Validation

Kaye Validator® AVS

User's Manual

M5100-EN Rev. E
April 2018

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Kaye Validator ® AVS

Thermal Process Validation System

User's Manual

M5100-EN Rev. E
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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, LTR –40/140 or LTR-150), 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

• IP55 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

• 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 a 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 yearly 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.*

1.4.4 LED Panel messages

The front panel of the Kaye Validator AVS displays the machine status with four LEDs. The LEDs can show red, green or both colors, steady or blinking.

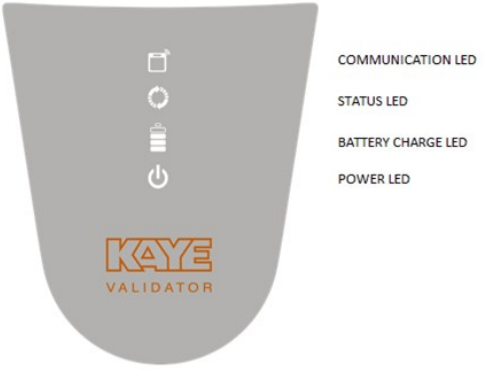


Figure 5: Validator AVS Front panel

The LEDs can indicate if a console is connected to the Validator, if a study is running and the status of the battery and AC power status. The details are described in Figure 6, below.

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

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

Figure 6: Validator AVS LED status messages

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 for different user levels that by default that define system access. These specific 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 for example 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 verification 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 be accessed through the AVS software. If the data is tampered with, the entire data file becomes inaccessible
- Password expiration feature allows to set a password expiration duration
- 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 based 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 via connection from your Console to the Validator AVS. See also the Validator AVS online Help for instructions on setting up a study.

1.5.5 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 on 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 the flexibility to design qualification procedures to fit 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, 32 GB of internal storage memory, and an USB flash drive interface. This chapter describes the Validator hardware and provides instructions for connecting the system. Included are sections describing:

- The back of the Validator AVS 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), used to connect sensors to the Kaye 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 32 GB of internal storage memory, and a backup battery in case the system loses AC power.

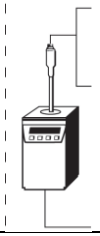
2.2.1 Connection Ports

The back of the Validator AVS (shown in the Figure 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 7: Connection Ports

2.2.1 Connection Ports (cont.)

Table 1: Connection Port Explanations

Icon	Connection Port
	**4 Pin Din Connector** 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!)
	**Output Relay Ports** There are two NO/NC relay outputs, labeled with a contact switch icon, for signaling a PLC or another device. Relay port 1 is second from the icon at the edge of the housing, Relay port 2 is near the icon. **Relay Rating:** 110 VAC ½ amp resistive load 24 VDC 2 amp resistive load 110 VAC ¼ amp inductive load 24 VDC 1 amp inductive load
	**USB Connector** One USB connector, labeled with a USB icon, is available for connecting an ICAL device. ICAL port is used for Service only
	**USB/ Ethernet Connector** There are two USB/Ethernet communications ports for connecting the Validator AVS and the Console. Ethernet cable to be less than 3 meters long

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

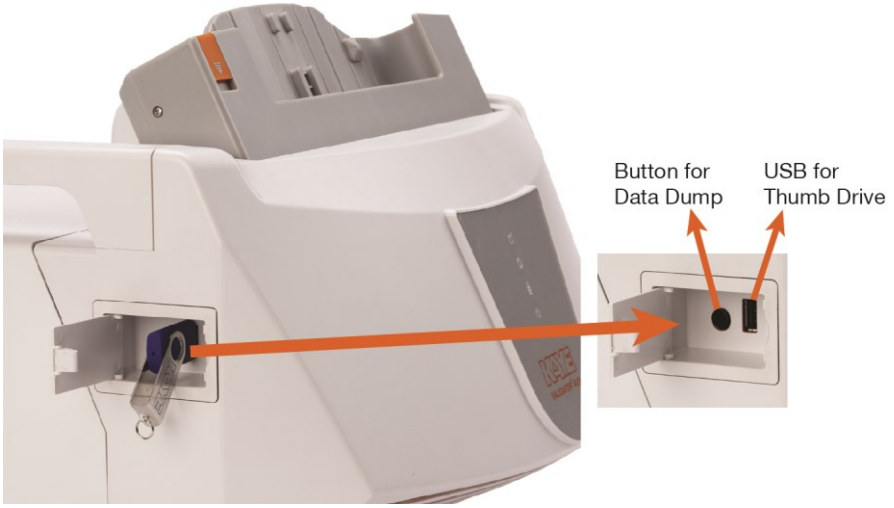


Figure 8: Side Port for Data Transfer

2.2.4 The Console

For programming and control, each Validator AVS includes the Kaye Validation Console with preinstalled Kaye software.
Figure below shows the procedure for docking a Console to a Validator AVS via its docking station.

Figure 9: 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 4 GB of internal memory to maintain qualification data during a study that is stored on the internal solid-state memory.

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.

Note: 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 = less than 25%. 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 should power down, insert your SIMs, and power up again. If a SIM is disconnected after power up, calibrated offsets or SIM data might not be read correctly. To rectify this, power down, reconnect the SIM, and power back up.*

2.3.1 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 below shows the inside of a SIM.

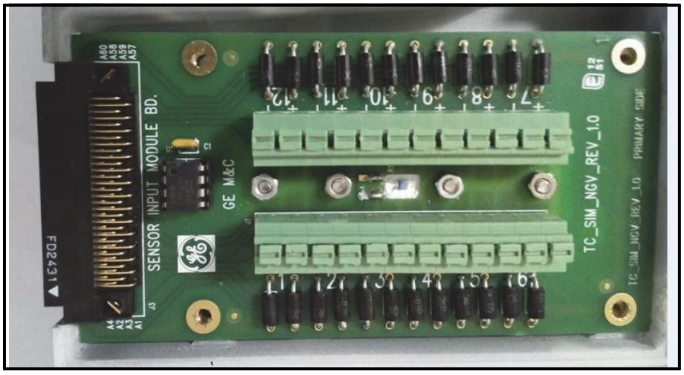


Figure 10: SIM Wiring

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* 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.

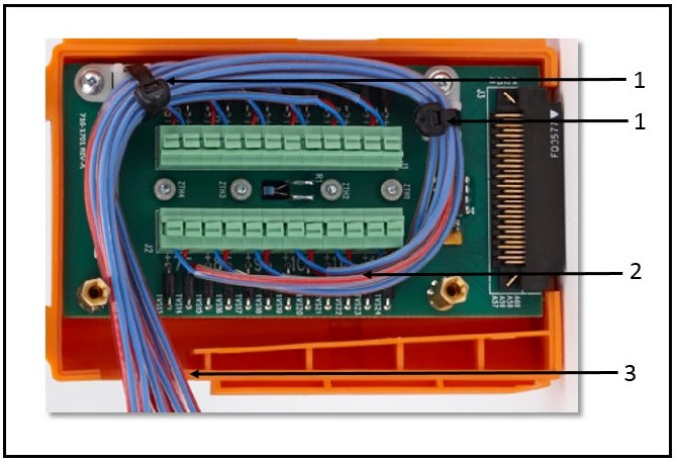


Figure 11: SIM Wiring

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 below. Cut through the outer insulation to separate the red and blue wires, and then strip back each wire approximately ½ inch to make the connection with the connector.

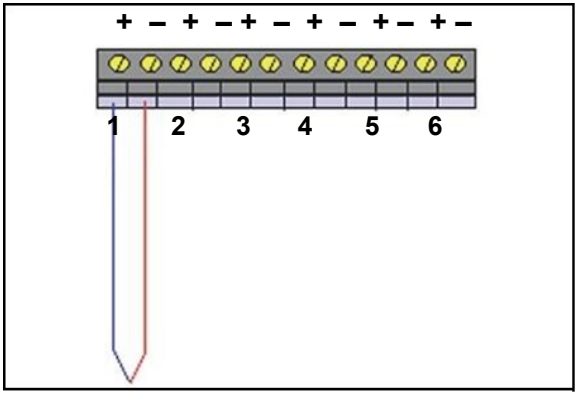


Figure 12: Thermocouple Connections

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 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 below).

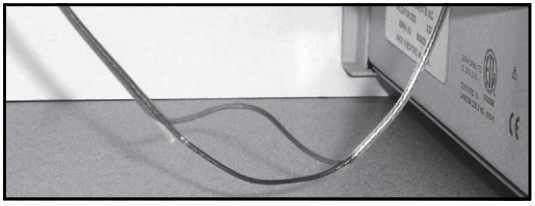


Figure 13: Drip Cut

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 below.

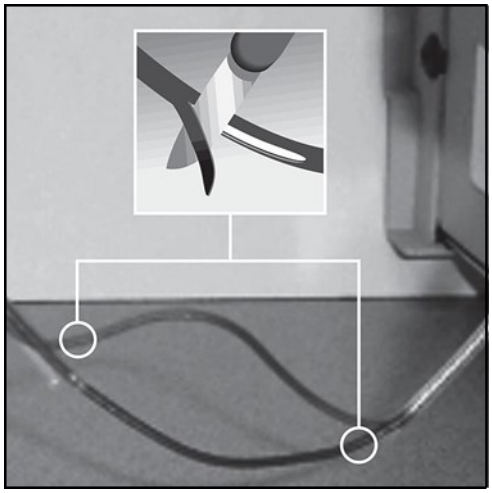


Figure 14: Shaving from the inner wire

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 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.

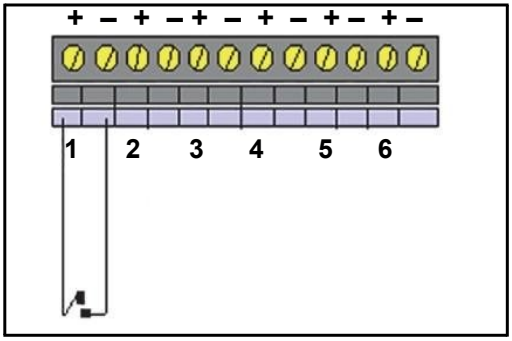


Figure 15: Connecting Dry Contact Inputs

2.3.1c Connecting a Voltage Input

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

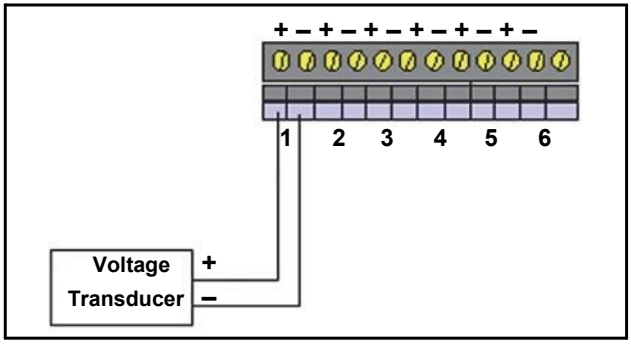


Figure 16: Voltage Input Connection

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 0.25-1.25 V. These voltages can be defined in the TC setup as voltages accordingly. For easier handling, we recommend using the dedicated 4-10 mA SIMs in the first place.

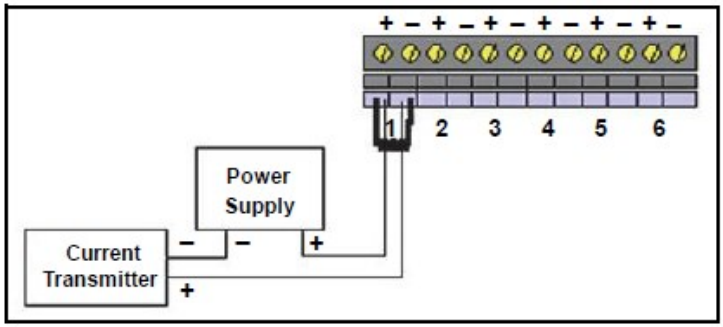


Figure 17: Current Transmitter Connection

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 4 mA 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.

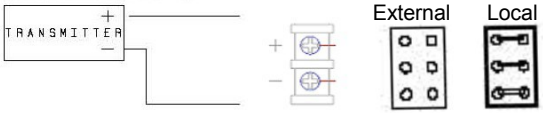


Figure 18: Configuration for Sensor with less than 4 mA Power

If the sensor requires more than 4 mA, 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.
• Configure the jumper block for External Power.

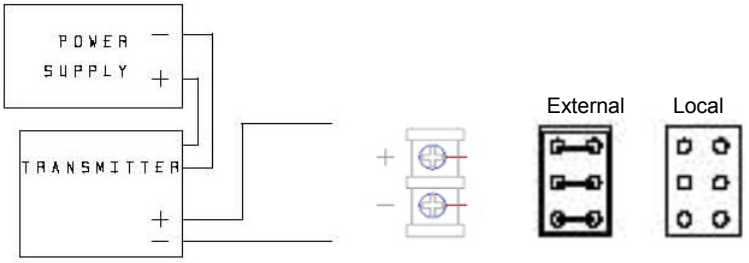


Figure 19: Configuration for Sensor with More than 4 mA Power

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

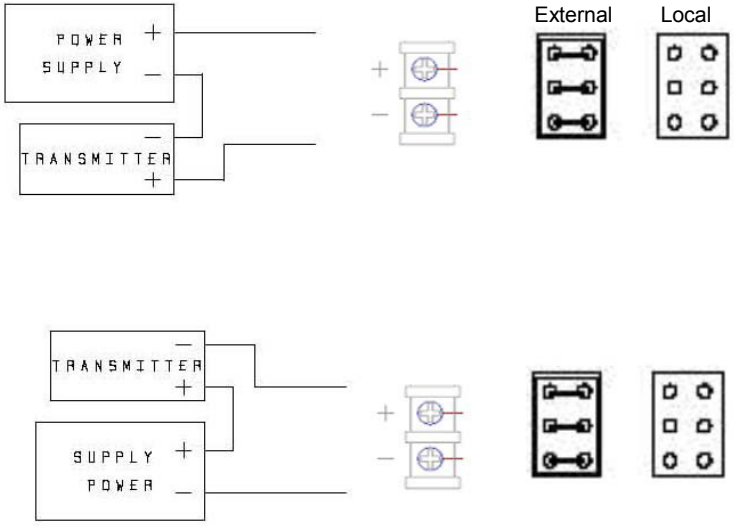


Figure 20: Configuration for Sensor with Less than 4 mA Power (Loop Powered Remotely)

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 0.025ºC, with a range of -196ºC to 420ºC.

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

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.
For calibration and verification studies only the upper IRTD port is active.

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.

LTR-150 (setpoint range -30°C to 150°C at 25°C ambient)
The Kaye LTR-150 is a multi-purpose calibrator specifically designed to calibrate 48 thermocouples at once and to function as a Dry Block, Liquid Bath or Surface calibrator.

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

To insert thermocouple sensors into the LTR-150 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-150 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-150, 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 (see 2.7 for details).
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 Connecting the Kaye Validation Console to the Kaye Validator AVS

The communication between the Kaye Console and the Kaye Validator AVS bases on the TCPIP protocol. The Kaye Validator AVS and the Kaye Validation Console usually connect through the integrated docking station but both components can utilize any kind of TCPIP based network to interconnect using a wired Ethernet or a wireless Wi-Fi connection.
For the connection through TCPIP an infrastructure (company network, router, or even smartphone hotspot) providing a DHCP-server is required.
There are different ways to establish a connection:

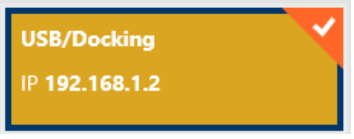
- Docking Port of the Kaye Validator AVS
- Wired connection via Ethernet infrastructure (LAN)
- Wireless connection via Access Point

Docking Port

This is the simplest way to establish a connection between console and hardware. Like illustrated in Figure 9 insert the console into the docking port of the AVS. The connection between is still based on TCPIP with the fixed IP address of 192.168.1.2 for the Validator AVS.

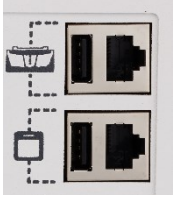
Note: The 192.168.1.2 is fixed in the system and cannot be changed. To avoid IP address conflicts please make sure this IP is not used in any connected hardware (e.g. Local networks).

For connection through the docking port simply select the USB/Docking button and press connect. The Console will start the connection with the Validator AVS.



- Connecting the Kaye Validator AVS to Ethernet

On the back of the Kaye Validator AVS are two Ethernet ports located. The icons beside the ports indicate the device the port is connecting to. Simply connect the Kaye Validator AVS to a LAN network with an Ethernet cable. The IP address needs to be provided by a DHCP server. Any console, connected to the same network (either wired or connected via Wi-Fi) can discover the AVS in the hardware screen and connect remotely. For a wired connection, the Ethernet port for the console of the Kaye Validator AVS can be used while docked to it. For office use, there is a separate docking station available.



- Connecting the Kaye Validation Console to Wi-Fi

Establishing a Wi-Fi connection of the console is very simple:
In the start menu swipe the Windows charms from the right side and choose “Settings” (See arrow in Figure below). It is not necessary to log in as Kaye Admin.

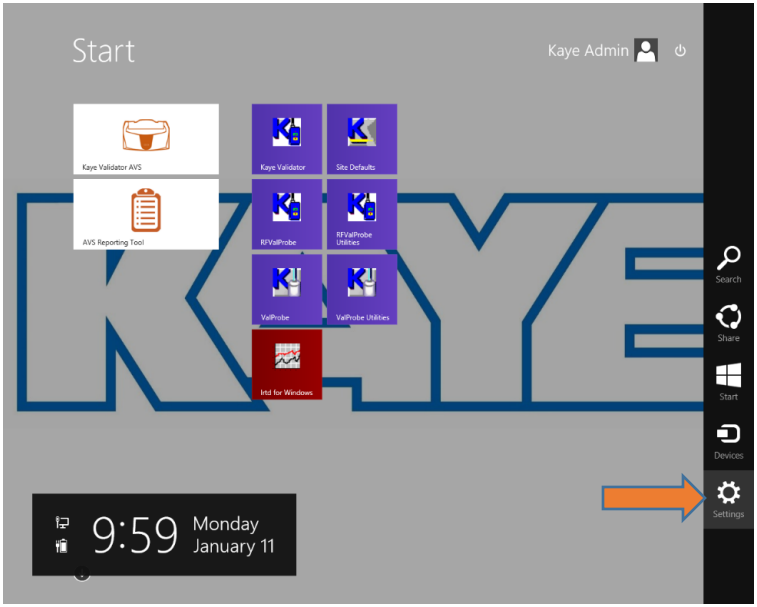
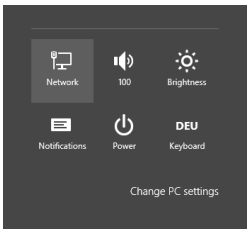


Figure 21: Startup screen with Windows charms

In the settings, choose “Network” out of the buttons.



This gives you a list of available network connections. If Wi-Fi is switched off, please switch it on now. You can see the available networks. In the example below, there are two networks available.

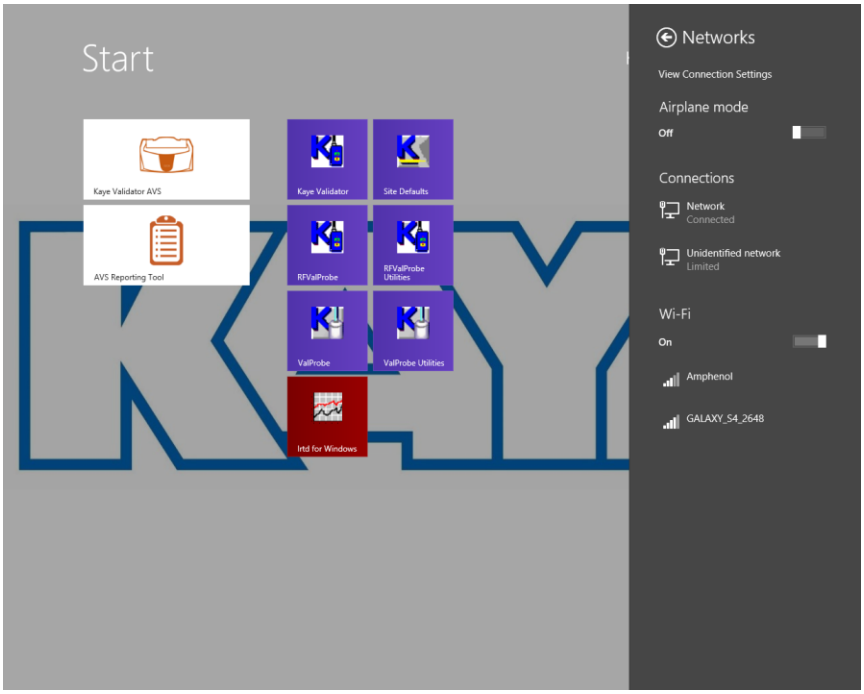
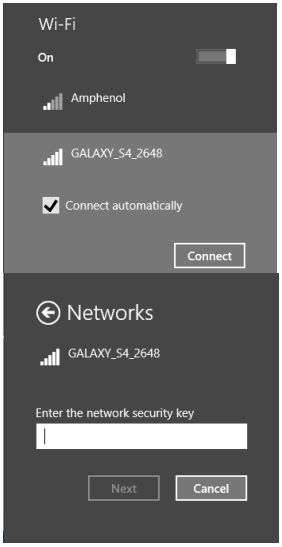


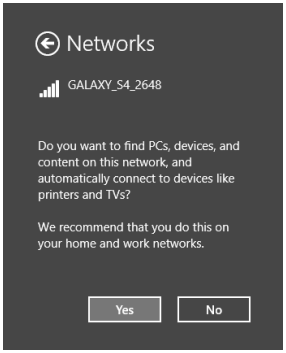
Figure 22: Startup Screen and network connections

After choosing a network (in the example below a mobile android phone configured as a hotspot, but any accessible Wi-Fi network will work), it is possible to connect by pressing the "Connect" button. If connect automatically box is checked the console will always automatically connect to this network if it is in range.

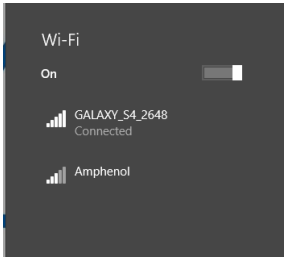


For establishing the connection, it is required to enter the Wi-Fi password. You can get the required information from your Wi-Fi administrator. In case of using the hotspot function of a mobile phone the password is listed in the configuration of the hotspot.

When connecting the first time to a network Windows asks for identifying devices in this network automatically. It is recommended to choose “Yes” for unrestricted access inside the network (please contact your IT administration for details).



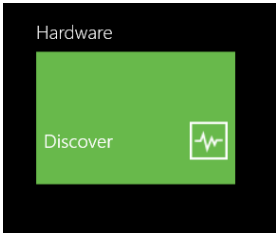
Now the console is listed as connected to the Wi-Fi network.



- Connecting the Kaye Validator AVS to Wi-Fi

For the configuration of the Wi-Fi connection of the Kaye Validator AVS another connection type is required firstly. The easiest way is to put the console into the docking port of the Kaye Validator AVS for a direct connection. Nonetheless an Ethernet connection using a wired connection would also work.

After docking the console, choose “Hardware/Discover” in the Homepage of the Kaye AVS software.

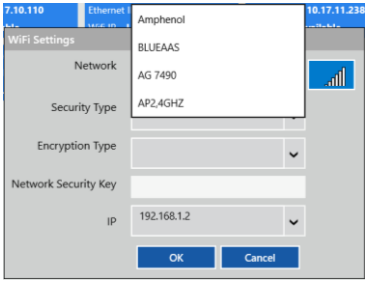


In the “Select AVS” Window, choose the AVS you want to configure for Wi-Fi. As mentioned already it is necessary to have established connection. It is recommended to dock the console to the AVS and choose “USB/Docking”

Figure 23: Select AVS screen

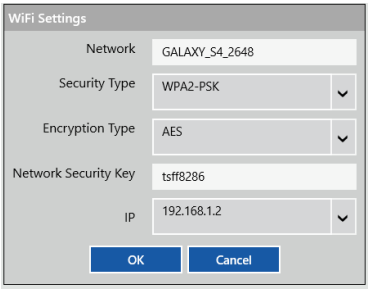
After choosing the AVS press the "Configure Wi-Fi" Button. A new dialog box will open.

Firstly, enter the Network name (or SSID) of the network manually or use the network button to prepopulate the available SSIDs automatically into a dropdown menu for selection. In the example below, it is again the name of the mobile hotspot.



Note: The SSIDs in the dropdown are copied from the console's discovered Wi-Fi list. In case you connect remotely to the Validator AVS via Ethernet these networks are maybe not available in the remote location.

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



Note: Usually modern Wi-Fi networks use WPA2-PSK and AES as listed in the example and there is the best chance it will work with most networks.

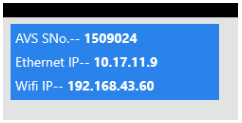
Lastly the Wi-Fi password: In the example below the password is generated by the mobile hotspot of the smartphone. Please ask your Wi-Fi administrator if you do not know the password.

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

Press “Ok” to transfer the new Wi-Fi setup to the Kaye Validator AVS

After a short time the message “Wi-Fi configured successfully” will display.

Note: In case of an error message (Wi-Fi Configuration failed), please make sure the Kaye Validator AVS is available, the Wi-Fi network is available and all information was entered correctly.
In case “Automatic” was used for the configuration of network security and encryption, it is possible the network does not provide this information and it is necessary to choose the correct values from the dropdown menus. The Kaye Validator AVS is limited to 2,4GHz networks and the channels 1 to 11. 5Ghz networks and channels 12 to 16 are not supported.
When pressing discover now the Wi-Fi IP address of the Kaye Validator AVS should be displayed.



Connecting via Wi-Fi: Select the AVS and press connect and in the small popup choose Wi-Fi as connection type.

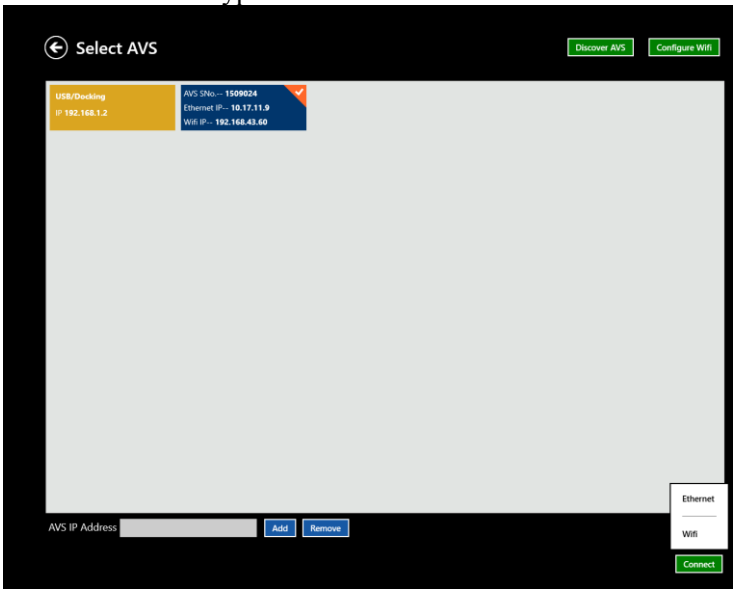


Figure 24: Select AVS screen with discovered AVS

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

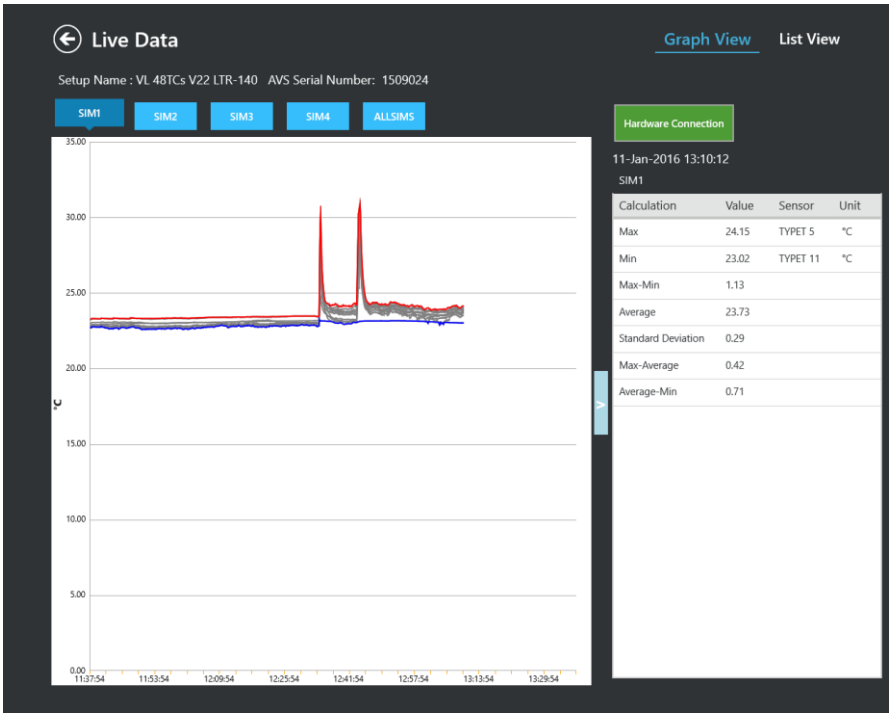
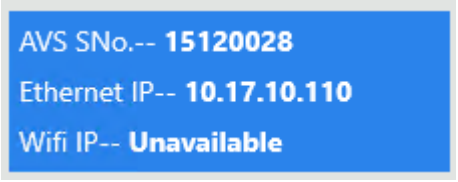


Figure 25: Live data provided via Wi-Fi connection

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

If the discovered Kaye Validator AVS has valid IP addresses for Ethernet and Wi-Fi, there is a choice when pressing the "Connect" Button.

In case only one IP address is available the Connection is established to this address without choice.

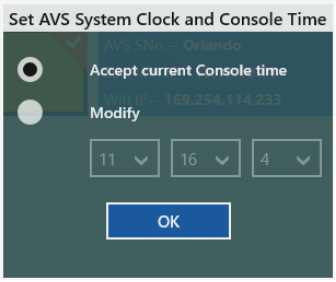


Note: Sometimes invalid IP addresses (starting with 169.x.x.x) are displayed but will not function.

2.8 Setting the Validator AVS Time and Date

When the Console starts any kind of study, the current time and date are automatically synchronized 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.

When creating a setup, there is an option in Qualification parameters for Clock adjustment. When enabled the user can change the console time when copying the setup to the Kaye Validator AVS. This feature can be useful to synchronize the Kaye Validator AVS with another device e.g. like the internal clock of an autoclave. It allows an adjustment of +/- 30 Minutes and is recorded in the audit trail.
The new timepoint is set after pressing the “Ok” button for user verification.



2.9 Preventive Maintenance

2.9.1 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.

2.9.2 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.

2.10 Transporting and Shipping

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

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

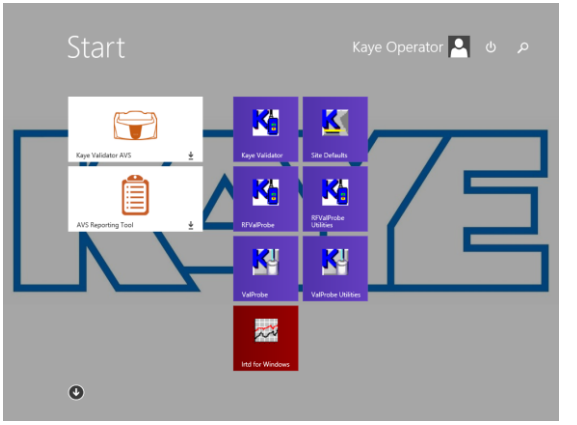


Figure 26: Login Screen

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

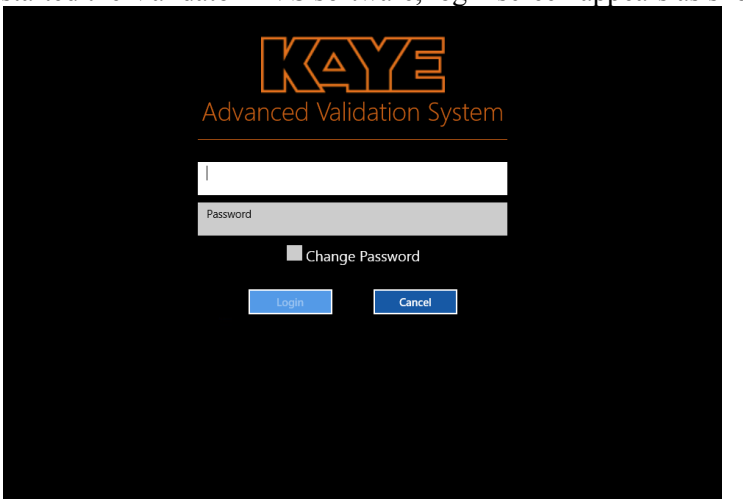


Figure 27: Login Screen

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.

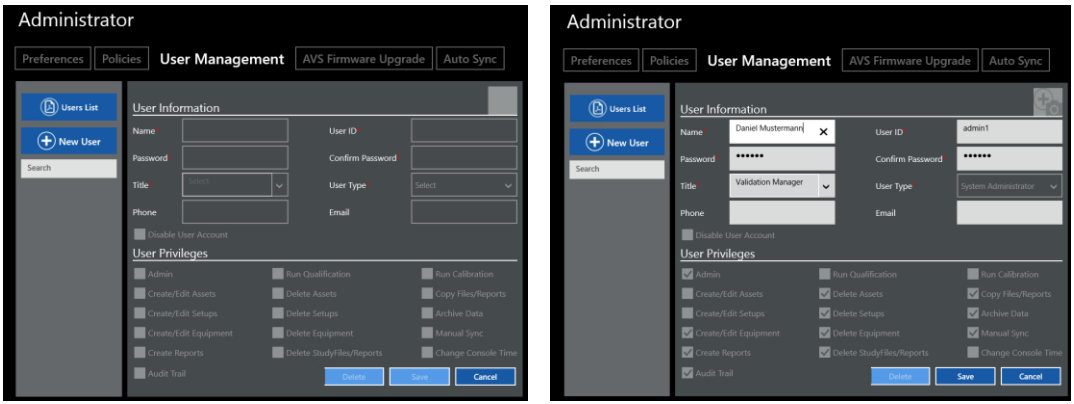


Figure 28: New User Screen - Create initial system administrator

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 can identify you by name using your unique user ID and password combination.

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

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

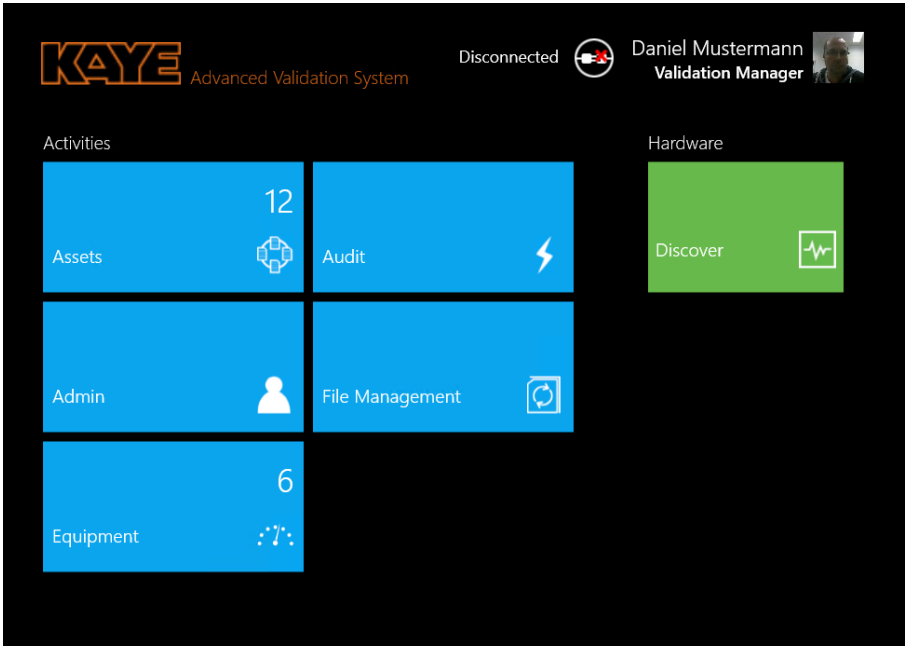


Figure 29: The Main Screen

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.)

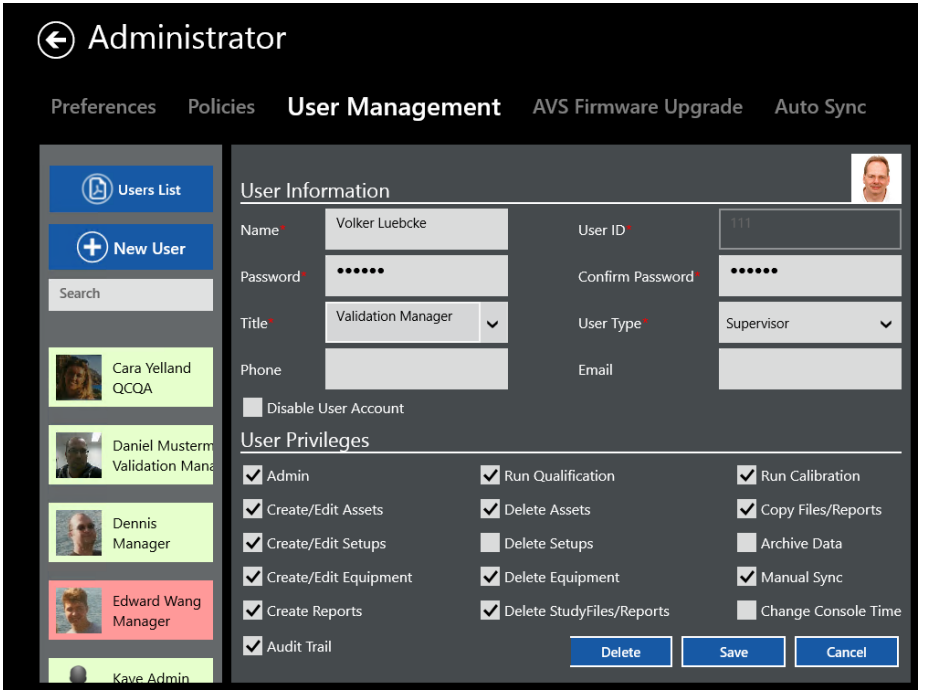


Figure 30: User Management Tab

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 has 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 to 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. To prevent discrepancies in the audit trail, the user ID of the deleted user is blocked for further usage. The deleted user is removed from the user list but the user information remains accessible via the printout of the user list.

Users List

The button "Users List" will generate a pdf report that list all active, disabled and deleted user information.

User search

For quick access, there is a search field that automatically filters for user name. Please not the field filters for the complete user name as one expression. As an example, if you enter a B all user names starting with a B are already listed. If you want to search for Bob Smith" entering "Smith" will not work.

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

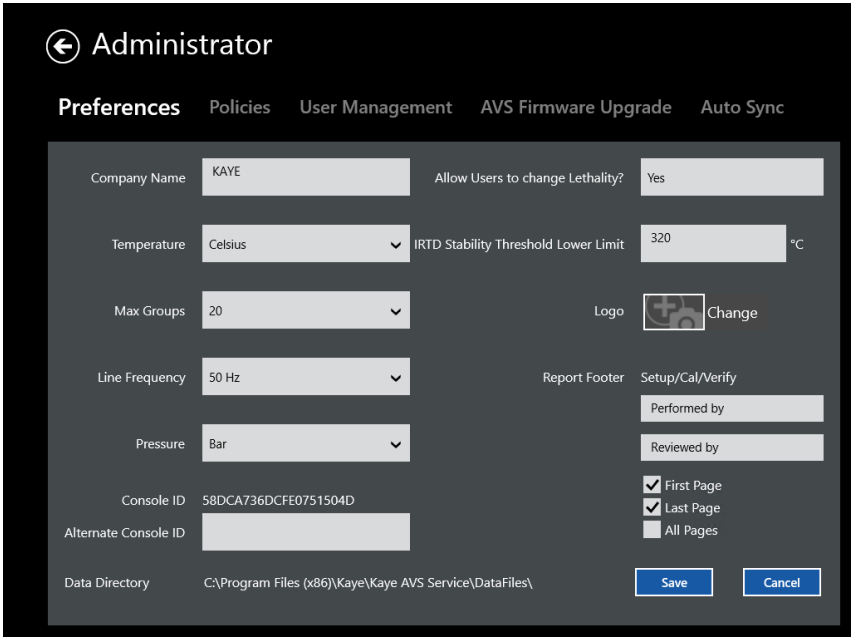


Figure 31: Preferences Tab in the Admin Menu

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

1. The company name as entered here is displayed in report headers.

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-150, LTR –25/140, LTR –40/140, HTR 400, CTR –40, or CTR –80) are also programmed to operate in these units.

   IMPORTANT: *If a setup was created before changing units on the Preferences screen, the software will prompt to change to the new settings the next time the setup is saved. However, only the label will be changed, not the temperature value. It is required to convert the temperature values manually to the new temperature units. For example, if you created a setup using °C, you may have entered 100.0°C as a calibration setpoint. If you change the temperature units to °F, the software will change the calibration setpoint to 100.0°F, not 212.0°F, changing the label from C to F but not the numeric value. If you want the setpoint to be 212.0°F, go to the Calibration screen and change the temperature value accordingly.*

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. Select 60 Hertz or 50 Hertz from the dropdown menu to set the line frequency. Choose the setting that matches your environment.

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

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

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

7. 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.

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

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

10. The path and folder that holds the Data Directory is displayed.

3.5 Setting Policies

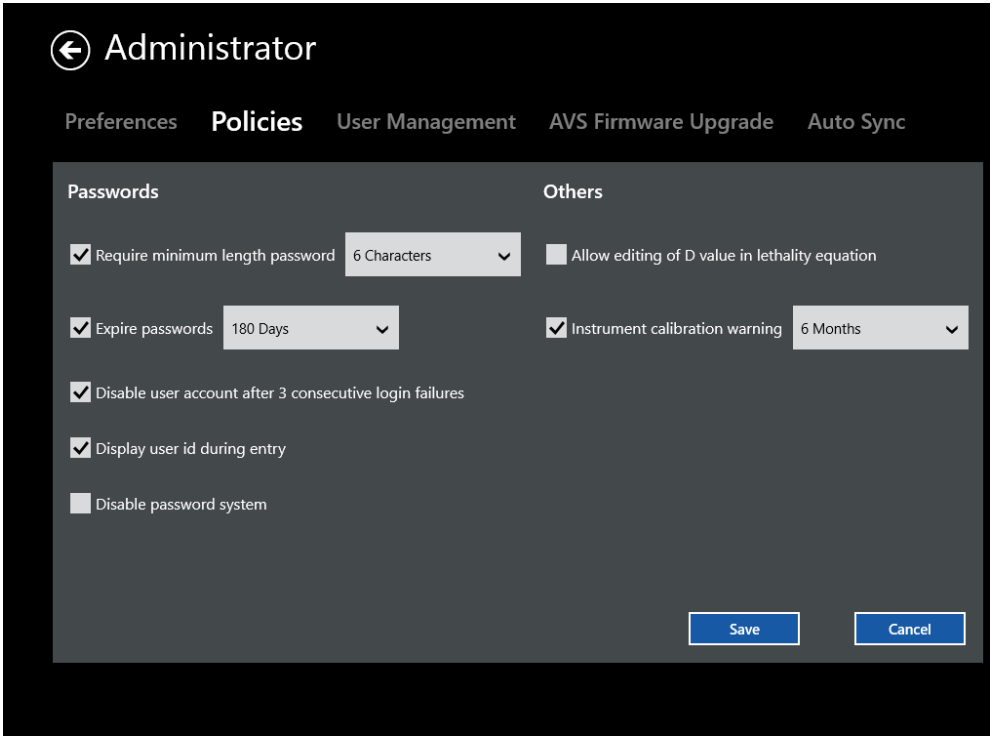


Figure 32: The Policies Tab

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

- Disable user accounts after 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 like the password entry with dots in the login screen.
- Disable the password system. User IDs and passwords will not be required to use the software.
- 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.
- The instrument calibration warning sets the prewarning interval for Kaye Equipment populated under the Equipment tile (see Chapter 4 Defining Equipment).

3.6 Updating the Kaye Validator AVS Firmware

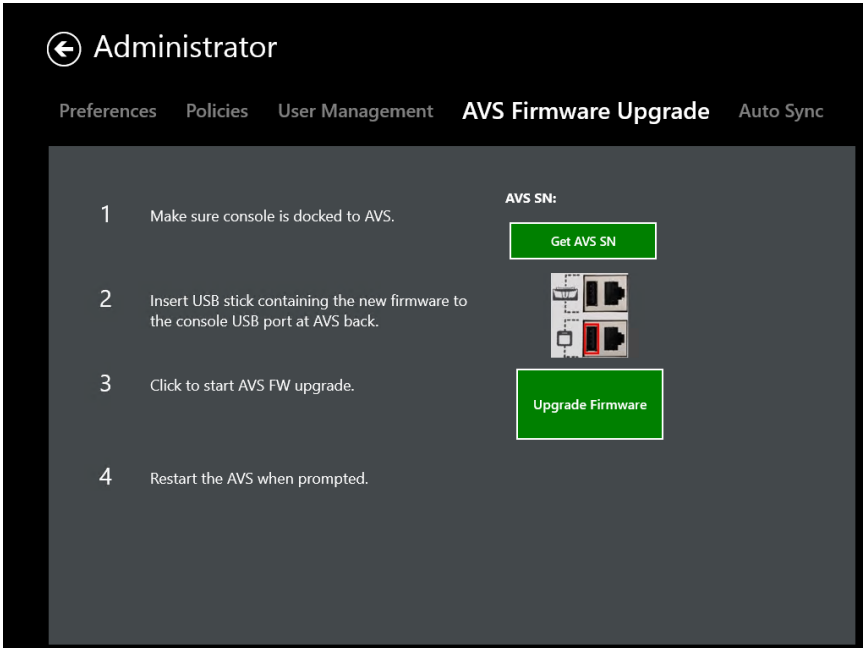


Figure 33: The Firmware Upgrade Tab

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!*
2. 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.
3. Insert a USB thumb drive with the firmware provided by Kaye into the USB port of the Kaye console on the backside of the Validator AVS. You can easily identify the correct USB port by referring to the displayed picture.
4. 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.

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

3.7 Handling Data Files

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 File Management tile on the main hub screen. When starting a sync operation, the software firstly asks for the sync folder location.

- **Sync Out**

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

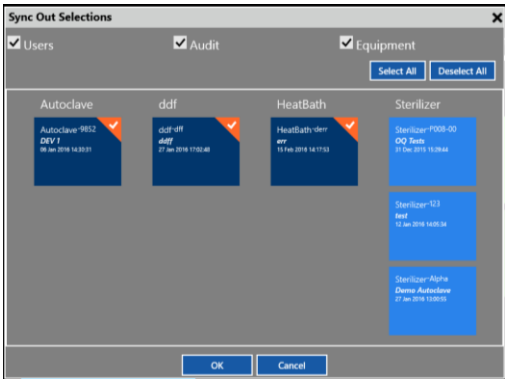


Figure 34: Sync Out selection box

- **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.

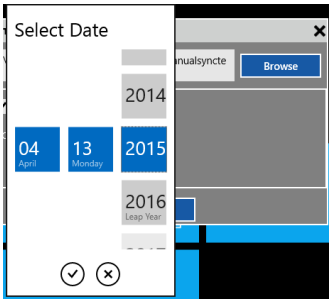


Figure 35: Sync In - Date Filter

- **Archive**

The Archive function works like the Sync out function except it will not copy but move files to a file location for archiving purpose, removing the files from the console.
Therefore, in addition to the Sync out function there is an archive date. All files that are older than the specified date are moved. Like in Sync out the assets can be selected individually.

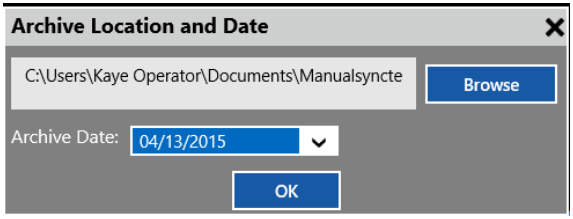


Figure 36: Archive Date Filter

- **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.

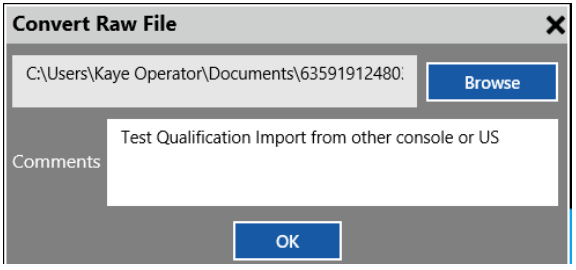


Figure 37: AVS Convert – Import comments

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

- **Using mapped Drives for Synchronization**

The synchronization function can be used for sharing data via a mapped drive to a server. The mapped drive should be mapped in the Windows console firstly. There are some rules to follow to make it work properly:

- The server should be entered as plain IP address; a server name will not work.
- The sync is always directly in the mapped drive; therefore, it is required to map the sync folder as a shared drive directly. Choosing subfolders will not work.
-

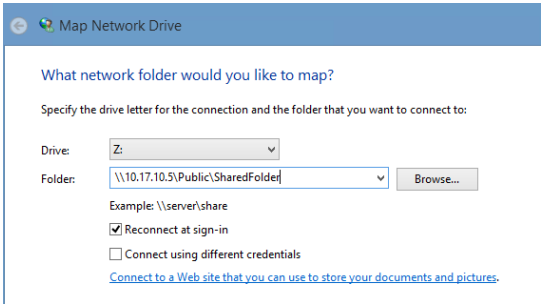


Figure 38: Windows – Mapping a drive

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

- Select mapped drive in the checkbox
- Browse to the mapped drive. It is maybe required to open it through the file explorer and entering windows credentials for access firstly.
- Enter your credentials for accessing the drive. If you are in a domain security you can add the domain information after the username with an @ extension as shown below.

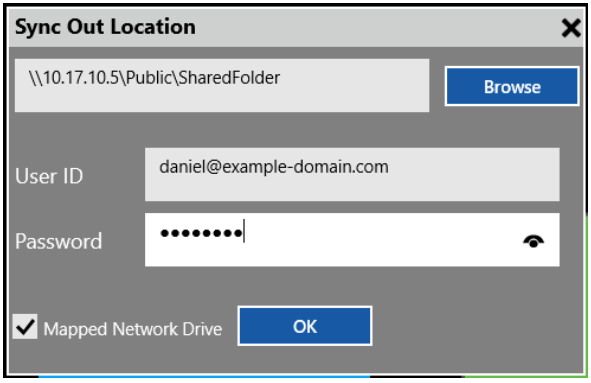


Figure 39: Mapped drive login credentials

The security setup for accessing the shared folder depends on your network environment. There are several scenarios:

- The folder can be accessed without any restriction. In that case, it is required to enter just something into user and password. The fields are not allowed to be empty but the content is not used.
- The folder has a user restriction. In that case enter your user credentials to access the folder.
- The folder is in a domain security policy. Please enter the domain after the user name with an @ between username and password. Some Domains will not accept this type of authentication and may require joining the console to the domain which will copy all domain security policies and user to the console. Please contact your IT department for further support.

• Auto Sync Function

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

The setup of the Auto Sync is located under the Admin tile in the tab “Auto Sync”

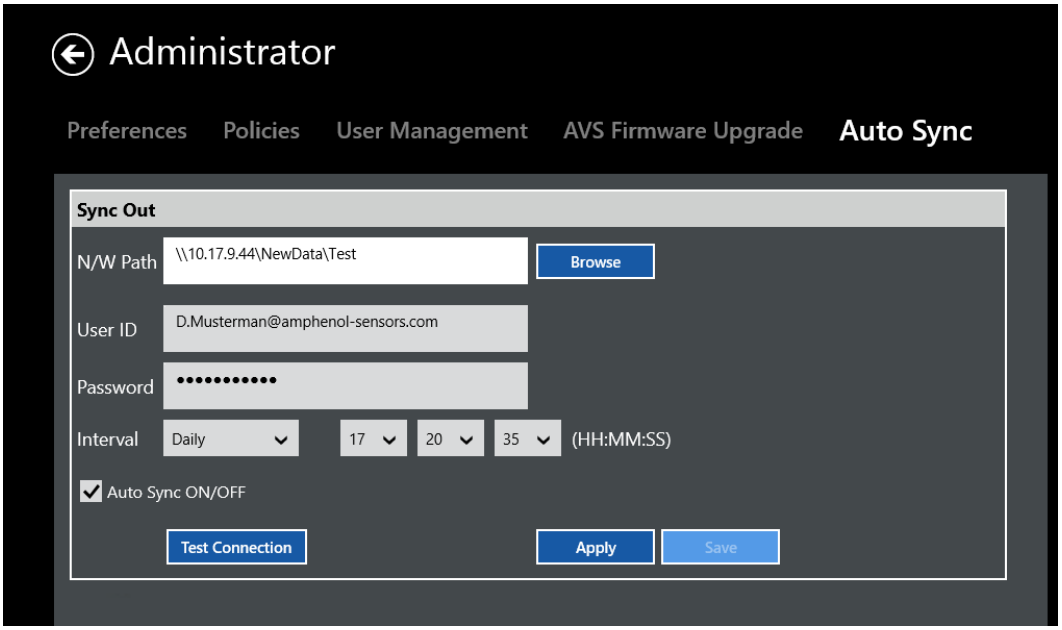


Figure 40: Auto Sync details

The Kaye Validator AVS software can sync the data automatically to a remote network folder in a defined time Interval. The setup for the sync location follows the same rules as described for manual sync out and how to use mapped drive in a network on the previous pages. Please note

that Auto Sync is expecting a mapped drive in the network as remote folder. Local drives or USB drives cannot be used for automatic synchronization.

- N/W Path: Browse to the mapped drive. It is maybe required to open it through the file explorer and entering windows credentials for access firstly.
- User ID / Password: Enter your credentials for accessing the drive. If you are in a domain security you can add the domain information after the username with an @ extension as shown below. Please use the Test connection button to check if the user/password combination works with the path.
- Interval: That the interval and time the automatic sync out should start.
- Auto Sync ON/OFF: Enable or disable the Auto Sync Function
- Test connection: When pressing the button, the software tries if the entered path and user credentials allows access and shows a message accordingly.
- Apply/Save: After changing the settings you can apply and test the connection. For permanent use of the setup please press save. When leaving the tab without saving the old credentials are still valid.

The results of the Auto sync functions are logged in the audit trail. In case the automatic sync fails a message with required user verification will appear on the screen to make sure the operators are notified of it.

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

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” button 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

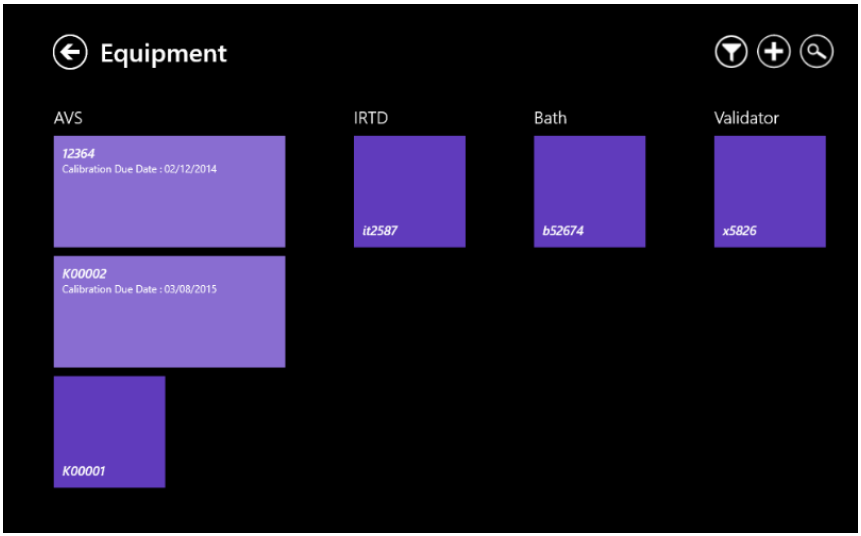


Figure 41: Equipment Hub

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 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.

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.

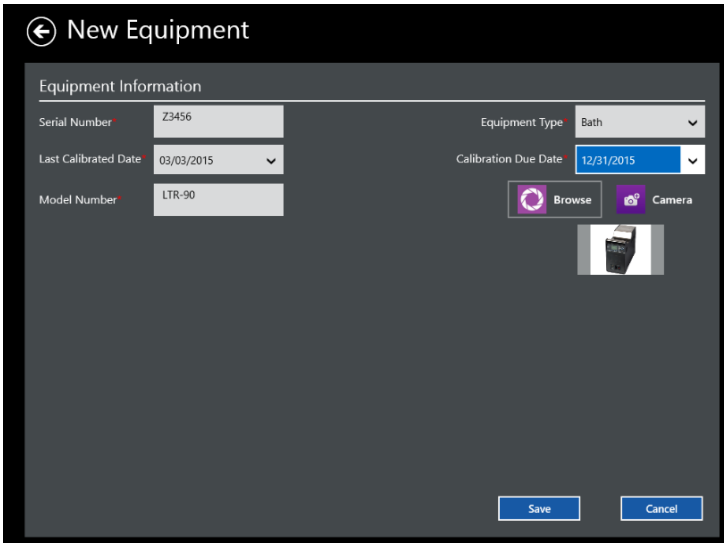


Figure 42: New Equipment Screen

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 item on the Equipment Hub screen. The Equipment Details screen opens.

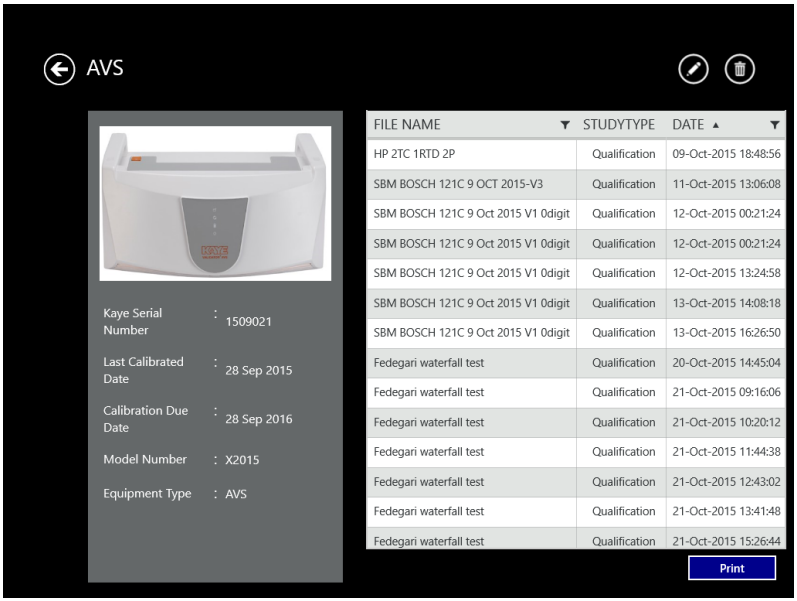


Figure 43: The Equipment Details Screen

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.

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 like Figure below.

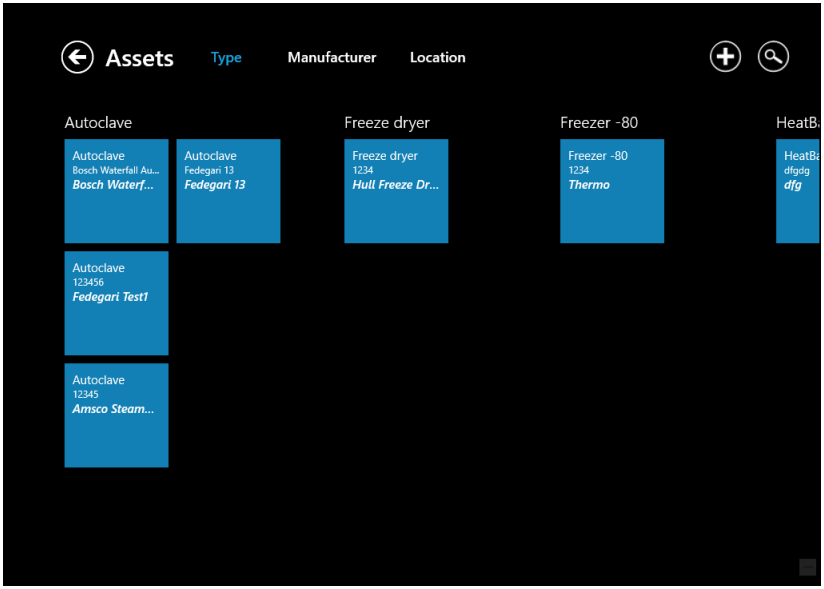


Figure 44: The Assets Hub

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
- 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 enter the search criteria / data.

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

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

5.1 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.

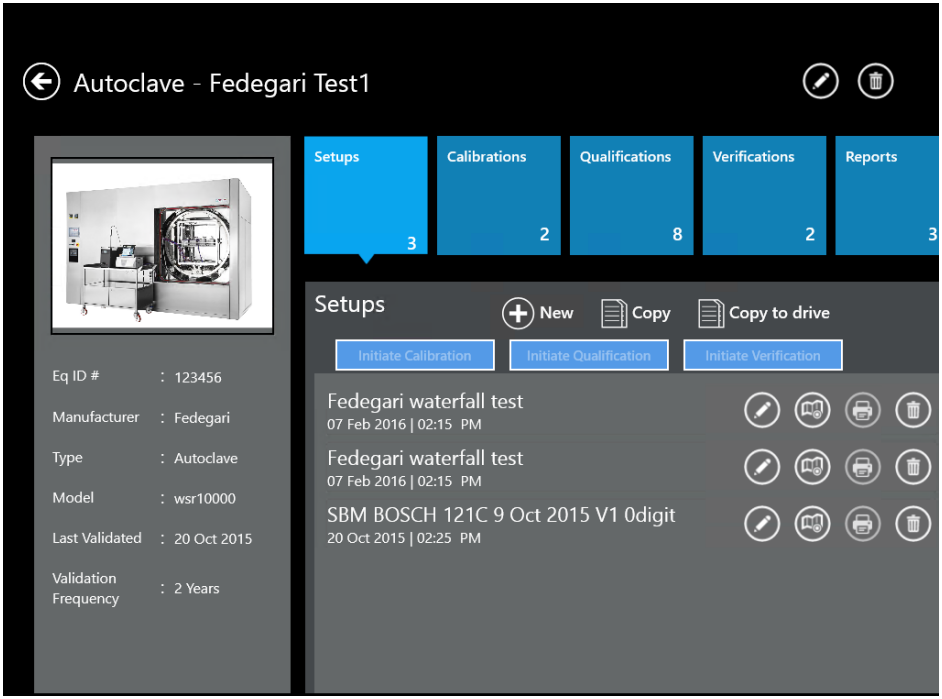


Figure 45: Asset Details

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.
- Manufacturer: Asset manufacturer name
- Type: Categorization of the asset
- Model: A model name or subtype can be specified
- Last validated: Date of the last validation as manually entered in the edit asset screen.
- Validation frequency:

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 to create a new setup by pressing the **Create New Setup** button.
A setup for the Asset holds all information 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 functionally 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.

For every setup, following action buttons are available:

- Pencil Button: Allows to edit an existing setup and save it under the same or a new name.
- Wiring Map button: Allows to review the wiring diagram for the sensors and export to pdf. Wiring diagrams are created inside the setup when defining the groups.
- Print button: Allows to export the setup report including the wire diagram to a pdf file
- Delete button: Allows to delete the setup.

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. Like the setup files the data 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 provides 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.

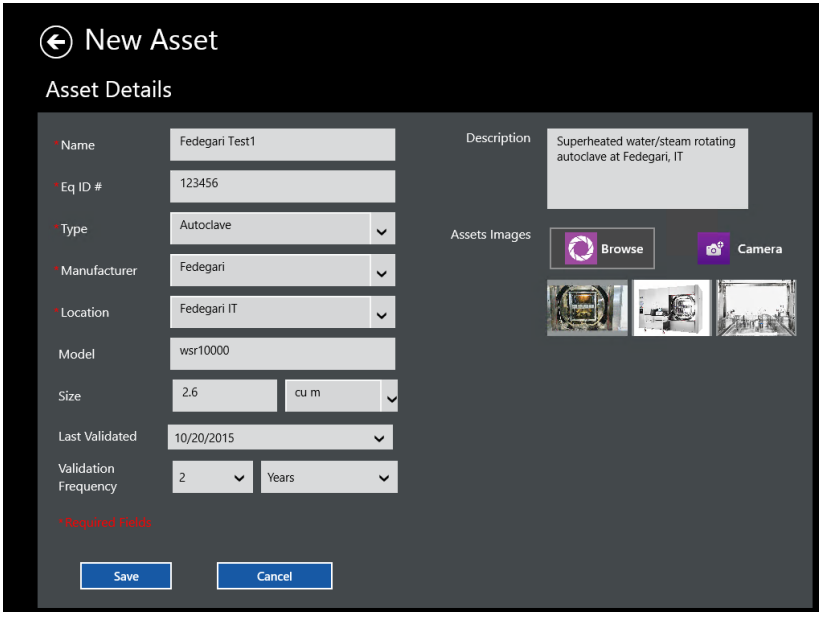


Figure 46: New Asset Screen

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

- The asset name: Asset names must be unique. Before synchronizing several asset data sets, it is recommended to make sure that there are no duplicate asset names utilized. This field is mandatory and required for unique identification.

- The Equipment ID: Equipment IDs must be unique. This field is mandatory and required for unique identification.

- The type of asset: Any new type definition will be available in the dropdown in the future. Please be careful as also test types or wrong spelled types will be available in the dropdown. This field is mandatory and required for sorting.

- Manufacturer: Specify the manufacturers name of the asset. This field is mandatory and required for sorting.

- Location: Specify the location of the asset. This field is mandatory and required for sorting.

- Model: Specifies the model number of the asset. This field is optional.

- Size: Specifies the volume of the asset in cubic units. In the dropdown, it is possible to select the appropriate units or enter custom units. This field is optional.

- Last Validated: Specifies the date of the last validation of the asset. This field is optional.

- Validation frequency: Specify the required validation frequency. This field is optional.

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

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

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).*

The setup is accessed 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.

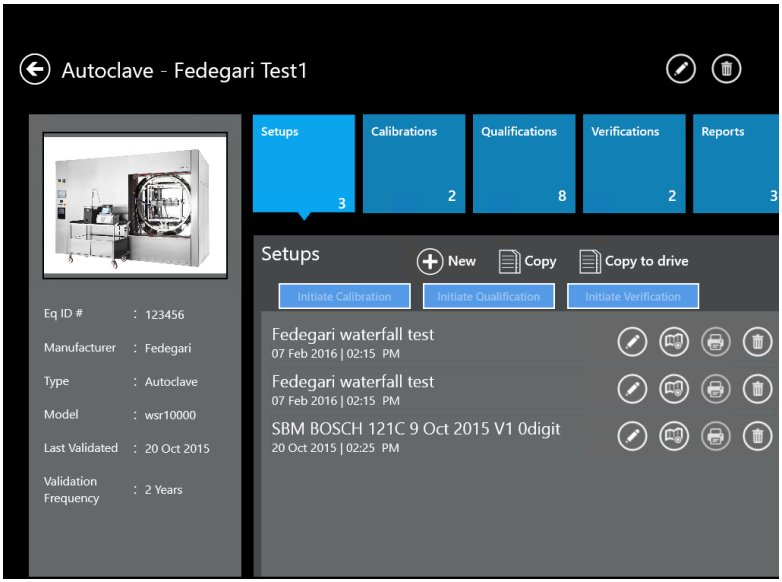


Figure 47: The Setup Hub Screen

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.

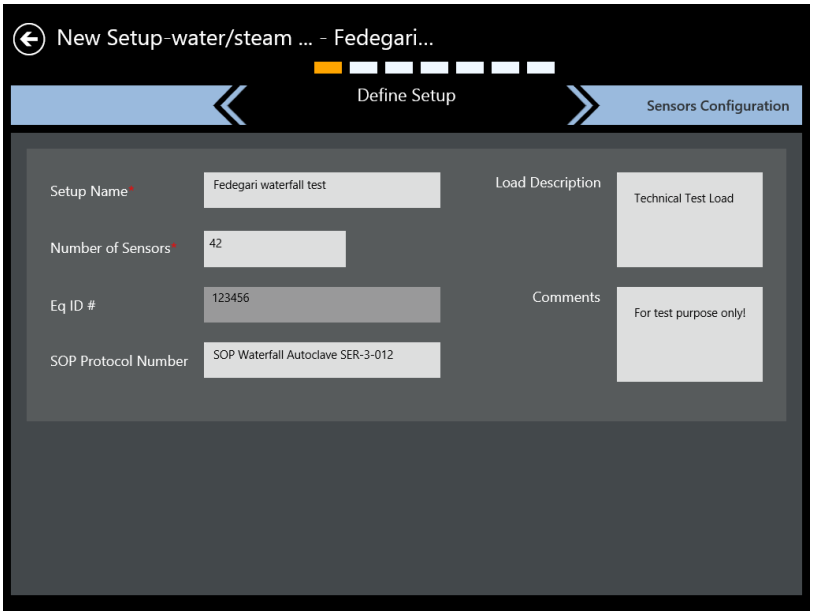


Figure 48: The Define Setup Screen

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.

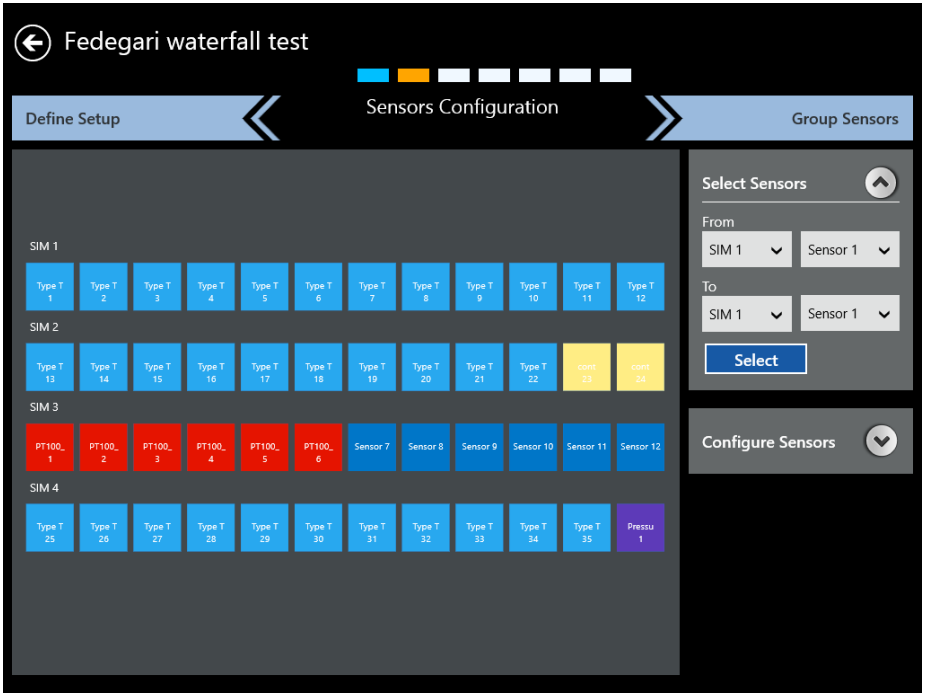


Figure 49: The Sensors Configuration Screen

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.

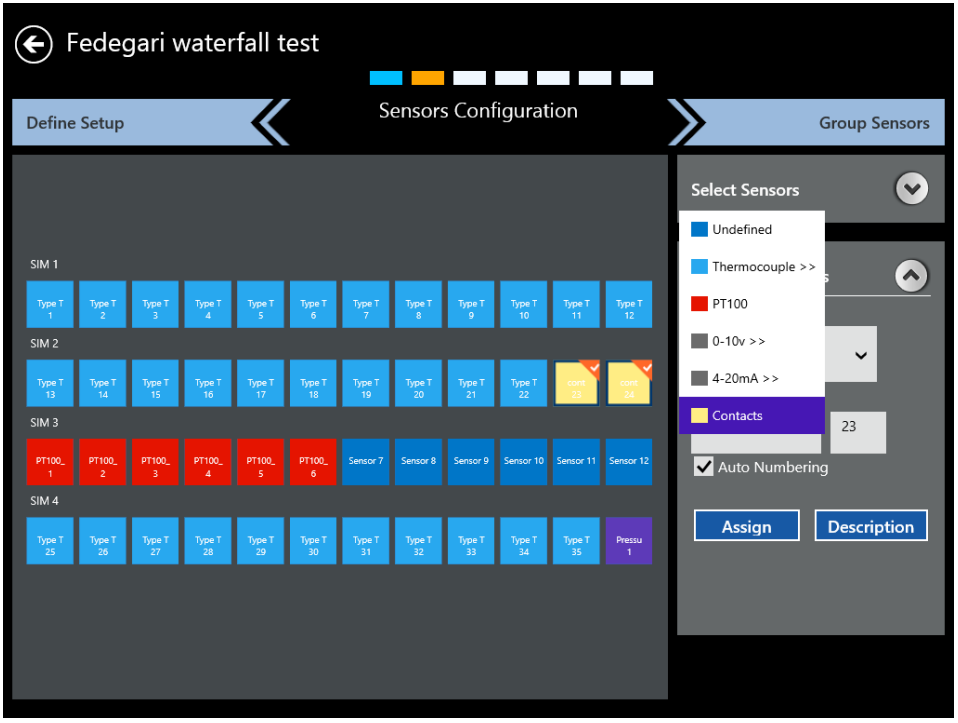


Figure 50: Configuring Sensors

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, with following supported ranges:

Thermocouple Type	***Lower Limit [°C/F]***	***Upper Limit [°C/F]***
E-TYPE	-200 / -328	900 / 1652
J – TYPE	-40 / -40	750 / 1382
T - TYPE	-200 / -328	400 / 752
K- TYPE	-200 / -328	1200 / 2192
N – TYPE	-200 / -328	1200 / 2192
S – TYPE	-40 / -40	1600 / 2912
R – TYPE	-40 / -40	1600 / 2912
B- TYPE	600 / 1112	1700 / 3092

- Voltage
- Current
- Pressure (V or mA, the output units are fetched from the preferences)
- 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

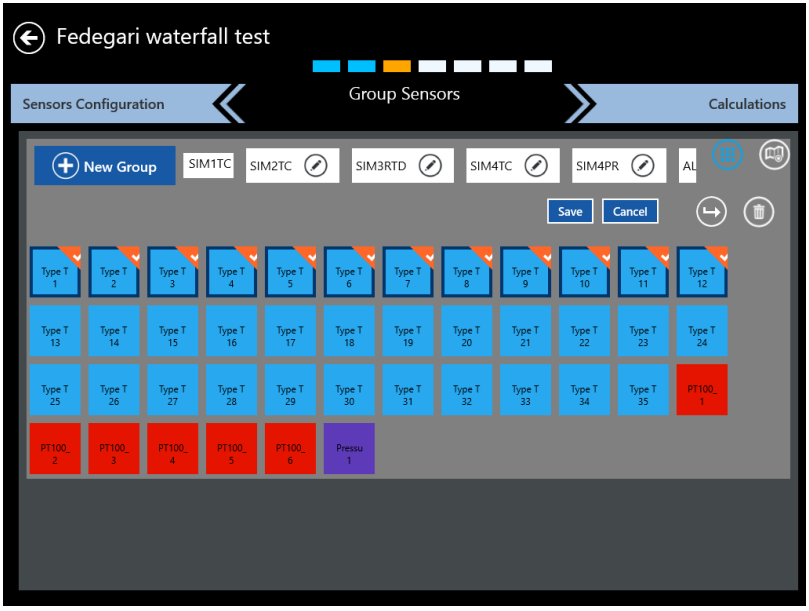


Figure 51: The Group Sensors Screen

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, numeric, 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 sensors
- 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 the wiring overlay configuration:

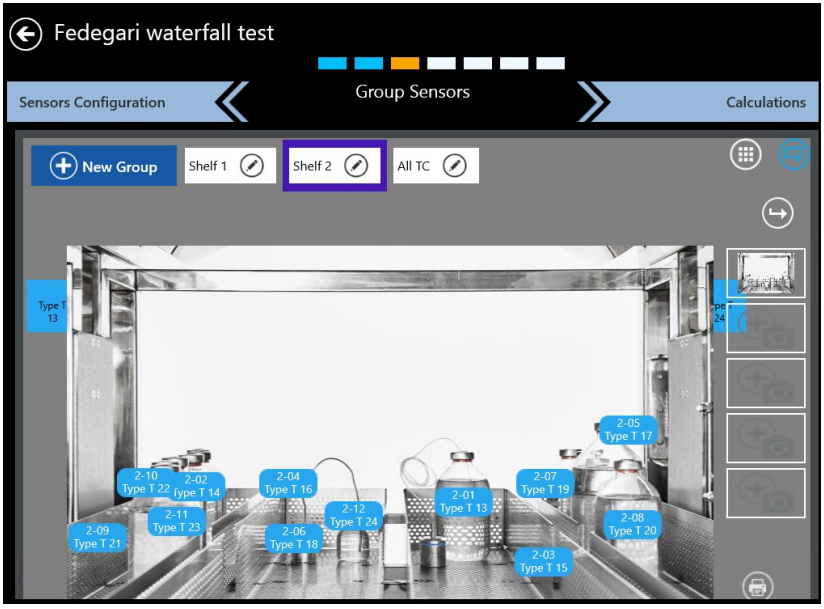


Figure 52: Wiring Overlay Diagram

The wiring diagram allows to define up to five pictures as background for placing the sensor positions. After clicking on a picture frame on the left side a picture can be loaded from disk or taken with the build in camera. The trash icon can be used to delete the picture again.
Note: When opening the camera, please make sure to allow the software to access the camera. The picture can be taken with a double tip on the screen.
The senor tags con be moved via drag & drop to the position reflecting the desired or actual position on the asset. The wiring diagram can be exported to pdf using the printer button. For every group, it is possible to select a picture and a sensor position and save it together with the setup. The wiring diagram can be printed from here or as a part of the setup report directly from the asset details. The wiring diagram is the basis for the layout view in live mode.

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

6.7 Specifying Group Calculations

Figure 53: Wiring Overlay Diagram

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: *If lethality is selected in the setup the report tool will require the definition of an exposure cycle as mandatory.*

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

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

6.8 Specifying Calibration Parameters

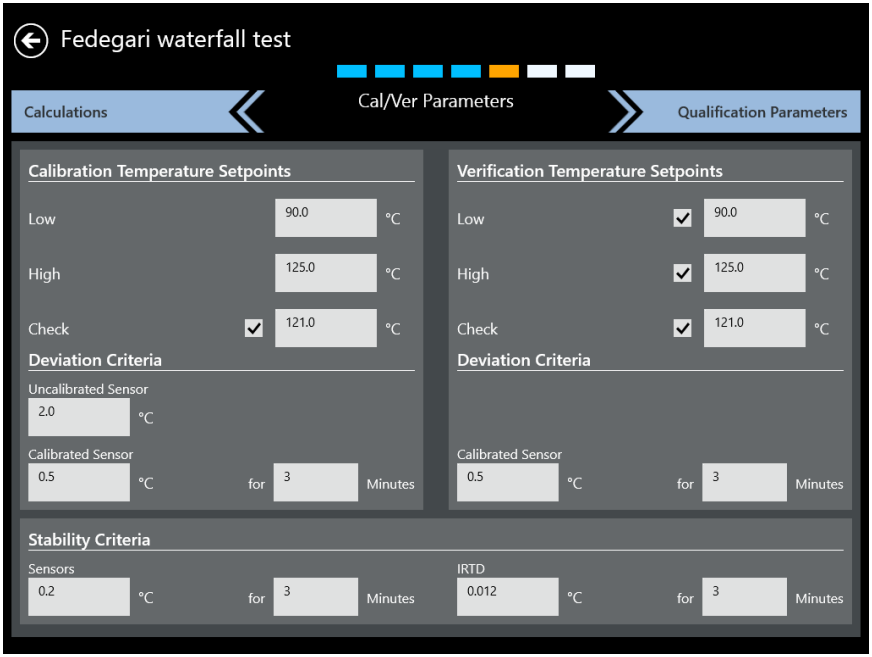


Figure 54: Calibration Parameters Screen

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 must specify a low setpoint and a high setpoint and optionally a check setpoint. If you specify low setpoint and high setpoint, the high setpoint must be at least 2° higher than the low setpoint.

- Temperature setpoints for calibration verification to verify that each sensor is still within your process criteria. You must select at least one 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 Parameter**s screen. From this screen, you specify:
- Qualification start/stop conditions - used to start and stop the qualification cycle manually or automatically
- Exposure start/stop conditions - used to start and stop the exposure cycle manually or automatically
- Data storage options - the rates at which data is written to disk during a qualification run
- Clock adjustment on qualification start – This feature helps to synchronize the study time with another device. It allows a change of plus/minus 15 minutes of the console time to adapt e.g. to the time of an autoclave for parallel protocols in sync. Please note after the study start you should reset the time manually or use an NTP server connection for automatic time setup.
- Output relay - the events that activate the two independent output relays

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

6.10 Reviewing and Changing the Setup

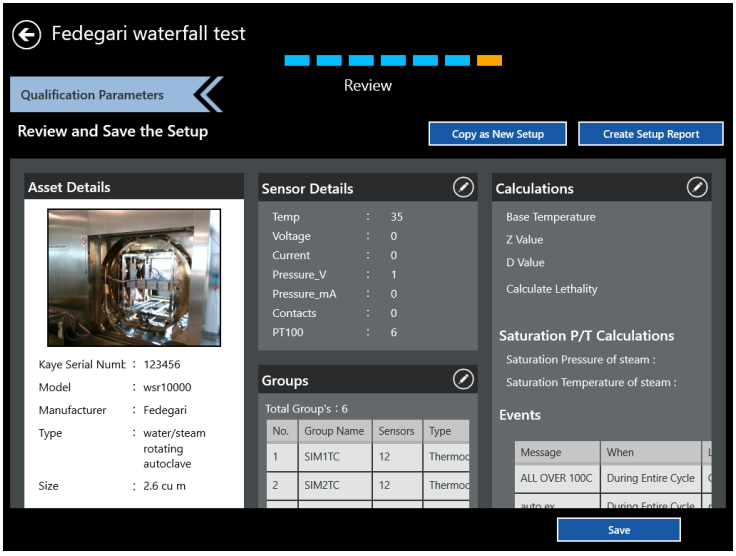


Figure 55: The Setup Review Screen

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 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 must load your setup into the Kaye Validator AVS. If a Kaye IRTD is used, then connect Kaye IRTD to **upper** port of the Validator AVS.

IMPORTANT: *Connecting the Kaye IRTD to the lower connection port can result in garbled data in the calibration reports. Please make sure to use the upper connection port, always!*

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.

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.*

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.
-

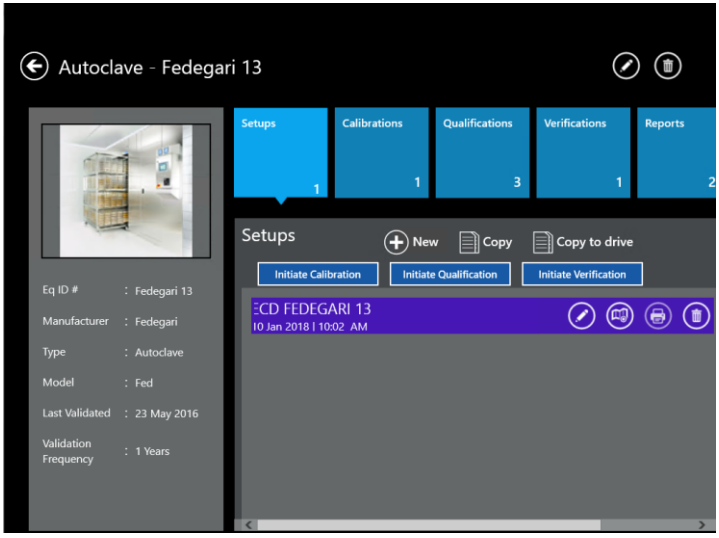


Figure 56: Initiate a Calibration from Asset Setups

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

The Kaye Validator AVS loads the setup and reads sensor information. This process may take a few seconds to complete. The

The Console, then, proceeds to the Sensor Selection screen.

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.

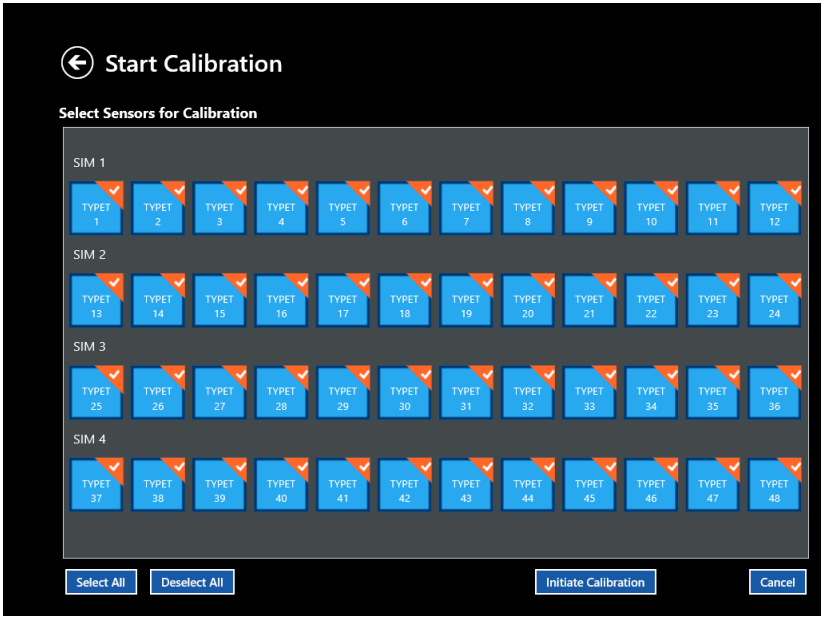


Figure 57: Sensor Selection Screen

- 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 displayed from connected sensors and IRTD before starting the study.*

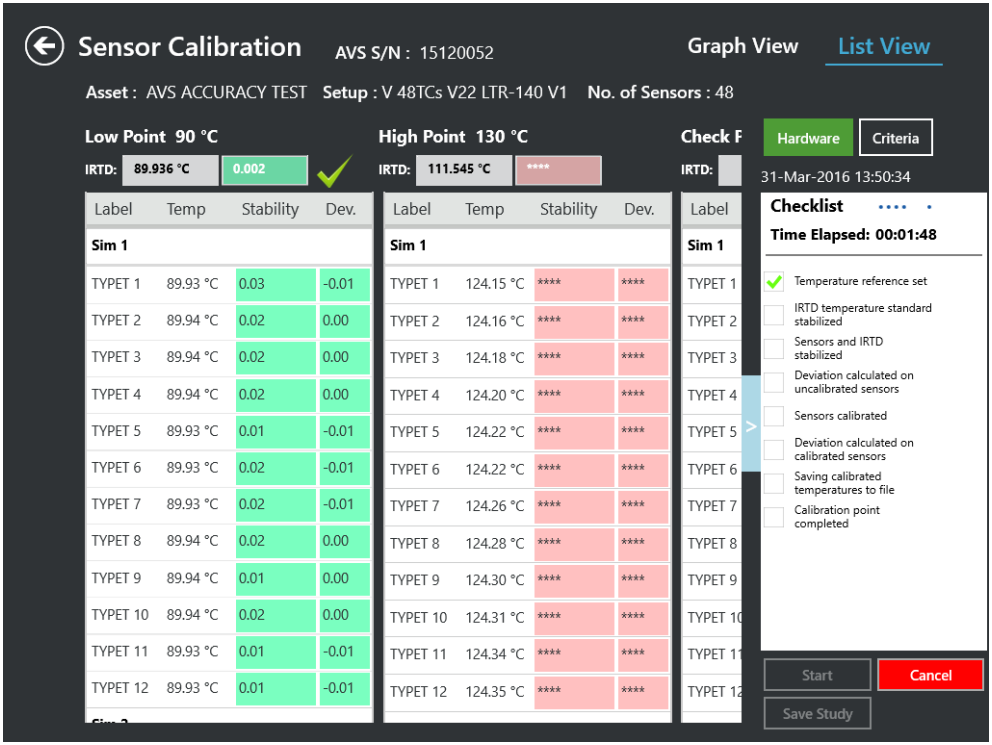


Figure 58: Calibration Study Screen

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

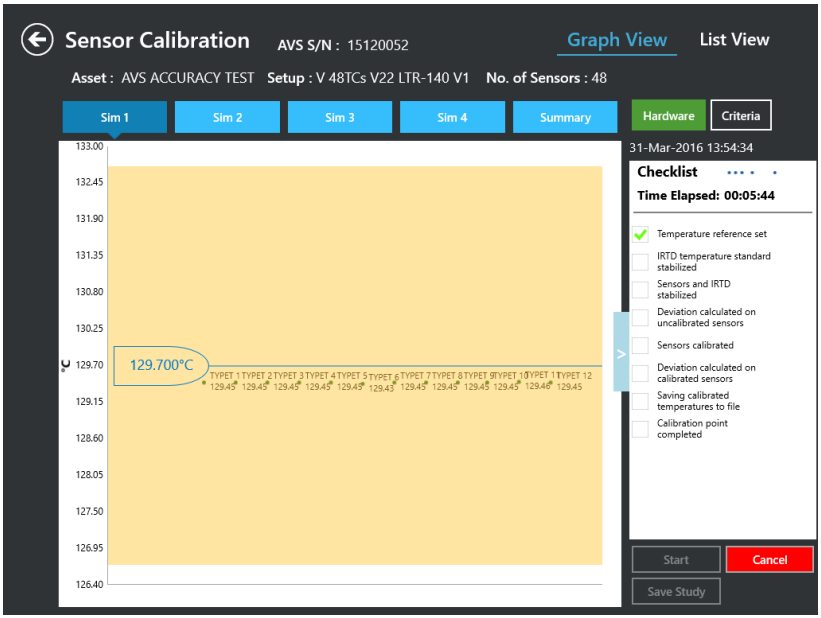


Figure 59: Calibration Study -- Graph View

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.

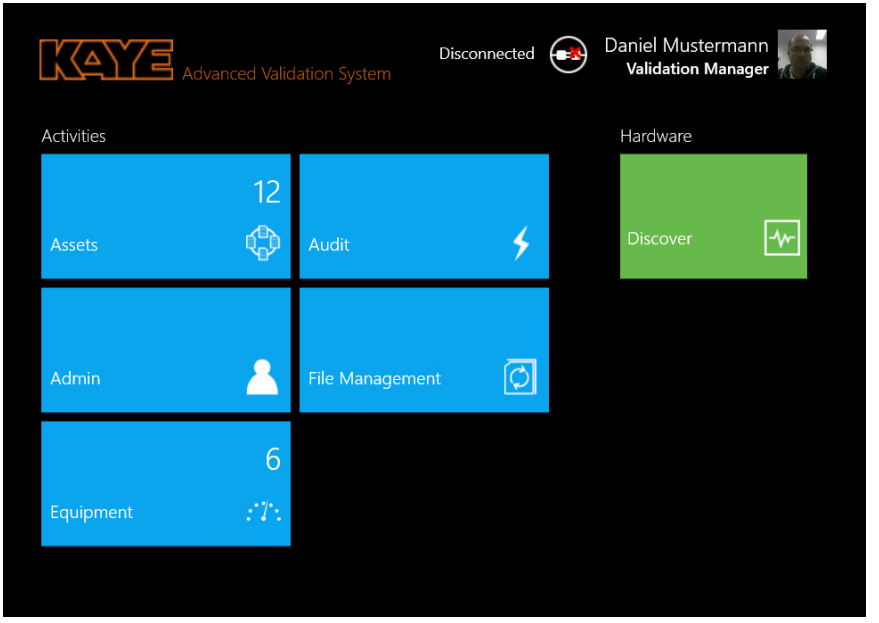


Figure 60: Main Menu with Hardware Discover Tile

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 docked-on 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 61: 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 Wi-Fi”. 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.

Please see Chapter 2.7 (Connecting the system) for detailed information how to connect the Kaye Validation console to the Kaye Validator AVS.

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.

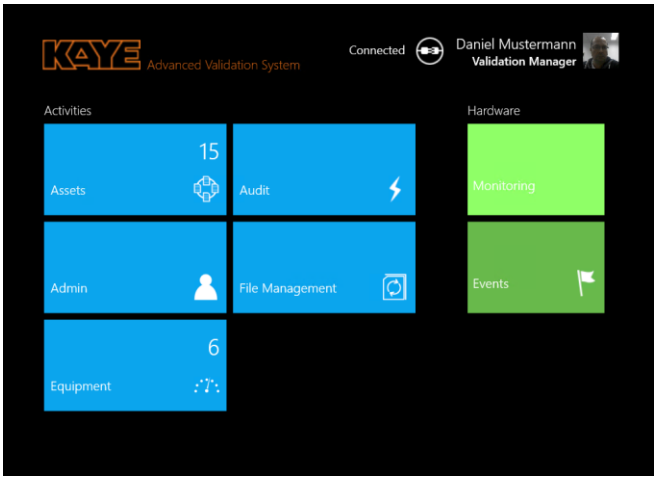


Figure 62: Main Menu with Events Tile

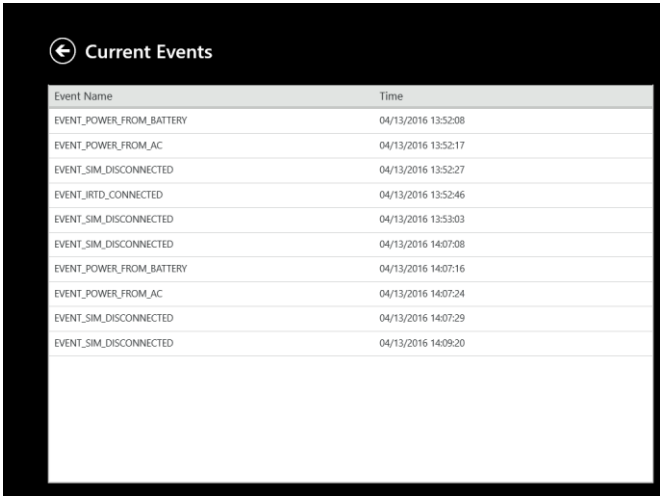


Figure 63: Current Events Screen

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

8.2 Monitoring Live Data (cont.)

Live Data during Qualification

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.

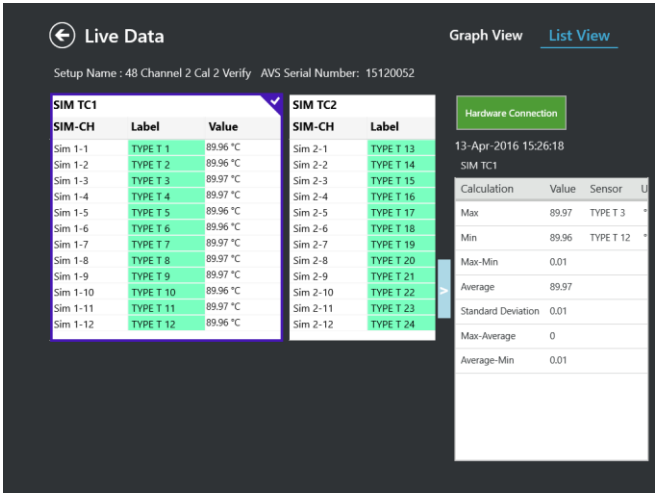


Figure 64: Monitoring in List View

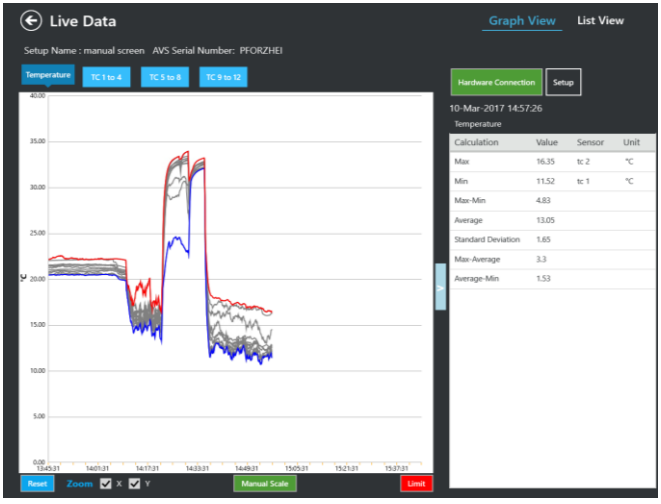


Figure 65: Monitoring in Graph View

8.2 Monitoring Live Data (cont.)

The header always displays the name of the active setup and the serial number of the connected Validator AVS.
In addition, by swiping up for the command charms and pressing on "About", all detailed information about the system which includes IP and MAC addresses of the connected devices together with software and firmware versions.
The Hardware buttons opens the hardware connection screen for reviewing the hardware connection status, the calibration offsets of the connected SIMs and access to the files stored on the Validator AVS (see chapter 8.3 for details).
It is possible to review (but not changing) the current setup parameters by clicking on the Setup button.
Below the buttons there is the timestamp of the clock of the connected Validator AVS displayed (not the console time that can be displayed with a swipe from right to left). On startup, the timestamp of the Validator AVS is synchronized with the Console time.

Live Data during Qualification

If the Validator AVS is in Qualification mode, the live screen displays groups as defined in the setup for this study.
In addition to the monitoring screen the number of defined sensors is displayed in the header and there are additional two windows and the study control buttons:

- The Message Window displays the study events.
- The Calculations Window displays statistical calculations and Min/Max value for the selected group but also cycle time and exposure time.
- Below the windows there are four buttons that controls the manual start and stop of study and exposure as defined in the setup.

- **List View**

The List view displays the live readings of sensor values of a group in a table. The first column shows the SIM number and channel, representing the physical connection of the sensor. In the second column, the label as assigned in the setup is shown, followed by the sensor value in the third column.
The forth column is available if lethality is defined in the setup and shows the ALeth value for accumulating lethality. The calculation of the displayed value follows the definition for the lethality calculation in the setup.
The Message Windows and button control can be switched aside with the small light blue arrow button between to have more area to display the data views.

8.2 Monitoring Live Data (cont.)

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

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

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

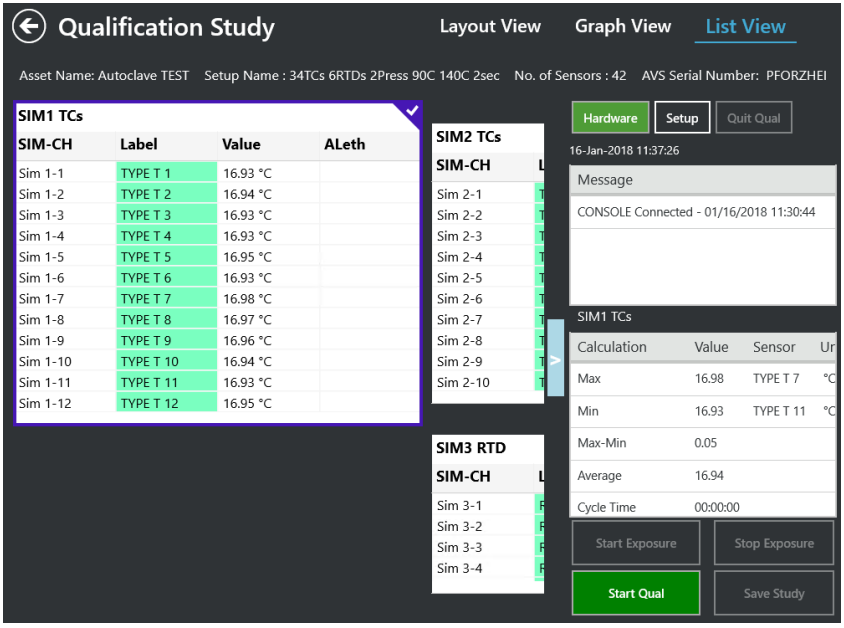


Figure 66: Qualification Study in List View

- **Graph View**

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

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

8.2 Monitoring Live Data (cont.)

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

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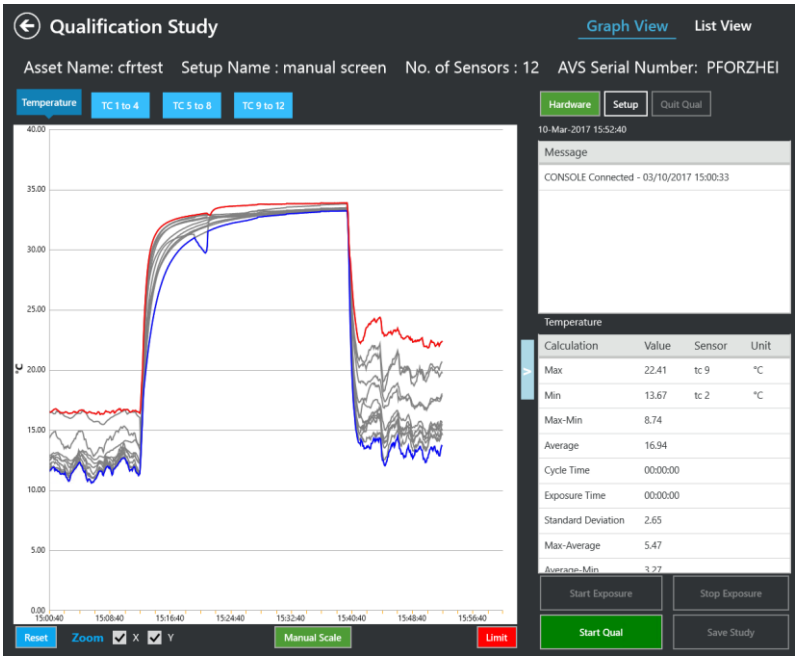


Figure 67: Qualification Study in Graph View

- **Historical Data View**

The Kaye Validator AVS stores the data of the current study in its internal memory. In addition to the real-time data view it is possible to review this historical data any time during a study. When connecting to an Kaye Validator AVS that runs a qualification study, when switching to the Graph View, a progress indicator represents the download of the data to the console. When finished, below the graph there are additional controls available to access historical data:

The historical data is represented by the chunks displayed with the timestamp the data was recorded. The size of the chunks can be set in the dropdown to display 1, 2, 4, 6, 12 and 24 hours duration. If such a chunk is selected the graph automatically switches to the historical mode.

Following functions are available in historical mode:

- The headline of the graph changes from Real-Time data to Historical data
- The Zoom allows to zoom and navigate inside the displayed chunk
- The groups selection works like in real-time view, only the selected group and corresponding calculations are displayed.
- The Manual scale button is extended to the scale the X-axis to set the displayed time.
- You can directly display a data chunk by selecting it
- A line in the Graph can be used to navigate to any timestamp in the graph and see the time and calculation data displayed for that specific timestamp.
- When selecting the "Sensor Value in table" checkbox the calculation window is replaced by the sensor readings for the timestamp selected with the selection line.
- With the arrow buttons, it is possible to navigate from data chunk to data chunk
- The double arrow on the left will jump directly to the first data chunk
- The double arrow on the right will jump back to the live data screen and the headline of the graph displays Real-Time data again.

On reconnect of the console to a Kaye Validator AVS shows the real-time data while the historical data is downloaded automatically to the console for review. The download of the historical data from the Validator AVS to the console is indicated by a progress cycle.

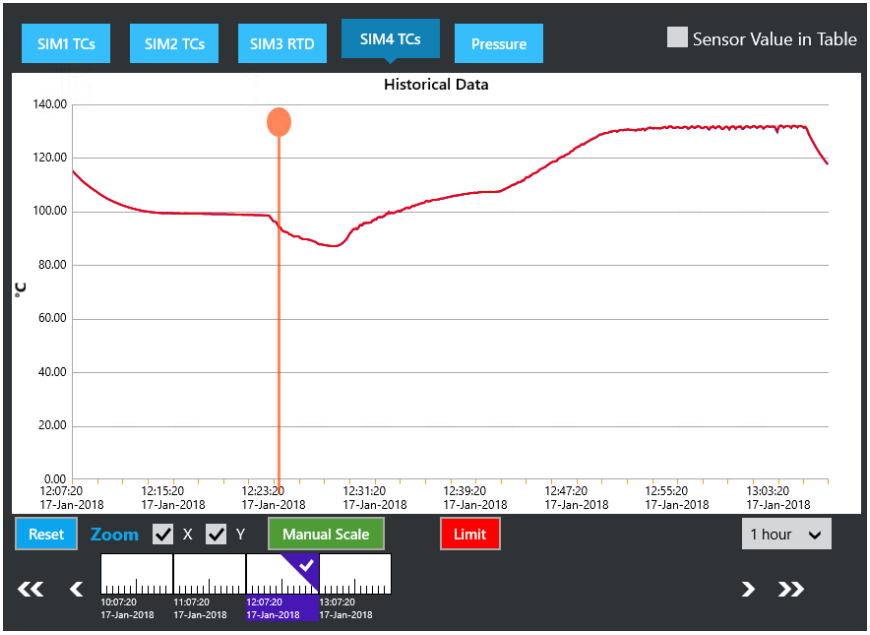


Figure 68: Historical data in Graph View

Pressing List view switches back to the table view of the sensor readings

8.2 Monitoring Live Data (cont.)

- **Layout View**

For a better understanding of the distribution of the live readings it is possible to display the data in the Layout View. The background picture and the sensor positions are defined in the Group configuration in the setup. It allows to take pictures using the build in camera or existing pictures and position the sensor tags via drag & drop. The real-time values are displayed inside the tags.

By activating "Sensor Value in Table" the live reading values is also shown in parallel in a table with sensor label and description.

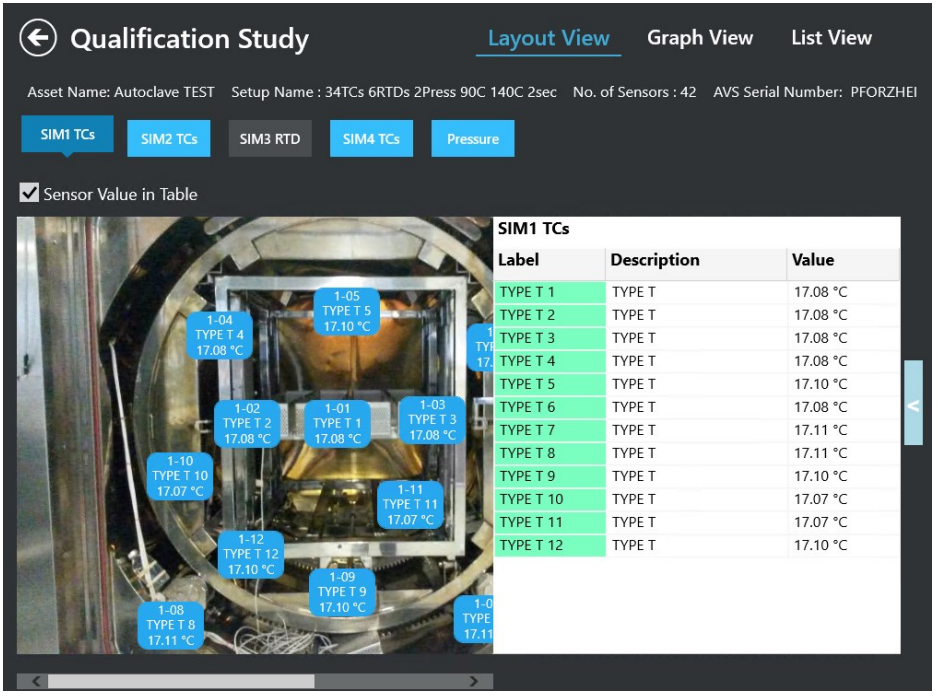


Figure 69: Qualification Study in Layout View with value table

8.2 Monitoring Live Data (cont.)

If the Validator AVS is in Calibration or Verification status, the live screen displays a table for every calibration or verification point sorted by the sensor input (SIM – Sensor). For watching all 48 inputs it is required to scroll inside the table.

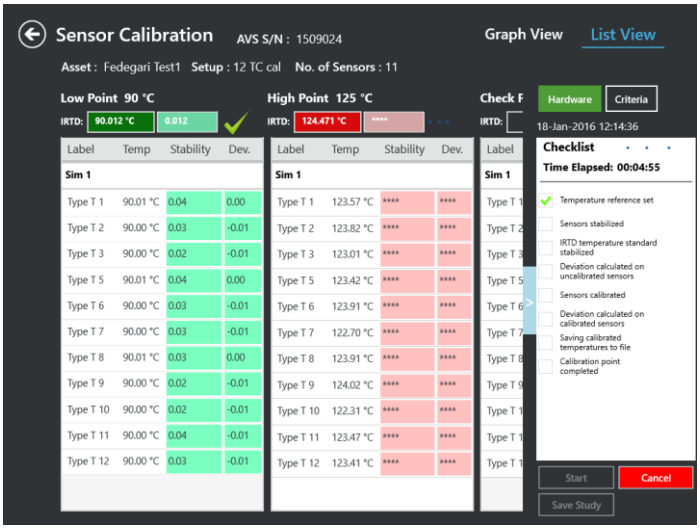


Figure 70: Calibration List View Screen

The User can initiate the Calibration or Verification from the Asset detail screen. Based on the user rights, user can stop Verification or Calibration activity. See Chapter 7 for details.

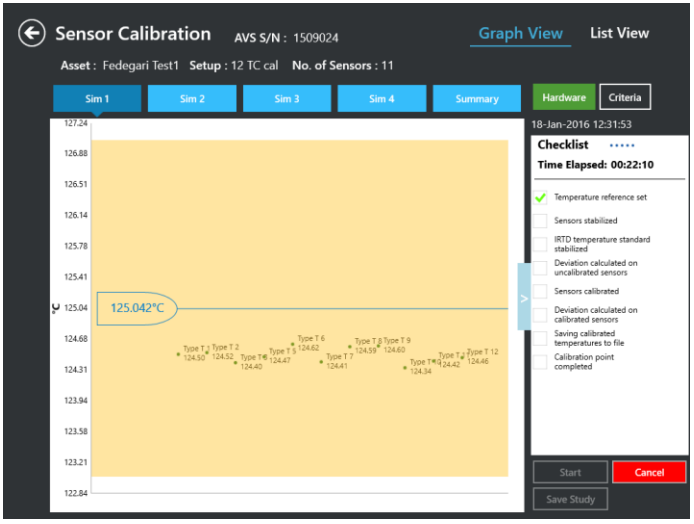


Figure 71: Calibration in Graph View Screen

8.2 Monitoring Live Data (cont.)

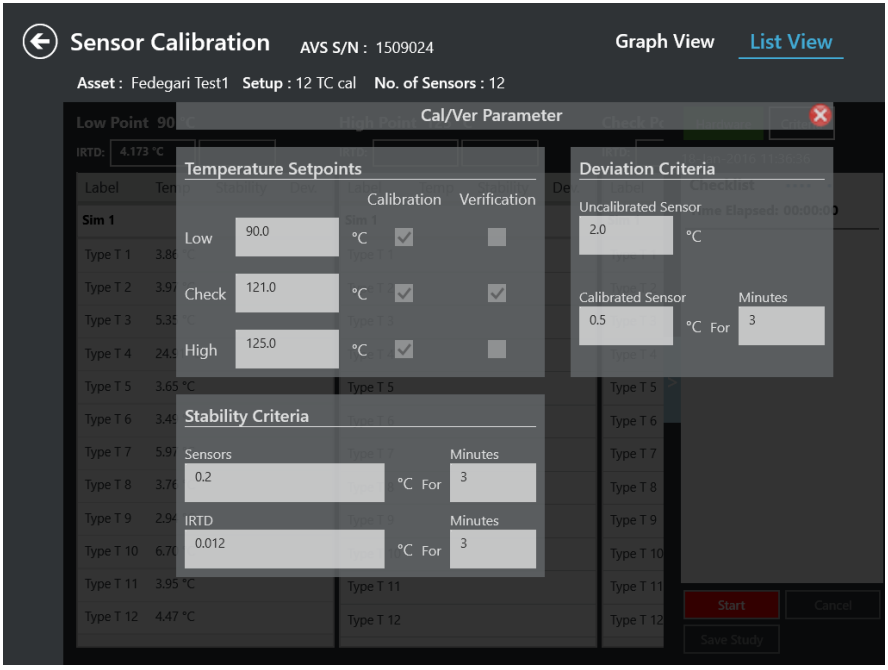


Figure 72: Calibration Parameter screen

By pressing the setup button, the Calibration or Verification parameters as defined in the setup can be reviewed. In case of the Verification, it is possible to edit the parameters before the start of the verification.

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.

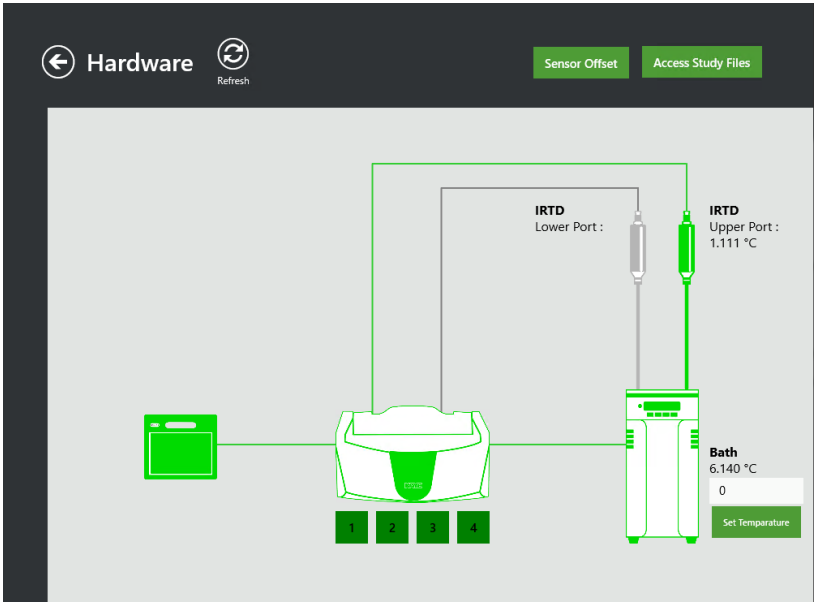


Figure 73: Hardware Screen

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

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

Each hardware item has got equipment-specific information which gets displayed on clicking the respective icons.

- Click the AVS unit graphic to display physical information about the Validator. The information displayed includes the Validator serial number, the date the Validator was last calibrated, the setup that is currently loaded into the Validator, and the version number of the Validator firmware.
- For each SIM, the SIM serial number, SIM Type, and the SIM calibration date are displayed.
- Click the temperature reference graphic to view the information on Model and Version.

Note: The current temperature reading of the reference is displayed. By entering a value into the set field and clicking "Set temperature" it is possible set the bath to a new target temperature.

- Click the IRTD1 or IRTD2 graphic to view the information on Address, Probe ID, Label (including the serial number), Calibration Date, User Label & Temperature scale.

Note: The current temperature reading of connected IRTDs is displayed.

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.
Note: For calibration and verification studies, only the upper port is recognized.

8.5 Sensor Offsets

Calibration offsets are stored in each SIM's memory. You can view the calibration offsets on the Sensor Offsets screen. Click the Sensor Offsets button in the hardware screen. The calibration offsets display on the Sensor Offsets screen.

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

8.6 Access Study Files

In monitoring mode (not while a study is running) it is possible to access the Validator AVS and review the study files stored in the machines memory. Click the Access Study Files button in the hardware screen. The last 10 studies are displayed in a table.

The table displays the name of the setup together with study type and date as well as the user who started the study. Select the files to delete the files from the AVS memory or import to the connected console. If the corresponding asset is not available it will automatically created as a new asset tile with the setup used for this study.

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 utilizes 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 last 10 study files are kept inside the memory for access via side port or 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 displays 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.

- The Kaye Validator AVS clears the internal memory from temporary files on startup. To ensure maximum memory availability it is recommended to power-cycle the Kaye Validator AVS from time to time, especially before running long studies.

- To provide maximum accuracy during the qualification study, power up the Validator AVS and let it run for approximately 30 minutes in the operating environment where qualification is to be performed for the Validator AVS to acclimate to the ambient temperature.

- Position the sensors in the vessel or chamber (the asset) being tested.

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 editable if required. Pressing Ok opens the “Select AVS” screen.

9.2.1 Select a Setup File (cont.)

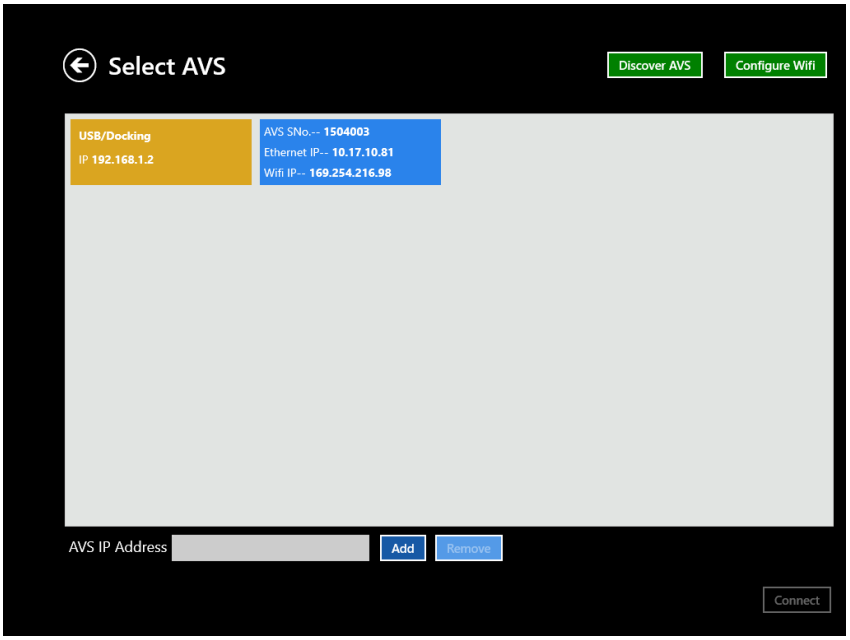


Figure 74: Select AVS

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

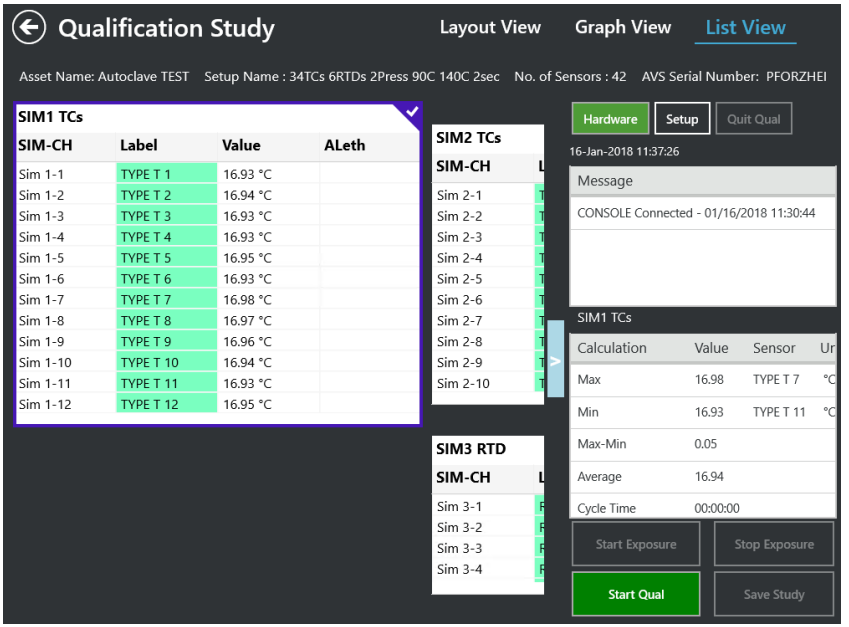
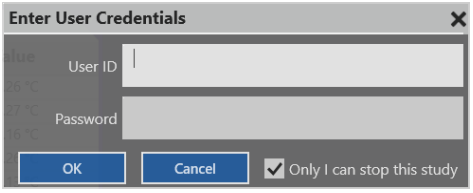


Figure 75: List View - Real-Time Readings

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). When starting the study, it is possible to lock the stop to the same user (override with Administrator privileges possible).



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.*

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 76: 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 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.)

The “Setup” button displays the Setup review page that contains all parameters for Qualification, Calibration and Verification. The page is like the setup review displayed as the last step of the setup creation wizard.

Beside the “Setup” button is the “Hardware”-

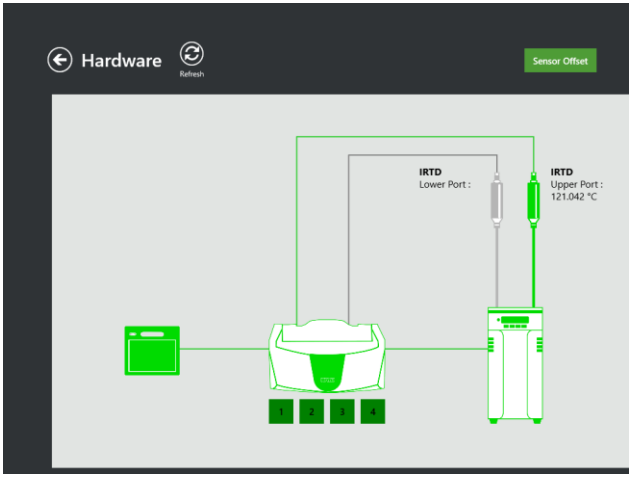


Figure 77: Hardware Screen

On the hardware screen all available hardware connected to the AVS is available including serial numbers and calibration dates. For review click on the device and a window with the data opens. The connected IRTDs will display the current temperature value for both connection ports. Please note that for calibrations only the upper IRTD port is active.
In addition, the Sensor Offsets can be reviewed per connected SIM. It displays the input value and the corrected output value for the calibration points (The difference of both values is the Offset value). Also, information of the serial number the sensors were calibrated and the SIM slot number are displayed. With the information, the calibration status for the connected sensors can be reviewed and corrected if required.

Note: We strongly recommend to power cycle the Kaye Validator AVS when changing SIM configuration. Otherwise the correct status of information read from the SIM memory may be incorrect.

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. The electronic signature technology is not provided by Kaye but by the installed PDF-Reader package.*

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.

- The signature fields for the setup report footer can be configured in the preferences (see above).

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.
The signature fields for the calibration report footer can be configured in the preferences (see above).

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.

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

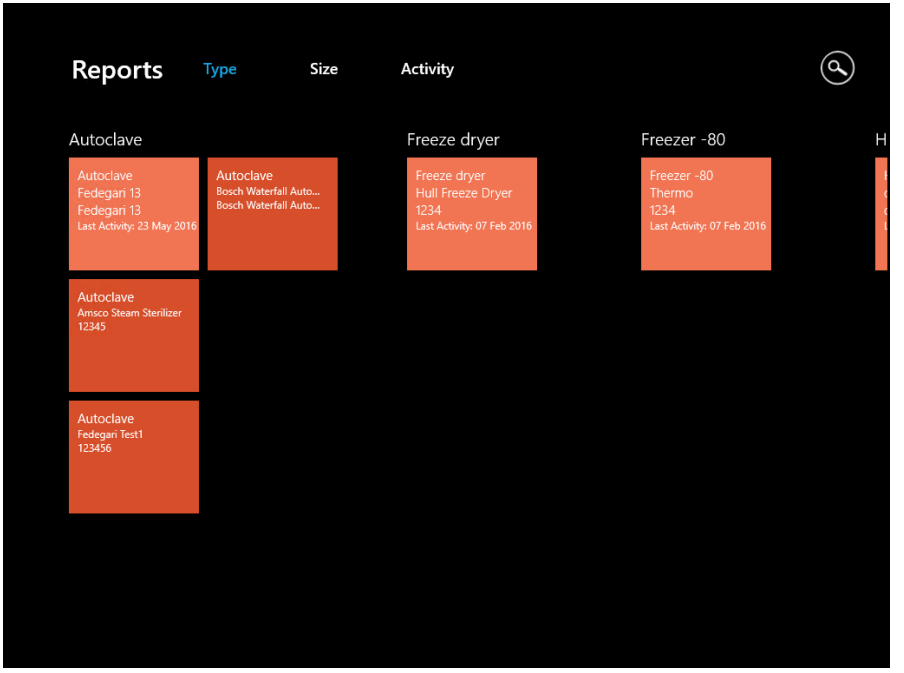


Figure 78: The Report Hub Screen

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 asset, press the button for that asset and the available studies for Report Analysis Screen opens.

Note: Studies imported from the Kaye Validator 2000 will be collect under an asset tile named "Others".

10.4 The Report Analysis Screen

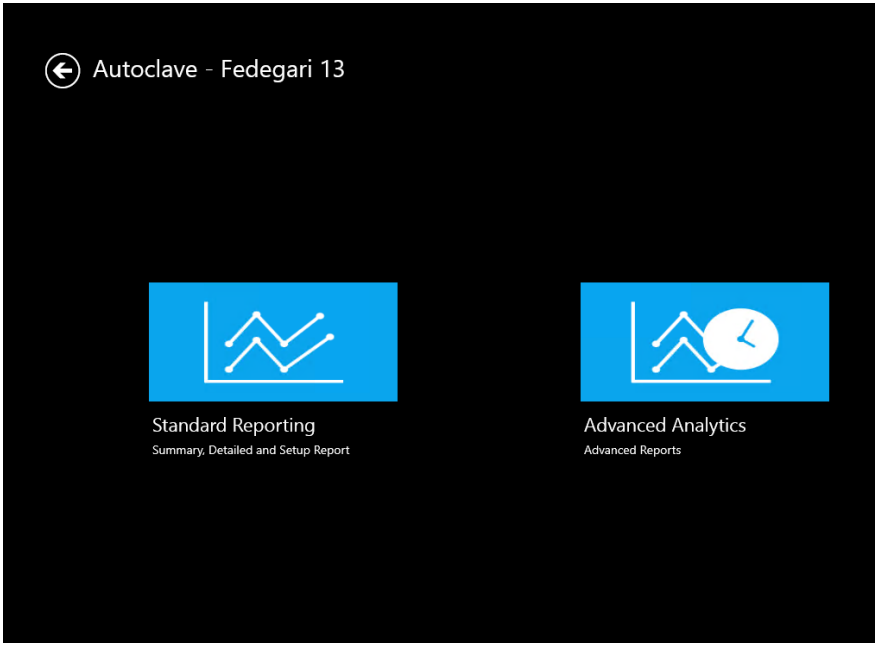


Figure 79: The Report Analysis Screen

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

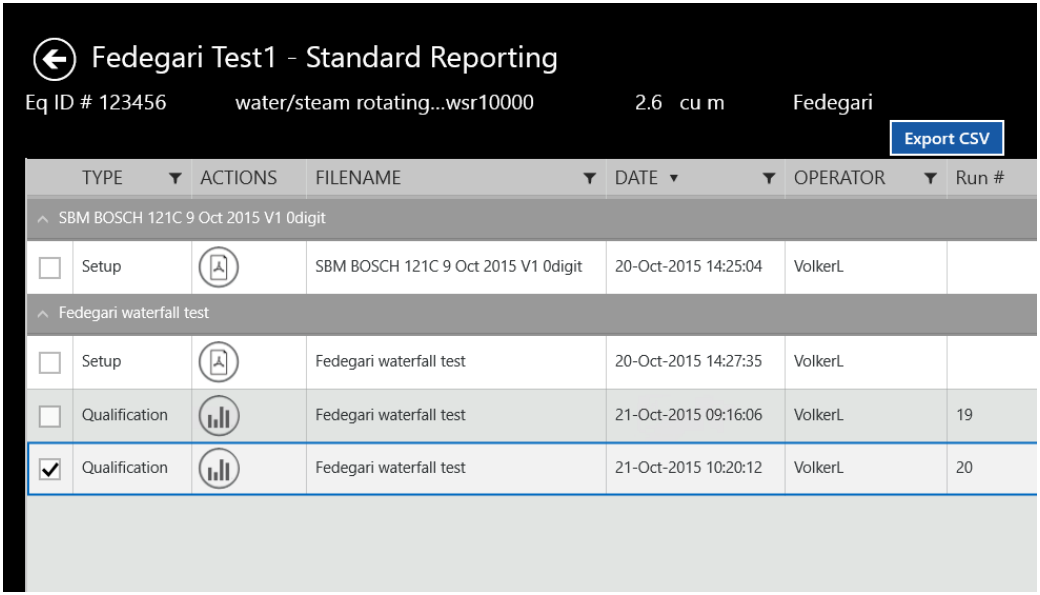


Figure 80: The Reports Details Screen

The Reports Details screen can be accessed via the Report Tool hub by selecting an asset or directly from the Asset details by selecting a qualification study and pressing "Generate Report".
When navigating through the Asset Details screen the preselected qualification study is the only data file in the list, while navigating through the report tool hub will show all available data files for this particular asset.

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

- Type – indicates if the report is based on setup, calibration, qualification or calibration verification.
- Filename – lists reports by the setup name of the studies.
- Date – lists reports by date.
- Operator – lists reports by User.
- Date – lists reports by date.
- Run – lists reports by the run number assigned during Qualification start.
- Study File Comment – lists reports alphabetically on the Study Comments

10.5 The Reports Details Screen (cont.)

Each category has a filter, where the search can be narrowed down to locate the report. To save a PDF of a report, select the report and click on the PDF icon. (Only available for Setup, Calibration and Calibration Verification reports; for Qualification reports you first need to go through reporting)

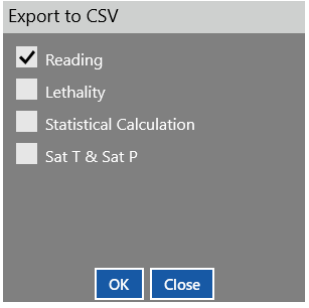
In case the report contains more than 1.2 million data points (the product of numbers of sensors and number of samples per sensor e.g. 12 sensors with 100000 data points per sensor or 24 sensors with 50000) the report tool will skip the "Mark Cycles" screen and jump directly to the Standard reports screen.

To generate a report, click the check box and then click on the graph icon.
Select Sensors type and click on OK to proceed to "Mark Cycles" screen.

In the action column, there are action button that depend on the kind of study. For setup, calibration and verification study pressing the PDF button will directly create a pdf report file and display it for preview. Please note the signature option for the footer are set in the preference of the application.

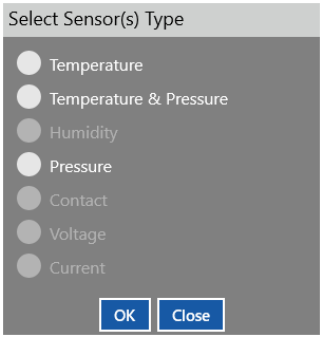
When selecting a qualification study the "Export CSV" button becomes active. It allows to export the study to an Excel readable format (.csv). The csv format is an open table format that can be easily imported in all kinds of spreadsheet programs. It is possible to select different datasets (Readings, Lethality, Statistical Calculations, Sat T & Sat P) for export. These data sets will be saved as single csv files together with an index file into one ZIP Archive file.

- **CSV-Export**



The study data can be exported to the CSV format which is an open file format that can be easily imported into Microsoft Excel or any other spreadsheet analysis program. The CSV file can only export on kind of data per file. Therefore, on pressing the export button you can select what kind of data is exported. Every selection will create a separate CSV file.
To make it easier, all CSV file will be packed together with an Index file into a ZIP Archive. This Archive can be import into Excel creating separate Tabs in one single Excel file for every CSV File. A Macro supporting this kind of Excel import is available on request.

- **Graph** – Pressing the "Graph" button of the action buttons starts the analysis part. In the next step it is required to mark the cycles of the study. The displayed the option asks to select the measurand used for the definition of the cycles (or select sync points in the Advanced Analytics) and depends on the available data in the study file. For sterilizers, the option to use both, temperature and pressure, enables a better understanding when both requirements are reached.



10.6 The Performance Analysis Screen

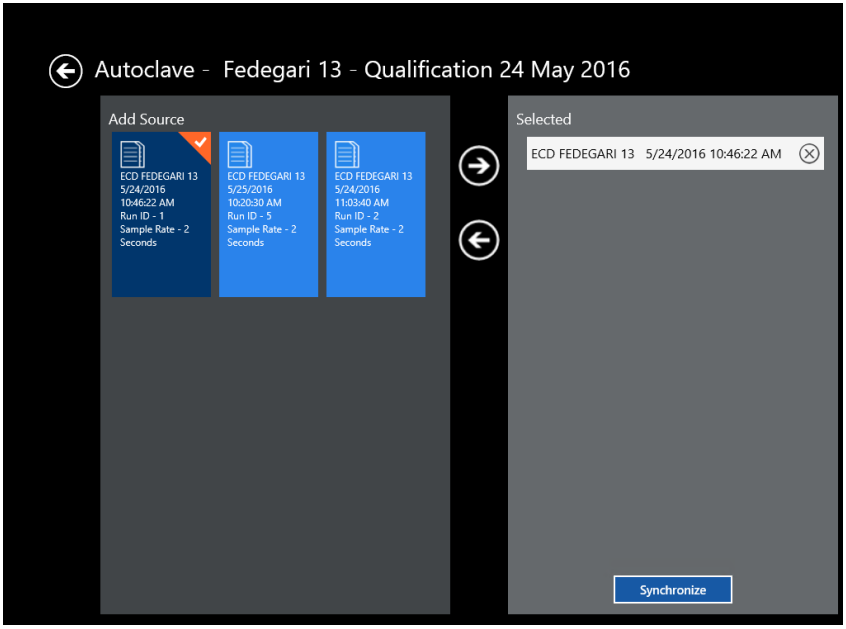


Figure 81: The Data Sources Screen

If user selects Advanced Analytics Option in Report Analysis Screen, it will be navigated to Report Detail Screen as well. After selecting particular file, it is required to select the measurand for comparison. In the next screen, the available data sources appear for selection with file name, date, run-ID and used sample rate.
Note: Only files with the same sample rate can be compared!
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.
Note: Because the software needs to process three graphs it may take a long time for analysis and presenting the next screen. This also applies if you go back to the screen.

10.6 The Performance Analysis Screen (cont.)

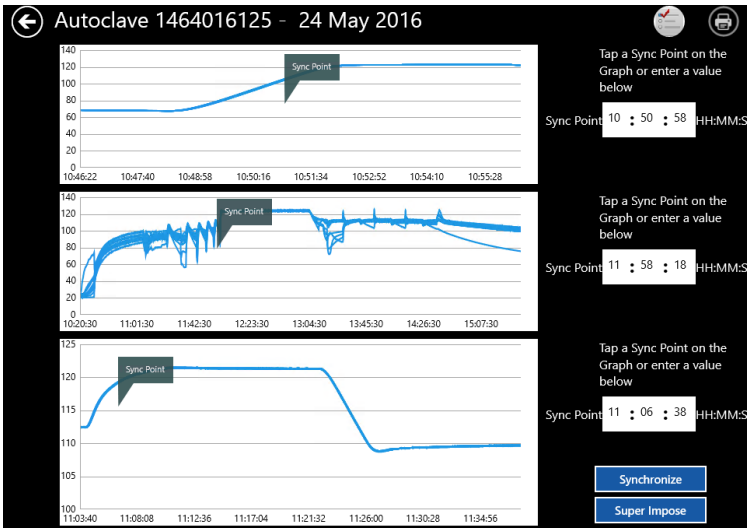


Figure 82: The Performance Analysis Screen with Sync points

In the next screen the starting point for each graph needs to be set manually. This can be either done by just tipping on the starting point or entering the timestamp in hh:mm:ss format into **Sync Point** text box at the right of each graph.

- **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.

After pressing “Synchronize” the graphs are shown with the sync point as starting point.

At any stage of the process, it is already possible to export the graphs to a pdf-report using the printer button on the top right of the screen. Also, the chart properties can be set

10.6 The Performance Analysis Screen (cont.)

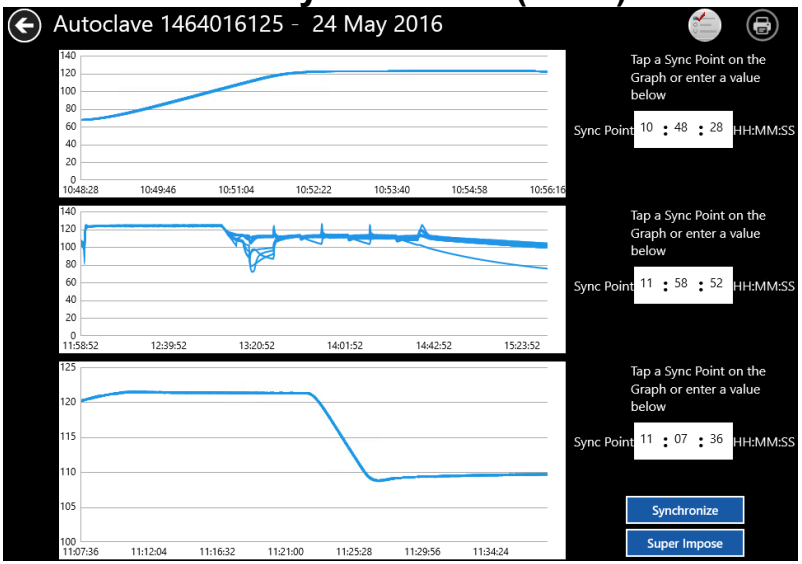


Figure 83: Performance analysis with synced graphs

In the next step, the superimpose function can create an overlay of the graphs. When pressing "Superimpose" the only information missing is the duration of the superimpose graph. That is defined with the timeline of the first graph. Enter the end-point for the superimpose function by selecting the timestamp accordingly. The duration is automatically applied to the other Graphs as well.

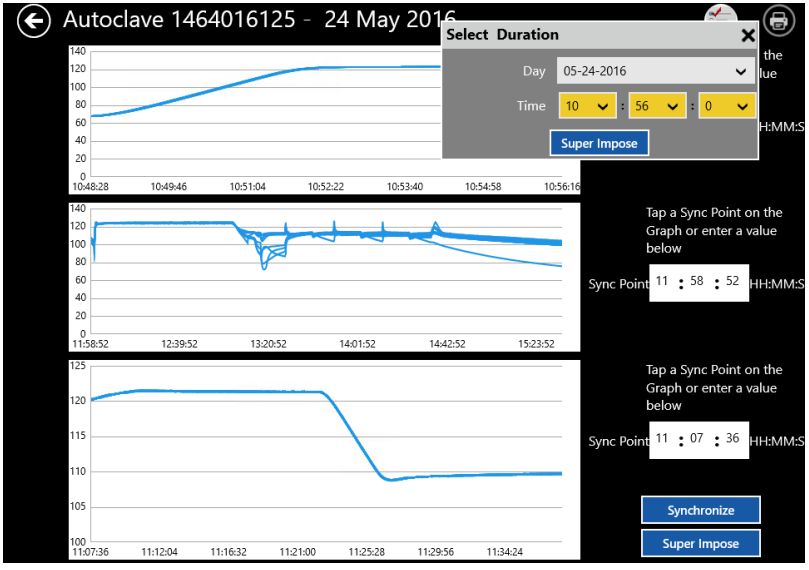


Figure 84: Performance analysis – Select duration

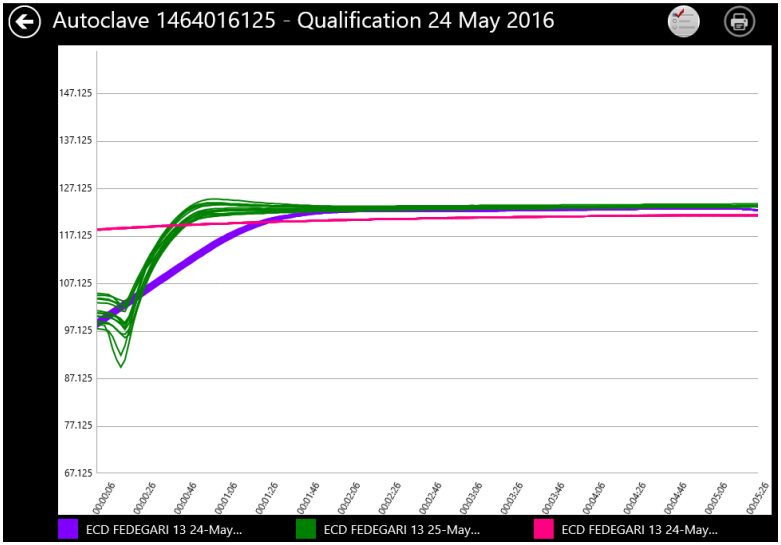


Figure 85: Merged File Data

The result is an overlay of the graphs with a synced starting point that can help to understand and compare the performance of a validated process. This result can be exported to a pdf File using the printer button. The properties of the graph (colors, Axis range) can be edited by clicking on the chart properties button. Both buttons are located on the top right side of the screen.

- **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 Mark Cycles Screen

• **Overview:**
Prior to generating graphs or text reports for your qualification file, the Cycle Selection screen allows the user to review, modify or create cycles from the qualification study data. Each cycle is defined with a Start and End time or events which defines the duration of the cycle. The Cycles defined are used in the Qualification Summary Report to provide detailed calculations and analysis during each cycle.
For each cycle, the Summary report contains the Min. Max, Max-Min and Lethality, if configured for each sensor. The Summary report also contains additional calculations such as Cycle duration, Min of Min, Max of Max, range, spread, Std Deviation, Min Lethality etc. to provide detail analysis of the Cycle.

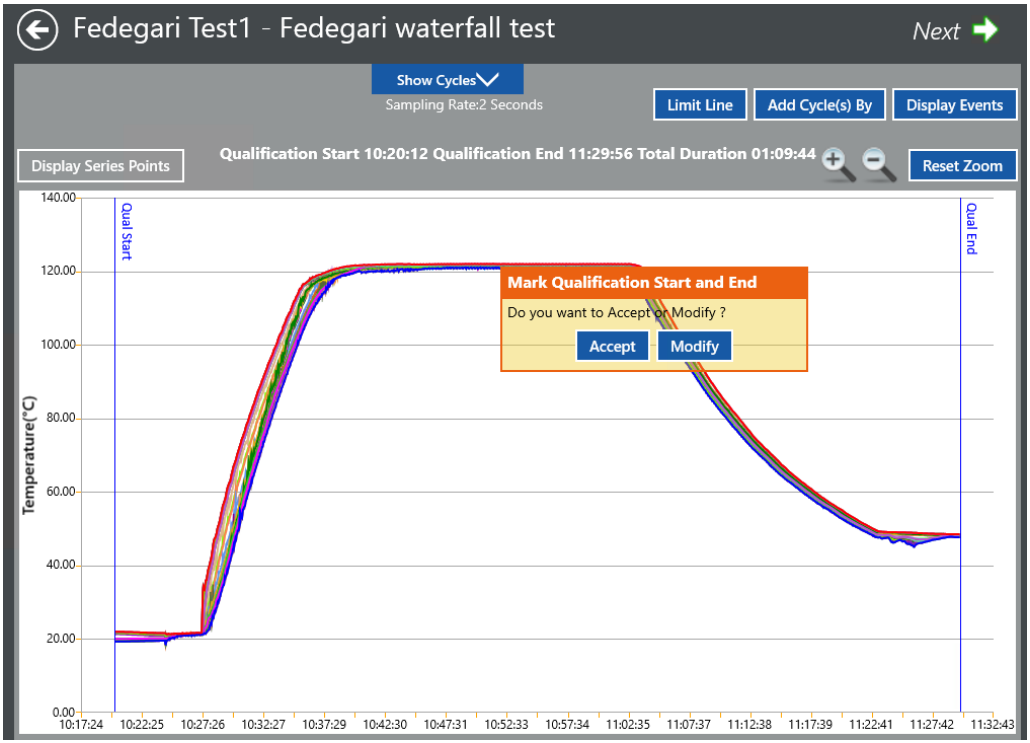


Figure 86: The Add Cycles Screen

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

10.7 The Mark Cycles Screen (cont.)

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

• **Exposure Start / End** - If your Setup included Lethality calculations, or Exposure Cycle parameters were defined, then the Exposure Start and End will be marked mandatory on the graph and the user will be prompted to "Accept" or "Modify" the Exposure Start and End times. If "Modify" is selected the user can chose to modify Exposure Start and/or End by "Time", "Selection Line ", or "Event.

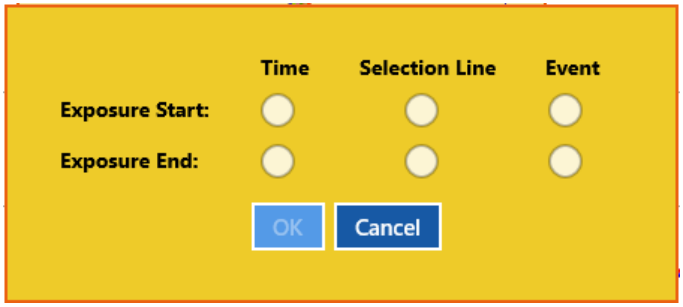


Figure 87: Exposure start Definition options

"Time" allows the users to manually enter the time for Exposure Start and/or End. (i.e. used to synchronize with Autoclave controller). "Selection Line" allows the user to manually move the line on the graph to Exposure Start and /or End then press OK. "Event" allows the user to utilize a previously defined Event in your setup as the Exposure Start and / or End or to create a "New Event".
If creating a new event, the user can specify a "Message" which will appear in the Detailed Report. The user can also specify "When" which defines when the event occurs, as well as a Label and the condition for the event. (e.g. Min Temp > 121.0 C). At the completion of marking Exposure Start / End the cycles shall be numbered 1-3. By selecting Show Cycles, the user can modify the Cycle names (e.g. Heat-up, Exposure, Cool-down).

10.7 The Mark Cycles Screen (cont.)

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

• **Show Cycles** – All the cycles created are displayed with the defined Start and End times. The Show Cycle screens also allows modifications of cycles names. 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. Hide Cycles will close the cycles window.

When all the desired cycles have been defined, the user can click "Next" at the upper right portion of the screen to move to Report /Graph creation

Click Next button and which takes one to the next screen to choose from either of the options; Customize Groups and Customize Calculations.

10.7 Edit Groups and Calculations

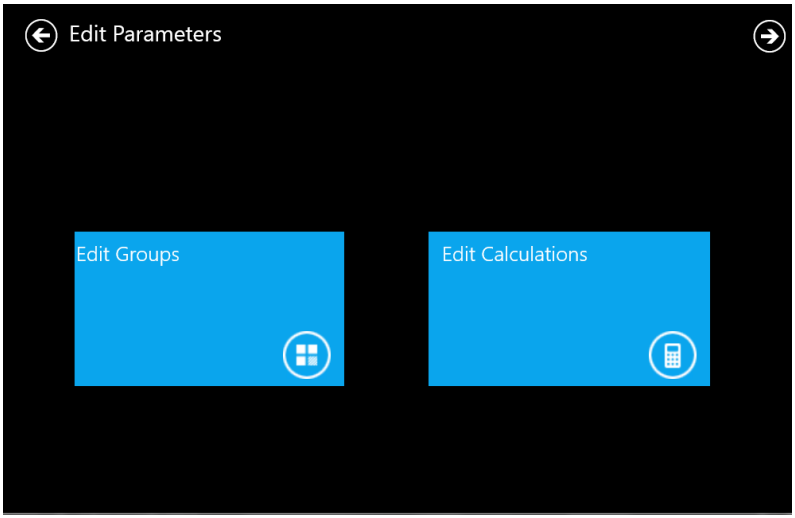


Figure 88: Edit Groups and Calculations Screen

This screen displays:

- Customize Groups: Enables editing of already defined groups and save it for generating graph report and qualification Report.
- Customize Calculations: Calculations can be customized and edited if enabled.

If groups and Calculations are already configured correctly in the setup of the study, there is no need to make any changes. In some cases, by editing the groups, it is possible to take a broken or unused sensor out of the calculations of the report (the sensor will still be listed in sensors table) or get new aspects out of the data by reorganizing the groups or calculations using an old set of data. It is possible to correct the configuration of the setup if required.

A click on the next arrow on the top right continues to the report selection screen.

10.9 The Customize Groups Screen

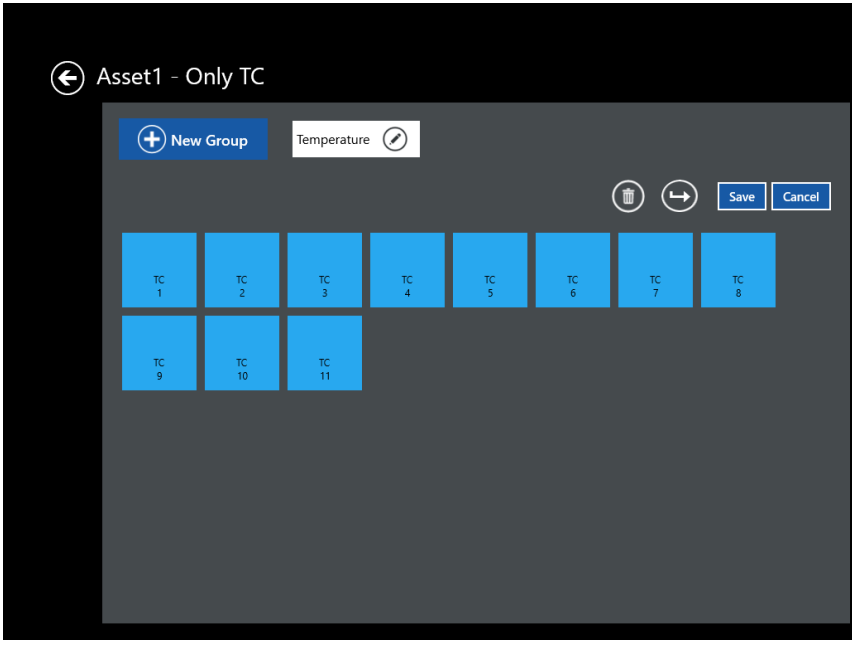


Figure 89: Customize Groups

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

Please note after changing the group definition of the setup it is required to select any new or changed groups in the report content page.

Click Back button to return to the previous screen.

10.10 The Customize Calculations Screen

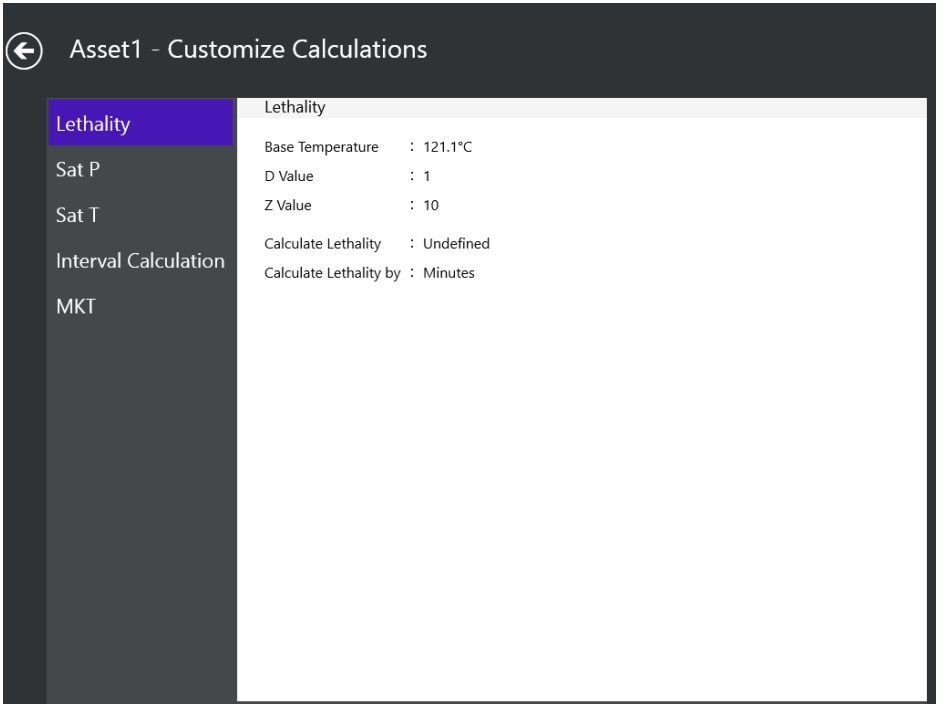


Figure 90: Customize Calculations

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. Calculations include statistical, lethality, interval, saturation pressure of steam and saturation temperature of steam calculations. If the calculations as defined in the setup are already correct there is no need to change them.

Note: To change lethality calculations this must be allowed in the preferences. The change of the D-Value can be allowed in the policies.

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.

Click Back button to return to the previous screen.

10.11 Standard Reports and Graph Reports.

The Report selection screen allows to select the kind of generated report.

Figure 91: Report selection Screen

- Standard Reports: Detailed and Summary report interface screen for generation of table format reports from qualification studies to pdf files. The Data is displayed as a text report with data tables:
    - The Qualification Detailed Report organizes information for each group by sensor data and type of calculation (lethality, statistical, saturated steam).
    - The Qualification Summary Report summarizes your study. It is possible to apply a number of calculations.

- Graph Report: Graph report interface screen for generation of graph format reports from qualification studies to pdf files. Generation of a Graph report for defined groups and Cycles, Graphical reports for statistical, Lethality, Saturation Pressure, Saturation Temperature and Equilibrium calculations.

10.12 Standard Reports

The final step in setting up the report for printing is the selection of the report options and types. At the top of the screen, the asset type and number, and study type and date appear.

• Report Content: allows to include/exclude selected group and calculations from the reports.
• Header/Footer: Allows to customize the Header/Footer, add comments on the first and last page of the report and include/exclude system messages.
• Select Print Rate option from drop down to adjust the print sampling rate of the Detailed Report

Qualification Report types:
- Select either Summary or Detailed option. The selected options are valid for types of reports.

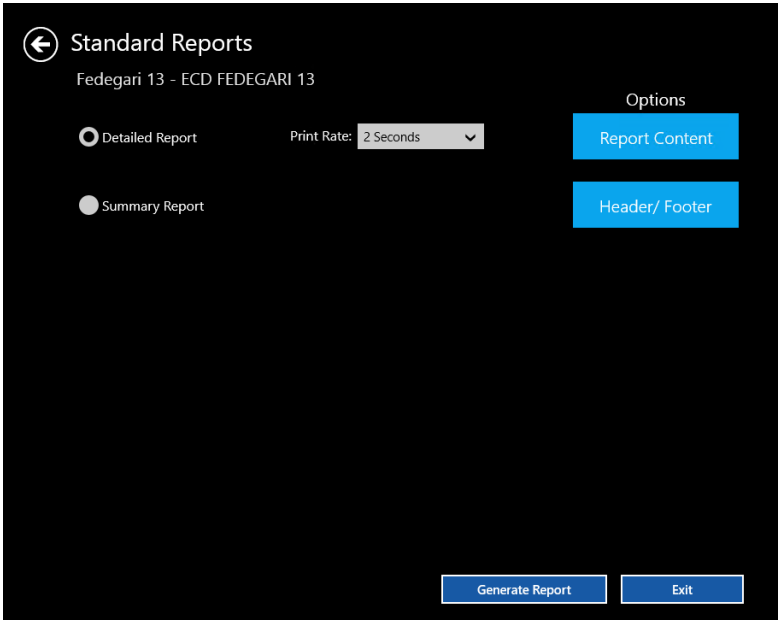


Figure 92: Report Options Screen

Click the Generate Report button at the bottom right corner to generate the respective report type or customize report options.
The report content can be selected via the report content button. The table lists all available groups and valid calculations for the sensors type of the group. It is not possible to select Lethality and MKT calculations into one single report. Saturation Temperature and Saturation pressure calculations can be selected or deselect for all groups in the report together.

Note: For a new group added under Edit Groups section to be part of the Detailed/Summary report, it is required to select the corresponding Groups and its calculations in Report Contents.

Figure 93: Report content selection

To customize the Header and Footer structure of the report select the "Header/Footer" Button. In the upper part the Comments allow to enter any free text that will be displayed on the first and last page of the report. The boxes below can be used to customize the header and foot of the report.

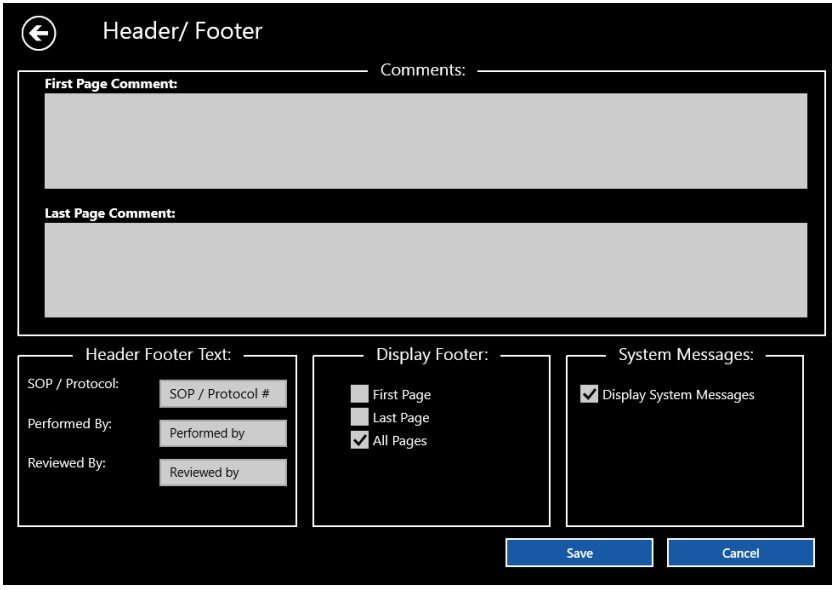


Figure 94: Report Header / Footer Content

In the "Header Footer Text", there are three editable text boxes, "Performed By", "Reviewed By" and "SOP / Protocol that allows 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.
If the "System Messages" selection checkbox is activated all system messages of the study are listed in the end of the report.

***Note**: If you select All Pages, the other selection boxes are not available.*

10.13 Graph Reports

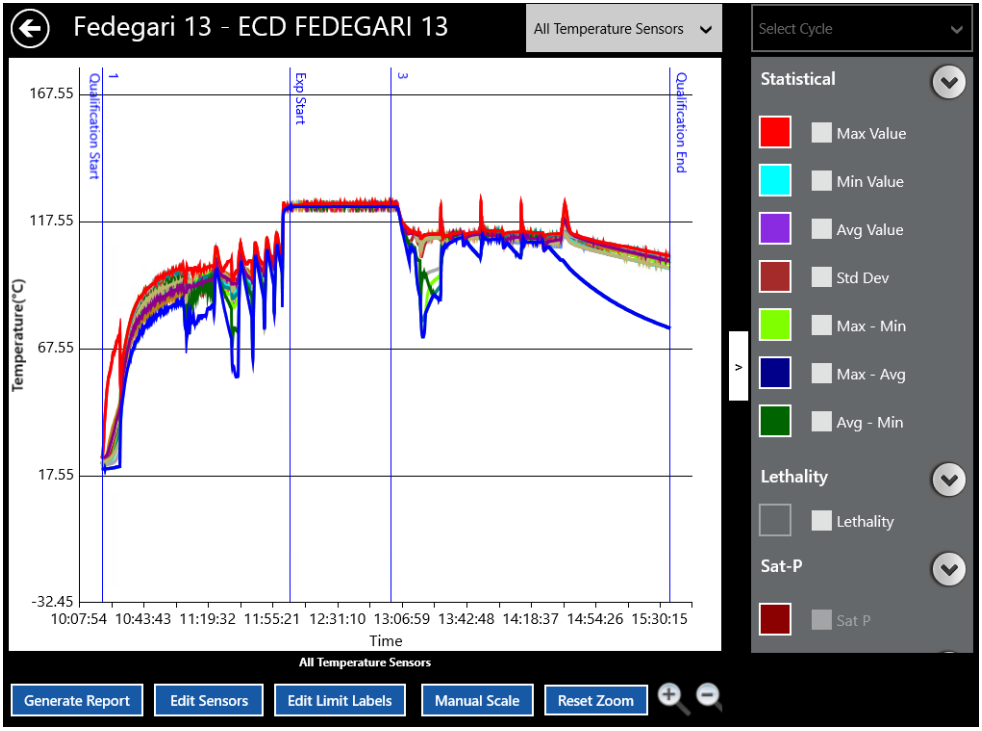


Figure 95: Graph Report Screen

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

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

10.13 Graph Reports (cont.)

There are different options to customize the displayed graph:

- The x-axis spans from the defined start of qualification to the defined end of qualification.
- The y-axis displays temperature, humidity, or pressure.

It is possible to zoom into the graph, move to graph or reset the zoom again. The "Manual Scale" button enable 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 and decimal).

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

Important

- *Excluded sensors from any of the graph reports will not be included in the calculations graphs. To include sensors again in calculation graphs excluded previously for another graph view, select it again before switching the next calculation graphs.*
- *Groups with only one sensor have no Statistical calculations available, the check boxes are greyed out.*

Above the Groups dropdown allows to display the values for the selected group only (e.g. Lethality, Saturation, Pressure and Saturation Temperature calculations).

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

10.13 Graph Reports (cont.)

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

Pressing "Generate Report" will generate a Graph report with exactly the same picture as displayed.

***Note**: For all types of graphs, Open, Under Range, Over Range or NO SIM sensor values are not displayed; for such failure values.*

Users can zoom in and out of any graph, or apply the print option to send graphs to a default printer. By default, 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.

To Generate a Graph Report:

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

• The Graph Report options available depends on the selections made during the study setup, the type of sensors used in the study and number of sensors in each group.

• Use the Statistical pane to select a Graph Report. To view data in greater detail, use the zoom or manual scaling to zoom into on a particular time period or sensor measurement range. The Zoom In and Zoom Out buttons change the graph magnification by preset levels. Whatever is displayed on the screen will be displayed in the generated Graph report

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

10.13 Graph Reports (cont.)

Edit Sensors
Allows you to select or unselect available sensors for the particular group selected from Select Group drop-down list to be displayed in the graph. Select All and Unselect All options are available for sensors selection along with manual selection one by one sensors.

Edit Limit Labels
The Edit Limit Labels screen allows you to display upper and lower limits on the graph. The sensor type available depends on the sensor type for the graph.
To add limit lines to the graph, enter an upper and/or lower limit values. These will display as horizontal lines at the selected measurement points.

- You can enter a MAX value for the line in the MAX box up to 6 characters
- You can enter a MAX label for the line in the Label text box to the right up to 50 characters
- You can enter a MIN value for the line in the MIN box up 6 characters
- You can enter a MIN label for the line in the Label text box to the right up to 50 characters

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

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

+ Increase zoom level
- Decrease zoom level
> Expand graph page to the right
< Collapse graph page to the left and show graph options.

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

Select Group
A drop-down list of available Sensors defined in setup to display in the graph report.
The following graphs are available on the Graph Report screen by selecting them from the Select Group drop-down list. Some options may not be available due to the type of sensors used in the study and the selections made during the study setup.

10.13 Graph Reports (cont.)

- All Temperature Sensors

The Temperature Sensors graph shows the readings for all temperature sensors in the study. You can remove individual temperature sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
The Temperature Statistical calculations are available for selection from Statistical pane.
Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report.

- All RH (Humidity) Sensors

The Humidity Sensors graph shows the readings for all humidity sensors in the study. You can remove individual humidity sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
The Humidity Sensors Statistical calculations are available for selection from Statistical pane.
Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report.

- All Pressure Sensors

The Pressure Sensors graph shows the readings for all pressure sensors in the study. You can remove individual pressure sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
The Pressure Sensors Statistical calculations are available for selection from Statistical pane.
Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report.

- All Current Sensors

The Current Sensors graph shows the readings for all current sensors in the study. You can remove individual current sensors from the Graph Report by clearing the sensor from the Edit Sensors screen.
The Current Sensors Statistical calculations are available for selection from Statistical pane.
Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report.

- All Voltage Sensors

The Voltage Sensors graph shows the readings for all voltage sensors in the study. You can remove individual voltage sensors from the Graph Report by clearing the sensor from the Edit Sensors screen. The Voltage Sensors Statistical calculations are available for selection from Statistical pane. Clear any of the calculations in the Statistical drop-down list to exclude them from the Graph Report

10.13 Graph Reports (cont.)

- All Contact Sensors

No calculations are available for a contact sensor group.

Statistical

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

• Max Value

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

• Min Value

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

• Avg Value

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

• Avg and Std Dev

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

• Max-Min

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

• Max-Avg

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

• Avg-Min

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

• Lethality

The Lethality calculation is available only if temperature sensors are present in the study.
The accumulated Lethality (Sensor Trends) graph shows the lethality trends for each included sensors at each timestamp programmed or defined to calculate lethality.
Remove individual sensors from the report by clearing them from the Edit Sensors screen.

• Sat P

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

10.13 Graph Reports (cont.)

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

To access the Saturation Pressure vs. Measured Pressure graph:

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

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

• Sat T

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

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

- All measured temperatures and the calculated saturation temperature are within the specified sterilization temperature band.
- Each measured temperature and the calculated saturation temperature do not fluctuate more than 1 K.
- All measured temperatures and the calculated saturation temperature do not differ from each other by more than 2 K.
- To access the Saturation Temperature vs. Measured Temperature graph:
- Select Temp and Pressure Sensors group from Select Group drop-down list.
- From the Statistical pane of the Graph Report screen, check the Sat T box. If you defined cycles on the Create Cycles screen, select a cycle from the Select Cycle drop-down list.
- Select a pressure sensor from the Edit Sensors screen.

10.13 Graph Reports (cont.)

• Equilibrium

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

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

This graph is only available if the sensors had a 1 second sampling rate during the equilibration period, and at least one sensor reached the lethality base temperature. If you did not define the lethality base temperature during the study setup, the default temperature of 121.1°C is used.

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

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

Note: For studies including Humidity/Temperature sensors, the minimum sampling rate is 2 seconds. You should not use humidity sensors in your study if you want to access the Equilibration Time graph.

To access the Equilibration Time graph:

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

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

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[No content intended for this page]

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

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		

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		

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	

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

Appendix B. Environmental Compliance

This appendix contains information on the following topics:

- WEEE Directive (*see Section B.1*)
- Battery disposal (see *Section B.2*)

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.

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 osteomalcia and osteoporosis. Cadmium may also cause anemia, discoloration of the teeth, and loss of smell (anosmia).
- **Lead** is poisonous in all forms. It accumulates in the body, so each exposure is significant. Ingestion and inhalation of lead can cause severe damage to human health. Risks include brain damage, convulsions, malnutrition, and sterility.
- **Mercury** creates hazardous vapors at room temperature. Exposure to high concentrations of mercury vapor can cause a variety of severe symptoms. Risks include chronic inflammation of mouth and gums, personality change, nervousness, fever, and rashes.

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 (Root 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: ±(0.003% of reading + 2 counts + 4 microvolts) 1 year: ±(0.006% of reading + 2 counts + 4 microvolts)
System accuracy with thermocouple (specified from 20 to 30°C for 30days)	±(0.003% of reading + 0.25°C)
System accuracy with thermocouple (specified from 0 to 50°C for 30days)	±(0.028% of reading + 0.56°C)
Sensitivity	0.5 microvolts/count on most sensitive range
Voltage Temp. Coef.	±(0.1 microvolts + 0.001% reading)/°C
Compensator Temp. Coef.	±0.01°C per °C
Input Terminal Temperature Non-uniformity	±0.1°C from calibrated terminal
Input Ranges	-6 to 30mV, -12 to 60mV, -60 to 300mV, -2 to 10V
Environmental	Temperature: 0 to 50°C (32 to 122°F) Relative humidity: 95% non-condensing
Power	90 to 250 VAC, 50/60 Hz
Fuse Rating	4A Slow Blow
Size	190H X 411W X 381 mm D (457 mm with SIM) 7.5 in H x 16.2 in W x 15 in D (18 in with SIM)
Weight	10.60 kg (23.4 lbs)
Battery	Lithium ion with minimum 60 minutes of battery backup

Console Specifications

	On	Off (Storage)
Temperature	5°C -40°C	-20°C -60°C
Humidity	8%-90% RH	5%-95% RH
Air Pressure	697-1060 hPa	187-1060 hPa
Power Supply (ITE) Delta Electronic, SADP-65NB Rev. BB	Input : 1.5A, 100-240VAC, 47-63Hz Output:19V DC, 3.42 A The power supply is compliant with UL-60950-1, CAN/CSA C22.2 No.60950-1, and IEC/EN 60950-1	

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 devise, as an intentional and / or unintentional radiator, cautions the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

15.105(a) “Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.”

“Caution: To maintain compliance with the FCC’s RF exposure guidelines, place the product at least 20 cm from nearby person”

Appendix C. Safety and Precautions

Fallowing 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

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

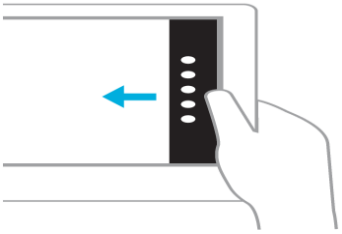
Tel.: +91 40 33147100

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.

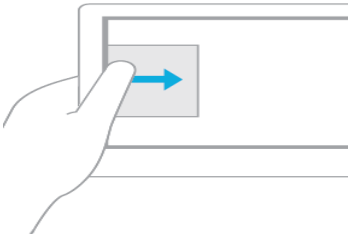
Swipe from the right edge for system commands
Swiping from the right side of the screen reveals the charms with system commands. Swiping from the left brings up previously used apps.

Mouse equivalent
Place the mouse pointer in the lower or upper-right corner of the screen



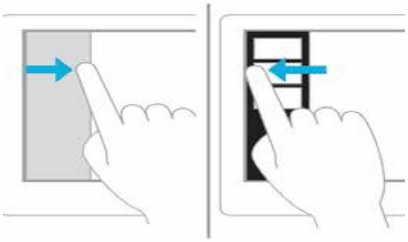
Swipe in from the left to switch apps
Swiping in from the left reveals thumbnails of your open apps so you can switch to them quickly.

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



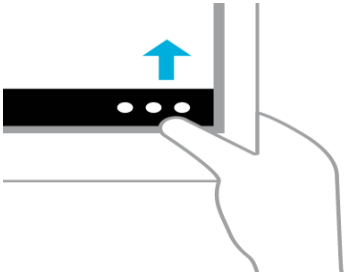
Swipe in and out on the left to bring up previously used apps
Swiping in and back out on the left brings up the most recently used apps and you can select an app from that list.

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

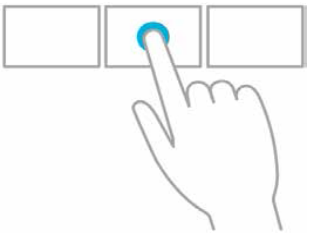


Swipe from the bottom or top edge for app commands
App commands are revealed by swiping from the bottom or top edge. You can swipe from the top to the bottom of the screen to dock or close the current app.

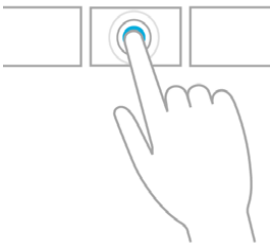
Mouse equivalent
Right-click the app to see the apps commands



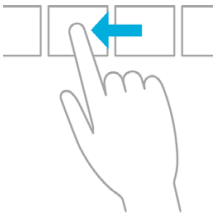
Press and hold to learn
You can see details when you press and hold. In some cases, pressing and holding opens a menu with more options.
Mouse equivalent
Point to an item to see more options.



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

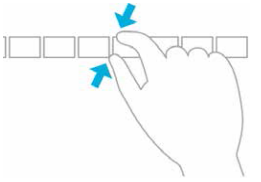


Slide to drag
This is mostly used to pan or scroll through lists and pages, but you can use it for other interactions, too, such as moving an object or for drawing and writing.
Mouse equivalent
Click, hold, and drag to pan or scroll. Also, when you use a mouse and keyboard, a scroll bar appears at the bottom of the screen so you can scroll horizontally.

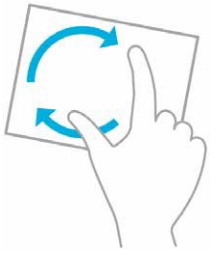


Swipe to select
Within an app, swipe down or across an item to select it. A quick, short movement works best. On Start, press and hold to select a tile.
Mouse equivalent
Simply right-click to select within the app.

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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