Validation

Kaye ValProbe® RT

User Manual

MXXX-EN Rev. 1.0
May 2020

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Kaye ValProbe® RT

Process Monitoring and Validation System

User Manual

M5XXX-EN Rev. 1.0
May 2020

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About this Manual

The first section of this manual provides an overview of the ValProbe RT hardware, instructions for creating user accounts, entering asset and equipment information, and an overview on using the ValProbe RT software. The second section of this manual covers, using the ValProbe RT, including verifying sensors, running qualification studies, and generating reports..

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

- *Chapter 1* provides an overview of the ValProbe RT system.
- *Chapter 2* explains the ValProbe RT hardware and provides instructions to connect 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.

Chapter 1. Kaye ValProbe RT System

1.1. Introduction

Figure 1: The Kaye ValProbe RT

The Kaye ValProbe RT is a wireless real-time process validation system designed around the measurement and reporting requirements of the Life Sciences and Food industry. The wireless and real-time aspect of the system make it ideal for harsh applications where the use of wires can be difficult to access and install. These applications include steam, dry heat, ovens, incubators, stability and temperature chambers, freezers and freeze dryers, and warehouses. A complete Kaye ValProbe package, includes:

- Base Station
- Kaye Validation Console and installed software
- Docking Station
- Kaye ValProbe RT Loggers
- Wakeup Device

1.2. Operational Description

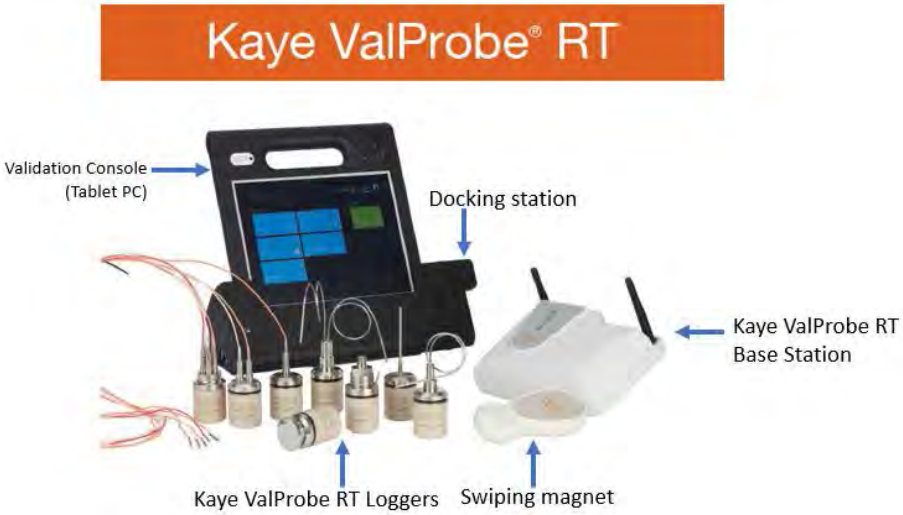


Figure 2: The Kaye ValProbe RT System

The ValProbe RT system has three main components the Base Station, the Loggers, and the Console/ Docking Station.

The Base Station is the main communication link/ hub between the Loggers and the Console. The Base Station and the Loggers communicate with each other via a star or point to point network using 2.4GHz frequency and a proprietary protocol which is compliant with IEEE802.15.4 protocol. The communications range between any Logger and the Base Station is 450 ft. (150 meters). Both the Loggers and Base Station utilize antenna diversity to provide optimum RF signal strength and reliability.

The Loggers are battery powered using a 3.6V ½ AA Lithium Thionyl Chloride battery. Dependent on model type the loggers can collect temperature and pressure data from (-85C to 140 C). Up to 25 Loggers and 50 sensors can be connected to a Base Station. The Loggers store the data in their internal memory based on a user defined sampling rate and have a capacity of up to 100,000 samples per sensor. The Loggers also transmit, based on a user defined transmission rate, the data to the Base Station.

The Loggers have a magnetic-based sensor element in the logger which gets activated by using the Wake- up Tool or the magnet inside the Base Station display to Wake up the logger from Shelf mode prior to running a Qualification or Verification.

Figure 3:Handheld Magnet

Figure 4: Magnet Inside Base Station

The Base Station collects and stores the data from all loggers and provides communications to the Console. The default communication between the Base Station and the Console/Docking Station is via direct Ethernet connection utilizing a pre-configured Static IP address. An additional option is to connect the Base Station and Console / Docking Station to a network utilizing dynamic DHCP address which are software configurable.

The Validation Console is pre-loaded with the ValProbe RT software and is the primary interface for the operator. The user utilizes the software to configure Setups, Start/ Stop Qualifications, perform Sensor Verifications, create reports, store Validation studies and provide real-time display. All commands and action generated at the Console are transmitted to the Base Station and then broadcast via RF from the Base Station to the Loggers.

1.3. Unpacking

Unpack the Kaye ValProbe® RT Loggers, Base Stations, Kaye Validation Console, and accessories carefully and inspect them for any damage that may have occurred during shipment. If there is shipping damage, notify the carrier immediately. Verify that the following are present:

S.No	Base Station Package	Qty
1	ValProbe RT Base Station	1
2	Power adapter for Base Station	1
3	Power cable for adapter	1
4	Kaye #200-166 3.7 V lithium secondary (rechargeable) batteries	2
5	Shielded Ethernet cable 2 meters	1
6	IRTD cable	1
7	Bath cable	1
8	User manual	1
9	Logger opener	1
10	Logger wakeup device	1

S.No	Logger Package	Qty
1	ValProbe RT Loggers	As per order
2	Logger batteries	As per order

S.No	Optional Accessories	Qty
1	Kaye Validation Console with docking station and power adapter	As per order
2	Logger transport/storage tray	As per order
3	Kayetenna 2.5 / 5 meters (extendable autoclave antenna)	As per order
4	Insulating Canister	As per order
5	Logger AA Battery Extension Kit	As per order

DANGER **Use ONLY Kaye #200-166 3.7 V lithium secondary (rechargeable) batteries inside the Base Station. Insertion of a non-rechargeable battery may cause over-heating and explosion.**

1.4. Safety Information

Use this instrument as specified in this Manual.

- Protection provided by the equipment may be impaired if the equipment is used in a manner not specified by Kaye.
- Do not use this equipment in environments other than those listed in the Manual.

CAUTION! Use ONLY Kaye #200-166 3.7 V lithium secondary (rechargeable) batteries. Using any other batteries renders the stated performance void as Kaye #200-166 3.7V batteries are the only brand tested and accepted.

DANGER **Use ONLY Kaye #200-166 3.7 V lithium secondary (rechargeable) batteries inside the Base Station. Insertion of a non-rechargeable battery may cause over-heating and explosion.**

Chapter 2. Kaye ValProbe RT Hardware

2.1. Kaye ValProbe RT Loggers

There are eight Kaye ValProbe RT Loggers types:

- Temperature - Measures temperature from –85°C to 140°C. The bendable Temperature Logger may be used in conjunction with an Insulating Canister to measure temperature up to 400°C.
- Pressure and Temperature - Measures pressure from 0 to 5bar absolute and temperature from 0°C to 140°C.

Figure 5: Kaye ValProbe RT Loggers

The Kaye ValProbe RT Loggers are made from pharmaceutical grade polyether ether ketone (PEEK), 316 stainless steel, and designed for in-situ use. For example, they can be immersed in cleaning fluid or detergents, or used in harsh environments. They can store the study setup and up to 100,000 pressure samples and 100,000 temperature samples with variable stop/start conditions in non-volatile memory.

WARNING! Substitution of components may damage the logger.

Do not heat the Temperature Logger above 140°C.

Do not heat the Pressure/Temperature Logger above 140°C.

Do not submerge the Logger in oil, cleansing liquid or detergents for more than two hours at temperatures below –20°C. After two hours the O-ring seal may degrade and should be replaced.

CAUTION! Any Logger dropped from 3 ft or higher is susceptible to inaccurate temperature readings; a dropped logger that inaccurately reads surface temperature is not considered a manufacturer defect and is not covered under warranty.

IMPORTANT: *To maintain the seal, the Logger contains a cup O-ring. The cup O-ring should be replaced whenever the Logger is opened.*

2.1.1. Temperature RT Loggers

The Kaye ValProbe RT Temperature Logger accurately measures temperature from -85°C to 140°C using a precision Platinum RTD element. The RTD element is housed in the probe tip and ensures the following accuracy:

Table 1: Temperature Logger Accuracy

Temperature	Accuracy
-85°C to 140°C	±0.1°C
Bendable Loggers Only: -85°C to 140°C 140°C to 400°C	 ±0.1°C ±0.25°C

For Logger part numbers see below:

S.no	Model name - PMN (Product Marketing Name)	Model Number	Comments
1	Kaye ValProbe RT Rigid Temperature Logger	XCVP-L-R-RT	L= Sensor length in inches, D= dual sensor
2	Kaye ValProbe RT Single Bendable Temperature Logger	XCBVP-L-G-RT	
3	Kaye ValProbe RT Dual Bendable Temperature Logger	XCDBVP-La-Lb-G-RT	
4	Kaye ValProbe RT Single Flexible Temperature Logger	XCFVP-L-RT	
5	Kaye ValProbe RT Dual Flexible Temperature Logger	XCDFVP-L-RT	
6	Kaye ValProbe RT Five Channel Flexible Temperature Logger	XC5FVP-L-RT	
7	Kaye ValProbe RT Surface Temperature Logger	X2534-RT	
8	Kaye ValProbe RT Std Rigid Temperature Logger	XSVP-L-T-RT	L= Sensor length in inches T= Tip configuration pointed as(P), round as R & Flat as (G) D= dual sensor
9	Kaye ValProbe RT Std Single Bendable Temperature Logger	XSBVP-L-T-RT	
10	Kaye ValProbe RT Std Dual Bendable Temperature Logger	XSDBVP-La-Lb-T-RT	
11	Kaye ValProbe RT Std Single Flexible Temperature Logger	XSFVP-C-L-T-RT	C= Sensor length in inches, L = Tip length in inches T= Tip configuration pointed as (P) and round as R & Flat as (G) D= dual sensor
12	Kaye ValProbe RT Std Dual Flexible Temperature Logger	XSDFVP-Ca-La-Ta-Cb-Lb-Tb-RT	

13	Kaye ValProbe RT G Single Bendable Temperature Logger	XGBVP-L-RT	L= Sensor length in inches T= Tip configuration pointed as (P) and round as R & Flat as (G) D= dual sensor
14	Kaye ValProbe RT G Dual Bendable Temperature Logger	XGDBVP-La-Lb-RT	
15	Kaye ValProbe RT CR Rigid Temperature Logger	X2535-RT	
16	Kaye ValProbe RT Pressure Temperature Logger	X2532-RT	

The Temperature Loggers are available in different probe configurations (see Figures below).

Single Type Loggers

Figure 6: Rigid

Figure 7: Flexible

Figure 8: Bendable

Figure 9: Surface

Two and Multiples Type Loggers

Figure 10: Dual Flexible

Figure 11: Dual Bendable

Figure 12: Five Flexible

The ValProbe RT Logger is a temperature logger that provides a single solution for a variety of applications, such as steam, dry heat, ovens, incubators, stability and temperature chambers, warehouses, cryogenic chambers, lyophilizes, ultralow freezers, and other ultra-low temperature applications. Users can perform periodically verifications during the year using the IRTD and any Kaye calibration bath.

Rigid Temperature RT Loggers

The Rigid Temperature RT Loggers have a temperature range from -85°C to 140°C. They are a single sensor only, with a sensor length of 1.5”, 3”, 6”, or 9”, and have a diameter of 3mm / 0.118”.

Figure 13: Rigid Temperature RT Loggers

Bendable Temperature RT Loggers

Bendable Loggers are available in two versions, single and dual. They feature a temperature range of -85 °C to 140°C. If used with an Insulating Canister the range can be extended to 360°C. Sensors can be provided in 12”, 18”, 24”, 36” and 48”. The sensor tip diameter is 2.4mm, 0,98”.

To prevent breaking and/or stress on the inner conductors of the bendable Temperature Logger probe, the following guidelines should be followed:

- Do not bend past the minimum bending radius is 2x the diameter of the probe. To ensure that the limit is not exceeded, Kaye recommends bending the probe around a cylinder with a diameter of the logger diameter.
- Avoid repeated bending of the probe at the same point.
- The probe should not be bent within 1 inch of the Logger body or 1 inch from where the tip is welded to the probe.

Figure 14: Single Bendable

Figure 15: Dual Bendable

Flexible Temperature RT Loggers

Flexible Temperature RT Loggers are available as single, dual, or 5-sensor versions. They feature a temperature range of -85 ° to 140°C. The length of the sensor is 40” with a sensor tip diameter of 2.4mm, and tip length of 25mm; 0,98”.

Figure 16: Flexible Temperature RT Loggers

Surface Temperature RT Loggers

Surface Temperature RT Loggers are ultra-flat surface sensors with a temperature range of -85 ° to 140°C. These sensors are optimized to be used for Shelf mapping for Freeze Dryers. The flat surface diameter of the sensor is 32mm.

Figure 17: Surface Temperature RT Logger

Pressure/Temperature Loggers

The ValProbe RT Pressure/Temperature Logger (X2532) can measure pressure from 0 to 5 Bar absolute using a strain gage pressure sensor, and temperature from 0°C to 140°C using a precision Platinum RTD element.

Figure 18: Pressure/Temperature Logger

<u>CAUTION!</u> Do not insert objects into the top of the Pressure Logger. This can damage the diaphragm in the Logger, invalidating the pressure readings.

Note: *Clean the Pressure Logger with an alcohol rinse and then airdry.*

2.1.2. Insulating Canister for High Temperatures

The Kaye ValProbe RT Insulating Canister (Part Number X2545) enables you to operate bendable Temperature Loggers from up to 360°C by ensuring that the Logger base does not exceed 140°C.

Figure 19: Insulating Canister (X2545)

IMPORTANT: *Use the Insulating Canister in air applications only; do not submerge the canister in liquid.*

CAUTION! **Use the Insulating Canister in non-hazardous locations only.**

2.1.3. Inserting a Logger into an Insulating Canister

1. For dual and single bendable Loggers only, unscrew the protective housing cap from the Logger.
2. Remove the cap by pressing down on the cap and turning it counterclockwise until the clips are free from the tabs.
3. Place the PEEK cylinder over the bendable Temperature Logger probe and slide it to the base of the Logger.
4. Place the Logger and PEEK cylinder into the canister.
5. Insert the probe through the Insulating Canister cap center hole and slide the cap to the cylinder base. Line up the clips with the tabs on the cylinder base. Press down on the cap and turn clockwise so that the clips are secured onto the tabs.

Figure 20: Inserting a Logger into an Insulating Canister

Table 2 displays the length of time a Logger can remain in a chamber with the internal Insulating Canister temperature remaining below 140°C.

Table 2: Logger Time Inside Canister

Note: *The table below assumes the Logger and Insulating Canister (including the cylinder) were initially at room temperature before being placed in the chamber and that the oven is stable.*

Temperature	Maximum Time
360°C	48 minutes
300°C	63 minutes
275°C	72 minutes
250°C	85 minutes
225°C	105 minutes
200°C	127 minutes

CAUTION! If the Logger and Insulating Canister remain at a high temperature longer than the maximum time indicated in the table, the Logger base may be subjected to temperatures greater than 140°C, which can damage the Lithium Thionyl Chloride battery. This may result in a leakage of electrolyte.

WARNING! In the event the Logger base has been subjected to temperatures above 140°C, safety glasses and protective gloves should be worn before attempting to service the Logger to avoid electrolyte contact with eyes and skin.

If skin contact occurs, flush with cold water for at least 15 minutes. If symptoms persist, seek medical attention.

If eye contact occurs, flush with cold water for at least 15 minutes and seek medical attention.

After a high-temperature study is complete, allow the canister to cool to room temperature. Remove the cap and the PEEK cylinder and if required, wakeup the Logger with a magnet to establish communication between the Logger and Base Station.

2.1.4. Measurement Range and Accuracy

The Kaye ValProbe RT Loggers are factory calibrated to the following accuracy specifications for one year:

Table 3: Logger Calibration Accuracy Specifications

Measurement Range	Accuracy
Temperature Loggers	
0°C to 140°C	±0.1°C
Bendable Temperature Loggers with Insulating Canister	
–80°C to –40°C *140°C to 400°C*	*±0.1°C* *±0.25°C*
Pressure Loggers	
0°C to 120°C *120°C to 135°C* *135°C to 140°C*	*±25 mb* *±10 mb* *±25 mb*

2.2. Data Collection

Each Kaye ValProbe RT Logger collects and stores up to 100,000 data samples per sensor in memory at a user-specified sample rate. If the Loggers reaches 100,000 samples then the Logger stops collecting any further data. Data stored in the Logger is stored in non – volatile memory and is retained until a new Qualification or Verification is loaded.

Loggers can be programmed to start data collection manually when the Qualification is started or based on Time of Day and programmed to stop collection manually or based on cycle time.

Table 4: Qualification Start/Stop Conditions and Related Delays:

Options	Qual Start	Qual Stop
1	Manual	Manual
2	Manual	Cycle Time
3	Time of Day	Manual
4	Time of Day	Cycle Time

- Time of Day cannot be programmed for more than 72 hours after the Loggers are programmed. After 72 hours, the Loggers are set to shelf mode if a study is not started.
- Cycle Time does not have any duration limit, cycle time duration depends on the sampling rate and number of samples. The maximum number of samples that can be collected is 100,000 per sensor.

2.3. Logger Battery

The Kaye ValProbe RT Logger contains a field-replaceable 3.6 VDC, Lithium Thionyl Chloride ½ AA battery.

WARNING! To prevent ignition in a hazardous atmosphere, the battery must be changed only in an area known to be non-hazardous.

Do not heat the battery above 140ºC. For measuring temperatures above 140ºC, a special probe and insulating canister are required to keep the temperature of the Logger below 140ºC for the duration of the study. (See Section 2.1.2 *on Page 12*.)

Use only the factory-specified battery (part number M3205) in the Kaye ValProbe RT Logger. The use of non-specified batteries will void the warranty and may damage the Logger and/or cause burns to the operator. Replacement battery kits are available from Kaye.

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

Battery life is affected by several factors, including sample rate, temperature, and hours of use. In addition, individual battery characteristics and capacity vary inherently from one battery to another by up to 10%. Refer to the battery life tables in the Kaye ValProbe RT online help for the best approximation of the number of runtime hours you can expect from the battery at different sample rates and temperatures.

The Kaye ValProbe RT software tracks each Logger's battery life to within 10% of a potential low-voltage occurrence to help prevent interrupted or incomplete studies. When determining the battery life remaining, the software bases its calculations on the assumption that the battery can supply a predictable amount of energy (mAh) over the temperature range.

When the batteries are used in environments at room temperature or above, and the battery life runs down to a fixed percentage, that remaining percentage is generally not available in environments below room temperature due to battery chemistry. The battery life calculation is accurate when a Logger is used exclusively for studies at or above room temperature, or exclusively for studies below room temperature.

Kaye recommends that you replace the battery when there is 10% battery life remaining. If the battery life falls below 10%, the study may stop early.

- If the battery is fully drained or is removed, the study setup and data, as well as the calibration information, are maintained in non-volatile memory inside the Logger.

- If the battery is fully drained during a study, the study is terminated at the point the battery failed. Study data to the point of termination is stored in the Logger and can be read once a new battery is installed.
- If a battery is fully drained after a study is complete, all study data can be read once a new battery is installed.
- If you change the battery before a study is started, you need to re-program the Logger. Although the setup is maintained in non-volatile memory, the Logger needs to be programmed in order to reset its clock.

2.3.1. Battery Replacement

Kaye recommends that you replace the battery when there is 10% battery life remaining. The battery percentage indicator (text color) is based on the battery percentage value, between 0-19% in Red, 20 to 49% in Orange, and 50% to 100% in Green.

Battery replacement is a three-step process involving:

- Removing the Existing O-ring and Battery
- Installing the Replacement O-ring and Battery
- Resetting the Battery Odometer

1. **Open the Logger and Remove the Existing O-ring and Battery**

WARNING! *To ensure that the Logger maintains its waterproof and pressure-tight seal, a thin coat of grease was applied to the O-ring. The grease material is KRYTOX GL-203, and safe handling and storage practices should be followed. KRYTOX is a registered trademark of DuPont Chemicals. Material Safety Data information is available from DuPont Chemicals.*

- Slide the Logger opener over the probe tip and onto the top of the Logger. Unscrew the bottom cup while holding the opener firmly against the probe base.

Figure 21: Open Logger

- Remove the battery cap by pressing down on it and turning counterclockwise.
- With the cap removed, pull the battery out of the enclosure.
- To remove the O-ring, lift it from the groove and slide off in the direction of the probe tip.

Figure 22: Remove the Old Battery and O-ring

2. Install the Replacement O-ring and Battery

Whenever you open a Logger, you need to replace the cup O-ring to ensure that the Logger maintains its seal. The ValProbe RT battery replacement kit contains two types of O-rings.

- For temperature ranges from –85 to 140ºC, use the orange (silicone material) O-ring.
- Before you install a new O-ring, you need to apply a thin coat of grease to the O-ring (see warning above regarding KRYTOX grease). Carefully apply the grease to all surfaces of the O-ring, ensuring not to cut or scratch the O-ring.

Figure 23: Apply Grease and Replace O-ring

- Slide the O-ring over the tip end of the probe and into the O-ring groove. Do not stretch or deform the O-ring and avoid contact with the threads to prevent nicking and/or cutting the O-ring.
- With the new O-ring in place, insert the pre-conditioned battery into the battery holder and place the battery cap on top and turn the cap down and clockwise to lock it into place.
- Once the battery is installed, a small red LED on the top edge of the board blinks three times to confirm that the Logger is powered on. If the LED light does not blink, follow the important note below to troubleshoot.

Figure 24: Insert New Battery / Verify LED

Important: I*f the LED does not blink, remove battery and wait (1-2 minutes) until all the residual power is released. Then use a magnet over the Logger without the battery. Reinstall the battery and wait for the LED to blink three times. If LED keeps blinking, remove the battery again and then reinstall the battery. If the Logger blinks more than three times, the Logger may have an issue with its hardware.*

- Reinsert the Logger cover and hand tighten until the cup O-ring is no longer visible. Clean the exterior of the Logger with a soft cloth to remove any excess lubricant.

3. **Reset the Battery Odometer**

When you change the battery in a Logger, you must also reset the battery odometer to 100% for the program to calculate the life of the new battery.

Reset Battery Life:

- Start the ValProbe RT software.
- Navigate to the Hardware Discover tile, select a Base Station and then select the **Connect** button.

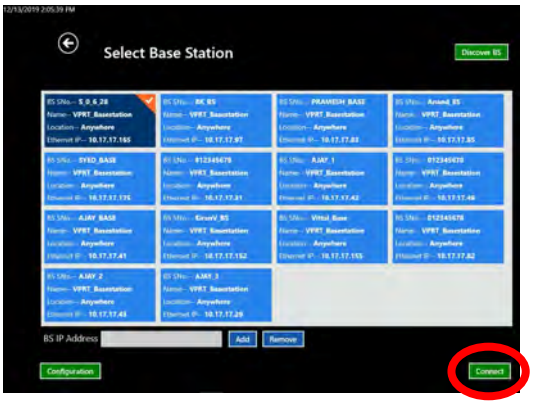


Figure 25: Connect Button

- Wake up all Loggers that have had battery replacements using the Wakeup device or the Base Station magnet.
- From the Logger Configuration screen, select the Loggers and then **Battery Reset**.

Figure 26: Select Loggers

- Once the Loggers Status window displays, select the Loggers to reset from the lower left dropdown in the Logger Reset screen, and press **Battery Reset**.

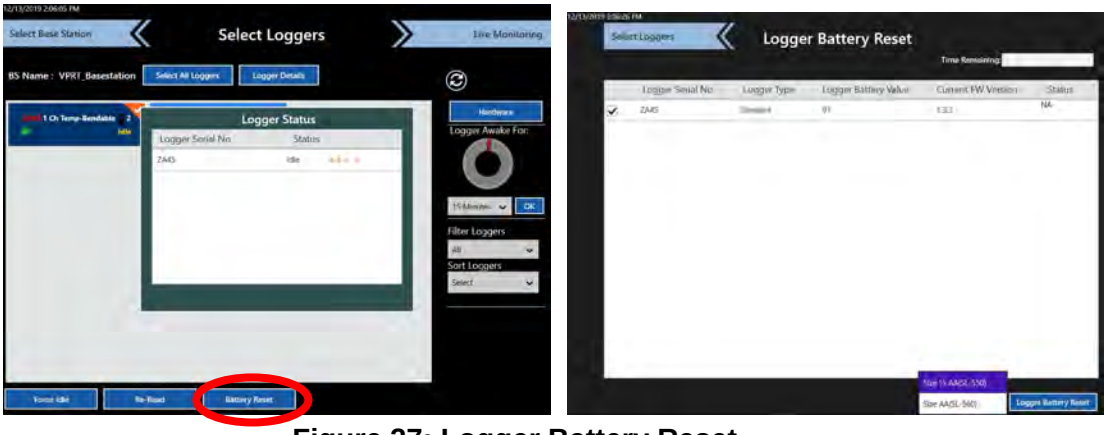


Figure 27: Logger Battery Reset

- Select **OK** when prompted to continue the battery reset and then enter your user credentials.

Figure 28: Logger Battery Reset Prompt

- When all Logger battery resets are complete, ensure that their status displays *Success* in the Status column.

2.4. Kaye RF ValProbe RT Base Station

2.4.1. Base Station Overview

The ValProbe RT Base Station acts as the central hub and communications link between the wireless Loggers and the ValProbe RT Console /software. The Base Station is responsible for establishing and maintaining wireless communications with the Loggers utilizing a 2.4GHz Star network with a proprietary and encrypted (AES128) protocol compliant to IEEE 802.15.4 standards. The wireless range from the Base Station to any Logger is 450 ft. (~150 meters).

Figure 29: RF ValProbe RT Base Station

<u>CAUTION!</u> Use only the Kaye power supply (Kaye #201-3006) provided with your ValProbe RT. The use of non-factory power supplies may damage the equipment and will void your warranty.

Base Station Power/Communications Connection

The Base Station also provides an Ethernet connection at the base of the unit for communications from the Base Station directly to the Console / Docking Station (Static IP) or by using an ethernet network connection via DHCP. (See Chapter 3 for details on connection options and configuration.)

The base of the unit also includes the connection for the supplied Power Supply as well as a Reset button for service emergencies (See Chapter 3).

Figure 30: Base Station Connections

2.4.2. Base Station IRTD / Bath Connections

At the rear of the Base Station there are connections for the IRTD and Kaye References which can be used for Sensor Verification. Using the supplied cables connect the IRTD and bath to the appropriately marked connectors. The provides cables and connections are backward compatible to all Kaye baths, dry block and IRTD's. The ValProbe RT software can provide fully automated sensor verification of your ValProbe RT loggers (See Chapter 10 for details on Sensor Verification).

Figure 31: IRTD / Kaye Bath Connections

2.4.3. Base Station Battery Backup

Kaye ValProbe RT base station has battery backup for up to 60 minutes. The Base Station is powered by two 3.7V AA size rechargeable Lithium batteries. The Base Station has a built-in charger, so batteries will be charged automatically when there is a main supply available to the base station. To replace the batteries, first shut off the base station using ON-OFF switch. Then open the sliding panel on the back of the base station and replace the batteries in the compartment displayed in Figure 32 below. Do not power on the Base Station until you have properly replaced the compartment cover.

Figure 32: ValProbe RT Base Station Battery Compartment

<u>CAUTION!</u> ONLY Use Kaye #200-166 3.7 V lithium secondary (rechargeable) batteries. Using any other batteries renders the stated performance void as Kaye #200-166 3.7V batteries are the only brand tested and accepted.

Insertion of non-rechargeable battery may cause over-heating and explosion.

2.4.4. Base Station LED Indications

The Base Station LED panel provides multi-colored status indications of item such as:

Figure 33: Base Station Status Panel

PWR Switch	POWER	PRE-CONDITION	CONDITION	LEDs: COMMUNICATION LED	STATUS LED	BATTERY CHARGE LED	POWER LED	BUZZER	BRIEF	REMARKS
ON	Battery	SBC is not active							All LED OFF - as AC is not available and Battery is LOW Battery voltage should be monitored when running on Battery supply.	
									All LEDs are lit RED and then Green and then Blue - only once to indicate all are functional	currently implemented 500ms for each color
									GREEN power LED should be blinking to indicate SBC turning ON	
									RED power LED should be blinking to indicate SBC is turning OFF	
		SBC is active							all leds are blinking in RED to indicate system error (CRITICAL ERROR) and User should turn OFF the BaseStation. Fault conditions to be defined.	
	AC or BATT		Logger detection upon wake-up by magnet					1 SEC	beep and all LEDs light in red for 1 second Logger is woken up by Magnet and logger is still running a study – qualification, calibration or verification and the study has not yet stopped	Every time a new Logger is WOKEN UP by Magnet, this command to be sent
								1 SEC	beep and all LEDs light in green for 1 second Logger is woken up by Magnet and logger is not running and not collecting any data – so is in idle mode (all data downloaded)	
								1 SEC	beep and all LEDs light in blue for 1 second Logger is woken up by Magnet and logger is not running anymore and the study was over – but data has not been fully downloaded	
								2 SEC	beep and all LEDs BLINK in red for 2 seconds Logger is woken up by Magnet and logger has very low battery or any other Issue	
			Study in progress						A study is ongoing with current BaseStation	
			RF data retrieval is in progress						Indicates Study data is being read from the logger via RF RF data retrieval is POST study, so Study and Retrieval LED will not co-incide. USB data dump is short duration and will be taken care to revert to previous state.	
			Study Completed but Data not retreived from all loggers						Stody is completed successfully. But the Study data is not yet retrieved at the BaseStation. This is user indication that Data is yet to be retrieved.	
									If data dump to pendrive indication is used with Green LED, Blue LED can be used to indicate data retrieval over RF	
								SHORT	Study was running and dump completed (pendrive) then back to Green LED indicating sludy continues	LED goes to its previous state.
								SHORT	Data dump complete (to pendrive or RF data retrieval) BS is now in IDLE mode	250ms beep when transfer started and '500ms Beep implemented after success
								LONG	RED led blinks for some time (duration tobe defined), after the set duration LED changes its state based on its state	USB Mount Error or Copy failed, RED Blink and 1 Sec Beep implemented
									Post error indication, the LED should continue its previous state of Study indication.	LED goes to its previous state.
									BS is now in IDLE MODE (no study)	
									If Console NOT connected	
									IF Console is connected	
	AC								Battery is charging, Green Blinking (Batteries available) Charging Completer, Green Stable (Batteries available) AC available, Switch is ON, Battery Voltage not detected (0 Volts) (Batteries NOT available)	
	Battery							SHORT	EVERY 10 SEC	
									Battery voltage is below the 'low voltage' threshold - Blink RED LED	
OFF									ALL LED are OFF as Main BS switch is turned OFF	No power = no LED

POWER LED:

- GREEN indicates that power input is operational.
- RED indicates an input power fail.

BATTERY CHARGE LED:

- GREEN indicates that battery has full capacity.
- GREEN blinking indicates the battery is charging.
- No indication that a battery is present or a battery issue.
- RED blinking indicates that battery is at low capacity or a battery issue.

STUDY STATUS LED:

- GREEN indicates that a study is in progress.
- GREEN blinking indicates that a data transfer is in progress to USB storage.
- RED blinking indicates a data transfer error to the USB storage.
- BLUE indicates that a firmware upgrade is in progress or the study stopped.
- BLUE blinking indicates that RF data retrieval is in progress.

COMMUNICATION LED:

- GREEN indicates that the console is connected with the base station.

Other Scenarios:

- All colors (RED, GREEN, and BLUE) blink once after power on,
- All four lights blink RED, indicates that a logger joined with the base station.

2.4.5. Base Station Wakeup Magnet

A powerful neodymium magnet is located behind the LED panel to the Kaye logo. The magnet can be used to wake up Loggers from sleep mode prior to connection and execution of a Qualification or Verification. Simply swipe the base of the Logger slowly over the Kaye logo. The Base Station LED's flash along with a buzzer sound to state the Logger has been woken. The magnet is only used to awaken a Logger and cannot stop a Logger. Stopping a Logger during Qualification or Verification is controlled by the completion or cancellation of a study by a user. Loggers return to a sleep mode if during Idle mode, there is inactivation of communication for 15 min. Keep any magnetic sensitive devices away from the Base Station.

Figure 35: Wakeup Magnet

2.4.6. Wakeup Device

Figure 36: Wakeup Device for Logger

The Wakeup device is a plastic enclosure with a permanent magnet inside. It helps to wake Loggers from Sleep mode. The powerful neodymium magnet is located exactly behind the Kaye logo. Keep the Wakeup device away from magnetic sensitive parts. A Logger can be woken from sleep mode by simply swiping near the Kaye logo on the Base Station.

<u>Caution:</u> The Base Station and Wakeup device contain magnets and may affect devices.

Magnet warning: Avoid placing any media that contains magnets or is sensitive to magnetism near this product. Magnet sensitive devices such as laptops, credit cards, or magnetic memory devices can be damaged if they are placed close to this product, so take extra care to prevent loss.

Pacemaker warning: Magnets inside the Base Station and Wakeup device may cause interference to near-by medical devices such as pacemakers, implanted heart defibrillators, etc. Do not carry or use the Base Station or Wakeup device near any medical devices and warn others who wear medical devices from getting close to the magnets.

2.4.7. Kayetenna - Extended Antenna Cable

The Base Station and Loggers are designed with a feature called Antenna diversity. Antenna diversity utilizes two separate antennas that look for the best signal strength across two planes to maximize distance, signal strength, and reliability. For some extremely difficult applications such as large autoclaves, with thick walls where communications could be difficult, Kaye offers an optional two-meter antenna cable (Kayetenna) that can be fed into the chamber via a feedthrough to improve communications reliability. The Kayetenna can be installed to the Base Station by replacing the diversity antenna on the Base Station.

Figure 37: Kayetenna

Figure 38: Base Station with Kayetenna

2.5. ValProbe RT Console / Docking Station

Figure 39: ValProbe RT Console

The ValProbe RT system includes a portable, hardened dedicated validation Console running Windows 10 LTSC. The ValProbe RT Console is pre-loaded with a customized Kaye core-load designed to meet data integrity and 21 CFR Part regulatory requirements, while limiting applications to those only necessary for validation needs. The Console also includes all related ValProbe RT software and documents such as the User Manual and SOP. Additional features include:

- IP54 rated (water, dust and splash resistant)
- Durable Gorilla Glass
- Rubberized for shock dampening
- Hot swappable battery (six hours)
- On-board camera for generation of sensor overlay pictures

The ValProbe RT System also includes a portable docking station for easy access and viewing. The docking mechanism can be adjusted for optimum viewing and includes additional USB and Ethernet ports for connection to the Base Station or network and optional equipment such as a wireless keyboard / mouse etc. The Docking Station includes a power supply (100 – 240 VAC) for charging the Console during use.

The ValProbe RT Console / Software provides an interface for the ValProbe RT system to configure and control the ValProbe RT Base Station and Loggers during the validation process. It also provides real-time display, data storage, and a powerful reporting tool for post analysis of Qualification data.

The ValProbe RT software contains features to perform the following validation tasks:

- Create Assets
- Create Setups
- Run Qualification Studies
- Perform Sensor Verification
- Create Qualification Reports and Graphs
- Storage of Validation files
- Sync In, Sync Out and Archive of Data
- User Permission management
- Audit Trail review and analysis

Chapter 3. ValProbe RT System Connections

The ValProbe RT system provides two options for connection from a Base Station to a Console /Docking Station; direct Ethernet connection via Static IP, or network Ethernet connection via DHCP.

3.1. Direct Ethernet Connection – Static IP

Figure 40: Direct Connection

The ValProbe RT Console and Base Station are factory configured for Direct Connection mode. The Base Station is programmed with a Static IP address of 192.168.99.50. The Console Ethernet adapter setting is set for a Static IP address of 192.168.99.55.

To connect via direct connection and verify system connectivity do the following:

1. Attach the supplied cross-linked Ethernet cable to the Ethernet connector located at the base of the Base Station to the Ethernet connector located on the Docking Station.

Figure 41: Base Station Connection

2. Power the Base Station and wait until the Power Led is solid green.

3. Ensure the Console is in the Docking Station and press the Power button on the Console.

4. Log in and proceed to ValProbe RT software.

5. From the Main Menu of the ValProbe RT software press the **Discover** tile.

6. From the Select Base Station screen, press **Discover BS** in the upper right of the screen.

Figure 42: Select Base Station Screen

7 If the Base Station was found and communication have been established, a blue tile signifying the Base Station appears with an IP Address 192.168.88.50.

Note: *If the Base Station's blue tile does not appear with the IP 192.168.99.50 proceed to Section 3.3 for instructions to reset the Base Station and then return and repeat Steps 5 - 7. If the problem persists, contact technical support.*

8 Press the Base Station tile and then press **Configure** to open the BaseStation Setup screen.

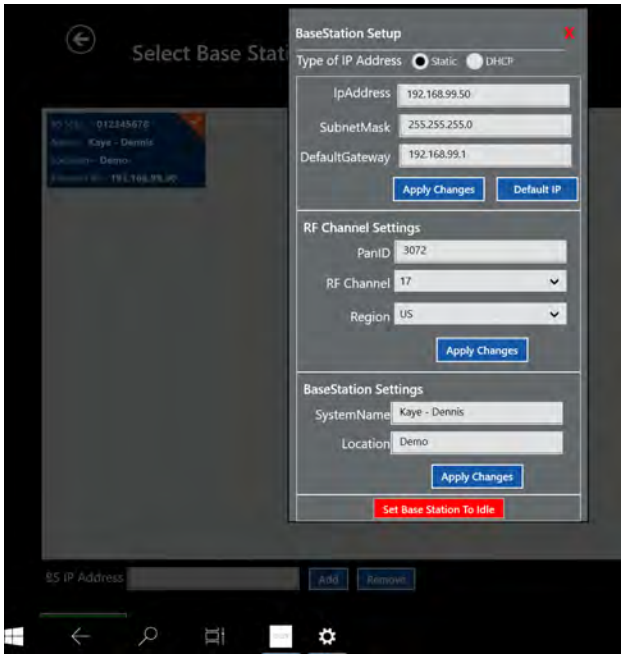


Figure 43: Select Base Station Screen

9 The BaseStation Setup screen details the settings stored in the Base Station. Settings include the Type of IP Address, related IP addresses, RF Channel settings, and Base Station settings. These settings are typically set once based on desired connectivity mode. Any changes to these fields are sent to the Base Station and stored in memory.

   a. Do not change the **Type of IP Address** or the **IP Addresses** if intending to use in Direct Connect mode.

   b. The RF Channel Settings **Pan ID** and **RF Channel** are for service use only and should not be adjusted. The **Region** dropdown permits selection between US or EU (Europe). This changes the licensed RF strength and should be set accordingly.

   c. Use the Base Station settings to customize the **System Name** and **Location** in the blue Base Station tile.

   d. The **Set Base Station to Idle** button resets the Base Station and Loggers to Idle mode if they are inadvertently shutdown in the middle of a process. This can be used if the Base Station fails to connect.

   Note: *To ensure changes are implemented, select **Apply Changes** to save any changes.*

10 When completed press the **X** to return to the Select Base Station screen.

3.2. Network Ethernet Connection – DHCP

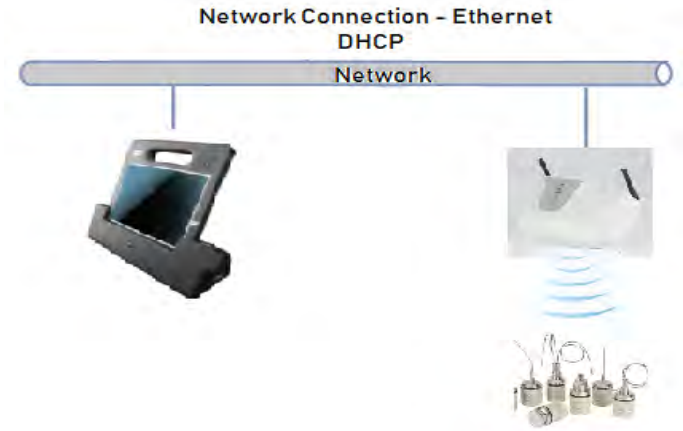


Figure 44: Network Connection

The ValProbe RT can also be configured to communicate using your company or private networks via DHCP. The ValProbe RT system is factory configure to utilize Direct Connection using a Static IP address of 192.168.99.55 for the Console and 192.168.99.50 for the Base Station. In order to change this for Network connection using DHCP the system must be first connected vis Direct Connection to communicate the changes to the Base Station.

To convert the system from Direct Ethernet connection via Static IP to a network connection via DHCP, perform the following steps:

1. First change the Base Station settings and connect the system via Direct Connection following Steps1-8 in Section 3.1.

2. In the Base Station Setup window, make any necessary changes to the RF Channel Settings and Base Station Settings:

    a. The RF Channel Settings of the **Pan ID** and **RF Channel** are for service use only and should not be adjusted. The **Region** dropdown includes selection between US or EU (Europe). This changes the licensed RF strength and needs to be set accordingly.

    b. Base Station settings permit the customization of the **System Name** and **Location** that appear in the blue Base Station tile.

    c. Select **Apply Changes** to save any changes made to the RF Channel Settings or BaseStation Settings.

3. From the Base Station Setup window change the **Type of IP Address** from Static to **DHCP** and press **Apply Changes**.

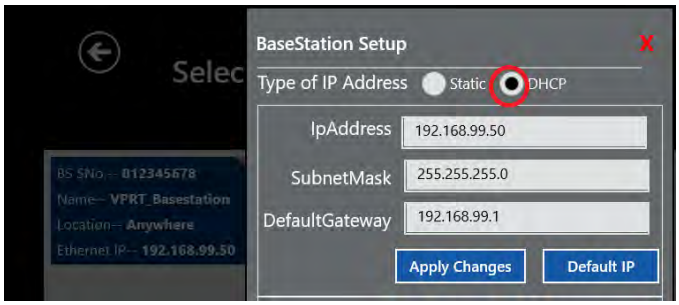


Figure 45: Change to DHCP

4. The changes are stored in the Base Station and the software tries, unsuccessfully, to rediscover the Base Station. The Base Station is not found because the Console IP settings need to be changed and an Ethernet cable needs to be connected from the Base Station to the network connected Console.

5. To change the Console IP settings, perform the following:

   a. In the taskbar, select **Start >Settings**

   b. Select **Network & Internet >Ethernet >Change Adapter Options**.

   c. Right Click **Ethernet >Properties**.

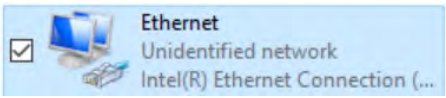


Figure 46: Ethernet

   d. Select **Internet Protocol Version 4 (TCP/IPv4) >Properties.**

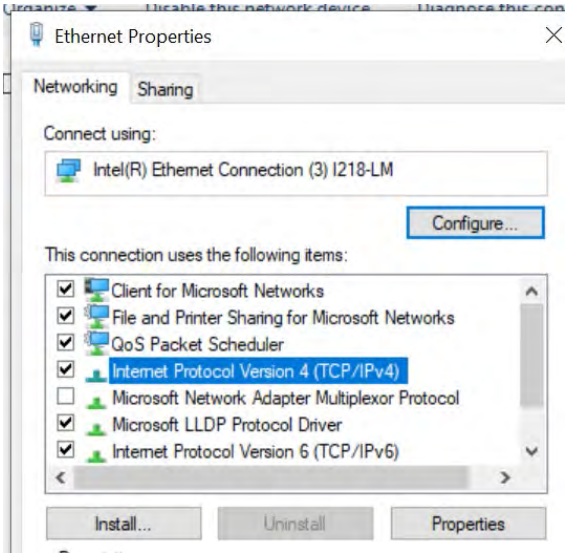


Figure 47: Ethernet Properties

e. Select **Obtain an IP address automatically**, then select **OK** and **Close**.

Figure 48: Ethernet Properties

f. Ensure that the Base Station and Console are connected to the Network via Ethernet cables.

6. Return to the ValProbe RT software's **Select Base Station** screen.

Figure 49: Select Base Station

7. Select the **Discover BS** button. If the Network connection and setup were successful, the Base Station blue tile appears with the network assigned IP address.

Note: *The discovery function can only detect Base Stations in the same IP segment and the same subnet as the computer. If the Base Station is not in the same sub segment or configured to another subnet mask, you must manually add the IP using the **Add** button.* If the Base Station discovery was unsuccessful, contact Kaye support or your company IT department.

WARNING! If a Base Station is configured to a static IP address, it is the only way to communicate with it. If the IP is changed and the "Apply" command is sent, the previous setup is not active for any further connection. If the IP address is not reachable or forgotten, the Base Station may need to be reset.

3.3. Resetting a Base Station

3.3.1. Initiating a Factory Reset

1. Press the **Reset** button displayed in Figure 41 for five seconds, note after one second there is an audible beep to indicate that **Reset** is pressed.

2. When the **Reset** button is pressed for five seconds, two audible beeps sound indicating that a reset has occurred. Release the **Reset** button.

Note: *During Factory reset, the Base Station restarts after a few seconds (10 seconds max), throughout this time the LED sequence is the same as initial power ON (all LED RED, GREEN, BLUE) and the Power LED blinks.*

3. When the Power LED is no longer blinking, but consistently lit, you can reconnect to the Base Station using the software.

At the completion of the Base Station reset, the following settings below are set and any connected Loggers are set to idle.

DEFAULT FACTORY SETTINGS	
Base Station mode	IDLE
Ethernet mode	STATIC
IP ADDRESS	192.168.99.50
PANID	3072
RF CHANNEL	23
REGION	US
System Name	VPRT Base Station
Location	Anywhere

<u>CAUTION!</u> Pressing RESET restores the Base Station to factory settings. The Base Station mode changes to IDLE, the IP address changes to the STATIC default of 192.168.99.50, the name and location are reverted to defaults, and all Loggers are forgotten.

Chapter 4. Creating User Accounts

4.1. Introduction

The Kaye ValProbe RT software includes a Kaye Default System Administrator account that allows you to log in to the Password Maintenance utility, following initial program installation, 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 system administration tasks.

On the Admin tile, the System Administrator has access to the preferences, policies, user management, firmware upgrades, and auto sync configuration.

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 a System Administrator account
- Create other user accounts.
- Upgrade ValProbe RT firmware
- Handle files
- Access the ValProbe RT online help
- Upgrade Base Station software

4.2. Logging in as a Default System Administrator

Before using the software, the computer automatically boots into the Kaye Operator windows account on startup. Inside the start menu, start the ValProbe RT software.

Once you have started the ValProbe RT software, the Login screen appears as displayed below:

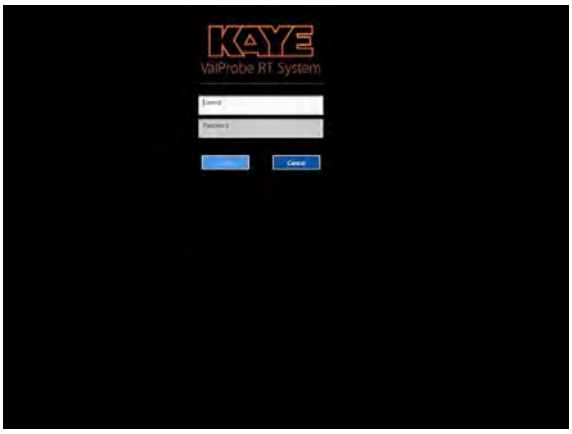


Figure 50: Login Screen

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

Note: *“Kaye” is the default System Administrator user ID, and the User ID textbox is case sensitive. Please ensure that you enter the default user ID exactly as it appears above.*

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

IMPORTANT: *The default user ID and password are as follows, “Kaye” and “411” respectively.*

3. Press **Login**.

4. Once logged in, the User Management screen opens.

5. For the first new user, the New User window opens automatically. For additional system administrators, press **New User**.

Note: *Red asterisks fields are mandatory: User IDs are unique, and the passwords must follow the default rules for passwords (minimum of six characters).*

6. Enter a User ID in the **User ID** textbox.

Note: *A User ID can use any combination of numbers and characters, up to a maximum of 16 and a user ID cannot be used by more than one active account.*

7. Enter a password in the **Password** textbox, a password must be at least a combination of six characters or numbers, up to a maximum of 16. It is recommended for security to use more than six.

8. In the **Confirm Password** field, enter your password and press **OK**.

Please record your new User ID and password for future reference. If you do not enter the correct user ID/password combination, you will be denied access. After the initial administrator account is created, the default “Kaye” “411” login credentials are no longer valid.

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 built-in camera. After completing the system administrator user setup, the system logs you out. To proceed, open the software, and log back in with your new account information.

When logged in for the first time you will see the ValProbe RT's Main Screen, where you can create new user accounts, set preferences and policies, discover new hardware, add/remove/view assets and equipment, and display an audit trail.

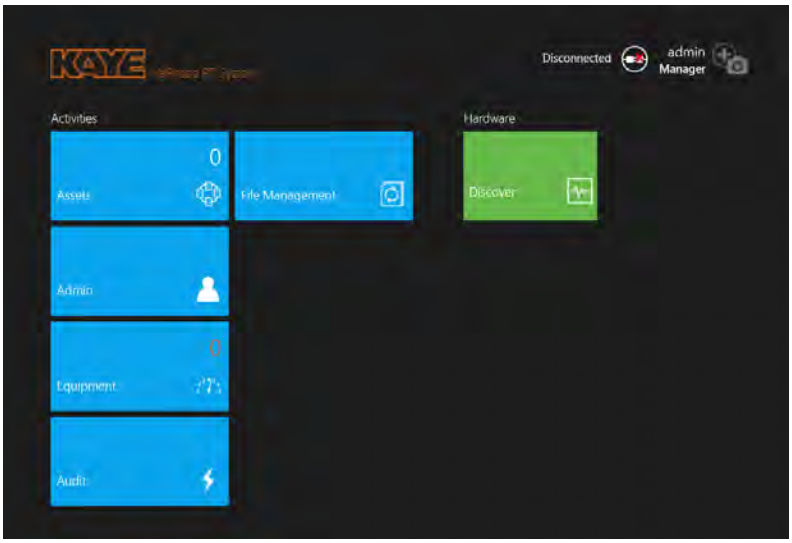


Figure 51: Main Screen

4.3. 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: *It is recommended to create more than one System Administrator account if access to one is lost.*

To create a new System Administrator account:

1. On the Main screen, press the **Admin** panel to open the Admin Settings window on the **Preferences** tab.

2. From the Admin Settings window, press **User Management**.

3. On the User Management screen, press **New User**, and enter your name in the **Name** textbox. This username appears in the active user list.

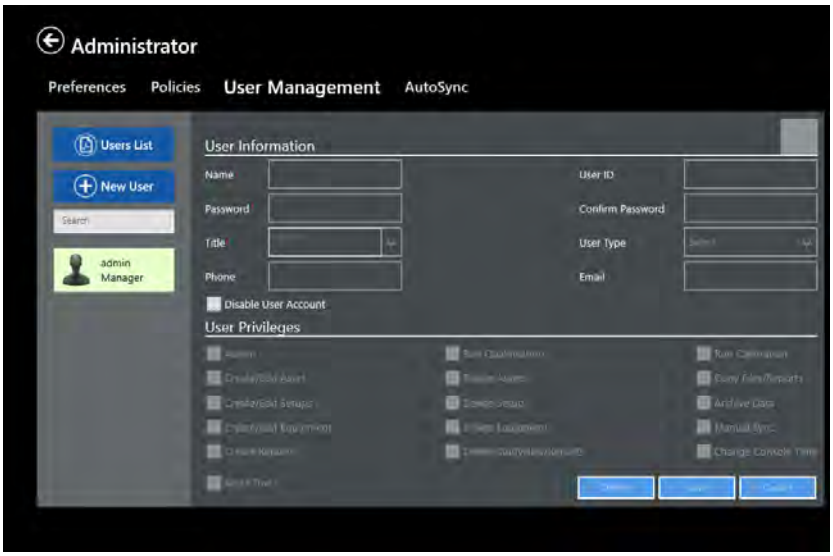


Figure 52: User Management Screen

4. Enter a new System Administrator User ID, any combination of numbers and characters, in the **User ID** textbox.

Note: *User IDs must be unique. Once a User ID has been used, it cannot be used again or used by more than one active account.*

5. Enter a new System Administrator password in the **Password** textbox. The 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. Re-enter the password in the **Confirm Password** textbox and press **OK**.

Note: *Please record the user ID and password for future reference.*

7. Enter your designation and your Phone number and Email ID as contact details. Press **Save** to save the information.

The User Management screen displays the list of active users. The System Administrator accounts just created is the only name on the list (the default System Administrator account Kaye has been deleted).

4.4. Creating New User Accounts

When creating a new user account, the username is added to the active user list. You assign a unique user ID for each user and a temporary password. The user has to change the password on 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 becomes active.

2. Enter a new username in the **Name** textbox.

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

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

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

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

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

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

Note: *Please record the new user ID and temporary password for the new user.*

A user ID and password are required anytime a user:

- Changes system preferences
- Creates or modifies a setup stored in the ValProbe RT
- Verifies sensor calibration
- Manually stops calibration verification
- Manually starts or stops a qualification study or exposure cycle
- Deletes or moves qualification data files
- Accesses report utilities

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

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

7. Select any permissions to give to the user. Some examples of permissions include:
    - Creating setups
    - Running studies
    - Viewing or editing reports

8. Press **Save**, and the username appears in the user list.

4.4.1. Deleting and Disabling User Accounts

Including active users, there are two additional states for a user:

Disabled User

A user can be disabled by an Administrator or automatically disabled after a certain amount of consecutive login failures (3-10) if enabled in Policies (see Setting Policies for details). A disabled user's account is marked in red in the user list. The disabled state is set with the checkbox Disabled User Account in User Information. An Administrator can re-enable the user account by unchecking Disabled User Account.

Deleted User

Press Delete at the bottom of the screen, if a user's account is no longer required an Administrator can delete the account. To prevent discrepancies in the audit trail, the deleted user's ID is blocked for further usage. The deleted user is removed from the user list, but the user information remains accessible via the user list printout.

Users List

Users List generates a pdf report that lists all active, disabled, and deleted user information.

User Search

There is a search field that automatically filters for username. As an example, if you enter "B" all usernames starting with a "B" are listed.

Note: *All users are listed in alphabetic order.*

4.4.2. One Time Emergency Access

Establishing more than one active Administrator account is good practice, if a system administrator is unavailable the system can still be maintained. If administrator access is no longer possible, Kaye can provide one-time Emergency access with the sole purpose of modifying an Administrator account. For this procedure, direct support from Kaye service is required.

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

4.5. Setting Preferences

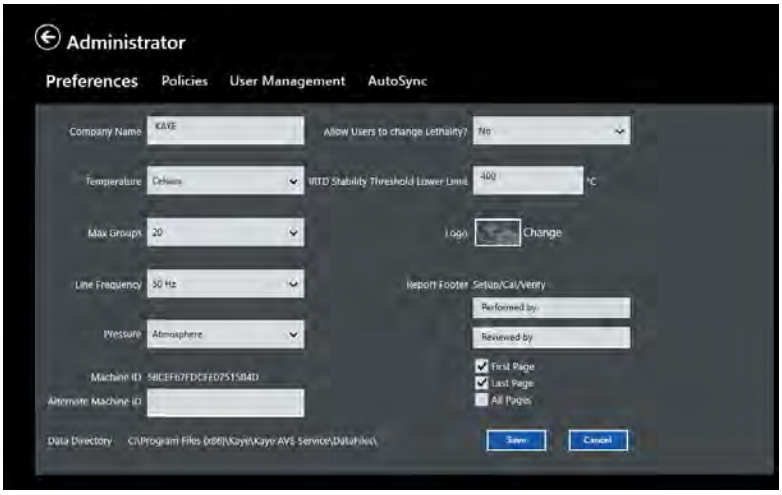


Figure 53: Preferences Tab in the Admin Menu

Once the initial ValProbe RT software installs with default system settings, you can change the settings inside the Preferences screen. The new settings become effective independently.

- **Company Name**: Enter a company name to display in report headers.
- **Temperature**: Use the drop-down to set the temperature units to Celsius or Fahrenheit. All calculations are performed in the temperature units specified here.

Note: *After switching to a different temperature unit, setups must be recreated for the new temperature unit.*

- **Max Groups**: Use the drop-down to select a maximum number of groups for a setup.
- **Line Frequency**: Use the drop-down to select a line frequency, 60 Hertz or 50 Hertz depending on your environment.
- **Pressure**: Use the drop-down to select the absolute pressure units for saturated steam calculations. If you are selecting “Other”, enter the value of 1 Atmosphere in the absolute pressure units you are using.
- **Alternative Machine ID**: If required, enter an alternate machine identification number, which appears in the audit trail as additional identification.
- **Allow Users to change Lethality**: Use the drop-down to decide if the user should be able to change lethality, Yes or No.
- **IRTD Stability Threshold Lower Limit**: 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.
- **Logo**: Press **Change** to browse to a location to add a logo to display in report headers. The graphic can be any bitmap and the preferable size is 90 x 30 pixel. Other formats are downsized.
- **Report Footer**: Decide if signature fields should be applied on first/last/every page for all report types. For detailed and summary reports, this is set in the report tool directly.
- **Data Directory**: Displays the path and folder holding the Data Directory.

4.6. Setting Policies

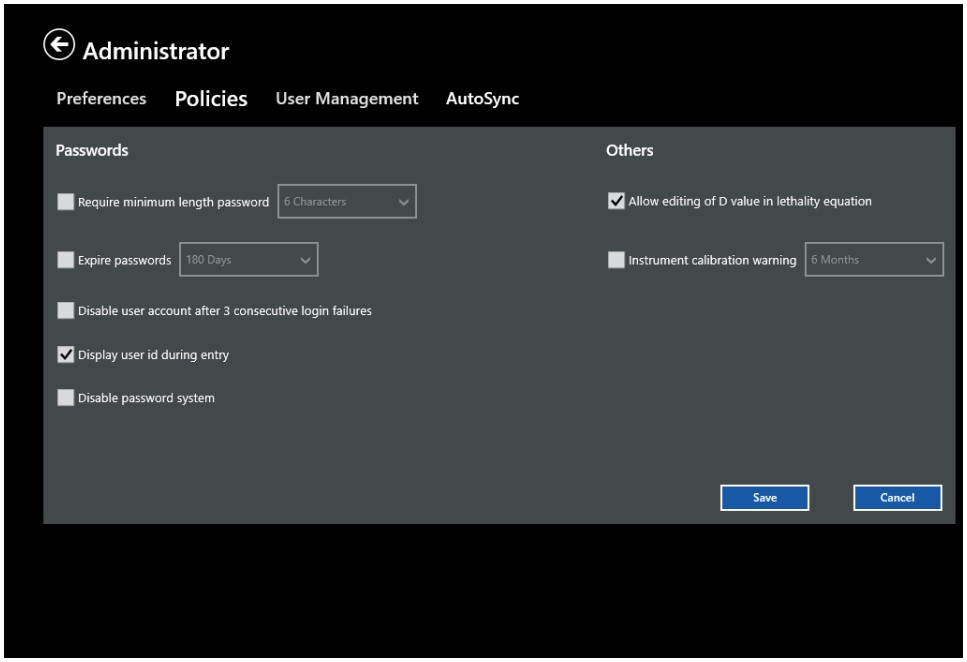


Figure 54: Polices Tab

Inside the Policies screen you can set policies that give users more flexibility on handling the password system, lethality, the D-Value, and calibration warning.

The System Administrator can adjust:

- **Require minimum length password**: Use the dropdown list to select how many characters are required for password length at a minimum.
- **Require Special Characters**: Enabled when the “Require Minimum Length Password' field is selected. Selecting this field forces a user to enter at least one special character, one numeric character, and one upper case letter when creating a password for a new user or updating the password of an existing user.
- **Set passwords to expire after a defined number of days**: Use the dropdown list to select how long to passwords take to expire, passwords are set to expire after 180 days. The password expiration date set here is displayed at login when there are five days or less before password expiration. Expired passwords can no longer be used as new passwords.
- **Disable user accounts after three unsuccessful login attempts**: Disable user accounts after a certain amount of unsuccessful login attempts: Check the checkbox to enable and set the amount of consecutive unsuccessful login attempts to disable a user account with the dropdown.
- **Disable user id during entry**: Check the checkbox to enable masking of the user ID during login.
- **Disable the password system**: Check the checkbox to disable the password system, meaning user ID’s and passwords are not required to use the software.
- **Allow editing the D value in the lethality calculation**: Check the checkbox to allow editing of the D value field on the Lethality Calculations screen. If not enabled, the D value field displays but is not editable when creating a new setup.
- **Instrument calibration warning**: Check the checkbox to set a pre-warning interval for Kaye Equipment populated under the Equipment tile.
- **Require Special Characters**:

4.7. Handling Data Files

The ValProbe RT software permits synchronizing data across several consoles. The functionality is also used to backup, restore, and archive files. The synchronization requires a location for commonly used data. This can be any folder in the operating system that can be accessed for read/write operations, like a shared folder in the network, an external USB device, 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 console's data sets following some rules for merging:

Preferences and policies are not synchronized.

If two items with the same name exist, the item is updated with the latest version (depending on the modified date) for users and assets. If two items have the same name but different dates (reports, study files), both are retained.

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

- **Sync Out**

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

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

  You can select data to be copied. If an asset is selected, the asset with all the information (setups, study files, reports, documents) is copied. It is possible to select only one or a few assets to transfer these from one console to another, but also possible to make a complete transfer with user, audit, equipment, templates, and asset data, depending on the setup.

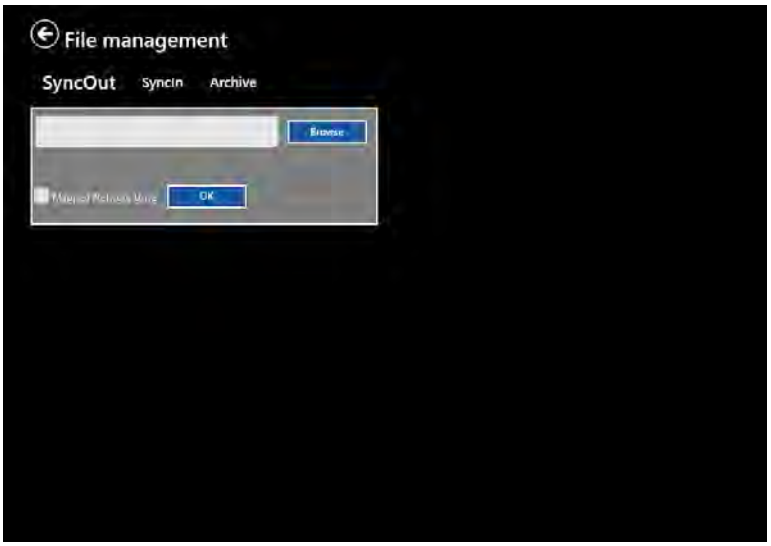


Figure 55: Sync Out

- **Sync In**

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

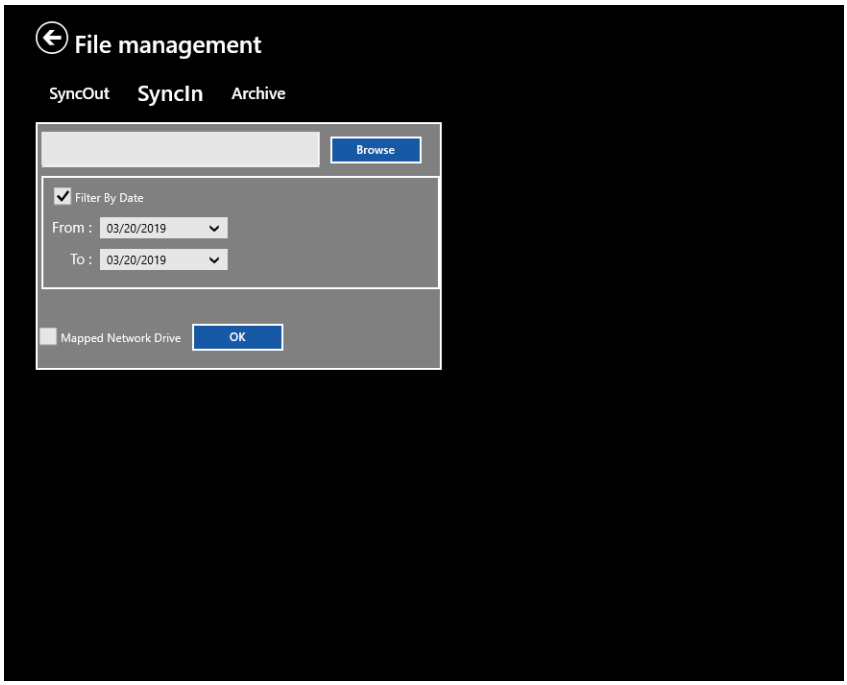


Figure 56: Sync In

- **Archive**

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

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

  If you select a folder with existing sync data as target, the copied data is merged with the existing console data.

Note: *It is recommended to use a separate folder for archived data, otherwise the data syncs back to the system.*

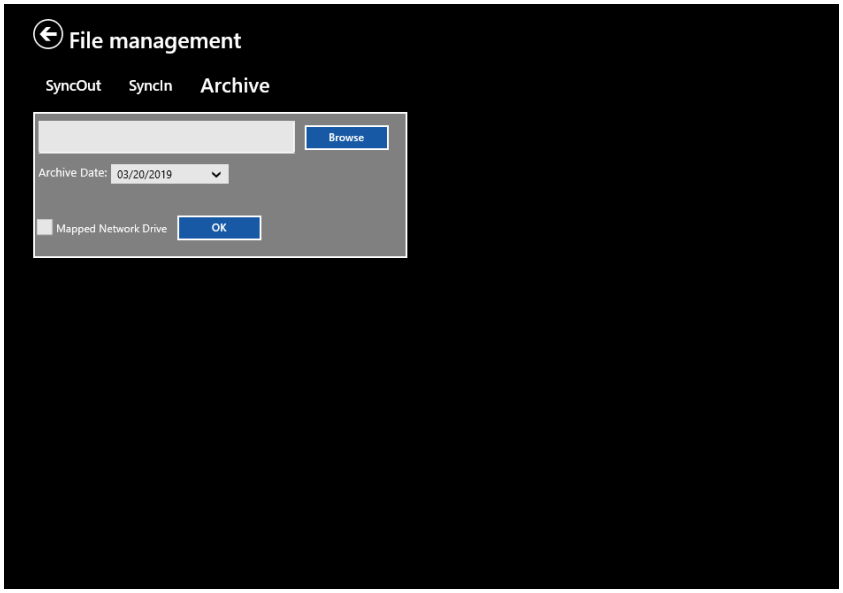


Figure 57: Archive

- **ValProbe RT Convert**

The ValProbe RT 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 ValProbe RT 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.

Note: *If a Study file of an already existing asset is selected, it will merge the study file with existing files into the asset without duplicates.*

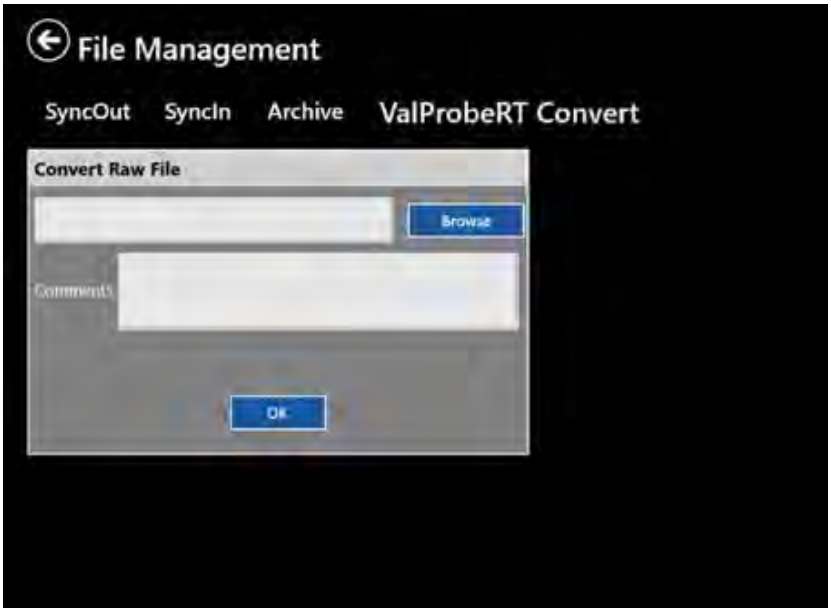


Figure 58: ValProbe RT Convert

- **Using Mapped Drives for Synchronization**

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

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

  It is possible to use subfolders inside the mapped drive.

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

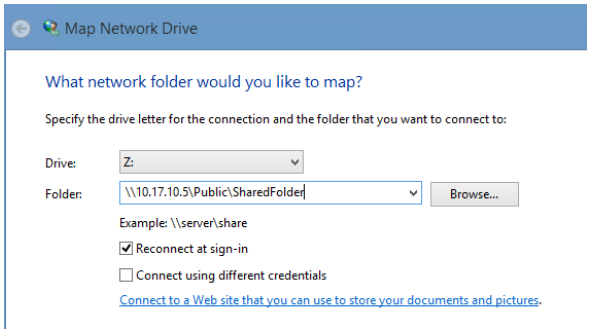


Figure 59: Windows – Mapping a Drive

When syncing from the software to a mapped location using the ValProbe RT software:

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

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

Enter your credentials for accessing the drive. If you are using a domain for security, you can add the domain information after the username with an @ extension as displayed in Figure 60 (alternatively, the domain\user format is accepted as well).

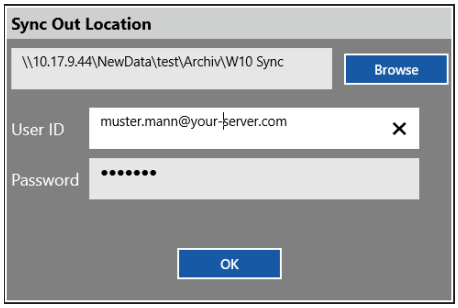


Figure 60: Mapped Drive Login Credentials

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

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

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

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

4.8. Hardware Maintenance

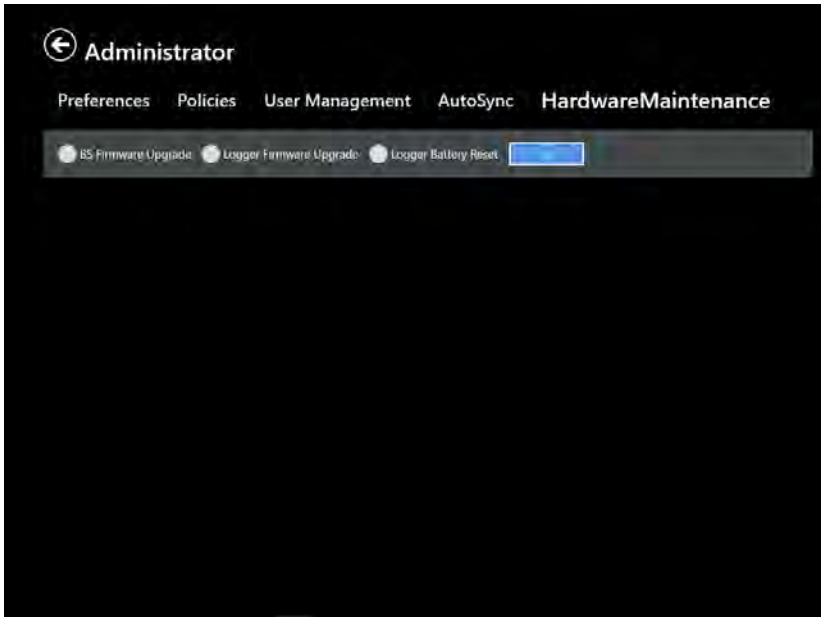


Figure 61: Hardware Maintenance

BS Firmware Upgrade: Select this option to upgrade the Base Station firmware and press **OK**.

Logger Firmware Upgrade: Select this option to upgrade the Logger firmware and press **OK**.

Logger Battery Reset: Select this option to reset he Logger batter and press **OK**.

4.9. 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”. Windows Help displays the help screen of the operating system; Help displays context-specific help for the open ValProbe RT application screen.

Chapter 5. Defining Equipment

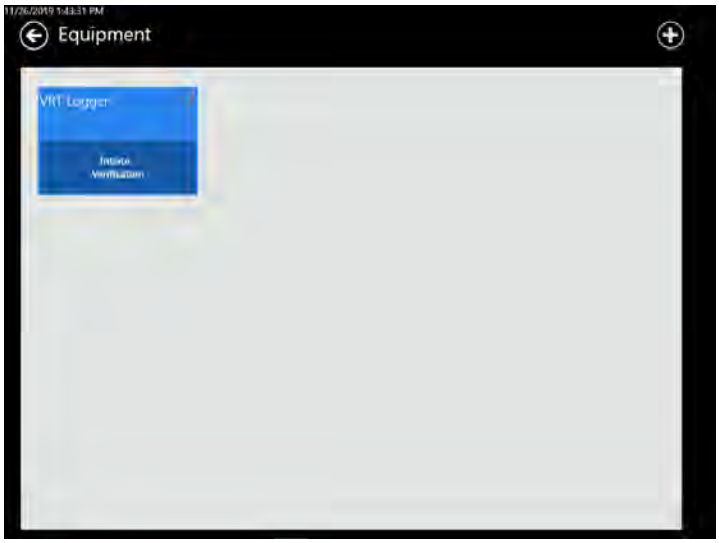


Figure 62: Equipment Screen

ValProbe RT software supports the organization of Kaye Validation Equipment. When accessed through the Main Menu, the Equipment hub displays Kaye equipment i.e. Base Stations, Loggers, IRTD as tiles. The following functionality is offered:

An all used Kaye Equipment database, that is identified by serial number, manufacturing calibration information, and an optional picture.

Calibration reminders set by a calibration reminder setting inside the system's preferences and the calibration due date.

An **Initiate Verification** button to verify the specific equipment based on temperature.

Study files searching by the location that certain Kaye equipment were used. To search, enter the Kaye Equipment Serial ID. Serial numbers saved within the study files are automatically retrieved.

Note: *No serial numbers are retrieved for temperature baths.*

5.1. Adding New Equipment

To add new Kaye equipment to the ValProbe RT system, press the **Plus (+)** icon on Equipment Hub screen. The New Equipment screen automatically opens (displayed below).

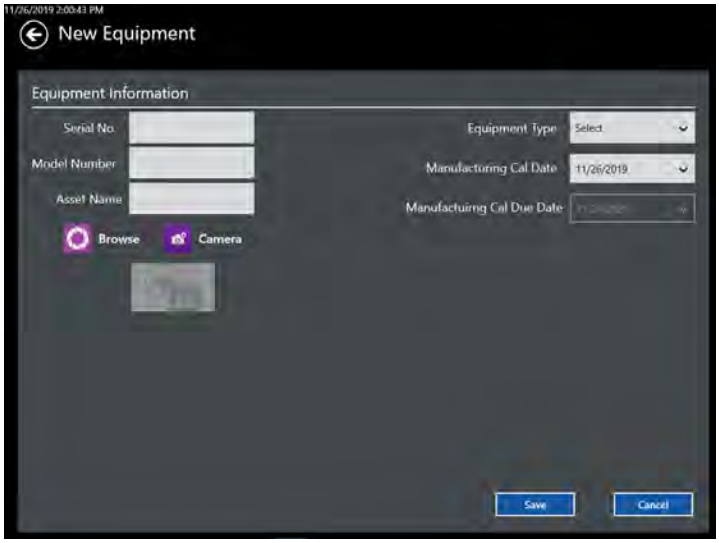


Figure 63: New Equipment Screen

Enter details for each new piece of equipment separately. Use the textboxes and drop-down menus to enter the following:

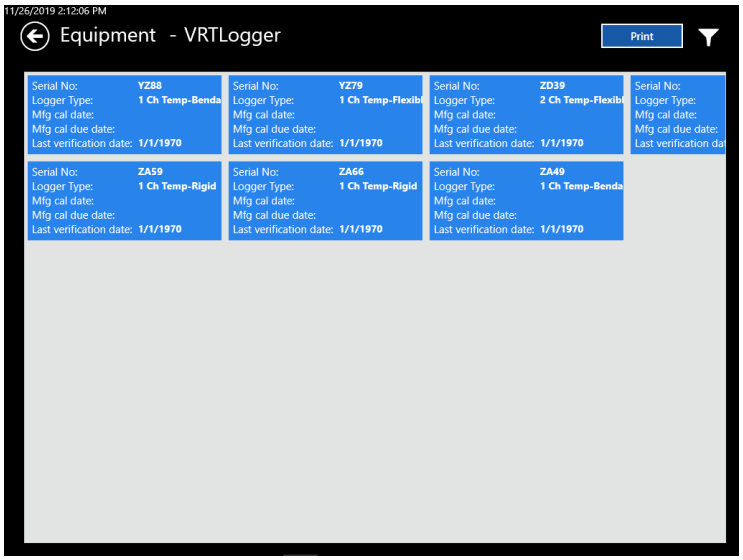
- Serial No.
- Model Number
- Asset Name
- Equipment Type
- Manufacturing Cal Date (Not editable)
- An image*

*An equipment image will be auto populated by the equipment type. However, a different image may be uploaded from a bmp, jpeg, or taken directly with the built-in camera.

Press **Save** to save the entry and return to the Equipment Hub or **Cancel** to reset all entries.

5.2. The Equipment Hub

To review what equipment has been added by type, select the tile on the Equipment Screen to open the Equipment Hub screen.



The Equipment Hub screen lists all added equipment for that particular type. The following information is displayed in each equipment tile,

- Serial No.
- Type.
- Mfg Cal Date
- Mfg Calibration Due Date
- Last Verification Date

In the top right corner of the screen is a **Filter** button where you can filter the equipment by serial no., type, Mfg calibration date, latest Mfg calibration due date, and verification date, using the drop-down.

5.3. Checking Details for Existing Equipment

To review the details for equipment added into the software, from the Equipment Hub screen select the equipment tile to open the Equipment Details screen.

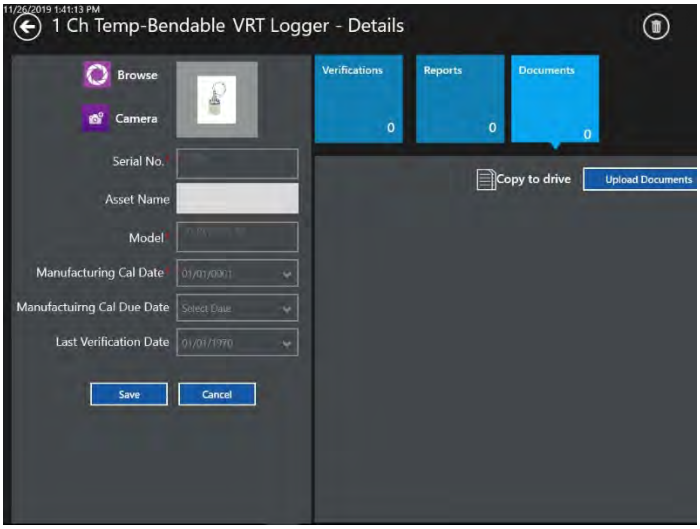


Figure 64: Equipment Details Screen

On the left side of the screen, the following equipment details are listed.

- An Image
- Serial No.
- Asset name
- Model
- Manufacturing Cal Date
- User Cal Date
- Calibration Due Date
- Last Verification Date

Note*: Only Asset Name and Image are permitted to be edited. A different image may be uploaded from a bmp, jpeg, or taken directly with the built-in camera.*

Inside the middle of the screen, all study files associated with this equipment are displayed, along with a **Trash Bin** icon to delete the study file, and a **Print** icon to print the study data. You can use the **Copy to Drive** button to copy your study files to an additional drive. To delete the selected equipment, select the **Trash Bin** icon at the top right of the screen.

Use the blue tiles at the top center of the screen to display Verifications, Reports, and Documents. Inside Verifications you can create a report by pressing the **Generate Report** button. Inside Documents you can upload relevant documents by pressing the **Upload Documents** button.

5.4. Calibration Reminder

The calibration date listed in the calibration reminder ensures that the operator does not miss calibration due dates.

To use the calibration reminder, you must activate and set the calibration reminder timeframe in the Policies, see page 44. When the equipment calibration due date is within the calibration warning message timeframe, the software reminds the operator when:

- Inside the Equipment tile on the Main screen: a number corresponding to the number of equipment due for calibration displays.
- Opening Equipment: the tiles for any equipment due for calibration are enlarged in light blue and display the calibration due date directly within the tile.
- When equipment is recalibrated: the user is required to manually update the calibration data and due date.

Chapter 6. Defining Assets

The ValProbe RT includes an intuitive Asset Centric Data Management concept (patent pending) which allows you to store and access data faster and more efficiently.

Each individual process that you validate whether a heat bath or sterilizer etc., can be set up 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 also possible to upload additional documents like standard operation procedures or certificates and associate them with an 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 the Main Menu. The Assets Hub appears as Figure 65 below.

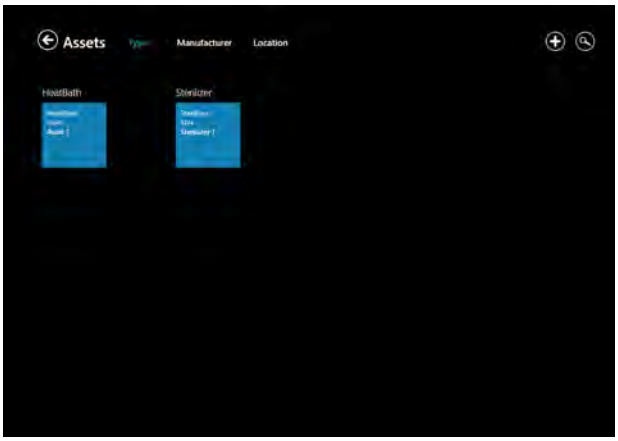


Figure 65: Assets Hub

The Asset Hub lists the various assets validated by your ValProbe RT system. On the top text line, you can press each 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 its Asset type, Asset ID, and Asset name. If the number of assets exceeds the screen size, scrolling and zooming enables viewing additional assets.

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

For further details regarding a particular asset, press the tile for that asset to open its 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.

6.1. Asset Details Screen

To learn more about an asset, select that tile asset's tile on the Assets screen, the Asset Details screen (shown below) opens:

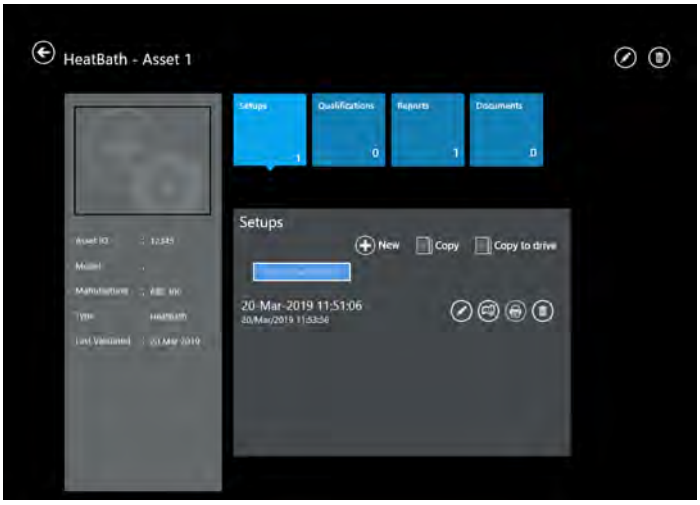


Figure 66: Asset Details

In the upper left, the asset type and name is listed as the Title. 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 with the following data:

- Asset ID: The internal asset number or serial number for unique identification.
- Manufacturer: Manufacturer name of the asset
- 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.

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

- Setups
- Qualifications
- Reports
- Documents

The number on each tile represents the number of available files under this specific tile. Select a 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" displays listing the number of additional associated setups. Press the downward arrow to open Setup List. On the list page, users can apply predefined filter options (Status, Activity, Setup Name, Date, Comments, and Actions) to sort the files. To create a new setup press, **Create New Setup**.

An asset setup includes all information to define sensors, groups, wiring diagram, calculations, verification, and qualification parameters required for a validation study.

The **New (+)** button creates a new setup, and it is also possible to copy existing setups from other assets as templates.

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

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

Use **Copy to Drive** to copy the selected setup file to a chosen folder. With the ValProbe RT it is not necessary to transfer setups via a USB thumb drive. USB functionally is used for support analysis by Kaye support who may request a setup file.

For every setup the following buttons are available:

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

Qualifications start from the setup pages of an asset. Firstly, select a setup to activate the initiation buttons. Pressing this button starts a qualification. The Hardware Discovery screen displays, and the setup is transferred to the selected ValProbe RT.

Inside the Equipment tile a list all available calibration study files including, the setup name, date, run number, and comments. After selecting a study file, you can open the report tool and create a report. Like the setup files, the data files can be displayed in a list, deleted, or copied to a drive. Copied study files can be reimported to other Kaye Validation Consoles using the **ValProbe RT Convert** import function in File Management.

The Qualification and Verification tiles have similar functionality. Starting the report tool, copying or deleting files is also provided for Qualification or Verification study files.

For reports, the tile displays all generated and available setups and qualification reports. Documents are sorted under tabs and can be displayed in the seamlessly integrated pdf-reader for review or printing.

For documents, the Document pane provides options to upload any pdf documents related to the asset, e.g. wiring diagrams, SOPs, or calibration certificates.

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

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

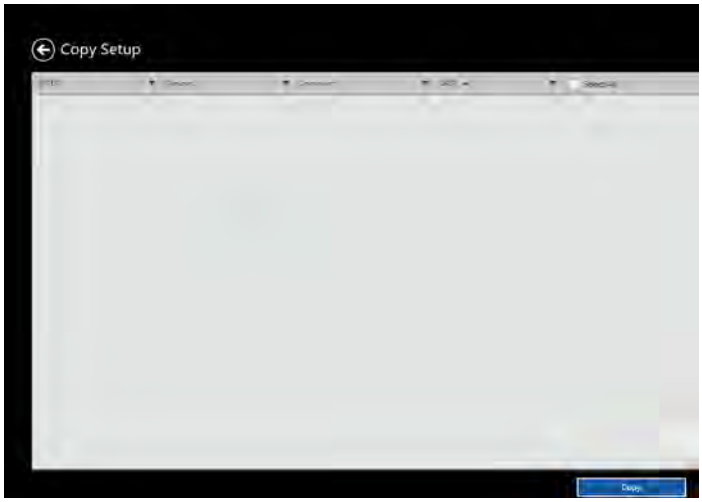


Figure 67: Copy Asset Screen

6.2. New Asset Screen

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

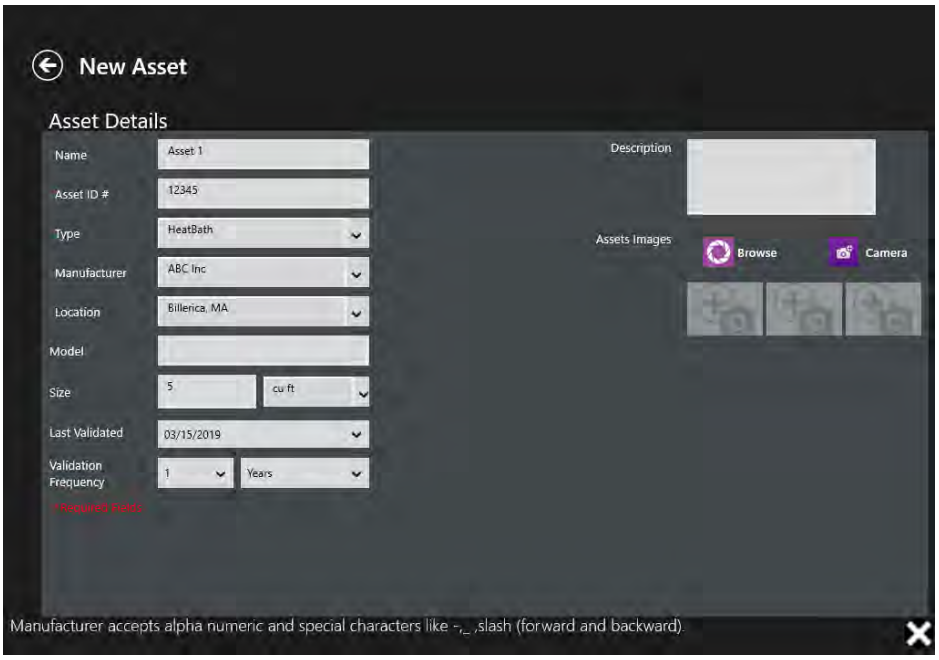


Figure 68: New Asset Screen

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

- Name: Asset names must be unique. Before synchronizing several asset data sets, it is recommended to ensure there are no duplicate asset names utilized. This field is mandatory and required for unique identification.
- Asset ID: This field is mandatory and required for unique identification.

- The type of asset: Any new type definition will be available in the drop-down in the future. Please be careful as also test types or wrong spelled types will be available in the drop-down. This field is mandatory and required for sorting.
- Manufacturer: Specify the manufacturers name of the asset. This field is mandatory and required for sorting.
- Location: Specify the location of the asset. This field is mandatory and required for sorting.
- Model: Specifies the model number of the asset. This field is optional.
- Size: Specifies the volume of the asset in cubic units. In the drop-down, it is possible to select the appropriate units or enter custom units. This field is optional.
- Last Validated: Specifies the date of the last validation of the asset. This field is optional.
- Validation frequency: Specify the required validation frequency. This field is optional.

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

When you have finished, press **Save** to save the entry and return to the Asset Hub.

Chapter 7. Defining Study Setups

Before you can run a qualification study, you must use the ValProbe RT software to create or modify a setup. A setup defines everything required to run a qualification study.

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

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

- Define the 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 start and stop conditions for qualification and exposure cycle

When the setup is created and saved, you can run a qualification study.

7.1. Create a Setup File

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

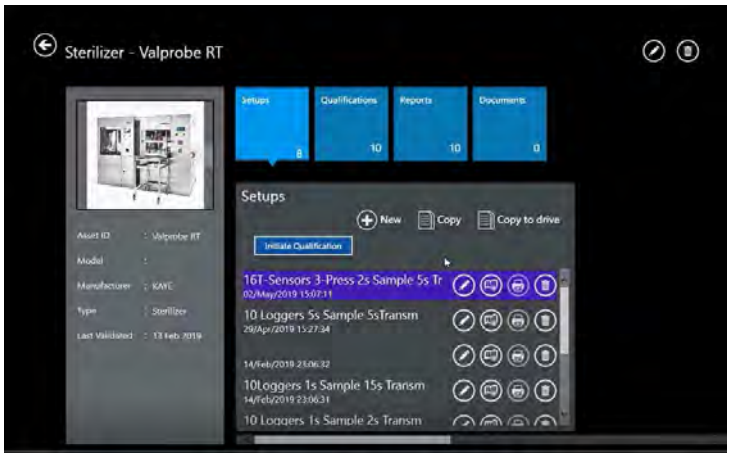


Figure 69: The Setup Hub Screen

To create a setup file:

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

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

7.2. Modify an Existing Setup

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.

Press the **Edit** (pencil) button.

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

7.3. Define Setup Screen

On the Asset Details Screen Setup Hub, press **New** to open Define Setup.

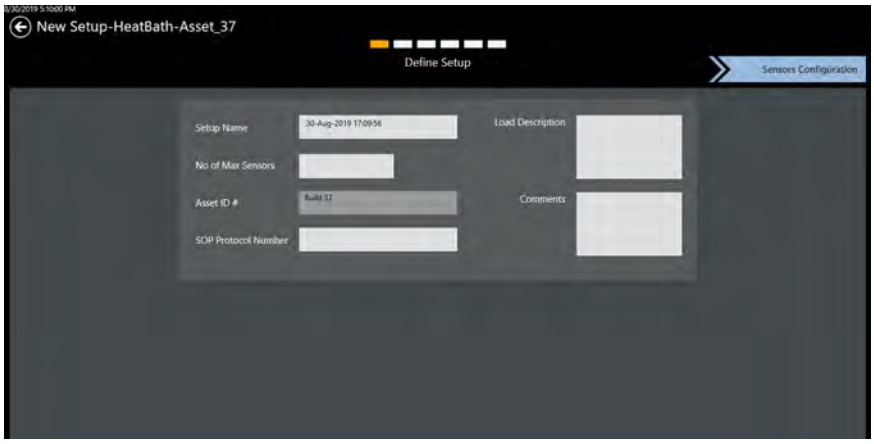


Figure 70: Define Setup Screen

On this screen, you define the setup for a study. Use the textboxes or drop-down lists to enter:

- Setup Name
- No (number) of Max Sensors
- Asset ID #
- SOP (Standard Operating Procedure) Protocol Number
- Load Description
- Comments

Note: *The Setup name and number of sensors fields are mandatory.*

The Setup Name and Comment fields accept alphanumeric characters and spaces; the Load Description and SOP fields can also include special characters (spaces,-,_,.,?,/,and \).

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

7.4. Sensors Configuration Screen

From the Asset Details screen, press **Sensors Configuration** to open the Sensors Configuration screen.

Figure 71: Sensors Configuration Screen

The Sensors Configuration screen graphically represents all connected sensors. The sensors are labeled based on their type.

Once you add sensors, they appear as blue tiles, to indicate that they have not been selected. To select a sensor tile, click each tile, the tile turns to dark blue and a selection icon in the upper right corner appears. You can also select a series of sensors in the Configure Sensors pane on the right. Select a range of sensors, press **Select**, and those sensors all appear as selected on the left pane. To deselect a sensor, select a sensor with a selection icon.

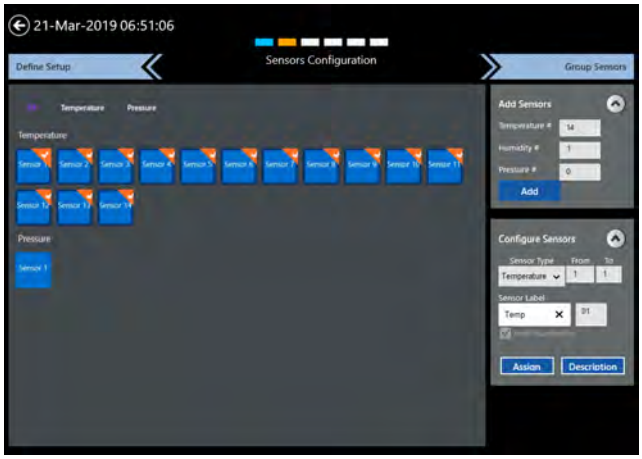


Figure 72: Configuring Sensors

- Sensor Type – Enter a range in the **From** and **To** textboxes.
- Sensor Label – Enter a sensor label in the textbox and a number to start labeling.
- Auto Numbering –. Auto numbering is always enabled.

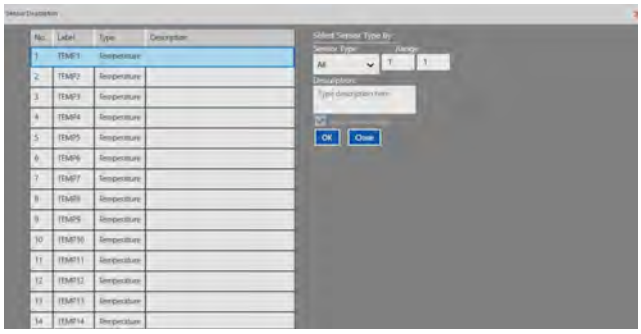


Figure 73: Sensor Description

Click the **Description** button to open the Sensors Description screen. On this screen all sensors are listed in a table with the information entered in the configuring sensors section. If desired, click a sensor and enter a description in the **Description** textbox and click **OK** to save the description or **Close** to cancel. To return to the Sensors Configuration screen click the red **X** in the upper left corner.

After sensor configuration, press the **Group Sensors** tab to advance to the next screen.

7.5. Understanding Groups

Grouping is a key concept of the ValProbe RT 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.

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.

7.6. Assigning Sensors to Groups

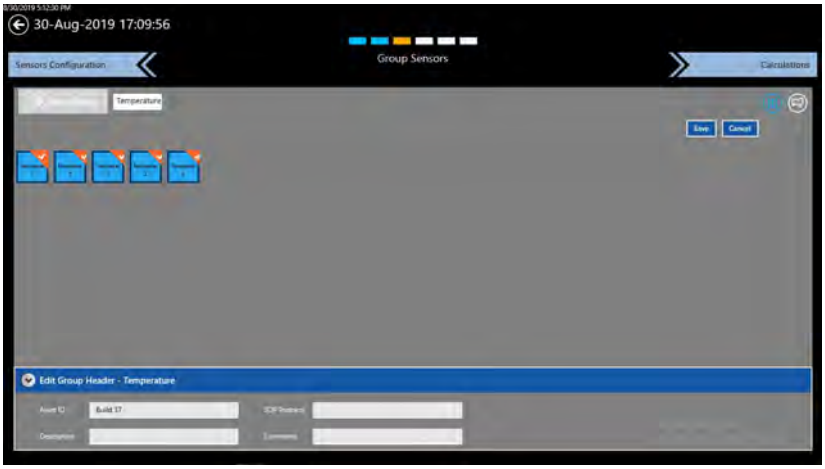


Figure 74: Group Sensors Screen

On the Group Sensors screen, Loggers 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 **Group Sensors**. The Group Sensors screen displays a scrollable listing of existing groups, as well as the **New Group** button.

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

To assign sensors to groups:

9. Select individual sensors to select them for the group. These sensors now appear deep blue with an orange checkbox.

Press the **New Group** button, and the Group Name textbox appears on the screen. The Group Name textbox accepts characters that can be upper and lower case, numeric, special characters like hyphen, underscore, slashes (forward and backward) and, blanks. Enter a name and toggle the **Save** button to save the group.

This screen also offers the following options:

- Delete - permits deletion of a group of sensors
- Move Sensors - permits moving sensors to another sensor group (specified in drop-down list)
- Customized Header for each group: The group specific header fields, Asset ID prepopulates from the Asset, and the SOP number field prepopulates from the Define setup screen. The header can be customized for each group. Any new information needs to be saved using the Save button before switching to another group.
- Add Sensors - add further sensors to a group
- A Wiring Overlay – accessible via the **Book** icon - enables wiring overlay configuration.

Figure 75: Wiring Overlay Diagram

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

Note: *If opening the camera, ensure that the software can access the camera. The picture can be taken by pressing the camera icon through the device camera.*

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

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

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

7.7. Specifying Group Calculations

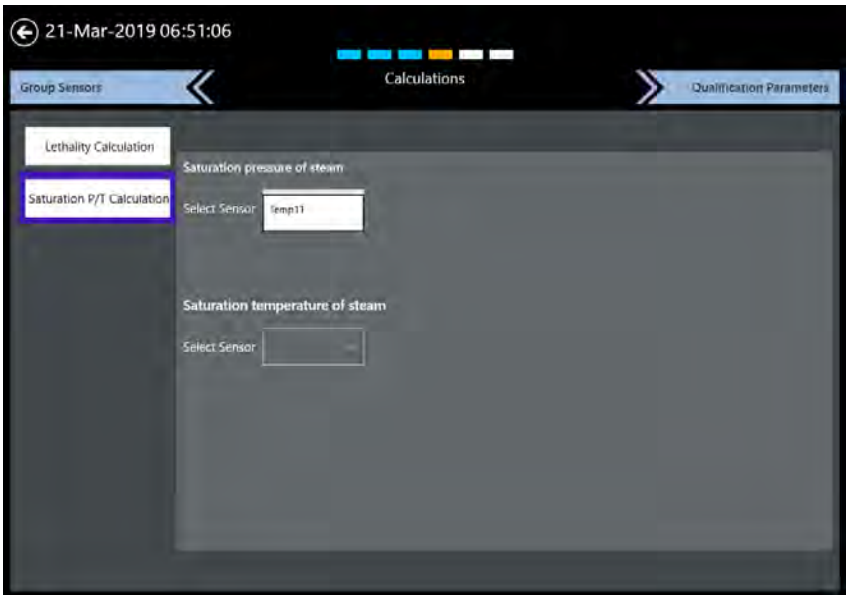


Figure 76: Calculations

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

The Statistical Calculations are all preselected by default and are calculated.

Note: *If lethality is selected in the setup, the report tool requires 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 reporting tool cycles.

7.8. Specifying Qualification Study Conditions

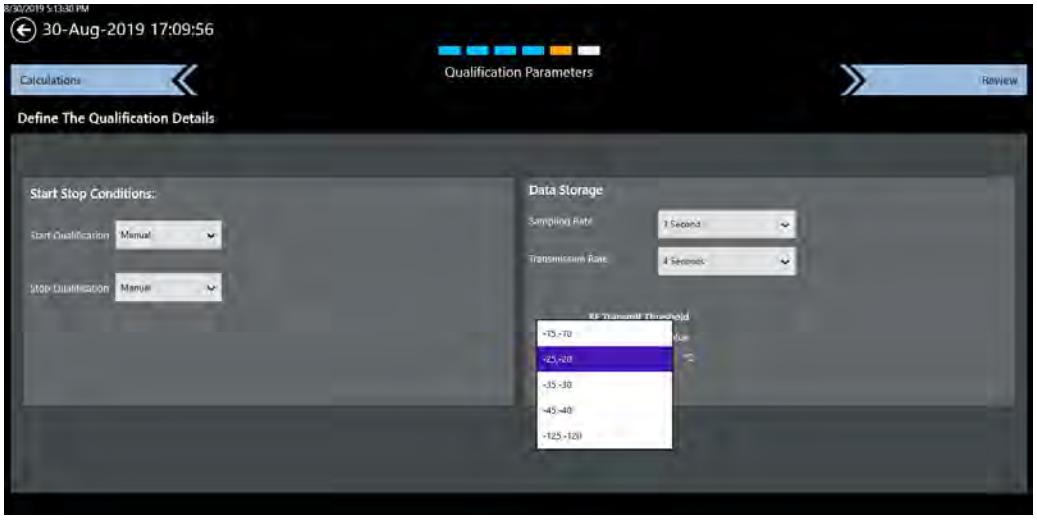


Figure 77: Qualification Parameters

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

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

Data storage options - the rates at which data is written to the memory of the Logger during a qualification run. There are three options, Sampling Rate, RF Transmission Rate, and RF Threshold.

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

7.9. Reviewing and Changing a Setup

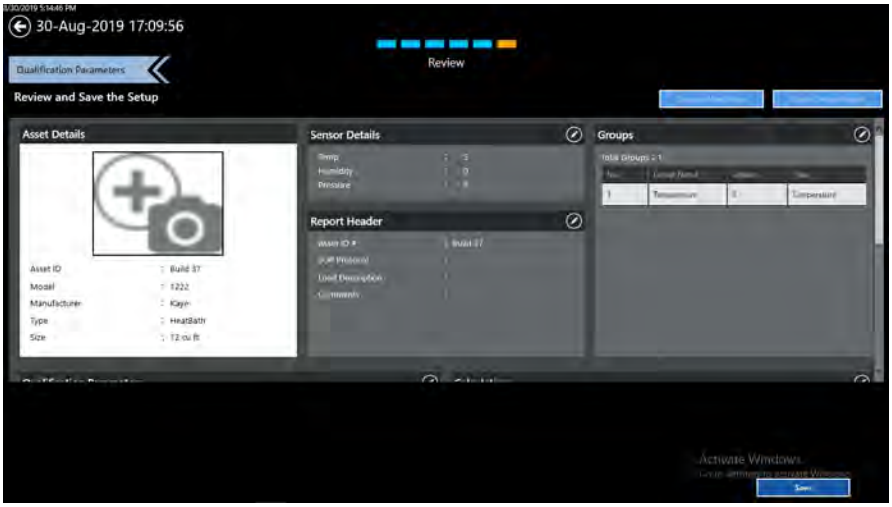


Figure 78: Setup Review Screen

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

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

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

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

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

Chapter 8. Viewing Live Data

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

8.1. Selecting a ValProbe RT

From the Main Menu, press the **Discover** tile, located under “Hardware”, to open the Select Base Station window.

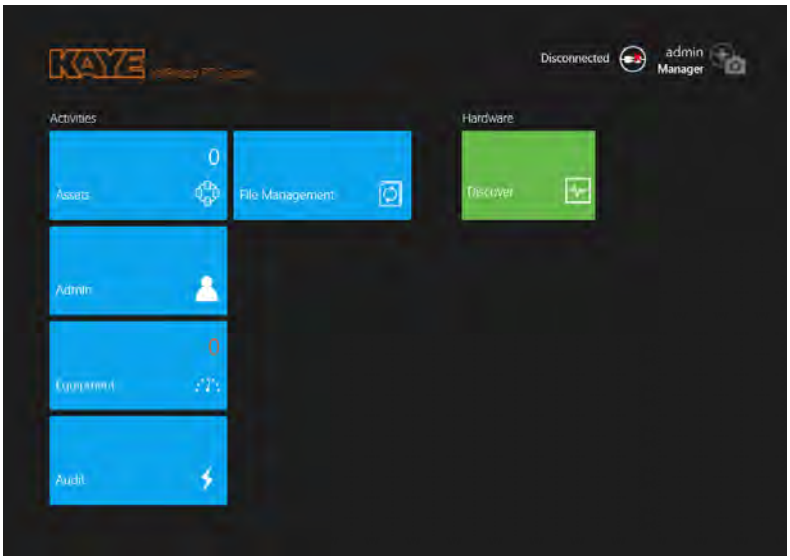


Figure 79: Main Menu with Hardware Discover Tile

Pressing **Discover BS** searches the connected Networks (LAN or Wi-Fi) for available Base Stations. They are listed with blue tiles displaying a serial number and IP address. The tile for the currently selected Base Station has an orange triangle in the upper right corner. To connect to a network connected Base Station, press **Connect** and select a connection via Ethernet or Wi-Fi.

Figure 80: Select Base Station

Note: *If a Base Station is not in the same IP segment the discover function will not be unable to find it. Nonetheless, if the TCPIP address of the Base Station is known and the connection is not blocked, a connection can be established by entering the IP address and adding the Base Station to the available devices manually.*

Select the tile for the Base Station you need to use, and then press **Connect** to establish the connection between the Console and the Base Station.

To configure a Wi-Fi connection, select a Base Station and press **Configure.** The connection needs to be established by docking (recommended) or Ethernet. Enter all necessary information and press **Ok** to transfer the information to the Validator. The Validator uses this information to connect to the specified Wi-Fi network and becomes available with the **Discover** button.

Please see Section 3.1 (Setting Up the Base Station) for detailed information on how to connect to a Base Station.

8.2. Monitoring Live Data

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

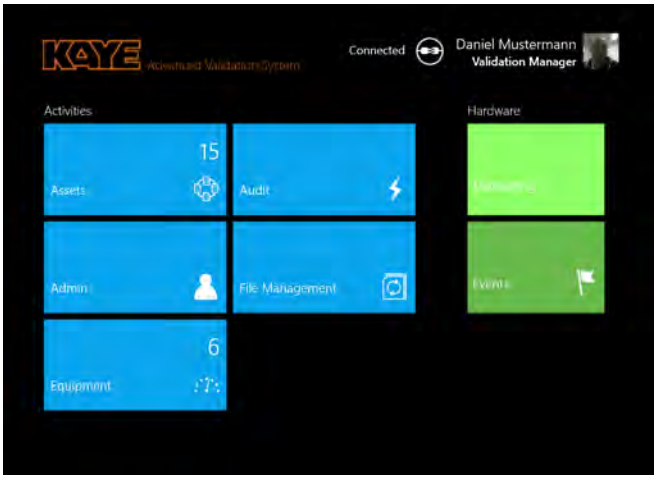


Figure 81: Main Menu with Events Tile

In the Events tile, connection specific events like sensor or power-disconnects are listed.

8.3. Live Data During Qualification

In the Live Monitoring mode, no study is running and the data collection structure (sensor and groups definition) are following the last transferred setup (to transfer a setup you need to start a study). If the ValProbe RT is in monitoring status, you can switch between List and Graph View to see live data.

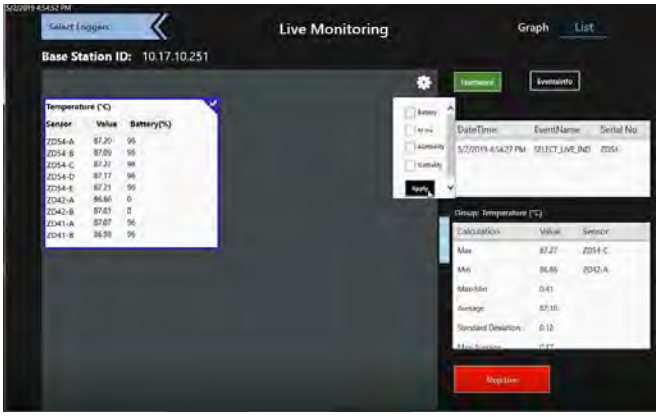


Figure 82: Monitoring in List View

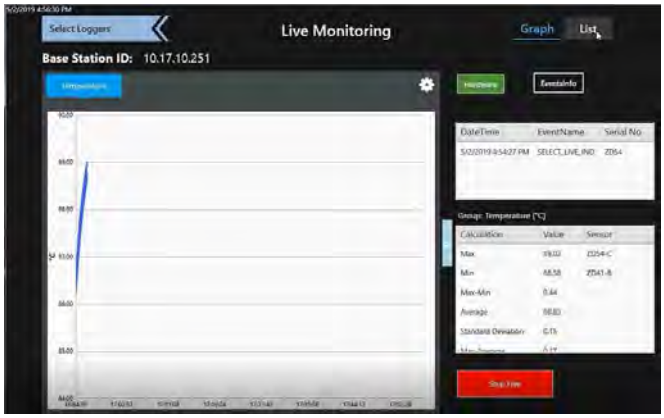
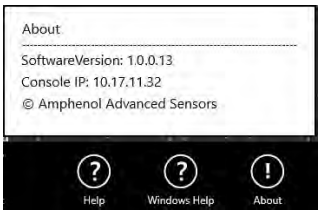


Figure 83: Monitoring in Graph View

The header always displays the name of the active setup and the serial number of the connected ValProbe RT.



For detailed information about the system (IP, software, and firmware versions), swipe up to display the command charms, and press **About**. For Windows 10, swipe down from the top right-side of the screen to open commands on the lower left-side of the screen and press **About**.

The Hardware button open the hardware connection screen to review hardware connection status and access to the files stored on the ValProbe RT. A Device Not Found symbol (gray color line) indicates a communication problem.

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

Displayed below the buttons, is a timestamp of the ValProbe RT clock (not the console time, that can be displayed with a swipe from right to left). On startup, the timestamp of the ValProbe RT is synchronized with the Console time.

Live Data during Qualification

If the ValProbe RT 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 study events.
- The Calculations Window displays statistical calculations, the Min/Max value for a selected group, cycle time, and exposure time.
- Below the windows are four buttons that control 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 displays the sensor number. The second column displays the label as assigned in the setup, followed by the sensor value in the third column.

The forth column displays the battery level of the sensor as a percentage. RF link status is listed in the fifth column. The sixth and seventh columns are available if lethality is defined in the setup and displays the ALeth and ILeth values respectively 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.

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

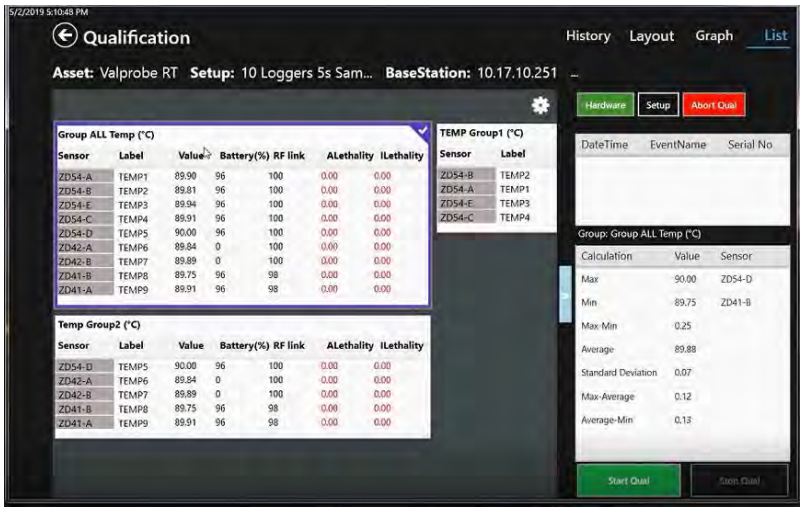


Figure 84: Qualification Study in List View

Graph View

Pressing **Graph View** switches to real-time graphing of 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. Zoom into the data 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.

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 are displayed. The current max and min value are also listed in the calculations pane.

Figure 85: Qualification Study in Graph View

Historical Data View

The ValProbe RT 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 anytime during a study.

When connecting to a ValProbe RT 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 to a console, the ValProbe RT displays real-time data, while historical data is downloaded automatically to the console for review. The download of historical data is indicated by a progress cycle.

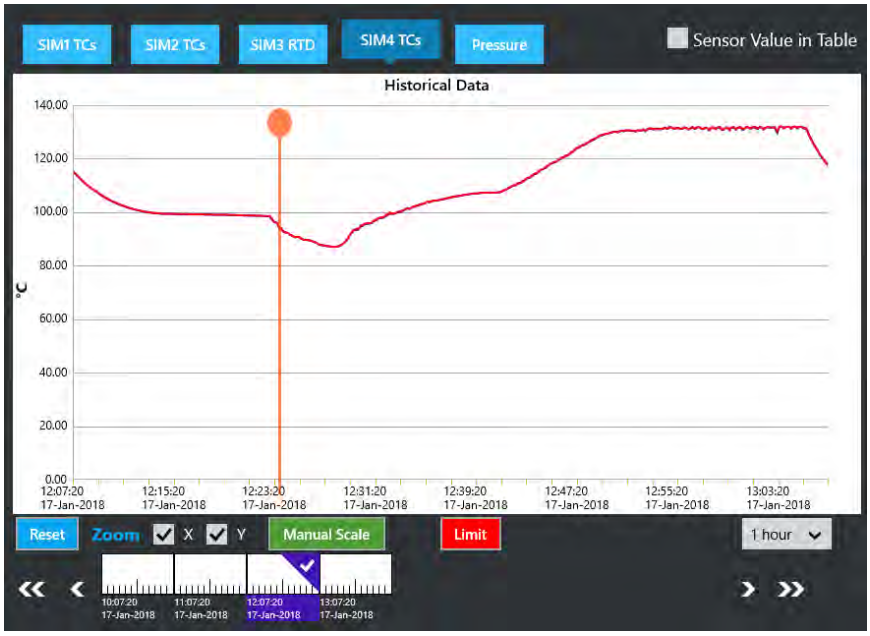


Figure 86: Historical Data in Graph View

Pressing **List** view switches back to a table view of sensor readings.

Layout View

The Layout View can be used to see an intuitive distribution of live readings data. The background picture and the sensor positions are defined in the Group configuration in the setup. You can take pictures using the built-in camera or add an existing picture 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 87: Qualification Study in Layout View with Value Table

8.4. Live Data During Verification

If the ValProbe RT is in Verification, the Verification List/Graph View screen displays a table or graph for the active verification setpoint sorted by the sensor input. On the right side of the screen, the set points are marked, when a set point is reached the set point is green. Below the set points the following is displayed:

Setpoint:

The setpoint Celsius temperature to reach.

Stability Criteria:

An IRTD temperature setpoint in Celsius textbox and a textbox for the length stability, in minutes, at that setpoint and a textbox for an additional time, in minutes, at stability.

Stability Status:

Time of Stability – a textbox displaying the time of stability when reached.

Stability – displays the current stability data, if red, stability has not been reached, if green stability has been reached.

Deviation of Stability – displays any deviation during stability in the textbox.

Message – lists any relevant information regarding the setpoint and stabilization.

For a large number of sensors, it may be required to scroll inside the table.

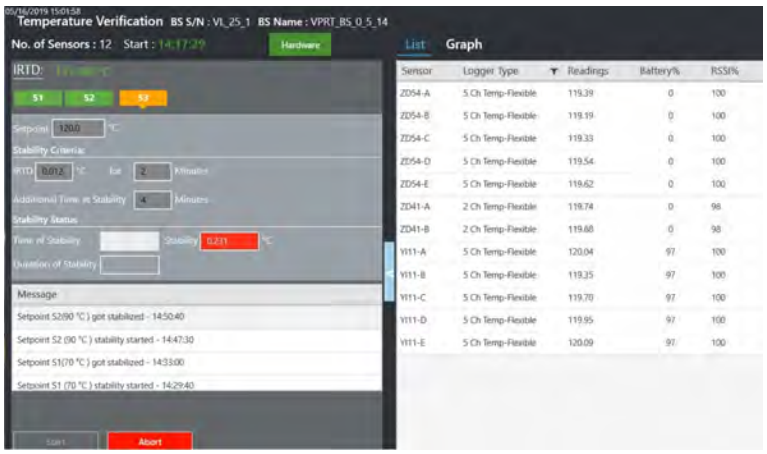


Figure 88: Verification List View Screen

Figure 89: Calibration in Graph View Screen

Figure 90: Verification Parameter Screen

By pressing **Initiate Verification**, the Verification parameters as defined in the setup can be reviewed, it is possible to edit the parameters before the start of the verification.

8.5. Check Communications Connections

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

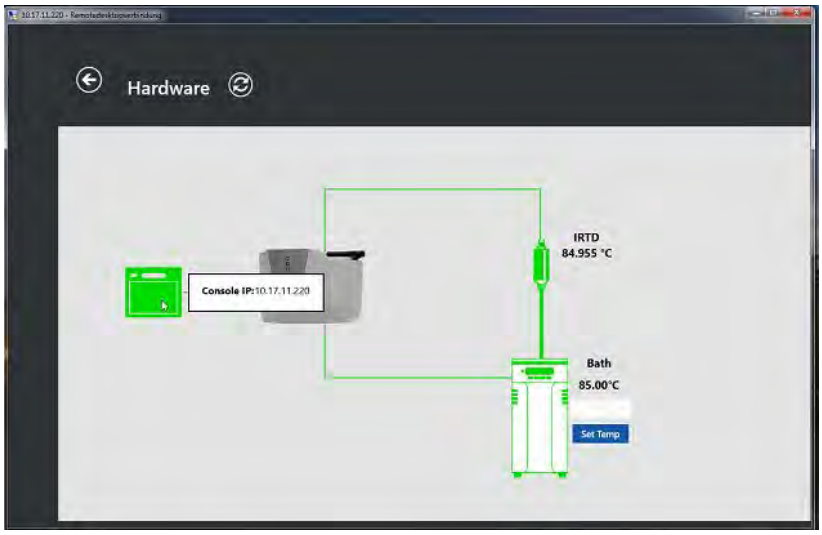


Figure 91: Hardware Screen

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

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

Select the ValProbe RT 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 Logger, the Logger serial number, Logger type, and the Logger calibration date are displayed.

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

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

Select the **IRTD1** or **IRTD2** graphic to view information on the address, probe ID, label (including the serial number), calibration date, user label, and temperature scale.

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

If the link to the Kaye ValProbe RT is not responding, all links are marked with a gray image of device.

8.6. Select a Temperature Standard

If you have two IRTDs connected to the Kaye ValProbe RT, IRTD on the upper port is used as temperature standard. The IRTD port displays in the hardware screen or used to power a pressure transducer with a special cable.

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

8.7. Access Study Files

In monitoring mode (not while a study is running) it is possible to access the ValProbe RT and review the study files stored in the machine's memory. Press **Access Study Files** in the hardware screen to display a table of the last ten studies.

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

Chapter 9. Qualification Study

9.1. Introduction

Once the setup is defined and loaded into the Kaye ValProbe RT and the sensors, if necessary, have gone through a Verification, everything is ready to run a qualification study.

The Kaye ValProbe RT uses the qualification parameters defined in the setup to perform the qualification study. Depending on the start and stop qualification conditions defined the study performs a fully automatic qualification, a fully manual qualification, or a mixture of automatic and manual.

During the qualification study, the Kaye ValProbe RT performs calculations and compiles data for the qualification reports. Qualification data is always written to the Logger's internal memory, as well as transmitted to the Base Station for storage in the Base Station memory.

The ValProbe RT Loggers utilizes internal memory to maintain qualification data during a study. During the study, data from the Loggers is transmitted via the transit rate to the Base Station for storage. When Qualification is complete, the Base Station searches for any missing samples and connects to the affected Loggers to collects missing samples. The User can then save the file and the study data is transferred to the Console. Qualification data resides in the internal memory of the Base Station until it is transferred to the console.

The Base Station is also equipped with a Lithium battery to provide short-term power, 60 minutes, in case of AC power loss during the run. The intent of the battery is to provide enough time (approximately 60 minutes) to perform an orderly shutdown of the system. When the Kaye ValProbe RT detects that the AC power has failed and the system is running from battery, it displays an indication on the front panel LED.

Note: *In the event of power glitches or short-term drops in supply voltage ("brownouts"), there is a remote chance that the Kaye ValProbe RT 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 ValProbe RT 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 ValProbe RT report generator (see Chapter 11). Before beginning the qualification study:

- Place the Kaye ValProbe RT 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 ValProbe RT clears the internal memory from temporary files on startup. To ensure maximum memory availability it is recommended to power-cycle the Kaye ValProbe RT from time to time, especially before running long studies.
- To provide maximum accuracy during the qualification study, power up the ValProbe RT and let it run for approximately 30 minutes in the operating environment where qualification is to be performed for the ValProbe RT 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, ensure that the defined setup for this asset is loaded from the Console into the Kaye ValProbe RT:

Select the predefined setup file for this asset. Load the setup into the Kaye ValProbe RT.

9.2.1. Select a Setup File

If the setup is not yet created, please see Chapter 7 for instructions on 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 setup and press **Initiate Qualification**.

The pop window gives the opportunity to change the SOP Protocol Number and display the run number. The run number counts automatically, but it is editable if required. Pressing **Ok** opens the Select Base Station screen.

Figure 92: Select Base Station

Select the Base Station to run the study. Then press **Discover,** a screen displaying all ValProbe RT's available opens. By default, this screen highlights the ValProbe RT that was last used with the Console. It is possible to connect the ValProbe RT in either of three ways:

- Direct wired from the Base Station to the Console (Fixed IP) through the docking station.
- Through the Network via Ethernet - the screen displays a list of ValProbe RT with same IP address or that are in range of the network.
- Through wireless connection - the screen displays a list of ValProbe RT with same IP address or that are in range of the network.

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

9.3. Viewing the Active Qualification Study

To start a study, press **Start Qual** or use the automatic start condition defined in the setup (if **Start Qual** is not available) and enter User Credentials.

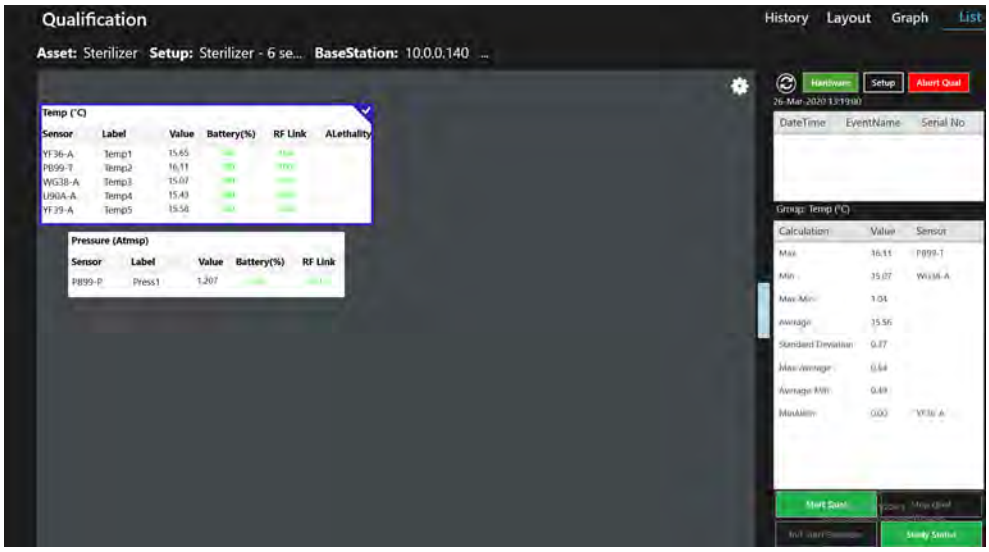


Figure 93: List View - Real-Time Readings

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

The following guidelines apply when viewing sensor readings and calculations:

- Calculations are computed, events are monitored and displayed on the Console screen.
- The resolution of sensor readings and calculation results are dependent on the lowest resolution in the group.
- Open, under-range, over-range, or failed sensors are not allowed to participate in calculations or events.
- Each box lists the group name, sensor serial number, sensor label, and associated measurand (temperature, pressure, etc.). Also listed are battery life, RF strength, and accumulated lethality if defined in the setup. If there are more sensors or calculations that can 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.

Note: *The ValProbe RT continues the study after disconnecting.*

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

After stopping the study, **Save Study** becomes active. Please save the study to your console. If a console is connected to a ValProbe RT Base Station with an unread study the Console insists on reading the study before starting any new studies.

9.4. Graph Real-Time Sensor Readings and Calculations

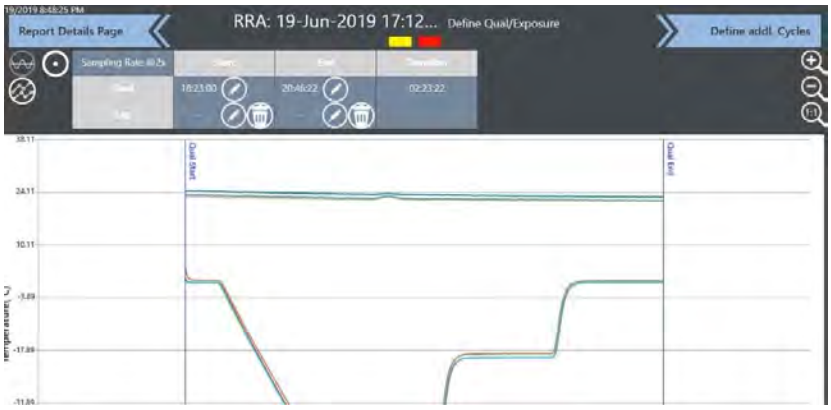


Figure 94: Graphing Sensor Readings

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

To graph real-time sensor readings and calculations:

- Press **Graph View**, to display the Graphs screen.
- All the available Groups in that setup are displayed, when pressing the button for each group, the corresponding graph is displayed.

The **Setup** button displays the Setup review page that contains all parameters for Qualification, Calibration and Verification. The page is similar to the setup review displayed on the last step of the setup creation wizard.

Located next to **Setup** is the **Hardware** button.

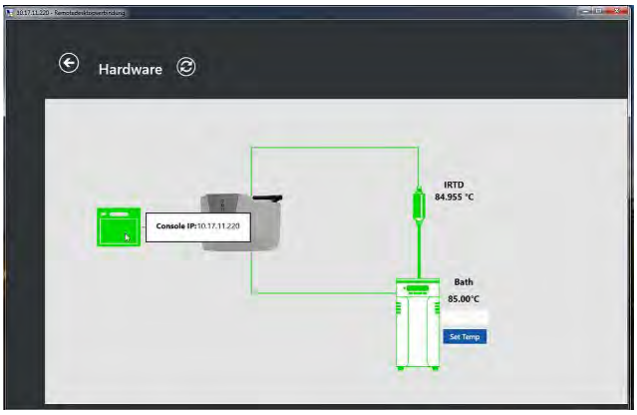


Figure 95: Hardware Screen

On the Hardware screen all available hardware connected to the ValProbe RT are available including serial numbers and calibration dates. For review, press the device and a window with data opens. The connected IRTD displays the current temperature value.

Chapter 10. Sensor Verification

10.1. Introduction and Overview

With the ValProbe RT system, you can verify sensors at up to six different temperature setpoints for Pressure/Temperature Loggers, each sensor type must be verified independently.

The ValProbe RT uses the parameters defined in your Verification setup to perform sensor verification. Verification parameters specify the temperature reference setpoints at which Verification is performed, and the stability and deviation criteria for the temperature sensors and the temperature standard. Verification requires the use of a Kaye IRTD as the temperature standard. The IRTD's measurement accuracy is 0.025ºC, with a range of –196ºC to 420ºC. The software requires a Temperature bath able to simulate the verification temperatures. If a Kaye bath is used, the system can perform automatic Verification in which the bath temperatures are automatically controlled. A manual Verification can be performed for non-Kaye baths. The bath used should have adequate stability and uniformity to meet your needs (see Section 10.1.2).

Principle of Operation

When you start the Verification, the ValProbe RT loggers begins to collect data every ten seconds to its internal memory for the duration of all defined setpoints. At the same time, measurements from the IRTD are collected every ten seconds by the Base Station. The Base Station uses the IRTD data, along with the specified criteria, to display and determine stability at each setpoint. At the conclusion of the Verification, the data from Loggers are read and the system calculates based on the Loggers and IRTD data, whether the Loggers have met the defined stability and deviation criteria. The ValProbe RT system generates a verification report for each sensor and setpoint – which is stored as a PDF file for Verification documentation printing.

When Verification is complete, the ValProbe RT system writes the Verification date into the Logger and stores each Logger's report file into the Console under the corresponding equipment tile by Logger serial number.

Along with the date of the last Verification, the Logger also contains the Factory Calibration date, including calibration offsets, in the Logger in non-volatile memory. This data remains intact even if the battery is depleted or exchanged.

10.1.1. Defining Verification Strategy and Criteria

The Kaye ValProbe RT software allows you to verify Logger accuracy at up to six set points. Verifications can be used for multiple purposes. Kaye recommends a quarterly verification to ensure the Loggers are still within their specification of 0.1°C, or based on you SOP's or Risk management assessment, perform a pre -Verification before your Qualification study and a post Verification after the study to ensure Logger temperature are within your defined process criteria.

In wired based systems utilizing thermocouples, it is common practice to run a Pre-Calibration prior to the Qualification and a Post Verification afterwards. The Pre-Calibration is required to compensate for the unknown error of the thermocouples and ensure that the loop measurement is within calibrated deviation criteria.

With the ValProbe RT Loggers it is not necessary to do a Pre–Calibration of the logger as the sensor and logger were already calibrated to within 0.1°C at the factory and any error for the sensor is already compensated for in the factory calibration. Therefore, a Pre-Verification should be performed prior to the Qualification to again ensure the Logger and sensors are within defined deviation criteria. At the end of the Qualification a Post-Verification can be performed to ensure the Loggers and sensors are still within defined criteria. (0.5°C)

Regulatory requirements while defining the need to ensure sensors used for Qualification studies should be calibrated and then verified, do not set any frequency guidelines other than at least once a year. The determination of whether to verify for every run or every day or once a quarter or only send them back to the factory once a year should be defined by a risk assessment or company SOP's. Kaye's recommendation is to run a verification against the IRTD at least once a quarter along with a once a year factory calibration.

10.1.2. Selecting the Proper Calibration Bath - Uncertainty

When performing any sort of or verification it is important to understand the required criteria, as well as the uncertainty of the Temperature Standard and Temperature Bath to ensure the equipment has the necessary stability and uniformity to verify the accuracy of the Loggers. When Kaye performs Factory calibration of the Loggers, we utilize a special IRTD and Oil bath that provides a total uncertainty of < 0.28°C. This allows enough ratio to safely calibrate and verify the accuracy of the Loggers to within specifications of 0.1°C.

If your verification strategy is to do a periodic check of the Kaye loggers to ensure they are within Kaye specifications of 0.1°C then you need to utilize Temperature Baths and References that have an adequate uncertainty to ensure valid results.

Table 6: Recommended Temperature Baths

Model	Bath Uncertainty	IRTD Uncertainty	Maximum Total Uncertainty
CTR-25 (-25°C to 140°C) – Liquid	0.020°C	0.025°C	0.045°C
CTR-40 (-40°C to 150°C) – Liquid	0.010°C	0.025°C	0.035°C
CTR-80 (-80°C to 30°C) – Liquid	0.012°C	0.025°C	0.037°C
LTR-150 (-30°C to 150°C) – Liquid/Dry	0.10°C	0.025°C	0.125°C

Note: *Dry Blocks cannot be utilized for Verification to manufacturers specifications (0.1°C) as they do not have the necessary Uncertainty.*

If your verification strategy is to do a periodic pre-Verification and post Verification of the process qualification, then the Verification criteria is usually < 0.5°C. In this case the above-mentioned baths or Kaye Dry Blocks can be utilized as they provide adequate uncertainty as compared to the criteria.

Table 7: Recommended Temperature Dry Blocks

Model	Bath Uncertainty	IRTD Uncertainty	Maximum Total Uncertainty
LTR-150 (-30°C to 150°C) – Dry Block	0.10°C	0.025°C	0.125°C
LTR-40 / 140 (-40°C to 150°C) – Dry Block	0.10°C	0.025°C	0.125°C
LTR-90 (-90°C to 140°C) – Dry Block	0.15°C	0.025°C	0..175°C
HTR 420 (30°C to 420°C) – Dry Block	0.10°C	0.025°C	0.125°C
HTR 400 (-25°C to 400°C) – Dry Block	0.10°C	0.025°C	0.125°C
LTR -25/140 (-25°C to 140°C) – Dry Block	0.15°C	0.025°C	0.04°C

Note: *The sensor tips of bendable or flexible loggers should be fully inserted to the bottom of the well. Rigid loggers with shorter tips have to utilize a liquid bath.*

Pressure Sensors

In order to verify the pressure sensors, meet the calibration accuracy specification, the pressure calibration equipment must have an accuracy of 0.15% full scale (of 5 bar) or better.

10.2. Creating a Verification Setup

Before you can run a verification process, you must create a Verification Setup. To create the Verification Setup, navigate to the Main screen and then select **Equipment**. and enter your ID and Password.

Figure 96: Select the Equipment Tile

Verifications are configured and initiated via the Equipment tile.

10. Select **Initiate Verification** to navigate to the Verification setup screen.

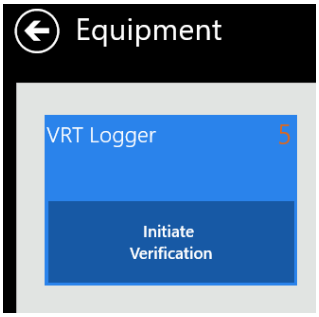


Figure 97: Initiate Verification

11. Enter your User credentials when prompted.

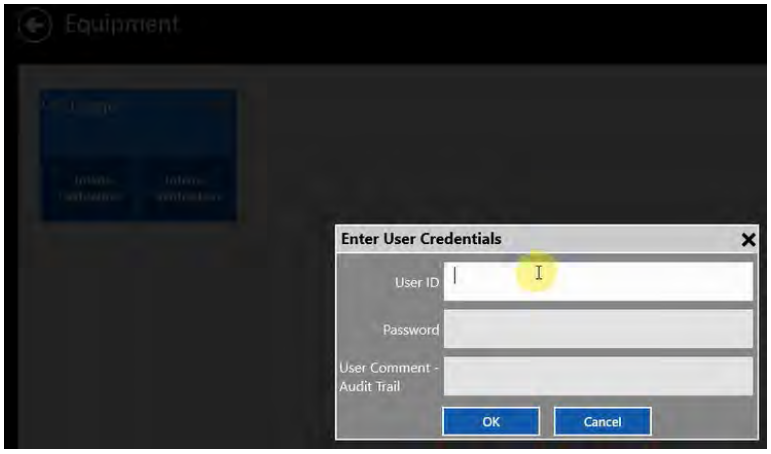


Figure 98: Enter User Credentials

12. Choose the **Temperature** verification type on the Select Verification Type window.

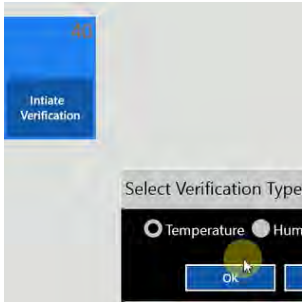


Figure 99: Select Verification Type

On the Temperature Verification Setup screen, the following options are available:

- Choose between one to six temperature setpoints
- Define for each setpoint the setpoint temperature, Pass/Fail criteria and results log times for reports
- Define sensor stability and minimum duration
- IRTD temperature reference stability criteria and duration
- Additional time at stability to ensure sensors, loggers, and references are stable
- SOP protocol numbers or other information

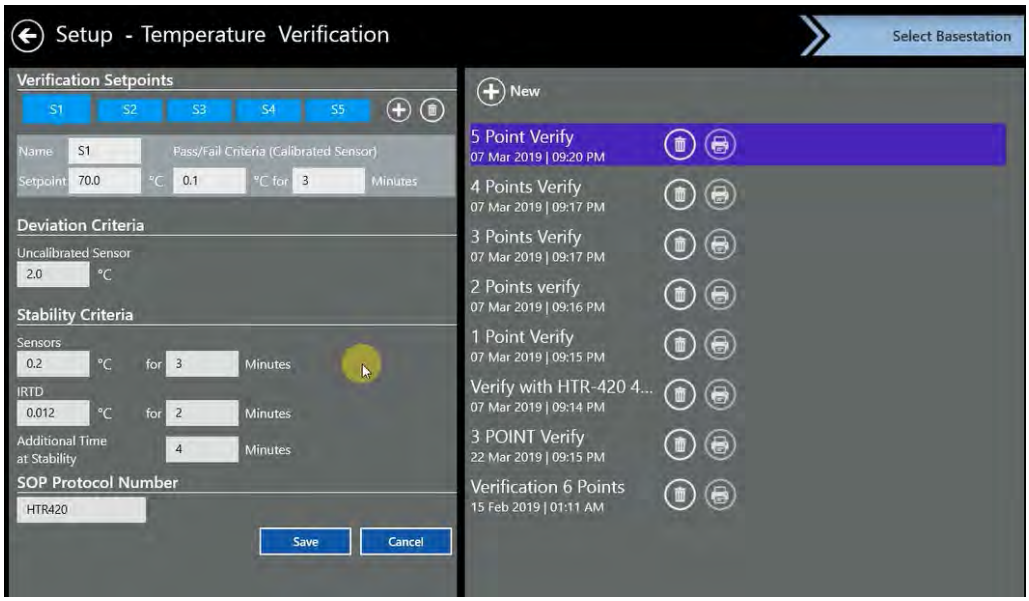


Figure 100: Setup Temperature Verification

To enter additional Setpoints or delete setpoints click on the appropriate icon. Once all setpoints and criteria are entered, save the Verification Setup under a specific name. If desired, setup printing is available by selecting the **Printer** icon. To delete a setup, click the **Trash Bin** icon.

Multiple Setups can be generated and saved with different configurations, all are listed on the right of the screen by Setup name and sorted by creation date. To modify an existing setup, double-click on it to open it, modify it and then click **Save** to save the changes or **Cancel** to revert your changes.

10.3. Loading a Verification Setup

Before you begin the Verification process, you must load your setup into the ValProbe RT loggers. A Kaye IRTD must be used to execute a Verification study. Please connect it and the Temperature bath / Drywell to the Base Station connectors on the rear of of the Base Station. Each connector is marked with the appropriate icon. Utilize the supplied cables for the connection. Power up the connected bath.

IMPORTANT: *If a calibration bath is not connected to the ValProbe RT base station, only a manual calibration can be performed. A fully automated calibration is only possible if a KAYE IRTD and a KAYE calibration bath is connected to the Base Station. Please ensure that the correct port is used for each instrument.*

Figure 101: Connecting a Bath to the Base Station

To load a setup:

From the Main Menu navigate to the **Equipment / Setup/ Temperature Verification** and select a setup from list of available setups.

After highlighting the required Verification Setup, click **Select Basestation**.

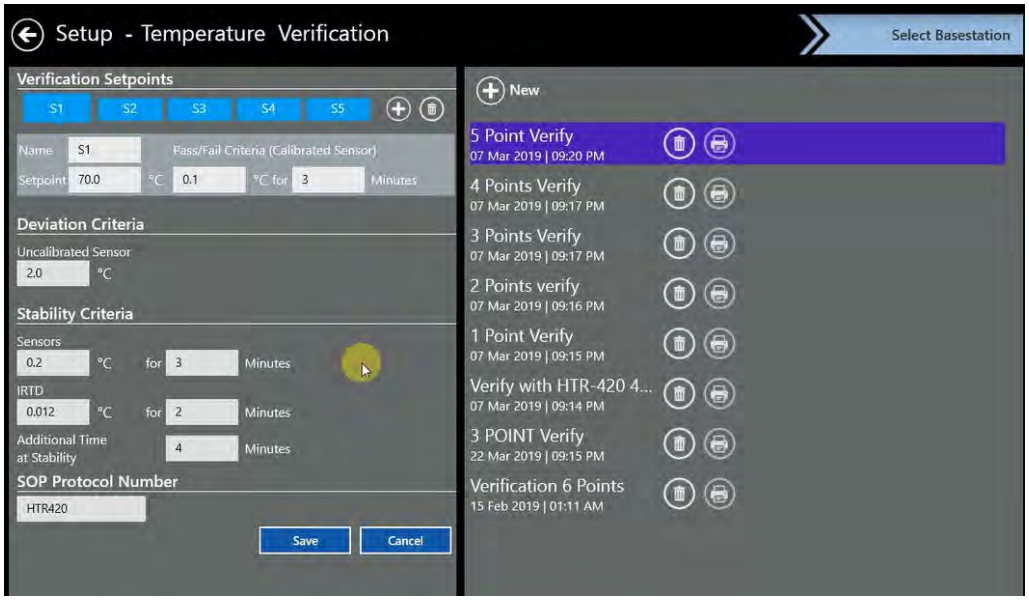


Figure 102: Select a Verification Setup from List

On the Select Base Station screen, click **Discover Base Station**, available devices are displayed. If there is an issue during discovery, ensure that the base station and Validation Console are properly connected

If no Base Stations are displayed check your connections and settings:

- If using direct connection using Fixed IP ensure the supplied ethernet cable is connected directly from the Base Station to the Console docking
- If the System is going to be on the network (DHCP) ensure the Console and Base Station and connected via ethernet cables to the network ethernet connections.

Select the desired Base Station tile, then press **Connect**.

Figure 103: Select Base Station

10.4. Selecting Sensors

When the desired Base Station is connected, select loggers to be verified on the Select Loggers screen.

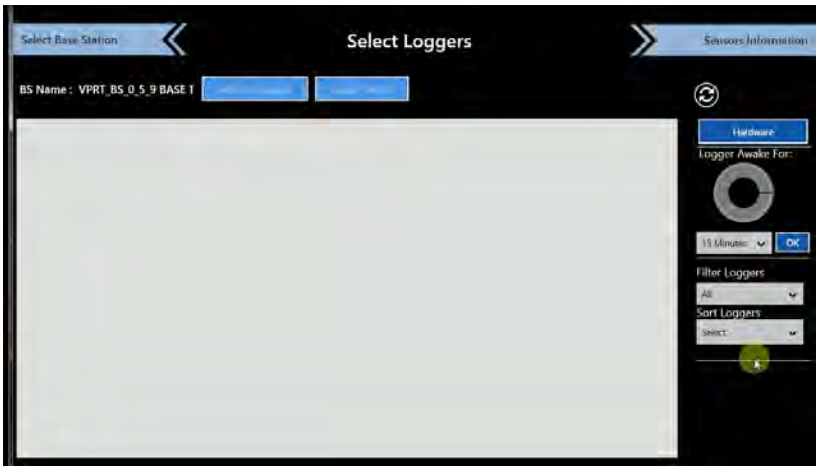


Figure 104: Select Loggers

If there are no Loggers listed on the screen you may need to wake up the loggers, using the magnetic Wake Up device or by passing them over status panel of the Base Station. Once all woken Loggers appear on screen, select the desired Loggers to be verified individually or all at once by clicking **Select All Loggers**. Selected Loggers' icon color changes to deep blue and the checkbox is enabled. All unselected Loggers are displayed without a checkmark.

You can filter Loggers or sort them by using the corresponding dropdowns on the right side of the screen. If you want to change the amount of time a selected Logger is awake, use the **Logger Awake For** dropdown and press **OK**.

For additional information on a Logger, select it and then press the **Logger Details** button. To proceed with the Verification study, click **Sensor Information.**

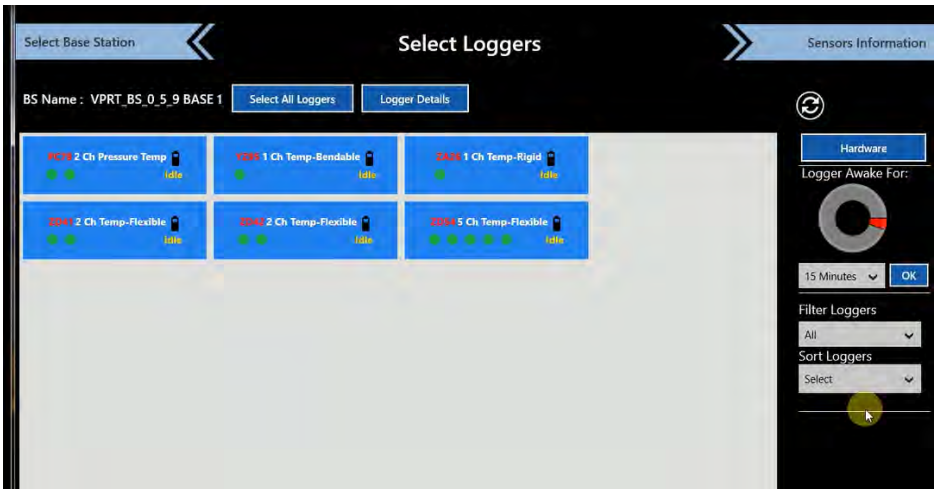


Figure 105: Loggers Listed

The Sensor Information screen will allow you to do a last review of the loggers about to be programmed. Ensure all Loggers selected are listed and then press **Program Loggers.**

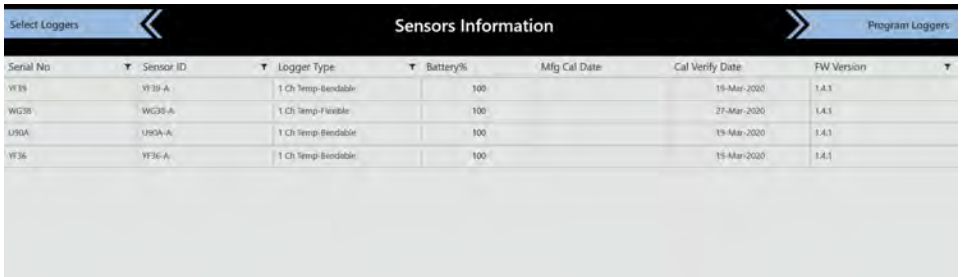


Figure 106: Loggers Listed

On the Program Loggers screen the Base Station receives the Verification Setup information and sends it via RF to the previously selected Loggers. The programming of the Loggers will be completed when all three status icons have turned green. Wait until completed and the Initiate Verification blinks yellow and press **Initiate Verification**

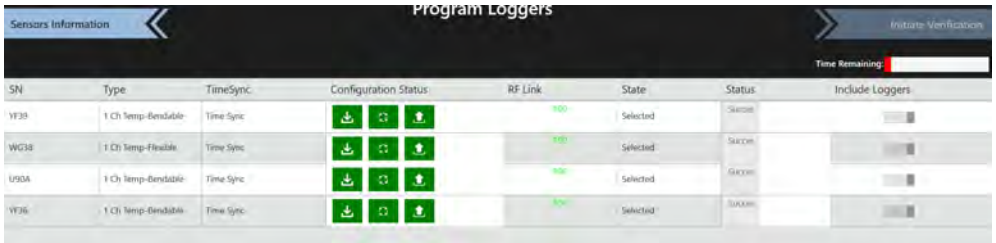


Figure 107: Program Loggers Screen

10.5. Running a Sensor Verification

Prior to starting the verification press the **Hardware** button and verify the IRTD and Kaye bath drywell are displayed as connected.

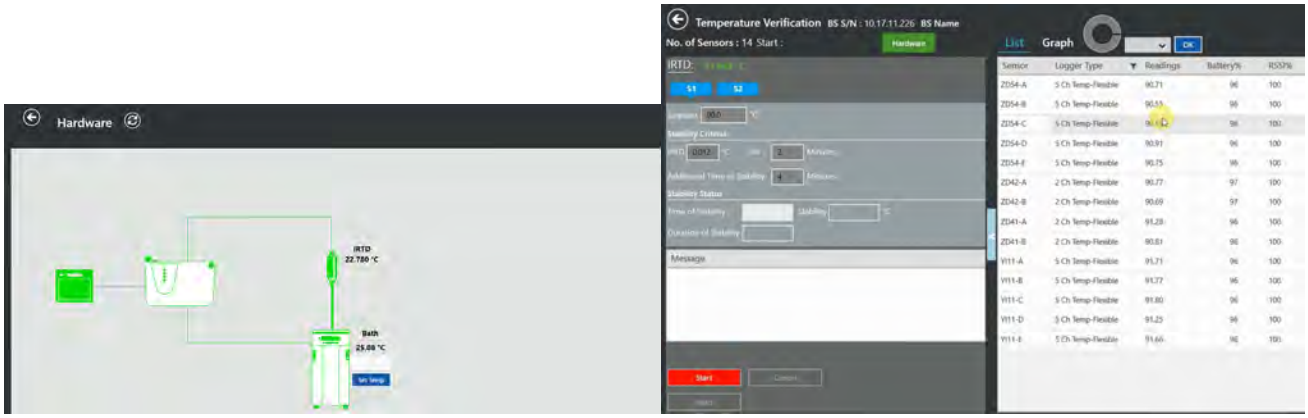


Figure 108: Verification Study Screens

Note: *It is important to ensure live data is displayed from the Logger sensors and IRTD before starting a Verification. This guarantees a good RF connection between Loggers and base station and so you can be sure that each logger receives the Start Verification command.*

If using a Dry Block reference, place the logger sensors into the Dry Block and then proceed to next step to Start. If using an oil bath press **Start** and then after sensor data is displayed, fully submerse Loggers into oil bath. In an oil bath, it is possible that live data from the Logger is no longer received. The verification study will not be affected, as the data is stored in the Loggers and can be read out after the study is finished.

Press **Start** on the Temperature Verification screen to start a Verification study.

When you start a Verification, the Kaye ValProbe RT software detects whether a Kaye temperature reference and an IRTD are connected. Both are required for a fully automatic operation. If there is no IRTD connected it is not possible to run a Verification study. If the Kaye temperature reference is not found, the system does not allow automated Verification. In this case, only a manual verification is possible. If neither can be found, Verification process cannot be run.

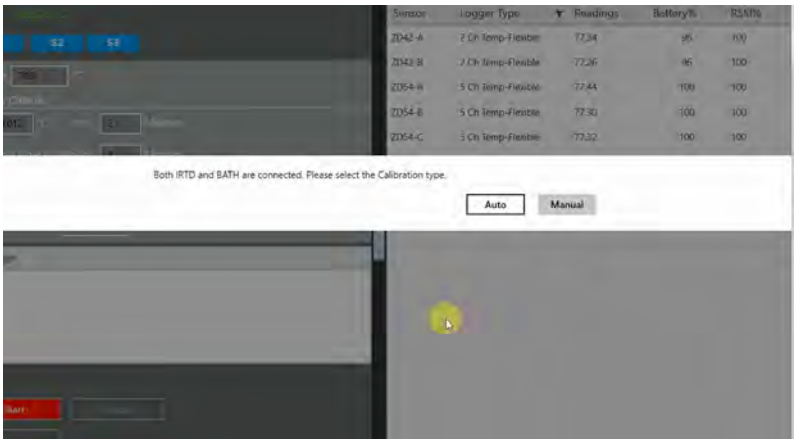


Figure 109: Auto / Manual Verification Prompt

If Auto calibration is selected the Base Station sends the corresponding temperature setpoint to the Temperature Reference

During the verification process, live data can be displayed in two ways, in a Graph view and a List view. If the list exceeds the screen size, you can scroll vertically through the remaining data. On the graph, temperature appears on the Y-axis, while the highlighted X-axis displays the stabilized IRTD temperature. All sample points that lie within the deviation specified are displayed as dots along with the label and the temperature point of the sensor. Samples that deviate from specification are displayed as red dots along with a sensor label, temperature point, and a value indicating how much the sensor is off.

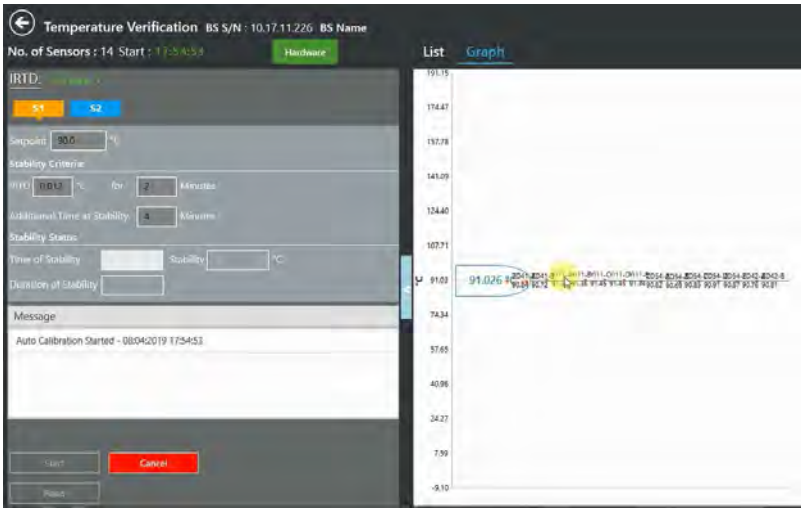


Figure 110: Temperature Verification Graph View

The first step in the Verification process is to verify that the IRTD is stable. Stability is the maximum allowable change in temperature for the temperature standard over the specified time interval. The maximum allowable change in temperature for the IRTD is fixed at 0.012°C if all temperature setpoints are equal to or greater than 0°C. If any temperature setpoint is less than 0°C, it is possible to change the IRTD stability value manually in your setup.

The stability calculation begins once the temperature reference is within five degrees of the setpoint. Sensor and IRTD readings are displayed on the Data screen. To achieve stability, the IRTD must meet the stability criteria defined in the setup.

When the IRTD is stable the Stability textbox changes from red to green and a timestamp appears in the Time of Stability textbox. At the same time, the duration of stability starts to count the time at stability. If IRTD gets unstable, the process starts restarts. When duration of additional time at stability meets the criteria the textbox changes to green and the setpoint is considered fulfilled.

Each setpoint that has met the criteria is displayed in green. Once all setpoints are met, the Study data from the Loggers can be read, click the green **Read** button to transfer the Logger and Base Station data to the Validation Console. If the **Read** button is not green, the setpoints are not completed.

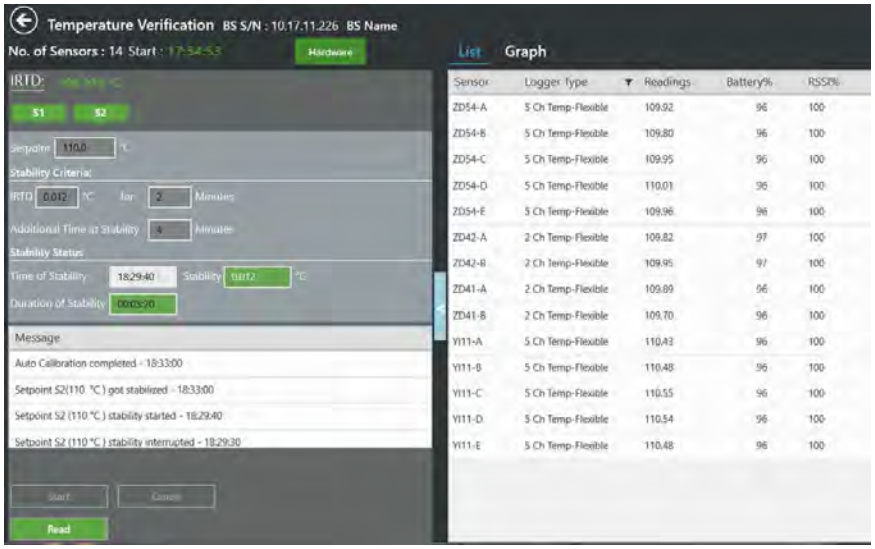


Figure 111: Temperature Verification List View / Green Read Button

Figure 112 below, displays the readout process of the loggers.

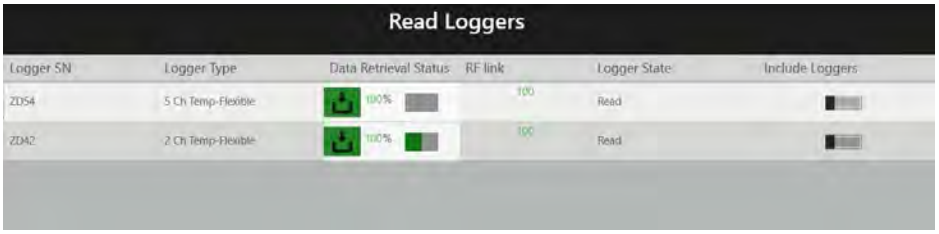


Figure 112: Read Loggers Screen

On the Verification Results screen perform the following

- Press **Save Study** to save the Study to the Console
- Press **Update Loggers** to update the last Verification date stored in the Logger firmware.

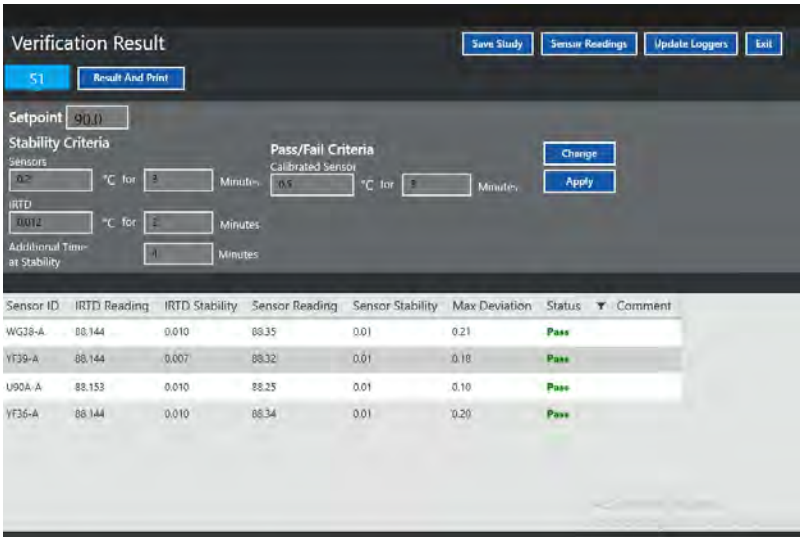


Figure 113: Calibration Result Screen

The Verification Results screen will display the Pass / Fail analysis results of the Verification for each sensor. You can select the setpoints to view the results for each setpoint.

Additional Verification report options:

- Check detailed sensor readings and IRTD readings using the Sensor Readings button.
- Display the sensor and IRTD readings in graphical format
- Generate a PDF Verification report for all selected verified sensors
- Change various criteria, in the textboxes

When completed with the Verification Results select **Exit**.

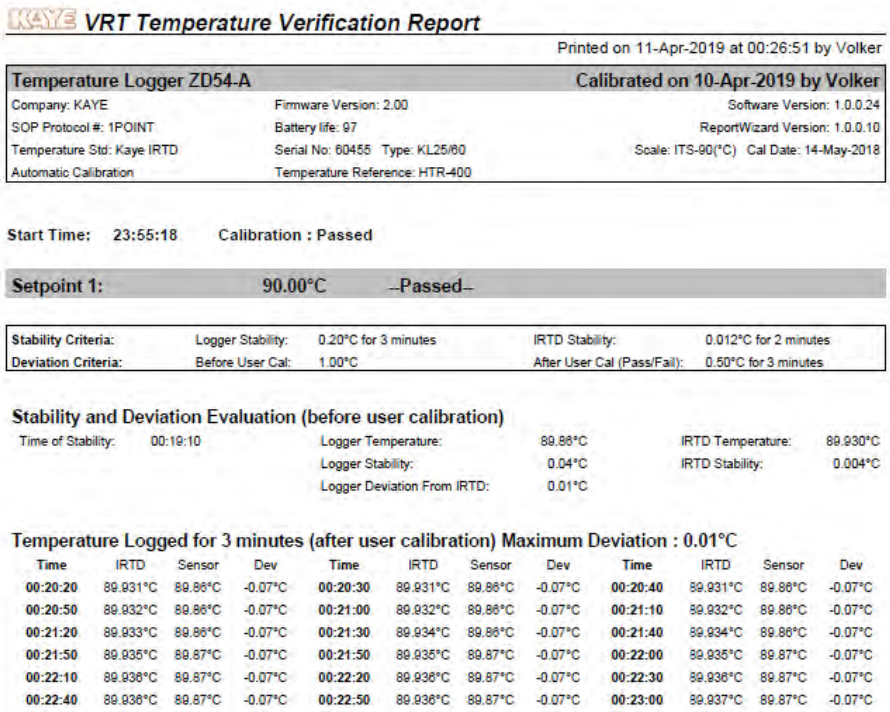
10.6. Reasons for Verification Failure

Verification may fail for some sensors due to one of the following reasons:

- Failed criteria of allowed Logger deviation
- Failed Verification due to unstable IRTD and Loggers
- Logger failed stability criteria and cannot be evaluated
- Time of stability of IRTD and Logger may not overlap a sufficient time
- Logger were removed from the bath/calibrator before the setpoint was reached

10.7. Verification Report

Once the process is completed, a Verification report can be generated



KAYE *VRT Temperature Verification Report*

Printed on 11-Apr-2019 at 00:26:51 by Volker

Temperature Logger ZD54-A		Calibrated on 10-Apr-2019 by Volker
Company: KAYE	Firmware Version: 2.00	Software Version: 1.0.0.24
SOP Protocol #: 1POINT	Battery life: 97	ReportWizard Version: 1.0.0.10
Temperature Std: Kaye IRTD	Serial No: 60455 Type: KL25/60	Scale: ITS-90(°C) Cal Date: 14-May-2018
Automatic Calibration	Temperature Reference: HTR-400	

Start Time: 23:55:18 **Calibration : Passed**

Setpoint 1: 90.00°C --Passed--

Stability Criteria:	Logger Stability:	0.20°C for 3 minutes	IRTD Stability:	0.012°C for 2 minutes
Deviation Criteria:	Before User Cal:	1.00°C	After User Cal (Pass/Fail):	0.50°C for 3 minutes

Stability and Deviation Evaluation (before user calibration)

Time of Stability:	00:19:10	Logger Temperature:	89.86°C	IRTD Temperature:	89.930°C
		Logger Stability:	0.04°C	IRTD Stability:	0.004°C
		Logger Deviation From IRTD:	0.01°C		

Temperature Logged for 3 minutes (after user calibration) Maximum Deviation : 0.01°C

Time	IRTD	Sensor	Dev	Time	IRTD	Sensor	Dev	Time	IRTD	Sensor	Dev
00:20:20	89.931°C	89.86°C	-0.07°C	00:20:30	89.931°C	89.86°C	-0.07°C	00:20:40	89.931°C	89.86°C	-0.07°C
00:20:50	89.932°C	89.86°C	-0.07°C	00:21:00	89.932°C	89.86°C	-0.07°C	00:21:10	89.932°C	89.86°C	-0.07°C
00:21:20	89.933°C	89.86°C	-0.07°C	00:21:30	89.934°C	89.86°C	-0.07°C	00:21:40	89.934°C	89.86°C	-0.07°C
00:21:50	89.935°C	89.87°C	-0.07°C	00:21:50	89.935°C	89.87°C	-0.07°C	00:22:00	89.935°C	89.87°C	-0.07°C
00:22:10	89.936°C	89.87°C	-0.07°C	00:22:20	89.936°C	89.87°C	-0.07°C	00:22:30	89.936°C	89.87°C	-0.07°C
00:22:40	89.936°C	89.87°C	-0.07°C	00:22:50	89.936°C	89.87°C	-0.07°C	00:23:00	89.937°C	89.87°C	-0.07°C

Figure 114: Verification Report

Chapter 11. Qualification Reports

11.1. Reports Overview

The Kaye ValProbe RT 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. These reports give the flexibility to perform a thorough analysis of process performance, while meeting regulatory guidelines for 21 CFR Part 11 and Data Integrity guidelines.

Available reports include:

- Setup reports
- Detailed reports
- Summary reports
- Graph reports
- Audit Trail
- CSV Export (Excel)
- Pass / Fail Criteria reports

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

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

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

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

Setup Report

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

- Defined number of sensors per type (Temp / Press)
- Details of sensor, types, labels and descriptions and firmware
- Sensor grouping
- Any defined overlay screens with sensor placement
- Defined calculations and parameters
- Data sample rate, transmission rate and Transmission active / inactive criteria
- Start/ Stop conditions

The header provides general information about a Setup including:

- Company name
- Date setup report printed
- Setup name
- Created by
- Created date / time
- Asset name
- Asset ID
- SOP #
- User comments

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

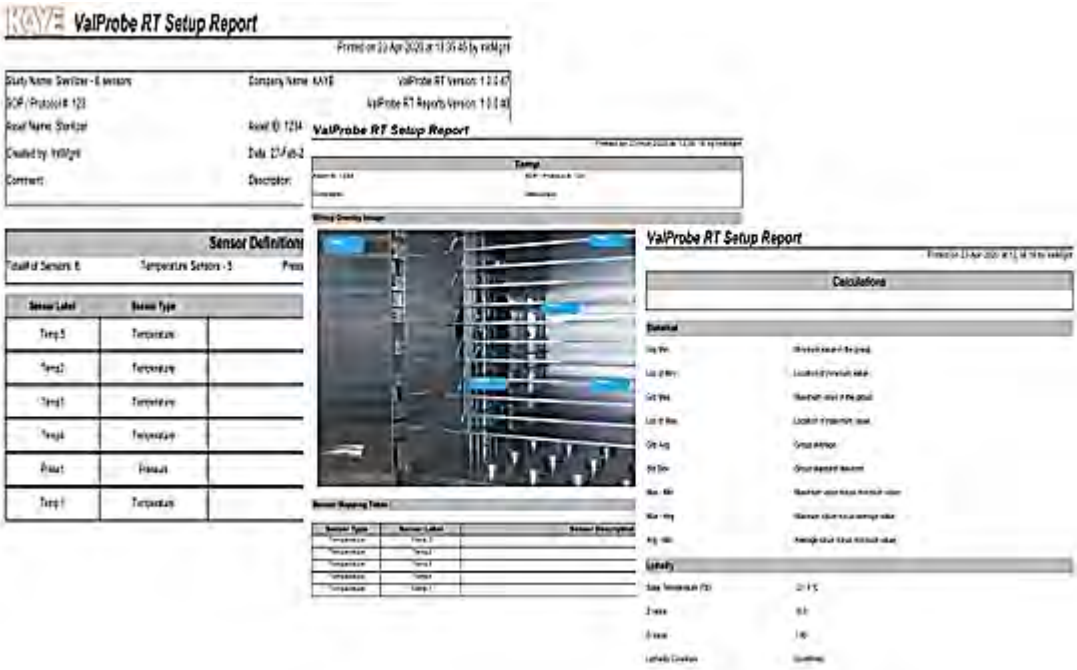


Figure 115: Setup Report

11.2. Qualification Detailed Report

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

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

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

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

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

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

The body of the report is arranged by Groups. For each Group the Detailed report contains pages detailing the sensor measurements, the Statistical calculations, Lethality calculations (if defined), and the Saturation Temp and Pressure calculations (if defined).The last pages of the report list the System and Event messages along with a Footer as defined in report options.

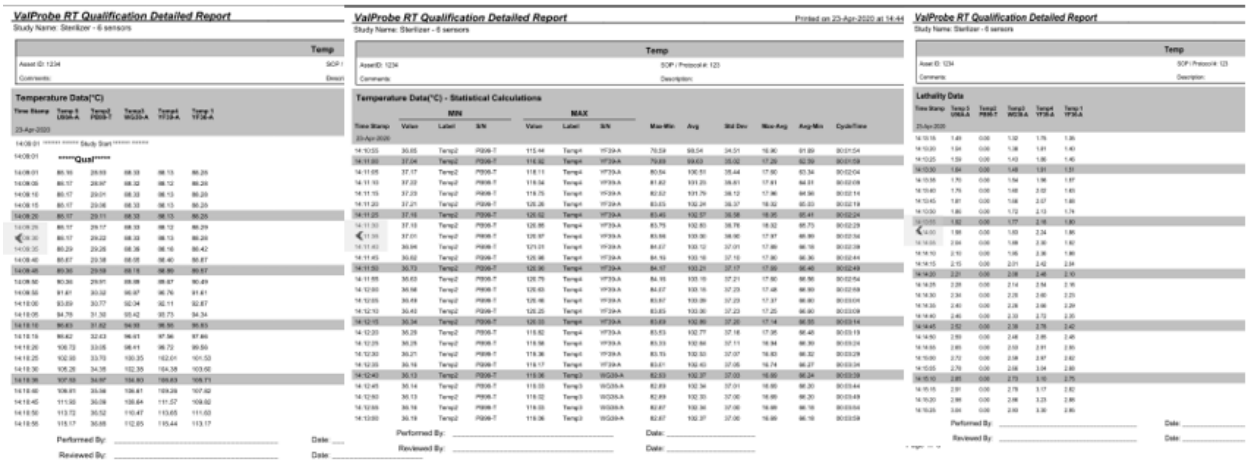


Figure 116: Qualification Detailed Report

11.3. Qualification Summary Report

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

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

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

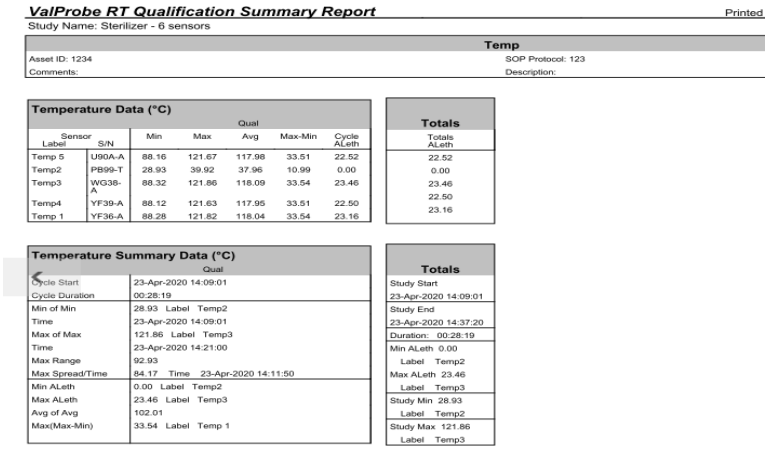
The Temperature Data Table include a listing of each sensor in the Group, the Min, Max, Avg, Lethality, and Max-Min values for each cycle defined in the study (i.e. Heat up, Exposure, Cooldown).

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

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

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

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



ValProbe RT Qualification Summary Report Printed

Study Name: Sterilizer - 6 sensors

Temp

Asset ID: 1234 SOP Protocol: 123

Comments: Description:

Temperature Data (°C)

Sensor Label	S/N	Min	Max	Avg	Max-Min	Cycle ALeth
Temp 5	U90A-A	88.16	121.67	117.98	33.51	22.52
Temp2	PB99-T	28.93	39.92	37.96	10.99	0.00
Temp3	WG38-A	88.32	121.86	118.09	33.54	23.46
Temp4	YF39-A	88.12	121.63	117.95	33.51	22.50
Temp 1	YF36-A	88.28	121.82	118.04	33.54	23.16

Totals

Totals ALeth
22.52
0.00
23.46
22.50
23.16

Temperature Summary Data (°C)

	Qual
Cycle Start	23-Apr-2020 14:09:01
Cycle Duration	00:28:19
Min of Min	28.93 Label Temp2
Time	23-Apr-2020 14:09:01
Max of Max	121.86 Label Temp3
Time	23-Apr-2020 14:21:00
Max Range	92.93
Max Spread/Time	84.17 Time 23-Apr-2020 14:11:50
Min ALeth	0.00 Label Temp2
Max ALeth	23.46 Label Temp3
Avg of Avg	102.01
Max(Max-Min)	33.54 Label Temp 1

Totals

Study Start
23-Apr-2020 14:09:01
Study End
23-Apr-2020 14:37:20
Duration: 00:28:19
Min ALeth 0.00
Label Temp2
Max ALeth 23.46
Label Temp3
Study Min 28.93
Label Temp2
Study Max 121.86
Label Temp3

Figure 117: Summary Report

11.4. Graph Reports

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

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

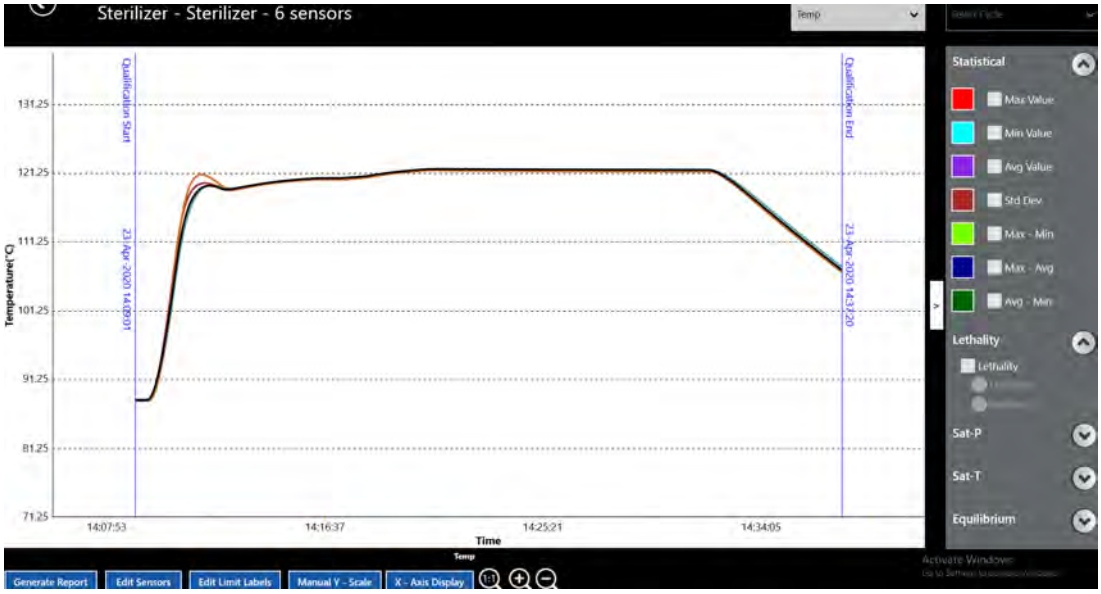


Figure 118: Graph Report Screen

The Graph report defaults to displaying All Temp Sensors for the duration of the Qualification study. Utilizing the Select Group drop down at the top right of the screen, you can select different type of sensors or groups to display. A Cycle drop down also allows you to select defined Cycles for graphing.

The graph screen can be maximized to full screen or minimized as displayed above, by utilizing the **>** or **<** to the right of the graph.

The pane to the right allows users to graph data based on different calculations such as Statistical calculations, Lethality, Saturation Pressure and Temperature or Equilibrium.

Statistical

Based on the Sensor Group selection, the following Statistical calculation graphs are available Max Value, Min Value, Avg Value, Avg and Std Dev, Max-Min, Max-Avg, Avg-Min.

Lethality

The Accumulated Lethality graph displays lethality totals for each included sensors at each timestamp programmed or defined to calculate lethality. Alternatively, the lethality accumulation can be displayed as a bar graph.

Sat P

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

The Saturation Pressure vs. Measured Pressure graph displays measured pressure from the selected pressure sensor and the saturation pressure calculated from the temperature sensors selected in the Edit Sensors screen. To access the Saturation Pressure vs. Measured Pressure graph, select Temp and Pressure Sensors group from **Select Group** drop-down list.

Sat T

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

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

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

Equilibrium

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

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

This graph is only available if the sensors had a one second sampling rate, 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.

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

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

Important:

- Excluded sensors from any graph reports are not included in the calculation graphs.
- Groups with only one sensor have no statistical calculations available and the checkboxes are grayed out.
- The Lethality calculation is only available if lethality has been defined for the study.
- The saturation pressure calculation is only available if the study includes at least one temperature sensor along with a pressure sensor.
- The saturation temperature calculation is only available if the study includes at least one pressure sensor along with temperature sensors.
- The Equilibrium calculation is only accessible if the Qualification data storage rate is 1 sec.

The following buttons on the bottom of the screen offer additional graphing options:

Zoom

By utilizing the zoom icons at the bottom of the screen or by using your fingers you can zoom in or out or rest the zoom for enhanced analysis.

Y / X Scaling

Pressing the **Manual Y – Scale** button allows you to manually adjust the Y axis scale. The **X-Axis Display** button allows you to select different options for displaying the X time axis.

Edit Sensors

Press **Edit Sensors** to choose the sensors 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. Options for choosing sensor colors and line thickness are available.

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

Edit Limit Labels

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

To add limit lines to a graph, enter an upper and/or lower limit value or Avg (s) and label. These display as horizontal lines at the selected measurement points. You can also select the line color, thickness and line style.

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

Generate Report

Press Generate Report to create a pdf report of the graph. Enter a custom label and select Apply. As many graphs as are necessary to properly evaluate your qualification study can be generated. An option in the Summary Report allows the graph of the complete study to automatically be included in your Summary report.

11.5. Audit Trail Report

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

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

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

The Audit Trail is stored in an encrypted file and protected from User access. The data in the Audit Trail cannot be deleted and or modified.

Actions which are captured include:

- User actions requiring a login with a User ID and Password.
- Automated system actions or events.
- Any additional actions deemed critical to the history of the data or Qualification files.
- To access the Audit Trail, navigate to the ValProbe RT Software Main screen and select Audit.

Logged In User Id	User Name	Date / Time	Actions	User
Admin	Admin	07 January 2020 21:00:30	User Id : "Admin" Logged in to System.	
Admin	Admin	07 January 2020 08:12:56	User Id : "Admin" Logged in to System.	
Admin	Admin	06 January 2020 15:16:23	User Id : "Admin" Logged in to System.	
Admin	Admin	05 January 2020 20:23:58	Preferences : "Allow Users to change Lethality?" field updated from "No to Yes " by User Id : "Admin" , User Name : "Admin";	
Admin	Admin	02 January 2020 12:21:22	User Id : "Admin" Logged in to System.	
Admin	Admin	02 January 2020 12:20:34	Setup : "test" is loaded to AVS "10.0.0.82" by User : "Admin", ID : "Admin"	
Admin	Admin	02 January 2020 12:20:02	Study file saved for "Demo" by User Name: "Admin", User ID : "Admin" at "02-Jan-2020 12:20:02" for AVS_1500002	
Admin	Admin	02 January 2020 12:14:14	Setup report creation in Asset Details screen done by User Id : "Admin", User Name : "Admin".	
Admin	Admin	02 January 2020 12:13:00	User Id : "Admin" Logged in to System.	
Admin	Admin	30 December 2019 11:25:04	User Id : "Admin" Logged in to System.	
Admin	Admin	23 December 2019 14:56:42	User Id : "Admin" Logged in to System.	
Admin	Admin	19 December 2019 12:44:19	Sync Out Successful	
Admin	Admin	19 December 2019 12:44:19	Equipment Sync Out operation	
Admin	Admin	19 December 2019 12:44:19	Audit Sync Out operation	
Admin	Admin	19 December 2019 12:44:19	Users Sync Out operation	
Admin	Admin	19 December 2019 12:44:19	Assets Sync Out operation	
Admin	Admin	19 December 2019 12:44:00	Templates Synced Out	

Figure 119: Audit Trail

The Audit Trail contains a complete history of the system. The entries include:

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

There are two ways to generate Audit Trail Reports, first, the user can select the Audit Trail and the date range of the Qualification study to provide a quick method of generating an Audit Trail tied to a Qualification Study.

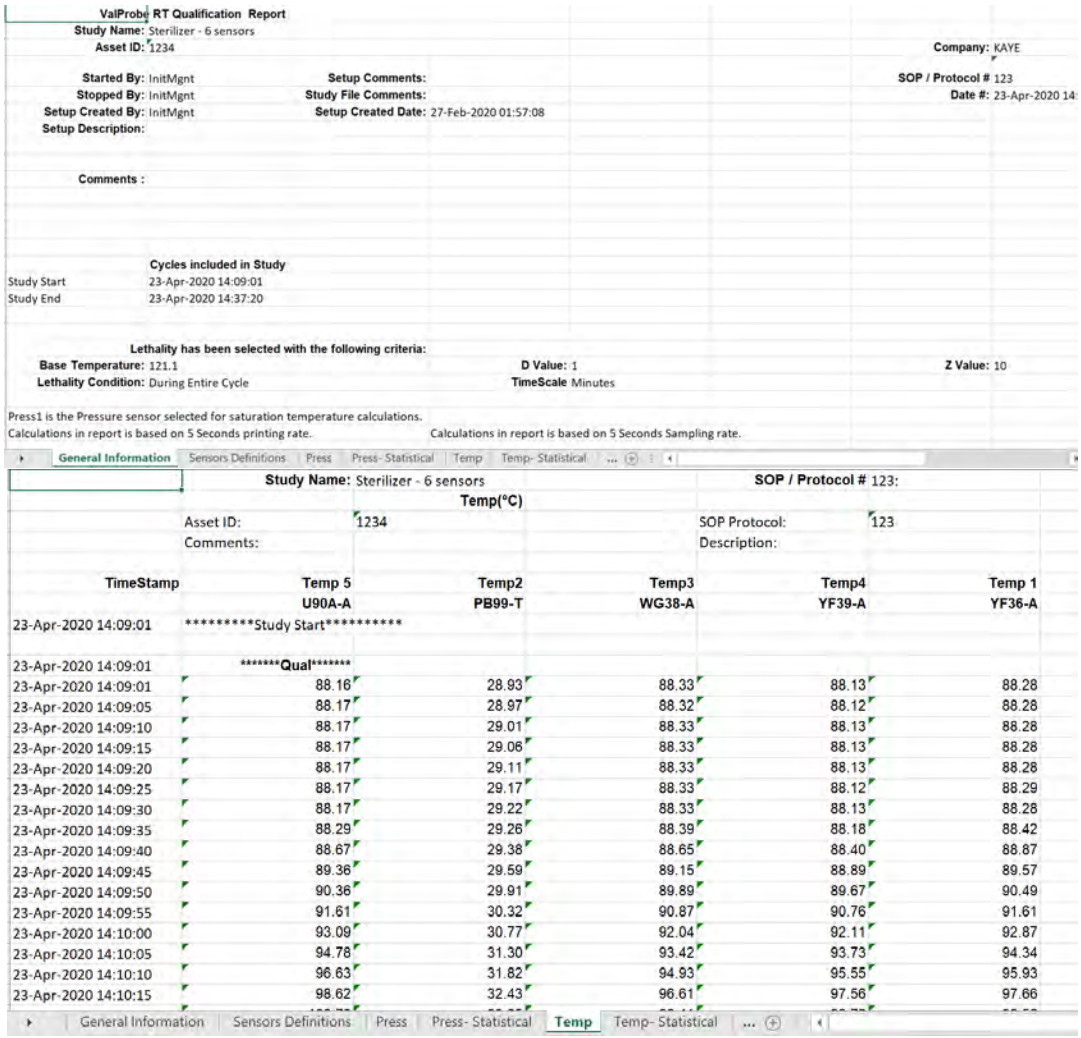
Figure 120: Audit Trail

For a more detailed review and report capability the user can go to Audit from the Main Menu. There the user can do a more detailed search over the complete history using the filters in each column. When the Audit Trail is filtered and printed, the header of the report lists all filters that have been applied along with the condition of the filters.

11.6. Spreadsheet Report

The Spreadsheet Report generates a CSV file which can then be used for those wishing to import their data into Excel for further analysis or graphing. The file is automatically divided into numerous tabs which provide detail Qualification data. The tabs consist of:

General Information	Sensor Definitions
Temperature Data	Temperature Statistical
Temperature Lethality	Pressure Data
Saturation P-T	Messages and Comments



ValProbe RT Qualification Report
Study Name: Sterilizer - 6 sensors
Asset ID: 1234
Company: KAYE
Started By: InitMgnt
Stopped By: InitMgnt
Setup Created By: InitMgnt
Setup Description:
Setup Comments:
Study File Comments:
Setup Created Date: 27-Feb-2020 01:57:08
SOP / Protocol # 123
Date #: 23-Apr-2020 14:
Comments :

Cycles included in Study
Study Start 23-Apr-2020 14:09:01
Study End 23-Apr-2020 14:37:20

Lethality has been selected with the following criteria:
Base Temperature: 121.1
Lethality Condition: During Entire Cycle
D Value: 1
TimeScale Minutes
Z Value: 10

Press1 is the Pressure sensor selected for saturation temperature calculations.
Calculations in report is based on 5 Seconds printing rate.
Calculations in report is based on 5 Seconds Sampling rate.

General Information | Sensors Definitions | Press | Press- Statistical | Temp | Temp- Statistical

Study Name: Sterilizer - 6 sensors
SOP / Protocol # 123:
Temp(°C)
Asset ID: 1234
SOP Protocol: 123
Comments:
Description:

TimeStamp	Temp 5 U90A-A	Temp2 PB99-T	Temp3 WG38-A	Temp4 YF39-A	Temp 1 YF36-A
23-Apr-2020 14:09:01	*********Study Start**********				
23-Apr-2020 14:09:01	*******Qual*******				
23-Apr-2020 14:09:01	88.16	28.93	88.33	88.13	88.28
23-Apr-2020 14:09:05	88.17	28.97	88.32	88.12	88.28
23-Apr-2020 14:09:10	88.17	29.01	88.33	88.13	88.28
23-Apr-2020 14:09:15	88.17	29.06	88.33	88.13	88.28
23-Apr-2020 14:09:20	88.17	29.11	88.33	88.13	88.28
23-Apr-2020 14:09:25	88.17	29.17	88.33	88.12	88.29
23-Apr-2020 14:09:30	88.17	29.22	88.33	88.13	88.28
23-Apr-2020 14:09:35	88.29	29.26	88.39	88.18	88.42
23-Apr-2020 14:09:40	88.67	29.38	88.65	88.40	88.87
23-Apr-2020 14:09:45	89.36	29.59	89.15	88.89	89.57
23-Apr-2020 14:09:50	90.36	29.91	89.89	89.67	90.49
23-Apr-2020 14:09:55	91.61	30.32	90.87	90.76	91.61
23-Apr-2020 14:10:00	93.09	30.77	92.04	92.11	92.87
23-Apr-2020 14:10:05	94.78	31.30	93.42	93.73	94.34
23-Apr-2020 14:10:10	96.63	31.82	94.93	95.55	95.93
23-Apr-2020 14:10:15	98.62	32.43	96.61	97.56	97.66

General Information | Sensors Definitions | Press | Press- Statistical | Temp | Temp- Statistical

Figure 121:Spreadsheet Report

11.7. Pass/Fail Report

Pass / Fail Report Overview

The Pass / Fail Criteria report eliminates hours of manual or spreadsheet based analysis, by providing an automated report, which analyzes Qualification raw data and provides a report detailing whether the Qualification data successfully passed or failed to meet user defined criteria.

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

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

Qualification Raw Data File

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

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

Qualification time stamps and associated data are captured:

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

Definition of Cycles

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

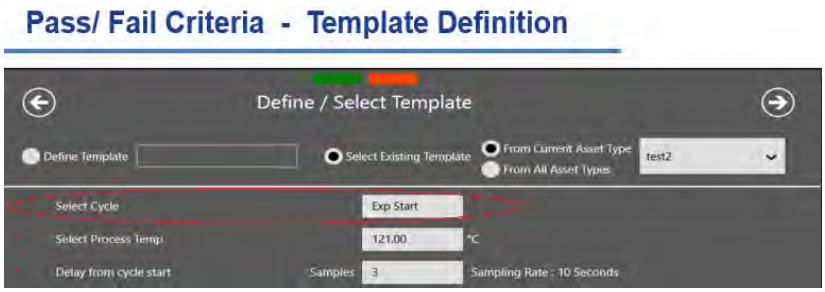


Figure 122: Pass/ Fail Criteria – Template Definition Screen

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

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

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

Statistical Calculations

All values are calculated from the data point values of the defined cycle. As the stop of the study is also the same timestamp and data for the start of the next cycle, it is **NOT** included into the statistical calculations unless it is the Qual End event.

Accumulation Calculations

Accumulation calculations look at the data samples and interval of time between two samples and accumulate them over the duration of the cycle. Typical calculations include: Lethality, Cycle /, and Time above/below Process Temp.

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

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

For Equilibration Time, the calculation is only enabled if the Setup is defined with a 1 sec sample/storage rate. The calculation starts when the first sample where the reference temp reaches the process setpoint, and ends when sample temperatures reach the process temp. For Time at/below Process Temperature per Sensor, the system accumulates time for each sample interval) only if both, the data points at the beginning and end of the sample interval are beyond (above/at/below) the defined condition.

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

If for example, a data point (A1) has reached the given criterion threshold, the system checks if the next data point (A2) has reached the given criterion threshold as well. In that case, the interval between the data points are counted toward the accumulated value.

Pass / Fail Criteria – Template Definition

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

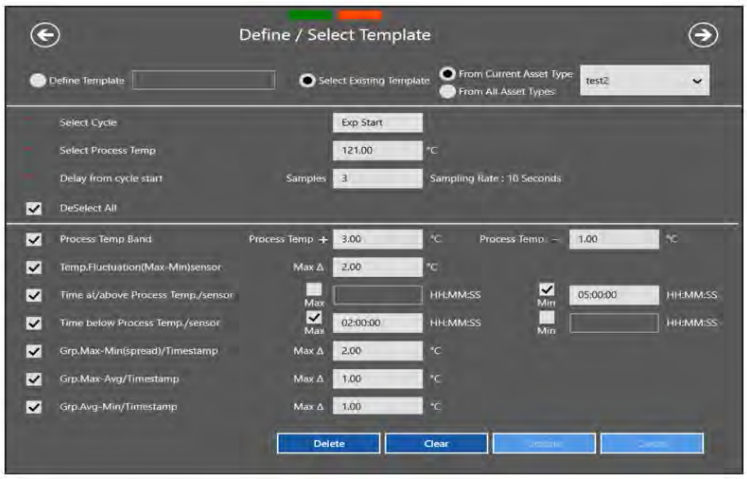


Figure 123: Define / Select Template Screen

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

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

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

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

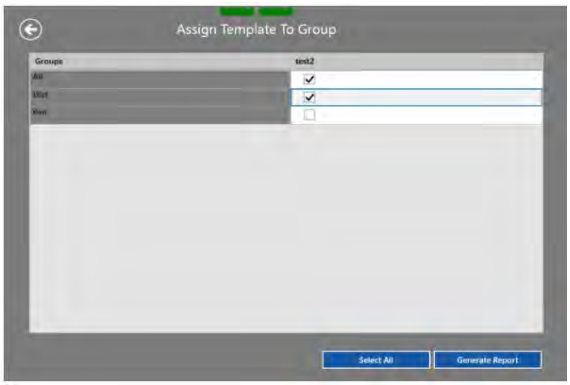


Figure 124: Template to Group Screen

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

Pass / Fail Criteria Calculations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

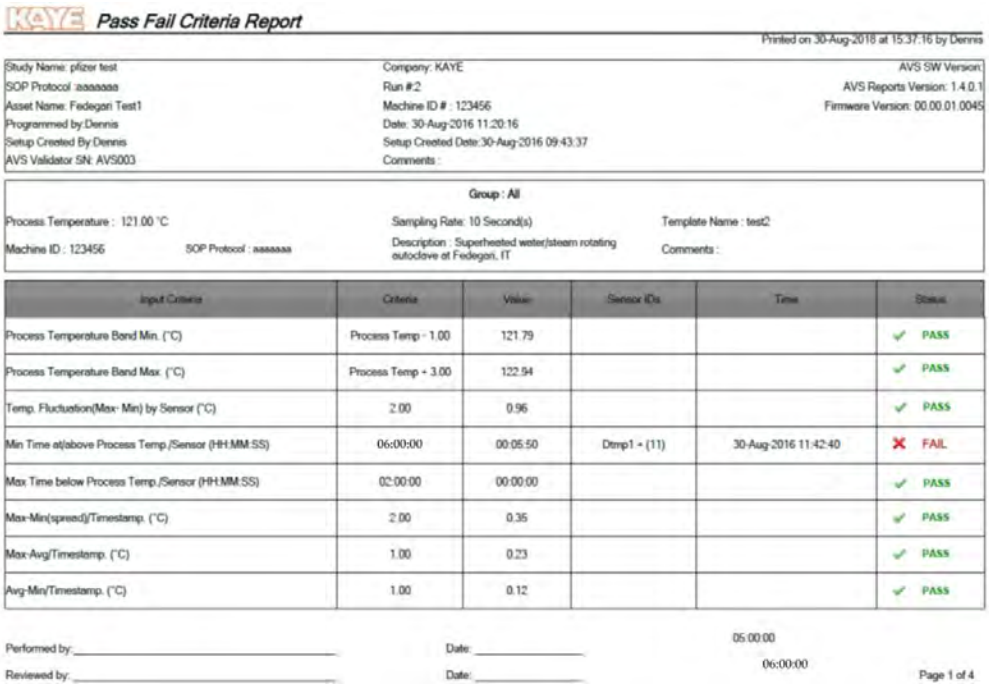
Pass / Fail Criteria Report

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

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

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

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



KAYE *Pass Fail Criteria Report*

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

Study Name: pfizer test	Company: KAYE	AVS SW Version:
SOP Protocol :aaaaaaa	Run #:2	AVS Reports Version: 1.4.0.1
Asset Name: Fedegari Test1	Machine ID # : 123456	Firmware Version: 00.00.01.0045
Programmed by:Dennis	Date: 30-Aug-2016 11:20:16	
Setup Created By:Dennis	Setup Created Date:30-Aug-2016 09:43:37	
AVS Validator SN: AVS003	Comments :	

Group : All

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

Input Criteria	Criteria	Value	Sensor IDs	Time	Status
Process Temperature Band Min. (°C)	Process Temp - 1.00	121.79			✓ PASS
Process Temperature Band Max. (°C)	Process Temp + 3.00	122.94			✓ PASS
Temp. Fluctuation(Max- Min) by Sensor (°C)	2.00	0.96			✓ PASS
Min Time at/above Process Temp./Sensor (HH:MM:SS)	06:00:00	00:05:50	Dtmp1 + (11)	30-Aug-2016 11:42:40	✗ FAIL
Max Time below Process Temp./Sensor (HH:MM:SS)	02:00:00	00:00:00			✓ PASS
Max-Min(spread)/Timestamp. (°C)	2.00	0.35			✓ PASS
Max-Avg/Timestamp. (°C)	1.00	0.23			✓ PASS
Avg-Min/Timestamp. (°C)	1.00	0.12			✓ PASS

Performed by:_____ Date: _____ 05:00:00

Reviewed by: _____ Date: _____ 06:00:00

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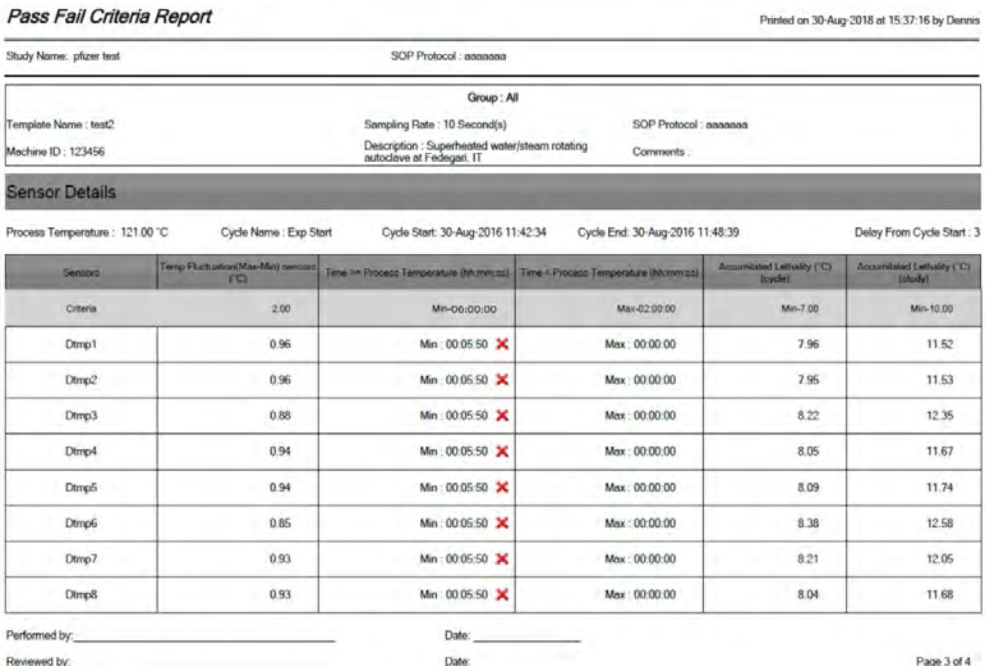
Figure 125: Pass Fail Criteria Report

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

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



Pass Fail Criteria Report

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

Study Name: pfizer test

SOP Protocol : aaaaaaa

Group : All

Template Name : test2

Sampling Rate : 10 Second(s)

SOP Protocol : aaaaaaa

Machine ID : 123456

Description : Superheated water/steam rotating autoclave at Fedegari, IT

Comments :

Sensor Details

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

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

Performed by:_____ Date: _____

Reviewed by: Date:

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Figure 126: Failed Sensors

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

11.8. Generating Qualification Reports

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

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

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

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

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

11.8.1. Selecting a Qualification File

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

Select the **Bar Graph** icon for the selected Qualification file.

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

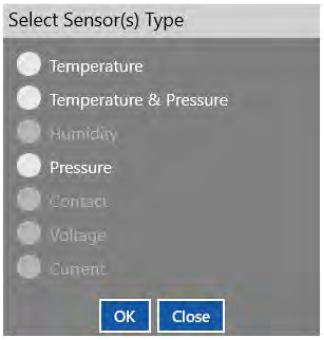


Figure 127: Select Sensor(s) Type

11.8.2. Mark Cycles

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

The existing Qual and Exposure times and duration are listed in the table above the graph. To edit any of the times press the pen icon for the selected time to change. A pop-up box will allow selection for **Time Marker** or **Events** to change the selected cycle time.

Figure 128: Mark Cycles Screen

Selecting Time /Marker displays a line marker. The time can be changed manually by using the dropdown from the time box or via the marker by sliding the line to the selected time and press the **Checkmark**. Options such as the Zoom icons, adding Limit Lines or Selecting the Marker Position, improve the ability to accurately edit times. The process can then be repeated for any necessary edits to Qual / Exposure times.

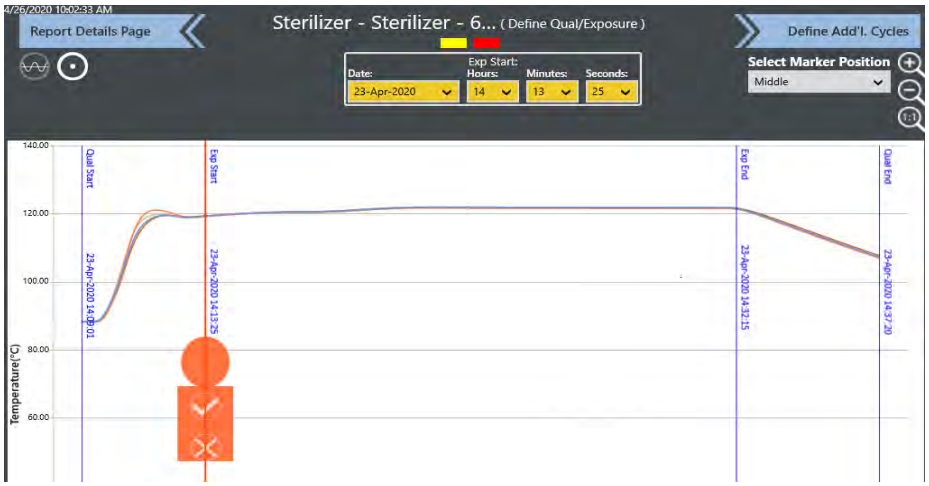


Figure 129: Mark Cycles Using Time / Marker

In the edit Cycle dropdown box select **Events** if you would like to select an existing event or create a new event.

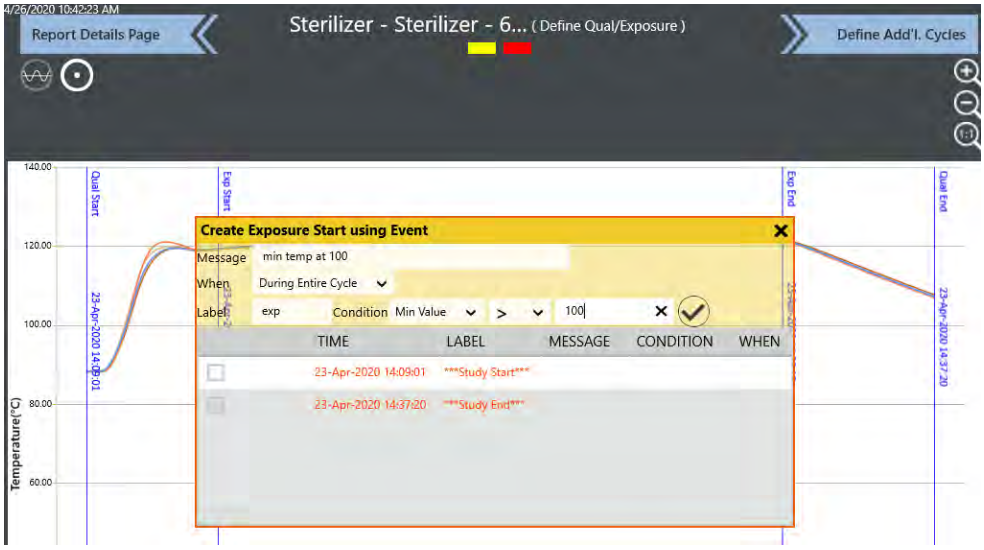


Figure 130: Mark Cycles Using Events

If creating a new event, the user can specify a message which appears in the Detailed Report and in the graph. 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 > 100.0 C). When all details are entered press the **Checkmark** and the selected time will be marked

When completed with any edits to the Qual / Exposure times press **Define Additional Cycles.**

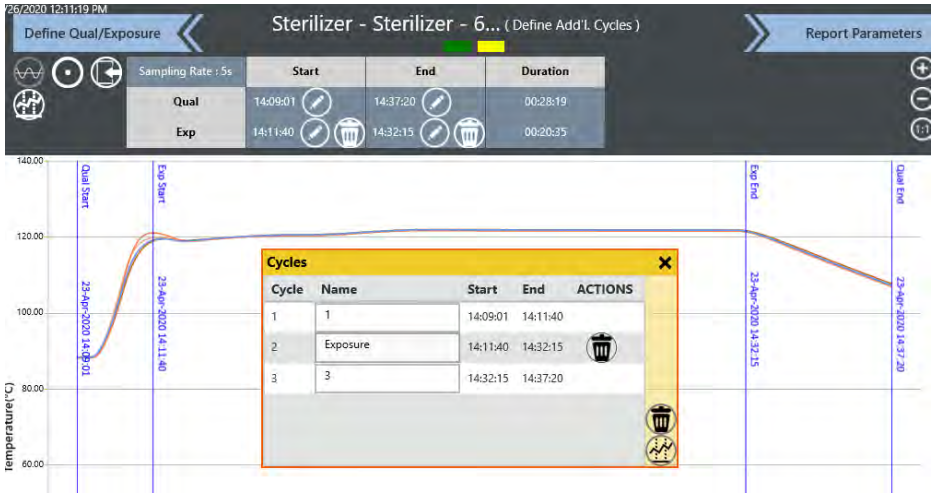


Figure 131: Define Additional Cycles screen

The **Define Add’L Cycles** screen can be utilized if additional cycles beside Qual and Exposure need to be defined. If no additional cycles need to be defined simply press Report Parameters at the top of the screen to proceed to the next step. The system allows up to 15 additional cycles to be defined. Press the button at the top right of the screen to go to Cycles window. The method and functionality for defining cycles is the same as defined in Exposure Start / End.

In the Cycles window all created cycles are displayed with the defined Start and End times. The Cycles window also allows modifications of cycles names. **UnMark Cycle** can be used to delete a cycle.

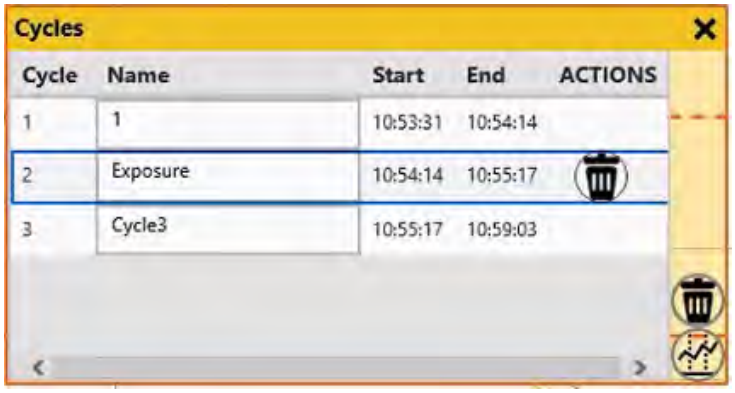


Figure 132: Define Additional Cycles Screen

To add additional cycles, press the button on the Cycles screen. A pop-up appears with a prompt on how to mark the additional cycle by Time / Marker or Event. The functionality for performing these tasks are the same as for the Qual / Exposure screen.

When all additional cycles are added, press the **Report Parameters** ribbon at the top of the screen to move to the next step of the reporting process.

11.8.3. Edit Parameters

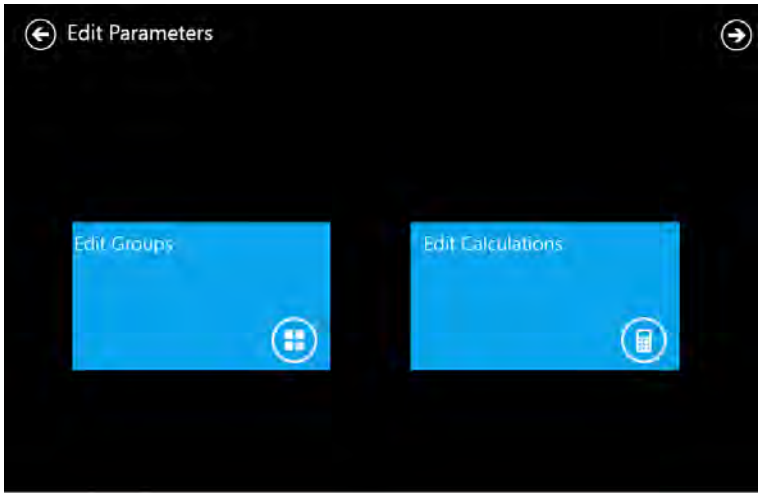


Figure 133: Define Additional Cycles Screen

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

If no changes are needed press the **Next** arrow at the top of the screen to proceed.

Edit Groups Screen

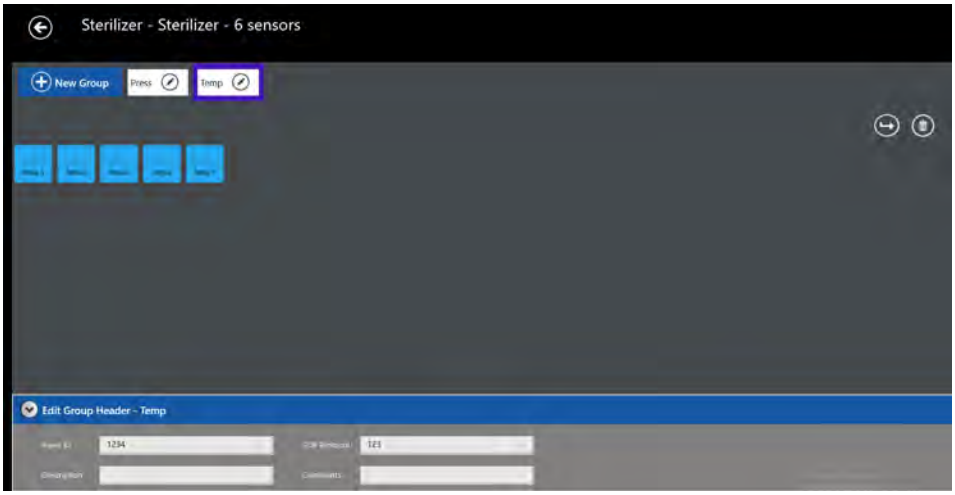


Figure 134: Edit Groups screen

The Edit Groups screen includes the following options:

- Add New Group – press **New Group** and enter a name, select sensors, and a title.
- Move Sensors between Groups –press .
- Delete Groups – select a Group Name and press **Delete** to delete individual sensors from a group.
- Edit Groups Header – select the Group name and press the **Edit Group Header** arrow.
- Edit Group Sensors – press the pen icon in the appropriate group and then select or de-select appropriate sensors.

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

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

Customize Calculations Screen

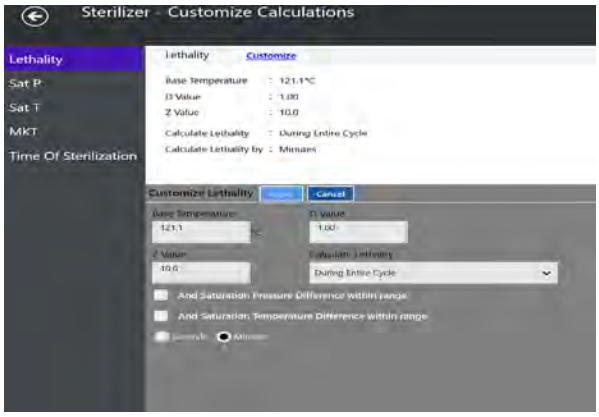


Figure 135: Customize Calculations

On the left panel select from the following list of calculations, Lethality, Sat P, Sat T, MKT, and Time of Sterilization to display information for each. With the desired calculation selected in the right panel press **Customize** to open the Customization options for the calculation.

Any changes to calculations are detailed in the Qualification report.

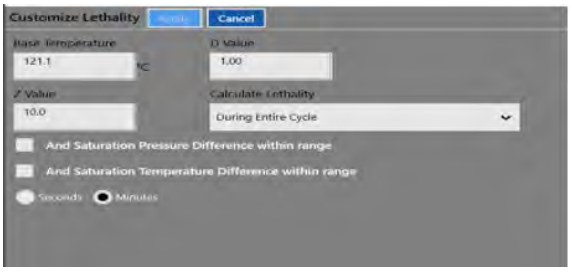
Some Calculations such as MKT and Time of Sterilization are done inside the software and cannot be set in the setup file:

- If the MKT calculation is desired the value of Heat activation can be set.

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

Lethality and Time of Sterilization

New European regulation have placed and emphasis on ensuring you have proper steam quality when calculating lethality. For this reason, we have added additional options which if checked will only calculated the Instantaneous lethality for the time stamp if the Saturation Pressure and Temperature are within defined limits set in the Time of Sterilization calculation.



The Time of Sterilization calculates the total time of sterilization by combining the Steam quality criterion, along with the measured reference temperature. Time is counted if the measured reference temperature is at or above the process temperature and the steam quality as defined by Temperature minus calculated Saturation Temperature (T-Sat) is within the specified range.

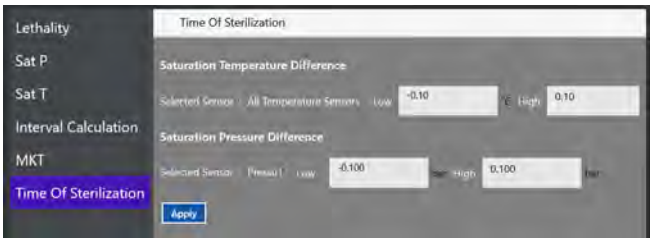


Figure 136: Time of Sterilization – Definition of Limits

Press **Back** to return to the Edit Parameters screen.

If Edits are completed or no edits were required press the **Next** arrow to proceed.

11.8.4. **Report Selection**

On the Report Selection screen, you can select between Standard text reports or Graph reports.

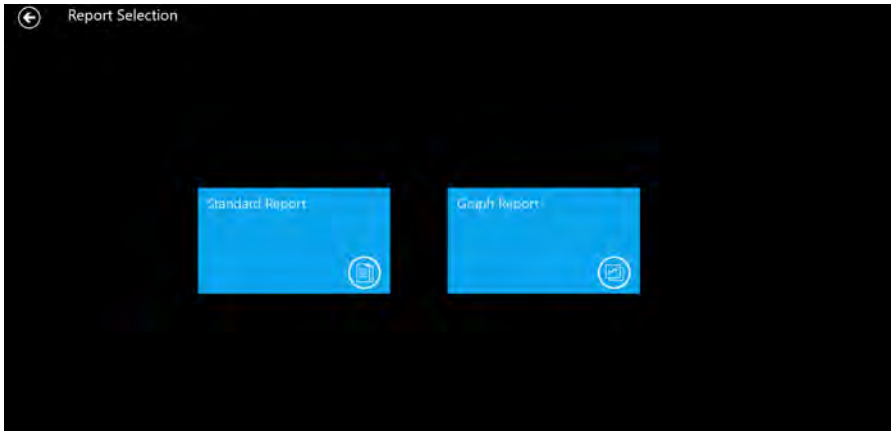


Figure 137: Report Selection Screen

Graph Reports:

The Graph Reports allows the user to report the Qualification data in graphical format. See section (**10.5 Graph Reports)** for a detailed explanation of the options and tools available for graphing.

Standard Reports:

The Standard Reports screen allows the user to select which reports to generate. All reports and calculations are based on the Storage/ Sample rate defined in the Setup.

Multiple reports can be selected at one time to improve efficiency. All reports generated are in pdf format. All pdf reports are automatically saved into the Asset where the Qualification file was stored and placed under the Report tile.

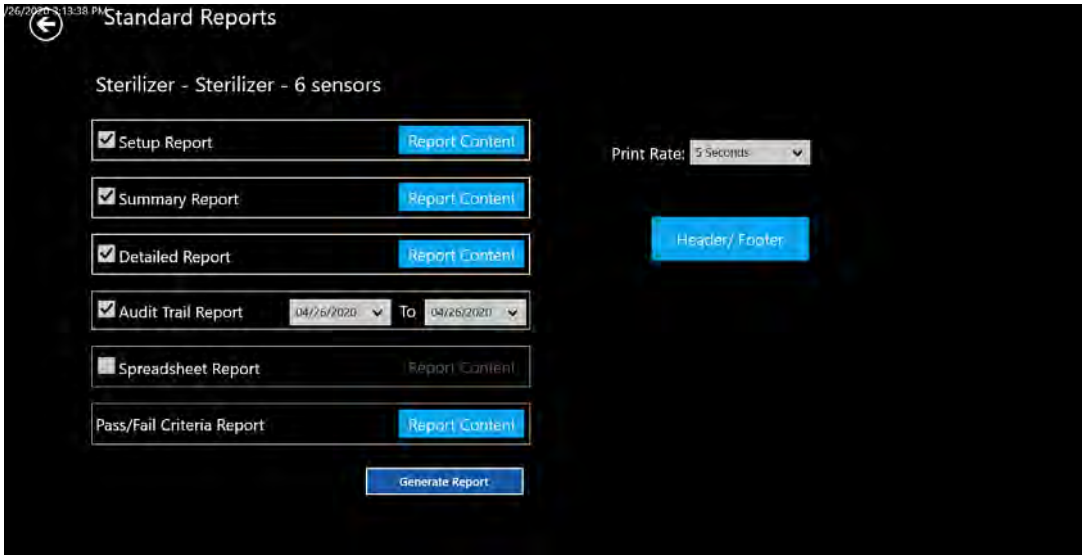


Figure 138: Standard Report Selection Screen

Prior to generating the selected reports ensure the Report Content for each selected report as well as the Header/Footer and Print Rate are defined.

Report Content:

The Report Content for each report defines which groups and or calculation are to be included in the reports.

Setup – Allows selection if overlay diagram is included in report

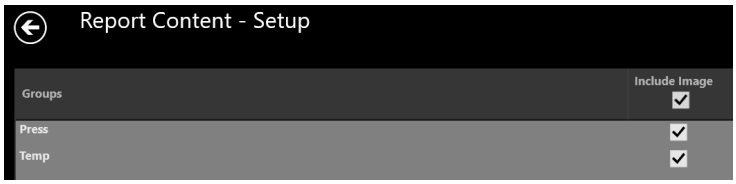


Figure 139: Setup Report Content Screen

Summary – Allows selection of groups included and Lethality or MKT calculation.

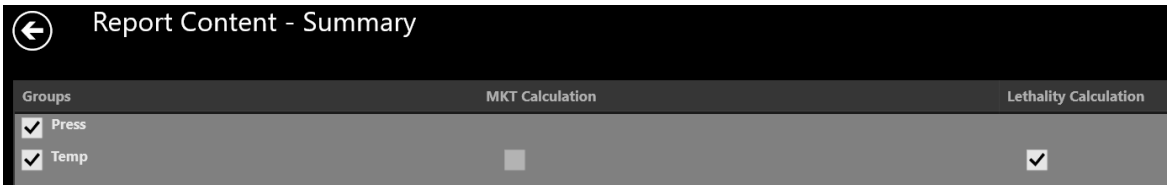


Figure 140: Setup Report Content Screen

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

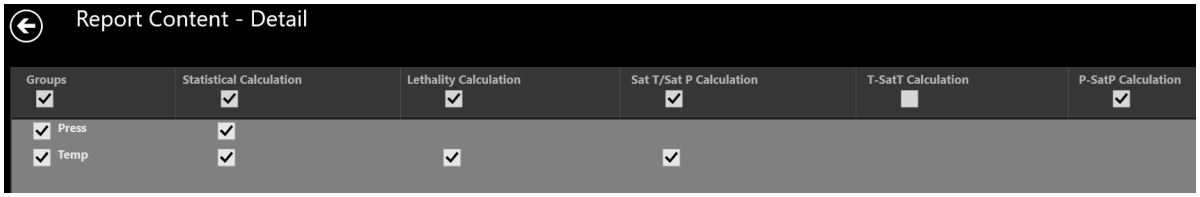


Figure 141: Detailed Report Content Screen

Audit Trail – Allows data duration of Audit Trail. Default is current date above.

Figure 142: Audit Trail Selection

Pass / Fail Criteria – Allows selection of which template is used for which groups.

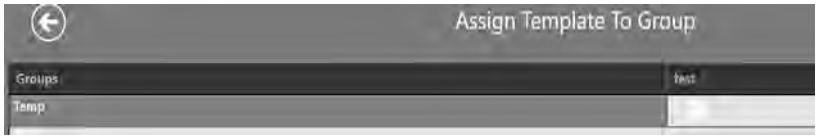


Figure 143: Setup Report Content Screen

Header / Footer:

The Header Footer allows customization that apply to all selected reports.

- User Comments can be added to the first and/or last page of the report.
- Header Footer Titles can be customized to be specific company needs.
- Footer signature lines can be selected to appear of first, last or all pages.
- System Messages can be selected or deselected to appear in reports.

Figure 144: Header / Footer Options

Print Rate:

The Print Rate applies only to the Detailed report and can be selected from the drop-down to be multiple of the Storage/Sample rate. All calculations in the reports are based on the Storage/Sample rate despite the print rate selected. (i.e. sample rate every 5 sec but print rate of 1 min). This can minimize the pages printed while still providing the granularity for the calculations and graphs.

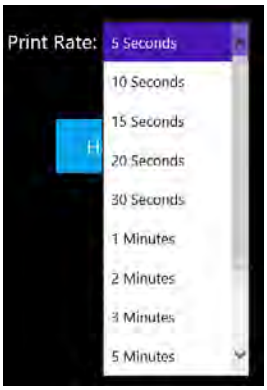


Figure 145: Print Rate

Press **Generate Report** to generate the respective report types.

11.9. Edit Parameters Screen

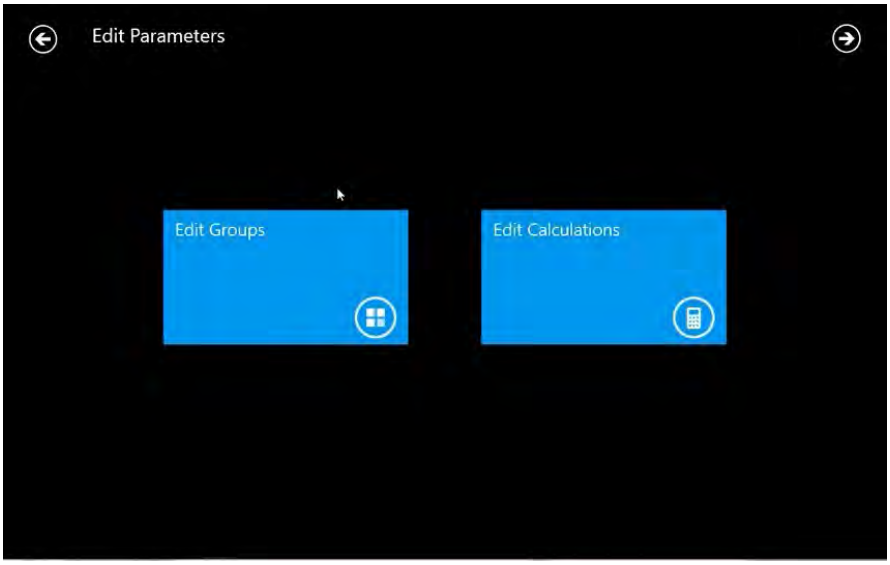


Figure 146: Edit Parameters Screen

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

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

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

11.10. Report Selection

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

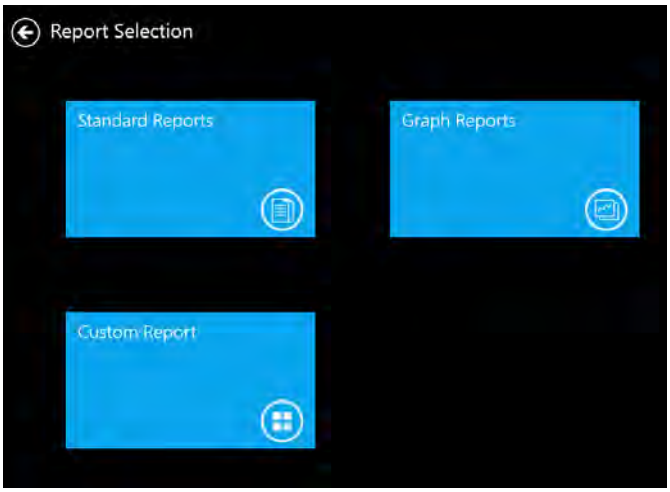


Figure 147: Report Selection Screen

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

The Qualification Detailed Report organizes information for each group by sensor data and type of calculation (lethality, statistical, saturated steam).

The Qualification Summary Report summarizes your study. It is possible to apply several calculations.

Interval Calculations report: Documents statistical calculations for defined intervals.

Pass-failed report: Analysis the data using a defined set of requirements.

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

Standard Report Options

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

Report Content: include/exclude a selected group and calculations from the reports.

Header/Footer: customize the header/footer, adding comments on the first and last page of the report and include/exclude system messages.

Select Print Rate: a drop-down to adjust the print sampling rate of the Detailed Report.

11.11. Grouping Sensors

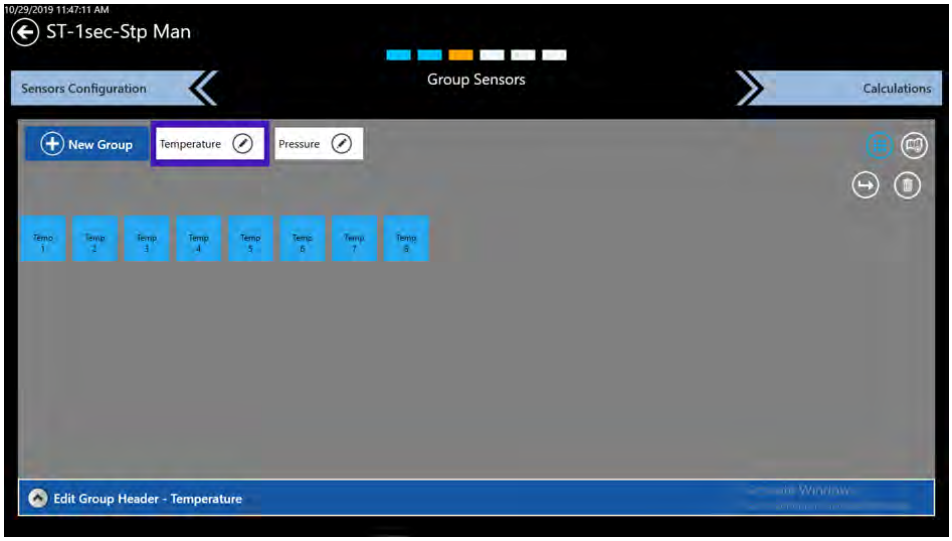


Figure 148: Group Sensors Screen

To assign sensors to groups:

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

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

The screen includes the following options:

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

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

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

Standard Report Types:

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

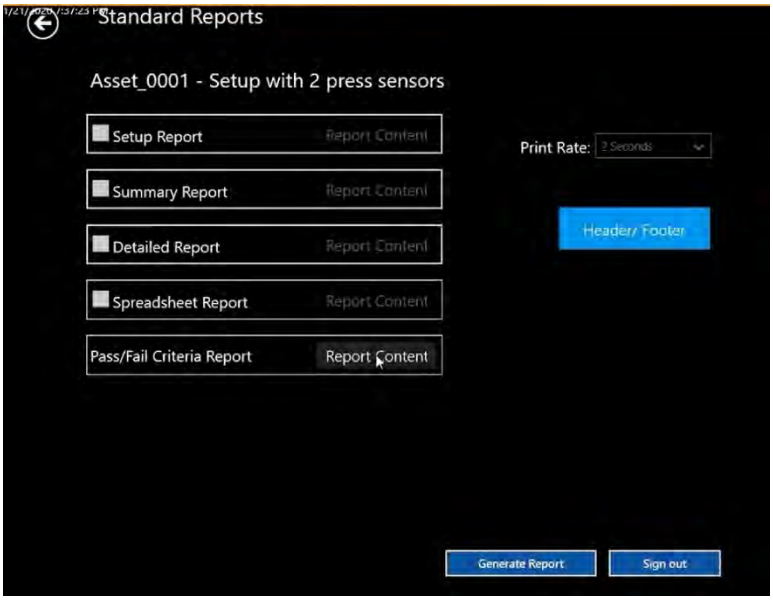


Figure 149: Report Options Screen

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

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

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

Figure 150: Report Content Selection - Detailed Report

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

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

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

Report Header / Footer Content

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

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

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

CSV-Export Report

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

For ease of use, all CSV files are 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.

[No content intended for this page]

Appendix A. Specifications

A.1 Kaye ValProbe RT System

A.1.1 List of Certified Countries

USA, Canada, European Union, and Puerto Rico.

A.1.2 Regulatory Compliance

CE, FCC and safety listed by Eurofins MET Labs, USA.

A.1.3 RF System Operating Frequency and Modulation

2.4 GHz unlicensed ISM band with modulation O-QPSK (IEEE 802.15.4 complaint).

A.1.4 RF Channels

15 RF channels (11th to 25th channels) - 2405 to 2475 MHz.

A.1.5 RF Network Topology and PAN ID (Network ID)

Star network topology and PAN ID from 0 to 9999.

A.1.6 Antenna Diversity

For higher signal reliability and robust RF link.

A.1.7 Data Rate and Data Encryption

250 kbps and AES 128 supported.

A.1.8 RF Range (Line of Sight and Outdoor)

Up to 150 meters.

A.1.9 Number of Loggers and Sensors Supported

Up to 25 Loggers and 50 sensors per Base Station.

A.1.10 Sensor Sampling Rate

1 sec to 10 minutes.

A.1.11 Data Transmission Rate

3 sec to 30 sec.

A.1.12 Sensor Samples Data Storage Capacity

Up to 100,000 samples per sensor in a study.

A.1.13 Optional Extendable Base Station Antenna

Optional Kayetenna for autoclave testing application - Length 2.5 and 5 meters.

A.2 Kaye ValProbe RT Base Station

A.2.1 Input Power and Adaptor Ratings

AC-DC adaptor input 100 to 240Vac 50/60Hz and output 12Vdc, 4A.

A.2.2 Installation Category

Pollution Degree 2, indoor use and maximum working altitude up to 2,000 meters.

A.2.3 Overvoltage Category and Electrical Safety Protection Class

Overvoltage category II and Electrical safety protection Class II.

A.2.4 Input DC Power On/Off Switch

Switch to turn on/off DC input power to Base Station.

A.2.5 Front Panel LED Indications and Buzzer

LED indications on front panel and internal buzzer for status monitoring and alarms.

A.2.6 Bath and IRTD Interface Ports

Bath port supports to interface all Kaye brand temperature baths and IRTD port to connect IRTD-400 temperature reference standard to run calibrations.

A.2.7 USB Port

USB port to connect USB storage thumb drive device to copy last ten raw study files.

A.2.8 Ethernet Communication Port

Ethernet RJ45 port to connect to LAN network or directly to console docking station.

A.2.9 Reset Switch to Reload Default Factory Settings

Push button reset switch to reset the base station to default factory settings.

A.2.10 Wakeup Magnet

Wakeup magnet (underneath LED panel) to wakeup Logger from shelf mode.

A.2.11 Batteries

Two 3.7V AA Lithium ion rechargeable batteries for 1-hour backup with three hour recharge time.

A.2.12 Unit Dimensions

190 mm (7.6”) x 130 mm (5.2”) x 55 mm (2.3”) (L x W x H).

A.2.13 Enclosure Material

Premium ABS plastic with FDA grade and conforming to safety UL 94-HB flammability rating.

A.2.14 Environmental Ratings

Operating temperature: 0 to 50°C.

Relative Humidity RH%: 0 to 90% RH, non-condensing.

Storage temperature: -40 to 60°C.

A.3 Kaye ValProbe RT Logger

A.3.1 Installation Category

Pollution Degree 2, indoor, and outdoor use, maximum working altitude up to 2,000 meters.

A.3.2 Overvoltage Category and Electrical Safety Protection Class

Overvoltage category I and electrical safety protection Class III.

A.3.3 Magnetic Switch

Magnetic switch to wake up a logger from shelf mode.

A.3.4 LED Indications

On board LED for diagnosis purpose.

A.3.5 Calibration

NVLAP accredited calibration along with user verification capability.

A.3.6 Real Time Clock Accuracy

15 sec per 24 hours (0.0174%).

Kaye ValProbe RT Temperature Logger: -85 to 140°C range.

Kaye ValProbe RT Pressure Temperature Logger: 0 to 140°C range.

Kaye ValProbe RT std Temperature Logger: -40 to 140°C range.

A.3.7 Sensing Elements

Temperature: Precision platinum RTD.

Pressure: piezo resistive mems.

A.3.8 Housing Material

Pharma grade PEEK (Polyetheretherketone) material housing and conforming to safety UL 94-V-0 flammability rating.

A.3.9 Logger Base Dimensions

Height 48mm (1.9”) / Diameter 36 mm (1.4”).

A.3.10 Ingress Protection

IP68 compliant.

A.3.11 Insulating Canister X2545

Size 149mm (5.87”) x 45mm (1.75”) (Length x diameter), weight 330grams (0.73 lb).

A.3.12 Battery

Field replaceable 3.6VDC ½ AA Lithium Thionyl Chloride primary battery.

A.3.13 Shelf Life

> ten years.

A.3.14 Battery Life

Battery life is affected by several factors, including sample rate, transmission rate, temperature, logger type and hours of use. Individual battery capacity can vary from one battery to another by up to 10%.

A.4 Kaye ValProbe RT Temperature Logger

A.4.1 Measurement Accuracy

±0.1°C from -85 to 140°C.

±0.25°C from 140 to 400°C for bendable models.

A.4.2 Body Environmental Ratings:

Temperature: -85 to 140°C.

Temperature: -85 to 360°C with canister model.

Humidity: 0 to 100%, condensing.

Pressure: 0 to 5 bar absolute.

A.4.3 Number of Input Channels

1, 2 and 5 channels (5ch logger sampling rate is min two secs).

A.4.4 Sensor Types and Measurement Range

Rigid, flexible, bendable and surface mount: -85 to 140°C.

Bendable Loggers: till 400°C (on request – please contact factory).

A.4.5 Sensor Lengths

Rigid 1.5, 3, 6 and 9” inches. Bendable 12, 24 and 36” inches. Flexible 40” inches.

Please contact factory for special lengths.

A.5 Kaye ValProbe RT Std Temperature Logger

A.5.1 Measurement Accuracy

±0.1°C from -40 to 140°C

±0.25°C from 140 to 400°C for bendable models

A.5.2 Body Environmental ratings:

Temperature: -40 to 140°C.

Temperature: -40 to 360°C with canister model.

Humidity: 0 to 100%, condensing.

Pressure: 0 to 5 bar absolute.

A.5.3 Number of Input Channels

1 and 2 channels.

A.5.4 Sensor Types and Measurement Range

Rigid and flexible: -40 to 140°C.

Bendable: -40 to 400°C.

A.5.5 Sensor Lengths

Rigid 1.5, 3, 6 and 9” inches. Bendable 12, 24 and 36” inches. Flexible 12, 24 and 36” inches. Please contact factory for special lengths.

A.6 Kaye ValProbe RT Pressure Temperature Logger

A.6.1 Measurement Accuracy

Temperature: ±0.1°C from 0 to 140°C.

Pressure: 0 to 5 bar absolute.

±25 mbar from 0 to 120°C.

±10 mbar from 120 to 135°C.

±25 mbar from 135 to 140°C.

Appendix B. Regulatory Compliance and Agency Approvals

Regulatory model numbers:

Kaye ValProbe RT Base Station Regulatory model number - RF3060

Kaye ValProbe RT Loggers Regulatory model number - RF3050

B.1 Electrical Safety Approvals:

Kaye ValProbe RT Product Electrical safety is certified by MET Laboratories, Inc. USA and product is complaint to IECEE CB-scheme for access into international market.

B.1.1 European Safety Certification

Low Voltage Directive 2014/35/EU.

EN 61010-1: 2010, Third Edition, Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: General requirements

EN 61010-2-030: 2010, First Edition, Safety requirements for electrical equipment for measurement, control and laboratory use; Part 2-30: Particular requirements for equipment having testing or measurement circuits

B.1.2 UL USA Safety Certification

E114957

UL 61010-1: Third Edition, Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: General requirements

UL 61010-2-030: Second Edition, Safety requirements for electrical equipment for measurement, control and laboratory use; Part 2-30: Particular requirements for equipment having testing or measurement circuits.

B.1.3 Canada Safety Certification

E114957

CAN/CSA 22.2 No. 61010-1: Third Edition, Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: General requirements.

CAN/CSA 22.2 No. 61010-2-030: First Edition Safety requirements for electrical equipment for measurement, control and laboratory use; Part 2-30: Particular requirements for equipment having testing or measurement circuits.

B.1.4 IEC and CB Scheme Certification

IEC 61010-1: Third Edition Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: general requirements.

IEC 61010-2-030: 2010, First Edition, Safety requirements for electrical equipment for measurement, control and laboratory use; Part 2-30: Particular requirements for equipment having testing or measurement circuits.

B.2 Radio and EMC Certification Approvals:

B.2.1 USA FCC and Canada ISED

Innovation, Science and
Economic Development Canada

Kaye ValProbe RT is certified for USA FCC and Canada ISED Radio and EMC standards listed below:

47 CFR, FCC Part 15 Subpart C §15.247; General technical requirements of operation of unlicensed Radio frequency Intentional radiator devices operation within the bands 902–928 MHz, 2400–2483.5 MHz, and 5725–5850 MHz.

47 CFR, FCC Part 2 Subpart J §2.1091: Radiofrequency radiation exposure evaluation for mobile devices > 20 cm separation distance to human body.

Canada ISED RSS-247 Issue 2, February 2017: Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and License-Exempt Local Area Network (LE-LAN) Devices.

Canada ISED RSS-102, Issue 5, March 2015: Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands).

Canada ISED RSS-Gen, Issue-5, Amendment 1, 2019-03; General Requirements for Compliance of Radio Apparatus.

47 CFR, FCC Part 15 Subpart B §15.107; Conducted emission limits for unintentional radiators.

47 CFR, FCC Part 15 Subpart B §15.109; Radiated emission limits for unintentional radiators.

ANSI/IEEE C63.4:2014; American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz.

Canada ICES-003 — Information Technology Equipment (Including Digital Apparatus) — Limits and Methods of Measurement.

B.2.2 European Radio and EMC Certification Approvals:

Kaye ValProbe RT is certified to Europe Radio and EMC standards listed below:

ETSI EN 300 328 V2.1.1:2016-11 Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques - RED (2014/53/EU).

ETSI EN 301 489-1 V2.2.0:2017-03 Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements - RED (2014/53/EU).

ETSI EN 301 489-17 V3.2.0:2017-03 Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems - RED (2014/53/EU).

EN 62311:2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz) - RED (2014/53/EU) and LVD (2014/35/EU).

EN 61326-1:2013 EMC requirements for Electrical equipment for measurement, control and laboratory use; Part 1: General requirements – EMC directive 2014/30/EU.

IEC 61326-1:2012 EMC requirements for Electrical equipment for measurement, control and laboratory use; Part 1: General requirements - ISO/IEC Directives, Part 2.

B.3 Ingress Protection for Kaye ValProbe RT Logger

Kaye ValProbe RT Logger is certified to EN60259 / IP68 Ingress Protection standard.

IP68 Ingress Protection (IP code): Degrees of protection provided by enclosures as per EN 60529:1991+A1:2000+A2:2013 standard.

IP6X: Protection against access to hazardous and solid foreign objects and dust proof test.

IPX8: Protection against continuous immersion in water test.

B.4 United States FDA 21 CFR Part 11 Complaint Software Application

Kaye ValProbe RT product software application is complaint to US FDA 21 CFR Part 11 regulatory standard for electronic records and electronic signatures.

US FDA 21 CFR Part11; United States Food and Drug Administration, Department of Health and Human Services – General Provisions; Electronic Records; Electronic Signatures.

B.5 Transportation Regulations

Batteries: Base Station shipping package has Lithium ion rechargeable batteries and Logger shipping package has Lithium primary battery. Both shipping packages are classified as non-restricted (can be shipped by common carrier without special requirements). Batteries should be separated from each other during shipment to prevent shorting.

Magnets: Base Station shipping package has magnets and packaging is compliant to air shipment as per IATA dangerous goods regulations as per UN 2807 magnetized material standard under packing instruction 953 guidelines.

B.6 FCC Compliance Statement

FCC §15.19 Labelling requirements:

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.

FCC §15.21 Information to user: Changes or modifications that have not been explicitly approved by the body responsible for the compliance with the requirements may void the authorization of the user to operate the device.

Kaye ValProbe RT Base Station **FCC ID: 2AJQZ-VPRT-BS1**

Kaye ValProbe RT Logger **FCC ID: 2AJQZ-VPRT-L1**

FCC 47 CFR §2.1091 RF Radiation Exposure statement:

This product complies with FCC 47 CFR §2.1091, Canada ISED RSS-102 and European committee for Electrotechnical standardization (CENELEC) EN 62311:2008 limits for exposure to radio frequency.

⚠ **WARNING:** To satisfy FCC RF exposure requirements for mobile transmitting devices, a separation distance of 20 cm or more should be maintained between the antenna of this device and persons during device operation. To ensure compliance, operations at closer than this distance is not recommended. The antenna used for this transmitter must not be co-located in conjunction with any other antenna or transmitter.

B.7 ISED Canada Compliance Statement

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference, and

2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1.L'appareil ne doit pas produire de brouillage;

2.L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Kaye ValProbe RT Base Station **Canada IC: 25680-VPRTBS1**

Kaye ValProbe RT Logger **Canada IC: 25680-VPRTL1**

B.8 EU Compliance Statement:

This compliance statement is based on information received from material suppliers and certification testing undertaken at test house supporting documents are available and can be disclosed to the competent authority on request.

⚠ This marking indicates that the user should read all included documentation before use. Retain this supplement for future reference.

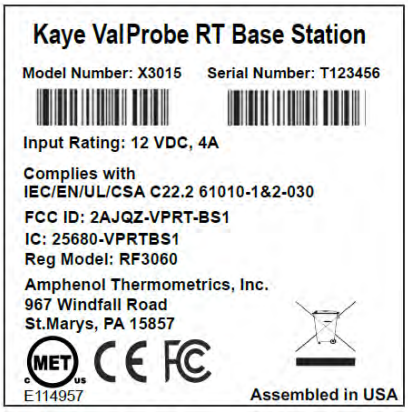
Battery recycling information

This product contains Lithium-ion (Li-ion) batteries. When the battery reaches to end of useful life, the used battery should be disposed of by a qualified recycler or hazardous material handler. Do not mix the batteries with solid waste stream. Contact your Amphenol service center for recycling or disposal information.

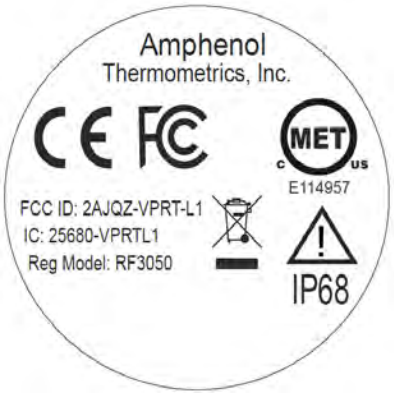
B.9

Product Certification Labels

B.9.1 Kaye ValProbe RT Base Station Label



B.9.2 Kaye ValProbe RT Logger Label



Appendix C. Environnemental Compliance

This appendix contains information on the following topics:

- WEEE Directive (see Section C.1 on page 146)
- Battery Disposal (see Section C.2 on page 146)

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

Amphenol Thermometrics, Inc. is a participant in Europe's Waste Electrical and Electronic Equipment (WEEE) take-back initiative, directive 2012/19/EU.

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.

Contact your Amphenol Thermometrics, Inc. team for additional take-back information.

C.2 Battery Disposal

This product contains a battery that cannot be disposed of as unsorted municipal waste in the European Union. See the product documentation for specific battery information. The battery is marked with this symbol, which may include lettering to indicate cadmium (Cd), lead (Pb), or mercury (Hg). For proper recycling return the battery to your supplier or to a designated collection point.

C.2.1 What do the Markings Mean?

Batteries and accumulators must be marked (either on the battery or accumulator or on its packaging, depending on size) with the separate collection symbol. In addition, the marking must include the chemical symbols of specific levels of toxic metals as follows:

- Cadmium (Cd) over 0.002%
- Lead (Pb) over 0.004%
- Mercury (Hg) over 0.0005%

C.2.2 The Risks and Your Role in Reducing Them

Your participation is an important part of the effort to minimize the impact of batteries and accumulators on the environment and on human health. For proper recycling you can return this product or the batteries or accumulators it contains to your supplier or to a designated collection point.

Some batteries or accumulators contain toxic metals that pose serious risks to human health and to the environment. When required, the product marking includes chemical symbols that indicate the presence toxic metals: Pb for lead, Hg for mercury, and Cd for cadmium.

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

Appendix D. Warranty and Returns:

Each instrument manufactured by Amphenol Advanced Sensors. is warranted to be free from defects in material and workmanship. Liability under this warranty is limited to restoring the instrument to normal operation or replacing the instrument, at the sole discretion of Amphenol Advanced Sensors. Fuses and batteries are specifically excluded from any liability. This warranty is effective from the date of delivery to the original purchaser. If Amphenol Advanced Sensors determines that the equipment was defective, the warranty period is:

One year for general electronic failures of the instrument one year for mechanical failures of the sensor

If Amphenol Advanced Sensors determines that the equipment was damaged by misuse, improper installation, the use of unauthorized replacement parts, or operating conditions outside the guidelines specified by Amphenol Advanced Sensors the repairs are not covered under this warranty.

The warranties set forth herein are exclusive and are in lieu of all other warranties whether statutory, express or implied (including warranties or merchantability and fitness for a particular purpose, and warranties arising from course of dealing or usage or trade).

Return Policy

If an Amphenol Advanced Sensors instrument malfunctions within the warranty period, the following procedure must be completed:

1. Notify Amphenol Advanced Sensors, giving full details of the problem, and provide the model number and serial number of the instrument. If the nature of the problem indicates the need for factory service, Amphenol Advanced Sensors will issue a RETURN AUTHORIZATION number (RA), and shipping instructions for the return of the instrument to a service center will be provided.

2. If Amphenol Advanced Sensors instructs you to send your instrument to a service center, it must be shipped prepaid to the authorized repair station indicated in the shipping instructions.

3. Upon receipt, Amphenol Advanced Sensors will evaluate the instrument to determine the cause of the malfunction.

Then, one of the following courses of action will then be taken:

If the damage <u>is</u> covered under the terms of the warranty, the instrument will be repaired at no cost to the owner and returned.

If Amphenol Advanced Sensors determines that the damage <u>is not</u> covered under the terms of the warranty, or if the warranty has expired, an estimate for the cost of the repairs at standard rates will be provided. Upon receipt of the owner’s approval to proceed, the instrument will be repaired and returned.

Appendix E. Service Information

We operate a global network of service centers and a field service organization to provide customer support for repair, returns, calibrations, technical support, evaluation and spare parts.

Americas

Amphenol Advanced Sensors
967 Windfall Rd
St. Mary's PA 15857
USA

Phone: 814-834-9140
Fax: 814-781-7969

Europe

Amphenol Advanced Sensors Germany GmbH
Sinsheimerstr. 6
75179 Pforzheim
Germany

Tel.: +49(0) 7231 14335 0
Fax: +49(0) 7231 14335 29

China

Amphenol (Changzhou) Connector Systems Co., Ltd.
Building 10, Jinton Industrial Park,
No. 8 Xihu Road, Wujin High-Tech Development Zone,
Changzhou, Jiangsu - 213164, China

Tel.: +86-519-88311899

India

Amphenol Interconnect India Pvt Ltd.,
Plot no.6, Survey No.64, Software Units layout,
MAHAVEER TECHNO PARK, Hitech City,
Madhapur,
Hyderabad, Telangana – 500081, India

Tel.: +91 40 33147100

Appendix E. Warranty and Disclaimer:

The information in this document is based on our current tests, knowledge, and experience. Because of the effect of possible influences in an application of the product, they do not exempt the user from their own test, checks, and trials. A guarantee of certain properties or a guarantee for the proper suitability of the product for a specific, especially permanent application cannot be derived from our data. Liability is therefore excluded to that extent permitted by law. Any proprietary rights of third parties as well as existing laws and regulations must be observed by the recipient of the product on his own responsibility.

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