



Validation

Kaye Validator[®] AVS

User's Manual



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Kaye Validator[®] AVS

Thermal Process Validation System

User's Manual

M5100-EN Rev. D
October 2016

Amphenol
Advanced Sensors

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Chapter 1. The Kaye Validator AVS

1.1 Introduction



Figure 1: The 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 sensor calibration and qualification reporting.

A complete Kaye validation package, which lets you perform a fully automated sensor calibration, includes:

- One or more Kaye Validator AVS
- One or more Kaye Validation Consoles for programming and control

- Up to four Kaye Sensor Input Modules (SIMs) per Validator (each SIM supplies up to 12 thermocouple sensors)
- A Kaye high temperature reference (HTR 400), a Kaye low temperature reference (LTR -90, LTR -25/140 or LTR -40/140), or a Kaye cold temperature reference (CTR -40 or CTR -80) for sensor calibration and verification
- A Kaye Intelligent RTD probe (IRTD)
- Premium grade thermocouples
- Additional temperature and non-temperature sensors for qualification studies (optional)

Users can select, and log in to, any Kaye Validation Console to communicate with any Validator AVS, monitoring current studies and calibrations. Using the synchronization all Assets, Studies, and Qualification data are visible across all Consoles. While a Console can log in to one Validator at a time, multiple Consoles can log in to the same Validator AVS. Users can disconnect a Console after initiating a study or qualification; also, any user with any Console can stop a calibration or study currently running on any Validator AVS. Both Consoles and Validator AVS' can be on a user's local network, and users can obtain software upgrades for the Consoles.

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 is used as the operator interface to the Validator AVS.

Selectable input capacity (1 to 4 SIMs) up to 48 total inputs.

Robust Design

- Robust industrial design with two handles
- IPL55 rating, chemical resistant ABS housing
- Dedicated Validation Console for improved user interface
- On-board docking station for Kaye Validation Console
- Battery backup with field replaceable battery pack (max 3 hours)

Data Security via Smart Redundancy Concept

- Standalone operation of Validator AVS – console connection not needed
- Validator AVS Internal Memory
- Second independent mirrored memory card for data redundancy
- Data download to validation console
- Forced download of study and audit data to USB
- Backup and restore – synchronization of console data with server and other consoles.

Hardware Connectivity

The Kaye Validator AVS comes complete with improved robust connections for IRTD and Calibration Baths. The Validator AVS is backward compatible with all existing IRTD and Kaye Baths for Automatic Calibration. Two relay outputs are also available to be activated via Qualification events.

Sensor Inputs

- Up to 4 SIMS: 48 channel capacity
- Scan speed of 36 channels per second / 48 channels 2 seconds
- SIMs for TCs, 4-20mA, 0-10V and RTDs
- Improved Sensor Connectivity (quick-fix & lock connectors)
- Accepts a wide range of thermocouple types (T, T premium, J, K, E, B, R, N, S)

1.3 About this Manual

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

The following is a brief description of each section 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 for connecting the system.
- *Chapter 3* provides instructions for creating user accounts.
- *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 displaying live data on the Console.
- *Chapter 9* provides instructions for performing a qualification study.
- *Chapter 10* provides instructions for creating reports.

1.4 The Kaye Validator AVS System

The Kaye Validator AVS system integrates hardware and software, and gives you the flexibility to design and run studies in the way you find most productive. This section provides an overview of the system and its use.

1.4.1 The Validator AVS Hardware

The Validator AVS is a self-contained instrument, incorporating high-accuracy sensor measurement hardware with secure data recording capability. It accepts programming and control from one or more Kaye Validation Consoles. The Validator AVS provides standalone functionality when calibrating sensors and running qualification studies.



Figure 2: The Validator AVS System

The Validator AVS accepts up to 48 inputs in any combination of thermocouple, voltage or current inputs or 24 RTD inputs. The instrument is equipped with an universal power supply (100-240 VAC) and connections for two Kaye temperature references (although only one standard can be used at any given time), one Kaye temperature standard, and two contact output for signaling a PLC or other devices.

1.4.2 Sensor Input Modules (SIMs)

The Validator AVS uses Sensor Input Modules to provide secure connection of sensors to the Validator AVS while protecting the electronics from draft, dust, humidity, electrical noise and mechanical shock. SIMs are designed to be wired once and used repeatedly. You can wire SIMs yourself, or buy pre-wired SIMs to reduce preparation time. Once the SIMs are wired, you can calibrate multiple harnesses at the same time and store them for later use.



Figure 3: Sensor Input Module

The Validator AVS can be configured for up to 4 SIMs. Each SIM has:

- Sensor inputs: TC-SIMs have 12 sensor input connections, RTD SIMs can connect 6 RTD sensors, 4-20mA SIMs can connect 12 sensors and one connection for an external power supply
- 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

Using 4 SIMs, you can attach up to 48 inputs in any combination of thermocouples, voltage, or current inputs. A dedicated 4-20 mA SIM is also available with 12 4-20 mA inputs and one connection for an external power supply.

1.4.3 Plug-In Hardware Connections

The Validator AVS has connectors on the back of the unit for easy plug-in of SIMs, temperature standards, temperature references. It also provides connection ports for USB and Ethernet for the Console and the Validator. Another separate USB port is utilized for the year device calibration USB with the ICAL software. The USB memory card port on the left side of the instrument can be used to dump the 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

For a more complete description of the hardware, see Chapter 2, *The Validator AVS Hardware*.

1.5 The Validator AVS Software

The Validator AVS software provides everything you need to perform validation testing. Using the Validator AVS software, you:

- Create user accounts and assign user IDs, passwords and permission levels.
- Create validation study setups that run on the Validator. When calibrating sensors and running qualification studies with the Console connected, the Validator AVS software features expanded tools for graphing study data.
- Generate reports from secure data files that contain original calibration and qualification data recorded during the study. Use the reporting utility to generate reports containing only the results you need to document your study.

1.5.1 User Access

You can set user access to the Validator AVS to match the way your company works. The Validator AVS software is designed user level has specific permissions that define system access. Permissions can also be customized for each user.

1.5.2 User Identification

Each user is assigned two distinct levels of identification, user ID and password, which are used to uniquely identify an authorized Validator AVS user. Each user ID is associated with a unique user name to provide traceability during the validation process.

The Validator AVS requires users to enter their user ID and password whenever they:

- Create, modify, or move a setup
- Change the setup stored in the Validator AVS
- Calibrate sensors or verify sensor calibration
- Manually start or stop a qualification study
- Change preferences

Whenever an action occurs that requires a user ID and password, the user name associated with that user ID and a time stamp are written to the audit file along with a description of the action.

1.5.3 Electronic Data Requirements

The Validator AVS is designed to help you meet the guidelines for electronic signatures as specified in FDA Regulation 21 CFR part 11, Electronic Records; Electronic Signatures.

- Two levels of identification - user ID and password
- Uniqueness of each user ID
- Users create their own passwords
- User ID and password required whenever an action affects the security or integrity of the data
- Electronic signature identifies the user, and includes the date and time of the action
- Data files are encrypted and can only accessed through the AVS software. If the data is tampered with, the entire data file becomes inaccessible
- Password expiration feature allows you to set a password expiration
- System Administrators can set a minimum-password length requirement
- Option to disable a user account if there are three consecutive login failures for the user ID
- Secure audit trail files provide a complete listing of events that affect the integrity of the Validator AVS program and the Validator AVS instrument. Audit trail files contain all events and identify the type of action performed, the date and time the action occurred, the name of the responsible operator, and any additional information required to understand the action taken.

1.5.4 The Study Setup

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

- Define the sensors you are going to use in the study
- Assign sensors to groups and specify group calculations
- 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 how often to scan sensors
- Define the output relays

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

1.5.5 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 check-point. 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 your reference.

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

1.5.6 The Qualification Study

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

1.5.6a Report Generation

The purpose of qualifying equipment is to document its performance, either to satisfy regulatory requirements or to perform studies of your production processes. 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
- Calibration Verification Report

Each report is traceable to the original study data. You create reports each time from the secure data files. If a secure data file is tampered with, it is no longer readable by the software and you will not be able to generate reports.

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

1.6 Using the Validator AVS System

The Validator AVS system allows you the flexibility to design your qualification procedures to fit your workplace requirements. To perform a typical qualification study, it is recommended to follow the following steps in order:

1. Use the Validator AVS software to define an Asset

An asset is the equipment that is validated in its specifications. This could be an autoclave, a freezer, an incubator or any other device that validated. It is entered into the AVS software with all relevant data including serial number, validation frequency, manufacturer and even pictures and wiring diagrams.

2. Use the Validator AVS software to create a setup.

A setup defines the type of sensors and the validation parameters specific to your asset. If you have pre-wired SIMs, assign your sensor locations according to the SIM configuration.

3. Generate the Setup Report.

Use the Setup Report to verify your validation parameters and as a reference for connecting your sensors.

4. If you do not have pre-wired sensors, wire your thermocouples and auxiliary sensors to the SIMs as based on the Setup Report.

5. Connect the hardware and confirm connections.

Once the hardware is connected, use the Validator AVS software to display a graphical representation of your validation equipment to verify hardware and communications connections.

6. Load the setup into the Validator AVS to calibrate sensors and run your study.

IMPORTANT: *During sensor calibration and the qualification study, you can use the Console to view data and track your progress.*

7. With your hardware configured for the validation study:

- Calibrate sensors against the temperature standard
- Run the qualification study
- Run post-qualification calibration verification

1.6 Using the Validator AVS System (cont.)

The Validator AVS collects all study data and stores it in a secure data file internally. When the study is finished the data is downloaded into your Console's memory.

8. With the secure data file loaded on your Console, use the Validator AVS software to design and generate reports to document the specifics of your study.
 - Reporting Tool, a reporting utility that enables you to create setup, calibration, calibration verification and qualification reports, and to export qualification data to a CSV file. With Reporting Tool, you can edit the groups and sensors that appear in a qualification report, select cycles and add comments. For qualification reports, enhanced graphing capabilities allow selecting and removing sensors, constants and calculations.
 - You can access and print out the Audit Trail

Chapter 2. The Validator AVS Hardware

2.1 Introduction

The Kaye Validator AVS comes equipped with a universal power supply, a power cord for 115 VAC (or 230 VAC as necessary), over 4 GB of internal memory, and a 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 instrument has connection ports for all system devices and a USB flash drive interface on the left side.
- Internal memory
- Backup battery
- Sensor Input Modules (SIMs), which are 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 system
- Setting the Validator AVS time and date
- Viewing calibration information
- Preventive maintenance
- Transporting and shipping

2.2 The Validator AVS Instrument

The Validator AVS instrument is equipped with over 4 GB of internal memory, and a backup battery in case the system loses AC power.

2.2.1 Connection Ports

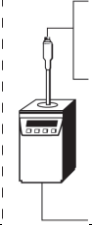



The back of the Validator AVS (shown in Figure 5 below) has ports for electrical and communication connections. Each connection port is labeled with an icon representing its function. The connection ports are defined on page 18. Below the ports are the ON/OFF switch and the AC power input.





Figure 5: Connection Ports

2.2.1 Connection Ports (cont.)

Table 1: Connection Port Explanations

Icon	Connection Port
	<p>4 Pin Din Connector</p> <p>There are three 4-pin Din connectors, labeled with a temperature reference icon, for connecting IRTDs and one Kaye 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!)</p>
	<p>Output Relay</p> <p>There are two NO/NC relay outputs, labeled with a contact switch icon, for signaling a PLC or other device.</p> <p>Relay Rating:</p> <ul style="list-style-type: none"> 110 VAC ½ amp resistive load 24 VDC 2 amps resistive load 110 VAC ¼ amp inductive load 24 VDC 1 amp inductive load
	<p>USB Connector</p> <p>One USB connector, labeled with a USB icon, is available for connecting an ICAL device. ICAL port is used for Service only</p>
	<p>USB/ Ethernet Connector</p> <p>There are two USB/Ethernet communications ports for connecting the Validator AVS and the Console. Ethernet cable to be less than 3 meters long</p>

2.2.2 Symbol Identification

	Protective Earth Terminal
	Caution (Refer to accompanying documentation.)

2.2.3 Side Port for Data Transfer

On its left side, the Validator AVS offers a side port with a USB port (to accommodate a USB flash drive) and a button for data transfer, as shown in Figure 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 10 studies are written to the Flash drive and can be reimported into the console through the AVS software. To provide data security, data is stored in 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 used only for data dump and not for connecting console.

Use the AVS convert function (see chapter 3.7) to import the files into the Validation console.

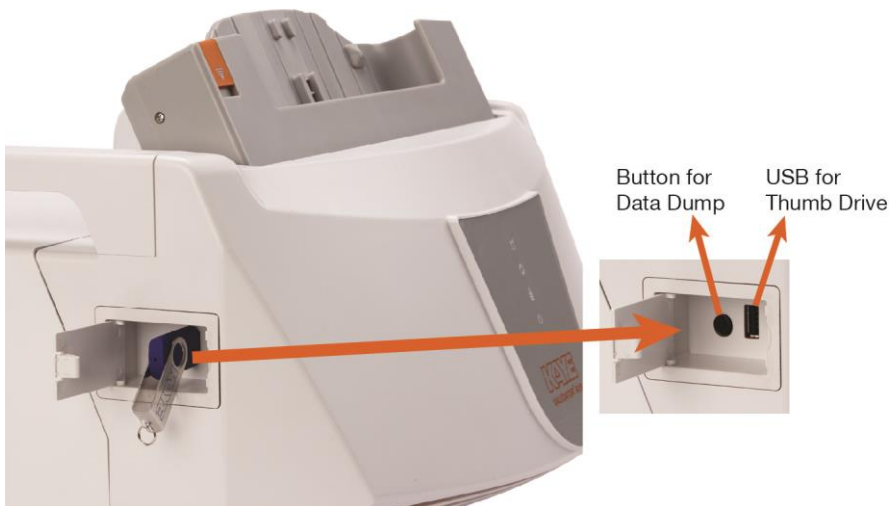


Figure 6: Side Port for Data Transfer

2.2.4 The Console

For programming and control, each Validator AVS includes a Microsoft Industrial Embedded OS based Console

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



Figure 7: Docking and Releasing Console

2.2.5 Internal Memory

The Validator AVS is designed to write data to internal memory during sensor calibration and qualification studies. Qualification data resides in internal memory until it is read out to a console. Up to 10 studies are stored in the internal drive.

The Validator AVS provides over 4 GB of internal memory to maintain qualification data during a study. The final study data is stored in the internal 32GB solid state memory. The 32GB solid state memory is mirrored to a 32GB SD-card memory that can get extracted by a Kaye technician for emergency recovery.

The Validator AVS allows you to scan data at 12 inputs per second per SIM slot during the qualification study. If SIM slot 4 is used the storage rate is reduced to 2 seconds allowing the maximum of 36 inputs per second or 48 inputs every 2 seconds.

Compared to the Kaye Validator 2000 there is no fast scan or slow scan available anymore.

2.2.6 Backup Battery

The Validator AVS is equipped with a 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 3 hours) so that you can perform an orderly shutdown of the system. 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 = battery capacity is near end and device will shut down within the next 15 Minutes,
- Solid red = battery defect).
- Blinking green = AC Power is connected and battery is charging

While running on battery power the AVS beeps every 10 Minutes.

IMPORTANT: *In the event of power glitches or short-term drops in supply voltage (“brownouts”), there is a remote chance that the Validator AVS will fail to fall back to its backup battery. In this case the Validator AVS will reset and potentially lose any study data stored in internal memory. To prevent this from occurring, it is recommended that you connect the Validator AVS to an Uninterruptible Power Supply (UPS) in areas likely to experience brownouts.*

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.**

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).

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



2.3 Sensor Input Modules

The Validator AVS plug-in Sensor Input Modules (SIMs) help reduce the time it takes to perform validation studies. Each SIM has:

- 12 sensor input connections, 6 for RTD SIMs
- 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 help maintain measurement accuracy through changing environmental conditions

Each TC SIM accepts T, J, B, S, R, N and K type thermocouples as well as inputs up to 10 VDC. Using 4 SIMs, you can attach up to 48 inputs in any combination of thermocouples, contact or voltage inputs. For 4 to 10mA current inputs a separate SIM is available.

SIMs are designed to be wired once and used repeatedly. You can wire SIMs yourself, or buy pre-wired SIMs to further reduce preparation time. Once the SIMs are wired, you can calibrate multiple harnesses at the same time and store them for later use, saving you valuable preparation time. 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 will alert you during the qualification run that the SIM is plugged into the wrong instrument or the wrong 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. Make sure all SIMs are connected prior to powering up the Validator AVS, or you will have to 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.

2.3.1 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 8 below shows the inside of a SIM.

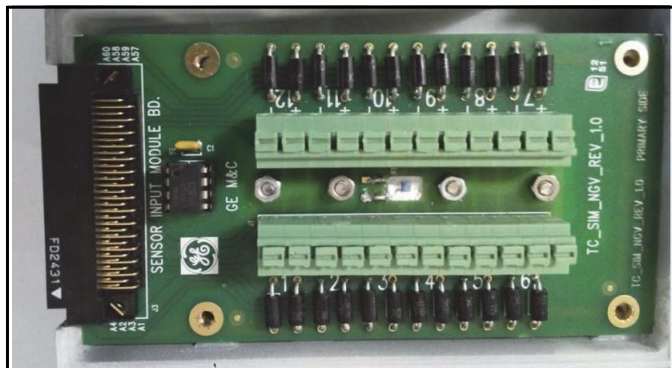


Figure 8: SIM Wiring

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.

3. Connect your inputs. Valid inputs are:
 - Thermocouples T, J, B, S, R, N and K (see *Connecting a Thermocouple* later in this chapter)
 - Contacts (see *Connecting a Contact* later in this chapter)
 - Voltage (see *Connecting a Voltage Input* later in this chapter)
 - Current (see *Connecting a Current Transmitter With a Precision Shunt Resistor* later in this chapter)
4. Release the two keys.
5. Repeat Steps 2 through 4 for remaining sensors.
6. 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 9 below to maintain the thermal accuracy of the module.

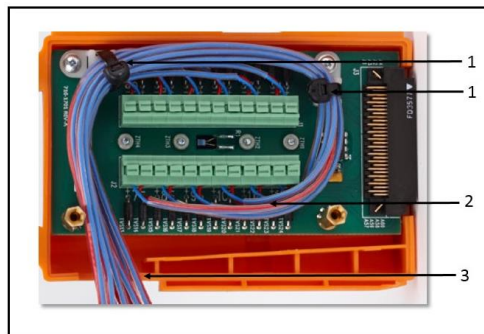


Figure 9: SIM Wiring

Legend:

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

7. Tighten the two screws in the top of the module to close the SIM.
8. 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 Z2036, “4 to 20 mA Sensor Input Module.”*

2.3.1a Connecting a Thermocouple

Connect types J, K and T thermocouples to the connectors as shown in Figure 10 below. Cut through the outer insulation to separate the red and blue wires, and then strip back each wire approximately ½ inch in order to make the connection with the connector.

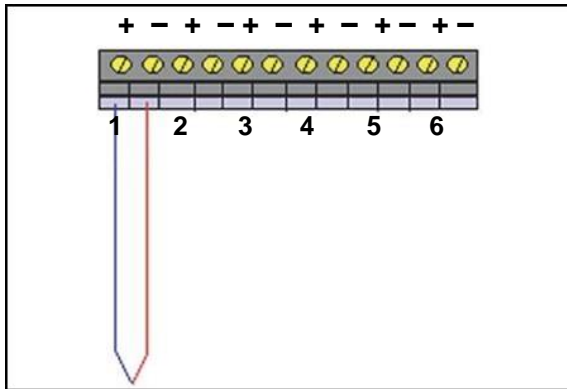


Figure 10: Thermocouple Connections

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

Moist Heat Environments

When validating moist heat processes, a sealed PTFE tip thermocouple should be used with a drip cut (shown in Figure 11 below) on the outer insulation close to the SIM module to reduce the possibility of drawing moisture into the SIM. To add a drip cut, remove 4 inches (10 cm) of the outer insulation from each thermocouple at a point where natural drainage can take place without water reaching the terminal screws (see Figure 11 below).

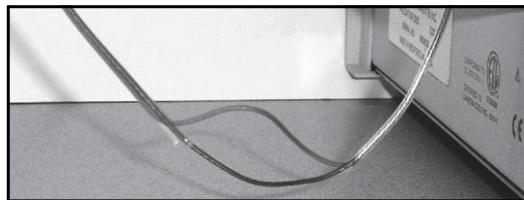


Figure 11: Drip Cut

2.3.1a *Connecting a Thermocouple (cont.)*

Also, it is recommended to shave open about 1/4 inch from each of the red and blue inner wire jackets at opposite ends of the outer insulation drip cut to allow condensate drainage from within the individual wires, as shown in Figure 12 below.

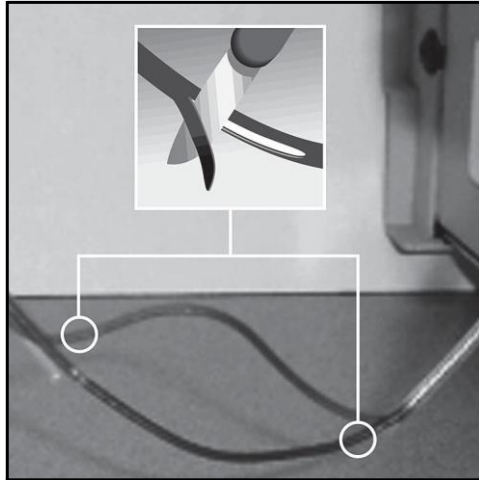


Figure 12: Shaving from Inner Wire Jackets

If moisture does collect in the SIM, remove the SIM from the instrument, open, and allow to 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 13 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.

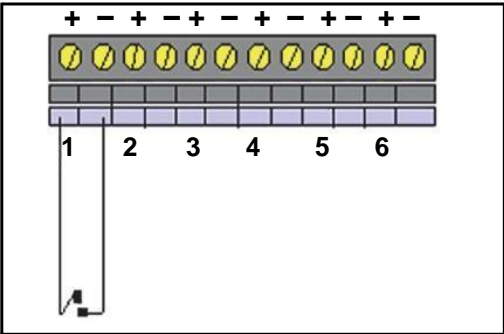


Figure 13: Connecting Dry Contact Inputs

2.3.1c Connecting a Voltage Input

Connect a voltage input (up to 10 VDC) to the connectors, as shown in Figure 14 below. Always connect the positive (+) lead to the positive (+) connector and the negative (-) lead to the negative (-) connector.

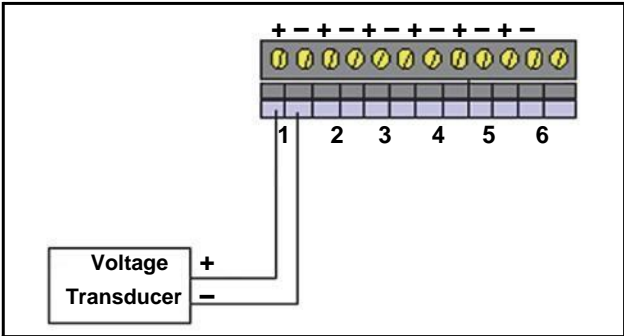


Figure 14: Voltage Input Connection

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 shown in Figure 15 below. A 250 Ω resistor converts a 4-20 mA signal to a Voltage signal. The 62.5 Ω resistor converts a 4-20 mA signal to 0.25-1.25V. These voltages can be defined in the TC setup as voltages accordingly. For easier handling we recommend using the dedicated 4-10mA SIMs in the first place.

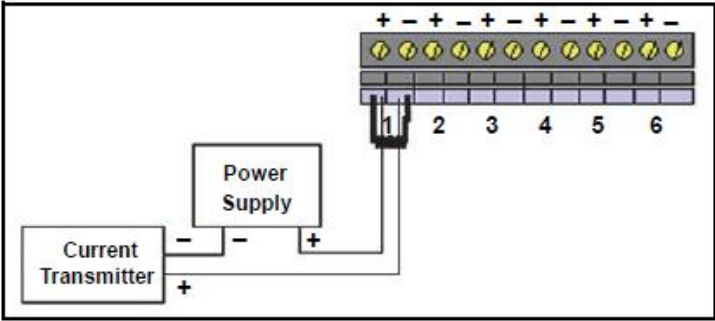


Figure 15: Current Transmitter Connection

The 4-20 mA SIM can be configured in two ways based on the power connections. The user can switch between externally powered or locally powered, based on the placement of the jumper blocks as shown in the figures. Please refer to the wording on the SIM itself to show current jumper placement and orientation.

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

If the sensor requires less than 4mA to operate,

- Connect the positive lead to the positive input channel and the negative lead to the negative input channel, as shown in Figure 1 below.
- Configure the jumper block for Local Power and attach 24V supply to J4.

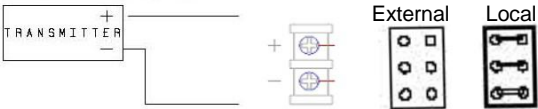


Figure 16: Configuration for Sensor with less than 4mA Power

If the sensor requires More Than 4mA, it will normally have a second set of terminals to supply power.

- Connect the transmitter output to the input channel (+ to + and - to -), as shown in Figure 2.
- Configure the jumper block for External Power.

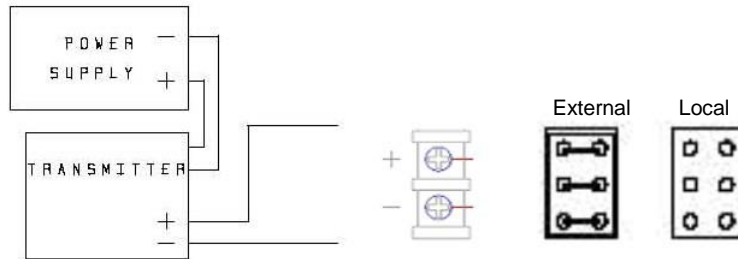


Figure 17: Configuration for Sensor with More than 4 mA Power

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

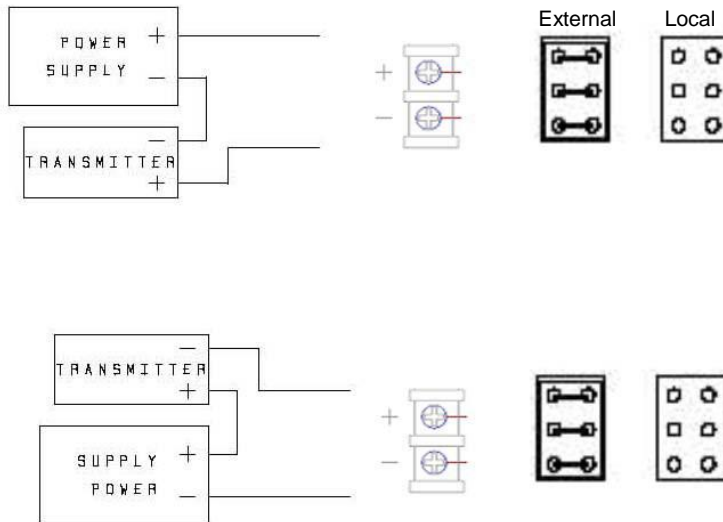


Figure 18: Configuration for Sensor with Less than 4 mA Power (Loop Powered Remotely)

The Red LED (on the SIM) is powered from the AVS and will be on when the AVS is on and the SIM is plugged in. The Green LED is on if the sensor is powered via the external power source connector.

2.4 Kaye IRTD

The Kaye IRTD temperature measurement standard is a self-contained measurement system providing temperature data directly to the Validator AVS software. The measurement accuracy is traceable to the national standard to 0.025°C, with a range of -196°C to 420°C.

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.

The IRTD probe is shipped from the factory with its baud rate set to 9600 and its address set to 01. The Validator AVS communicates with IRTD probes with addresses 01 or 02. However, if both IRTD probes are set to 01, the system displays a communications error. The Validator AVS also reports a communications error if an IRTD is disconnected from the unit during sensor calibration or a qualification study.

2.5 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.

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.

HTR 400 (setpoint range 25°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.

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

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)

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

2.5.1 Sensor and IRTD Installation

The Kaye 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 will result 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-90, LTR -25/140, LTR -40/140, and HTR 400

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

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

IMPORTANT: *The LTR-90 comes with a rubber insulator. This rubber insulator must be used at all times. If it is not used, specifications are not guaranteed. Also, at cold temperatures, there will be significant ice buildup, that will 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-90, LTR -25/140, LTR -40/140, and HTR 400:

- For LTR-90, insert the IRTD through the rubber insulator first.
- Insert the IRTD very slowly 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.

2.5.1 Sensor and IRTD Installation (cont.)

CTR -80

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 access cover, which is 7.5 inches wide, can be used as a measuring device in 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.

2.6 Connecting the System

All system connections are on the back of the Validator AVS. Make sure the unit is powered off before connecting the IRTD, temperature reference (LTR-90, LTR -25/140, LTR -40/140, HTR 400, CTR -80, or CTR -40), and SIMs

To connect your Validator AVS, complete the following steps:

1. Connect the IRTD to one of the 4 pin Din sockets, using the cable supplied for IRTD.
2. Connect the temperature reference to one of the 4 pin Din sockets, using the cable supplied for temperature reference.
3. Insert the wired SIMs into their associated slot positions.
4. Insert the thermocouple sensors into the temperature reference. See the previous section, *Sensor and IRTD Installation*, for installation instructions.
5. Connect your Console to the Validator AVS.
6. Connect the temperature reference power cable and the Validator AVS power cable to a grounded power source.
7. Turn the temperature reference power switch to the ON position.
8. Turn the Validator AVS power switch to the ON position.

IMPORTANT: *SIMs are only recognized by the system properly when you power up the Validator AVS. If a SIM is disconnected after power up and reconnected, offsets and internal SIM data are might not recognized correctly. To rectify this, power down and power back up.*

2.7 Setting the Validator AVS Time and Date

When the Console starts any kind of study, the current time and date are automatically transferred to the attached Validator AVS. No action on your part is required. Refer to the Windows documentation for instructions for changing the date and time.

2.8 Preventive Maintenance

2.8.1 Fuse Replacement

The Validator AVS is equipped with a 250V T 4A fuse. The fuse is located 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.

2.8.2 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 if circuit boards are replaced or added, you may need to certify the calibration more often.

2.9 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 (lb) 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 such as SIMs and cables.

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

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. Creating User Accounts

3.1 Introduction

The Kaye Validator AVS software Password Maintenance utility allows a user with System Administrator permission to create and maintain user accounts, set site options, backup and restore user information, and view, print, and maintain the audit trail. All system administration tasks are accomplished through the Password Maintenance utility program and logged in the audit trail.

The Kaye Validator AVS software includes a Kaye Default System Administrator account that allows you, first to set site options, and then to log in to the Password Maintenance utility, following initial program installation, in order to create your own System Administrator account. The Kaye default System Administrator account is automatically deleted when you exit the Password Maintenance utility. You can then use your own account to perform all your system administration tasks.

In this chapter you:

- Start the program and log in to the Password Maintenance utility using the default System Administrator account
- Set policies and preferences
- Create your System Administrator account
- Create other user accounts
- Upgrade the AVS Firmware
- 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 start menu, you can start the Kaye Validator AVS software or use Kaye legacy software (Administrator password required!).



Figure 19: Login Screen

Once you have started the Validator AVS software, login screen appears as shown in Figure 16 below.

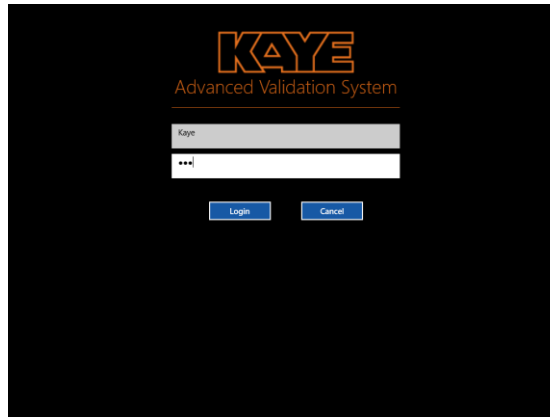


Figure 20: Login Screen

1. Enter “Kaye” in the User ID text box.
“Kaye” is the default System Administrator user ID. The User ID text box is case sensitive. Please make sure you enter the default user ID exactly as it appears here.
2. Enter “411” in the Password text box, as one time default System Administrator password.
3. Press Login.

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

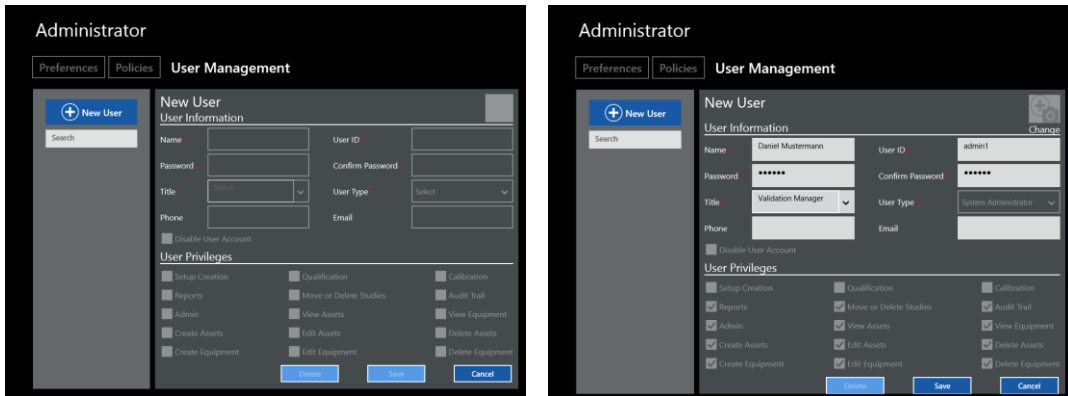


Figure 21: New User Screen - Create initial system administrator

1. Press the blue “New User” button 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 in the **User ID** text box. 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** text box. 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 Kaye Validator AVS Software, you will need to enter your own System Administrator user ID and password. The system is able to 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 accounts and set the preferences and policies as required.

3.2 Logging in as a Default System Administrator (cont.)

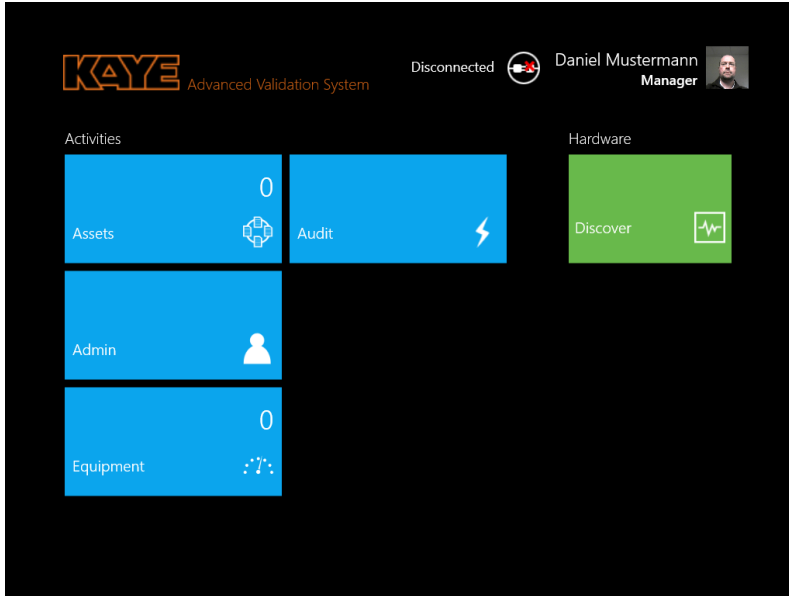


Figure 22: The Main Screen

3.2.1 Creating New System Administrator Accounts

Once you are logged in with the new system administrator account, you can add users 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** pane 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 text box.

3.2.1 Creating Your System Administrator Account (cont.)

The screenshot shows the 'Administrator' interface with the 'User Management' tab selected. On the left, there is a 'New User' button and a search bar. Below the search bar is a list of existing users, including Anna Musterfrau, Axel Musterfrau, John Doe, Ralf Wottrich, and Volker Luebcke. The main area is titled 'New User' and contains the following fields and options:

- User Information:**
 - Name: Volker Luebcke
 - User ID: 111
 - Password: [masked]
 - Confirm Password: [masked]
 - Title: Validation Manager
 - User Type: Supervisor
 - Phone: [empty]
 - Email: [empty]
- Disable User Account
- User Privileges:**
 - Setup Creation
 - Reports
 - Admin
 - Create Assets
 - Create Equipment
 - Qualification
 - Move or Delete Studies
 - View Assets
 - Edit Assets
 - Edit Equipment
 - Calibration
 - Audit Trail
 - View Equipment
 - Delete Assets
 - Delete Equipment

At the bottom of the form are three buttons: 'Delete', 'Save', and 'Cancel'.

Figure 23: 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 the User ID, the User names 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 in to the Validator AVS.

4. Enter your new System Administrator identification in the **User ID** text box. 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** text box. 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.

3.2.1 Creating Your System Administrator Account (cont.)

7. Enter your designation and your contact names. As a system administrator, you should give yourself all User Privileges listed below. 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 users to the system.

3.3 Creating New User Accounts

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

1. From the Admin menu, press User Management and then press New User. The New User screen gets active.
2. Enter the new user name in the Name text box.

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 text box.

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 text box.

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

3.3 Creating User Accounts (Cont.)

5. Enter the temporary password again in the Confirm password text box.

At this point you should record the new account's user ID and temporary password. You will need to supply this information to the new user. A user ID and password is required any time a user:

- Changes system preferences
- Creates or modifies a setup
- Changes the setup stored in the Kaye Validator AVS
- Calibrates sensors or verifies sensor calibration
- Manually stops sensor calibration or calibration verification
- Manually starts or stops a qualification study or exposure cycle
- Deletes or moves calibration or qualification data files
- Accesses report utilities

Note: *A user account is not active until the user changes the temporary password when he or she logs in to the Console for the first time.*

6. Set the default Designation by pressing the entry on the drop-down list.

7. Enter contacts in the Primary Contact and Secondary Contact text boxes.

8. Press on any specific permissions you wish to give a particular user. These permissions can include:

- Create setup
- Stop study
- View or edit reports

9. Press **Save**.

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

3.3.1 Deleting and Disabling User Accounts

Beside the 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 can get automatically disabled after three consecutive login failures if this option is enabled in the Policies (see Chapter 3.5 Setting Policies for details). A disabled user account is marked with red color in the user list but will stay in the alphabetic sort order of users. The disabled state is set with the checkbox “Disabled User Account” in the User Information. By unchecking an Administrator can re-enable the user account.

Deleted User

If a user account is not required anymore an Administrator can delete the account using the delete button at the bottom of the screen. In order to prevent discrepancies in the audit trail the user ID of the deleted user is block for further usage. The delete is marked in yellow and moved to the bottom of the user list automatically. The user information remains visible but is not editable and cannot be activated again.

3.3.1 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. In case there is no known Administrator access anymore to the system possible Kaye can provide a one-time Emergency access with the sole purpose to add a new Administrator account. For this procedure the direct support of Kaye service is required.

In the login screen without any user enter “Ctrl e” into the password field to start the emergency login. Please contact the Kaye support directly to receive the required information. The emergency access is logged in the audit trail.

3.4 Setting Preferences

The screenshot shows the 'Administrator' window with the 'Preferences' tab selected. The settings are as follows:

Field	Value
Company Name	KAYE
Allow Users to change Lethality?	No
Temperature	Celsius
IRTD Stability Threshold Lower Limit	250 °C
Max Groups	20
Alternate Machine ID	
Line Frequency	50 Hz
Machine ID Logo	5649DACE80000B6BB9F Amphenol Advanced Sensors
Pressure	Atmosphere
Display Rate	5/6 seconds
Data Directory	C:\Program Files (x86)\Kaye\Kaye AVS Service\DataFiles\

Figure 24: Preferences Tab in the Admin Menu

The Kaye Validator AVS software installs with default system settings. You can change any or all of the settings on the Preferences screen. The new settings become effective independently.

1. Use the keyboard to enter your company name.
2. 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 (LTR -90 , LTR $-25/140$, LTR $-40/140$, HTR 400, CTR -40 , or CTR -80) are also programmed to operate in these units.

IMPORTANT: *If you create a setup using one temperature unit and then change units on the Preferences screen, you'll be prompted to change to the new settings the next time you save that setup. However, only the label will be changed, not the temperature value. You need to make sure that all temperature values you entered are still appropriate for the new temperature units. For example, if you created a setup using $^{\circ}\text{C}$, you may have entered 100.0°C as a calibration setpoint. If you change the temperature units to $^{\circ}\text{F}$, 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.*

3. 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.
4. Press the 60 Hertz or 50 Hertz radio button to set the line frequency. Choose the setting that matches your environment.

IMPORTANT: *The aye Validator AVS filters noise induced by the AC Power in order 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.*

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.
7. If necessary, you can enter an alternate machine identification number. The machine ID appears in the audit trail for identification of the console.
8. Logo: Import of a custom logo that can be any kind bitmap.
9. Display rate: Defines the rate the live data is updated in the monitoring view. It is not affecting the data storage rate as defined in the setup.
10. The path and folder that holds the Data Directory is displayed.

3.5 Setting Policies

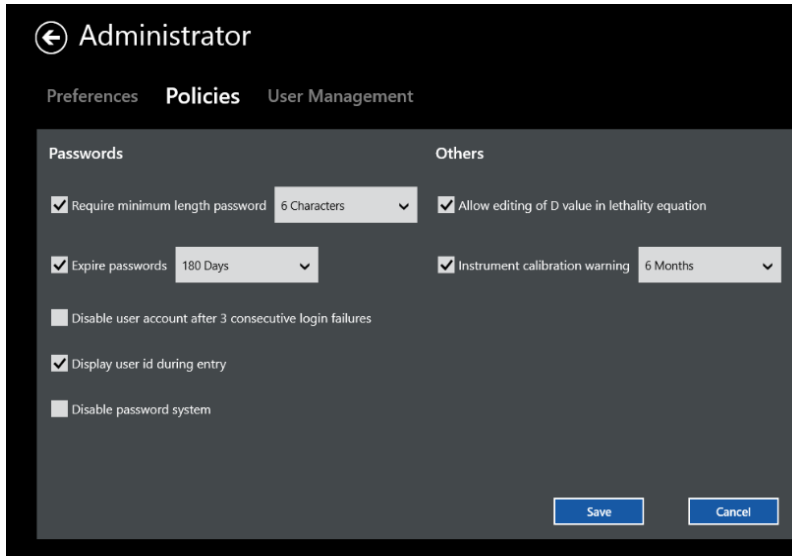


Figure 25: The Policies Tab

The Kaye Validator AVS software allows you to set policies that give users more flexibility 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 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.
- Disable user accounts after 3 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 similar to 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.
- 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 but is not editable when creating a new setup.

3.6 Updating the Kaye Validator AVS Firmware

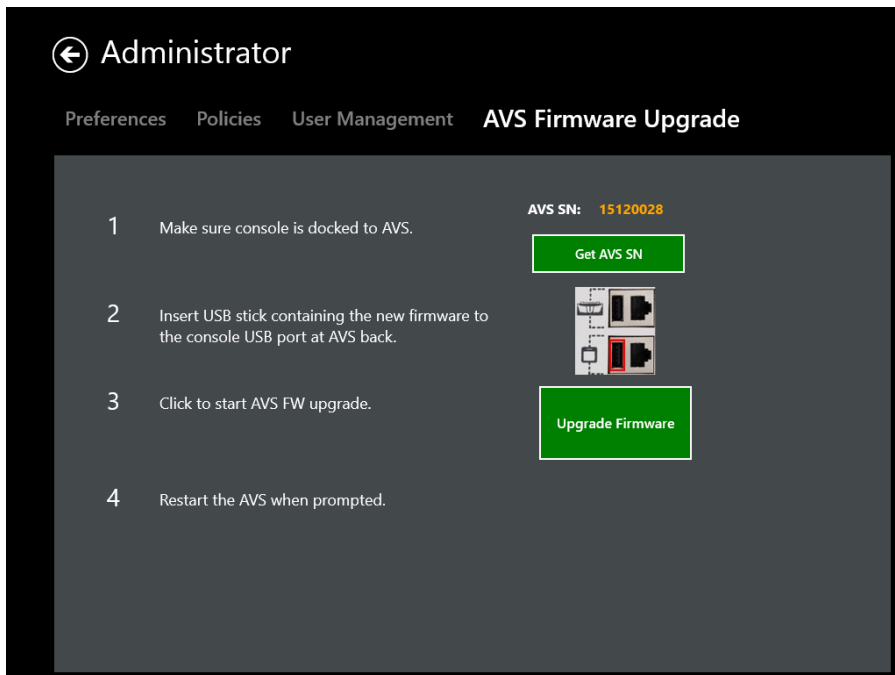


Figure 26: The Firmware Upgrade Tab

A new firmware release upgrade release for the Kaye 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 Kaye Validator AVS that is supposed to get upgraded

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

Press the “Get AVS SN” number to establish a connection to the Kaye Validator AVS. This assures the connectivity and retrieves the serial number for the audit trail entry.

2. 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.
3. Now everything is ready to upgrade the firmware. Please make sure the Validator AVS is properly powered and not switched off during the upgrade process. Otherwise the system can be damaged and need to get restored in a Kaye Service Center.
Press “Upgrade Firmware” and wait until a message tells you to restart the Kaye Validator AVS.

3.7 Handling Data Files

The Kaye Validation console software allows to synchronize data across several consoles. The functionality is also used to backup, restore and archive files. The synchronization requires a location for the commonly used data. This can be any folder the Operating system can access for read/write operations, like a shared folder in the network but also an external drive or USB thump drive or a folder on the Kaye console itself. Please contact your system administrator for setting up a file location.

The sync functions can be used for a simple backup but also to merge the data of several Validation console data sets following some rules for merging:

- 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.
- In case two items have the same name but different dates (reports, study files) both will be retained
-

The sync operations are started from the App command bar, accessible with a swipe from the button up or from the top down. When starting a sync operation the software firstly asks for the 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. In case the data of two or more consoles synchronizes to the same folder the data is merged together which enables to build up a pool of shared data for a work group.

It is selectable which data is actually copied. If an asset is selected the asset with all the information (setups, study files, reports, documents) is copied. It is also 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 and asset data, depending on the setup.

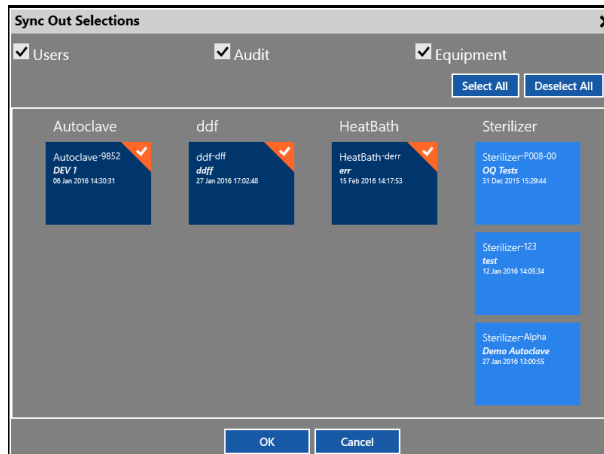


Figure 27: Sync Out selection box

- **Sync In**



The sync in functions 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 dropdown selection. The copied data is merged with the existing console data.

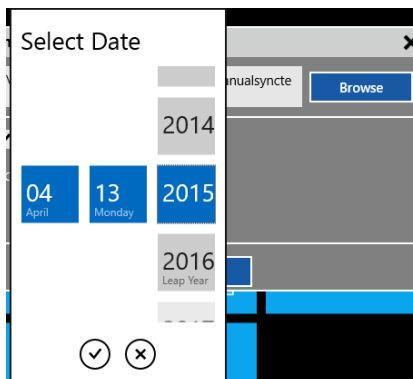


Figure 28: Sync In - Date Filter

- **Archive**



The Archive function works similar to 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 are moved. Like in Sync out the assets can be selected individually.

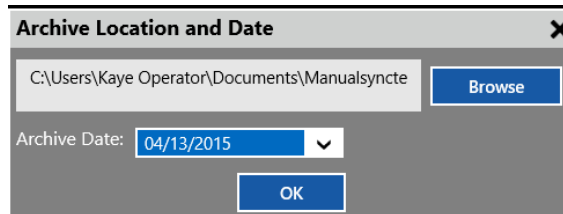
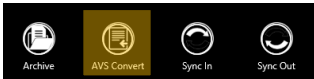


Figure 29: Archive Date Filter

- **AVS Convert**



The AVS Convert function imports single study files into the Asset system of the console. Single study files can be copied to disk out of the Asset details for importing them into another console or send them by email. Also the study files copied through the USB side port copies the files in a single file format that needs to be imported into the AVS software. Simply select a single data file in the browser, it is possible to add a comment for easier identification. If the corresponding asset is not existing already in the system, the software will now create a new asset and setup file from the information stored in the study file.

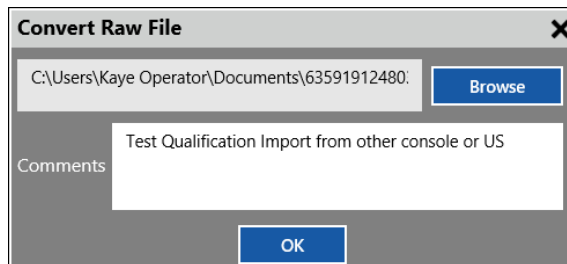


Figure 30: AVS Convert – Import comments

Note: Imported Validator 2000 files are not available under an Asset but in the report tool under the tile “Others”.

3.8 Online Help

For online help, you need to swipe from the bottom or top edge for the app commands. There are two icons with a question mark, labeled as “Windows Help” and “Help”. While “Windows Help” shows the help screen of the operating system, the “Help” button displays context-specific help for that AVS application specific screen.

Chapter 4. Defining Equipment

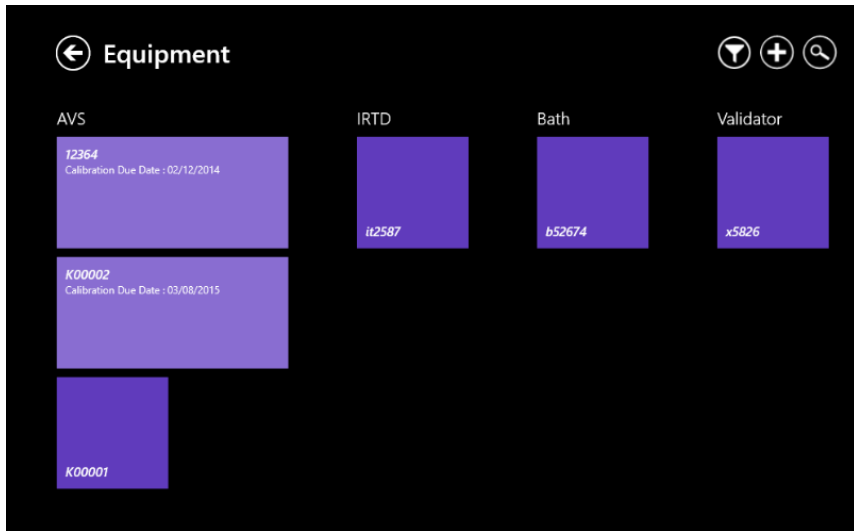


Figure 31: Equipment Hub

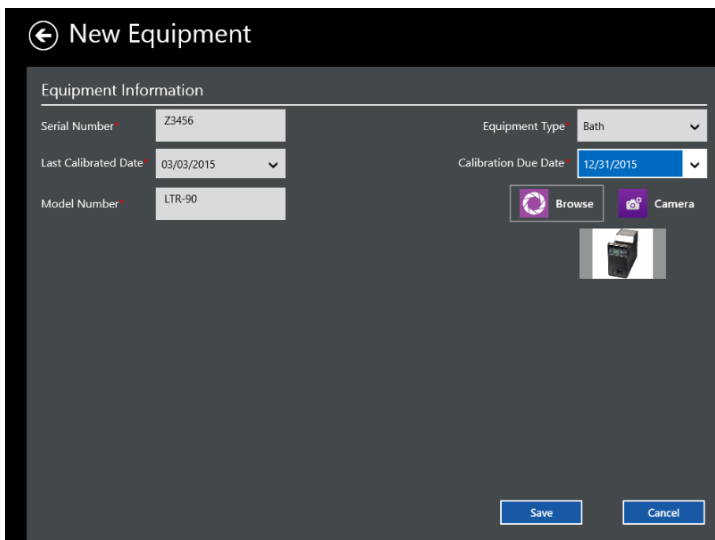
The Kaye Validator AVS software supports organizing the Kaye Validation Equipment. Accessed from the Main Menu, the Equipment hub displays Kaye equipment like Validator AVS, IRTD etc. as single tiles. Following functionality is provided:

- Database of all used Kaye Equipment identified by serial number with calibration information and optional picture.
- Calibration reminder based on the calibration reminder setting in the preferences and the calibration due date.
- Search study files where a particular Kaye equipment was used. The search bases on the entered serial ID of the Kaye equipment and the automatically retrieved serial numbers saved within the study files. For temperature bath no serial is retrieved.

Note: *In the current software version IRTD serial search is not supported, yet.*

4.1 Adding New Equipment

To add a new piece of Kaye equipment to your Kaye Validator AVS system, press the plus (+) icon on Equipment Hub screen. The New Equipment screen opens.



The screenshot shows the 'New Equipment' screen with the following details:

Equipment Information	
Serial Number	Z3456
Last Calibrated Date	03/03/2015
Model Number	LTR-90
Equipment Type	Bath
Calibration Due Date	12/31/2015

Buttons: Browse, Camera, Save, Cancel

Figure 32: New Equipment Screen

You enter details separately for each new piece of equipment. Use the text boxes and drop-down menus to enter:

- The Equipment Serial number as unique identifier
- Last Calibrated Date
- The model number
- The Equipment Type
- The Calibration Due Date

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

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

4.2 Checking Details for Existing Equipment

To review the details for a particular piece of Kaye equipment press the tile for that particular item on the Equipment Hub screen. The Equipment Details screen opens.

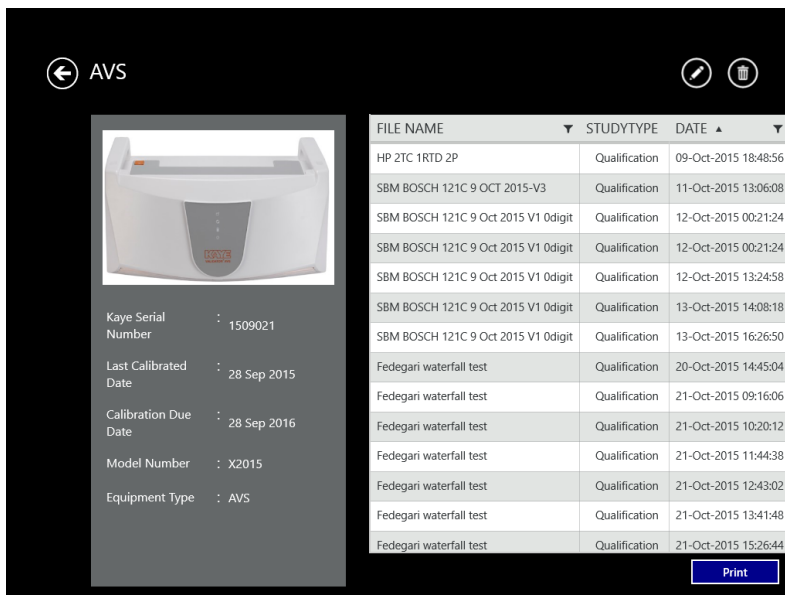


Figure 33: The Equipment Details Screen

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

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

Press the **Edit** button to change any of these parameters. On the left side of the screen shows the study files associated to this equipment.

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

Note: *In the current software version IRTD serial search is not supported, yet.*

4.3 The Calibration reminder

The calibration build in calibration reminder supports the operator not to miss the calibration due dates.

In the first step, it is necessary to activate and set the calibration reminder timeframe in the policies as described in 3.5 in this manual. As soon as the equipment calibration due date, as entered in the equipment details, is within the calibration warning message timeframe, the software will remind the operator:

- In the Equipment tile in the Main screen the Equipment tile will display a number corresponding to the number of equipment due for calibration.
- When opening the Equipment the tiles for equipment due for calibration will be displayed enlarged in light blue and showing the calibration due date directly within the tile.

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

Chapter 5. Defining Assets

The Kaye Validator AVS includes an intuitive Asset Centric Data Management concept (patent pending) which allows you to 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 even 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, manufacturer etc. for easy access.

To open the Assets Hub, press the Assets tile on Main Menu. The Assets Hub appears similar to Figure below.

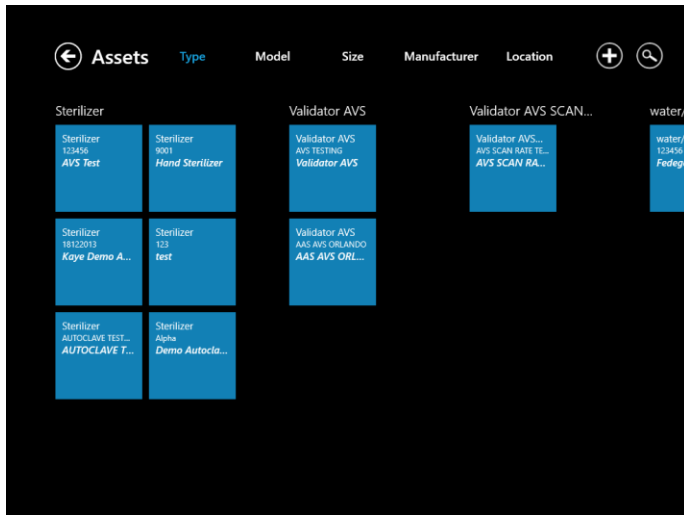


Figure 34: The Assets Hub

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

- Type (sterilizer, dry heat oven, controlled temperature, etc.) up to 20 user-designated types
- Model number
- Size (in units of cubic feet, cubic meters, or cubic inches)
- 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 the other assets.

To search for a particular asset, press on the Search (magnifying glass) icon, and a text box enables entering search 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 The Asset Details Screen

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

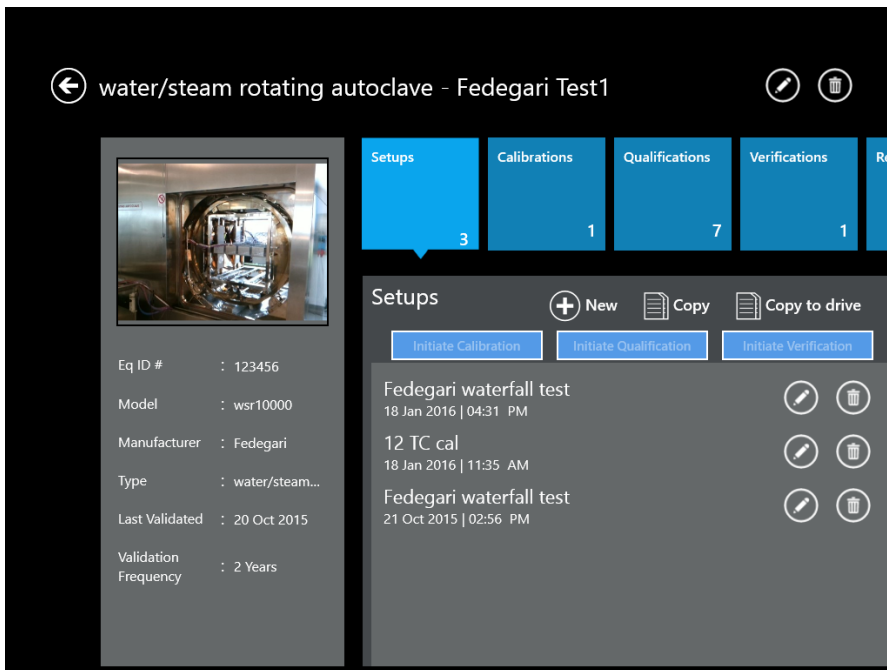


Figure 35: Asset Details

In the upper left, the title will be the type and name of the asset. The pane on the left displays up to three user-loaded photos (swipe to change to the next picture) of the asset, and lists the asset information as entered by the user with following data:

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

At the upper right, tiles list the following categories associated with this asset:

- Setups
- Calibrations
- Qualifications
- Verifications
- Reports
- Documents

The number on the tile represents the number of available files under this specific tile. Press on a given tile, and the lower right window displays the list of related data.

For setups, the panel displays the latest setup files. If more setup files are in the database, the option, “Other Setups” shows the number of additional associated setups. Press a downward arrow to launch the Setup List page. On the list page, users can apply predefined Filter options (Status, Activity, Setup Name, Date, Comments, and Actions) to sort the files. You also start create a new setup by pressing the **Create New Setup** button.

A setup for the Asset holds all information necessary to define the sensors, groups wiring diagram, calculations, calibration, verification and qualification parameters required for a validation study. The “(+) New” buttons creates a new setup from the scratch but it is also possible to copy existing setups from other assets as templates. Pressing the copy button beside the “New” button opens a list of all available setups on the machine. Depending on the number of assets and setups the population of this list might take some minutes.

In this list the Assets are listed with names and setups listed with the setup name, number of sensors, comments and last modification date. The last column let you select the setups you want to copy to the asset.

With the “Copy to drive” button it is possible to copy the selected setup file to a chosen folder. With the new Kaye Validator AVS system it is not necessary anymore to transfer setups via an USB thumb drive anymore. The functionality is purely for possible support analysis by the Kaye support that might request a setup file from the operator for analysis of issues with a study run.

Every existing setup can be individually edited (by pressing the pencil button) or deleted (by pressing the trash bin button).

Calibrations, Qualifications and verifications are started from the setups page of the asset. Firstly select a setup to activate the initiate buttons. Pressing one of these buttons starts a calibration, qualification or verification. The “Hardware Discovery” screen will appear and the setup transferred to the selected Kaye Validator AVS.

The Calibration tile provides a list of all available calibration study files with the setup name, the date, run number and comments. After selecting a study file, it is possible to seamlessly open the report tool and create the report from here. Similar to the setup files can be also displayed in a list, deleted or copied to a drive. Copied study files can be reimported to other Kaye Validation Consoles using the “AVS convert” import function of the command center.

Under the Qualification and Verification tile, the similar functionality, starting the report tool, copy or delete files, is provided for qualification or Verification study files, too.

For reports, the tile displays all already generated and available setup, calibration, qualification and verification reports. The documents are sorted under the tabs and can be directly displayed in the seamlessly integrated pdf-reader for review or printing.

For documents, the pane provide option to upload any pdf documents related to the Asset like e.g. wiring diagrams, SOPs or calibration certificates..

5.2 The 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.

New Asset

Asset Details

Name	Fedegari Test1	Description	Superheated water/steam rotating autoclave at Fedegari, IT
Eq ID #	123456	Assets Images	Browse Camera
Type	water/steam rotating autoclave	Wiring Overlay	Browse Camera
Model	wsr10000		
Size	2.6 cu m		
Manufacturer	Fedegari		
Last Validated	10/20/2015		
Validation Frequency	2 Years		
Location	Fedegari IT		

Save Cancel

Figure 36: New Asset Screen

You enter details separately for each new asset. Use the text boxes and drop-down menus to enter:

- The asset name. Asset names have to be unique. Before synchronizing several asset data sets it is recommended to make sure that there are no duplicate names.
- The Equipment ID: Equipment IDs have to be unique.
- The type of asset: Any new type definition will be available in the dropdown in the future. Please be careful as also test types or wrong spelled types will be available in the dropdown.
- The model number: Specifies the
- The size in cubic units: In the dropdown it is possible to select the appropriate units or enter custom units. For the sort function only the number is used, therefore it is recommended to use a unified unit.
- The manufacturer: Specify the manufacturers name
- The Validation frequency: Specify the required validation frequency.
- Location: Specify the location of the asset

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.

Chapter 6. Defining Study Setups

Before you can run a qualification study, you must use the Kaye 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).*

You access setups from the Asset Details screen, through the Setup pane. When you create a setup, you:

- Define the sensors you are going to use in the 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 the output relays

After you have created and saved your setup, you can calibrate sensors and run a qualification study.

6.1 Create a Setup File

A setup defines everything required to calibrate sensors and run a qualification study for a specific asset. You create setup files from the Setup screens, from Setup pane in Asset Details. You must have permissions assigned by your System Administrator to create setups.

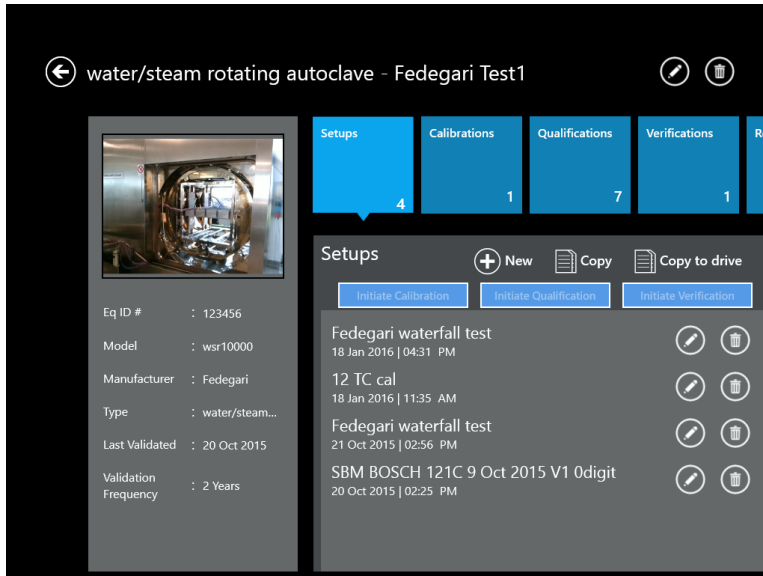


Figure 37: The Setup Hub Screen

To create a setup file:

- From the Asset Details screen for a particular asset, press Setups. In the Setup pane Hub, press New Setup to enter the Study Details screen.
- Now you can 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

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

- From the Setup Hub screen for your asset, select the setup file that you want to modify

You must have user permissions to modify a setup.

6.3 The Define Setup Screen

After you have pressed the New Setup button in the Setup Hub pane of Asset Details screens, the Define Setup screen opens.

Figure 38: The Define Setup Screen

Here you define the setup for a study. Use the text boxes or drop-down lists to enter:

- The Setup Name
- The Number of Sensors
- 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, while the EQ ID, Load Description and SOP fields can also accept special characters (hyphen, underscore, forward and backward slash.)

When you have completed entering asset data, press the **Sensors Configuration** button at the upper right to continue.

6.4 The Sensors Configuration Screen

From the Study Details screen, press **Sensors Configuration** to open the Sensors Configuration screen. Below the current study title, asset and ID number, the header row shows that you have reached the Sensors Configuration screen, in the setup creation process.

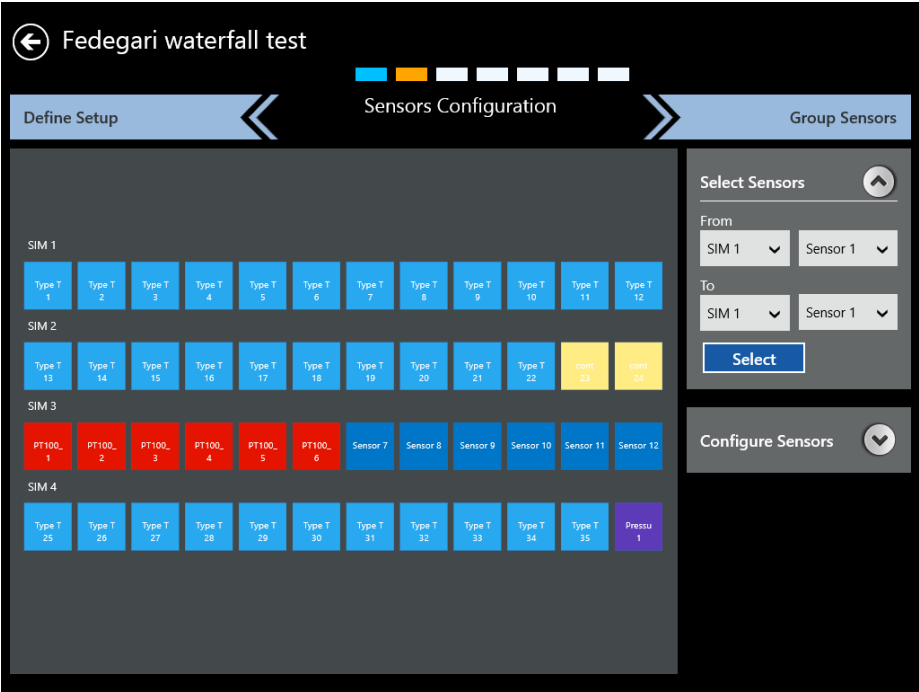


Figure 39: The Sensors Configuration Screen

The Sensors Configuration screen graphically represents the four Sensor Input Modules labeled SIM 1, SIM 2, SIM 3 and SIM 4. The numbers on the icons correspond to the numbers on the input connectors (up to 12) mounted inside the SIM.

For an initial setup, all the input connector tiles are blue, to indicate that they have not been selected. Press an individual connector tile to select it, and the tile turns to dark blue, with a selection icon in the upper right corner. You can also select a series of sensors in the Select Sensors series of drop-down boxes at the right. Select a range of sensors from one SIM to another SIM, press Select, and those sensors all appear as selected on the left pane. To deselect a sensor, press on the individual sensor, or select a range of previously selected sensors on the Select Sensors pane, and press **Select**.

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

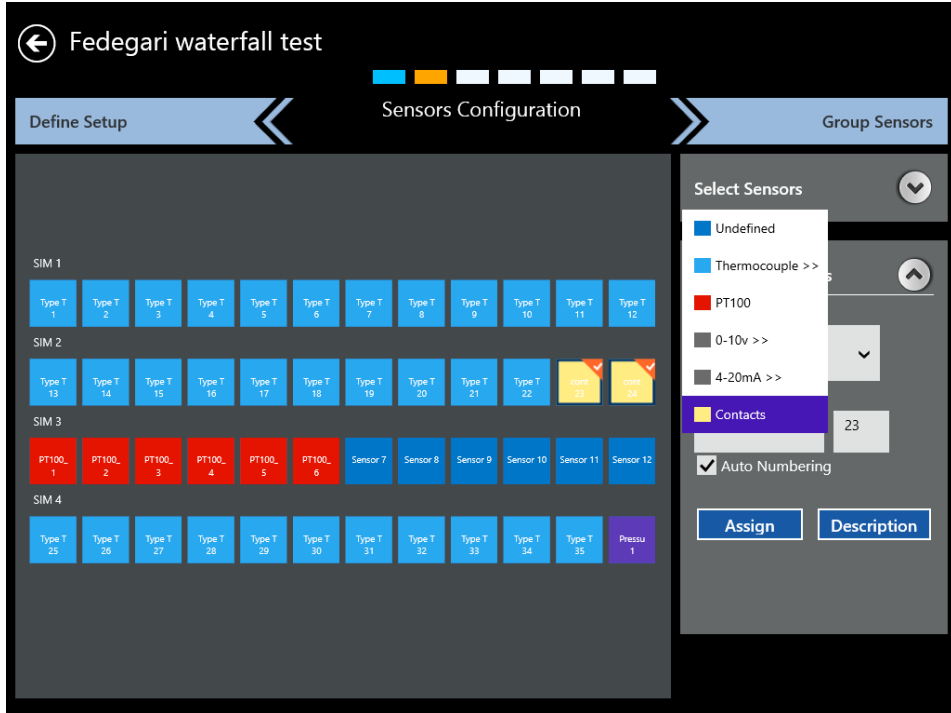


Figure 40: Configuring Sensors

IMPORTANT: If one sensor type is selected for a SIM, then all sensors in that SIM should be of the same type. Mixed sensor types are not allowed within a SIM.

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

- Thermocouple (Sub Types) J, K, T, E, B, R, S, N
- Voltage
- Current
- Pressure (V or mA)
- Contacts (Open/close, On/Off, 1/0).
- RTD (PT100, 4-Wire)

For voltage, you can enter up to 3 decimal values in the input and output fields. The default values are: Input Min = 0.00 V, Input Max = 10.00 V, Output Min = 0.00 Output Max = 10.00. The input voltage range can be -1 to 12 V.

For current, you can enter up to 3 decimal values in the input and output fields. The default values are: Input Min = 4.00 mA, Input Max = 20.00 mA, Output Min = 0.00, Output Max = 10.00. The range of input current is from 1 up to 25 mA.

For pressure:

You can enter up to 3 decimal values in the voltage input and output fields. The default values are: Input Min = 0.00 V, Input Max = 10.00 V, Output Min = 0.00 Output Max = 10.00. The input voltage range can be -1 to 12 V.

You can enter up to 3 decimal values in the current input and output fields. The default values are: Input Min = 4.00 mA, Input Max = 20.00 mA, Output Min = 0.00, Output Max = 10.00. The range of input current is from 1 up to 25 mA.

In the last step the sensor input is marked with a Description sensor label number, and to enable/disable auto numbering. Auto numbering is enabled only if more than one sensor is selected. After the sensor configuration pressing the **Group Sensors** tab to the right advances to the next screen.

6.5 Understanding Groups

Grouping is a key concept of the Kaye Validator AVS software. After your qualification study is complete, grouping allows you to customize your reports. Use the following guidelines when defining 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 can assign a sensor to more than one group to relate the sensor's output to different conditions. For example, you might have the same sensors in more than one group to look at data over different intervals. You could specify the maximum sensor reading during exposure for one group, and specify the maximum sensor reading during the entire qualification cycle for another 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.

6.6 Assigning Sensors to Groups

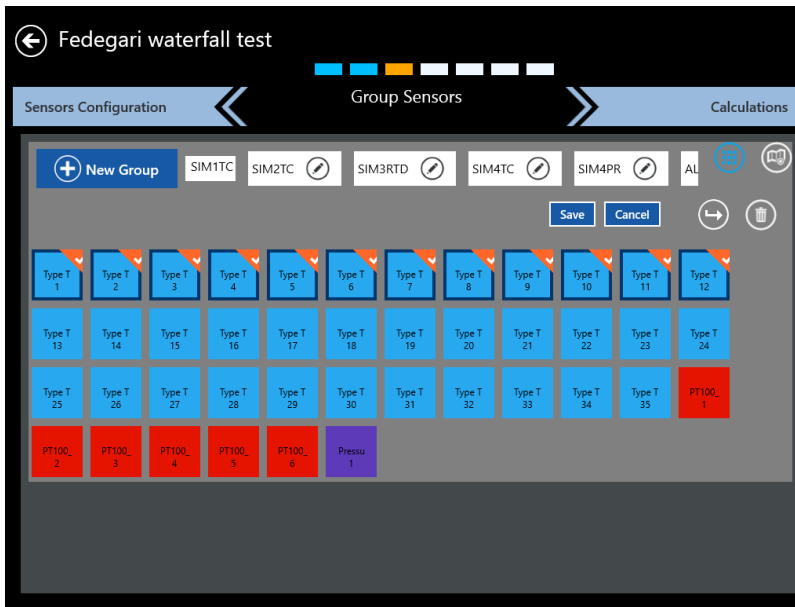


Figure 41: The Group Sensors Screen

On the Group Sensors screen, sensors from any SIM are assigned to groups. The same sensor can be assigned to multiple groups.

After the configuration of the sensors, the next step is to group them by pressing the Group Sensors button. 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 will automatically generate groups for sensors with the same measured variable, like Temperature, Voltage, Current etc. To assign sensors to groups:

1. Press on individual sensors to select them for the group. These sensors now appear as a deep blue with an orange checkbox.
2. Press the New Group button. A Group Name text box appears on the screen.

The Group name text box should allow characters that can be upper and lower case, numerics, special character like hyphen, underscore, slash (forward and backward) and blank. Enter the name, and toggle the save button to save the group.

The screen also offers the following options:

- Delete - permits deletion of a group of sensor
- Move Sensors - permits moving sensors to another sensor group (specified in drop-down list)
- Add Sensors - allows users to add further sensors to a group
- Wiring overlay – accessible via the book icon - enables displaying the wiring overlay graphic:

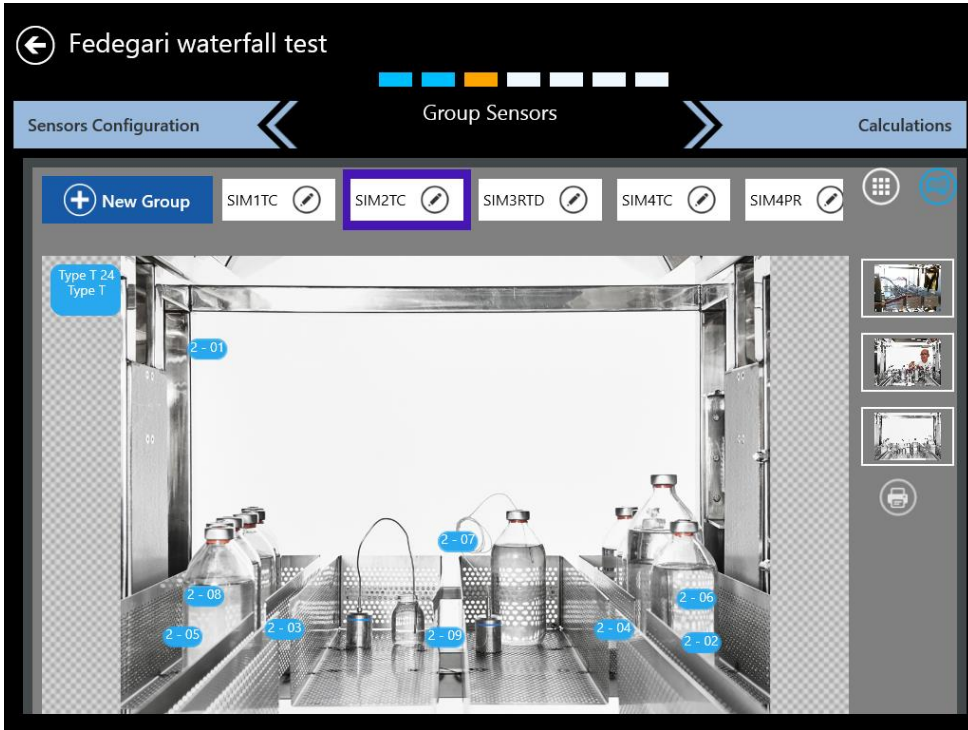


Figure 42: Wiring Overlay Diagram

In the wiring overlay one of the pictures predefined in the asset details can be chosen as a background while the sensors per group can be dragged into the picture to reflect the position during the study. The sensor positions are stored in the setup. The printer button enables the export of the wiring overlay to a pdf file that can be uploaded to the asset with the upload document function in the asset details.

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

6.7 Specifying Group Calculations



Figure 43: Calculations

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

The Statistical Calculations are all fixed preselected by default and will be all calculated.

***Note:** Lethality calculations needs to be defined in the setup!*

It is also possible to define events to monitor during the study. These events are listed in the reports and can be imported into the define cycles screen of the reporting tool.

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

6.8 Specifying Calibration Parameters

← Fedegari waterfall test

Calculations << Cal/Ver Parameters >> Qualification Parameters

Calibration Temperature Setpoints

Low 90.0 °C

High 125.0 °C

Check 121.0 °C

Deviation Criteria

Uncalibrated Sensor 2.0 °C

Calibrated Sensor 0.5 °C for 3 Minutes

Verification Temperature Setpoints

Low 90.0 °C

High 125.0 °C

Check 121.0 °C

Deviation Criteria

Calibrated Sensor 0.5 °C for 3 Minutes

Stability Criteria

Sensors 0.2 °C for 3 Minutes

IRTD 0.012 °C for 3 Minutes

Figure 44: Calibration Parameters Screen

The Kaye Validator AVS provides both sensor calibration and calibration verification.

Before performing a qualification study, calibrate the temperature sensors to correct raw temperature readings to a NIST-traceable temperature standard. During calibration the Kaye Validator AVS automatically corrects raw temperature sensor readings to a NIST-traceable temperature standard to compensate for any errors inherent in sensor materials, and stores these offsets in the associated SIMs. You can specify a two-point calibration, or a two-point calibration with one check point.

Sensors that do not meet the calibration test criteria for uncalibrated sensors are marked as failed and are not calibrated. A Calibration signature will be matched before running a Qualification, Calibration or Verification process. Calibration and Verification Temperatures, chosen Set points, Stability criteria and Deviation criteria together constitute 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 to 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 the calibration parameters by specifying:

- Temperature setpoints for calibration. You have to 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 check point for calibration verification.
- 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 Parameters** 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
- Data storage options - the rates at which data is written to disk during a qualification run
- Output relay - the events that activate the two independent output relay

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

6.10 Reviewing and Changing the Setup

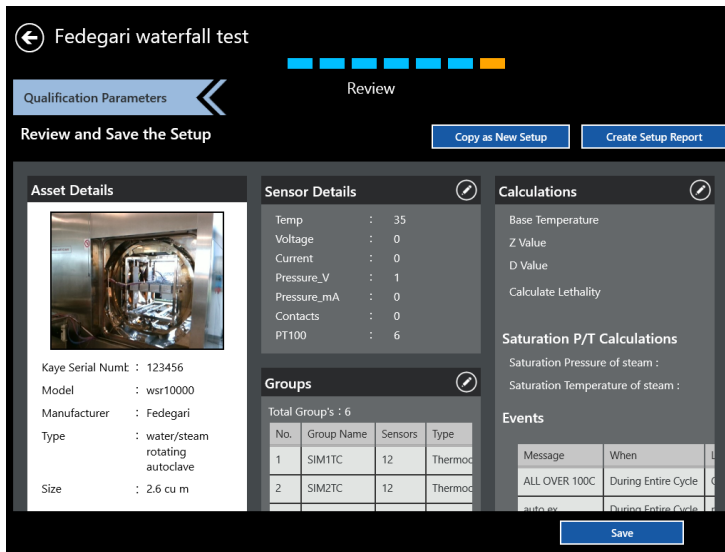


Figure 45: The Setup Review Screen

After you have finished entering qualification parameters, press the Review button. The Review screen opens, listing all the pertinent details about the setup you have just created. Review screen provide following actions you can take:

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

The screen also shows 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 the back button** 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 Kaye 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:

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

The Kaye 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 Kaye Validator AVS, you calibrate sensors at a low setpoint and a high setpoint. When you start calibration, the Kaye 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 Kaye Validator AVS logs the stability readings to the calibration report file. The Kaye Validator AVS then computes and logs deviation on the uncalibrated sensors, and calibrates all sensors that passed the deviation criteria. Finally, the Kaye Validator AVS computes and logs deviation on the calibrated sensors for a specified time period.

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

When calibration is complete, the Kaye Validator AVS writes the calibration offsets, the serial number of the Kaye Validator AVS measurement board where calibration was performed, 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 Kaye Validator AVS in a location with stable and even temperature, 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 Kaye Validator AVS and let it run for approximately 30 minutes in the operating environment where calibration is to be performed in order for the Kaye Validator AVS to acclimate to the ambient temperature.
- Place the temperature sensors and the IRTD into the temperature reference. The temperature reference provides the stable temperature required for sensor calibration.

7.2 Loading a Setup into the Validator AVS

Before you begin the calibration or calibration verification process, you have to load your setup into the Kaye Validator AVS. If a Kaye IRTD is used then connect Kaye IRTD to top port of 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 will be 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 are marked as calibrated.*

When you load a setup with a different line frequency than the setup currently in memory, you must wait for the Kaye Validator AVS to stabilize (approximately 2 - 3 minutes) before calibrating sensors or verifying sensor calibration or you may see invalid sensor data displayed. You can also turn the Kaye Validator AVS off and then back on, and then calibrate your sensors or verify sensor calibration.

To load a setup:

- From the Main Menu go to the Asset details and then select a setup from list of available setups. Now the buttons for initiating a study are active, and pressing “Initiate Calibration” or “Initiate Verification” starts the corresponding process.

Select the Kaye Validator AVS to use. The docking mode is already preselected but it is possible to select any AVS from the list populated after pressing the discovery button, of Kaye Validators AVS that are currently available through a network connection and idle. Select the desired Kaye Validator AVS and press the “Connect” button (see also Chapter 8 for details of selecting a Kaye Validator AVS).

The Kaye Validator AVS loads the setup and reads sensor information. This process may take a few seconds to complete. The Console then proceeds to the Sensor Selection screen.

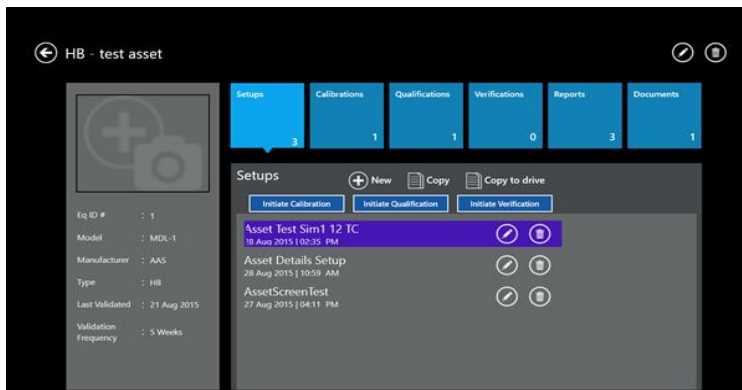


Figure 46: Initiate a Calibration from Asset Setups

7.3 Selecting Sensors

You select the sensors to be calibrated or verified on the Select Sensors screen. This screen (Figure 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.

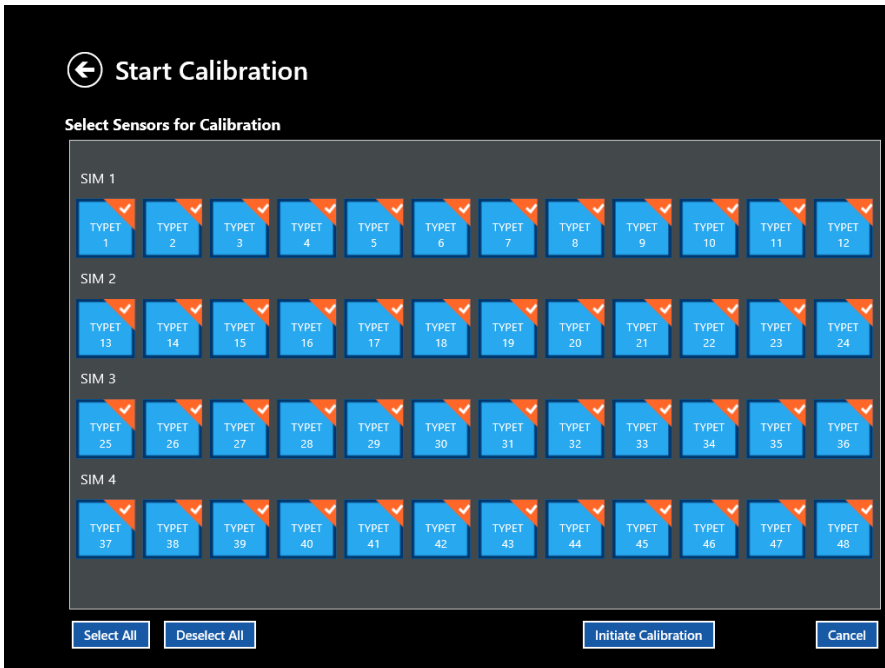


Figure 47: Sensor Selection Screen

- To select sensors individually, press the individual sensor tile. The icon color changes to deep blue and the check box 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 the sensor selections and return to a fresh screen. Press the return button in the upper left to exit the option.)

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

7.4 Calibrating or Verifying Sensors

The Calibration study can be started in the calibration study screen by pressing the start button. The Kaye 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 setting via the Criteria button before starting the run to allow to adapt to changed requirements.

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

Note: It is recommended to make sure live data is actually displayed from connected sensors and IRTD before starting the study.

The screenshot shows the 'Sensor Calibration' interface. At the top, it displays 'AVS S/N : 15120052', 'Graph View', and 'List View'. Below this, it shows 'Asset : AVS ACCURACY TEST', 'Setup : V 48TCs V22 LTR-140 V1', and 'No. of Sensors : 48'. There are two main sections for 'Low Point 90 °C' and 'High Point 130 °C'. The 'Low Point' section shows an IRTD of 89.936 °C and a stability of 0.002 with a green checkmark. The 'High Point' section shows an IRTD of 111.545 °C and a stability of ****. To the right, there are buttons for 'Check F', 'Hardware', and 'Criteria'. A date and time stamp '31-Mar-2016 13:50:34' is visible. Below these are three tables for 'Sim 1' and a 'Checklist' on the right.

Label	Temp	Stability	Dev.
Sim 1			
TYPET 1	89.93 °C	0.03	-0.01
TYPET 2	89.94 °C	0.02	0.00
TYPET 3	89.94 °C	0.02	0.00
TYPET 4	89.94 °C	0.02	0.00
TYPET 5	89.93 °C	0.01	-0.01
TYPET 6	89.93 °C	0.02	-0.01
TYPET 7	89.93 °C	0.02	-0.01
TYPET 8	89.94 °C	0.02	0.00
TYPET 9	89.94 °C	0.01	0.00
TYPET 10	89.94 °C	0.02	0.00
TYPET 11	89.93 °C	0.01	-0.01
TYPET 12	89.93 °C	0.01	-0.01

Label	Temp	Stability	Dev.
Sim 1			
TYPET 1	124.15 °C	****	****
TYPET 2	124.16 °C	****	****
TYPET 3	124.18 °C	****	****
TYPET 4	124.20 °C	****	****
TYPET 5	124.22 °C	****	****
TYPET 6	124.22 °C	****	****
TYPET 7	124.26 °C	****	****
TYPET 8	124.28 °C	****	****
TYPET 9	124.30 °C	****	****
TYPET 10	124.31 °C	****	****
TYPET 11	124.34 °C	****	****
TYPET 12	124.35 °C	****	****

Label
Sim 1
TYPET 1
TYPET 2
TYPET 3
TYPET 4
TYPET 5
TYPET 6
TYPET 7
TYPET 8
TYPET 9
TYPET 10
TYPET 11
TYPET 12

Checklist
Time Elapsed: 00:01:48

- Temperature reference set
- IRTD temperature standard stabilized
- Sensors and IRTD stabilized
- Deviation calculated on uncalibrated sensors
- Sensors calibrated
- Deviation calculated on calibrated sensors
- Saving calibrated temperatures to file
- Calibration point completed

Start Cancel

Save Study

Figure 48: Calibration Study Screen

The Kaye Validator AVS clears calibration offsets stored in the SIMs for the selected sensors, and establishes communications with the temperature reference and the IRTD. The Calibration screen displays the temperature readings and stability readings for each sensor being

calibrated, the temperature and stability readings of the IRTD, 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 the temperature set points displayed at the top of each block along with °C or °F. Each block also has an interior header with the heads Temperature, Stability and Deviation. (On the first block, the 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. The Stop Calibration button enables you to stop calibration.

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

Note: *All calibration offsets will be 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 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 calibration, the Kaye Validator AVS software detects whether or not a Kaye temperature reference and an IRTD are connected. Both are required for fully automatic operation. If either the Kaye temperature reference or the IRTD is not found calibration verification switches to semi-automatic mode. If neither can be found, calibration verification switches to manual mode.

7.4.2 Calculate Stability

The first step in the calibration process is to verify that the sensors and IRTD are stable. 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 stability calculation begins once the temperature reference is within 5 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.

When stable, the sensor and IRTD readings change to a green background. If any sensors fail to reach stability, the calibration process remains there.

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

7.4.3 Calculate Deviation of Uncalibrated Sensors

When the IRTD and all sensors reach stability, the Kaye 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 Kaye Validator AVS marks any sensor outside the deviation criteria as failed. When uncalibrated deviation is complete, the Kaye Validator AVS calibrates all sensors that passed uncalibrated deviation at the low setpoint.

7.4.4 Calculate Deviation of Calibrated Sensors

The Kaye Validator AVS then calculates calibrated deviation. The corrected results for each sensor are compared to the IRTD, and logged and displayed on the Data screen every 5 or 10 seconds as per display rate for the time period specified in the setup. Sensors that fail the calibrated deviation evaluation are displayed with a red background, and marked as failed in the calibration report file.

7.4.5 Data Logging Complete at Setpoint

When the Kaye 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 calibration process is complete for the high setpoint, the Kaye Validator AVS automatically sets the Kaye temperature reference to the check setpoint. The only difference between the low and high setpoint calibration and the check setpoint is that calibration offsets are not changed during check setpoint.

7.4.6 The 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

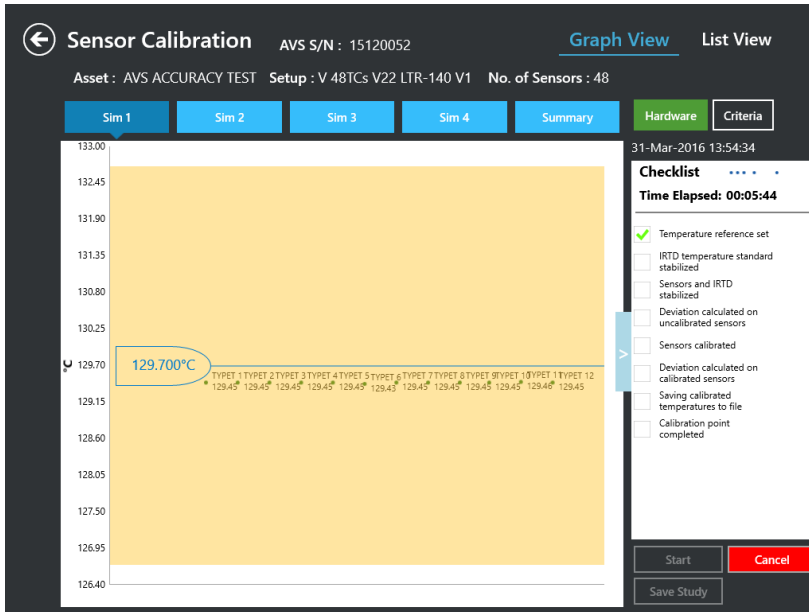


Figure 49: Calibration Study -- Graph View

On the graph, the temperature appears on the Y axis, while the highlighted X axis shows the stabilized IRTD temperature. All the sample points that lie within the deviation specified are displayed in green dots along with the label and the temperature point of the sensor. All the samples that deviated from the specification are displayed in red dots along with the label of the sensor, the temperature point of the sensor and the value that indicates how much the sensor is off.

On the summary tab, the outliers of all the SIM are displayed, along with the SIM number, sensor label, the temperature point of the sensor and the value of how much the sensor is off.

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 -- A calibration checklist allows users to keep track of their 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 Reasons for Calibration Failure

Calibration or verification might fail for one of four reasons:

- Failed calibrated deviation
- Failed uncalibrated deviation
- Failed calibration due to Unstable IRTD and loggers
- Failed calibration due to not enough data

Data for a live calibration or verification refreshes every 5 or 10 seconds as per display rate.

Chapter 8. Viewing Live Data

Once you have entered a setup into your Validator AVS, you can monitor live data or calibration or qualification study progress on the Console.

8.1 Select Validator AVS

From the Main Menu the hardware area in the center displays a tile, **Discover**. Press this tile to open select Validator AVS window.

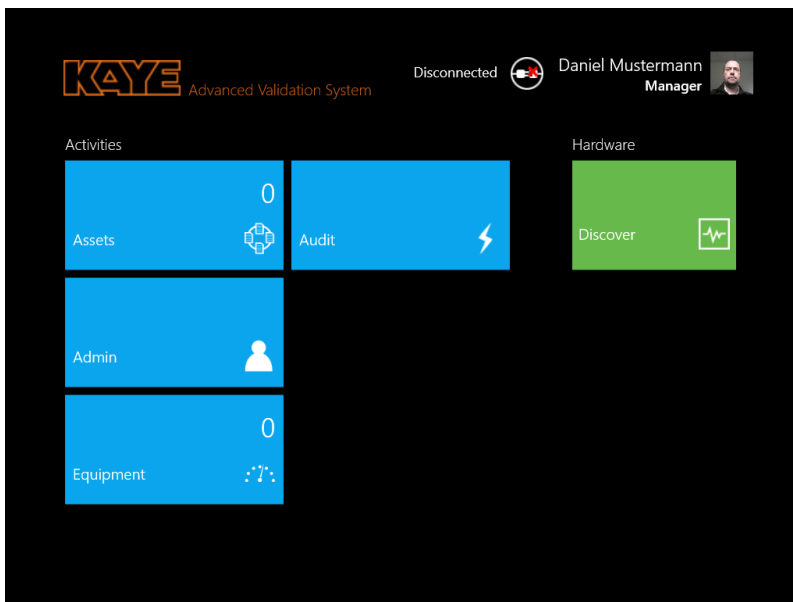


Figure 50: Main Menu with Hardware Discover Tile

The easiest way to connect to a Validator AVS is to dock the Validation console into the docking port of the Validator AVS. The Docking Connection is represented by the preselected orange “USB/Docking” Tile. Simply press “Connect” to connect to the Validator AVS.

Pressing “Discover” will search the connected Networks (LAN or Wi-Fi) for available Validators. They are listed with blue tiles showing serial number and IP address. The tile for the currently selected Validator AVS has an orange triangle in the upper right corner. When connecting to a Validator in the network, on pressing “Connect” it is necessary to select a connection via Ethernet or Wi-Fi.

8.1 Select Validator AVS (cont.)



Figure 51: Select Validator AVS Screen

Note: In case a Validator AVS is not in the same IP segment the discover function will not find it. Nonetheless if the TCPIP address of the Validator is known and the connection not blocked the connection can be established by entering the IP address and adding the Validator AVS to the available devices manually.

Press the tile for the Validator AVS you need to use, and then press Connect to establish the connection between the Console and the Validator AVS.

For configuring the Wi-Fi connection select a Validator and press “Configure WiFi”. The connection needs to be established by docking (recommended) or Ethernet. Enter all the necessary information and after pressing “ok” the information is transferred to the Validator. The Validator will now use this information to connect to the specified Wi-Fi network and will be available with the “Discover”-Button.

8.2 Monitoring Live Data

The Monitoring screen displays live data. Pressing the Back (←) button returns to the Main Menu, which now shows the connected status along with a Disconnect option.

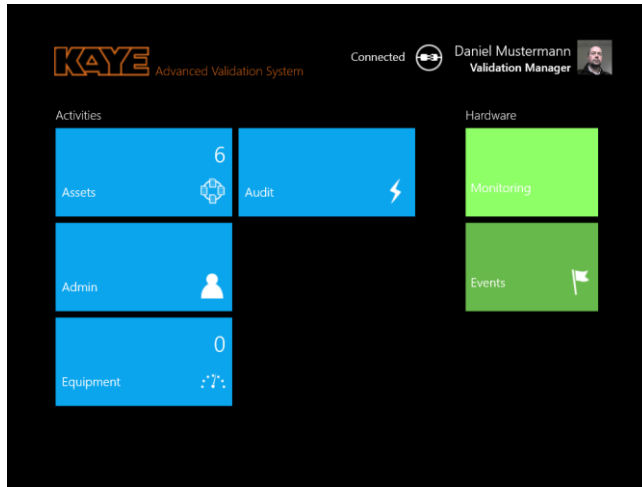


Figure 52: Main Menu with Events Tile

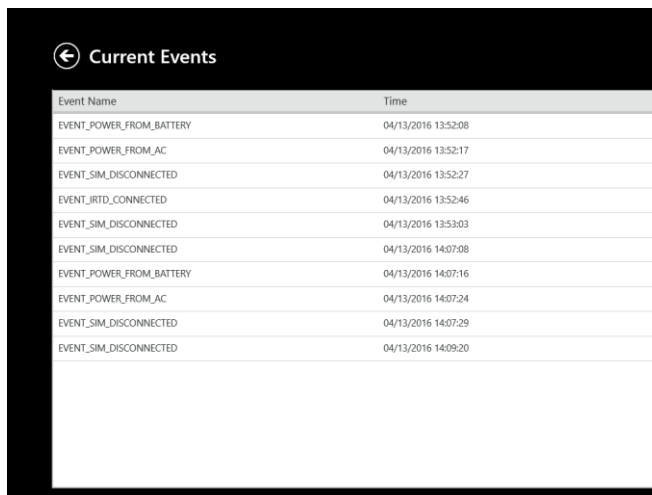


Figure 53: Current Events Screen

In the Events connection specific events like SIM or Power-disconnects are listed.

8.2 Monitoring Live Data (cont.)

In the Monitoring of Live data mode no study is running and the data collection structure (sensor & groups definition) is following 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.

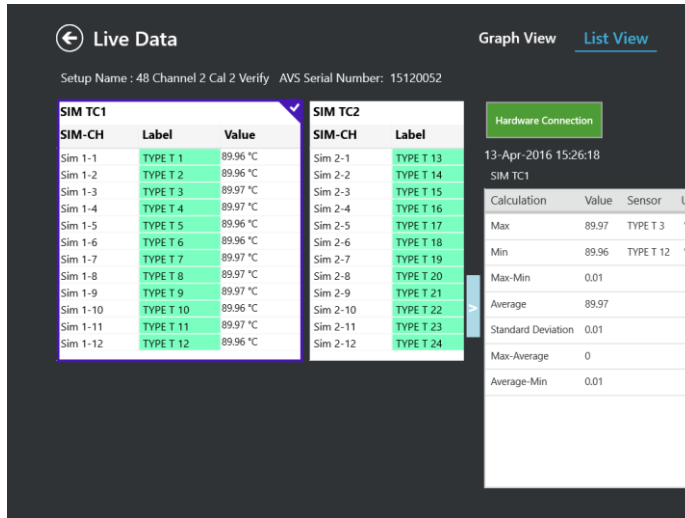


Figure 54: Monitoring in List View

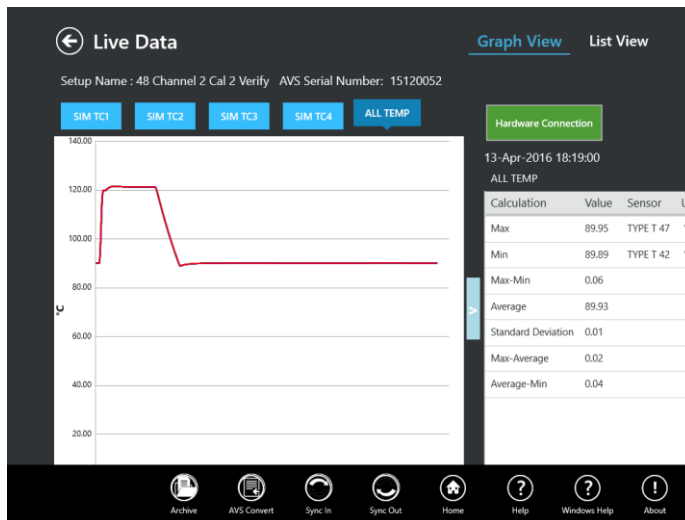


Figure 55: Monitoring in Graph View

8.2 Monitoring Live Data (cont.)

If the Validator AVS is in Qualification status, the live screen displays groups as defined in the study.

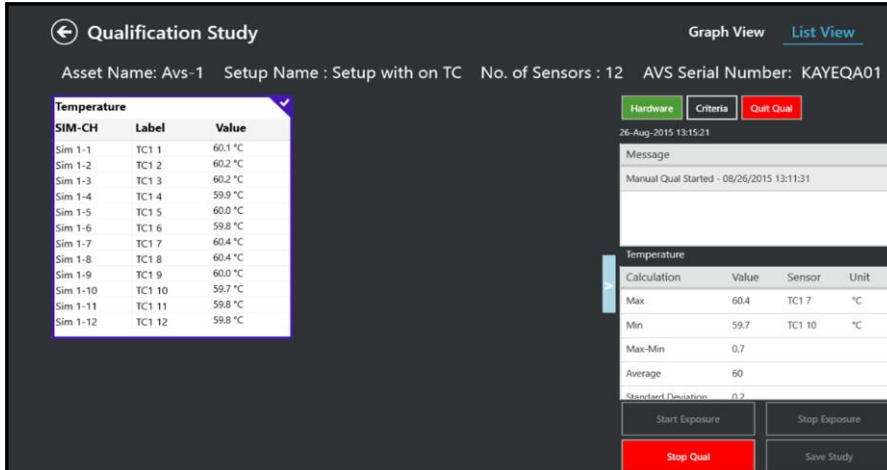


Figure 56: Qualification Study in List View



Figure 57: Qualification Study in Graph View

8.2 Monitoring Live Data (cont.)

If the Validator AVS is in Calibration or Verification status, the live screen displays groups as defined in the study

Sensor Calibration AVS S/N : KAYEQA01
 Asset : test asset Setup : Asset Test Sim1 12 TC No. of Sensors : 12

Low Point 80 °C High Point 100 °C Check Point 90 °C

IRTD: 78.917 °C 0.000 ✓ IRTD: 100.042 °C 0.023 ✓ IRTD: 100.038 °C

Label	Temp	Stability	Dev.	Label	Temp	Stability	Dev.	Label	Temp	Stability	Dev.
Sim 1											
Tc 1	79.9 °C	0.20	0.00	Tc 1	100.0 °C	0.20	0.00	Tc 1	100.0 °C	****	****
Tc 2	79.9 °C	0.10	0.00	Tc 2	100.0 °C	0.20	0.00	Tc 2	100.0 °C	****	****
Tc 3	80.0 °C	0.30	0.10	Tc 3	100.0 °C	0.30	0.00	Tc 3	100.0 °C	****	****
Tc 4	79.9 °C	0.20	0.00	Tc 4	100.0 °C	0.30	0.00	Tc 4	100.0 °C	****	****
Tc 5	79.9 °C	0.20	0.00	Tc 5	100.0 °C	0.20	0.00	Tc 5	100.0 °C	****	****
Tc 6	80.0 °C	0.40	0.10	Tc 6	100.0 °C	0.40	0.00	Tc 6	100.0 °C	****	****
Tc 7	79.9 °C	0.30	0.00	Tc 7	100.1 °C	0.50	0.10	Tc 7	100.1 °C	****	****
Tc 8	80.0 °C	0.40	0.10	Tc 8	100.0 °C	0.30	0.00	Tc 8	100.0 °C	****	****
Tc 9	80.0 °C	0.30	0.10	Tc 9	100.0 °C	0.30	0.00	Tc 9	100.0 °C	****	****
Tc 10	79.9 °C	0.30	0.00	Tc 10	100.1 °C	0.50	0.10	Tc 10	100.1 °C	****	****
Tc 11	80.0 °C	0.40	0.10	Tc 11	100.0 °C	0.40	0.00	Tc 11	100.0 °C	****	****
Tc 12	79.9 °C	0.10	0.00	Tc 12	100.0 °C	0.10	0.00	Tc 12	100.0 °C	****	****

28-Aug-2015 14:58:44

Hardware Connection Criteria

Checklist
 Time Elapsed: 00:00:04

- Temperature Reference Set
- Sensors Stabilized
- IRTD Temperature Standard Stabilized
- Deviation Calculated on Uncalibrated Sensors
- Sensors Calibrated
- Deviation Calculated on Calibrated Sensors
- Saving Calibrated Offsets to file
- Calibration Point Completed

Start Cancel

Save Study

Figure 58: Calibration List View Screen

8.2 Monitoring Live Data (cont.)

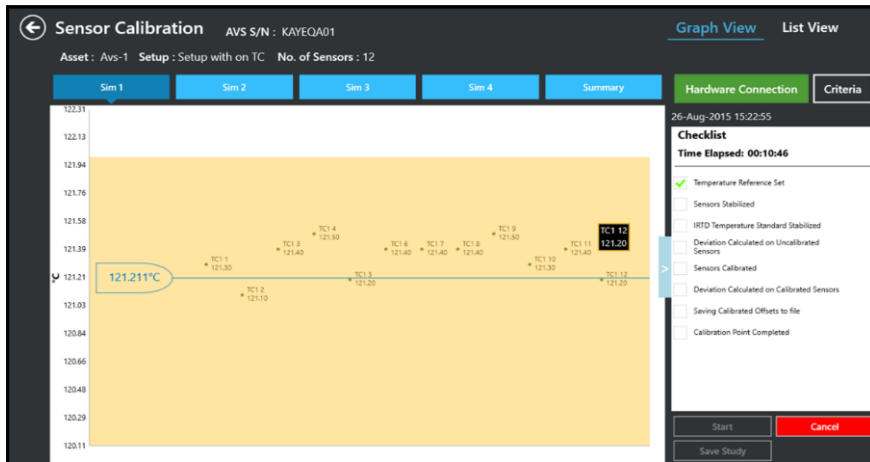


Figure 59: Calibration in Graph ViewScreen

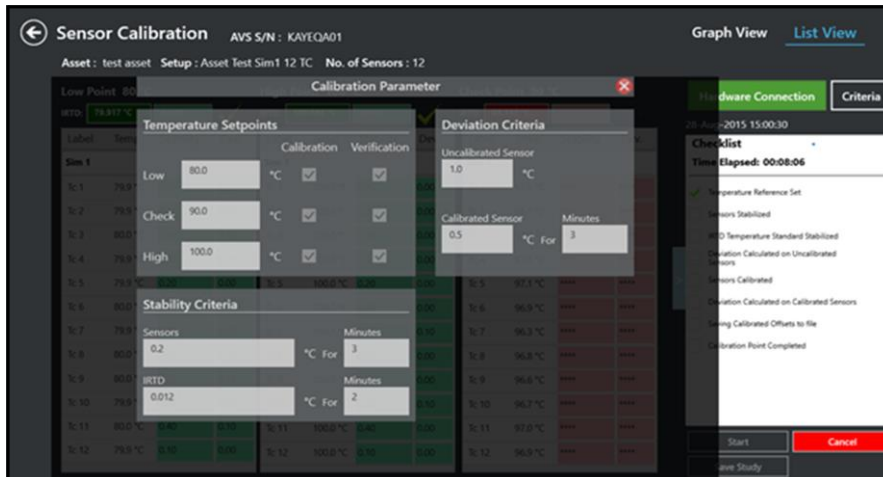


Figure 60: Calibration Parameter screen

User can start the Qualification or Calibration from the Asset detail screen. Based on the user rights, user can stop Qualification or Calibration activity.

8.3 Check Communications Connections

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

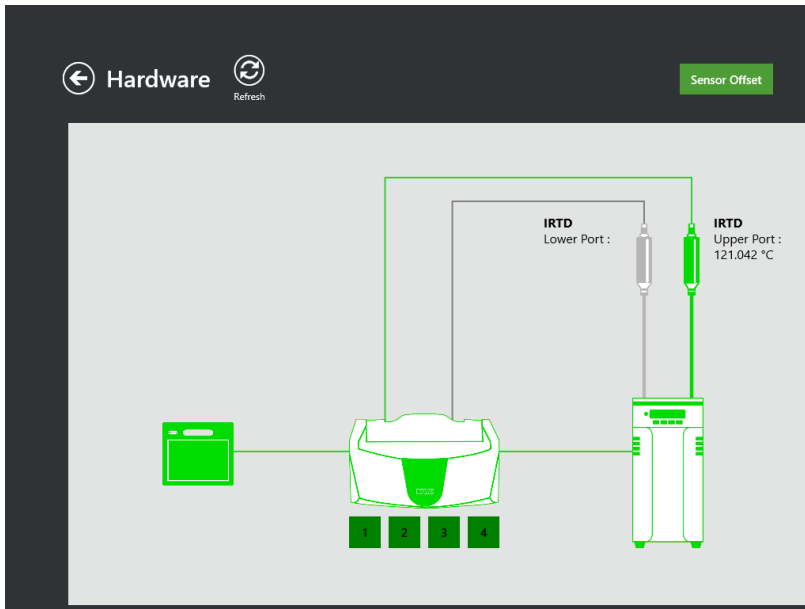


Figure 61: Hardware Screen

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

If the link to the Kaye Validator AVS is not responding, all links will be marked with a grey image of device.

8.4 Select a Temperature Standard

If you have two IRTDs connected to the Kaye Validator AVS, IRTD on the upper port will be used as temperature standard. The lower IRTD port will display in the hardware screen or can be used to power a pressure transducer with a special cable. For calibration and verification studies only the upper port is recognized.

Chapter 9. The Qualification Study

9.1 Introduction

Once the setup is defined and loaded into the Kaye Validator AVS and the sensors are calibrated everything is ready to run a qualification study.

The Kaye 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, in 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 Kaye Validator AVS performs calculations and compiles data for the qualification reports. Qualification data is always written to the Kaye Validator AVS internal memory.

The Kaye Validator AVS provides 32GB of internal memory to maintain qualification data during a study. Once study is complete and stop qualification is executed the study data is saved into Validator AVS memory. Qualification data resides in the internal memory until it is transferred to the console.

The Kaye 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) so that you can perform an orderly shutdown of the system. When the Kaye Validator AVS detects that the AC power has failed and the system is running from battery, it display indication on front panel LED. When the battery has approximately six minutes of power remaining, the Kaye Validator AVS stops collecting data and closes its data files.

9.1 Introduction (cont.)

Note: *In the event of power glitches or short-term drops in supply voltage (“brownouts”), there is a remote chance that the Kaye Validator AVS will fail to fall back to its backup battery. In this case, the Validator could reset and potentially lose any study data stored in internal memory. To prevent this from occurring, Kaye recommends connecting the Validator AVS to an Uninterruptible Power Supply (UPS) in areas likely to experience brownouts.*

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

Before beginning the qualification study:

- Place the Kaye Validator AVS in a location with stable and even temperature, not exposed to any local heat sources (i.e., close directly to a sterilizer, an open door causing a draft, etc.). Temperature variations and/or exposure to external heat sources during qualification studies may cause temporary temperature measurement errors.
- 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 in order for the Validator AVS to acclimate to the ambient temperature.
- Position the sensors in the vessel or chamber (the asset) being tested.

9.2 Load a Setup

Before the start of the qualification process, make sure to load the defined setup for this asset from the Console into the Kaye Validator AVS.:

- Select the predefined setup file for this asset
- Load the setup into the Kaye Validator AVS

IMPORTANT: *When loading a setup with a different calibration signature (calibration parameters and/or temperature units) than the setup currently in memory, any sensors already calibrated will be 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 are marked as calibrated.*

When loading a setup with a different line frequency than the setup currently in memory, the Kaye Validator AVS must stabilize for approximately 2 - 3 minutes before running a qualification study or invalid data is displayed.

9.2.1 Select a Setup File

If the setup is not yet created please see chapter 6 for instruction how to create a setup.

If a setup for the asset is available, go to the Asset Details page and, from the Setup pane select the desired set up and press **Initiate Qualification**.

The pop window gives the opportunity to change the SOP Protocol Number and display the run number. The run number is counting up automatically but is changeable if required. Pressing Ok opens the “Select AVS” screen.

9.2.1 Select a Setup File (cont.)

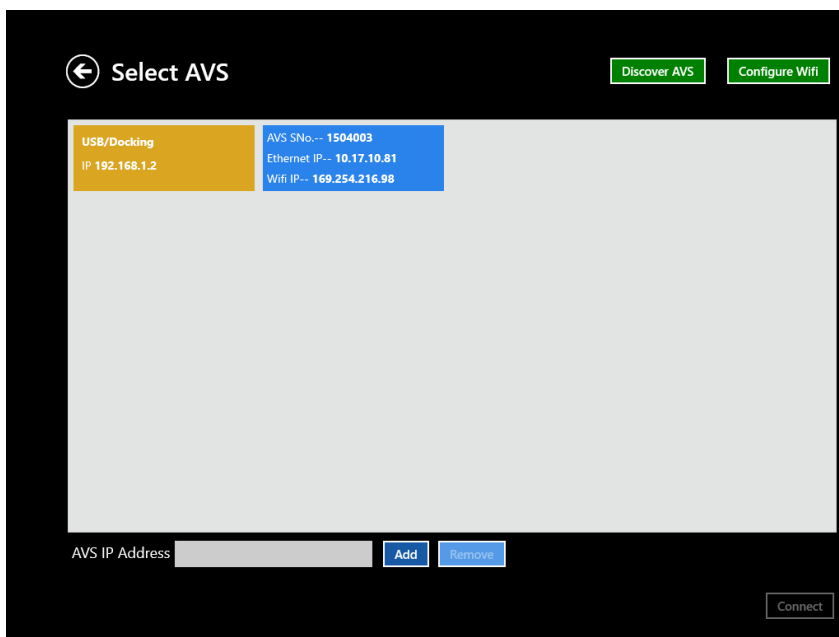


Figure 62: Select AVS

Select now the Validator AVS to run the study. After pressing the “Discover” button the screen displays all the Validator AVS’ that are available. By default, the screen highlights the Validator AVS that was last used with this particular Console. It is possible to connect the Validator AVS in either of three ways:

- Through the docking station
- Through Ethernet - the screen displays a list of Validator AVS with same IP address or that are in range of the network.
- Through Wireless connection - the screen displays a list of Validator AVS with same IP address or that are in range of the network.

Press **Connect** to start the transfer of the setup for qualification study and proceed to the next screen, or press **Cancel** to return.

9.3 Viewing the Active Qualification Study

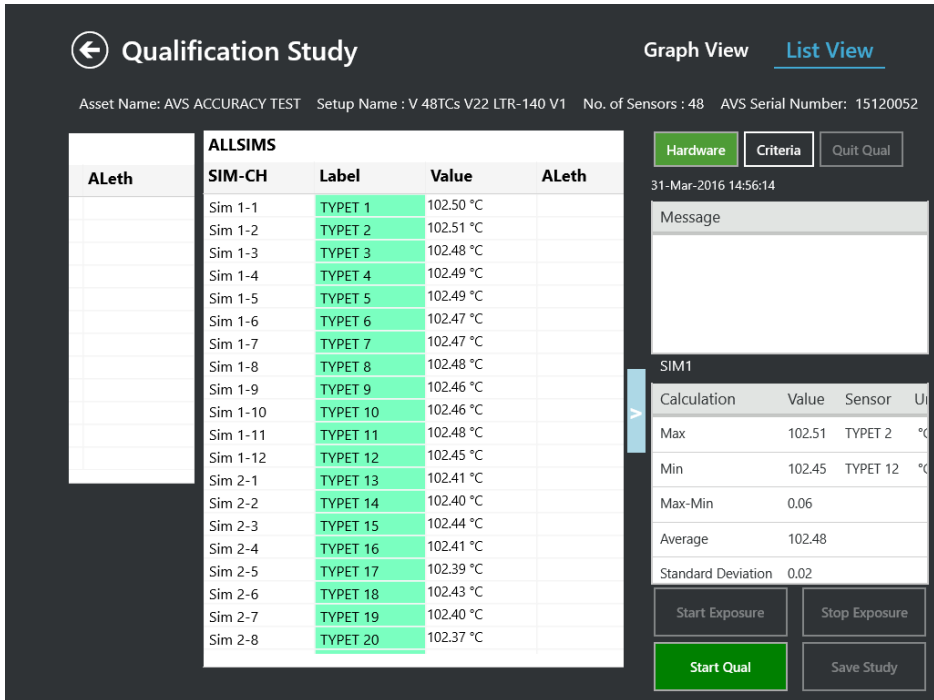


Figure 63: Real-Time Readings

The Study is started by pressing the **Start Qual** or by the automatic start condition defined in the setup (in that case the start button is not available).

During the qualification study, real-time sensor readings and calculations for each group defined in the setup are displayed. Also view real-time events that apply to the whole study (start/stop qualification, start/stop exposure), as well as all group-specific events are displayed in the message window. Graph option enables to view the data graphically.

When viewing sensor readings and calculations, the following guidelines apply:

- Calculations are computed, events are monitored and displayed on the Console screen.
- The resolution of sensor readings and calculation results is dependent on the lowest resolution in the group.

9.3 Viewing the Active Qualification Study (cont.)

- Open, under-range, over-range or failed sensors are not allowed to participate in calculations or events.
- Each box lists the SIM number, group name, sensor label and associated measurand (temperature, humidity, pressure, etc.) If there are more sensors or calculations than fit on the screen, use the scroll bar to display the remaining data.
- A button to stop qualification is available at the bottom of the screen. Data is refreshed as per display rate 5 or 10 seconds selected on preferences screen the rates shown below:

Note: After disconnecting the console the Validator AVS continues the study. Live monitoring data are discarded after disconnecting and will resume on reconnecting the console.

Depending on the setup the exposure can be started and stopped manually or will start automatically depending on the setup definition (in that case that “Start exposure” Button is not available).

To stop the study, press the **Stop Qual** button.

After stopping the study the **Save Study** button becomes available. Please save the study to your console. If a console is connected to a Kaye Validator AVS with an unread study it will insist on reading the study before starting any new study.

9.4 Graph Real-Time Sensor Readings and Calculations



Figure 64: Graphing Sensor Readings

During the qualification data samples are displayed as per display rate.

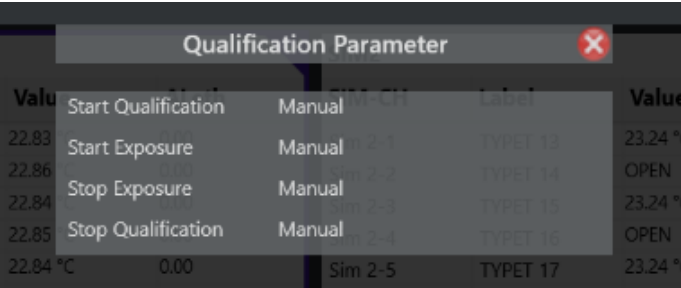
To graph real-time sensor readings and calculations:

1. Press the **Graph View** option.

The Graphs screen displays.

All the available Groups in that particular setup are displayed, when pressing the button for each group, the corresponding graph is displayed.

9.4 Graph Real-Time Sensor Readings and Calculations(cont.)



Value	Start	Stop	Label	Value
	Start Qualification	Manual	TYPET 13	23.24 °C
22.83	Start Exposure	Manual	TYPET 13	23.24 °C
22.86	Stop Exposure	Manual	TYPET 14	OPEN
22.84	Stop Qualification	Manual	TYPET 15	23.24 °C
22.85	Start Exposure	Manual	TYPET 16	OPEN
22.84 °C	0.00	Sim 2-5	TYPET 17	23.24 °C

Figure 65: Qualification Parameters

The criteria button displays the Qualification Parameters for reviewing the start and stop conditions for Qualification and Exposure.

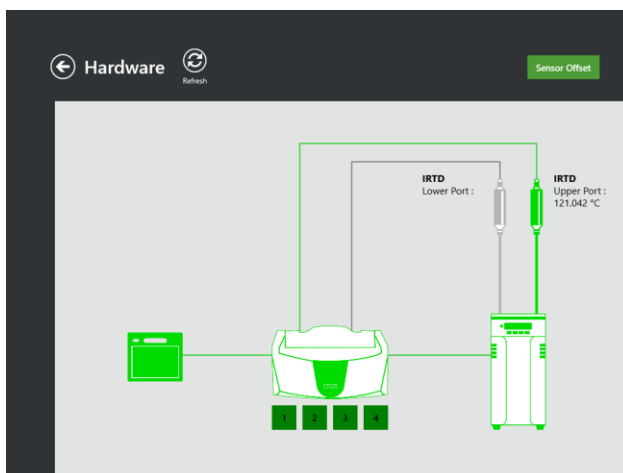


Figure 66: Hardware Screen

On the hardware screen all available hardware connected to the AVS is available including serial numbers and calibration dates. In addition the Sensor Offsets can be reviewed.

Chapter 10. Generating Reports

10.1 Reports Overview

The Kaye Validator AVS software includes a comprehensive reporting utility that allows you to generate Setup, Calibration, Qualification, and Calibration Verification reports to document the specifics of your validation study. All reports are generated from secure data files that can only be read by the Kaye Validator AVS software. Reports are not saved; you create reports each time from the secure data files. If a secure data file is tampered with, it is no longer readable by the software and you will not be able to generate reports.

Since reports are created each time from a secure data file, you can specify which groups to include in your Qualification Report. For qualification reporting, in addition to reporting the data that was available during the study, the software allows you to perform post-qualification analysis. You can add statistical calculations, events, and time intervals to your report based on the stored data. The secure data file remains unchanged; you can always access the secure data file to recreate reports using the Kaye Validator AVS software.

Note: *You can create Portable Document Format (PDF) files from the study data and then electronically sign the reports.*

10.2 Report Types

10.2.1 Setup Report

The Setup Report documents sensor labels and definitions for each SIM, wiring locations, and the parameters for sensor calibration, qualification and system preferences. Individual group information includes the sensors assigned to that group, statistical, lethality, and saturated steam calculations, the event defined for that group, and group-specific information such as vessel ID, SOP/protocol number, load description, asset details (if associated with a report) and comments. Sensor calibration parameters can include high, low and check set point, Stability and Deviation criteria defined while creating the setup. Qualification parameters include Start stop conditions, scan rate and data storage. For current, voltage and pressure sensors, the report lists scaling information such as min and max of input and output. System preferences such as temperature units, pressure units, and line frequency also appear. The report header lists the date and time the report was printed, the setup name, your company name, the firmware and software version numbers, the date this setup was saved, and identifies the person who saved this setup.

The Setup Report can be generated directly from the setup review page or using the reporting tool.

- When you generate this report independent of the full study, you can use the Setup Report to check your setup configuration and/or as a guide for wiring SIMs.

10.2.2 Calibration Report

The Calibration Report documents the SIMs used in calibration by slot number and serial number, the calibration setpoints, stability and deviation criteria, and the evaluation of stability, deviation, and the results for each temperature setpoint.

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 report header lists the date and time the report was printed, and identifies the name of the setup used to calibrate the sensors, your company name, the Kaye Validator AVS serial number, and the firmware and software version numbers.

10.2.3 Qualification Reports

There are two different reports that document the qualification study: the Qualification Detailed Report, and the Qualification Summary Report.

10.2.3a Qualification Detailed Report

The Qualification Detailed Report organizes information for each group by sensor data and type of calculation (lethality, statistical, saturated steam). You can customize the Qualification Report by specifying the groups to be reported, add events based on the stored data, and add explanatory notes and comments to the beginning or end of the report.

The report header lists the date and time the report was printed, the name of the setup the qualification study is based on, the name of the person who performed the study, your company name, the Kaye Validator AVS serial number, the qualification study run number, and the firmware and software version numbers.

The overview section documents 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 user comments added during post-qualification reporting.

10.2.3 Qualification Reports (cont.)

The following sections of the Qualification Report are documented on a group basis. Data is reported at the data storage rate specified in the setup or the print sampling rate defined in post-qualification reporting. When an event occurs, whether it is Start Qualification, Start Exposure, Stop Exposure, Stop Qualification, or one of the group events, the message appears in each section of the report with a snapshot of the data at that time. If this was a manual event, the name of the person who manually started or stopped the event is also printed. Data is displayed in columns with shaded areas to help you locate data associated with a specific time period. Sensors that are excluded from post-qualification calculations are marked with an asterisk (*).

- The Sensor Inputs section documents the raw data collected during the study.
- If you are conducting penetration studies, the Lethality Calculations section documents accumulated lethality for each sensor, and the minimum accumulated lethality value and its location.
- The Statistical Calculations section documents the calculations specified in the setup and/or the calculations specified during post-qualification reporting. This section also documents exposure time, cycle time, and temperature standard readings.
- The Saturated Steam Calculations section documents the saturation temperature of steam calculation and the saturation pressure of steam calculation.
- The last section of the report, System Messages, consists of two parts. The first part describes events that occurred during the qualification study.

These are the events that are common to all groups:

- Start/Stop Qualification
- Start/Stop Exposure

The second part of this section documents event timer intervals added during post-qualification reporting.

10.2.3b Qualification Summary Report

The Qualification Summary Report summarizes your study. You can apply a number of calculations, and generate a variety of calculation graphs.

The report header lists the date and time the report was printed, the setup name, your company name, the name of the person who performed the qualification study, the run number, the Kaye Validator AVS serial number, and the firmware and software version numbers.

The overview section lists the groups included in the report, the date and time the study started and ended, the duration of the qualification study, the duration of the exposure cycle, the SIMs used in the study by slot number and serial number, and user comments entered during post-qualification reporting.

For each group, the Summary Report documents interval calculations, lethality calculations, any sensors that have been deleted from group calculations, event messages generated during the qualification study, and group events that were added during post-qualification reporting.

- For lethality calculations, the Summary Report documents the lethality calculation parameters, the lethality calculation condition, the lethality calculation start/stop times, and the minimum lethality for that group by sensor label, value, and location.
- If you enabled the Lethality option on the Print Options screen, the total accumulated lethality for each sensor is reported.

10.2.4 Calibration Verification Report

The Calibration Verification Report documents the SIMs used in calibration verification by slot number and serial number, the calibration setpoints, stability and calibrated deviation criteria, and the evaluation of stability, deviation, and the results for each temperature setpoint.

Note: *If a sensor fails calibration 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 report header lists the date and time the report was printed, and identifies the name of the setup used to verify sensor calibration, your company name, the Kaye Validator AVS serial number, and the firmware and software version numbers.

Validator AVS Audit Trail

The Kaye Validator AVS audit trail provides a complete listing of events that affect the integrity of the Kaye Validator AVS PC program and the Kaye Validator AVS instrument. Audit trail events are stored in secure data files to help you meet 21 CFR Part 11 requirements.

10.2.5 Audit Trail

The Kaye Validator AVS software maintains the audit trail, which contains all events and identifies the type of action performed, the date and time the action occurred, the user ID of the responsible operator, and any additional information required to understand the action taken. A new audit trail file is automatically created each month and placed in the Kaye Validator AVS application folder.

When running the Kaye Validator AVS in standalone mode, each Kaye Validator AVS maintains its own audit trail events which identifies the type of action performed, the date and time the action occurred, and any additional information required to understand the action taken. The program extracts the Kaye Validator AVS audit trail events when the program establishes communication with the Kaye Validator AVS. Each event is appended with the name of the responsible operator and added to the audit trail of the Console.

Audit trail data is available to authorized personnel through the Audit trail tile. The System Administrator can:

- View and print the audit trail

Table 3 below includes a list of system and user-defined audit trail events.

Table 3: Audit Trail Events

User defined Events
0 - Undefined
1 to 96 - Sensor ID
97 - EventCond_MaxMinusAvg
98 - EventCond_MinMinusAvg
99 - EventCond_MaxValue
100 - EventCond_MinValue
Audit Events
EVENT_PROGRAM_START,
EVENT_PROGRAM_CLOSE,
EVENT_HMI_CONNECT,
EVENT_HMI_DISCONNECT,
EVENT_SIM_CONNECT,
EVENT_SIM_DISCONNECT,
EVENT_IRTD_CONNECT,
EVENT_IRTD_DISCONNECT,
EVENT_BATH_CONNECT,
EVENT_BATH_DISCONNECT,
EVENT_THUMBDRIVE_CONNECT,
EVENT_THUMBDRIVE_DISCONNECT,
EVENT_AC_POWER_FAILURE,
EVENT_AC_POWER_RESTORATION,
EVENT_POWER_FROM_BATTERY
EVENT_BATTERY_AT_THRESHOLD,
EVENT_BATTERY_LOW,

Table 3: Audit Trail Events (Continued)

EVENT_VALIDATOR_SHUTDOWN_DUE_TO_LOW_BATTERY,
EVENT_BATTERY_CHARGING_STARTED,
EVENT_BATTERY_CHARGING_STOPPED,
EVENT_FAN_FAULT,//2 fans
EVENT_SETUP_UPDATED,
EVENT_AUTO_QUAL_STARTED,
EVENT_AUTO_QUAL_STOPPED,
EVENT_MANUAL_QUAL_STARTED,
EVENT_MANUAL_QUAL_STOPPED
EVENT_AUTO_EXPOSURE_STARTED,
EVENT_AUTO_EXPOSURE_STOPPED,
EVENT_MANUAL_EXPOSURE_STARTED,
EVENT_MANUAL_EXPOSURE_STOPPED,
EVENT_AUTO_SENSOR_CAL_STARTED,
EVENT_AUTO_SENSOR_CAL_DONE,
EVENT_MANUAL_SENSOR_CAL_STARTED,
EVENT_MANUAL_SENSOR_CAL_DONE,
EVENT_MANUAL_SENSOR_CAL_TERMINATED,
EVENT_SENSOR_CAL_VERIFICATION_STARTED,
EVENT_SENSOR_CAL_VERIFICATION_SUCCESS,
EVENT_SENSOR_CAL_VERIFICATION_FAILURE,
EVENT_INST_CAL_STARTED,
EVENT_INST_CAL_DONE,
EVENT_INST_CAL_TERMINATED,
EVENT_INST_CAL_VERIFICATION_STARTED,
EVENT_INST_CAL_VERIFICATION_SUCCESS,
EVENT_INST_CAL_VERIFICATION_FAILURE,
EVENT_CALIBRATION_OVERDUE,
EVENT_STUDY_COPIED_TO_THUMBDRIVE,

Table 3: Audit Trail Events (Continued)

EVENT_STUDY_COPIED_TO_HMI,
EVENT_OUTPUT_RELAY_ACTIVATED,
EVENT_OUTPUT_RELAY_DEACTIVATED,
EVENT_SBC_FW_UPGRADE,
EVENT_DAQ_FW_UPGRADE,
EVENT_POWERBOARD_FW_UPGRADE,
EVENT_FILE_CREATION_FAILURE,
EVENT_HMI_SUBSCRIPTION_FAILURE,
EVENT_AUDIT_LOG_AT_THRESHOLD,
EVENT_AUDIT_LOG_FULL,
EVENT_AUDIT_LOG_CLEARED,
EVENT_AUDIT_LOG_COPIED_TO_HMI,
EVENT_TIME_SYNC,
EVENT_CONDITION_OCCURED

For a further explanation of audit trail events, refer to Appendix A.

10.3 The Reports Hub



Figure 67: The Report Hub Screen

The Reports Hub enables users to access any report on the Console. To access the Reports Hub, press the Reports icon from the Start page.

To study the content of a particular report, press the button for that report. The Report Analysis Screen opens

10.4 The Report Analysis Screen

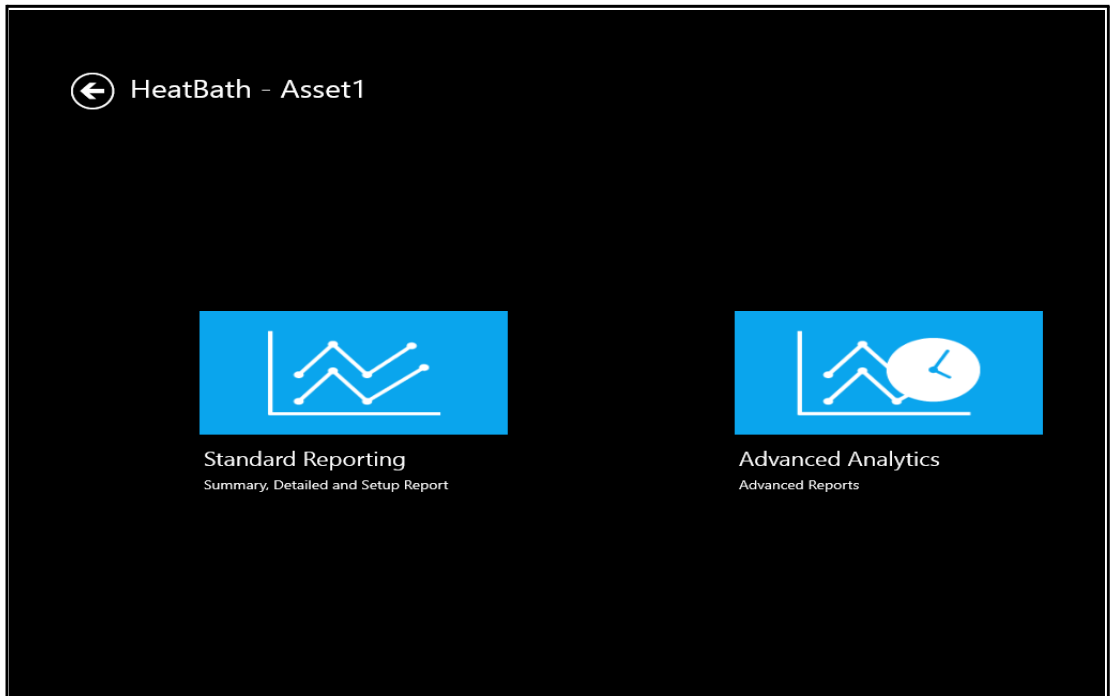


Figure 68: The Report Analysis Screen

The header of the Report Analysis screen displays the type of the asset (e.g., Sterilizers or Autoclaves or Heat Chambers), ID, the activity and the date on which the run was performed. You can choose from different types of analyses for a qualification study:

- Standard Reporting – summarizes the entire study.
- Advanced Analytics – provides a more detailed analysis of the study.

Press either **Standard Reporting** or **Advanced Analysis** to proceed to the Report Detail Screen.

10.5 The Reports Details Screen

Asset1 - Standard Reporting

Eq ID #	Eq-1	HeatBath	Mdl-1	1 cu ft	AAS	
TYPE	ACTIONS	FILENAME	DATE	OPERATOR	Run #	
^ TC_Volt_RTD_Current with events						
<input type="checkbox"/>	Qualification		TC_Volt_RTD_Current with events	16-Apr-2015 14:46:15	user1	1
^ Only TC						
<input type="checkbox"/>	Setup		Only TC	05-May-2015 14:45:56	a	
<input type="checkbox"/>	Qualification		Only TC	13-Apr-2015 15:01:16	User-1	4
<input type="checkbox"/>	Qualification		Only TC	13-Apr-2015 16:10:45	User-1	1
<input type="checkbox"/>	Qualification		Only TC	04-May-2015 17:51:35	a	7
<input type="checkbox"/>	Qualification		Only TC	05-May-2015 14:47:13	a	8
^ ds1						
<input type="checkbox"/>	Setup		ds1	15-May-2015 14:25:04	a	
<input type="checkbox"/>	Setup		ds1	15-May-2015 15:19:39	a	
^ d1s3						

Figure 69: The Reports Details Screen

To access the Reports Details screen (which has data for any particular report selected through the Reports Hub), press the button for a specific asset on the Reports Hub.

The header lists the particular asset for which you are looking up reports. A row below includes information such as Equipment ID, Water Spray, VRX-Fq1, Capacity and Manufacturer name. You can sort the reports by clicking on four subheads:

- Activity – indicates if the report is based on setup, calibration, qualification or calibration verification.
- Setup – lists reports by the setup name of the studies.
- Date – lists reports by date.

10.5 The Reports Details Screen (cont.)

Use the up and down arrows to arrange the reports in ascending or descending order. A Comments column allows users to review the comments entered for a particular setup. The Actions column shows icons:

- Graph - navigates to Summary/Advanced Analysis page and ask for Option to Select for unit
 - Temperature
 - Humidity
 - Pressure
 - Contact
 - Voltage
 - Current
- Delete – Delete the selected file

Asset1 - Standard Reporting							
Eq ID # Eq-1 HeatBath Mdl-1 1 cu ft AAS							
TYPE	ACTIONS	FILENAME	DATE	OPERATOR	Run #	Stu	
^ TC_Volt_RTD_Current with events							
<input type="checkbox"/>	Qualification		TC_Volt_RTD_Current with events	16-Apr-2015 14:46:15	user1	1	
^ Only TC							
<input type="checkbox"/>	Setup		Only TC	05-May-2015 14:45:56	a		
<input type="checkbox"/>	Qualification		Only TC	13-Apr-2015 15:01:16	User-1	4	
<input type="checkbox"/>	Qualification		Only TC	13-Apr-2015 16:10:45	User-1	1	
<input type="checkbox"/>	Qualification		Only TC	04-May-2015 17:51:35	a	7	
<input type="checkbox"/>	Qualification		Only TC	05-May-2015 14:47:13	a	8	
^ ds1							
<input type="checkbox"/>	Setup		ds1	15-May-2015 14:25:04	a		
<input type="checkbox"/>	Setup		ds1	15-May-2015 15:19:39	a		
^ d1s3							

Figure 70: Report Detail Screen When Standard Reporting is selected

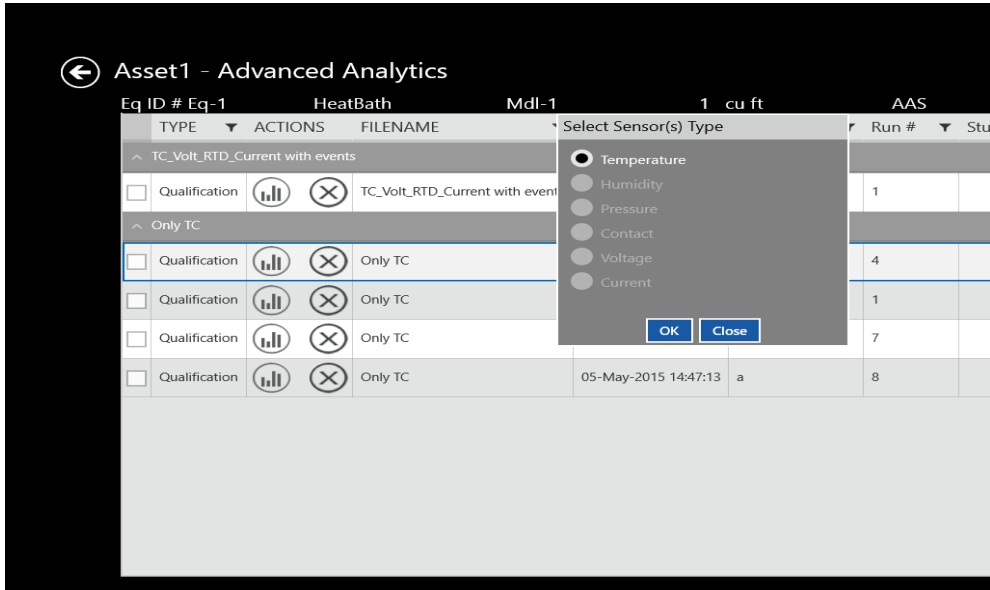


Figure 71: Report Analysis Screen when Advanced Analytics is selected

10.6 The Performance Analysis Screen

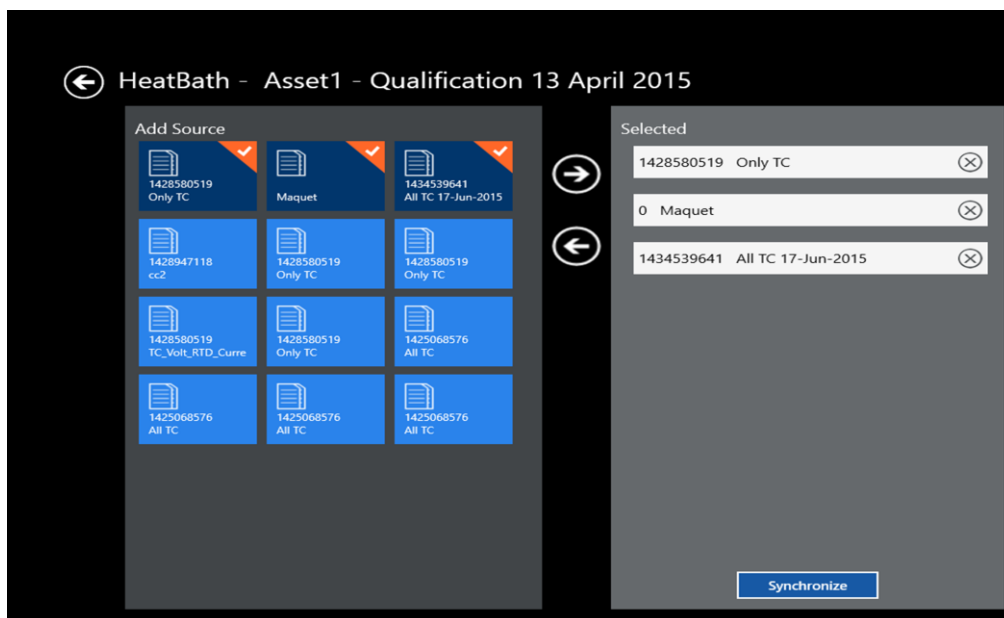


Figure 72: The Data Sources Screen

If user selects Advanced Analytics Option in Report Analysis Screen then from there it will be navigated to Report Detail Screen. In Report Detail Screen after selecting particular file data sources screen appears. If you highlight a study file and touch the forward (right) arrow, the file moves to the right panel, which displays the setup files selected for the report. (To remove the file from the report, touch the backward (left) arrow.) The selected files are highlighted in a mix of dark blue and orange on the left, while the unselected files appear in light blue. You can add up to three qualification study files. (A warning appears if you try to add a fourth study.) When you select two or three studies, the **Synchronize** button appears at the bottom of the right panel. If you press **Synchronize**, the data of the merged files appears in graph form in a sequence.

When you press **Data Sources**, the screen displays two panels. The left panel, **Add Source**, with a More button that displays all other study files.

10.6 The Performance Analysis Screen (cont.)



Figure 73: The Performance Analysis Screen

10.6 The Performance Analysis Screen (cont.)

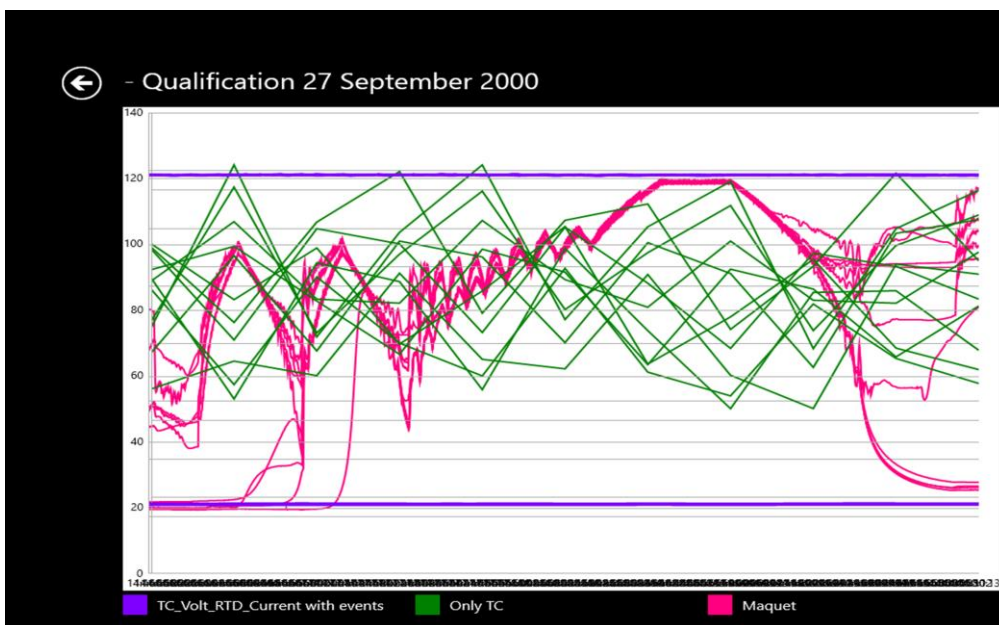


Figure 74: Merged File Data

At the right of each graph, a **Sync Point** text box allows you to enter the starting point of synchronization time in hh:mm:ss format. Three buttons appear at the bottom right:

- **Synchronize** — Redraws the graphs with a user-defined starting point and the conclusion of the study as the end point.
- **Superimpose** — Superimposes one file on another for comparative analysis.

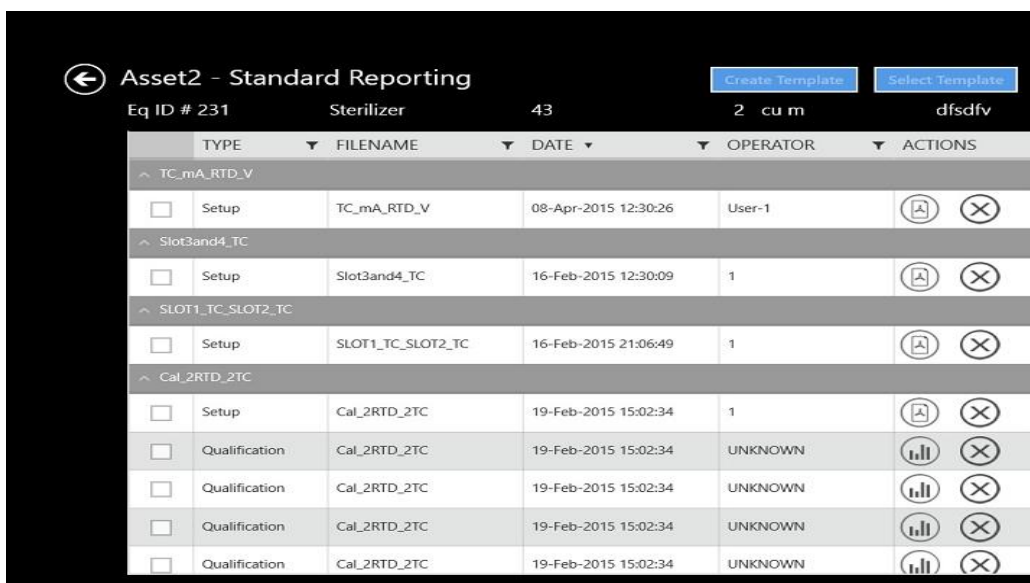
Press the **Chart Properties** button to edit Graph properties.

Press back arrow to return to previous screen

10.7 The Standard Reporting Screen

If user selects Summary Analysis Option in Report Analysis Screen then from there it will be navigated to Report Detail Screen. After Selecting Study file in the Report Detail Screen we will be moved to Template Selection Screen.

10.8 The Report Template Screen



	TYPE	FILENAME	DATE	OPERATOR	ACTIONS
TC_mA_RTD_V					
<input type="checkbox"/>	Setup	TC_mA_RTD_V	08-Apr-2015 12:30:26	User-1	
Slot3and4_TC					
<input type="checkbox"/>	Setup	Slot3and4_TC	16-Feb-2015 12:30:09	1	
SLOT1_TC_SLOT2_TC					
<input type="checkbox"/>	Setup	SLOT1_TC_SLOT2_TC	16-Feb-2015 21:06:49	1	
Cal_2RTD_2TC					
<input type="checkbox"/>	Setup	Cal_2RTD_2TC	19-Feb-2015 15:02:34	1	
<input type="checkbox"/>	Qualification	Cal_2RTD_2TC	19-Feb-2015 15:02:34	UNKNOWN	
<input type="checkbox"/>	Qualification	Cal_2RTD_2TC	19-Feb-2015 15:02:34	UNKNOWN	
<input type="checkbox"/>	Qualification	Cal_2RTD_2TC	19-Feb-2015 15:02:34	UNKNOWN	
<input type="checkbox"/>	Qualification	Cal_2RTD_2TC	19-Feb-2015 15:02:34	UNKNOWN	

Figure 75: Report Template Screen

If you have selected Summary Analysis at the Reports Analysis screen, once you have selected a particular file in Report Detail Screen after selecting particular file Template Screen Appears

If you have not yet created any report templates, the drop-down list on the Template Analysis screen is initially empty. Once you have created templates, this list displays all the templates

Note: If all the groups listed are empty, you cannot launch the Next screen until you have assigned sensors to at least one group in the Group pane.

10.9 The Add Cycles Screen

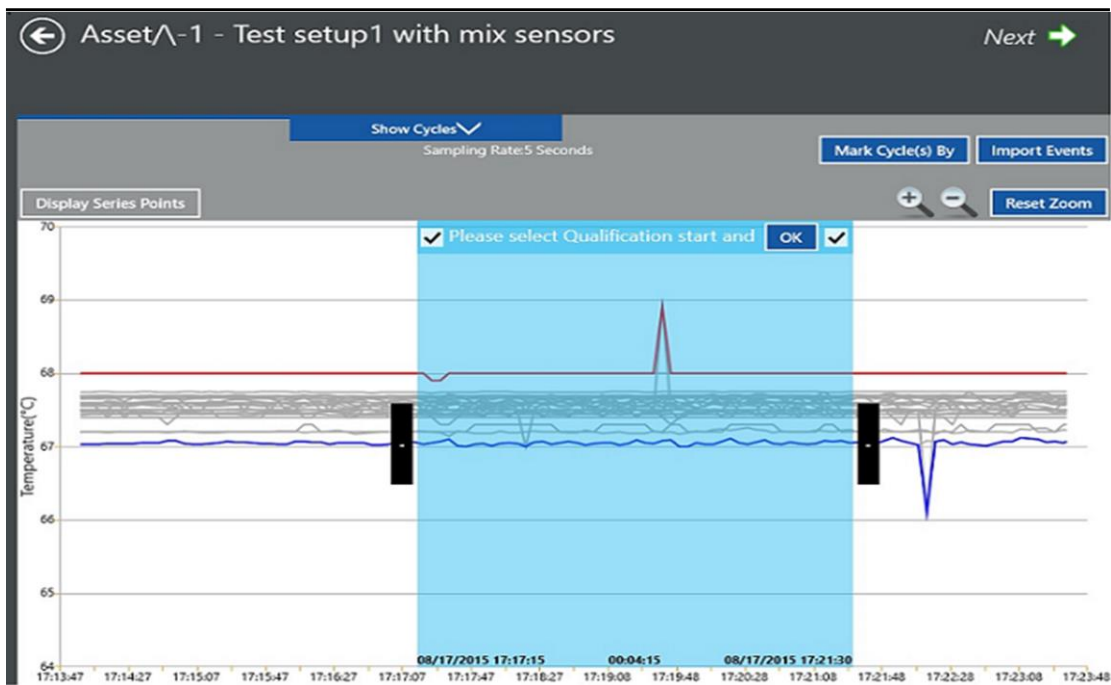


Figure 76: The Add Cycles Screen

Define the **start and end of the qualification** cycle using either

1. Cycle selection box option (default) or
2. Time selection box.

10.9 The Add Cycles Screen (cont.)

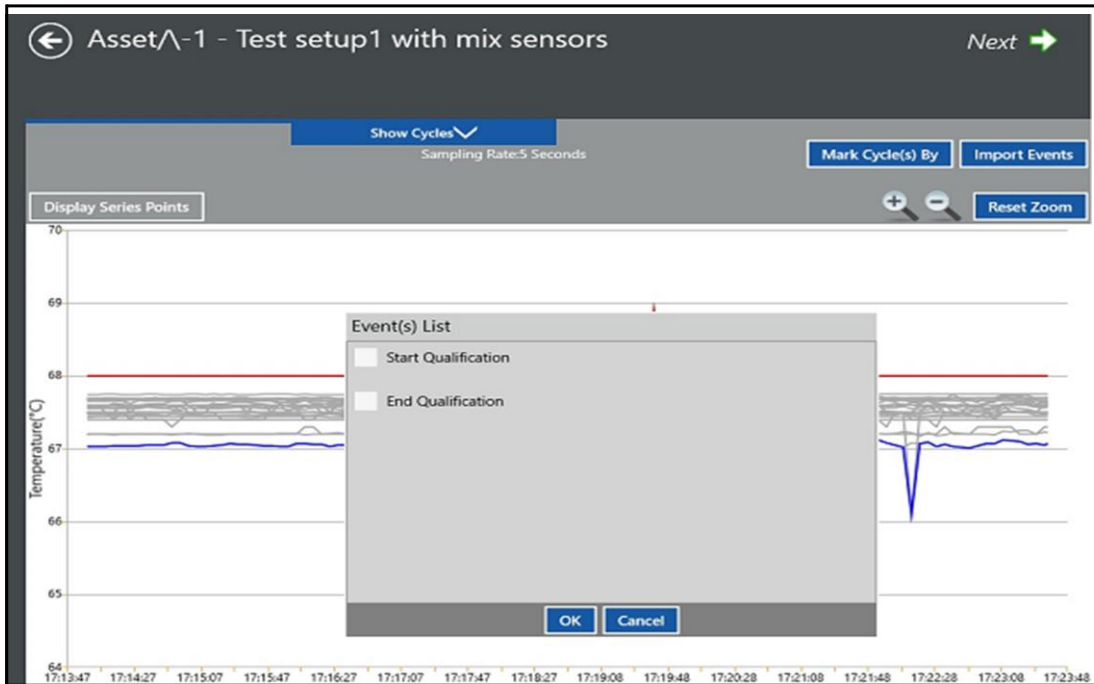


Figure 77: Window with Cycle Names

1. Cycle selection box:

- Move the slider in the center of the graph to mark either Start and End or Start or End of the study by clicking the OK button in Cycle selection box.
- The left check box corresponds to the **Qualification Start** with the timestamp displaying at the bottom left side of the box.
- The right check box corresponds to the **Qualification End** with the timestamp displaying at the bottom left side of the box.
- The center of the cycle selection box displays the interval period corresponding to Start and End of cycle.

10.9 The Add Cycles Screen (cont.)

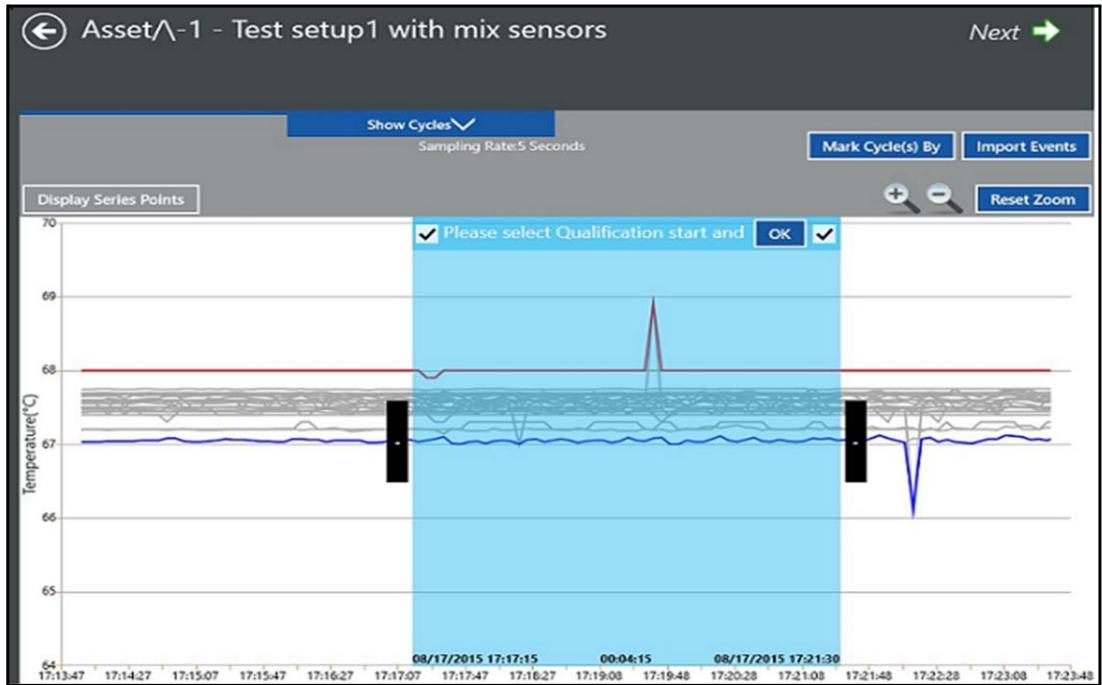


Figure 78: Cycle Name Box

Define the data cycles

- Move the cycle selection box slider to mark the Start & End of the cycle and click **OK**. The data is partitioned into either three or two cycles based on the left/right check box selection, with assigning the cycle names into the respective fields.
- The timestamp for the start/end of the cycle in focus is displayed at the bottom of left right corners of the cycle selection box.
- Maximum of 15 cycles can be defined.
- All the cycles created above are now displayed under the **Show Cycles** dropdown list box at top

Click **Unmark Cycle/Unmark Cycles** button in Show cycles window to remove the last cycle defined or all cycles at one shot respectively

10.9 The Add Cycles Screen (cont.)

Time selection box:

One can also define cycles by clicking the **Mark Cycle by > Time Selection** option. Enter the required time stamp(s) in the time selection window in DATE and HH:MM:SS format for defining Qualification Start and End.

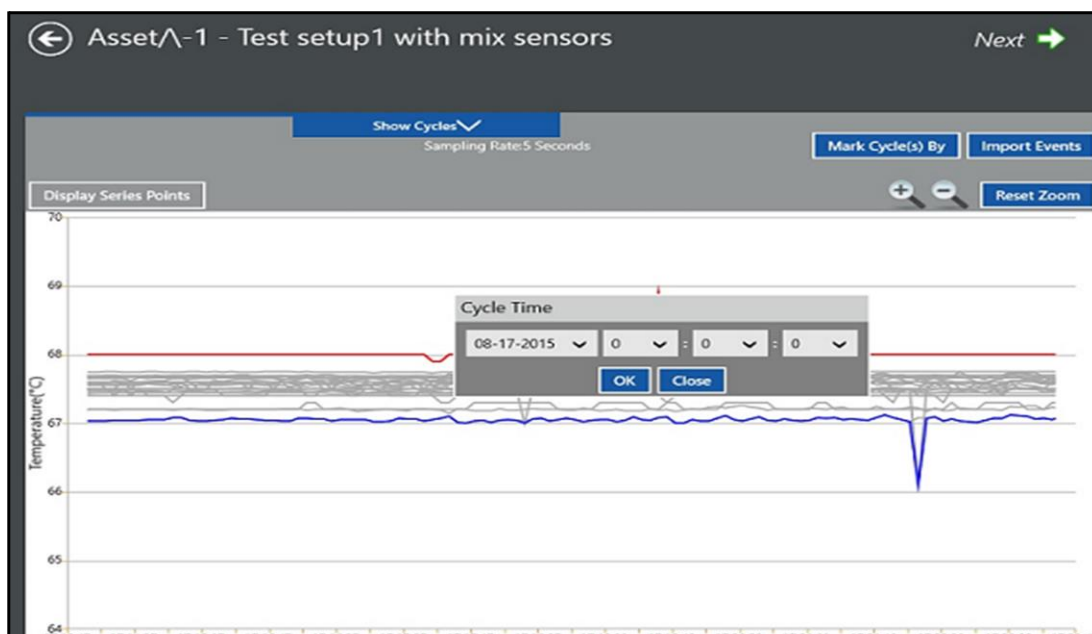


Figure 79: Added Cycle Screen

By clicking Show Cycles down arrow, list of cycles will be displayed. UnMark Cycle button 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 will unmark all the cycles, including study start and end.

10.10 The Report Screen

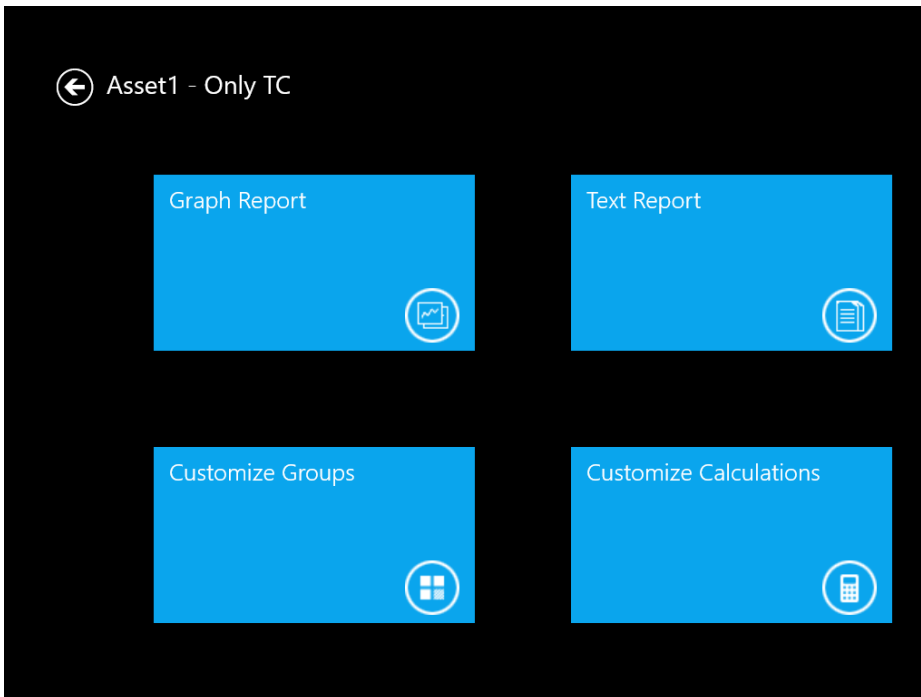


Figure 80: Report Screen

This Screen Displays

1. Text Report: Which describes the Report after selecting cycle displays Report Options Screen and pdf file of qualification can be generated.
2. Customize Groups: we can edit already defined groups and save it for generating graph report and qualification Report.
3. Customize Calculations and modifications in Calculations can be customized and edited.
4. Graph Report: we can generate Graph for defined group and selected Cycle accordingly

10.11 The Graph Report Screen

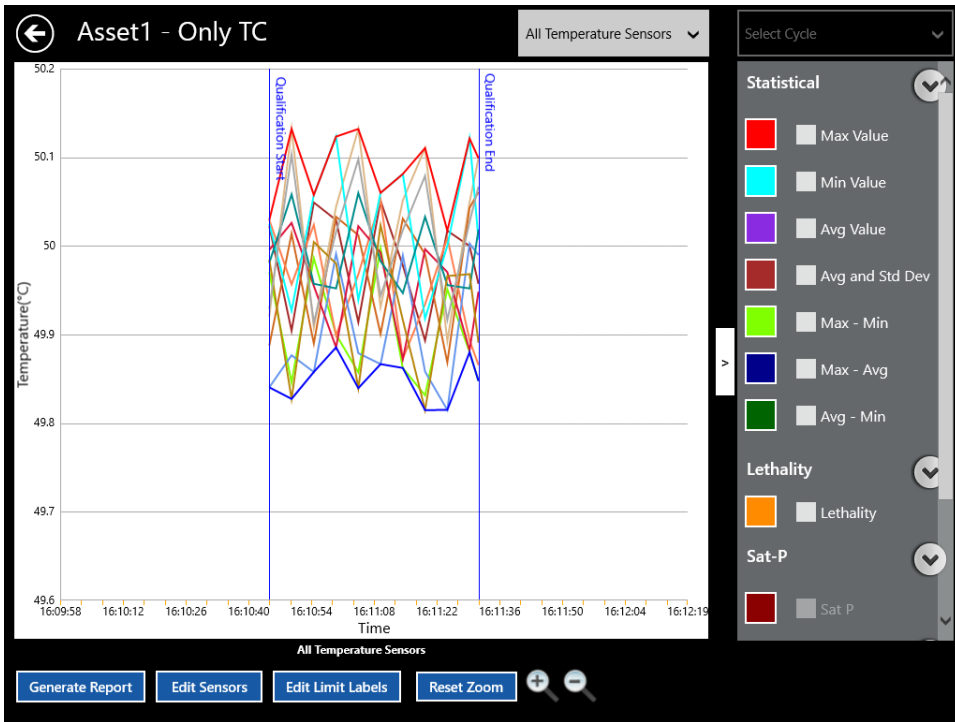


Figure 81: Graph Report Screen

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

Text boxes enable you to select the minimum and maximum values of the Y axis for the selected calculation graph. (These boxes accept only numerics, along with the minus sign, decimal point and comma.)

Above the Groups/Sensors pane, three tabs allow you to select the Lethality, Saturation Pressure and Saturation Temperature calculations.

- The Lethality calculation is available only if temperature sensors are present in the study. The left pane has the lethality graph for the entire study, while the right pane enables you to change the D, Z and Base temperature values.
- The Saturation Pressure calculation is available only if the study includes at least one temperature sensor along with pressure sensors.
- The Saturation Temperature calculation is available only if the study includes at least one pressure sensor along with temperature sensors.
- No calculations are available for a contact sensor group.

Based on the 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

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, the 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.

10.12 The Customize Calculations Screen

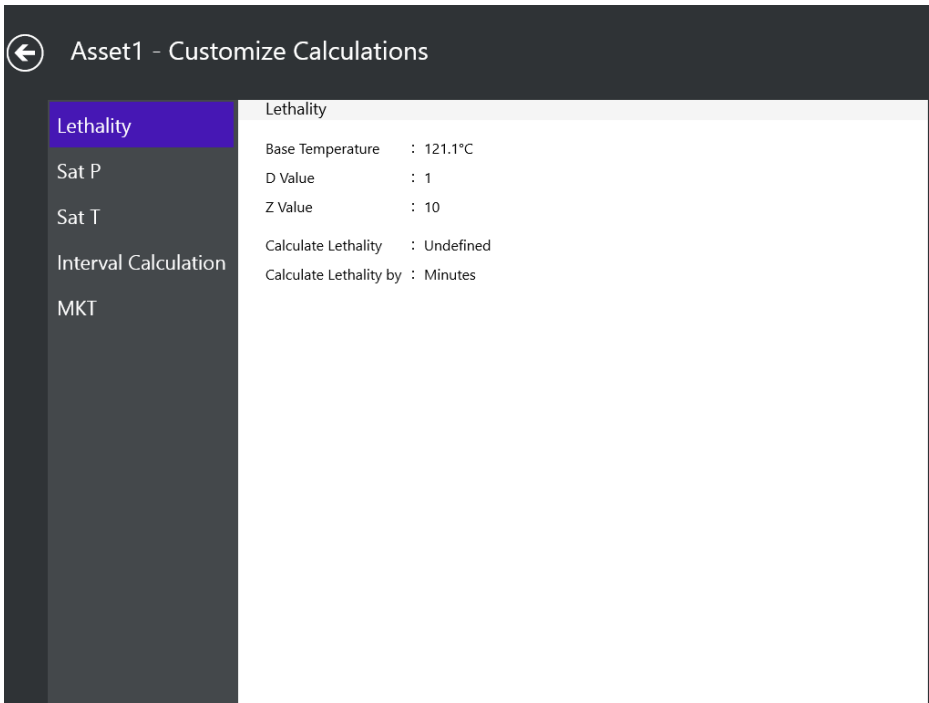


Figure 82: Customize Calculations

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

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

10.13 The Customize Groups Screen

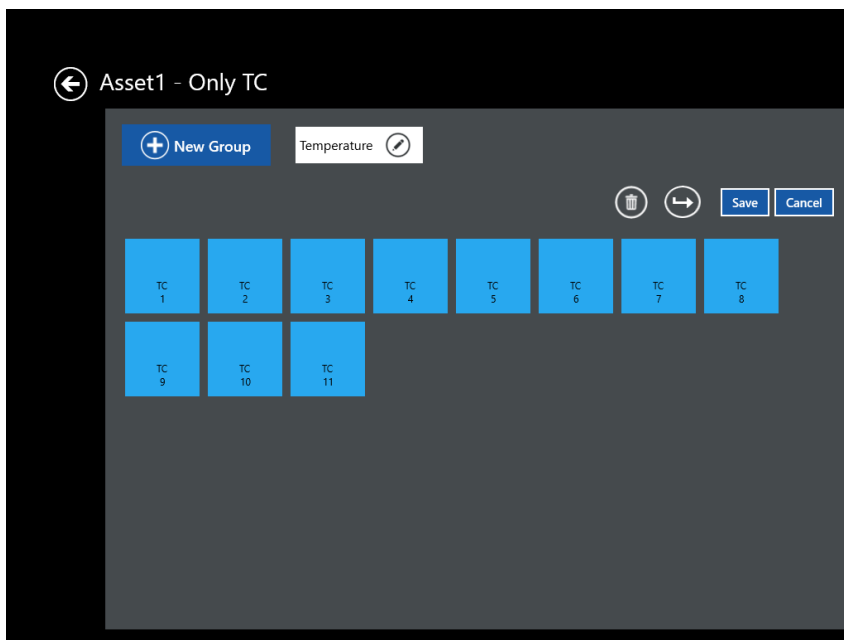


Figure 83: Customize Groups

To assign sensors to groups:

Press on individual sensors to select them for the group. These sensors now appear as a deep blue with an orange checkbox.

Press the New Group button. A Group Name text box appears above the selected screens.

Enter the name, and toggle the button to save the group.

The screen also offers different options:

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

10.14 Report Options Screen

Figure 84: Report Options Screen

When user selects Text Report Tile in the Report Screen it is redirected to Report Options Screen. The final step in setting up the report for printing is the selection of the report options. The first row header, “First Page”, display information as entered during study creation.

At left side the Groups list, two editable text boxes, “Performed By” and “Reviewed By”, allow you to enter the names of users who conduct or review the study. Three check boxes enable you to indicate whether these names will be displayed on the First Page, Last Page or All Pages.

Note: If you select All Pages, the other selection boxes are not available. Report structure can be customized

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Appendix A. Understanding Audit Trail Events

All events include the following mandatory data: date and time, user name, user ID, Console ID, Validator ID and Console- Validator ID combination.

Table 4: Audit Trail Events

Tabulation 1				
Users				
Create a user	Date/time of event	Create user	Name of system administrator	
		Name of new user	Success or Failure	Permission level
Modify a user	Date/time of event	Modify user	Name of system administrator	
		Name of modified user	Success or Failure	Permission level
Delete a user	Date/time of event	Delete user	Name of system administrator	
		Name of deleted user		
Failed login	Date/time of event	Login Failure	Unknown user	
		User ID entered		
Permission violation	Date/time of event	Permission violation	Name of user	
		Attempted action		
Password change	Date/time of event	User password change	Name of user	Success or Failure
Back up passwords	Date/time of event	Passwords backed up	Name of system administrator	
Restore passwords	Date/time of event	Passwords restored	Name of system administrator	Date/time of password file

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Table 4: Audit Trail Events (Continued)

Account disabled	Date/time of event	User account disabled	Name of system administrator	
		User name		
		User ID		
Account disabled after 3 consecutive login failures	Date/time of event	User account disabled	Automatic Event	
		User name		
		User ID		
Site Options	Date/time of event	Site options modified	Name of system administrator	
		Modification		
Preferences	Date/time of event	Preferences modified	Name of user	
		Modification		
Serial Numbers				
Validator	Date/time of event	Voltage calibration performed	Name of system administrator	
		Validator serial number, MAC		
SIM	Date/time of event	SIM calibration performed	Name of system administrator	
		SIM 1 serial number	SIM 2 serial number	SIM 3 serial number
CONSOLE	Date/time of event	serial number	Mac ID	

Table 4: Audit Trail Events (Continued)

Instrument Calibration				
Digitizer	Date/time of event	manufacturing		
Reference Voltage	Date/time of event	manufacturing		
SIM	Date/time of event	manufacturing		
Report Files				
Copy Calibration	Date/time of event	Calibration file copied	Name of user who copied file	
		Setup name		
		User who ran calibration		
		Date calibration started		
		Source directory		
		Destination directory		
Delete calibration	Date/time of event	Delete calibration file	Name of user who deleted file	
		Setup name		
		User who ran calibration		
		Date calibration started		
		Source directory		
		Destination directory		
Copy qualification	Date/time of event	Qualification file copied	Name of user who copied file	
		Setup name		
		User who ran qualification		
		Date qualification started		
		Source directory		
		Destination directory		

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Table 4: Audit Trail Events (Continued)

Delete qualification	Date/time of event	Delete qualification file	Name of user who deleted file	
		Setup name		
		User who ran calibration		
		Date calibration started		
		Source directory		
		Destination directory		
Copy calibration verify	Date/time of event	Calibration verification file copied	Name of user who copied file	
		Setup name		
		User who ran cal verification		
		Date cal verification started		
		Source directory		
		Destination directory		
Delete calibration verification	Date/time of event	Delete calibration verification file	Name of user who deleted file	
		Setup name		
		User who ran calibration		
		Date calibration started		
		Source directory		
		Destination directory		

DRAFT

Table 4: Audit Trail Events (Continued)

Setup Files				
Create	Date/time of event	New setup created	Name of user who created setup	
		Setup name		
		User who created Setup		
		Date created		
Modify	Date/time of event	Setup modified	Name of user who modified setup	
		Setup name		
		User who modified Setup		
		Date created		
Delete	Date/time of event	Setup deleted	Name of user who deleted setup	
		Setup name		
		User who created Setup		
		Date created		
Miscellaneous				
PC program started	Date/time of event	Program launch	Windows User ID of currently logged-in user	
PC program exited	Date/time of event	Program termination	Automatic Event	
PC program exited due to 3 unsuccessful logins	Date/time of event	Login failure termination	Automatic Event	
New audit trail	Date/time of event	Start audit trail	Automatic Event	

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Table 4: Audit Trail Events (Continued)

		Directory		
Restart due to tampering	Date/time of event	Tampering –restart audit trail	Automatic Event	
		Directory		
Back up audit trail	Date/time of event	backup	Name of system administrator	
		Directory		
Software upgraded	Date/time of event	Software version change	Name of user who upgraded software	
		Old version to new version		

Tabulation 2

SIM Connect and Disconnect
Temperature bath Connect and Disconnect
IRTD Connect and Disconnect
Power Loss
Under /Over Voltage

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Appendix B. Environmental Compliance

This appendix contains information on the following topics:

- WEEE Directive (*see Section B.1*)
- Battery disposal (*see Section B.2*)
- FCC Part 15 details (*see Section B.3*)

B.1 Waste Electrical and Electronic Equipment (WEEE) Directive



The equipment that you 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.

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B.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.

B.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%

B.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 osteomalacia 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.

B.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.

Kaye 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 (Route Sum Square)	0.055 °C	k=1
Total System Uncertainty	0.11°C	k=2

Kaye Validator AVS Specifications

Analog Input	Up to 48
Voltage Input Accuracy	30 days: $\pm(0.003\%$ of reading + 2 counts + 4 microvolts) 1 year: $\pm(0.006\%$ of reading + 2 counts + 4 microvolts)
System accuracy with thermocouple (specified from 20 to 30°C for 30days)	$\pm(0.003\%$ of reading + 0.25°C)
System accuracy with thermocouple (specified from 0 to 50°C for 30days)	$\pm(0.028\%$ of reading + 0.56°C)
Sensitivity	0.5 microvolts/count on most sensitive range
Voltage Temp. Coef.	$\pm(0.1$ microvolts + 0.001% reading)/°C
Compensator Temp. Coef.	± 0.01 °C per °C
Input Terminal Temperature	± 0.1 °C from calibrated terminal
Non-uniformity	
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	

B.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 device, 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 person"

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Appendix C. Safety and Precautions

Following safety precautions should be taken for proper operation of the unit and to avoid any manual injury



To ensure proper air flow, Fans should not be blocked



The unit should be serviced by authorized service personnel only.

Caution / Prudence

*Remove Battery Before Opening Unit
for service*

*Retirez la batterie Avant Unité ouverture
pour service*



This unit must be opened by Amphenol authorized service technicians only, tempering 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

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Appendix D. Service information

We operate a global network of service centres 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

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.

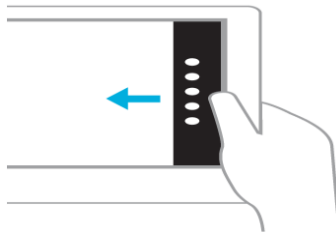
Swipe from the right edge for system commands

Swiping from the right side of the screen reveals the charms 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

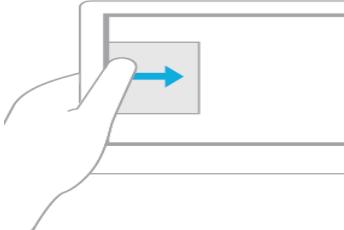


Swipe in from the left to switch apps

Swiping in from the left reveals thumbnails of your open apps so you can switch to them quickly.

Mouse equivalent

Place the mouse pointer in the upper-left corner, and click to cycle through apps, or in the lower-left corner to see the Start screen.

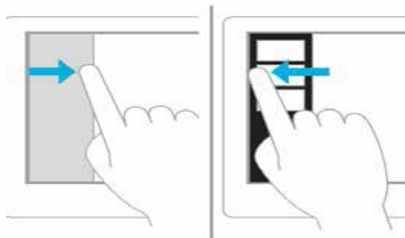


Swipe in and out on the left to bring up previously used apps

Swiping in and back out on the left brings up the most recently used apps and you can select an app from that list.

Mouse equivalent

Place the mouse pointer in the upper left and slide down the left side of the screen to see the most recently used apps

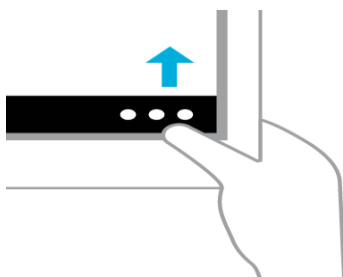


Swipe from the bottom or top edge for app commands

App commands are revealed by swiping from the bottom or top edge. You can swipe from the top to the bottom of the screen to dock or close the current app.

Mouse equivalent

Right-click the app to see the apps commands



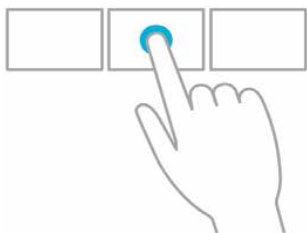
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Press and hold to learn

You can see details when you press and hold. In some cases, pressing and holding opens a menu with more options.

Mouse equivalent

Point to an item to see more options.

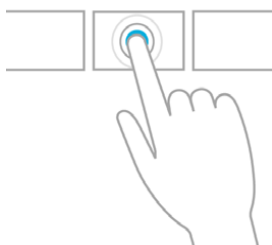


Tap to perform an action

Tapping something causes an action, such as launching an app or following a link.

Mouse equivalent

Click an item to perform an action



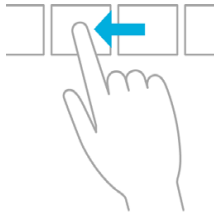
Slide to drag

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.

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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.

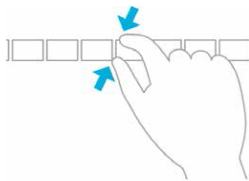


Pinch or stretch to zoom

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.



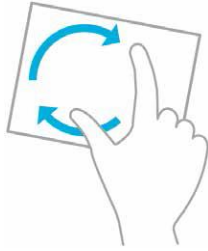
Rotate to turn

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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