configuration of a Setup. The Setup report contains:

- Details of sensor quantities, types, labels and descriptions
- Sensor grouping
- Any defined overlay screens with sensor placement
- Defined calculations and parameters
- Calibration setpoints, stability, and deviation criteria
- Data storage rate and Start/ Stop conditions
- Temperature preference (C° / F°) and pressure units

The header provides general information about a Setup including:

- Company name
- Date setup report printed (with time zone)
- Setup name
- Created by
- Created date / time (with time zone)
- Asset name
- Asset ID
- SOP #
- User comments
- AVS software and firmware versions

The signature fields in the footer can be configured in the Admin / Preference screen.

10.1.1. Generating the Setup Report

The Setup report can be generated from three different locations:

- From **Setup Review** after creation.
- From the Asset screen under the **Setup** tile; select the **Setup** name and press **Print**.
- When selecting the Qualification file to print; press the **Setup** icon to print the Setup report tied to the Qualification study.

10.2. Sensor Calibration Report

The Sensor Calibration Report is created from the select raw encrypted calibration file and provides detailed results of the sensor calibration process.

The Sensor Calibration report contains:

- Cover page detailing the SIM, sensors. and Temp Standard/ Reference along with the calibration setpoints and criteria used for the calibration process
- Separate pages for each Setpoint detailing the results of the Stability, as well as uncalibrated and calibrated deviation criteria.

Note: *If a sensor fails calibration, it is marked with a double asterisk (**) to the right of the value in the temperature column, and from then on it is marked as Failed.*

The header provides the general information about the Calibration including:

- Company name
- Date calibration report printed
- Study name
- Created by
- Created date / time / time zone
- Calibrated start date / time/ time zone
- Started by name
- Asset name
- Asset ID
- AVS serial number
- User comments
- AVS reporting software
- AVS Firmware versions

The signature fields in the footer can be configured in the Admin / Preference screen.

10.2.1. Generating Sensor Calibration Report

To generate the Sensor Calibration report, go the appropriate Asset where the sensor calibration was initiated. Select the **Calibration** tile, then select the appropriate raw encrypted Sensor Calibration file and select the **Generate Reports** button.

The software automatically launches the Reporting Tool software and navigates to the Standard Reports page. Select **Standard Reporting**, then the **Calibration Report** icon.

After the Calibration report is generated, the software automatically loads the .pdf file into the Reports tile of the Asset for future retrieval and printing.

10.3. Sensor Verification Report

Sensor Verification Reports are created from a selected raw encrypted verification file and provide detailed results of the sensor verification process.

Unlike Calibration reports, where each uncalibrated sensor is compared to the IRTD and offsets are written to the SIMS, Verification does not calibrate or create offsets but rather verifies the calibrated sensors are still within the calibrated deviation criteria. Sensor Verification reports contain:

- Cover page detailing the SIM, sensors. and Temp Standard/ Reference along with the verification setpoints and criteria used for the verification process
- Separate pages for each setpoint detailing the results of the Stability and calibrated deviation criteria.

Note: *If a sensor fails verification, it is marked with a double asterisk (**) to the right of the value in the temperature column, and from then on it is marked as Failed.*

The header provides the general information about the Verification including:

- Company name
- Verification report date printed
- Study name
- Created by
- Created date / time / time zone
- Verification start date / time / time zone
- Started by name
- Asset name
- Asset ID
- AVS serial number
- User comments.
- AVS reporting software
- AVS Firmware version

Signature fields in the footer are configured in the Admin / Preference screen.

10.3.1. Generating Sensor Verification Report

To generate the Sensor Verification report, go the appropriate Asset where the sensor calibration was initiated from. Select the **Verification** tile, then select the appropriate raw encrypted Sensor verification file and select the **Generate Reports** button.

The software automatically launches the Reporting Tool software and navigates to the Standard Reports page. Select **Standard Reporting**, then the **Verification Report** icon.

After the Verification report is generated, the software automatically loads the .pdf file into the Reports tile of the Asset for future retrieval and printing.

10.4. Qualification Reports

Qualification reports offer several different report types to document and analyze Qualification study performance.

Standard Qualification Reports:

- Detailed report
- Summary report
- Interval report
- Graph reports
- Pass / Fail report
- CSV Export (Excel)

Custom Reports:

- CEI 60068

Qualification reports are created from a raw encrypted Qualification file. The content of the Qualification file is based on the parameters defined in the Setup. The Setup defines the number and type of sensors utilized, the arrangement of sensors into groups, the specific calculations to be performed, the Start and Stop conditions for Qualification and Exposure, and the data storage rate.

Aside from the data storage rate, additional time stamps of data are generated into the raw file whenever events or Start/ Stop conditions occur. All calculations for the Qualification reports are based on the data storage rate.

10.4.1. Qualification Detailed Report

Detailed Reports are created from the raw encrypted Qualification files and provide the complete details of all sensor measurements and calculations (Statistical, Lethality, Steam Saturation) during a Qualification study.

The content of the Qualification file is based on the parameters defined in the Setup. The Setup defines the number and type of sensors utilized, the arrangement of sensors into Groups, the specific calculations to be performed, the Start and Stop conditions for Qualification and Exposure, and the data storage rate.

Prior to generating the Detailed report, you have the option to set a separate print rate which can be a multiple greater than the storage rate; allowing you to maximize the accuracy for graphs and calculations (i.e. storing data every ten seconds but printing once a minute) and minimizing the number of pages printed.

The main report header provides traceability information for the study including:

- Company name
- Date printed, username
- Study name
- Created by
- Created date / time / time zone
- Study started by with date / time / time zone
- Asset name
- Asset ID
- AVS serial #
- User comments.
- AVS Reporting Software
- AVS Firmware and Software versions

The remaining sections of the cover page include, the groups included in the report, any sensors excluded from group calculations, the SIMs used in the study by slot number and serial number, and any user comments added during post-qualification reporting.

The body of the report is arranged by Groups. For each Group the Detailed report contains pages detailing the sensor measurements, the Statistical calculations, Lethality calculations (if defined), and the Saturation Temp and Pressure calculations (if defined).

Once all the groups are documented, the last pages of the report list the System and Event messages along with a Footer as defined in the report options.

10.4.2. Qualification Summary Report

Summary Reports are created from raw encrypted Qualification files and as titled, for each Group provide a summary by cycle of all sensor measurements during the Qualification study. All calculations performed by the Summary report are set by the Storage rate as defined in the Setup. The main report header provides the same traceability information for the study as defined in the Detailed report.

The remaining sections of the Summary cover pages include the same information as defined in the Detail Report.

The body of the report is arranged by groups. For each group, the Summary report contains two sections, Temperature data tables and Temperature Summary data tables.

The Temperature Data Table include a listing of each sensor in the Group, the Min, Max, Avg, Lethality, and Max-Min values for each cycle defined in the study (i.e. Heat up, Exposure, Cooldown).

Temperature Summary data tables include at the bottom of the page, a data summary for each cycle for all sensors in the group. Table calculations include:

- Cycle start time / date / time zone
- Cycle duration
- Min of Min, Sensor ID, date and time of occurrence
- Max of Max, Sensor ID, date and time of occurrence
- Max range
- Max spread and time of occurrence
- Min and Max accumulated Lethality and from which sensor
- Avg of Avg
- Max of all (Max - Min) for all sensors contained in the group.

Once groups are documented, the last pages of the report list System and Event messages and the Footer as defined in the report options.

Prior to printing the Summary report, inside the Report content options, you can add Setup information and a graph of the complete study to the Summary report.

10.4.3. Qualification Interval Calculations Report

The Qualification Interval Calculations Report is comprised of statistical calculations performed on groups based on cycle intervals. The start / stop conditions and the performed statistical calculations for the interval calculations report are defined in the Setup. This report type is only available as a Standard Report if the interval is defined in the calculations screen of the setup.

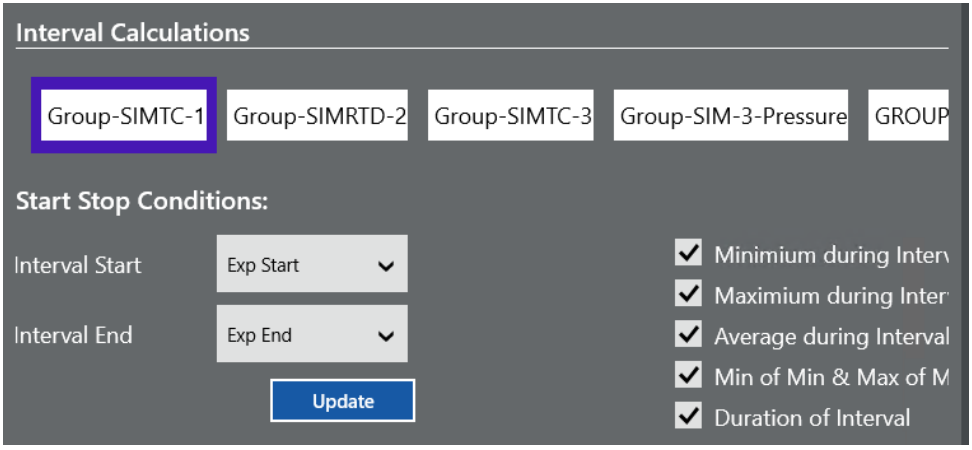


Figure 78: Interval Calculations Definition in the Setup

All calculations can be defined per group with different start / stop events. Results are displayed with customized group headers.

Note: *The values displayed on the interval live screen are calculated in real-time from the display rate. If the display rate is different than the storage rate, the results of the interval report might differ from the observed live screen results.*

10.4.4. Graph Reports

Graphs reports offer a flexible tool to analyze the data from the raw encrypted Qualification file and create numerous graph reports.

The Graphs reports and the calculations and Groups they utilize are based on the Storage rate and other parameters defined in the Setup.

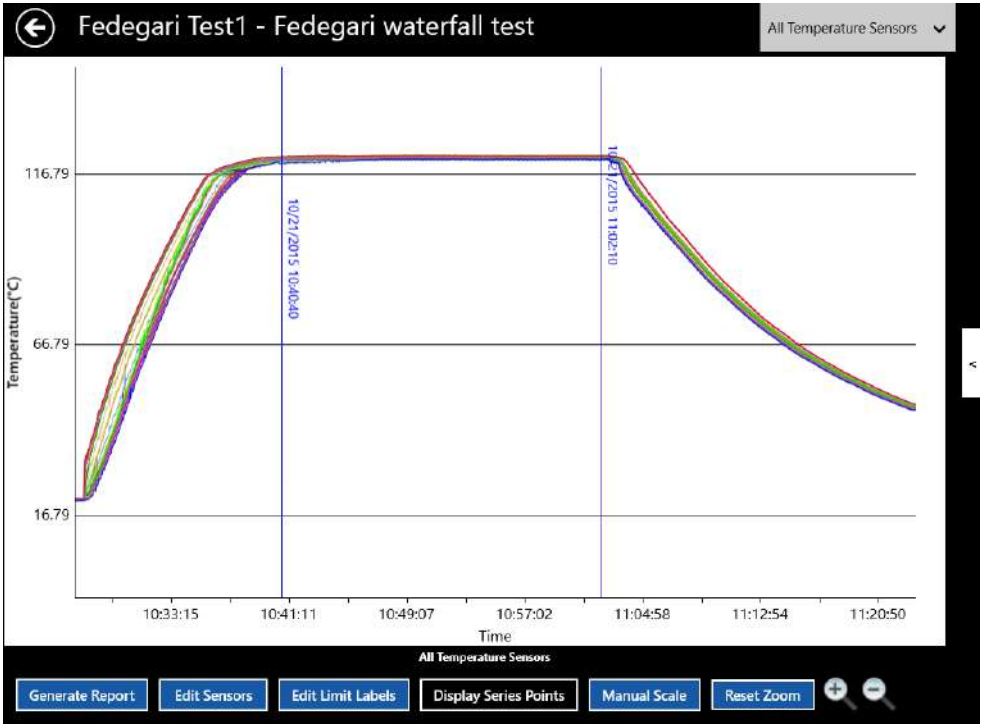


Figure 79: Graph Report Screen

In the Graph report, study data is presented in graph form. Depending on the sensor group and graph type selected, you can apply the following calculations:

- Max value
- Min value
- Avg and Std Dev
- Max-Min
- Max-Avg
- Avg-Min
- Lethality
- Sat P
- Sat T
- MKT calculations

There are different options to customize the displayed graph:

- The X-axis spans from the defined start of qualification to the defined end of qualification.
- The Y-axis displays temperature, humidity, or pressure. You can zoom into the graph, move the graph, or reset the zoom. Pressing **Manual Scale** enables you to select the minimum and maximum values of the Y-axis for the selected calculation graph (these boxes accept only numeric characters, along with minus sign and decimals).

Press **Edit Sensors** to choose the sensors or calculations to include in each Graph Report. Selections made on the Graph Report screen are unique to the Graph Report and do not affect the contents of the Setup, Qualification Detailed, or Qualification Summary Reports. The exception is the pressure sensor selected for saturation temperature reporting.

Important:

Excluded sensors from any of the graph reports are not included in the calculations graphs. To include sensors in calculation graphs excluded previously for another graph view, select it again before switching the next calculation graphs.

Groups with only one sensor have no statistical calculations available and the checkboxes are grayed out.

Above the Groups drop-down, values for the selected group (e.g. Lethality, saturation, pressure, and saturation temperature calculations) are displayed.

The Lethality calculation is only available if temperature sensors are present in the study and can be activated in the left pane.

The saturation pressure calculation is only available if the study includes at least one temperature sensor along with pressure sensors.

The saturation temperature calculation is only available if the study includes at least one pressure sensor along with temperature sensors.

No calculations are available for a contact sensor group.

Based on group selection, the following calculation graphs are generated:

- Temperature Sensors
- Temperature Sensors Calculations
- RH (Humidity) Sensors
- RH Sensors Calculations
- Pressure Sensors
- Pressure Sensors Calculations
- Current Sensors
- Current Sensors Calculations
- Voltage Sensors
- Voltage Sensors Calculations
- Contact Sensors
- Lethality Sensor Trends
- Saturation Temperature
- Saturation Pressure

Pressing **Generate Report** generates a graph report with the same picture as displayed.

Note: *For all types of graphs, Open, Under Range, Over Range, or NO SIM sensor values are not displayed; for such failure values.*
Users can zoom in and out of any graph or apply the print option to send graphs to a default printer. By default, graph reports are saved with a unique name, along with the date and timestamp. Header and footer details remain the same as in all other reports.

To Generate a Graph Report:

Use the Select Group drop-down list to change the selected group for graphing.

Available Graph Report options depend on selections made during study setup, the type of sensors used in the study, and number of sensors in each group.

Use the Statistical pane to select a Graph Report. To view data in more detail, use zoom or manual scaling to magnify a time-period or sensor measurement range. The **Zoom In** and **Zoom Out** buttons change the graph magnification by preset levels. The view displayed on the screen displays inside the generated Graph report

The **Generate Report** is available at the left low corner of the screen.

Edit Sensors

Permits selecting or unselecting available sensors for the group selected from **Select Group** drop-down list displayed in the graph. Select **All** and **Unselect All** options are available for sensors selection along with manual selection.

Edit Limit Labels

The Edit Limit Labels screen displays upper and lower limits on the graph. Available sensor types depend on the sensor type for the graph.

To add limit lines to a graph, enter an upper and/or lower limit value(s). These display as horizontal lines at the selected measurement points.

- You can enter a MAX value for the line in the MAX textbox, up to six characters.
- You can enter a MAX label for the line in the Label textbox to the right, up to 50 characters.
- You can enter a MIN value for the line in the MIN textbox, up six characters.
- You can enter a MIN label for the line in the Label textbox to the right, up to 50 characters.

When you have finished, press **Apply** on the Edit Limit Labels screen.

Reset Zoom

The **Zoom In** and **Zoom Out** buttons change the graph magnification by preset levels.

+ Increase zoom level

- Decrease zoom level

> Expand graph page to the right

< Collapse graph page to the left and show graph options

Select Cycle

The Select Cycles option is available for selection if cycles were created from the Create Cycles screen. All cycles can be selected from the Select Cycle drop-down list if enabled.

Select Group

A drop-down list of available sensors to display in the graph report as defined in the setup. On the Graph Report screen, the following graphs (listed below) are available from the Select Group drop-down. Some options may not be available due to the type of sensors used in the study and the selections made during the study setup.

All Temperature Sensors

The Temperature Sensors graph displays readings for all temperature sensors in the study. You can remove individual temperature sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
Temperature Statistical calculations are available for selection from the Statistical pane.
To exclude calculations from the Graph Report, clear them from the Statistical drop-down.

All RH (Humidity) Sensors

The Humidity Sensors graph displays readings for all humidity sensors in the study. You can remove individual humidity sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
Humidity Sensors Statistical calculations are available for selection from the Statistical pane.
To exclude calculations from the Graph Report, clear them from the Statistical drop-down.

All Pressure Sensors

The Pressure Sensors graph displays readings for all pressure sensors in the study. You can remove individual pressure sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
The Pressure Sensors Statistical calculations are available for selection from Statistical pane.
To exclude calculations from the Graph Report, clear them from the Statistical drop-down.

All Current Sensors

The Current Sensors graph displays readings for all current sensors in the study. You can remove individual current sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
The Current Sensors Statistical calculations are available for selection from the Statistical pane.
To exclude calculations from the Graph Report, clear them from the Statistical drop-down.

All Voltage Sensors

The Voltage Sensors graph displays readings for all voltage sensors in the study. You can remove individual voltage sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
The Voltage Sensors Statistical calculations are available for selection from the Statistical pane.
To exclude calculations from the Graph Report, clear them from the Statistical drop-down.

All Contact Sensors

No calculations are available for a contact sensor group.

Figure 80: Statistical Calculation Graph

Statistical Calculation Selection

Based on the Sensor Group selection, the following Statistical calculation graphs are generated:

Max Value

The maximum reading among all included sensors at a specific timestamp.

Min Value

The minimum reading among all included sensors at a specific timestamp.

Avg Value

The average reading among all included sensors at a specific timestamp.

Avg and Std Dev

The average reading and the standard deviation of all included sensors at a specific timestamp.

Max-Min

The maximum reading among all included sensors at a specific timestamp minus the minimum reading of all included sensors at a specific timestamp.

Max-Avg

The maximum reading among all included sensors at a specific timestamp minus the average reading of all included sensors at a specific timestamp.

Avg-Min

The average reading of all included sensors at a specific timestamp minus the minimum reading of all included sensors at a specific timestamp.

Lethality

The Lethality calculation is only available if temperature sensors are present in a study.
The accumulated Lethality (Sensor Trends) graph displays lethality trends for each included sensors at each timestamp programmed or defined to calculate lethality. Alternatively, the lethality accumulation can be displayed as a bar graph. The calculation follows the parameters set inside the Edit Calculations screen.
Remove individual sensors from the report by clearing them from the Edit Sensors screen.

Sat P

The Saturation Pressure calculation is only available if the study includes at least one temperature sensor and pressure sensors.

The Saturation Pressure vs. Measured Pressure graph displays measured pressure from the selected pressure sensor and the saturation pressure calculated from the temperature sensors selected in the Edit Sensors screen. You can remove temperature sensors from the Graph Report by clearing the sensor from the list. Change the pressure sensor by selecting a new sensor from the Edit Sensors screen.

To access the Saturation Pressure vs. Measured Pressure graph:

- Select Temp and Pressure Sensors group from **Select Group** drop-down list.
- From the Statistical pane of the Graph Report screen, check the **Sat P** box. If you defined cycles on the Create Cycles screen, select a cycle from the **Select Cycle** drop-down list.
- Select a temperature sensor from the Edit Sensors screen.

Saturation Pressure calculation is only available if the study includes at least one temperature sensor and pressure sensors.

Sat T

The Saturation Temperature calculation is only available if the study includes at least one pressure sensor along with temperature sensors.

The Saturation Temperature vs. Measured Temperature graph displays the saturation temperature calculated from the selected pressure sensor and the measured temperature from the sensors selected in the Edit Sensors screen. Red horizontal lines on the graph display the base temperature (Tb) entered during the study setup, and the base temperature +3 K. The text at the bottom of the graph displays if the data passed or failed three conditions:

- All measured temperatures and the calculated saturation temperature are within the specified sterilization temperature band.
- Each measured temperature and the calculated saturation temperature do not fluctuate more than 1 K.
- All measured temperatures and the calculated saturation temperature do not differ from each other by more than 2 K.

To access the Saturation Temperature vs. Measured Temperature graph:

- Select Temp and Pressure Sensors group from **Select Group** drop-down list.
- From the Statistical pane of the Graph Report screen, check the **Sat T** box. If you defined cycles on the Create Cycles screen, select a cycle from the **Select Cycle** drop-down list.
- Select a pressure sensor from the Edit Sensors screen.

Equilibrium

The Equilibration Time graph displays whether all temperature sensors in the Edit Sensors list reached the lethality base temperature within a 15 or 30 second time period, satisfying the equilibration conditions.

Regulations require that sterilization chambers less than 800 liters have an equilibration time no greater than 15 seconds; sterilization chambers greater than 800 liters should have an equilibration time of no more than 30 seconds.

This graph is only available if the sensors had a one second sampling rate during the equilibration period, and at least one sensor reached the lethality base temperature. If you did not define the lethality base temperature during the study setup, the default temperature of 121.1°C is used.

The first vertical red line indicates the time the first Temperature sensor reached the lethality base temperature (Tb). The lethality base temperature is marked by the horizontal red line.

The second vertical line is either 15 or 30 seconds after the first Temperature sensor reached the base temperature, depending on the time period you select. The text at the top right of the graph indicates if the sensors passed (including the actual equilibration time) or failed according to the equilibration criteria.

To access the Equilibration Time graph:

From Graph Report screen, check the Equilibrium box. This displays the Edit Sensors screen. From this screen you can:

- Select/unselect sensors
- Select the Reference Sensor from the drop-down list
- Enter a reference temperature
- Choose a time of 15 or 30 seconds from the drop-down list
- Select **OK** to display the Equilibration Time graph

10.4.5. Pass / Fail Criteria Report

Pass / Fail Report Overview

With the release of AVS Version 1.4 software, Kaye has introduced a very powerful post-analysis tool called the Pass / Fail Criteria Report. The Pass / Fail Criteria report eliminates hours of manual or spreadsheet based analysis, by providing an automated report, which analyzes Qualification raw data and provides a report detailing whether the Qualification data successfully passed or failed to meet user defined criteria.

To better understand the functionality of the Pass / Fail Criteria report it is important to understand the details of the following key elements:

- What data from the Qualification raw data file is utilized to perform the Pass / Fail analysis?
- How are the Pass / Fail Criteria calculations applied?

Qualification Raw Data File

The Qualification raw data file contains all the data captured from the *Qualification Start time* to the *Qualification End*. The amount and content of the data is defined by the user in the Setup report. The Setup defines the following:

- Number and type of sensors included (i.e. temperature, pressure, humidity, etc.)
- Grouping of sensors (Distribution, Penetration, Shelf 1/Shelf 2 etc.)
- Calculations (Statistical, Lethality, Saturation etc.)
- Events triggering: Start and Stop of Qualification, Start and Stop of Exposure
- Any additional events based of defined process conditions
- Sample / Storage Rate of data capture (timestamp interval)

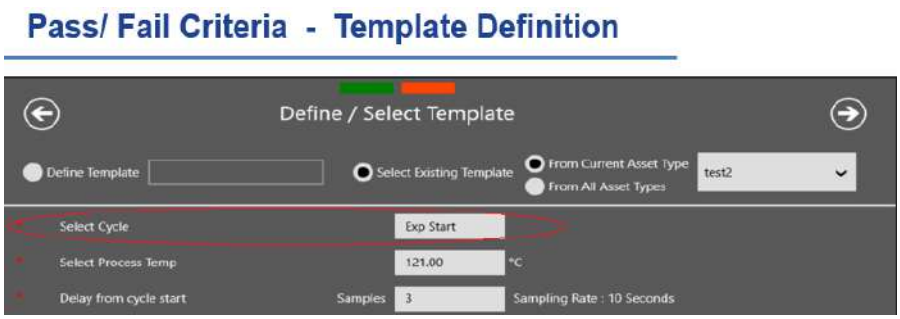
Qualification time stamps and associated data are captured:

- At the time Events occur (i.e. Qualification Start/Stop, Exposure Start/Stop, or defined process events)
- At user defined intervals based on configuration of the Sample/Storage rate.

Definition of Cycles

The Pass / Fail Criteria report allows the user to define a Cycle during the Qualification study during which captured process data is analyzed. A cycle is a defined period during the Qualification study. The AVS software allows the user in the Setup report to define cycles (i.e. Qual Start to Qual End, Exposure Start to Exposure End etc.). Cycles can also be added or modified in the Reporting Tool prior to generation of reports.

In the configuration of the Pass/Fail Report the User can select which Cycle from the Qual File to utilize for the analysis.



Once the Cycle is defined, the user can delay the Cycle Pass/ Fail evaluation by a defined number of samples. The number of samples times the sampling rate defines the delay time. This delay allows the cycle to stabilize or equilibrate prior to evaluation.

The following rules are applied to determining timestamps and associated data included in the interval of a Cycle:

- The start of the cycle is the first timestamp of data used for calculations
- The stop of a cycle is the first timestamp of data of the following cycle. If the stop of the cycle is the End of Qualification, then that time stamp of data is included in the cycle.
- Cycles do not overlap and no timestamp of data is used with two different cycles.

The Pass/ Fail Report analysis for the cycle consist of two types of calculations: Statistical calculations and Accumulation calculations. The following sections and diagram define the time stamps and data used for the calculations.

Statistical Calculations

All values are calculated from the data point values (e.g. A1 to A5 in the figure below) of the defined cycle. As the stop of the study is also the same timestamp and data for the start of the next cycle, it is **NOT** included into the statistical calculations unless the B1 is the Qual End event.

Accumulation Calculations

Accumulation calculations look at the data samples and interval of time between two samples and accumulate them over the duration of the cycle (e.g. Interval A1…A2, A2…A3, etc. in the figure below). Typical calculations include: Lethality, Cycle /, and Time above/below Process Temp.

For Lethality, the system measures the temperature and calculates the instantaneous lethality for each data sample. The calculation then factors in the interval times between data samples to integrate the Accumulated Lethality over the complete cycle (A1…B1).

For Cycle / Exposure Time, the Start and End of the cycle are triggered by manual or automated events, timestamps are generated for these events whenever they occur. The calculation accumulates the total time from the Start of the cycle to the end of the cycle, considering all intervals (A1…B1).

For Equilibration Time, the calculation is only enabled if the Setup is defined with a 1 sec sample/storage rate. The calculation starts when the first sample where the reference temp reaches the process setpoint, and ends when sample temperatures reach the process temp. The calculated time accumulates the total time considering each interval (A1…B1).

For Time at/below Process Temperature per Sensor, the system accumulates time for each sample interval A1/A2, A2/A3,..A5/B1) only if both, the data points at the beginning and end of the sample interval are beyond (above/at/below) the defined condition.

In the figure below, if data point (A1) has reached the given criterion threshold, the system checks if the next data point (A2) has reached the given criterion threshold as

well. In that case, the interval between the data points are counted toward the accumulated value.

In the example below, the criterion threshold is indicated as a dotted line. Following this rule A1…A2, A2…A3 and A4B1 are not counted, while A3…A4 are counted to the accumulated value.

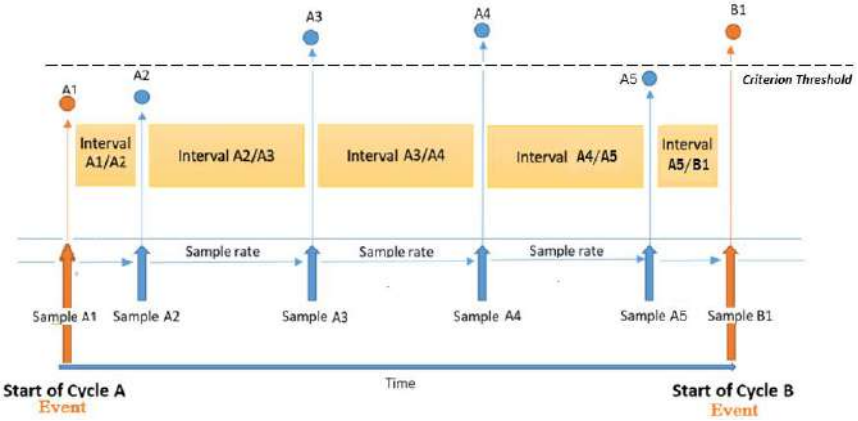


Figure 81: Cycles

Pass / Fail Criteria – Template Definition

The Pass / Fail Criteria template screen allows the user to create and save new templates or to select an existing template for generation of a report. The existing template selection can be limited to similar asset types or selected from all available asset types. For each template, the user can define the selected cycle, the process temperature, and the selected criteria they want applied and analyzed.

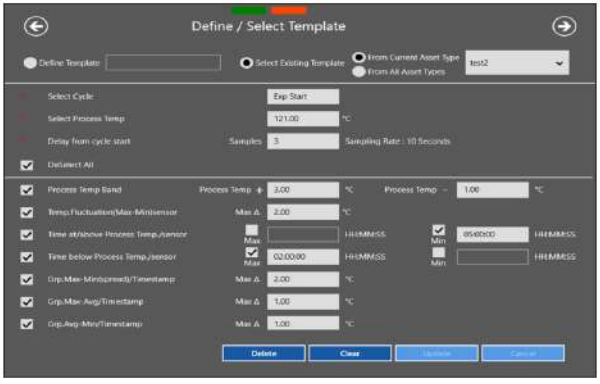


Figure 82: Define / Select Template Screen

The template definition screen offers a total of up to 16 different criteria to select from. The criteria are based on years of experience, as well as specific regulatory requirements from a host of different processes (i.e. Sterilizers – EN285).

Users can create and save an unlimited number of Pass/ Fail Criteria templates which can then be selected and run to analyze any Qualification study.

The AVS User Management section of the software allows the Administrator to define access and privileges associated with the creation and modification of the templates.

Once the template has been selected or defined the user can select which Groups to include in the report and used for the analysis. Each Group of sensors has their own analysis and report pages.

Users can return to and select different templates for different groups (i.e. Distribution, Penetration or different chambers in one study).

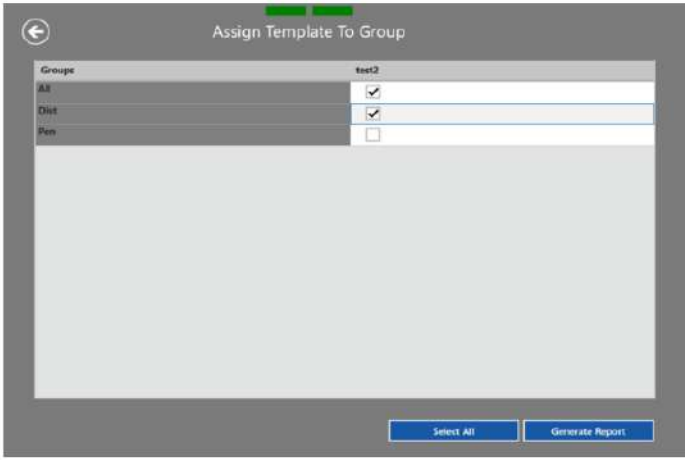


Figure 83: Template to Group Screen

Pass / Fail Criteria Calculations

A User can select up to 16 commonly utilized and regulatory driven criteria to customize their reports based on their specific needs. The following definitions help clarify how these criteria are utilized and applied:

Note: *Only values that are outside the defined criteria are considered "Failed". All values that are equal to or within the defined criteria defined criteria are considered as "Pass".*
Each Group included in the Pass/Fail Criteria Report shall have a separate analysis and report based on each group of sensors.

Process Temp Band: Using the defined process temperature as a basis, the criterion describes an allowable temperature band above and below the process temperature. The criterion is defined as the number of degrees above or below the criteria. For example, if the Process Temperature is 121°C and you enter a max value of 2 and min value of –2, the application checks whether all the sensor values are within 123 (121 + 2) and 119 (121 - 2). The criterion only "Passes" if all sensor readings are equal to or within the range of 119°C to 123°C.

Temperature Fluctuation (Max-Min) per Sensor: The Temperature Fluctuation (Max-Min) per Sensor field defines the max fluctuation allowed for each sensor during the cycle. The criterion "Passes" if all sensors (Max – Min) readings are equal to or less than the defined criteria.

Temperature at / above Process Temp per Sensor: The Time at/above Process Temperature per Sensor calculates for each sensor the total time for each sensor equal to or above the process temperature during the cycle. The criteria fields allow the definition of the maximum time, the minimum time or both. To meet the minimum criteria all sensor calculated times must be equal to or above the minimum criteria. To meet the maximum criteria all sensor calculated times must be equal to or below the maximum criteria. If both maximum and minimum are specified, then all sensor calculated time must be equal to or within the defined range.

Temperature at / Below Process Temp per Sensor: The Time at/below Process Temperature per Sensor calculates for each sensor the total time for each sensor at or below the process temperature during the cycle. The criteria fields allow the definition of the maximum time, the minimum time or both. To meet the minimum criteria all sensor calculated times must be equal to or above the minimum criteria. To meet the maximum criteria all sensor calculated times must be equal to or below the maximum criteria. If both maximum and minimum are specified, then all sensor calculated times must be equal to or within the defined range.

Group Max-Min (spread) per Timestamp: The Grp. Max-Min (spread)/ Timestamp calculates the Group maximum-minimum value for each timestamp. The criteria defines the maximum allowable spread for all timestamps during a cycle. The criterion “Passes” if all Group Max-Min temperature timestamps are equal to or less than the defined criteria.

Group Max-Average per Timestamp: The Grp. Max-Avg/ Timestamp calculates the Group maximum-average value for each timestamp. The criteria defines the maximum allowable difference between the maximum value and the average value for all timestamps during the cycle. The criterion “Passes” if all Group Max-Avg temperature timestamps are equal to or less than the defined criteria.

Group Average-Min per Timestamp: The Grp. Avg-Min/ Timestamp calculates the Group average – minimum temperature for each timestamp. The criteria defines the maximum allowable difference between the average temp and the minimum temp for all timestamps during the cycle. The criterion “Passes” if all the Group Avg-Min temperature timestamps are equal to or less than the defined criteria.

Group (Max of Max)- (Min of Min): The Grp. (Max of Max) – (Min of Min) calculates the maximum value for all sensors in a group and all timestamps, minus the minimum value for all sensors in the group for all timestamps in the cycle. The criteria defines the maximum allowable difference between the (Max of the Max) and the (Min of the Min) for the Cycle. The criterion “Passes” if the calculated value is equal to or less than the defined criteria.

Accumulated Lethality for (Exposure) Cycle: The Accumulated Lethality / Exposure Cycle criteria is only selectable if the lethality condition is defined and included in the Setup or edited in the edit calculations tile. The calculated lethality value applies only to the selected cycle. The calculated value is the minimum Accumulated Lethality for all sensors in the group. The criteria defines the Minimum Accumulated Lethality that must be reached by all sensors in the Group. The criterion “Passes” if the calculated value is equal to or greater than the defined criteria.

Accumulated Lethality as in “Edit calculations”: The Accumulated Lethality as in Edit Calculations criteria is selectable if the lethality condition is defined and included in the Setup or edited in the edit calculations tile. The calculated lethality value does not apply to the selected cycle, but rather to the **Calculate Lethality** field in the “Edit Calculations” tile. The calculated value is the minimum Accumulated Lethality for all sensors in a group. The criteria defines the Minimum Accumulated Lethality that must be reached by all sensors in the Group. The criterion “Passes” if the calculated value is equal to or greater than the defined criteria.

Note: *This is the only criterion that is not using the cycle defined in the criteria template, but the definition of the lethality calculation set in the Edit Calculations screen.*
Only lethality per cycle or per Edit Calculations can be calculated within the same report. The selection of one automatically deselects the other one.

T-SAT T / Timestamp - Temperature - Saturation Temp Band per Timestamp: Steam quality can be analyzed by comparing the measured process temperature value against the calculated Saturation Temperature derived from pressure measurements for every timestamp. The pressure sensor used as the reference is displayed. The criterion describes a steam quality band and is specified as the Min and Max allowable deviation from the measured temperature to the calculated Saturation temperature. The criterion “Passes” if all values are equal to or within the defined range.

P-SAT P / Timestamp - Pressure - Saturation Pressure Band per Timestamp: Steam quality can be analyzed by comparing the measured pressure value against the calculated Saturation Pressure derived from reference temperature measurements for every timestamp. The temperature sensor used as the reference is displayed. The criterion describes a steam quality band and is specified as the Min and Max allowable deviation from the measured pressure to the calculated Saturation pressure. The criterion “Passes” if all values are equal to or within the defined range.

Time of Sterilization (T – Sat T): The Time of Sterilization (T-Sat T) calculates the total time of sterilization by combining the Steam quality criterion, as defined in the Edit Calculations screen, along with the measured reference temperature. Time is counted if the measured reference temperature is at or above the process temperature and the steam quality as defined by Temperature minus calculated Saturation Temperature (T-Sat) is within the specified range. A criterion for a minimum and a maximum time of sterilization can be defined independently. The minimum time criterion “Passes” if the calculated time is equal to or above the defined criteria. The maximum time criterion “Passes” if the calculated time is equal to or below the defined criteria. If both Min and Max fields are defined the criterion “Passes” if the calculated time is equal to or within the defined range.

Time of Sterilization (P – Sat P): The Time of Sterilization (P-Sat P) calculates the total time of sterilization by combining the Steam quality criterion, as defined in the Edit Calculations screen, along with the measured reference pressure. Time is counted if the measured reference temperature is at or above the process temperature and the steam quality as defined by Temperature minus calculated Saturation Temperature (T-Sat) is within the specified range. A criterion for a minimum and a maximum time of sterilization can be defined independently. The minimum time criterion “Passes” if the calculated time is equal to or above the defined criteria. The maximum time criterion “Passes” if the calculated time is equal to or below the defined criteria. If both Min and Max fields are defined the criterion “Passes” if the calculated time is equal to or within the defined range.

Equilibrium Duration: The Equilibrium Duration calculates the time in seconds from when the defined Reference Sensor in the Group reaches the Process Temperature until the last sensor in the Group reaches the Process Temperature. The dropdown menu allows selection of the reference sensor. The **Equilibrium Duration** field is only definable if the study has a one second sampling rate. The criterion value is the Maximum time in seconds allowed. The maximum definable criterion is 59 seconds. The criterion is “Passed” if the calculated Equilibrium time is equal to or less than the defined criteria.

Exposure Duration/Holding Duration: The Exposure / Holding Duration calculates the total time of Exposure / Hold. This criterion is only displayed if the selected cycle is an exposure cycle. A criterion for a minimum and a maximum time of Exposure/Hold can be defined independently. The minimum time criterion “Passes” if the calculated Exposure/Hold time is equal to or above the defined criteria. The maximum Exposure/Hold time criterion “Passes” if the calculated time is equal to or below the defined criteria. If both Min and Max fields are defined the criterion “Passes” if the calculated Exposure/Hold time is equal to or within the defined range.

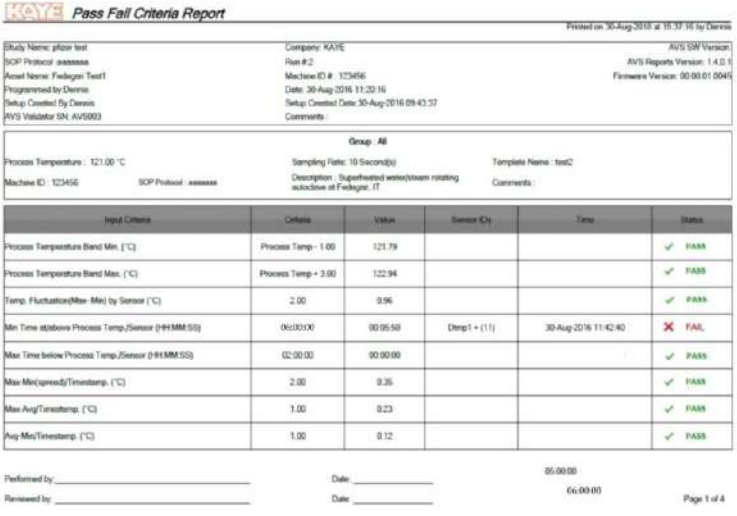
Pass / Fail Criteria Report

Once the Pass/ Fail Criteria template has been selected or defined, the User can then define which groups from the Qualification file they wish included in the Pass / Fail Report.

The Pass/Fail Criteria Report contains two sections: Criteria Evaluation and Sensor Detail.

For each Group selected, the Criteria Evaluation page evaluates the performance of the calculated values against the defined criteria and indicates a “Pass” or “Fail”.

If there is a “Fail”, additional information such as the failed Sensor ID and the timestamp of the occurrence is listed.


Pass Fail Criteria Report

Printed on 30-Aug-2016 at 15:37:16 by Dennis

Study Name: pfizer test	Company: KAYE	AVS SW Version:
SOP Protocol: *******	Run #:2	AVS Reports Version: 1.4.0.1
Asset Name: Fedegari Test1	Machine ID #: 123456	Firmware Version: 00.00.01.0049
Programmed by:Dennis	Date: 30-Aug-2016 11:20:16	
Setup Created By:Dennis	Setup Created Date:30-Aug-2016 09:43:57	
AVS Validator SN: AVS003	Comments :	

Group : All

Process Temperature : 121.00 °C	Sampling Rate: 10 Second(s)	Template Name : test2
Machine ID : 123456 SOP Protocol : *******	Description : Superheated water/steam rotating autoclave at Fedegari, IT	Comments :

Input Criteria	Criteria	Value	Sensor IDs	Time	Status
Process Temperature Band Min. (°C)	Process Temp - 1.00	121.79			✓ PASS
Process Temperature Band Max. (°C)	Process Temp + 3.00	122.94			✓ PASS
Temp. Fluctuation(Max- Min) by Sensor (°C)	2.00	0.96			✓ PASS
Min Time at/above Process Temp./Sensor (HH:MM:SS)	00:30:00	00:05:50	Dtmp1 + (11)	30-Aug-2016 11:42:40	✗ FAIL
Max Time below Process Temp./Sensor (HH:MM:SS)	02:00:00	00:00:00			✓ PASS
Max Min(spread)/Timestamp. (°C)	2.00	0.35			✓ PASS
Max Avg/Timestamp. (°C)	1.00	0.23			✓ PASS
Avg Min/Timestamp. (°C)	1.00	0.12			✓ PASS

Performed by:_____ Date: _____

Reviewed by: _____ Date: _____

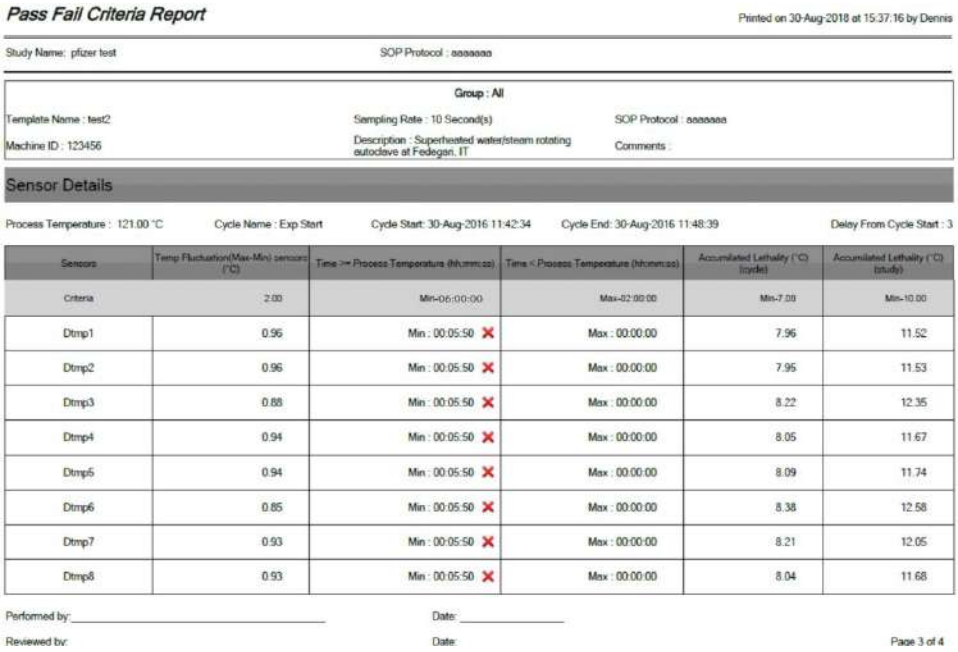
05:00:00

06:00:00

Page 1 of 4

Figure 84: Pass Fail Criteria Report

For each selected Group, the Pass/ Fail Criteria Report contains a Sensor Detail section. This section provides additional information for certain Pass/Fail criteria on the performance of each sensor in a group. The Sensor Detail lists each sensor in the group as well as its criteria and performance. Failed sensors are marked with a red **X** next to the failed criteria, providing valuable information as to which sensor or sensors caused the main criteria to “Fail”.



Pass Fail Criteria Report

Printed on 30-Aug-2018 at 15:37:16 by Dennis

Study Name: pfizer test — SOP Protocol : aaaaaaa

Group : All

Template Name : test2 — Sampling Rate : 10 Second(s) — SOP Protocol : aaaaaaa

Machine ID : 123456 — Description : Superheated water/steam rotating autoclave at Fedegari, IT — Comments :

Sensor Details

Process Temperature : 121.00 °C — Cycle Name : Exp Start — Cycle Start: 30-Aug-2016 11:42:34 — Cycle End: 30-Aug-2016 11:48:39 — Delay From Cycle Start : 3

Sensors	Temp Fluctuation(Max-Min) sensors (°C)	Time >= Process Temperature (hh:mm:ss)	Time < Process Temperature (hh:mm:ss)	Accumulated Lethality (°C) (cycle)	Accumulated Lethality (°C) (study)
Criteria	2.00	Min-06:00:00	Max-02:00:00	Min-7.00	Min-10.00
Dtmp1	0.96	Min : 00:05:50 X	Max : 00:00:00	7.96	11.52
Dtmp2	0.96	Min : 00:05:50 X	Max : 00:00:00	7.95	11.53
Dtmp3	0.88	Min : 00:05:50 X	Max : 00:00:00	8.22	12.35
Dtmp4	0.94	Min : 00:05:50 X	Max : 00:00:00	8.05	11.67
Dtmp5	0.94	Min : 00:05:50 X	Max : 00:00:00	8.09	11.74
Dtmp6	0.85	Min : 00:05:50 X	Max : 00:00:00	8.38	12.58
Dtmp7	0.93	Min : 00:05:50 X	Max : 00:00:00	8.21	12.05
Dtmp8	0.93	Min : 00:05:50 X	Max : 00:00:00	8.04	11.68

Performed by:_____ Date: _____

Reviewed by: Date:

Page 3 of 4

Figure 85: Failed Sensors

For additional information on the Pass/Fail Criteria report contact technical support or your local Account Manager.

Note: *Users of the Kaye Report Tool acknowledge that the pass/fail criteria included in the software is not a substitute for calculation and analysis of pass/fail criteria by a skilled technician. The automated functionality for pass/fail is intended to be used as a guide only. Amphenol is not liable for any damages resulting from reliance on the pass/fail criteria included in the software in making product release decisions. The Kaye Report Tool users waive and release Amphenol, its directors, officers, employees, and affiliates from all liability, claims or demands for any alleged loss, damage or injury related to the use of the Kaye report tool software outside of Amphenol’s recommendations.*

10.4.6. Qualification CEI 60068 Report

The standard CEI 60068 is a European standard to help manufacturers and users of thermostatic or climatic chambers to test performance of the equipment.

This specific report helps you state on pass/failed criteria based on specific calculations describe in the regulatory standard.

Select process temp: Define the setpoint of the chamber.

EMT/MET: Set the tolerances applied on the setpoint for the chamber to qualify.

Uncertainty of the Sensors (Ucj): Set the uncertainty that you have calculated for your Validation equipment (Validator AVS, ValProbe RT, etc.).

Average of the display: If you want to have a pass/failed status based on the display of the chamber to qualify, enter the average of the display during the study. The user calculates this value with the display of the chamber.

10.4.7. CSV-Export Report

The study data can be exported to the CSV format which is an open file format that can be easily imported into Microsoft Excel or any other spreadsheet analysis program. The CSV file can only export one kind of data per file. When pressing **Export**, you can select what kind of data is exported. Every selection creates a separate CSV file.

Figure 86: Export to CSV

For ease of use, all CSV files are packed together with an Index file into a ZIP archive. This archive can be imported into Excel creating separate tabs in one single Excel file for every CSV file. A macro supporting this Excel import is available on request.

10.5. Generating Qualification Reports

Before selecting a report type, the AVS software permits the user one last opportunity to verify or edit parameters such as:

- Start / Stop conditions (Marking Cycles)
- Sensor groupings
- Sensor calculations

Using these parameters, any errors or omissions can be corrected before generation of the report.

These changes do not affect the raw sensor data, or storage rate of the Qualification file. All changes made during these steps are documented in the report.

To begin the Qualification report generation, perform the following steps.

10.5.1. Selecting a Qualification File

To select the Qualification file, select the Asset where the Qualification was initiated from. Select the **Qualification** tile, then the desired raw encrypted Qualification file and press the **Generate Reports** button.

The software automatically launches the Reporting Tool software and opens the Standard Reports page. Select **Standard Reporting**, then the **Bar Graph** icon for the Qualification Report.

A Select Sensor Type pop-up appears requesting the measurand type to graph when defining cycles. Select the appropriate sensor type and press **OK** to open the Mark Cycles Graph. For sterilizers, the option to use both temperature and pressure provides a better understanding for when both requirements are reached.

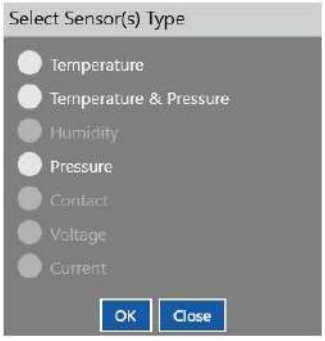


Figure 87: Select Sensor(s) Type

10.5.2. Mark Cycles Screen

Before generating Qualification reports, use the Cycle Selection screen to review, modify, or create cycles from Qualification study data. Each cycle is defined with a start and end time or events, which define the cycle duration. The defined cycles are used in the Qualification Summary and Pass/Fail Criteria report to provide detailed calculations and analysis during specified cycles.

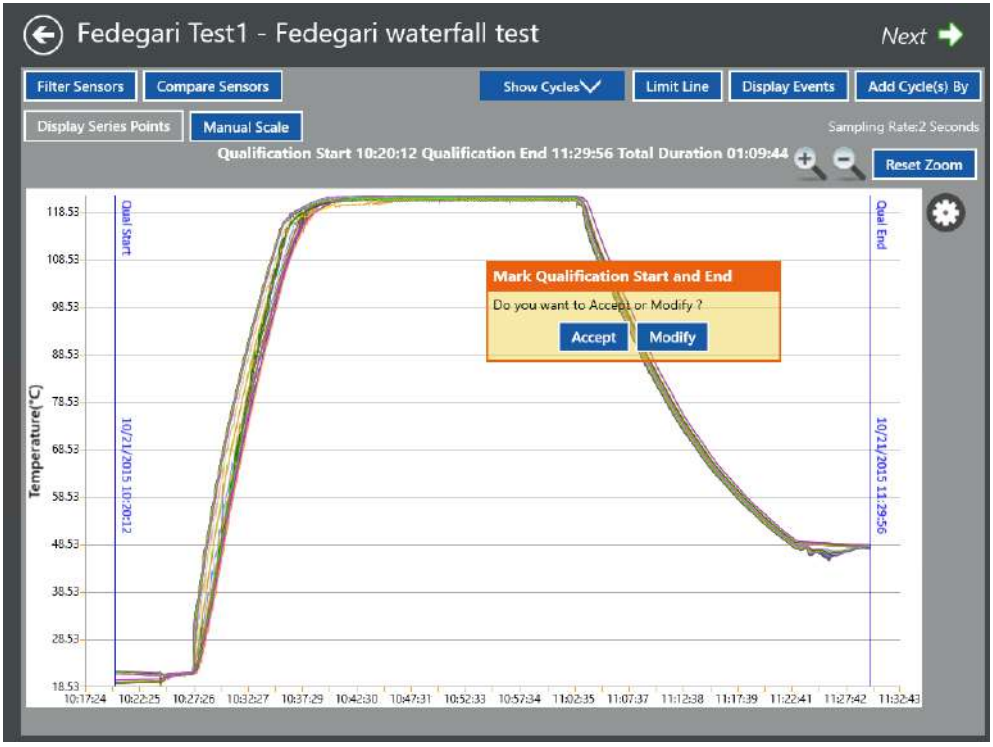


Figure 88: Add Cycles Screen

Qualification Start / End - Upon entering the Cycle selection screen the system displays a graph, based on the sensor type selected, with the Qual Start and End marked on the graph and listed above showing the Start and End of Qual defined during the Qualification study. A pop-up appears where you can **Accept** or **Modify** the existing Start and End of Qual. If **Modify** is selected, the user can modify the Start and End of Qual by either “Time” or "Selection Line ".

Select **Time** to enter time manually for Start and End Qual. Select **Selection Line** to manually move the line on the graph to the Start of Qual and then press **OK**. The process can then be repeated for the End of Qual. Features such as Zoom, Limit Lines, and Display Events assist in defining cycle markings.

Exposure Start / End - If your Setup included Lethality calculations, or exposure cycle parameters were defined, the Exposure Start and End is marked on the graph and you are prompted to **Accept** or **Modify** the Exposure Start and End times. If no modifications are required when entering the Mark Cycles screen, you can simply accept the Qualification Start /Stop and Exposure Start/Stop markings and press the **Arrow** at the top right of the screen to move on. If **Modify** is selected, the user can choose to modify the Exposure Start and/or End by "Time", "Selection Line ", or "Event".

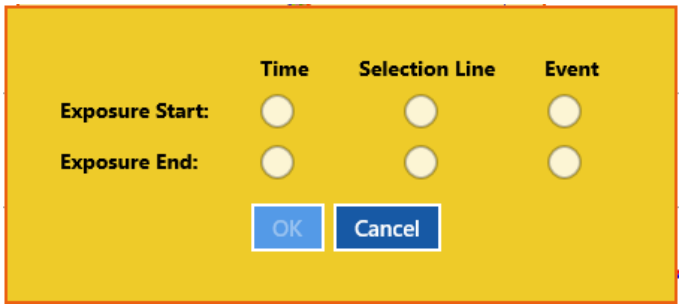


Figure 89: Exposure Start Definition Options

Select "Time" to manually enter the time for Exposure Start and/or End (i.e. used to synchronize with autoclave controller). Select **Selection Line** to manually move the line on the graph to Exposure Start and /or End then press **OK**. Select **Event** to utilize a previously defined Event in your setup as the Exposure Start and / or End or to create a New Event.

If creating a new event, the user can specify a message which appears in the Detailed Report. The user can also specify "When", which defines when the event occurs, as well as a “Label” and the condition for the event. (e.g. min temp > 121.0 C). At the completion of marking Exposure Start / End the cycles are numbered 1-3. By selecting **Show Cycles**, the user can modify the cycle names (e.g. heat-up, exposure, cool-down).

- **Adding Cycles** – The system allows up to 15 additional cycles to be defined. For each cycle a start and end time can be marked by “Time”, “Selection Line”, or Event. The method and functionality for defining cycles is the same as defined in Exposure Start / End.

- **Show Cycles** – All created cycles are displayed with the defined Start and End times. The Show Cycle screen also allows modifications of cycles names. **UnMark Cycle** can be used to delete a cycle. This option deletes from the last cycle to first, end of study, and then start of study. **UnMark All** unmarks all cycles, including study start and end. **Hide Cycles** closes the cycles window.

There are additional tools available to simplify cycle selection:

Settings: This button opens the display settings. It is possible to enable the display of time & date for the cycle lines.

Magnifier: Pressing the magnifier buttons to zoom in or out of the graph. That can be useful when using the line selection to zoom to the exact timestamp.

Reset Zoom: Resets the zoom to overview.

Show Datapoint: Activates a point for every data sample. In studies with many datapoints this affects the performance significantly and will not show more than bold lines because the datapoints are overlapping. The strength of this option is to show the exact datapoint in a zoomed mode while using the line selection.

Show Limit Line: The limit line is a tool like a ruler that simplifies to determine e.g. the point in time when one or all sensors reached a specific value graphically. It is a tool for the Mark Cycles screen only and not related to the graph report limit lines.

Filter Sensors: In the drop-down check and uncheck sensors for accurate marking of cycles by focusing on one or a subset of reference sensors. In the alternate view for large study files, it will show the data in the same chunks as the complete study data.

Compare Sensors: Select two sensors of the same type for graphical comparison. Because the study data is reduced to two sensors, for large files the study data is displayed as a complete study instead of data chunks.

If the report contains more than 150,000 data points (the product of numbers of sensors and number of samples per sensor e.g. 15 sensors with 10,000 data points per sensor) the report tool opens an alternative Mark Cycles screen presenting data in packages of 5,000 data points.

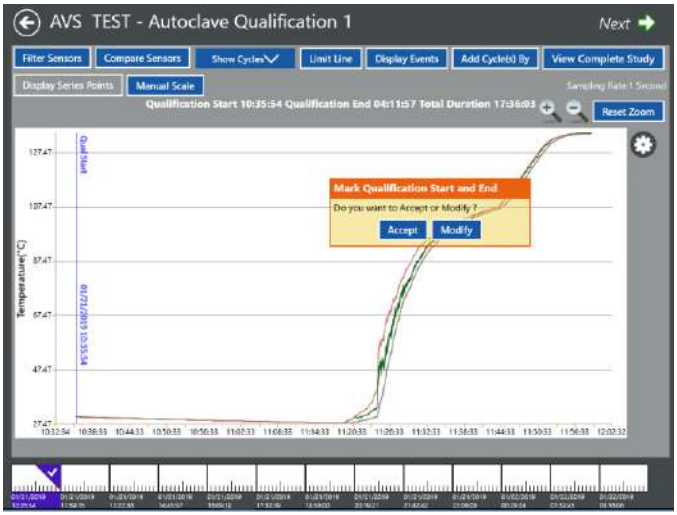


Figure 90: Alternative Mark Cycles for Long Studies

Select a data package on the bottom of the screen to jump through the complete dataset. Inside every data package all operations to mark the start and stop of the qualification and cycles are available. Additionally, an overview of data can be displayed.

When all the desired cycles have been defined, press **Next** to navigate to the Edit Parameters screen.

Press **Next** to navigate to the next screen and choose from either of the options; **Customize Groups** and **Customize Calculations**.

10.5.3. Edit Groups and Calculations

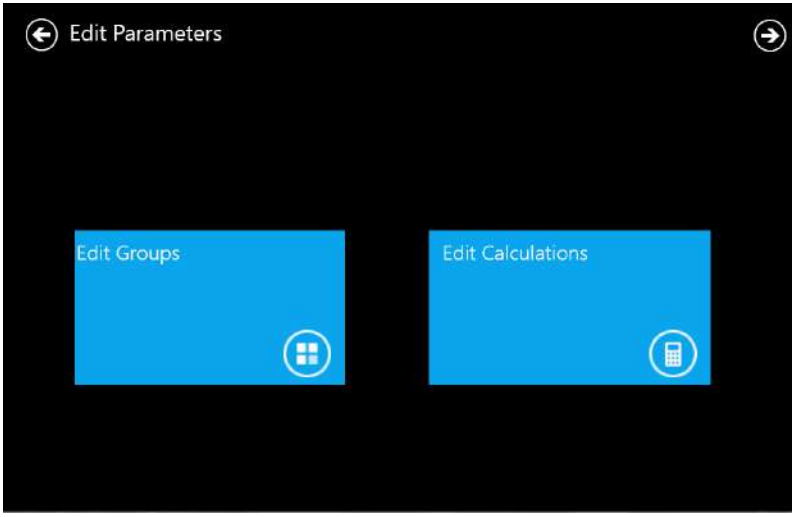


Figure 91: Edit Groups and Calculations Screen

Inside the Edit Parameters screen the User can make any necessary changes to Groups and or Calculations prior to reporting. Any changes to Groups or Calculations are listed in the report.

If groups and calculations are configured correctly in the study setup, there is no need to make changes.

Press the **Next** arrow to continue to the Report Selection screen.

Customize Groups Screen

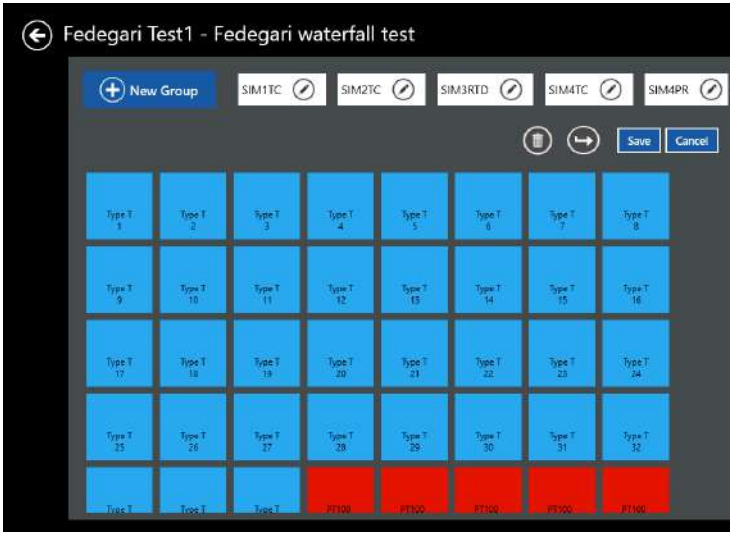


Figure 92: Customize Groups

To assign sensors to groups:

Select individual sensors to select them for a group. These sensors appear blue with an orange checkbox.

Press **New Group**, a group name textbox appears above the selected screens and enter a name and press **Save** to save the group.

The screen includes the following options:

- Delete - permits deletion of a sensor group
- Move Sensors - permits moving sensors to another sensor group
- Delete individual sensors from a group

Any changes to groups or removal of sensors are listed inside the report.

Press **Back** to return to the previous screen.

Customize Calculations Screen

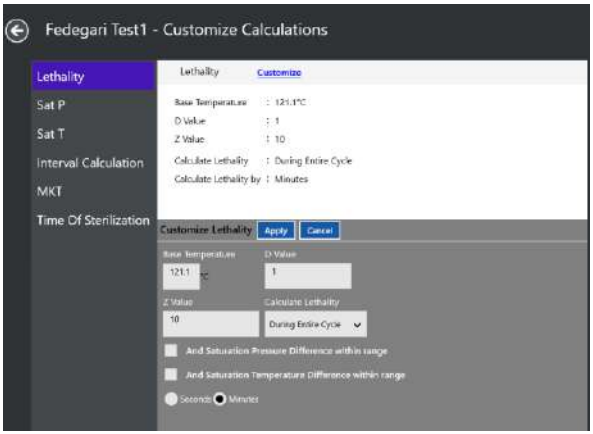


Figure 93: Customize Calculations

On the Edit Calculations screen, before reporting, users can make any necessary changes to Lethality, Saturation, or Interval calculations via the **Customize** button.

Any changes to calculations are detailed in the Qualification report.

Some calculations are done inside the software and cannot be set in the setup file:

- If a lethality calculation is required to be calculated in relation to the steam quality that requirement can be set here. The Time of Sterilization defines the required steam quality that is used to calculate the time of sterilization in the Pass-Fail criteria report.
- If the MKT calculation is desired the value of Heat activation can be set here.

Note: *Changes to lethality calculations are permitted only if given permission inside preferences. Changes to D-Value can be permitted inside policies.*

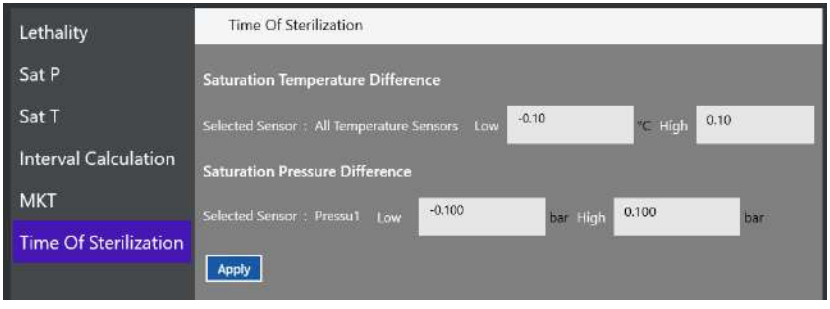


Figure 94: Time of Sterilization – Definition of Required Steam Quality

If calculations have already been specified for statistical, lethality, or interval calculations a **Customize** button displays to the left of the calculation label. Press **Customize** to change calculations. When a user modifies lethality, interval, or saturations calculations values they are applied to generate report.

Press **Back** to return to the previous screen.

10.6. Select Report Type and Options

On the Report Selection screen, you can select the type of Qualification report to generate.

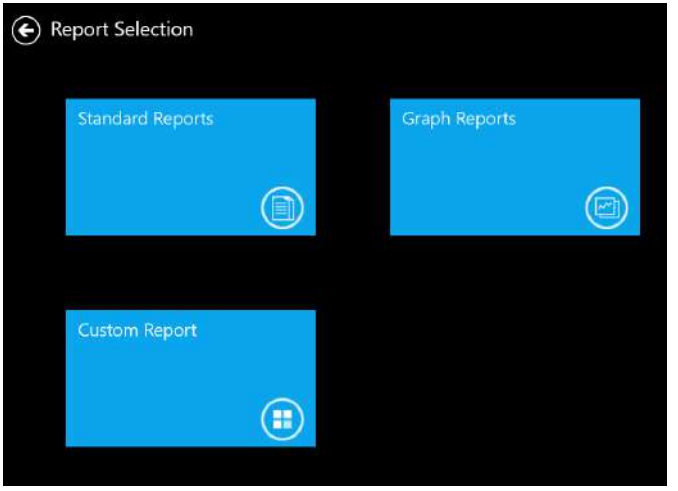


Figure 95: Report Selection Screen

Standard Reports: The Detailed and Summary report interface screens are used for generation of table format reports from qualification studies to pdf files. The data is displayed as a text report with data tables:

- The Qualification Detailed Report organizes information for each group by sensor data and type of calculation (lethality, statistical, saturated steam).
- The Qualification Summary Report summarizes your study. It is possible to apply several calculations.
- Interval Calculations report: Documents statistical calculations for defined intervals.
- Pass-failed report: Analysis the data using a defined set of requirements.

- Audit Trail Report: The Audited Trail automatically captures all system and Operator actions which affect the creation, modification, deletion, or storage of GXP data and reports.

Graph Report: Graph report interface screen for generation of graph format reports from qualification studies to pdf files. Generation of a Graph Report for defined groups and cycles; graphical reports for statistical, Lethality, saturation pressure, saturation temperature, and equilibrium calculations.

Standard Report Options

The final step to set up a report for printing, is selection of report options and types. At the top of the screen.

- Report Content: include/exclude a selected group and calculations from the reports.
- Header/Footer: customize the header/footer, adding comments on the first and last page of the report and include/exclude system messages.
- Select Print Rate: a drop-down to adjust the print sampling rate of the Detailed Report.

Qualification Report Types:

Select either **Detailed**, **Summary**, **Interval**, **Pass-Fail**, or **Audit Trail** options. The selected options are valid for types of reports.

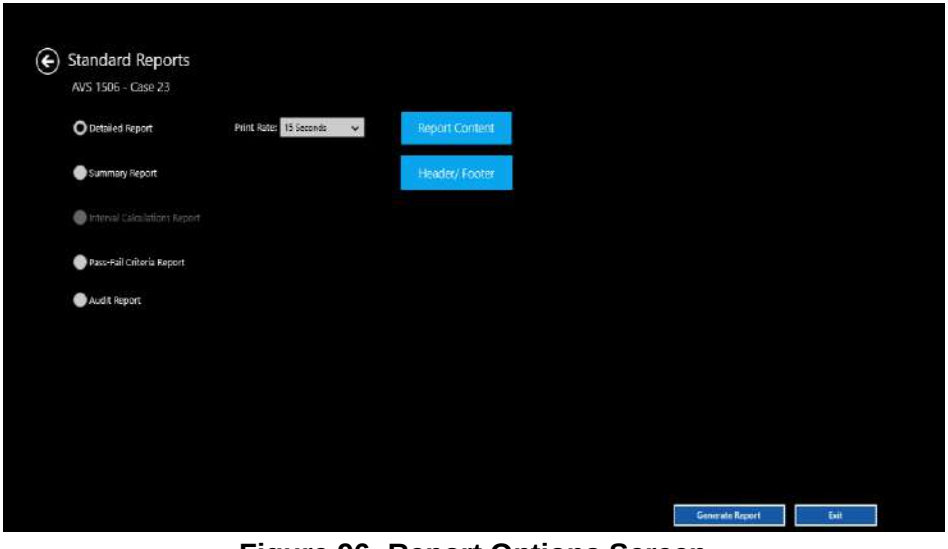


Figure 96: Report Options Screen

Press **Generate Report** to generate the respective report type or customize report options.

Content for the selected report can be customized via the **Report Content** button. A table opens, listing all available groups and valid calculations for the sensors type of the group. Lethality and MKT calculations cannot be selected for one single report. Saturation, temperature, and saturation pressure calculations can be selected or deselected for all groups together in a report.

Availability of a saturation calculation is dependent on whether there is a pressure sensor and temperature sensor defined in the study. The calculation is selectable per group for all sensors. If the calculation for all sensors is selected, group selection is automatically overridden.

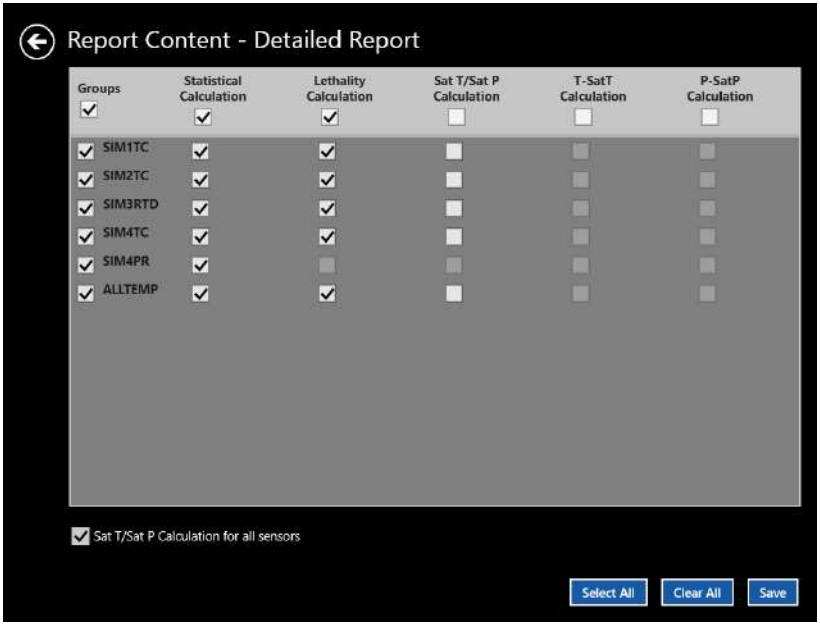


Figure 97: Report Content Selection - Detailed Report

Inside the Summary Report, you can choose between Lethality and MKT calculations. In addition, there are options to include a Setup Report (including the wiring diagram if specified) and a study overview graph.

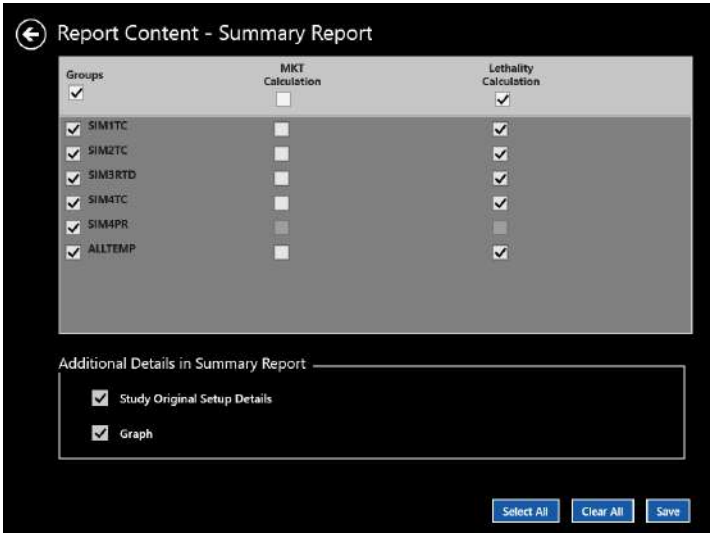


Figure 98: Report Content Selection – Summary Report

Note: *For a new group added in "Edit Groups" to be included in the Detailed/Summary Report, it is required to select the corresponding groups and its calculations in Report Contents.*

To customize the header and footer report structure, select **Header/Footer**. Use the **Comments** textboxes to enter any free text to display on the first and last page of the report. The textboxes below "Header Footer Text" can be used to customize the header and footer of the report.

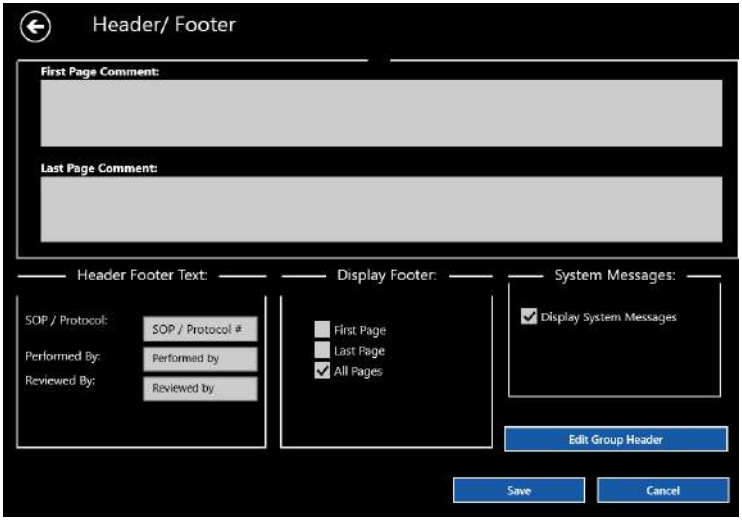


Figure 99: Report Header / Footer Content

Under “Header Footer Text”, there are three editable textboxes, **Performed By**, **Reviewed By**, and **SOP / Protocol** to enter the names of users who conduct or review the study. Three checkboxes enable you to indicate whether these names are displayed on the **First Page**, **Last Page**, or **All Pages**.

Note: *When selecting **All Pages**, the other checkboxes are not available.*

If the **System Messages** selection checkbox is activated, all system messages for study are listed at the end of the report.

Use **Edit Group Header** to edit the groups headers independently.

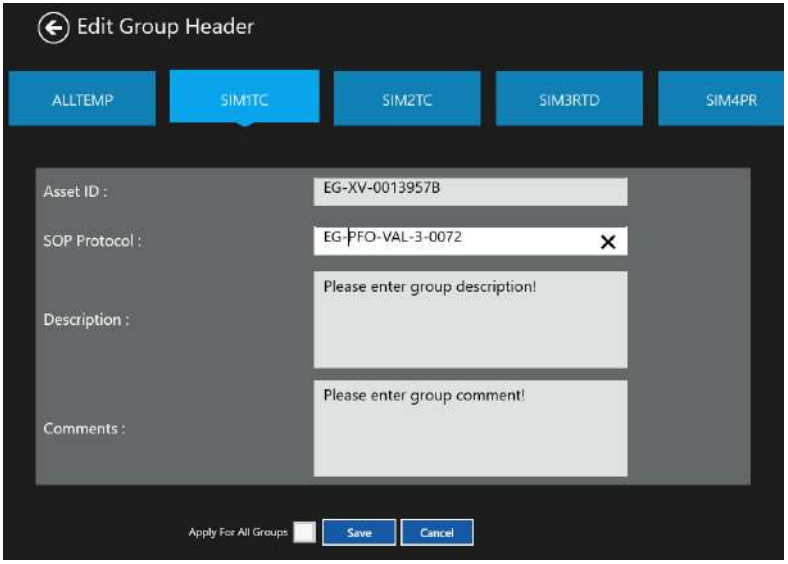


Figure 100: Edit Group Headers

10.7. Audit Trial

To meet 21 CFR Part 11 and Data Integrity requirements, the Validator AVS system includes a robust and comprehensive Audit Trail.

The Audited Trail automatically captures all system and Operator actions which affect the creation, modification, deletion, or storage of GXP data and reports.

The purpose of the Audit Trail is to give users the ability to review and print the history of actions affecting Gxp files and events.

The Audit Trail is stored in monthly encrypted files as well as backed up locally every time the system is booted up to ensure protection of the files. The data in the Audit Trail cannot be deleted and or modified.

Actions which are captured include:

- User actions requiring a login with a User ID and Password.
- Automated system actions or events.
- Any additional actions deemed critical to the history of the data or Qualification files.
- To access the Audit Trail, navigate to the AVS Software Main screen and select **Audit**. You can also create an Audit Trail Report from the Standard Reports screen.

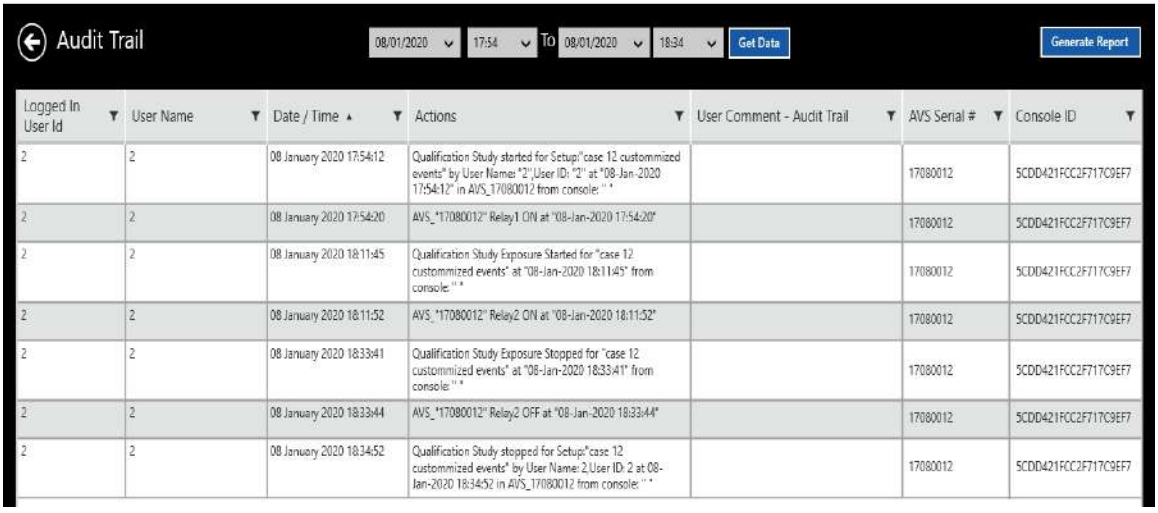


Figure 101: Audit Trail

The Audit Trail contains a complete history of the system. You have the option to filter the data by the following options:

- User ID and Name of Operator initiating the action
- Date and time action was taken (hh:mm)
- Description of action taken. If action was to change value description includes original value and well as new value
- User comments entered when action was taken
- AVS hardware serial number of units affected
- AVS Console Machine ID to identify from which Console action was initiated

Note: *If the study is imported or synced to the system, there might be no related audit trail entries!*

After filtering is applied, Start time is set from 0 secs and end time to 59 secs. For review and printing purposes, each column has filters to filter by any parameter.

When the Audit Trail is filtered and printed, the header of the report lists all filters that have been applied along with the condition of the filters.

[No content intended for this page]

Appendix A. AVS Calculations Lethality, Saturation, and MKT Calculations

The following is a detail listing of the calculations utilized by the AVS for Lethality, Saturation, and MKT calculations.

Lethality Calculation

Lethality is the ratio of time required at base temperature to the time required at the measured product temperature to achieve the same total effective reduction of the microbiological population. The Instantaneous Lethality (Ileth) formula is shown below.

Instantaneous Lethality = $\frac{1}{D}\left[10^{\left(\frac{T-T_b}{z}\right)}\right]$

Where:

- D is the time required to reduce microbiological population by 90% (D = 1)
- Z is the temperature difference required to change the D value by a factor of 10
- T is the product temperature
- Tb is the temperature at which the D value is determined (base temperature)
- Δt is found by dividing the number of seconds between samples by 60 seconds

Accumulated Lethality (Aleth) is the sum of the Instantaneous Lethality values over a selected period of time. The Accumulated Lethality formula accounts for a change in temperature by averaging the current Ileth and previous Ileth values. The data storage rate for a Qualification study should be as small as possible so that the Lethality calculation can account for any change in temperature.

Accumulated Lethality = $\left(\frac{PreviousIleth+CurrentIleth}{2}\right)\Delta t + PreviousAleth$

Saturation Calculation

- **Saturation Pressure as a Function of Temperature**

This function calculates the saturation pressure as a function of temperature (in degrees F or C). The function gives the saturation line, which is the boundary between steam and water.

- **Algorithm**

The function first converts the measured temperature to reduced temperature θ (alias Tr). Then the dummy variable x is calculated:

$$x = 1 - \theta$$

The first intermediate term is defined by the following:

$$term1 = \frac{k_1 \cdot x + k_2 \cdot x^2 + k_3 \cdot x^3 + k_4 \cdot x^4 + k_5 \cdot x^5}{\theta \cdot \left(1 + k_6 \cdot x + k_7 \cdot x^2\right)}$$

$k_1 = -7.69123456$

$k_2 = -2.60802370E+1$

$k_3 = -1.68170655E+2$

$k_4 = 6.42328550E+1$

$k_5 = -1.18964623E+2$

$k_6 = 4.16711732$

$k_7 = 2.09750676E+1$

The second intermediate term is calculated:

$$term2 = \frac{x}{k_8 \cdot x^2 + k_9}$$

$k_8 = 1.0E+9$ $\qquad$ $k_9 = 6$

The reduced saturation pressure β_K is then calculated:

$$\beta_K = \exp\{\text{term1} - \text{term2}\}$$

The reduced saturation pressure is then converted to atmospheres:

$$P_{norm} = \beta_K \cdot P_C = \beta_K \cdot 218.307$$

Finally, the saturation pressure is converted to the desired units by multiplying by the user-defined scale factor representing the value of 1 atmosphere:

$$P = P_{norm} \cdot P_{atm}$$

- **Saturation Pressure as a Function of Pressure**

This function is the complement to the saturation pressure function. It calculates the saturation temperature (in degrees F or C) which corresponds to a given pressure. It is based on a table lookup of values calculated from the ASME Steam Table formulas and fitted to a polynomial function.

- **Algorithm**

The input to the polynomial function is a dummy variable x derived from the measured pressure P by the following formula:

$$x = \ln\left(\frac{P}{P_{atm}}\right)$$

The absolute temperature T_K (in degrees K) is calculated by means of the following polynomial function:

$$T_K = \sum_{n=0}^{10} c_n \cdot x^n$$

$$c_0 = 3.7315985\text{E+2}$$

$$c_1 = 2.8009302\text{E+1}$$

$$c_2 = 2.3847554$$

$c_3 = 2.1460044E\text{-}1$

$c_4 = 2.5829468E\text{-}2$

$c_5 = 9.8936202E\text{-}4$

$c_6 = -9.2209486E\text{-}4$

$c_7 = 2.4247001E\text{-}5$

$c_8 = 4.9851762E\text{-}5$

$c_9 = -7.4897696E\text{-}7$

$c_{10} = -9.1044518E\text{-}7$

The absolute temperature is converted to degrees F by means of the following:

$T = (T_K \cdot 1.8) - 459.69$ (using original values for absolute zero in degrees F).

The absolute temperature is converted to degrees C by means of the following:

$T = T_K - 273.16$ (using original values for absolute zero in degrees C).

- **Conversion of Variables**

The measured temperature is converted to absolute temperature (in degrees K) by means of the following formulas:

$T_K = \frac{T + 459.67}{1.8}$, for temperature in degrees F (revised April 1987).

$T_K = T + 273.15$, for temperature in degrees C (revised April 1987).

The absolute temperature is then converted to reduced temperature θ (alias Tr) by means of the following formula:

$\theta = \frac{T_K}{T_C} = \frac{T_K}{647.3}$

The measured pressure is converted to normalized pressure by means of the following formula:

$$P_{norm} = \frac{P}{P_{atm}}$$

The normalized pressure is then converted to reduced pressure β (alias Pr) by means of the following formula:

$$\beta = \frac{P_{norm}}{P_C} = \frac{P_{norm}}{218.307}$$

MKT - Mean Kinetic Temperature

Mean Kinetic Temperature -- Mean Kinetic Temperature (MKT) is a simplified way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods.

Mean Kinetic Temperature (MKT) is defined as the single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures. Thus, MKT may be considered as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variation. It is not a simple arithmetic mean.

Algorithm:

Formula is as follows:

$$MKT = \frac{\Delta H / R}{-\ln\left(\frac{e^{-\Delta H / RT_1} + e^{-\Delta H / RT_2} + ... + e^{-\Delta H / RT_n}}{n}\right)}$$

Where T = average daily temperature in degrees Kelvin

$\Delta H = 83.144 \text{ KJ} * \text{mole}^{-1}$

$R = 8.3144 \times 10^{-3} \text{ KJ} * \text{mole}^{-1}$

n = number of samples

e = 2.71828

AVG = $(T_1 + T_2 + \ldots + T_n) / n$

Difference = (MKT-AVG)

All calculation may be performed manually with a scientific calculator if a copy of Excel is not available.

References Required:

- USP24/NF19, <1151>Pharmaceutical dosage forms, stability

Appendix B. Understanding Audit Trail Events

All events include the following mandatory data: date and time, username, user ID, Console ID, Validator ID, and Console-Validator ID combination.

Table 4: Audit Trail Events

Tabulation 1					
User Management					
Create a user	Date/time of event	Create user			
		Name & ID of new user	User Level	User Privileges	Name & ID of system Admin
Modify a user	Date/time of event	Modify user			
			User Privileges or corresponding parameters of Modified user		Name &ID of system administrator
Delete a user	Date/time of event	Delete User			
			Name & ID of deleted user		Name &ID of system administrator
Failed login	Date/time of event	Login Failure	Unknown user		
		User ID entered	Username entered		
Permission violation	Date/time of event	Permission violation			
			Name & ID of user		Attempted Action
Password change	Date/time of event	User password change	Name & ID of user		
Account disabled	Date/time of event	User account disabled	Name & ID of user		Name & ID of system administrator

Table 4: Audit Trail Events (Continued)

Account disabled after three consecutive login failures	Date/time of event	User account disabled		Automatic Event
		Name & ID of the user	Login attempt fail	
Preferences	Date/time of event	Preferences modified		
		Modified field		Name & ID of system administrator
Policies	Date/time of event	Policies modified		
		Modified field		Name & ID of system administrator
Auto Sync	Date/time of event	Auto Sync Out operation	Auto Sync Out Successful	
		Auto Sync Out interval change	Interval Changed timestamps	
Assets	Date/time of event	Asset creation	Name of the asset	Name & ID of user
		Asset Modification	Name of the asset	
			Modified field	Name & ID of user
		Asset Deletion	Name of the asset	Name & ID of user
Setup	Date/time of event	Setup Creation	Name of the setup	Name & ID of user
		Setup Modification	Name of the setup	
			Modified in tab	Name & ID of user
		Setup Deletion	Name of the setup	Name & ID of user

Table 4: Audit Trail Events (Continued)

File Management	Date/time of event	AVS Convert	Name of the file	Name & ID of user
		Sync In	Selected items Sync In Operation	Sync In Successful
		Sync Out	Selected items Sync Out Operation	Sync Out Successful
		Archive		Archive Successful
Calibration / Qualification / Verification				
Loaded	Date/time of event	Setup loaded		
		Name of the setup	AVS IP	Name & ID of user
Calibration	Date/time of event	Calibration Started	Event timestamp	
		Name of the setup	AVS Serial Number	Name & ID of user
	Date/time of event	Calibration Completed	Event timestamp	
		Name of the setup	AVS Serial Number	
	Date/time of event	Calibration File Saved	Event timestamp	
		Name of the setup	AVS Serial Number	Name & ID of user

Verification	Date/time of event	Verification Started	Event timestamp	
		Name of the setup	AVS Serial Number	Name & ID of user
	Date/time of event	Verification Completed	Event timestamp	
		Name of the setup	AVS Serial Number	
	Date/time of event	Verification file saved	Event timestamp	
		Name of the setup	AVS Serial Number	Name & ID of user

Table 4: Audit Trail Events (Continued)

Qualification	Date/time of event	Qualification Started	Event timestamp	
		Name of the setup	AVS Serial Number	Name & ID of user
	Date/time of event	Exposure Started		
		Name of the setup	Event timestamp	
	Date/time of event	Exposure Stopped		
		Name of the setup	Event timestamp	
	Date/time of event	Qualification Stopped	Event timestamp	
		Name of the setup	AVS Serial Number	Name & ID of user
Audit Report	Date/time of event	Generate Audit Report	Name & ID of user	
Pass/Fail Template	Date/time of event	Create Template	Type of operation	Name & ID of user
	Date/time of event	Edit Template	Type of operation	Name & ID of user
	Date/time of event	Delete Template	Type of operation	Name & ID of user
Equipment	Date/time of event	Equipment creation	Name of the Equipment	Name & ID of user
		Equipment Modification	Name of the setup	
			Modified field	Name & ID of user
		Equipment Deletion	Name of the Equipment	Name & ID of user

Appendix C. Environmental Compliance

This appendix contains information on the following topics:

C.1 Waste Electrical and Electronic Equipment (WEEE) Directive

The equipment that you have bought, has required the extraction and use of natural resources for its production. It may contain hazardous substances that could impact health and the environment.

In order to avoid the dissemination of those substances in our environment and to diminish the pressure on the natural resources, we encourage you to use the appropriate take-back systems. Those systems will reuse or recycle most of the materials of your end life equipment in a sound way.

The crossed-out wheeled bin symbol invites you to use those systems.

If you need more information on the collection, reuse and recycling systems, please contact your local or regional waste administration.

C.2 Battery Disposal

This product contains a battery that cannot be disposed of as unsorted municipal waste in the European Union. See the product documentation for specific battery information. The battery is marked with this symbol, which may include lettering to indicate cadmium (Cd), lead (Pb), or mercury (Hg). For proper recycling return the battery to your supplier or to a designated collection point.

C.2.1 What do the Markings Mean?

Batteries and accumulators must be marked (either on the battery or accumulator or on its packaging, depending on size) with the separate collection symbol. In addition, the marking must include the chemical symbols of specific levels of toxic metals as follows:

- Cadmium (Cd) over 0.002%
- Lead (Pb) over 0.004%
- Mercury (Hg) over 0.0005%

C.2.2 The Risks and Your Role in Reducing Them

Your participation is an important part of the effort to minimize the impact of batteries and accumulators on the environment and on human health. For proper recycling, you can return this product or the batteries or accumulators it contains to your supplier or to a designated collection point.

Some batteries or accumulators contain toxic metals that pose serious risks to human health and to the environment. When required, the product marking includes chemical symbols that indicate the presence toxic metals: Pb for lead, Hg for mercury, and Cd for cadmium.

Cadmium poisoning can result in cancer of the lungs and prostate gland. Chronic effects include kidney damage, pulmonary emphysema, and bone diseases such as osteomalcia and osteoporosis. Cadmium may also cause anemia, discoloration of the teeth, and loss of smell (anosmia).

Lead is poisonous in all forms. It accumulates in the body, so each exposure is significant. Ingestion and inhalation of lead can cause severe damage to human health. Risks include brain damage, convulsions, malnutrition, and sterility.

Mercury creates hazardous vapors at room temperature. Exposure to high concentrations of mercury vapor can cause a variety of severe symptoms. Risks include chronic inflammation of mouth and gums, personality change, nervousness, fever, and rashes.

C.2.3. System Specifications

Total System Specifications

When you use specifications to compare equipment, be sure to establish an error budget that accounts for all possible measurement uncertainty. Sensor calibration is an integral part of validation, and total system accuracy should include potential error from the recorder, as well as the temperature reference and traceable standard. Since all component errors are additive to the total system, every potential error is significant. A summary of the error budget for a validation system after sensor calibration with type T thermocouples, used at steam and dry heat with a Kaye HTR-400 as temperature reference and a Kaye IRTD-400, is listed below.

Validator AVS (resolution and short-term stability)	0.017°C	k=1
IRTD Temperature Standard (IRTD-400)	0.013°C	k=1
Temperature Reference (HTR-400 @121°C)	0.051°C	k=1
Accumulated Uncertainty (Root Sum Square)	0.055 °C	k=1
Total System Uncertainty	**0.11°C**	**k=2**

Validator AVS Specifications

Analog Input	Up to 48
Voltage Input Accuracy	30 days: ±(0.003% of reading + 2 counts + 4 microvolts) 1 year: ±(0.006% of reading + 2 counts + 4 microvolts)
System accuracy with thermocouple (specified from 20 to 30°C for 30days)	±(0.003% of reading + 0.25°C)
System accuracy with thermocouple (specified from 0 to 50°C for 30days)	±(0.028% of reading + 0.56°C)
Sensitivity	0.5 microvolts/count on most sensitive range
Voltage Temp. Coef.	±(0.1 microvolts + 0.001% reading)/°C
Compensator Temp. Coef.	±0.01°C per °C
Input Terminal Temperature Non-uniformity	±0.1°C from calibrated terminal
Input Ranges	-6 to 30mV, -12 to 60mV, -60 to 300mV, -2 to 10V
Environmental	Temperature: 0 to 50°C (32 to 122°F) Relative humidity: 95% non-condensing
Power	90 to 250 VAC, 50/60 Hz
Fuse Rating	4A Slow Blow
Size	190H X 411W X 381 mm D (457 mm with SIM) 7.5 in H x 16.2 in W x 15 in D (18 in with SIM)
Weight	10.60 kg (23.4 lbs.)
Battery	Lithium ion with minimum 60 minutes of battery backup

Console Specifications

	On	Off (Storage)
Temperature	5°C -40°C	-20°C -60°C
Humidity	8%-90% RH	5%-95% RH
Air Pressure	697-1060 hPa	187-1060 hPa
Power Supply (ITE) Delta Electronic, SADP-65NB Rev. BB	Input : 1.5A, 100-240VAC, 47-63Hz Output:19V DC, 3.42 A The power supply is compliant with UL-60950-1, CAN/CSA C22.2 No.60950-1, and IEC/EN 60950-1	

C.3 FCC Part 15 Details

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The manufacturer of this devise, as an intentional and / or unintentional radiator, cautions the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

15.105(a) “Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.”

CAUTION: **To maintain compliance with the FCC’s RF exposure guidelines, place the product at least 20 cm from nearby persons.**

Appendix D. Safety and Precautions

The following safety precautions should be taken for proper operation of the unit and to avoid any manual injury

☞ To ensure proper air flow, do not block fans.

☞ The unit should be serviced by authorized service personnel only.

☞ This unit must be opened by Amphenol authorized service technicians only, tampering by unauthorized representatives could void the warranty.

☞ This unit must be operated under specified environmental conditions only, usage of unit beyond these conditions could damage the unit and voids the warranty.

Appendix E. Service Information

We operate a global network of service centers and a field service organization to provide customer support for repair, returns, calibrations, technical support, evaluation and spare parts.

Americas

Amphenol Advanced Sensors
967 Windfall Rd
St. Mary's PA 15857
USA

Phone: 814-834-9140
Fax: 814-781-7969

Europe

Amphenol Advanced Sensors Germany GmbH
Sinsheimerstr. 6
75179 Pforzheim
Germany

Tel.: +49(0) 7231 14335 0
Fax: +49(0) 7231 14335 29

China

Amphenol (Changzhou) Connector Systems Co., Ltd.
Building 10, Jinton Industrial Park,
No. 8 Xihu Road, Wujin High-Tech Development Zone,
Changzhou, Jiangsu - 213164, China

Tel.: +86-519-88311899

India

Amphenol Interconnect India Pvt Ltd.,
Plot no.6, Survey No.64, Software Units layout,
MAHAVEER TECHNO PARK, Hitech City, Madhapur,
Hyderabad, Telangana – 500081, India

Tel.: +91 40 33147100

Appendix F. Warranty and Disclaimer:

The information in this document is based on our current tests, knowledge, and experience. Because of the effect of possible influences in an application of the product, they do not exempt the user from their own test, checks, and trials. A guarantee of certain properties or a guarantee for the proper suitability of the product for a specific, especially permanent application cannot be derived from our data. Liability is therefore excluded to that extent permitted by law. Any proprietary rights of third parties as well as existing laws and regulations must be observed by the recipient of the product on his own responsibility.

The Language of Touch

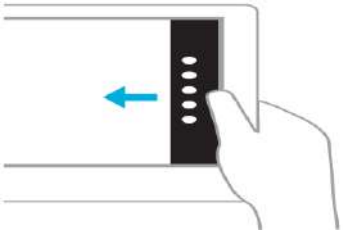
With specific gestures on a touch enabled device, you can quickly perform key activities like Search and Share; there's a corresponding command for using a mouse or keyboard, so you can interact in whatever way you prefer.

Swipe from the right edge for the **Action Center**.

Swiping from the right side of the screen reveals the Windows Action Center with system commands. Swiping from the left brings up previously used apps.

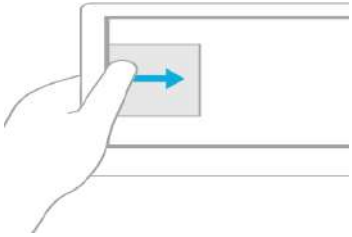
Mouse Equivalent

Place the mouse pointer in the lower or upper-right corner of the screen.



Swipe in from the left to view all your open apps in task view.

Swiping in from the left reveals thumbnails of your open apps so you can switch to them quickly.



Swipe in from the top to view a full-screened app's title bar.

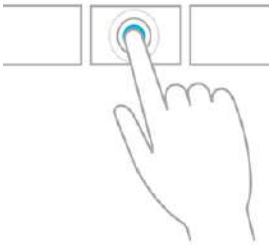
Swipe in from the bottom to view the task bar in full-screened apps.

Tap to perform an action

Tapping something causes an action, such as launching an app or following a link.

Mouse Equivalent

Click an item to perform an action.

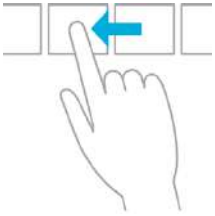


Slide to Drag

This is mostly used to pan or scroll through lists and pages, but you can use it for other interactions, too, such as moving an object or for drawing and writing.

Mouse Equivalent

Click, hold, and drag to pan or scroll. Also, when you use a mouse and keyboard, a scroll bar appears at the bottom of the screen so you can scroll horizontally.

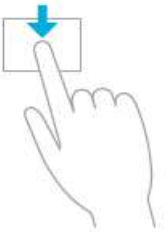


Swipe to select

Within an app, swipe down or across an item to select it. A quick, short movement works best. On Start, press and hold to select a tile.

Mouse Equivalent

Simply right-click to select within the app.

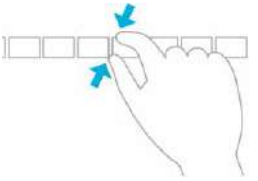


Pinch or stretch to zoom

Zooming provides a way to jump to the beginning, end, or a specific location within a list. You can start zooming by pinching or stretching two fingers on the screen.

Mouse Equivalent

Hold down the control key on the keyboard while using the mouse wheel to expand or shrink an item or tiles on the screen.

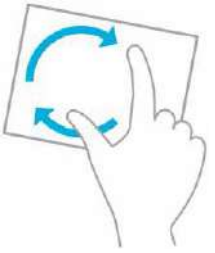


Rotate to turn

Rotating two or more fingers turns an object. You can turn the whole screen 90 degrees when you rotate your device.

Mouse Equivalent

Support for rotating an object depends on whether the specific app supports it.



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