



Validation

Kaye ValProbe® RT

User Manual



M5630-EN Rev. D
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Kaye ValProbe[®] RT

Process Monitoring and Validation System

User Manual

M5630-EN Rev. D

October 2022

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Chapter 1. Kaye ValProbe® RT System	2
1.1. Introduction.....	2
1.2. Operational Description.....	3
1.3. Unpacking.....	4
1.4. Safety Information	5
Chapter 2. Kaye ValProbe RT Hardware	6
2.1. Kaye ValProbe RT Loggers	6
2.1.1. Temperature RT Loggers	8
2.1.2. Pressure/Temperature Loggers.....	12
2.1.3. Humidity Loggers	13
2.1.4. Insulating Canister for High Temperatures	14
2.1.5. Inserting a Logger into an Insulating Canister.....	14
2.1.6. Measurement Range and Accuracy	16
2.2. Data Collection	16
2.3. Logger Battery.....	17
2.3.1. Battery Estimator	18
2.3.2. Battery Replacement	19
2.4. Kaye ValProbe RT Base Station.....	23
2.4.1. Base Station Overview	23
2.4.2. Base Station IRTD / Bath Connections	24
2.4.3. Base Station Battery Backup.....	24
2.4.4. Base Station LED Indications.....	25
2.4.5. Base Station Wakeup Magnet.....	28
2.4.6. Wakeup Device.....	28
2.4.7. Kayetenna - Extended Antenna Cable.....	30
2.5. ValProbe RT Console / Docking Station.....	30
Chapter 3. ValProbe RT System Connections	32
3.1. Direct Ethernet Connection – Static IP	32

3.2.	Network Ethernet Connection – DHCP.....	35
3.3.	Resetting a Base Station.....	37
3.3.1.	Initiating a Factory Reset.....	37
Chapter 4.	Initial ValProbe RT Software Setup	38
4.1.	Introduction.....	38
4.2.	Initial Log in as a Default System Administrator.....	39
4.2.1.	Setting Up Initial Administrator using Local Security and Policies.....	40
4.2.2.	Setting Up Initial Administrator using Active Director Security and Policies.....	42
4.2.3.	Adding / Managing User Accounts – Local Security	45
4.2.4.	Deleting and Disabling Local Security User Accounts.....	47
4.2.5.	Local Security - One Time Emergency Access.....	48
4.2.6.	Adding / Managing User Accounts – Active Directory™*	48
4.3.	Setting Preferences.....	50
4.4.	Hardware Maintenance.....	51
4.5.	Online Help.....	54
Chapter 5.	File Management.....	55
5.1.	Overview.....	55
5.1.1.	Sync Out	56
5.1.2.	Sync In	57
5.1.3.	Archive	57
5.1.4.	ValProbe RT Convert.....	58
5.2.	Using Mapped Drives for Sync Functions	58
Chapter 6.	Equipment.....	60
6.1.	Equipment Assets	60
6.1.1.	Manually Adding Equipment Assets.....	61
6.1.2.	Equipment Contents	61
6.2.	Calibration Reminder	62
Chapter 7.	Defining Assets.....	63

7.1. Overview.....	63
7.2. Asset Details Screen.....	64
7.3. Creating A New Asset.....	69
Chapter 8. Defining Study Setups	70
8.1. Initiating a New Setup	70
8.2. Define Setup Screen.....	71
8.3. Sensors Configuration Screen.....	72
8.4. Understanding Groups.....	74
8.5. Assigning Sensors to Groups	75
8.6. Specifying Calculations.....	77
8.7. Specifying Qualification Parameters.....	79
8.8. Reviewing and Saving a Setup.....	80
8.9. Modify an Existing Setup.....	81
Chapter 9. Qualification Study	82
9.1. Overview.....	82
9.2. Initiating a Qualification Study.....	83
9.2.1. Select a Setup File.....	83
9.2.2. Connecting to Base Station	84
9.2.3. Selecting and Connecting to Loggers	84
9.2.4. Re-reading Loggers	86
9.2.5. Battery Estimate.....	86
9.2.6. Mapping Sensors	87
9.1. Auto Mapping Sensors.....	88
9.1. Real Time Off Study.....	89
9.2. Program Loggers.....	92
9.3. Qualification Study Start / Stop Conditions.....	93
9.4. Viewing Qualification Real-Time Displays.....	94
9.4.1. List View.....	95

9.4.2.	Graph View	95
9.4.3.	Layout View.....	96
9.4.4.	History View	97
Chapter 10.	Live Monitoring Mode.....	98
10.1.	Initiating Monitor Mode	98
10.2.	Live Monitoring Displays	99
10.2.1.	Hardware Communications Connections	100
Chapter 11.	Sensor Verification	102
11.1.	Introduction and Overview.....	102
11.1.1.	Defining Verification Strategy and Criteria.....	103
11.1.2.	Selecting the Proper Calibration Bath – Uncertainty (Temperature)	103
11.2.	Creating a Verification Setup.....	105
11.2.1.	Temperature Verification.....	106
11.2.2.	Humidity Verification	107
11.3.	Loading a Temperature Verification Setup	108
11.4.	Loading a Humidity Verification Setup.....	110
11.5.	Selecting Sensors.....	111
11.6.	Running a Sensor Verification.....	113
11.7.	Reasons for Verification Failure	118
11.8.	Verification Report	118
Chapter 12.	Qualification Reports	119
12.1.	Reports Overview	119
12.2.	Qualification Detailed Report.....	121
12.3.	Qualification Summary Report.....	122
12.4.	Graph Reports	123
12.5.	Audit Trail Report.....	127
12.6.	Spreadsheet Report	129
12.7.	Pass/Fail Report.....	130

12.8.	Generating Qualification Reports.....	138
12.8.1.	Selecting a Qualification File.....	138
12.8.2.	Mark Cycles.....	138
12.8.3.	Edit Parameters.....	141
12.8.4.	Report Selection.....	144
Appendix A. Specifications		148
A.1	Kaye ValProbe RT System	148
A.2	Kaye ValProbe RT Base Station.....	149
A.3	Kaye ValProbe RT Logger	150
Appendix B. Regulatory Compliance and Agency Approvals		154
B.1	Electrical Safety Approvals:	154
B.2	Radio and EMC Certification Approvals:	155
B.3	Ingress Protection for Kaye ValProbe RT Logger	157
B.4	United States FDA 21 CFR Part 11 Complaint Software Application	157
B.5	Transportation Regulations.....	158
B.6	FCC Compliance Statement	158
B.7	ISED Canada Compliance Statement	159
B.8	EU Compliance Statement:.....	159
B.9	Product Certification Labels.....	160
B.10	China Compliance Statement.....	161
B.11	Australia Compliance Statement.....	162
Appendix C. Environmental Compliance.....		163
C.1	Waste Electrical and Electronic Equipment (WEEE) Directive.....	163
C.2	Battery Disposal	163
Appendix D. Warranty and Returns:.....		165
Appendix E. Service Information		166
Appendix F. Warranty and Disclaimer:		166

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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 system connections
- *Chapter 4* provides instructions for initial software setup.
- *Chapter 5* provides instructions for managing system files.
- *Chapter 6* provides instructions for entering Kaye equipment into the system.
- *Chapter 7* provides instructions for entering assets into the system.
- *Chapter 8* provides instructions for creating setups.
- *Chapter 9* provides instructions for performing a qualification study.
- *Chapter 10* provides instructions for displaying live data on the Console.
- *Chapter 11* provides instructions on verifying sensors.
- *Chapter 12* provides instructions for qualification reports.

*Active Directory™ is a registered trademark of the Microsoft Cooperation.

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 is difficult to access and install. These applications include steam sterilizers, dry heat, ovens, incubators, stability and temperature chambers, freezers and freeze dryers, and warehouses.

A complete Kaye ValProbe RT package, includes:

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

Note: The *ValProbe RT* product was developed to operate on dedicated networks and should always be used on networks without Internet access. Furthermore, the *ValProbe RT* product does not require an Internet connection to run its functionalities, as it can function independent of the Internet in either Ethernet or USB mode while in standalone operation. The product should be connected to non-Internet based LAN networks to avoid any cyber security issues.

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. 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 their base, which is activated by using the Wakeup device or the magnet inside the Base Station display to wake the Logger from Shelf mode before 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. As an additional option, connect the Base Station and Console / Docking Station to a network utilizing dynamic DHCP address, DHCP addresses 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 a real-time display. All commands and action generated at the Console are transmitted to the Base Station and 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	Accessories	Qty
1	Kaye Validation Console with docking station and power adapter (required)	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.

Utilisez **UNIQUEMENT** les piles secondaires (rechargeables) au lithium 3,7 V Kaye #200-166 à l'intérieur de la station de base. L'insertion d'une batterie non rechargeable peut provoquer une surchauffe et une 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! **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.

ATTENTION ! Utilisez cet instrument comme indiqué dans le présent manuel. La protection fournie par l'équipement peut être compromise si l'équipement est utilisé d'une manière non spécifiée par Kaye.

▲ DANGER Insertion of non-rechargeable battery may cause over-heating and explosion.
L'insertion d'une batterie non rechargeable peut provoquer un surchauffage et une explosion.

Chapter 2. Kaye ValProbe RT Hardware

2.1. Kaye ValProbe RT Loggers

The ValProbe RT loggers measure three critical measurands and in eight different hardware configurations:

- 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, Loggers immersed in cleaning fluid or detergents, or used in harsh environments. Loggers store study setups 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.

Do not heat the Humidity/Temperature Logger with RH sensor above 70°C .

ATTENTION ! La substitution de composants peut endommager l'enregistreur.

Ne chauffez pas l'enregistreur de température à plus de 140°C .

Ne pas chauffer l'enregistreur de pression/température à plus de 140°C .

N'immergez pas l'enregistreur dans de l'huile, un liquide de nettoyage ou des détergents pendant plus de deux heures à des températures inférieures à -20°C. Après deux heures, le joint torique peut se dégrader et doit être remplacé.

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.

ATTENTION ! Tout Logger tombé d'un mètre ou plus est susceptible de donner des lectures de température inexactes ; un Logger tombé qui donne une lecture inexacte de la température de surface n'est pas considéré comme un défaut de fabrication et n'est pas couvert par la garantie.

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 Temperature 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	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
11	Kaye ValProbe RT Std Single Flexible Temperature Logger	XSFVP-C-L-T-RT	
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

14	Kaye ValProbe RT G Dual Bendable Temperature Logger	XGDBVP-La-Lb-RT	T= Tip configuration pointed as (P) and round as R & Flat as (G) D= dual sensor
15	Kaye ValProbe RT CR Rigid Temperature Logger	X2535-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

Multi Type Loggers



Figure 10: Dual Flexible



Figure 11: Dual Bendable



Figure 12: Five Flexible

The ValProbe RT temperature Loggers provide a single solution for a variety of applications, such as steam, dry heat, ovens, incubators, stability and temperature chambers, warehouses, cryogenic chambers, lyophilizers, ultralow freezers, and other ultra-low temperature applications. Users can perform periodic 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 tip 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, a range of 360°C is achievable. Sensor tips are provided in 12", 18", 24", 36" and 48". 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 which 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 one inch of the Logger body or one 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 tip 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

2.1.2. Pressure/Temperature Loggers

The ValProbe RT Pressure/Temperature Logger (X2532-RT) 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

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

ATTENTION! N'insérez pas d'objets dans le haut de l'enregistreur de pression. Cela pourrait endommager le diaphragme de l'enregistreur et invalider les relevés de pression.

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

2.1.3. Humidity Loggers

The Kaye ValProbe T/H Logger (model X2520) utilizes a field replaceable digital sensor to accurately measure Temperature and Humidity from 0C° to 70C° and 15% to 95% relative humidity. The accuracy is $\pm 0.15\text{C}^\circ$ for temperature and up to $\pm 2\%$ accuracy. The Humidity logger includes a removable filter cap and a one-meter extension cable for verifying the temperature sensor inside a dry block.

Note: When performing user verification, first complete the temperature calibration/verification and then the humidity verification. Ensure the Logger is allowed time to dry following the temperature verification. The verification procedures are described in the online help included with the Kaye ValProbe software.



Figure 19: Humidity Loggers

2.1.4. Insulating Canister for High Temperatures

The Kaye ValProbe RT Insulating Canister (Part Number X2545) enables operation of bendable Temperature Loggers from up to 400°C, by ensuring that the Logger base does not exceed 140°C.



Figure 20: 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.

ATTENTION ! N'utilisez le boîtier isolant que dans des endroits non dangereux.

2.1.5. 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 21: 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	40 minutes
300°C	60 minutes
250°C	90 minutes
200°C	120 minutes
175°C	180 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.

Si la Logger et la boîte isolante restent à une température élevée plus longtemps que le temps maximal indiqué dans la table, la base de Logger peut être soumise à des températures supérieures à 140°C, ce qui peut endommager la batterie de chlorure de thionyl au lithium. Cela peut entraîner une fuite d'électrolyte.

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.

Dans le cas où la base Logger a été soumise à des températures supérieures à 140°C, des lunettes de sécurité et des gants de protection doivent être portés avant de tenter de servir le Logger pour éviter tout contact électrolyse avec les yeux et la peau.

Si un contact cutané se produit, rincer à l'eau froide pendant au moins 15 minutes. Si les symptômes persistent, consultez un médecin.

Si un contact visuel se produit, rincer à l'eau froide pendant au moins 15 minutes et consulter un médecin.

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.

2.1.6. 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
<i>Temperature Loggers</i>	
-85°C to 140°C	±0.10°C
<i>Bendable Temperature Loggers with Insulating Canister</i>	
140°C to 400°C	±0.25°C
<i>Pressure Loggers</i>	
0°C to 120°C	±25 mb
120°C to 135°C	±10 mb
135°C to 140°C	±25 mb
<i>Humidity Logger</i>	
15% to 95% RH (non-condensing)	±2% RH at 25°C to 40°C
0°C to 70°C	±0.15°C

2.2. Data Collection

Each Kaye ValProbe RT Logger collects and stores up to 100,000 data samples per sensor in onboard Logger 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 may be programmed to start data collection manually when the Qualification is started 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, if a study is not started, Loggers are returned to sleep / shelf mode.
- Cycle Time does not have a duration limit, cycle time duration depends on the sampling rate and number of samples. The maximum number of samples collected are 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 140°C. For measuring temperatures above 140°C, a special probe and insulating canister are required to keep the temperature of the Logger below 140°C for the duration of the study (See Section 2.1.4).

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.

ATTENTION ! Pour éviter tout allumage dans une atmosphère dangereuse, la batterie doit être changée uniquement dans une zone connue pour être non dangereuse.

Ne pas chauffer la pile à plus de 140°C. Pour mesurer des températures supérieures à 140°C, une sonde spéciale et un conteneur isolant sont nécessaires pour maintenir la température du Logger en dessous de 140°C pendant toute la durée de l'étude. (Voir Section 2.1.4).

Utilisez uniquement la batterie spécifiée en usine (référence M3205) dans l'enregistreur Kaye ValProbe RT. L'utilisation de batteries non spécifiées annulera la garantie et peut endommager le Logger et/ou causer des brûlures à l'opérateur. Des kits de batteries de remplacement sont disponibles auprès de Kaye.

Les batteries doivent être mises au rebut conformément aux réglementations locales, nationales et fédérales.

Before starting a Qualification in the Select Logger screen, a Battery Estimate button displays, that if selected, navigates to a screen to enter the min and max temperature of the process and the duration of time. Once entered the estimator displays the battery life remaining as well as the estimated usage during the Qualification. This provides assurances that you have ample battery life remaining for the study.

2.3.1. Battery Estimator

Logger SN	Logger Type	Description	Active %	Required %	Remaining %	Sufficient Energy	Below Threshold
ZA58	Standard	1 Ch Temp-Rigid	91	0.05	90.95	✓	Proceed

Figure 22: Battery Estimation Screen

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 replacing 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 read once a new battery is installed.
- If a battery is fully drained after a study is complete, all study data is readable once a new battery is installed.
- If changing the battery before a study is started, 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.

2.3.2. Battery Replacement

Kaye recommends replacing 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.*

ATTENTION ! Pour garantir que le Logger conserve son étanchéité à l'eau et à la pression, une fine couche de graisse a été appliquée sur le joint torique. La graisse est du KRYTOX GL-203, et des pratiques de manipulation et de stockage sûres doivent être suivies. KRYTOX est une marque déposée de DuPont Chemicals. Les informations sur les données de sécurité sont disponibles auprès de 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.

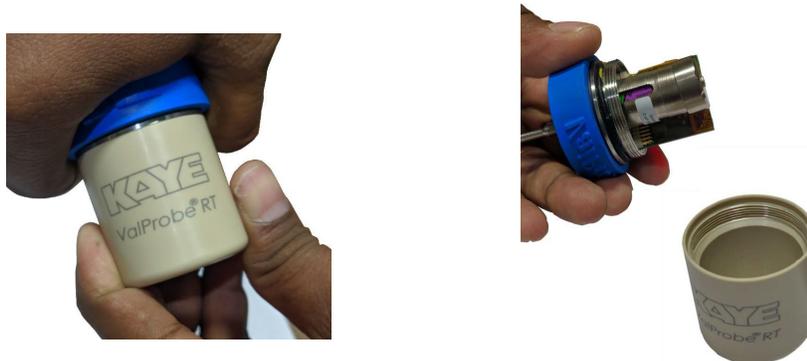


Figure 23: Open Logger

- 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 24: Remove the Old Battery and O-ring

2. Install the Replacement O-ring and Battery:

Whenever opening a Logger, 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 140°C , use the orange (silicone material) O-ring.
- Before installing a new O-ring, 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.

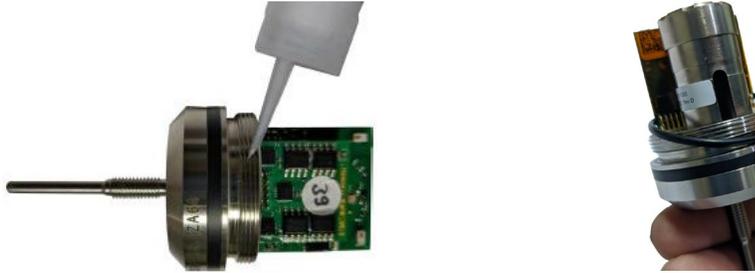


Figure 25: Apply Grease and Replace O-ring

- 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 26: Insert New Battery / Verify LED

Important: If 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 changing the battery in a Logger, 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.

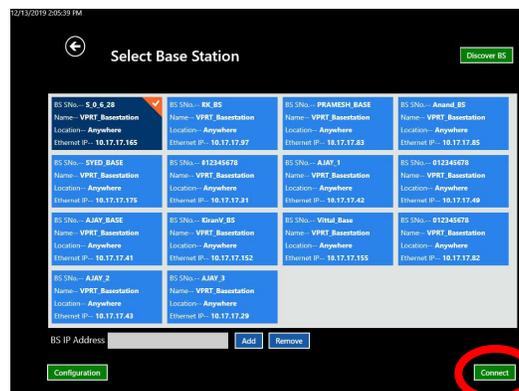


Figure 27: Connect Button

- 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**.

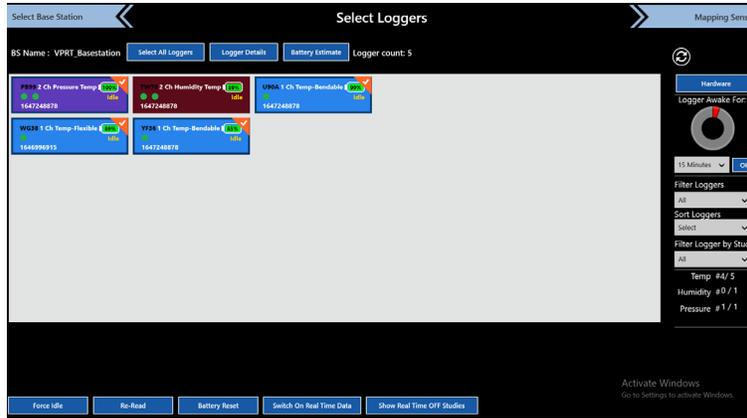


Figure 28: Select Loggers

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

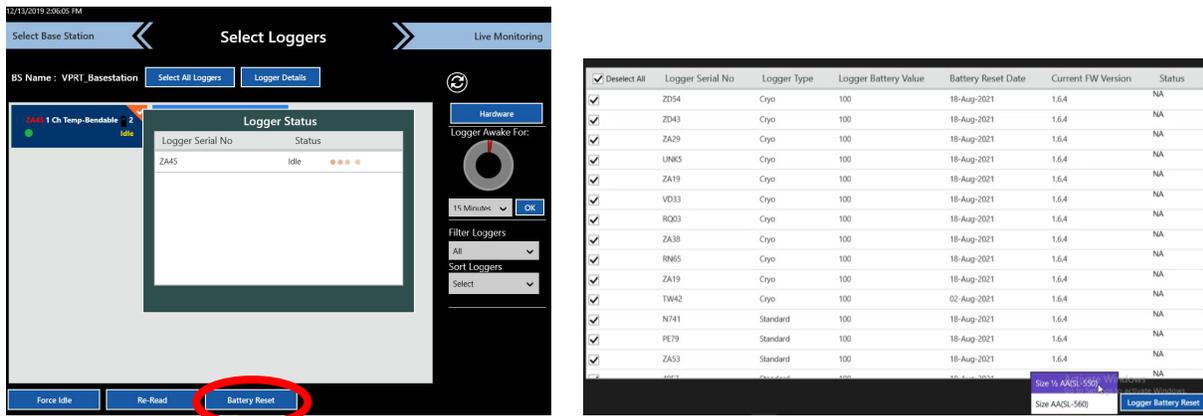


Figure 29: Logger Battery Reset

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

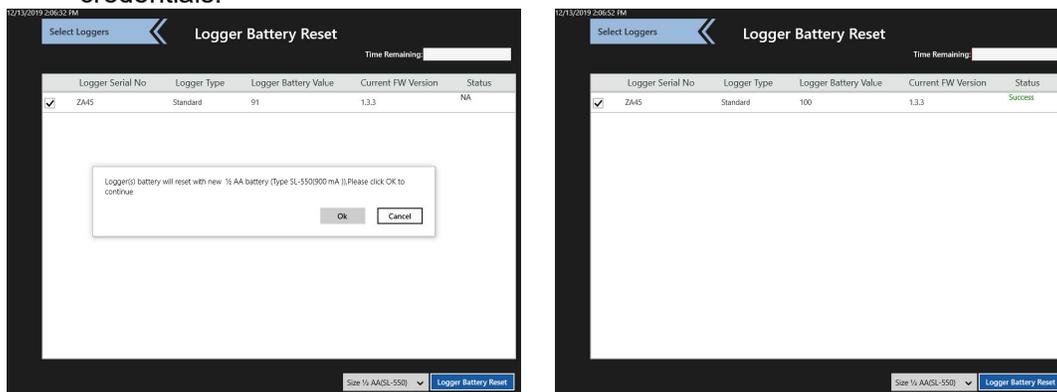


Figure 30: Logger Battery Reset Prompt

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

2.4. Kaye 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 31: ValProbe RT Base Station

CAUTION! 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.

ATTENTION !Utilisez uniquement l'alimentation Kaye (Kaye #201-3006) fournie avec votre ValProbe RT. L'utilisation d'alimentation non-usine peut endommager l'équipement et annuler votre garantie.

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 32: Base Station Connections

2.4.2. Base Station IRTD / Bath Connections

Located at the rear of the Base Station, IRTD and Kaye References connections are used for Sensor Verification. Using the supplied cables, connect the IRTD and bath to the appropriately marked connectors. Cables and connections are backward compatible to all Kaye baths, dry blocks, and IRTDs. The ValProbe RT software provides fully automated sensor verification of ValProbe RT Loggers (See Chapter 11 for details on Sensor Verification).



Figure 33: IRTD / Kaye Bath Connections

2.4.3. Base Station Battery Backup

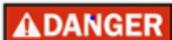
Kaye ValProbe RT Base Station has battery backup for up to 60 minutes. The Base Station is powered by two 3.7V AA size rechargeable Lithium batteries. The Base Station has a built-in charger, so batteries are charged automatically when there is a main supply available to the Base Station. To replace 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 the figure below. Do not power on the Base Station until the compartment cover is properly secured.



Figure 34: ValProbe RT Base Station Battery Compartment

CAUTION! 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.

ATTENTION ! Utilisez UNIQUEMENT les piles secondaires (rechargeables) au lithium 3,7 V de Kaye #200-166. L'utilisation de toute autre pile annule les performances indiquées, car les piles Kaye #200-166 3,7 V sont les seules à avoir été testées et acceptées.



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

L'insertion d'une batterie non rechargeable peut provoquer une surchauffe et une explosion.

2.4.4. Base Station LED Indications

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



Figure 35: Base Station Status Panel

PWR Switch	POWER	PRE-CONDITION	CONDITION	LEDs				BUZZER	BRIEF	REMARKS	
				COMMUNICATION LED	STATUS LED	BATTERY CHARGE LED	POWER LED				
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	
										all leds are blinking in RED to indicate system error (CRITICAL ERROR) and User should turn OFF the BaseStation. Fault conditions to be defined.	
									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	
				AC or BATT	SBC is active	Study in progress					
	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 retrieved from all loggers									Study 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 study 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 to be 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 Complete, Green Stable (Batteries available)		
	Battery							AC available, Switch is ON, Battery Voltage not detected (0 Volts) (Batteries NOT available)			
						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		

Figure 36: Base Station LED Indication Chart

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 is used to wake up Loggers from sleep mode prior to connection and execution of a Qualification or Verification. 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. In addition to the Wakeup device the Base Station can also be used to wake up loggers.



Figure 37: Wakeup Magnet

2.4.6. Wakeup Device



Figure 38: 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 behind the Kaye logo. Keep the Wakeup device away from magnetic sensitive parts. To wake a Logger from sleep mode swipe near the Kaye logo on the Wakeup Device.

CAUTION! The Base Station and Wakeup device contain magnets and may affect devices.

Attention ! La station de base et le dispositif de réveil contiennent des aimants et peuvent affecter les appareils.



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.

Avertissement concernant les stimulateurs cardiaques : Les aimants à l'intérieur de la station de base et de l'appareil de réveil peuvent causer des interférences avec les appareils médicaux situés à proximité, tels que les stimulateurs cardiaques, les défibrillateurs cardiaques implantés, etc. Ne transportez pas et n'utilisez pas la station de base ou l'appareil de réveil à proximité d'appareils médicaux et avertissez les autres personnes qui portent des appareils médicaux de ne pas s'approcher des aimants.



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.

Avertissement concernant les aimants : Évitez de placer tout support contenant des aimants ou sensible au magnétisme à proximité de ce produit. Les appareils sensibles aux aimants, tels que les ordinateurs portables, les cartes de crédit ou les dispositifs de mémoire magnétique, peuvent être endommagés s'ils sont placés à proximité de ce produit, alors prenez des précautions supplémentaires pour éviter toute perte.

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) to fed into the chamber via a feedthrough to improve communications reliability. To install the Kayetenna to the Base Station, replace the diversity antenna on the Base Station.



Figure 39: Kayetenna



Figure 40: Base Station with Kayetenna

2.5. ValProbe RT Console / Docking Station



Figure 41: 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 layout pictures

The ValProbe RT System also includes a portable docking station for easy access and viewing. The docking mechanism is adjustable 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 42: 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 43: Base Station Connection

2. Plug in the Docking Station to a power source.
3. Ensure the Console is in the Docking Station and press the Power button on the Console.
4. Power the Base Station and wait until the Power Led is solid green.
5. Log in and proceed to ValProbe RT software.
6. From the Main Menu of the ValProbe RT software select the **Discover** tile.

(If the Base Station is properly connected the Base Station blue tile appears and the Ethernet IP address of 192.168.99.50).

7. Select the Base Station and then Connect. The Base Station should connect and move to the Select Loggers screen.

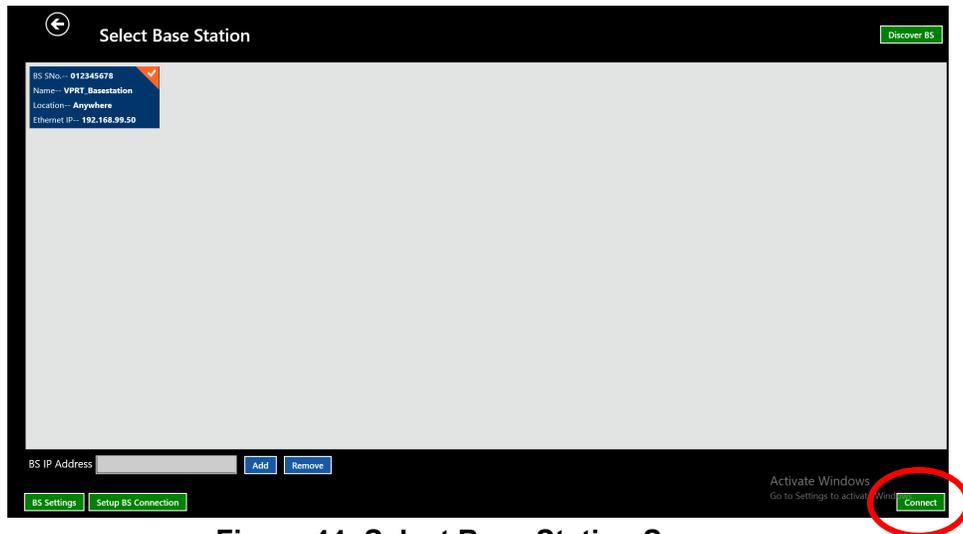


Figure 44: Select Base Station Screen

8. If the Base Station was found and communication have been established, a blue tile signifying the Base Station appears with an IP Address 192.168.99.50.
9. Select the Base Station tile and then select **Setup BS connection** to open the Base station Setup screen.

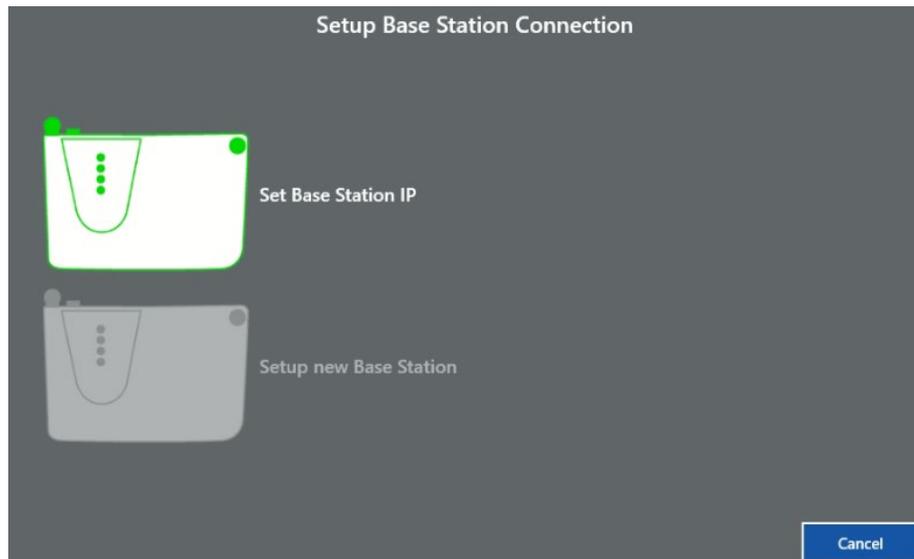


Figure 45: Select Base Station Screen

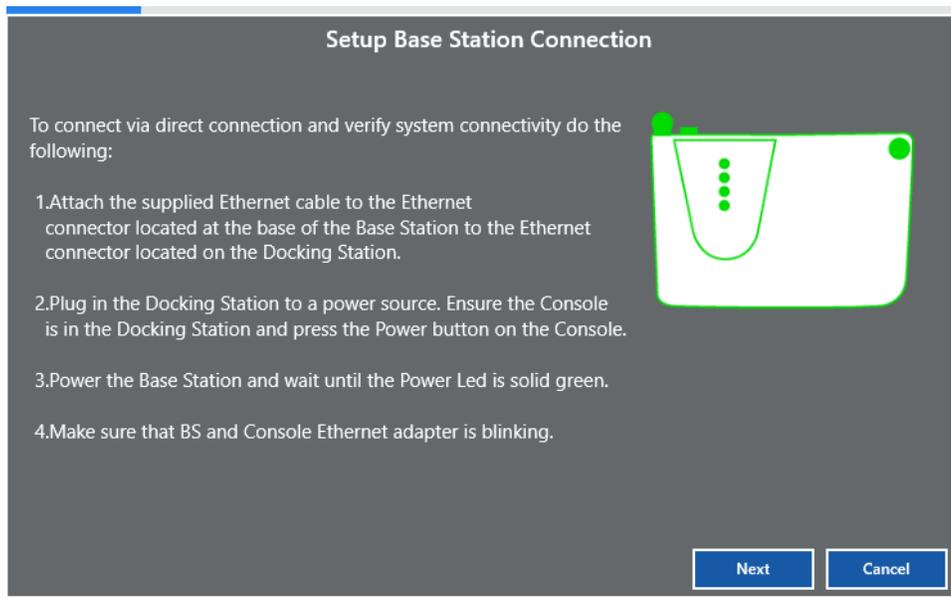


Figure 46: Setup Base Station Connection

Note: *If the problem persists, contact technical support.*

- Once the Base Station is discovered and selected the **BS Settings** offers additional customization of your Base Station. 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.

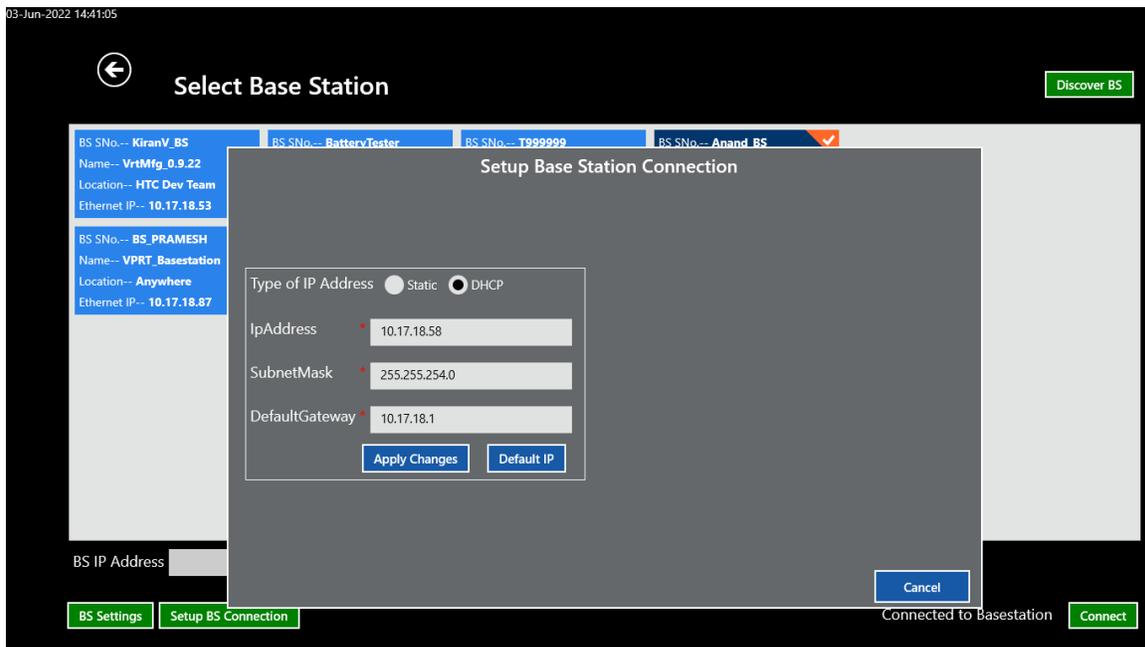


Figure 47: Setup BS Connection

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

- When completed, select the **X** to return to the Select Base Station screen.

3.2. Network Ethernet Connection – DHCP

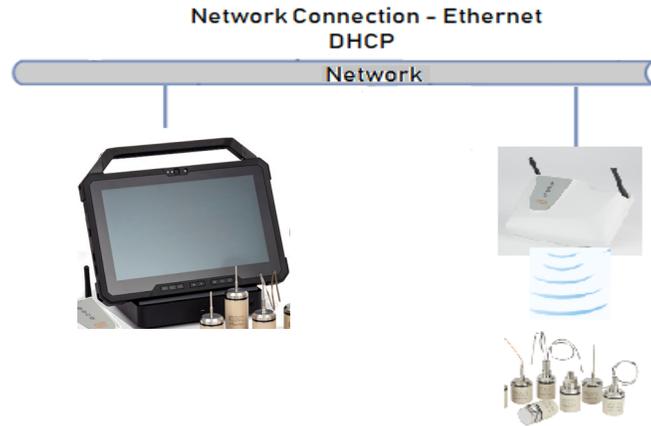


Figure 48: Network Connection

The ValProbe RT can also be configured to communicate using a company or private network via DHCP. The ValProbe RT system is factory configured 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. To change this for Network connection using DHCP the system must be first connected via 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. Connect the system via Direct Connection following Steps 1-9 in Section 3.1.
2. From the Main Menu select Discover to go to the Select Base Station Screen. Select the Base Station connected via direct connect with an IP address of 192.168.99.50 then press **Setup BS Connection**.
3. Select **Set Base Station IP**.

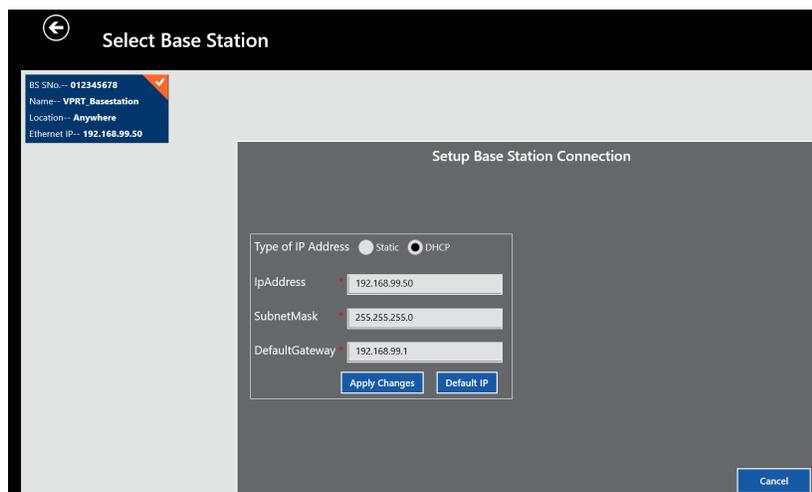


Figure 49: Set Base Station IP

- From the Setting Base Station Connection window change the **Type of IP Address** from Static to DHCP. Connect the supplied Ethernet cable from the Base Station to the network ethernet port and define network IP Address, Subnet Mask, and Default Gateway and then select **Apply Changes**.

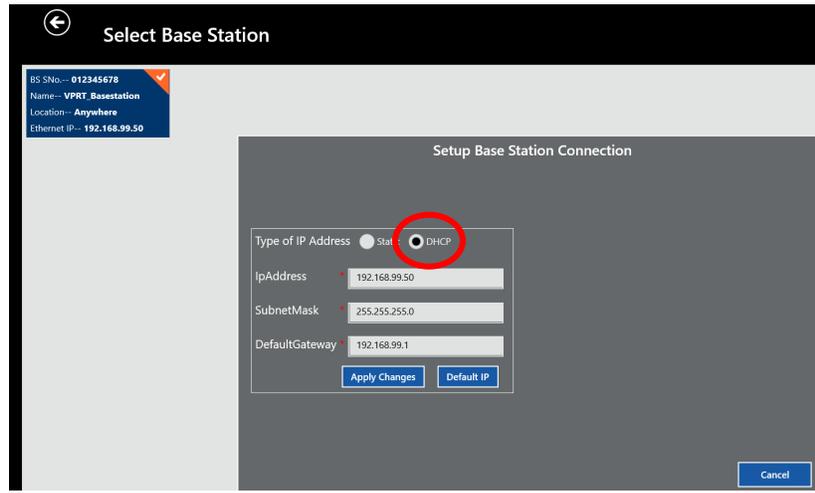


Figure 50: Change to DHCP

- The changes are stored in the Base Station and the software attempts to communicate with the Base Station. Follow the prompts until Base Station connection is found.

Note: *If you ever want to return to Direct / Static IP connection simply select Static and select **Default IP**.*

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

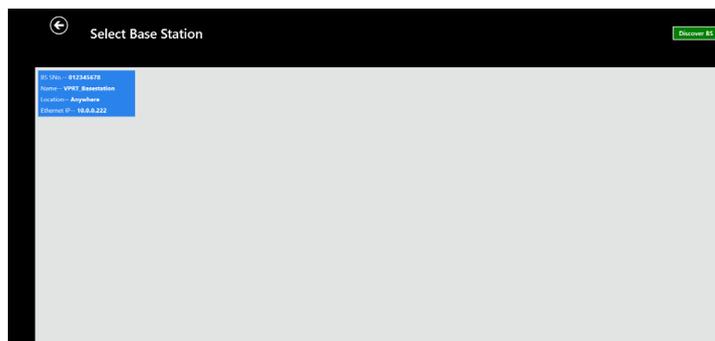


Figure 51: Select Base Station

- 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, manually add the IP using the **Add** button. If 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.**

ATTENTION ! Si une station de base est configurée avec une adresse IP statique, c'est le seul moyen de communiquer avec elle. Si l'adresse IP est modifiée et que la commande "Appliquer" est envoyée, la configuration précédente n'est pas active pour toute autre connexion. Si l'adresse IP n'est pas joignable ou si elle est oubliée, la station de base peut avoir besoin d'être réinitialisée.

3.3. Resetting a Base Station

3.3.1. Initiating a Factory Reset

1. Press the **Reset** button 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, 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

CAUTION! 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.

ATTENTION ! En appuyant sur RESET, la station de base revient aux réglages d'usine. Le mode de la station de base passe à IDLE, l'adresse IP passe à la valeur par défaut STATIC de 192.168.99.50, le nom et l'emplacement sont rétablis aux valeurs par défaut et tous les enregistreurs sont oubliés.

Chapter 4. Initial ValProbe RT Software Setup

4.1. Introduction

Before utilizing the ValProbe RT software to run Qualification studies, it is necessary to initially sign in using the Default Kaye ValProbe RT account and then create a System Administrator account. The Kaye Default System Administrator account is automatically deleted when the Password Maintenance utility is exited. From then on, use your own administrator account to perform Admin tasks.

When a new System Administrator account is setup, the Administrator can select the Administrator tile to define system preferences, policies, User management, and as needed, perform Hardware Maintenance, such as Base Station and Logger firmware upgrades.

In this Chapter:

- Start the program and log in to the ValProbe RT software using the default System Administrator account.
- Select security and Log-in authentication mode; Local security and Users or Active Directory™* (LDAP).
- Set System Policies
- Create System Administrator account (local / Active Directory™*)
- Utilize User Management to create other User accounts. (local / Active Directory™*)
- Set Preferences
- Utilize Hardware Maintenance to upgrade Logger and Base Station firmware for future upgrades.
- Access ValProbe RT online help

4.2. Initial Log in as a Default System Administrator

When the Console is initially powered on, it automatically boots into the Kaye Operator Windows account. Inside the Start Menu, navigate to, and start the ValProbe RT software, the Login screen appears as displayed below:

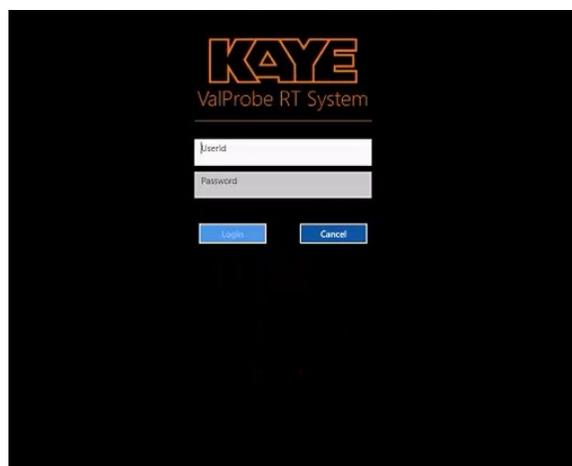


Figure 52: Login Screen

1. Enter the one time default User ID “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 the default User ID is entered 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. Select **Login**.
4. Once logged in, the Policies screen opens.

The Policies screen is used to define if the Security and sign in for the ValProbe RT software utilizes Active Directory™* for sign in or the local security and policies of the ValProbe RT software.

5. If utilizing Local Security and Policies proceed to Section 4.2.1. If planning to utilize Active Directory™* proceed to Section 4.2.2.

4.2.1. Setting Up Initial Administrator using Local Security and Policies

1. When the Initial default User ID and Password are entered, the system automatically opens the Policy screen and defaults to Local security and policies.
2. Ensure that **Active Directory* Connected** displays **NO**. If not, select **ActiveDirectory User** button to toggle Off Active Directory*.

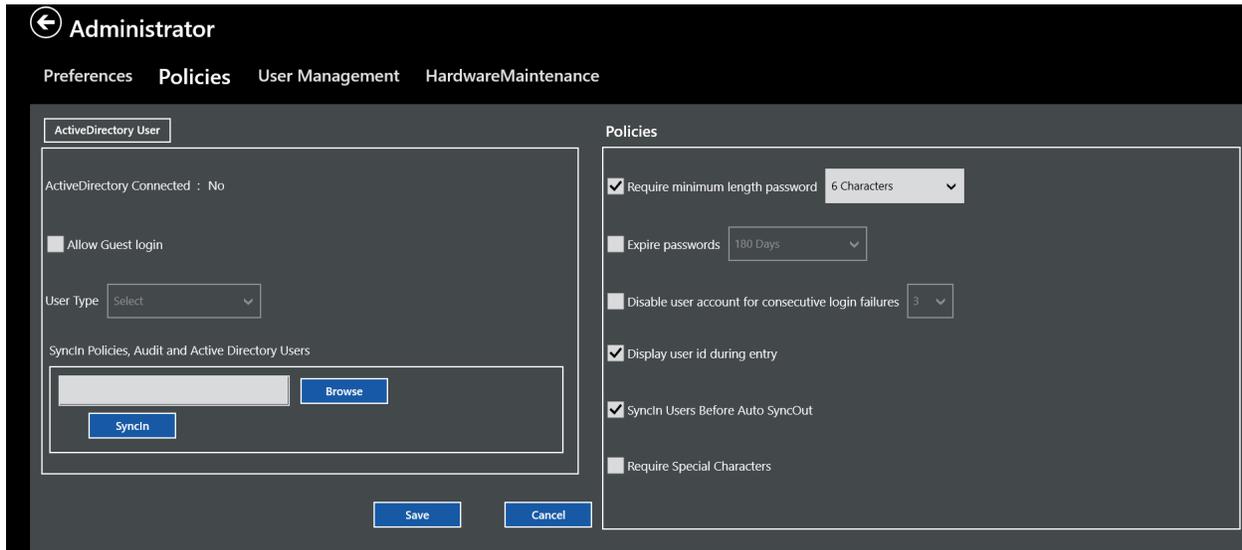


Figure 53: Login Screen

3. In the policies window define the local security and 21 CFR Part 11 options to meet your security needs. The options include:
 - Set passwords to expire after a defined number of days: Use the dropdown list to select how long to passwords take to expire. 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 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. Only System Administrators can re-enable Users
 - 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. Only allow by Admin and documented in the Audit Trail
 - Require Special Characters:

Additional options as part of Policies include:

- Syncin User before Auto Sync Out: If enabled Users will be automatically Synced In from backup prior to automatic Sync Out. This can automate control of ensuring all Console have same Users

4. Once the Local Policies have been defined select "**Save**" and then proceed to the **User Management** screen to define a Local Administrator.

- Define a System Administrator to replace the Default Kaye account. For the replacement Administrator, the New User window opens automatically.

The screenshot shows the 'Administrator' interface with the 'User Management' tab selected. On the left, there is a sidebar with 'Users List' and 'New User' buttons, and a search bar. Below the search bar, a list of users is shown, with 'Admin Manager' and 'Dennis P Val Eng' highlighted. The main area contains a 'New User' form. The 'User Information' section includes fields for Name, Password (with a red asterisk), Title (a dropdown menu), and Phone. To the right of these fields are fields for User ID (with a red asterisk), Confirm Password, User Type (set to 'SystemAdministrator'), and Email. Below the 'User Information' section is a 'User Privileges' section with a grid of checkboxes for various permissions. The 'Admin' settings are expanded, showing a list of checked options: User Management, Policies, Preferences, and HardwareMaintenance. At the bottom right, there are 'Save' and 'Cancel' buttons.

Figure 54: User Management Screen

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

- 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 75 and a User ID cannot be used by more than one account.

- 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.
- In the **Confirm Password** field, enter the password and select **OK**.

Record the new Administrator User ID and password for future reference. If an incorrect User ID/password combination is entered, access is denied. After the initial administrator account is created, the default “Kaye” “411” login credentials are automatically deleted.

For the initial system administrator, the User Type and User privileges are preset. Enter a title, phone, email, and associate a picture by using the built-in camera. After completing the system administrator User setup, the system logs out. To proceed, open the software, and log in with the new Administrator account information.

To return to the User Management screen to add additional Administrators or Users, select the **Admin** tile.

4.2.2. Setting Up Initial Administrator using Active Directory Security and Policies

Kaye ValProbe RT has built in Active Directory™* system support. You can connect your company's users in your Active Directory™* with the ValProbe Rt system, allowing more freedom to handle user management. To set up initial Active Directory™* security and policies, follow the instructions below:

Note: To set up Active Directory™*, you must be an administrator with read rights to read your company's Active Directory™*.

Note: The ValProbe RT software is only able to connect to one company's Active Directory™* at a time.

1. At the initial Login Screen, 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 the default User ID is entered exactly as it appears above.

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

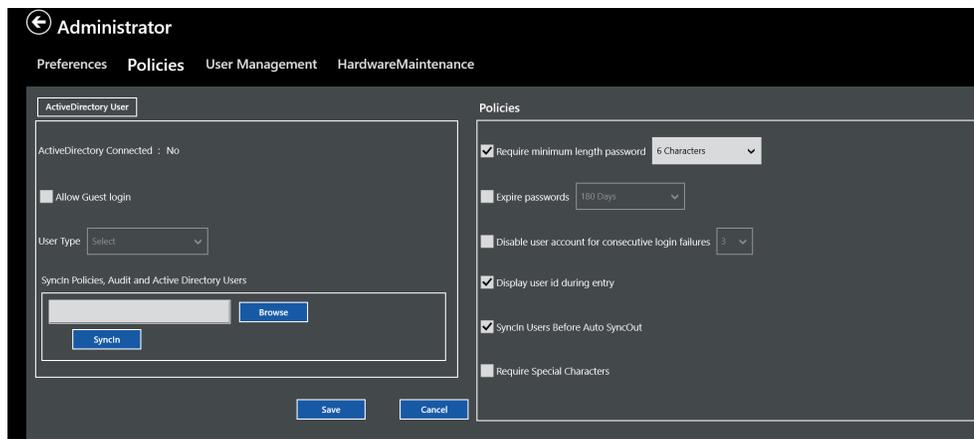


Figure 55: Policies Screen

3. To enable the utilization of Active Directory™*, ensure the ValProbe RT console is connected to the domain and select the **ActiveDirectory User** box. A window appears to define User Credential and Domain connectivity parameters.

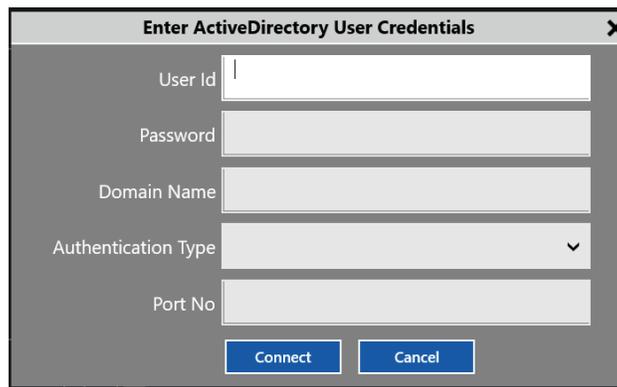


Figure 56: Active Directory* Credentials

(LDAP - “Lightweight Directory Access Protocol”, is a software protocol that stores and arranges data to make it easily searchable. Microsoft uses this for their Active Directory™* system.)

4. Enter your Administrator **User ID and Password** provided by your company in the designated boxes.
5. Enter your company’s **Domain Name**, contact your IT department if you require assistance getting the correct domain name.
6. Using the dropdown select the **Authentication Type**, contact your IT department if you require assistance getting the correct authentication type.
7. Enter the **Port number** to connect to your Active Directory*, contact your IT department if you require assistance getting the correct port number.
8. When completed press **Connect**. If communication with the domain was successful, ActiveDirectory Connected displays **Yes**. If connection failed, contact your IT department, and retry.

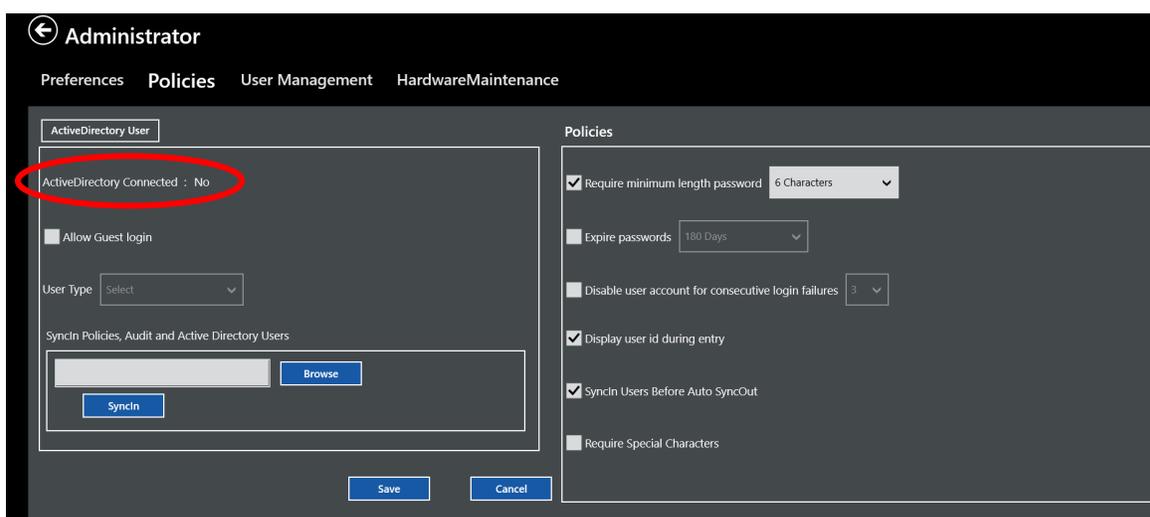


Figure 57: Active Directory* Connected

9. If desired, select **Allow Guest Login** to allow any Active Directory™* users that are not members of configured groups to login with the selected privileges
10. Once the Active Directory™* parameters have been defined and connection has been established, select **Save** to save settings.

Note: *With Active Directory™* enabled, all local security policies are greyed out as all security policies follow company domain policies.*

11. Proceed to the User Management screen to define Administrator Active Directory™* Groups and permissions.



Figure 58: Sync In Active Directory* Users and Policies

The Active Directory* setup window has a feature that allows locally saved policies, parameters, and User Management definition to be Synced-In to other ValProbe RT Consoles to avoid having to reconfigure them individually. From the Console with the configured Policies and User Management, open the *Main screen>File Management>SyncOut*. Define the path (USB, Folder on Domain) and then select *Users>Audit>SyncOut*. On the other ValProbe RT Console, open the *Admin>Policies* screen and enter the path where the Users and Audit were stored and select **SyncIn**.

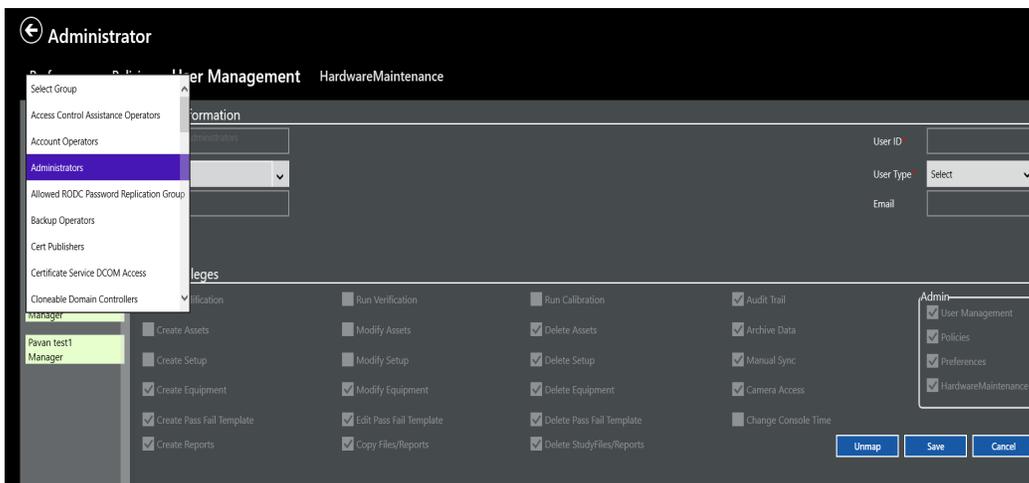


Figure 59: Active Directory User Management Screen

If the Active Directory™* configuration and connection were successfully established in the Policies screen, when entering the User Management screen, a complete list of all active Groups within the defined domain is displayed.

Important: *Prior to defining the User Management screen, it is necessary for the Validation Manager to work with their IT department to define and configure on the defined domain, the various Groups and people within each group who need access to the ValProbe RT system. Each Group can be assigned a User Type which defines what permissions are granted for each member of the group.*

Important: *For the ValProbe RT system to operate there must always be an Administrator defined group. Upon first time startup of the system, the Administrator must define and set permissions for an Administrator Group. Once completed the Default User ID and Password are deleted and the system reboots.*

To map the predefined Administrator Group:

1. Select the domain group to assign as Administrators. In the **Title** box use the dropdown to define the User title. If the desired title is not listed, press **Select** and type in the desired title, the title appears in the active group users listed below the Username.

- In the User **Type** box, use the dropdown to select System **Administrator**. The Default Users Privileges appear.
- Select **Save** once completed the Default User ID and Password is deleted and the complete Policies and User Management configuration is saved locally to the console to allows Users to still utilize Active Directory™* login even when not connected to the domain the system then reboots.
- Log in using the Administrator password and proceed to User Management to map other User groups.

4.2.3. Adding / Managing User Accounts – Local Security

When logged in with a new system administrator account, additional Users may be added to the system. The software supports up to 500 Users.

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

To create a new or additional System Administrator account:

- On the Main screen, select the **Admin** tile to open the Admin Settings window.
- From the Admin Settings window, select **User Management**.
- On the User Management screen, select **New User**, and enter the User's name in the **Name** textbox. This Username appears in the active User list.

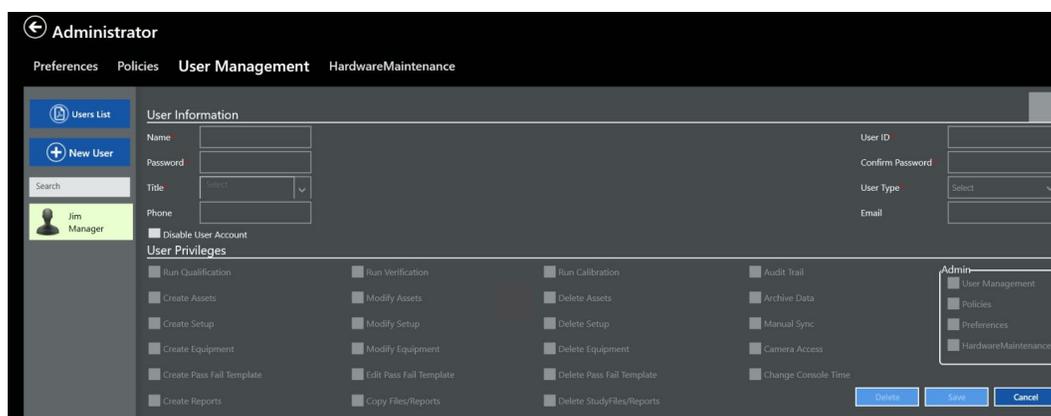


Figure 60: User Management Screen

- Use the dropdown to select your desired Authentication Type, if you do not know it, contact your IT department.

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.*

- Enter a new System Administrator/User password in the **Password** textbox. Passwords are 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.
- Reenter the password in the **Confirm Password** textbox and select **OK**.

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

7. Optionally, you may enter a designated Phone number and Email ID as contact details that are for contact information only. Select **Save** to save the information.

The User Management screen displays a list of active Administrators accounts. The default Administrator Kaye account is deleted.

Only Administrator accounts can enter the admin tile and create new Operator accounts. Unlike Administrator level accounts, an Operator account is added by the Administrator it is assigned a temporary password which will be required to be changed by the Operator when they first login. When creating a new Operator account, the Username is added to the active User list. To create an Operator account:

8. 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. There is a limit of 500 Users, creation of a 501st User causes a warning message to appear and does not allow any further User creation.*

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

User IDs are 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.

10. Enter a temporary password for the User in the **Password** textbox.

The temporary password is any combination of numbers and characters. The User must change this password on their first ValProbe RT software login.

11. Enter the temporary password again into the **Confirm Password** textbox.

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

Note: *A User account is not active until the User changes their temporary password after logging in for the first time.*

12. Define the **Title**.

13. Select the User Type dropdown to select from previously created user types or create a new User Type by typing in a new name over the previously created one in the dropdown. Select which privileges to add or remove for the new User type by selecting or deselecting the checkboxes and select **Save**. To return to the User management screen and not save your changes, select the black **X** or **Cancel**.

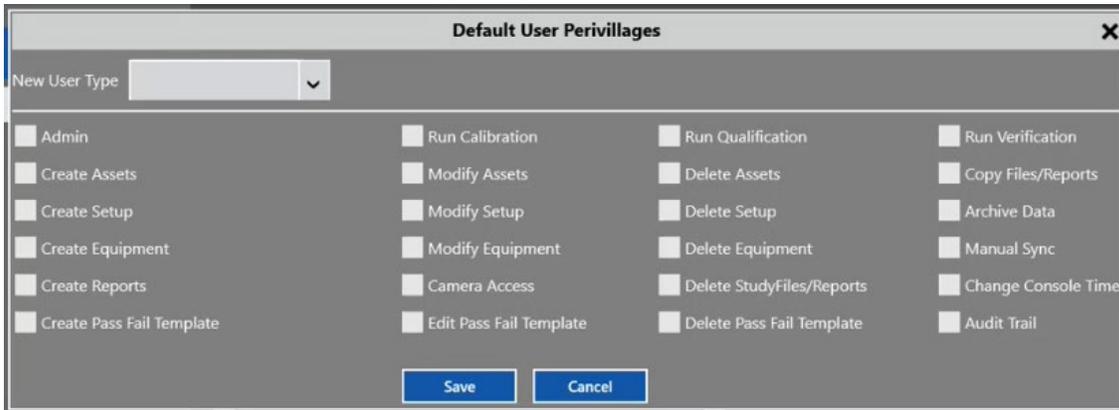


Figure 61: Default User Privileges Window

14. Once saved, the new User Type is displayed in the **User Type** dropdown on the User Management screen.

4.2.4. Deleting and Disabling Local Security User Accounts

There are two additional states for a User:

Disabled User

A User may be disabled by an Administrator or automatically disabled after a certain amount of consecutive login failures (3-10) if enabled in Policies (see Section 4.2 for details). A disabled User 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 checkbox.

Deleted User

If a user account needs to be removed, an Administrator can delete it by selecting **Delete** at the bottom of the screen. To prevent discrepancies in the audit trail, the deleted User ID is blocked for further usage. The deleted User is removed from the User list, but the User's information remains accessible via the User list printout.

Users List

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

User Search

A search field that filters for Username. As an example, if "B" is entered all usernames starting with "B" are listed.

Note: All Users are listed in alphabetic order.

4.2.5. Local Security - One Time Emergency Access

It is good practice to establish more than one active Administrator account, if a system administrator is unavailable the system is still maintained. If administrator access is not possible, Kaye can provide a one-time Emergency access with the sole purpose of modifying an Administrator account. For this procedure, direct support from Kaye service is required.

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

Figure 62: Authentication Types

4.2.6. Adding / Managing User Accounts – Active Directory™*

To add / modify additional groups and privileges in your company's Active Directory™* do the following:

1. Define within your Active Directory™* company domain the desired Users and Groups for the ValProbe RT system.
2. From the User Management screen, select the dropdown list under **User List** to display all groups in your company's Active Directory™*.

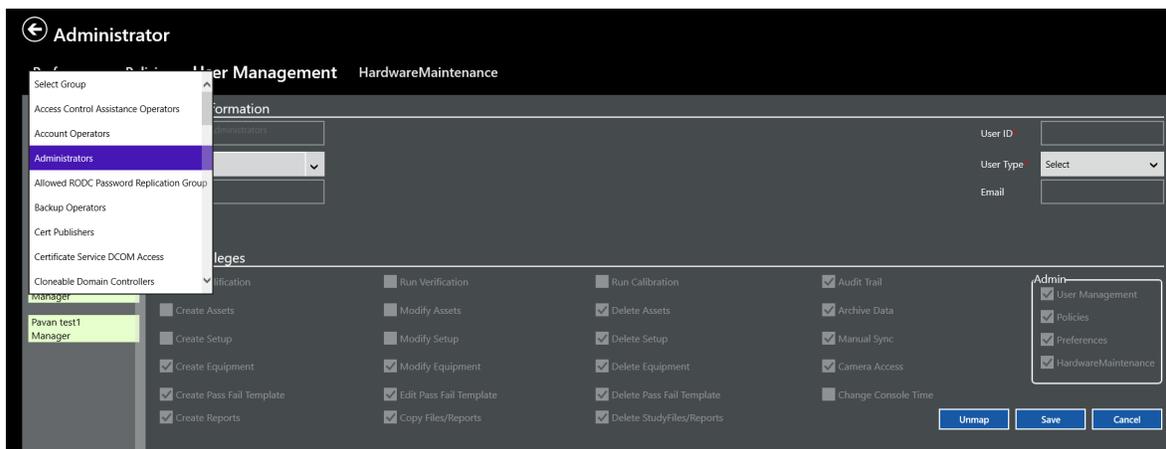


Figure 63: Active Directory* Groups

3. Select the desired group from your defined company domain.
4. Select or type the **Title** for the group.
5. Select the User **Type** dropdown.

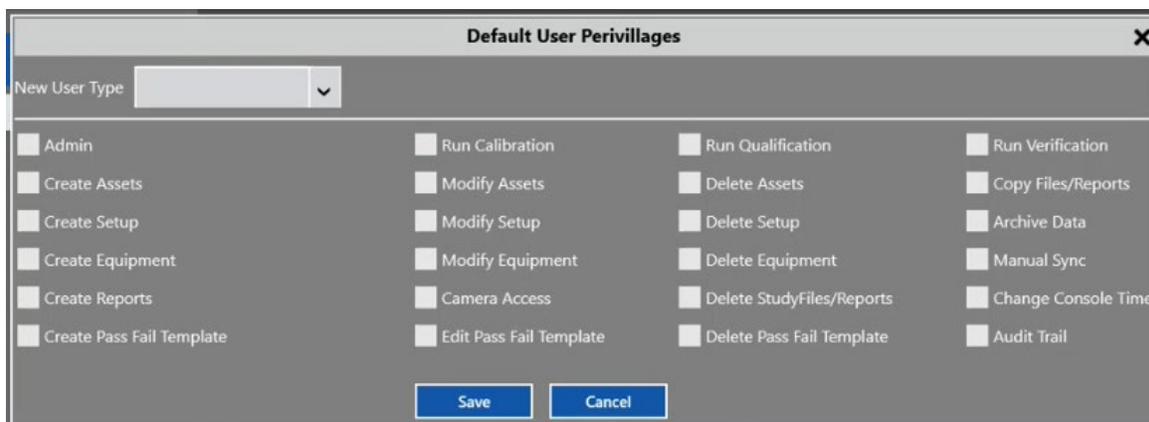


Figure 64: Default User Privileges Window

6. Use the **User Type** dropdown to select from previously created user types or create a new User Type by typing in a new name over the previously created one in the dropdown. Select which privileges to add or remove for the new User type by selecting or deselecting the checkboxes and select **Save**. To return to the User management screen and not save your changes, select **X** or **Cancel**.
7. Once saved, the new User Type is displayed in the **User Type** dropdown on the User Management screen.

Note: *If a user is in multiple Active Directory™* groups and there are changes to their user type in multiple groups, the last group updated is saved. For example, if a User is in both group A and group B as an operator user type, and someone makes a change for that user in group B, for example, to make them a System Administrator, they become a System Administrator in both groups.*

4.3. Setting Preferences

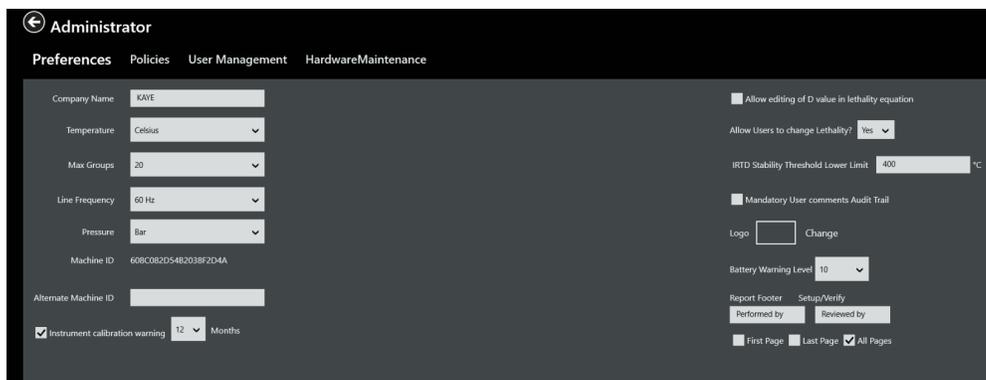


Figure 65: Preferences Tab in Administrator Menu

Changing system Preferences is an Administrator task and requires an Administrator account to edit the above defaults. Any edited settings become effective immediately after selecting the **Save** button. The following preferences are available to be set:

- **Company Name:** Enter a company name to display in report headers.
- **Temperature:** Temperature units are set to Celsius only. All calculations are performed in the temperature unit specified here.
- **Max Groups:** Use the dropdown to select a maximum number of groups for a setup.
- **Line Frequency:** Use the dropdown to select a line frequency, 60 Hertz or 50 Hertz depending on your environment.
- **Pressure:** Use the dropdown to select the absolute pressure units for saturated steam calculations.
- **Alternative Machine ID:** If required, enter an alternate machine identification number, which appears in the audit trail as additional identification.
- **Instrument calibration warning:** Sends a user a warning after a set amount of time, using the dropdown, when calibration is required.
- **Allow editing of D value in lethality equation:** Allows the user to edit the D value in the lethality equation.
- **Allow Users to change Lethality:** Use the dropdown to decide if the User should be able to change lethality, Yes or No.
- **IRTID 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.
- **Mandatory User Comments in Audit Trail:** When enabled/checked, user comments are mandated when user credentials are validated to log the audit entries.
- **Logo:** Select **Change** to browse to a location to add a logo to display in report headers. Use any bitmap for the graphic, with a preferable size of 90 x 30 pixels. Other formats are downsized.
- **Logger Battery Warning Threshold:** Set at what battery percentage a warning displays, default is 10% and can be set between 10%-40%.
- **Report Footer:** Set if signature fields are applied on the first/last/every page for Setup and Sensor Verification reports. Note, this is set directly in the reporting tool for qualification reports such as Detailed, Summary, and Pass / Fail.
- **Data Directory:** Displays the path and folder of the Data Directory.

4.4. Hardware Maintenance

The Hardware Maintenance screen allows the Administrator the ability to upgrade the Base Station and Logger Firmware whenever desired upgrades are released from Kaye. This eliminates the need to have to return the Loggers and Base Station to the factory when desired upgrades become available.

All upgrades are posted on the Kaye website for download to a USB drive or computer. Use a USB inserted into a Console Docking Station to install the upgrade, or if downloading to a PC, use tools such as Remote Access to connect to the Validation Console and copy the files from a PC to the Console.

Note: Refer to release notes and instructions provided with the appropriate upgrade download.

Note: Firmware upgrades usually include both the Base Station firmware and associated Logger firmware. It is recommended to perform the Base Station firmware upgrade prior to upgrading the Logger firmware.

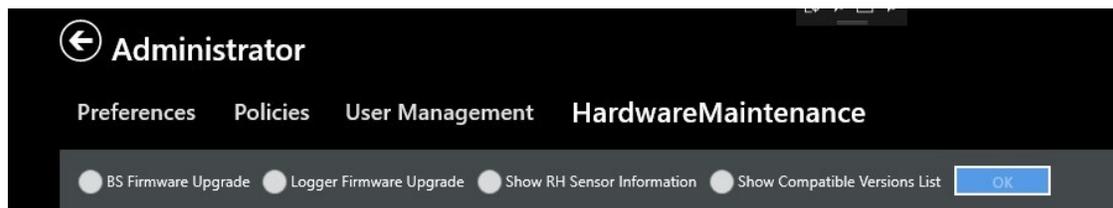


Figure 66: Hardware Maintenance

BS Firmware Upgrade:

1. From the Admin / Hardware Maintenance screen, select **BS Firmware Upgrade** and select **OK**.
2. Ensure that the Base Station is properly connected and powered on.
3. From the Select Base Station screen select the desired Base Station to upgrade and select **Connect**.

Logger Firmware Upgrade:

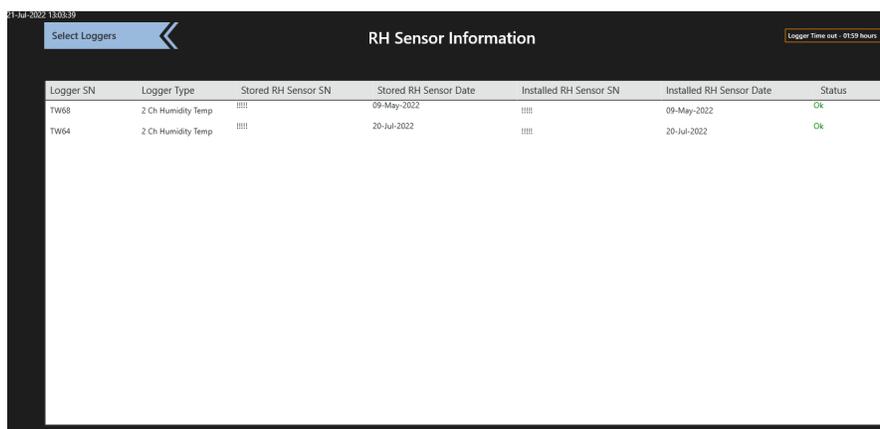
1. From the Admin / Hardware Maintenance screen, select **Logger Firmware Upgrade** and select **OK**.
2. Ensure that the Base Station is properly connected and powered on.
3. From the Select Base Station screen, select the desired Base Station and select **Connect**.
4. Wake up and select Loggers to be upgraded.

Logger Battery Reset: Select this option to reset the Logger batter and select **OK**.

Contact Kaye technical support for additional assistance or instructions.

RH Sensor Information Screen

The ValProbe RT Temp / Humidity Logger has a digital T/H sensor with its own serial number. The Logger and sensor work as unit and are excluded from qualification studies if the sensor serial doesn't match the serial number stored in the Logger memory. The Logger and sensor serial numbers can be verified in the RH Sensors Screen to correct mismatches that could happen e.g., after use of extension cables were loggers and sensors were accidentally changed.



Logger SN	Logger Type	Stored RH Sensor SN	Stored RH Sensor Date	Installed RH Sensor SN	Installed RH Sensor Date	Status
TW68	2 Ch Humidity Temp	!!!!	09-May-2022	!!!!	09-May-2022	Ok
TW64	2 Ch Humidity Temp	!!!!	20-Jul-2022	!!!!	20-Jul-2022	Ok

Figure 67: RH Sensor Information

Opening a Logger and Connecting an Extension Cable

1. Unscrew the PTFE filter cap (rotate counterclockwise).



Figure 68: Unscrewing the Filter Cap

2. Remove the sensor module, rotate counterclockwise as per the figure below.



Figure 69: Removing the Sensor Module

3. Note the serial number which is listed below the black material.



Figure 70: Sensor Serial Number

4. Plug the extension cable into the Logger where the sensor module was removed.
5. Connect the sensor module to the other end of the extension cable. Before proceeding, verify the serial number of the sensor is the same as Step 3.



Figure 71: Extension Cable Connected

6. When finished with the extension cable, remove the cable, and then secure the PTFE filter cap, rotate clockwise to tighten.

Show Compatible Versions List

1. From the Admin / Hardware Maintenance screen, select **Show Compatible Versions List** and select **OK**.
2. A window opens displaying the firmware versions of the software, Base Station, and Loggers.

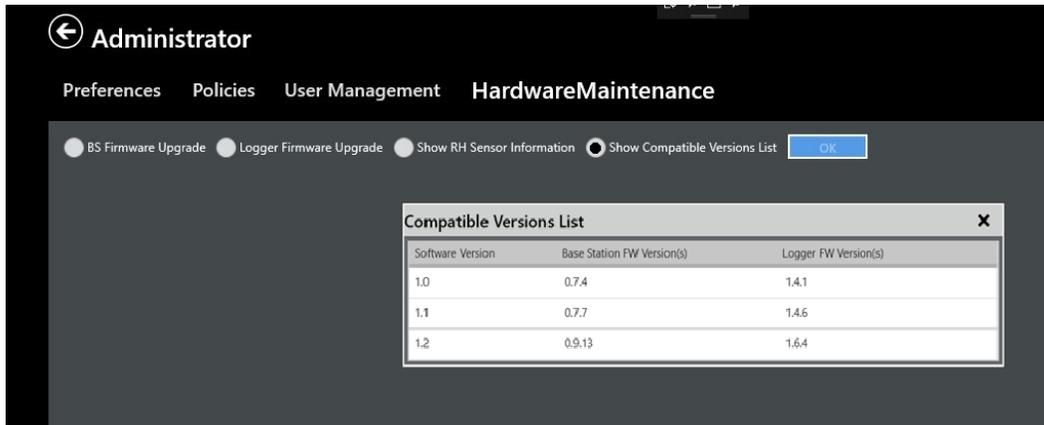


Figure 72: Show Compatible Versions List

3. Select **X** to close the window.

4.5. Online Help

To display online help, 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. File Management

5.1. Overview

As a dedicated validation system, the ValProbe RT system is responsible for the collection, reporting and storage of GxP files related to Thermal Validation studies. Data which is collected by the ValProbe RT system is stored locally as raw encrypted data files along with .pdf files of the reports used for analysis.

To meet Data Integrity, and 21 CFR Part 11 requirements, Kaye has designed the ValProbe RT Console / software with the following features to protect data stored in the Console / software:

- Dedicated Console and core load with only programs necessary to perform validation activities (no internet access, e-mails, Microsoft office).
- Restricted access to modify or delete files/ date-time using Windows 10 LTSC OS and permission rights for Operators.
- Ability for IT to download Virus protection programs and perform manual patches of OS.
- File Management tools which include the ability to Sync Out / Sync In and Archive all data to defined paths such as share folder and mapped drives on the Domain.

The sync functions are used for a 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 manually generated and started from the File Management tile on the Main screen. Access to the File Management feature is controlled by User privileges defined in User Management.

5.1.1. Sync Out

The Sync out function is used to copy the data content of the console to another User defined 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. Data that is sync'd out to the master folder is appended to existing data. Only files which are not already present on the current master folder are copied.

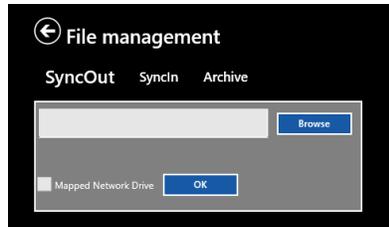


Figure 73: Sync Out

To perform the Sync Out function, select **Sync Out**. In the pop-up box enter the path to Sync to. To simplify selection, select the **Browse** button to view all drives and folders. When completed select **OK**.

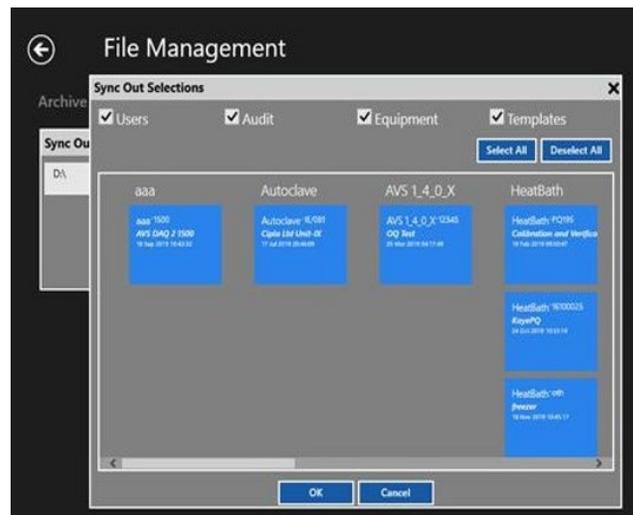


Figure 74: Sync Out Data Selection

The Data selection screen displays and specifies the data to Sync Out. Data selections include:

- Current Users and privileges from User Management
- Audit Trail
- Equipment including Logger Sensor Verification files
- Pass-Fail Criteria Templates
- Desired Assets (includes Setups, Qualifications, Reports, and Documents)

Select **OK** when all selections have been completed. Unless there are existing folders, separate folders are automatically created for the different choices of data. As required, Sync Out additional folders.

5.1.2. Sync In

The Sync In function copies data from a file location to the console. Sync In is used to restore data from a backup generated with the Sync Out or Archive function. Like 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 is a date filter to specify a data range to allow more selectivity on the data copied to the console. The date filter specifies a timeframe with a dropdown selection.

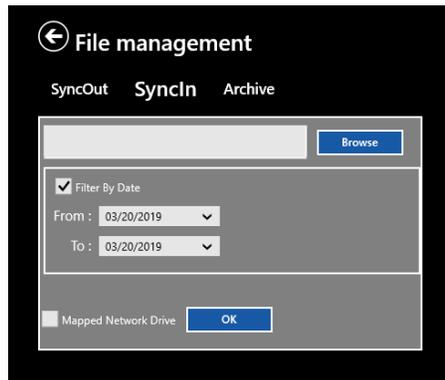


Figure 75: Sync In

5.1.3. 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 may be selected individually.

If selecting 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.*

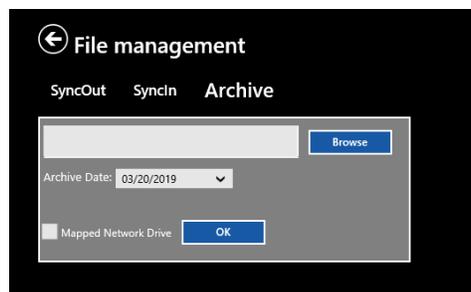


Figure 76: Archive

5.1.4. ValProbe RT Convert

The ValProbe RT Convert function imports single study files into the Asset system of the console. Single study files may be copied to a disk from Asset details to import into another console or sent 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.

Select a single data file in the browser, add a comment for easier identification if needed. If the corresponding asset is not in the system, the software creates a new asset and setup file from the information stored in the study file.

Note: *If a Study file from an existing asset is selected, it merges the study file with the existing files into the asset without duplicates.*

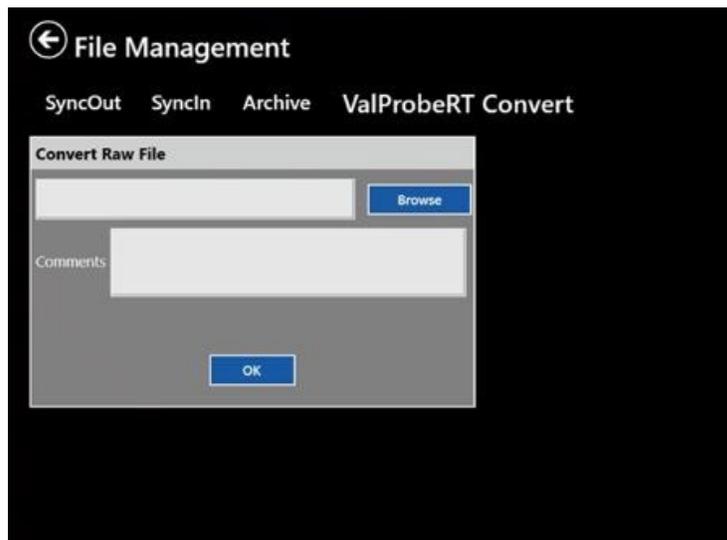


Figure 77: ValProbe RT Convert

5.2. Using Mapped Drives for Sync Functions

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

It is recommended to enter the server address as a 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.

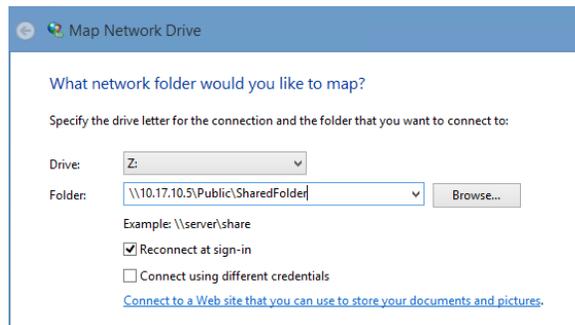


Figure 78: Windows – Mapping a Drive

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

Browse to the mapped drive. It 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 proper credentials for accessing the drive. When using a domain for security, add the domain information after the Username with an @ extension as displayed in the figure below (alternatively, the domain\User format is accepted).

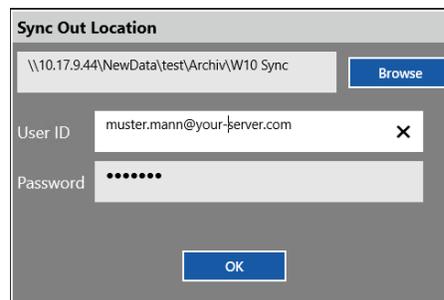


Figure 79: Mapped Drive Login Credentials

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

If the folder is accessible without restrictions, 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 proper 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.

Chapter 6. Equipment

The ValProbe RT includes a unique feature called "Equipment". Equipment is accessed from the Main Menu, by selecting the **Equipment** tile. Equipment provides the User with a tool that assists in tracking their Kaye calibration and verification data associated with their ValProbe RT Loggers, IRTD's and Temperature References. The Equipment tile is the take off point for performing Sensor Verifications for all ValProbe RT Loggers and sensors.

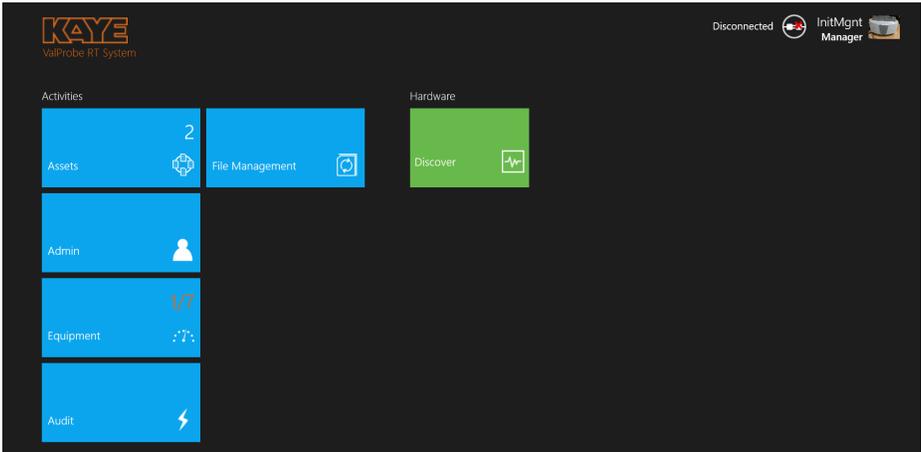


Figure 80: Equipment Tile

6.1. Equipment Assets

Select the **Equipment** tile on the Main screen, to open the Equipment Assets screen. The Equipment Assets screen displays all equipment connected or manually created (i.e., five VPRT Loggers, one Calibration Bath, and two IRTD's) to the system.

Note: *The ValProbe Logger tile has an option to Initiate Verification to perform periodic pre and post Sensor Verifications of Loggers. A detailed explanation on Sensor Verification capabilities and processes is highlighted in Chapter 11.*

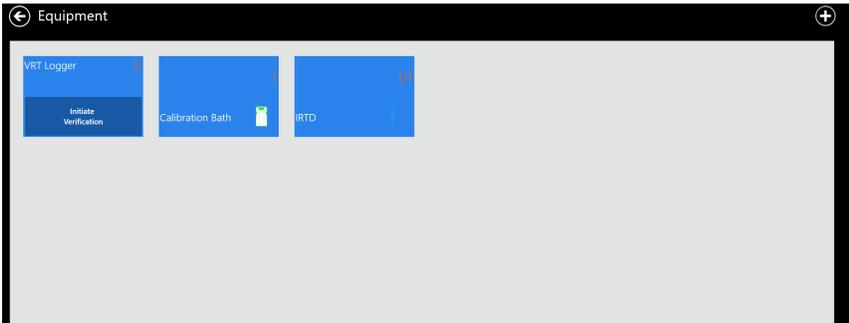


Figure 81: Equipment Asset display

- Kaye equipment Assets are automatically created the first time the equipment is connected to the ValProbe RT system.
- Additional Kaye equipment or non-Kaye equipment can be manually added to the Equipment Asset list.

6.1.1. Manually Adding Equipment Assets

To add a new piece of equipment inside Equipment assets, select the **Plus (+)** icon on Equipment screen. The New Equipment screen opens.

Figure 82: New Equipment Screen

Use textboxes and dropdown menus to enter the following:

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

To upload an image of the equipment, browse for a bmp or jpeg or access the camera to take a picture directly.

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

6.1.2. Equipment Contents

To view the Equipment tile contents for a specific piece of equipment (i.e Logger), from the Equipment Asset screen select the **VRT Logger** tile.



Figure 83: Equipment Assets

The software then displays five VPR T Loggers, each tile contains the serial number of the Logger, the Logger type, the manufacturing Calibration date, and the Manufacturing Cal Due date. Select the desired Logger.



Figure 84: VRT Loggers

The Logger tile lists all available Sensor Verification study files including, the setup name, date, run number, and comments. After selecting a study file, **Generate Report** or select the blue Reports tile and a previously generated Verification .pdf report.

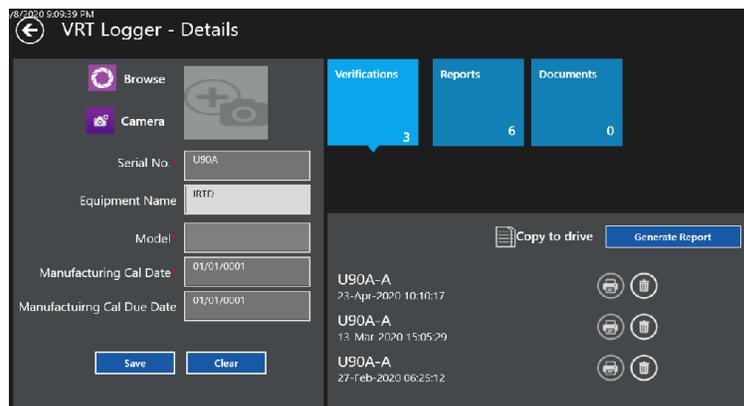


Figure 85: Logger Contents

Select the blue Documents tile to upload documents such as Logger manufacturing Calibration certificate for storage and easy access.

6.2. Calibration Reminder

The Equipment tile includes a Calibration reminder and alert for all equipment.

To use the calibration reminder, activate and set the calibration reminder timeframe in the Admin / Policies. The reminder timeframe specifies the number of months ahead of the Calibration due date a User is alerted. When the equipment calibration due date is within the calibration warning timeframe, the software alerts the User by:

- 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 7. Defining Assets

7.1. Overview

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

Each individual validation process, whether a sterilizer, freeze dryer, cold room etc. may be set and defined as an asset. All files and data related to the asset, like setups, calibrations, or study files, are organized and accessed in one single screen around the basic asset data. It is possible to upload additional documents like standard operation procedures or certificates and associate them with an asset. Assets are sortable and searchable by type, location, manufacturer, etc. for easy access. A maximum of 200 assets may be defined.

To open the **Assets** hub, select the Assets tile on the Main Menu. The Assets Hub appears as below.

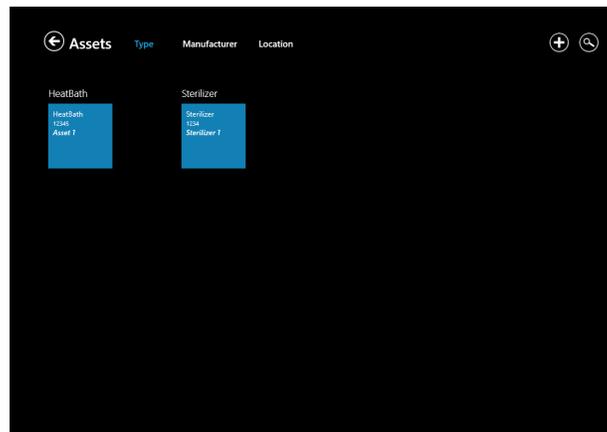


Figure 86: Assets Hub

The Asset Hub lists the various assets validated by the ValProbe RT system. On the top text line, select 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, select the **Search** (magnifying glass) icon, and enter search criteria / data.

For further details regarding a particular asset, select the tile for that asset to open its Asset Details window.

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

7.2. Asset Details Screen

To learn more about an asset, select its asset tile to open the Asset Details screen (displayed below).

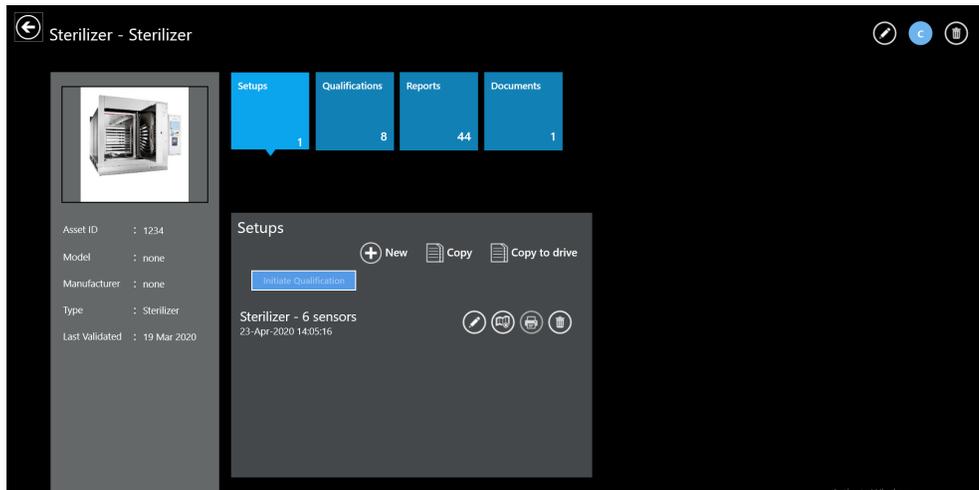


Figure 87: Asset Details

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.

The action buttons in the upper right corner allow editing of the asset details (pencil) and the ability 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.

Note: All available actions within each tile are controlled by the privileges assigned to the logged in User account. All actions are logged into the Audit Trail

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. This is useful if there are multiple chambers of the same type.

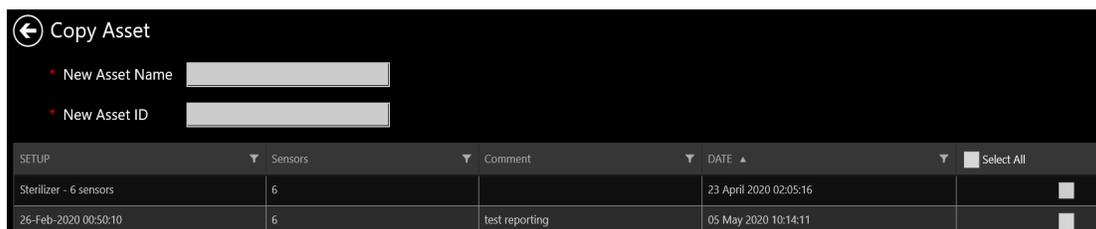


Figure 88: Copy Asset

The Asset screen also contains separate blue tiles for Setups, Qualifications, Reports, and 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 as well as the actions available to perform from this tile.

Note: All available actions within each tile are controlled by the privileges assigned to the logged in User account. All actions are logged into the Audit Trail

Setup

Selecting the Setup tile displays a listing of all available Setups for the Asset. A scroll bar to the right will be displayed to allow access to all Setups.

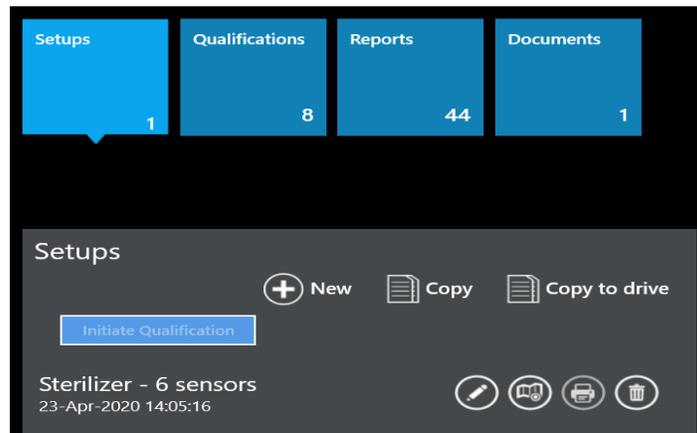


Figure 89: Setup Tile

The Setup file contains all the configuration information to define sensors, groups, wiring diagram, calculations, and qualification parameters which define the requirements for the validation study.

For every Setup listed 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 (privileges required).

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

The **Copy** button opens a list of all available setups on the console. Assets are listed by their names and setup names, number of sensors, comments, and last modification date. Select setups to copy to the Asset and select **Copy**.

Use **Copy to Drive** to copy the selected setup file to a chosen drive. This is primarily used for service as requested Setup files are copied to a USB and then sent to Technical Support for review.

The **Initiate Qualification** button is used to initiate the Qualification process. Firstly, select the desired Setup file and then select the **Initiate Qualification** button. Selecting this button starts a qualification process. The Hardware Discovery screen displays, and the setup is transferred to the selected ValProbe RT.

Qualification

Selecting the Qualification tile displays a listing of all available Qualification files that have been saved. A scroll bar displays for access to all Qualifications.

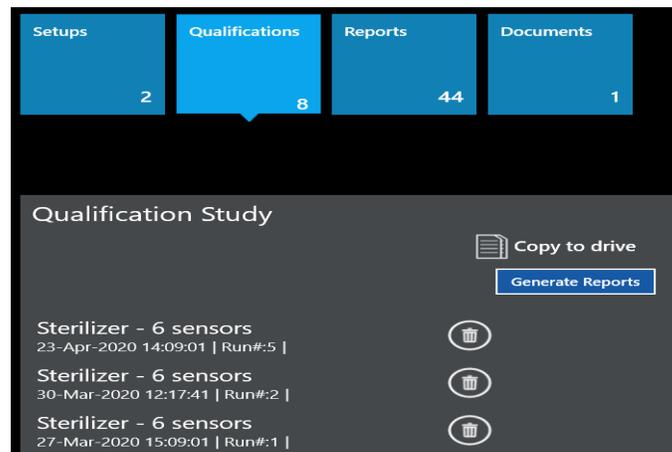


Figure 90: Qualification Tile

The Qualification files contain all the collected raw encrypted data gathered during the Qualification study. The Qualification file names are the names of the Setup used along with the date they were performed.

If the Logged in User has the proper permission rights a **Delete** button is available to delete the Qualification file.

Use **Copy to Drive** to copy the selected Qualification file to a chosen drive. This is primarily used for service as requested Qualification files are copied and then sent to Technical Support for review.

The **Generate Reports** button is used to initiate the selection and generation of reports for the Qualification file. Firstly, select the desired Qualification file and then select the **Initiate Qualification** button.

Reports

Any reports which have been generated from a Qualification file are automatically stored as .pdf files under the Report tile for easy access and viewing. The reports are sorted and listed by report types; Setup, Qualification, and Pass / Fail. Selecting one of the report types provides a listing of all the available .pdf reports. A scroll bar to the right may be used to access additional reports of the selected type.

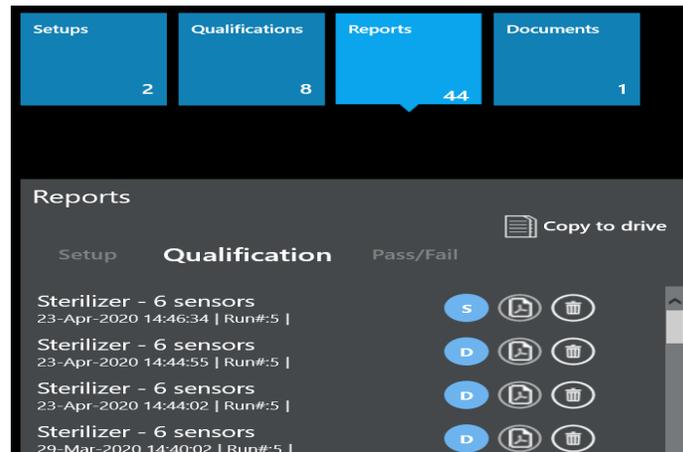


Figure 91: Report Tile

The blue circle to the right of the Qualification file names, represent whether the report is a Detailed or Summary report.

For every report listed the following buttons are available:

- **Pdf icon:** Permits viewing or printing of the .pdf report.
- **Delete:** Permits deletion of a .pdf report (privileges required).

Use **Copy to Drive** to copy the selected .pdf report to a chosen drive.

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

Documents

The Documents tile provides the ability to upload external documents, pictures, word, or .pdf documents, to store as part of an Asset. These can include Manuals, SOP's, Protocols, Diagrams, etc.

Selecting the Documents tile provides a list of all uploaded documents. Use the scroll bar to the right to scroll through any additional documents.

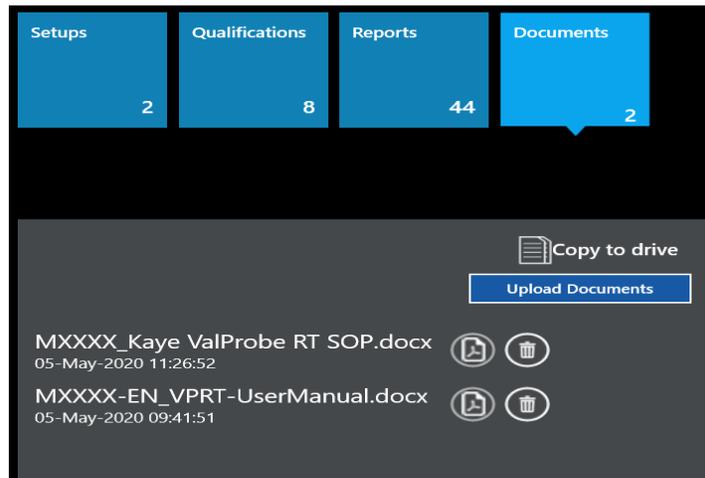


Figure 92: Documents Tile

For every document listed the following buttons are available:

- **Pdf icon:** Permits viewing or printing of the selected document.
- **Delete:** Permits deletion of a .pdf report (privileges required).

Use **Copy to Drive** to copy the selected document to a chosen drive.

Use the **Upload Documents** button to browse to the source of the desired document.

7.3. Creating A New Asset

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

Figure 93: New Asset Screen

Enter each new asset details separately, use the textboxes and dropdowns to enter:

Note: All fields highlighted with an asterisk are required fields to allow sorting of Assets.

- **Name:** Asset names must be unique. Before synchronizing several asset data sets, it is recommended to ensure there are no duplicate asset names utilized.
- **Asset ID:** This field is used to specify a company asset number or ID.
- **Type:** Select an existing asset type or enter a new type. Any new type definition will be available in the dropdown in the future.
- **Manufacturer:** Specify the manufacturers name of the asset.
- **Location:** Specify the location of the asset. This could represent the building or department.
- **Model:** Specifies the model number of the asset. This field is optional.
- **Size:** Specifies the volume of the asset in cubic units. In the dropdown, it is possible to select the appropriate units or enter custom units. This field is optional.
- **Last Validated:** Specifies the date of the last validation of the asset. This field is optional.
- **Validation frequency:** Specify the required validation frequency. This field is optional.

Enter an optional Description of the asset located on the right. Up to three images may be uploaded to appear on the Asset Details screen, as well as a wiring layout image(s) to provide Users with sensor placement details. Alternatively, utilize the camera to take pictures.

Select **Save** to save the entry and return to the Asset Hub.

Chapter 8. Defining Study Setups

Before running a qualification study, 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, permissions must be established and given by the System Administrator in the Admin menu (User Management tab).*

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

- Define the number and type of sensors to use in the study
- Assign sensors to groups and generate a wiring diagram
- Specify calculations to be monitored during qualification study
- Specify start and stop conditions for qualification
- Specify Logger Sample Rate, Transmission Rate, and RF Transit Threshold

When the setup is created and saved, a qualification study is ready to run.

8.1. Initiating a New Setup

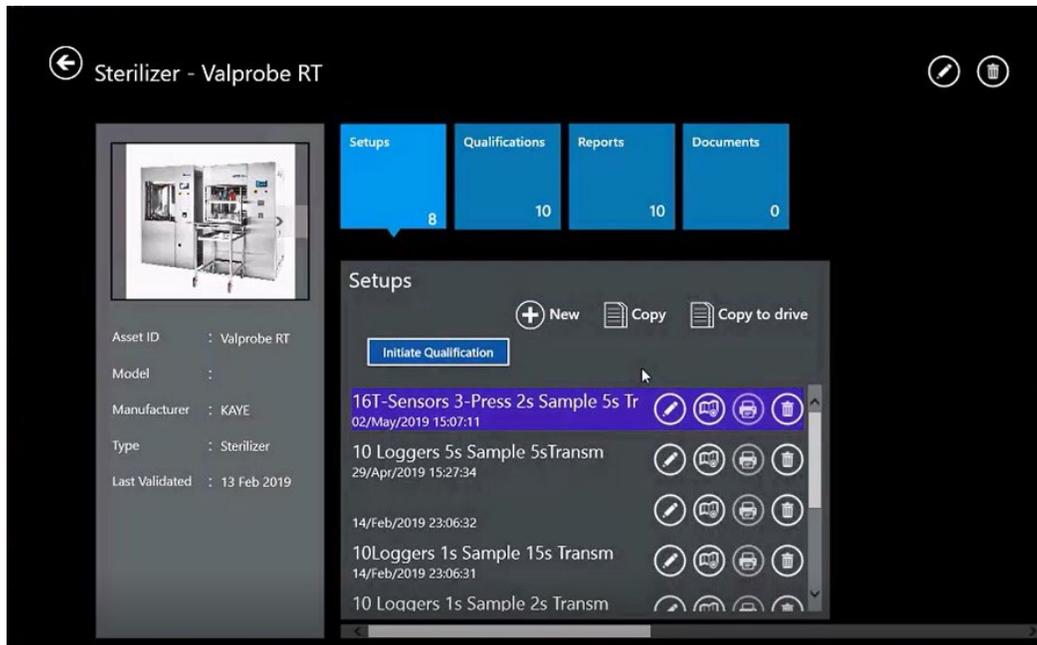


Figure 94: Setup Hub Screen

From the Asset Details screen, select **Setups** to open the Setup Pane Hub. Select **New** to open the Study Details screen.

8.2. Define Setup Screen

Use the Define Setup screen to define descriptive information detailing a Setup. The screen header lists the name of the new setup and six separate boxes signifying the steps or screens to complete the Setup.

Figure 95: Define Setup Screen

Use the textboxes or dropdowns 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, select **Sensors Configuration** to continue.

8.3. Sensors Configuration Screen

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

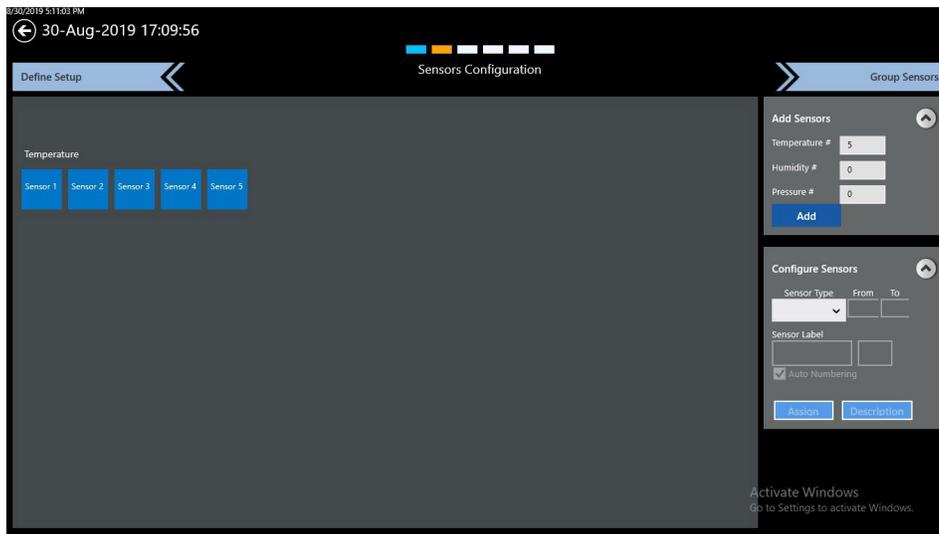


Figure 96: Sensors Configuration Screen

The Sensors Configuration screen permits the User to define the number and type of sensors to be used, as well as labels and descriptions for each defined sensor

The Sensor Configuration process is two steps:

- Add Sensors
- Configure Sensors

Note: *Sensor Configuration defines the number and type of sensors intended to be used for the study. The serial numbers of the actual Loggers and sensors are not defined in the Setup but rather defined just prior to starting a Qualification.*

Select the **Down Arrow** to open the Add Sensors window. For each type of sensor, define the intended number of sensors for use. Select **Add** to add sensors, they newly added sensors appear as blue tiles for each type of sensor defined (Temp, Pressure).

Select the **Down Arrow** to open the Configure Sensors window. For example, to select a series of *humidity* sensors:

- Select Humidity from the Sensor Type dropdown.
- Defined the consecutive range of sensors to configure.
- If desired, modify the Sensor Label and define the sensor number to begin with when Auto numbering.
- Select **Assign** and all selected sensors will be assigned and have the defined labels. Repeat the procedure for Pressure or Temperature if defined.

To individually select sensors, select each sensor tile, then select the type of sensor, label, and number. Select **Assign** to complete configuration of sensor.

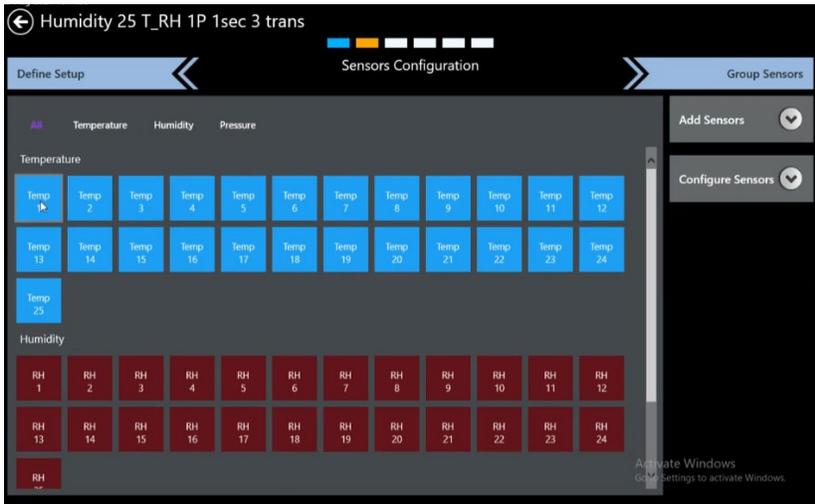


Figure 97: Configure Sensors

Select the **Description** button to open the Sensors Description screen. On this screen all sensors are listed in a table, along with information entered during sensor configuration.

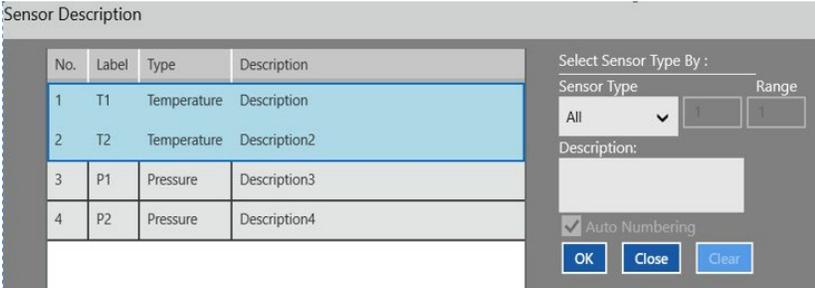


Figure 98: Sensor Description

To define descriptions, select the sensor type to display that type of sensor. Select a single sensor or multiple sensors from the table. Enter descriptions in the **Description** textbox and select **OK** to save the description or **Close** to cancel. Use the **Clear** button to clear all. Use the **Auto Numbering** checkbox to enable auto numbering to the sensor description. To return to the Sensors Configuration screen select the red **X** in the upper right corner.

Select the **Group Sensors** tab to advance to the next screen.

8.4. Understanding Groups

Grouping sensors is a powerful analysis tool to utilize for validation studies.

The following rules apply when assigning groups:

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

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

Assign a sensor to more than one group.

Sensors do not have to be in consecutive locations. Assign any sensor from any Logger to a group.

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

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

Grouping Examples:

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

8.5. Assigning Sensors to Groups



Figure 99: Group Sensors Screen

When the sensors are configured, the next step is to group the sensors by selecting **Group Sensors**. The Group Sensors screen displays a scrollable listing of existing groups and the **New Group** button.

To assign sensors to groups:

- Select the **New Group** button, to open the Group Name textbox. The **Group Name** textbox accepts upper- and lower-case characters, numeric characters, special characters like hyphens, underscores, slashes (forward and backward), and spaces.
- Enter a name for the group and select **Enter**
- Select individual sensors to add them to the group. These sensors appear deep blue with an orange checkbox on screen.
- If desired, customize the header for each group: The group specific header fields are pre-populated with the information from the asset. Use the **Save** button before switching to another group to save changes.

The screen has the following options:

- **Delete:** delete a group of sensors.
- **Customized Header:** the group specific header fields Asset ID prepopulates from the Asset and the SOP number prepopulates from the Define setup screen. The header is customizable for each group. Select **Save** before switching to another group to save any changes to the header.
- **Edit Group:** select the **Pen** icon inside the Group name to edit the group.
- **Add Sensors:** add additional sensors to a group.
- **Wiring Layout:** accessible via the **Book** icon, enables wiring layout configuration.

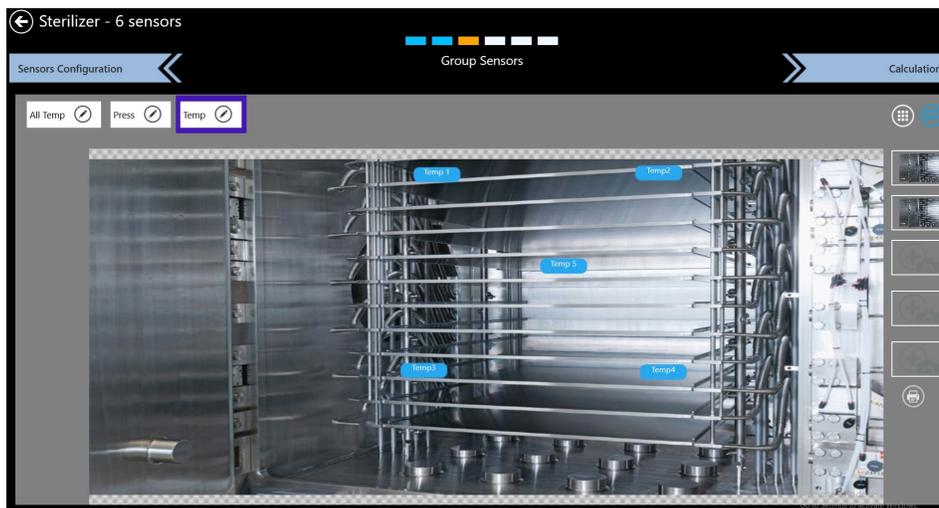


Figure 100: Wiring Layout Diagram

Using the wiring layout diagram, define up to five pictures as a background when positioning sensors. Select a picture frame on the right side of the screen and load a picture from a file using the **Pen** icon or **Camera** icon to take a picture with the built-in camera. Use the **Trash** icon to delete pictures.

Note: Take pictures by selecting the **Camera** icon through the device 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 are movable, via drag and drop, to a position reflecting their position on the asset. Use the **Printer** button to export the Wiring diagram into a .pdf.

For every group, select a picture and a sensor position, then save it along with the setup. The wiring diagram is printed from the Wiring Layout screen or as a part of the Setup report directly from the Asset Details screen. The wiring diagram is used in Layout View during Qualification to provide live data.

To clear a sensor, select the sensor label and then select **Clear Sensor**.

When finished, select **Calculations** to proceed to the Calculations screen.

8.6. Specifying Calculations

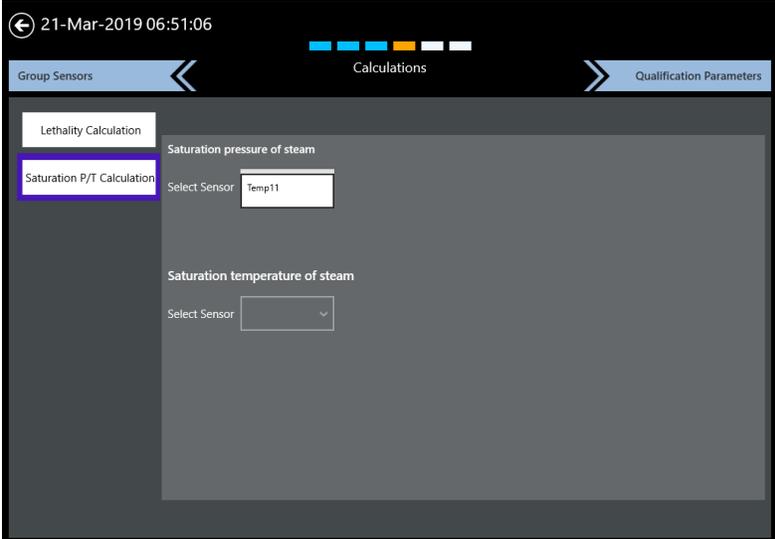


Figure 101: Calculations

With sensors defined and assigned to one or more groups, calculations must be specified for all sensor groups during the qualification study. Calculations include, Statistical, Lethality, Saturation pressure of steam, and Saturation temperature of steam calculations.

Statistical

The Statistical Calculations are automatically generated and include Min, Max, Max and Min Sensor Label, Max-Min, Avg and Standard Deviation, Max-Avg, Avg-Min, and Cycle Time.

Lethality

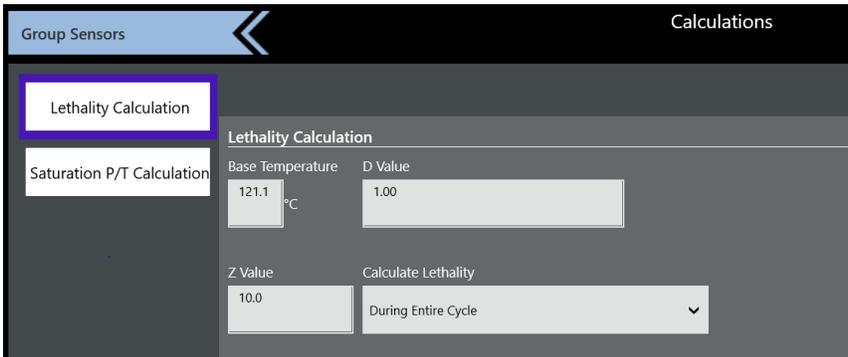


Figure 102: Lethality Calculation

Lethality calculation is typically used for most types of sterilization and Depyrogenation ovens etc. It calculates the number of equivalent minutes spent at the Base Temperature for each sensor.

To specify the Lethality calculation, enter the following parameters:

- Base Temperature
- Z value
- D value if enabled in preferences (default one minute)
- Calculate Lethality (dropdown includes “During Entire Cycle” and “During Exposure Cycle”).

Note: *Defining of an Exposure Cycle is only required if lethality is defined “During Exposure”.*

Saturation Temp / Pressure of Steam

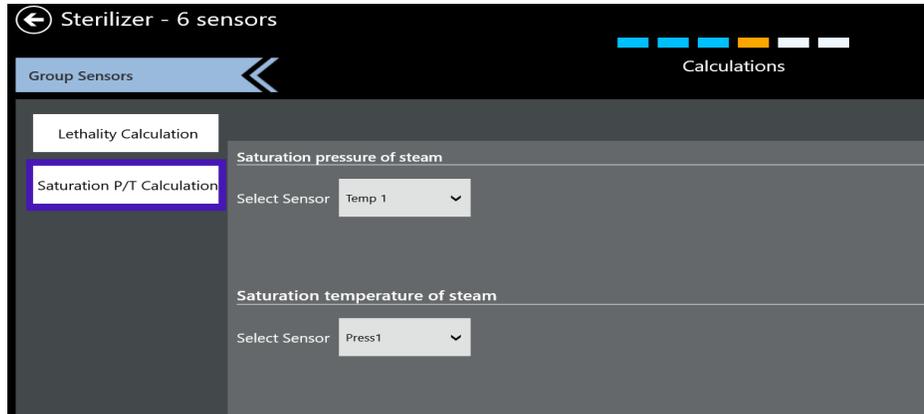


Figure 103: Saturation P/T of Steam

The Saturation Pressure of Steam is calculated based on a selected temperature sensor. It calculates what the ideal temperature should be for a saturated steam condition. The calculation is then compared to an actual pressure sensor.

The Saturation Temperature of Steam is calculated based on a selected live Pressure Logger. It calculates what the ideal pressure should be to for a saturated steam condition. The calculation is then compared to an actual temperature sensor.

Note: *If a Temp / Pressure Logger is not specified in the Sensor Configuration screen, then the Saturation Temperature of Steam cannot be defined.*

When all calculation definitions are completed, select **Qualification Parameters** to enter the Qualification parameters screen.

8.7. Specifying Qualification Parameters

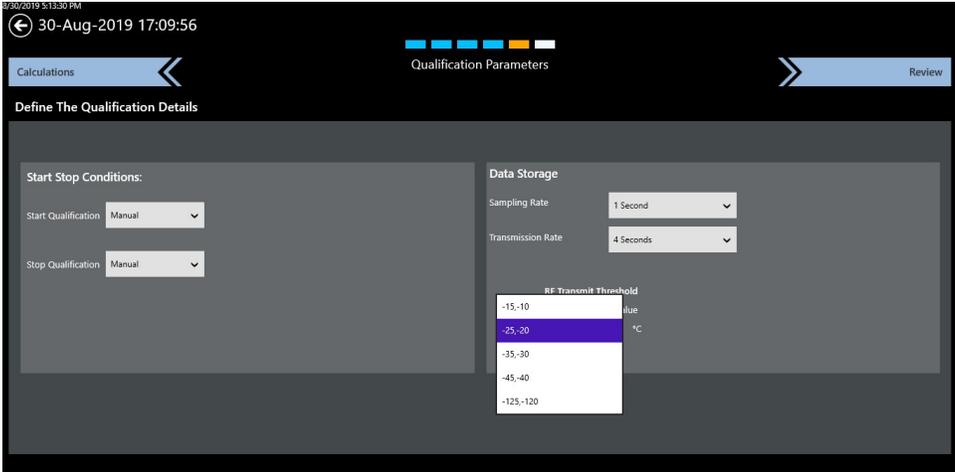


Figure 104: Qualification Parameters

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

Start / Stop Conditions

Loggers may be programmed to start data collection Manually when the Qualification is started or based on the Date / Time of Day. Loggers may be programmed to stop collection Manually or based on Cycle time. If the Users selects start Qual on time, they can enter a date and time up to three days from the current time. When the Setup is saved, the software prompts the User if they would like to edit the time before starting the Qual. If yes is selected, then the User can edit the time just prior to programming the Loggers.

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 Loggers are programmed. After 72 hours, the Loggers are set to shelf mode if a study is not started.

Note: When programming the start on time of the day, program one sample before the required first sample timestamp. E.g., If the first sample is required at 14:30:00 and the sample rate is 30 seconds, program the study start for 14:29:30.

- Cycle Time does not have any duration limit, cycle time duration is dependent on sampling rate and the number of samples. The maximum number of collected samples is 100,000 per sensor.

Data Storage / Transmission

The Sample Rate is how often the Loggers store the data to their internal memory. The memory capacity of each sensor is 100,000 samples. When the Loggers reach 100,000 samples the Loggers automatically stop collecting any new data. The sample rate dropdown has several choices ranging from every one second to ten minutes.

The Transmission rate is how often the Logger transmits samples to a Base Station. It also dictates how often the live and historical data updates on the Console. Transmission rate impacts battery life.

Note: When a User manually stops a study the Base Station waits until the next transmission rate to notify the Loggers, therefore if a ten-minute transmission rate is selected, it could take up to ten minutes after Qual Stop is pressed for the Loggers to stop collecting data. When Qualification Parameters definitions are complete, select **Review** to check the entries and save the Setup.

RF Transmit Threshold

Battery Life is considerably affected by cold temperatures, if you are operating at cold temperatures and do not necessarily need to see live data, then set the RF Transmit Threshold to automatically turn-off RF transmission when inactive temperature is reached. The internal data storage rate to the Logger is not affected and continues uninterrupted, only the transmission of data is affected. When a Logger's body temperature, note, not the sensors temperature, climb above the Active temperature the RF transmission is activated, and the Loggers begin to retransmit all old and current data to the Base Station and Console.

8.8. Reviewing and Saving a Setup

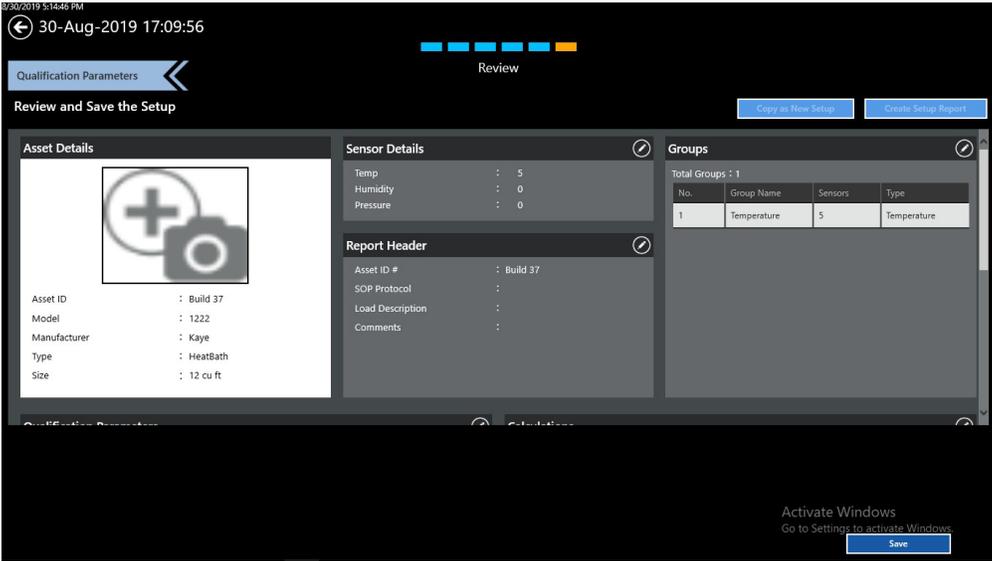


Figure 105: Setup Review Screen

After pressing **Review**, the Review screen opens, listing all the pertinent details about the setup that was created.

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

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

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 a .pdf file for saving and printing.

8.9. 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, select the setup file to modify.

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

Note: *User permissions must be given to modify a setup.*

Chapter 9. Qualification Study

9.1. Overview

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 selected 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.

The ValProbe RT Loggers utilizes internal memory to maintain qualification data during a study. During the study, data from the Loggers is stored in internal memory based on the defined Sample Rate and transmitted via the transit rate to the Base Station for storage. The Base Station also transmits the data to the Console for display and viewing. When Qualification is complete, the Base Station searches for any missing samples and connects to the affected Loggers to collect missing samples. The User can then save the file and the study file 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.

When the qualification study is complete, and the Study file has been transferred to the software it is automatically stored to the Asset under Qualifications. From there reports are generated via the software to document the specifics and results of the study (See Chapter 12).

9.2. Initiating a Qualification Study

Before the initiation of the qualification process, ensure the following.

- Base Station is located as close as possible to Asset being validated to maximize signal strength (Max distance from Base Station to all Loggers 450 ft (~150 meters) line of sight).
- Base Station is connected to Console / Docking Station via Direct Ethernet connection via Static IP or to Network via Ethernet DHCP. (See Chapter 3). After physical connections are made and then Power Up the Console and then the Base Station.
- Ensure all Loggers to be utilized for the study are available, and near the Base Station.

Note: Kaye recommends that the User first connect, program, and Start the Qualification before placing the Loggers in the Asset. This ensure all Loggers are properly started. The additional data collected prior to starting the process can be disregarded when marking cycles.

9.2.1. Select a Setup File

The Qualification Study is based on the parameters defined in the Setup file. Prior to the Qualification the Setup file that will be used needs to be selected. To select and load the Setup file perform the following steps:

- From the Main menu select **Assets**
- From the Setup tile select the desire Setup to be run and select **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.

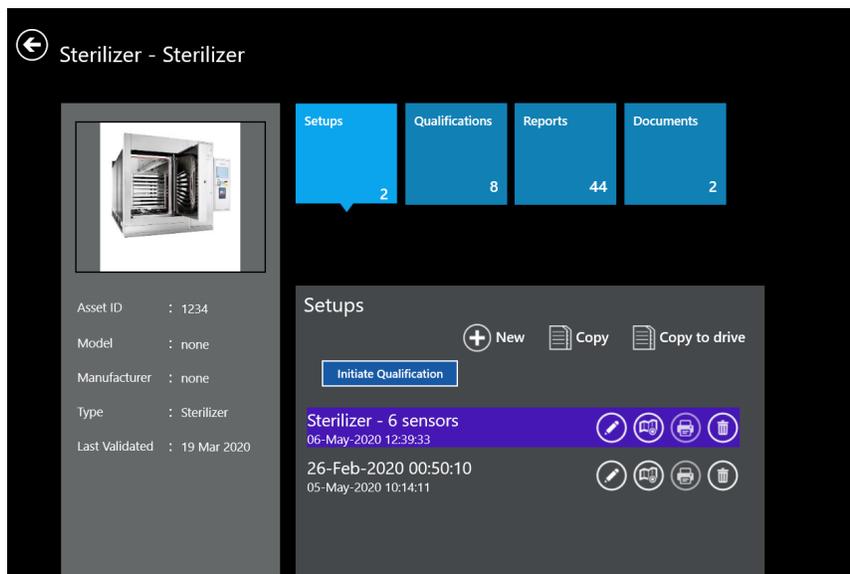


Figure 106: Selecting Setup File

9.2.2. Connecting to Base Station

From the Select Base Station screen select Discover to search for all available connected Base Stations.

Note: *If connected via Static IP only one Base Station should appear. If connected via Network DHCP all Base Stations which can be seen on the Network will appear. Only one Base Station can be connected during the Qualification study.*

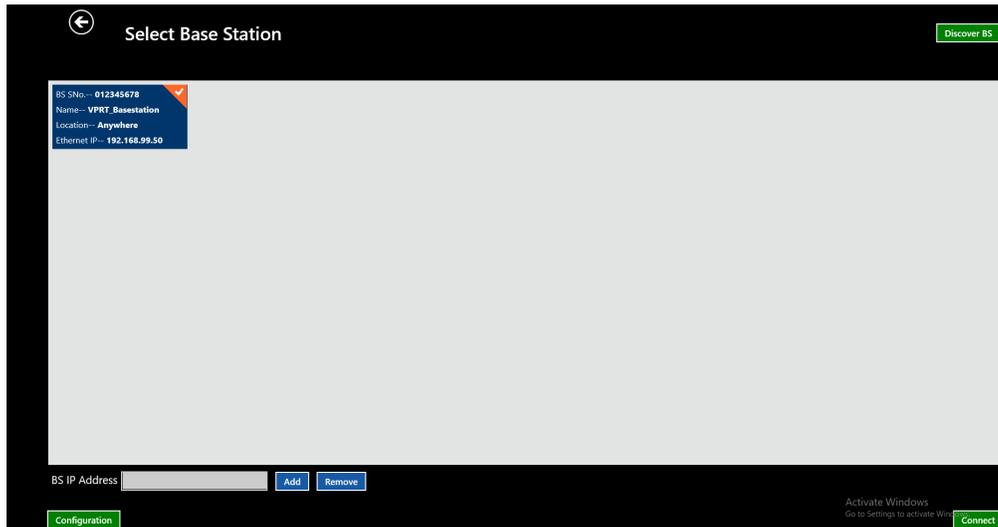


Figure 107: Select Base Station

Select the Base Station to be used for the Qualification study and select **Connect**. The software will connect to the Base Station, load the selected Setup, and move to the Select Loggers screen

Note: *If the Base Station fails to connect, select the Base Station, and select **Configure** and then select **Set Base Station to Idle**. This resets Base Station and Loggers to Idle mode. Select **Connect** to connect to the Base Station.*

Each Base Station firmware version is compatible with a specific Logger firmware version. The software checks for Base Station and Logger firmware compatibility and warns or blocks user action if they are incompatible with a message window.

9.2.3. Selecting and Connecting to Loggers

If the Loggers are not running a Verification or Qualification they are placed in Idle mode and then, after 15 min of no communications, in Sleep mode to preserve battery. To connect to the Loggers, they need to be awakened. The Loggers internally contain a magnetic switch which is only used to awaken the Loggers.

Note: *To wake Loggers, swipe the supplied Wakeup Device over the base of each Logger, or swipe the base of each Logger over the Kaye Logo on the Base Station LED panel.*



Figure 108 Wakeup Device & Base Station

As each Logger is awakened, a long beep is audible from the Base Station and the Logger tile appears with the serial #, Logger type, battery indication, mode, and a green dot specifying the number of sensors in the Logger. The bottom right of the screen displays the number of sensors that are configured in the Setup for the study.

Note: *If any Loggers fail to awake and cannot be detected, place the Logger on the Wakeup device for 30 second. The Logger initiates a reset and moves to Idle mode and try to awake the Logger again. If the Logger still does not awaken the battery may need to be changed.*

Once all Logger have been awakened, select which Loggers to use in the study by selecting them individually or by pressing **Select All Loggers**.

Note: *When using more than 25 Loggers, ensure that the transmission rate is equal or greater than the sampling rate. If not, a message displays a warning that you cannot move forward. Modify the setup and the transmission/sampling rates before proceeding with 25 or more Loggers.*

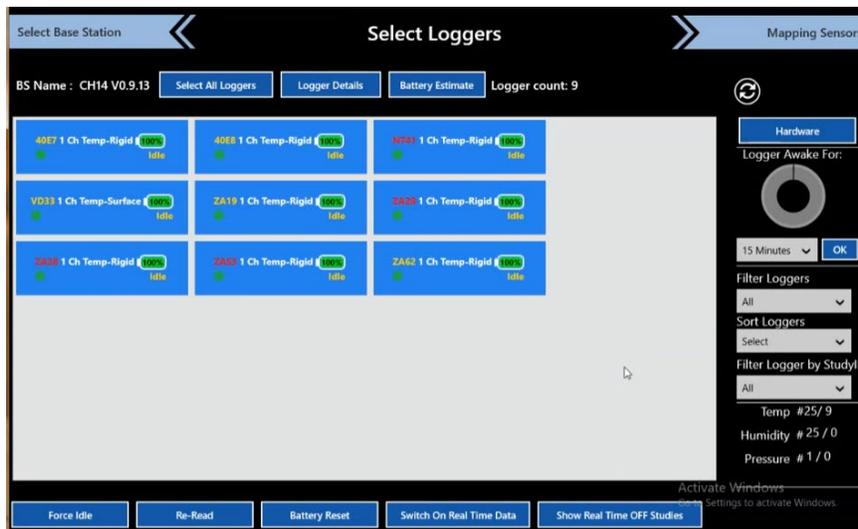


Figure 109: Select Loggers

Select the **Logger Details** button to display detailed information about each Logger. Information includes Type, Serial #, Battery %, Battery Reset Date, RF Link, Study Stop Reason, FW Version, the last manufacturing Cal date, and the last User Verification date. Select **Live Loggers** to return to the previous screen.

Note: *The Loggers Detail screen provides an easy way to check that each Logger has the appropriate amount of battery life for the upcoming Qualification study. If a Logger needs to be replaced prior to the study, see Chapter 2 to manually replace the battery. From the Select Loggers screen select the involved Logger and select **Battery Reset** to reset battery odometer.*

Select the **Sorted** button to sort Loggers by Serial#, Battery %, and Signal Strength. Select the **Filtered** button to filter by Logger type to provide an easier analysis of selected Loggers.

The “Logger Awake For” and the dropdown below it, display the amount of time Loggers will remain awake before starting the Qualification then go back to Sleep. The awake time dropdown includes times up to an hour.

9.2.4. Re-reading Loggers

Loggers maintain data from the previous study until they are programmed with a new Setup. Loggers may be re-read prior to being programmed and cleared. Use the **Re-Read** button to re-read Loggers. Select the Loggers that need re-reading and then select **Re-Read**. A window opens, select the Study by checking the checkmark and then **OK**. Use the **Save Study** button to save the study once any Loggers are re-read.

Note: A **Merge** checkbox is enabled if a study file already exists (StudyID). To merge, check the **Merge** checkbox, then **OK**. The prompt below displays, to merge the studies, select **Create a new file using an existing file**, to create a separate file select, **Create a new file independently**.

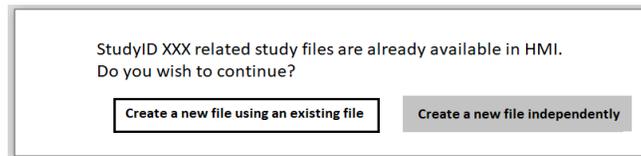


Figure 110: Merging Prompt

9.2.5. Battery Estimate

Logger SN	Logger Type	Description	Active %	Required %	Remaining %	Sufficient Energy	Below Threshold
40E7	Standard	1 Ch Temp-Rigid	100	0.36	99.64	✓	Proceed
40E8	Standard	1 Ch Temp-Rigid	100	0.36	99.64	✓	Proceed
N741	Standard	1 Ch Temp-Rigid	100	0.36	99.64	✓	Proceed
PE79	Standard	2 Ch Pressure Temp	100	0.38	99.62	✓	Proceed
RN65	Cryo	2 Ch Temp-Flexible	100	0.35	99.65	✓	Proceed
RQ03	Cryo	1 Ch Temp-Flexible	100	0.34	99.66	✓	Proceed
TW42	Cryo	2 Ch Humidity Temp	100	0.35	99.65	✓	Proceed
LUNK5	Cryo	1 Ch Temp-Flexible	100	0.34	99.66	✓	Proceed
VD33	Cryo	1 Ch Temp-Surface	100	0.34	99.66	✓	Proceed
VR85	Standard	1 Ch Temp-Bendable	100	0.36	99.64	✓	Proceed
ZA19	Cryo	1 Ch Temp-Rigid	100	0.34	99.66	✓	Proceed
ZA19	Cryo	1 Ch Temp-Rigid	100	0.34	99.66	✓	Proceed
ZA29	Cryo	1 Ch Temp-Rigid	100	0.34	99.66	✓	Proceed
ZA38	Cryo	1 Ch Temp-Rigid	100	0.34	99.66	✓	Proceed
ZA53	Standard	1 Ch Temp-Rigid	100	0.36	99.64	✓	Proceed
ZA62	Standard	1 Ch Temp-Rigid	100	0.36	99.64	✓	Proceed
ZD43	Cryo	2 Ch Temp-Flexible	100	0.35	99.65	✓	Proceed
ZD54	Cryo	5 Ch Temp-Flexible	100	0.37	99.63	✓	Proceed

Figure 111: Battery Estimate Screen

Select the Battery Estimate button to open the Logger Battery Estimation screen. Here you can ensure that the selected Loggers have enough battery life for the length of the study. Fill in the information under Study Details, dependent on the particular study and select **Calculate** to begin displaying battery levels in the table on the right. If a Logger's battery is sufficient for the study, a green checkmark and "Proceed" displays in the far-right columns otherwise, a red checkmark and "Warning" displays. Select the **X** in the top-right corner when ready to leave the screen, if you have any Loggers that have a warning, the prompt below displays, either select **Yes** to unselect the Loggers listed or select **Continue Anyway** to return to the Select Loggers screen.

Following logger(s) have insufficient battery:
40E7,40E8,N741,PE79,RN65,TW42,VR85,ZA53,ZA62,ZD43,ZD54.

Do you wish to Unselect these logger(s)?

Yes

Continue Anyway

Figure 112: Insufficient Battery Prompt

When all Loggers have been selected select **Mapping Sensors**.

9.2.6. Mapping Sensors

In the Setup, the number, type (Temp, Press), label, and description of each Logger is defined, however the configuration is not tied to a specific Logger serial number or sensor. Before starting a qualification, select Loggers and then map or link the specific Logger and sensor to the Logger types defined in the Setup.

On the Mapping Sensors screen, the blue tile above the overlay diagram represents the different groups assigned in the Setup. If defined in the Setup, each selected group displays a layout diagram.

The sensors pane on the right displays sensors from the Loggers that have been previously selected. To map the serial number of the Logger sensor to the configured sensors, drag the serial number over the sensor label location. The Logger label is then tied to the serial number of the Logger sensor. Continue until all sensors have been assigned or mapped. As each sensor serial number is mapped, the color of the sensor serial number changes from white to black. Above the group tile, “Unassigned Sensors” displays the number of sensors yet to be assigned or mapped.



Figure 113: Mapping Loggers - Overlay

To move sensor layout positions, drag each label to the new position. If no Overlay picture was created in the Setup, select the icon below the sensor pane and import a new picture or use the camera to take a picture.

Use the **Clear Map** button to clear all group mapping and restart the process. Double select any sensor to open a **Clear** button, select **Clear** to remove the mapping for the selected sensor.

Selecting the **Print** icon opens a selection box to create a .pdf file of the current displayed group overlay or all group overlays. These .pdf files can later be downloaded into the Documents section of the Asset screen for future reference.

For an alternate method to map sensors, select the icon to the right of the Printer icon to assign sensors from a tabular format, define or edit sensor descriptions, by selecting the description field. Select the same icon to return to the Overlay view.

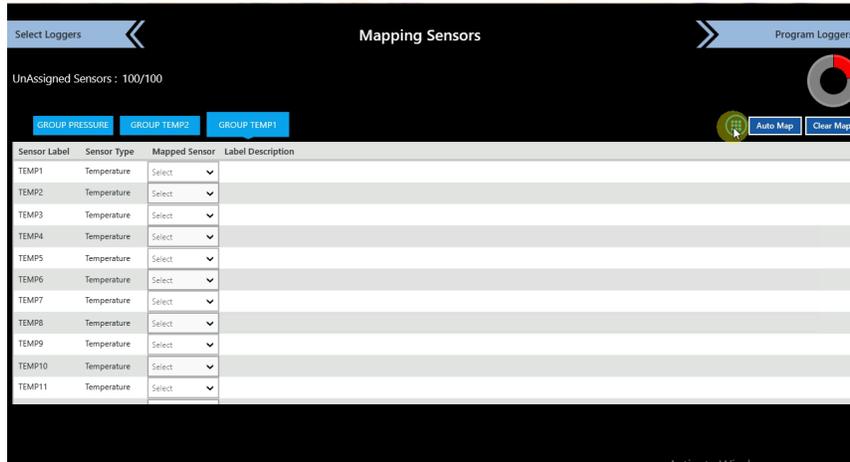


Figure 114: Mapping Loggers - List

9.1. Auto Mapping Sensors

Additionally, the ValProbe RT System can automatically select Loggers and then map or link the specific Loggers and sensors to the Logger types defined in the Setup. To do this, select the **Auto Mapping** button and then check either Select All or each individual group of sensors and select **OK**. A combination of both manual and auto mapping is possible.

Use the **Clear Map** button to clear all group mapping and restart the process. Double select any sensor to open a Clear button

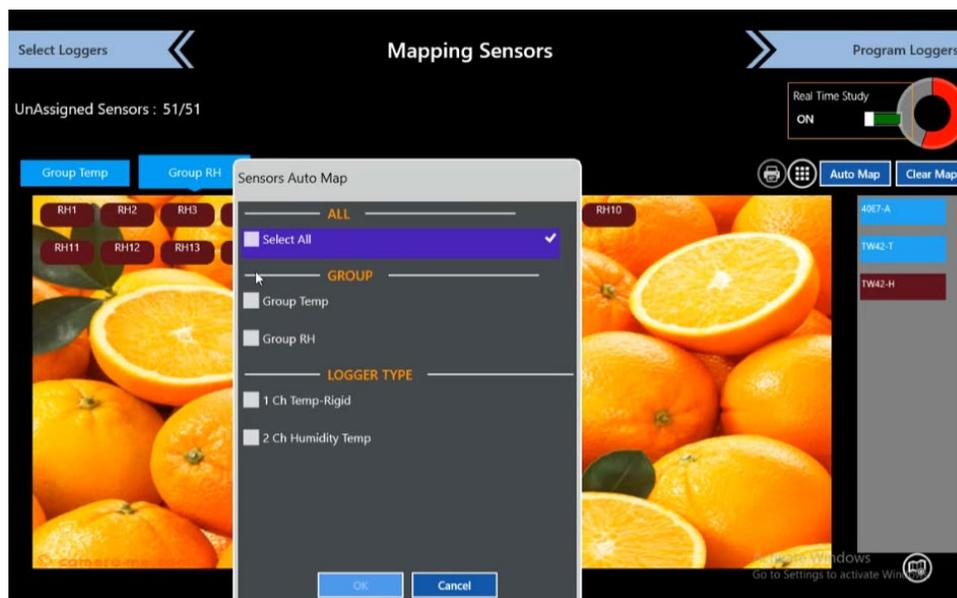


Figure 115: Auto Mapping Sensors

9.1. Real Time Off Study

On the Mapping Sensors screen there is the option to turn Real Time Data off. Use this option if you would like to run a study without the need to see data as it is recorded in real time. Move the **Real Time Study** switch to **Off** by selecting the switch. When real time data is off, the switch is red and begins to blink.

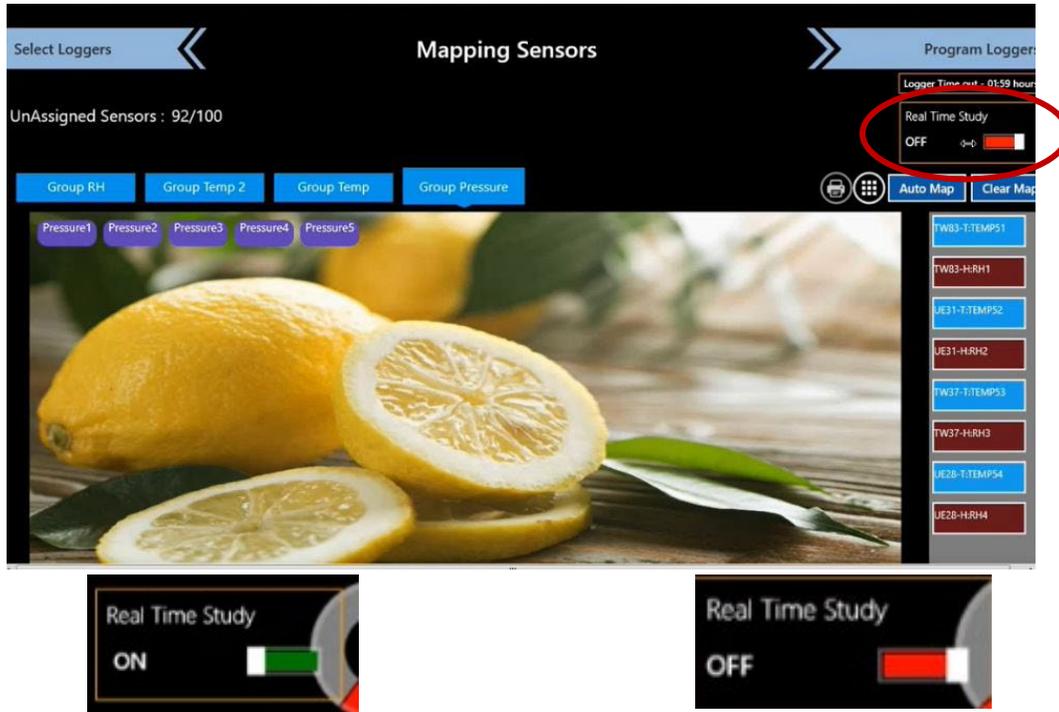


Figure 116: Real Time Study Switch

Select **Program Loggers**, a window opens prompting you with an acknowledgement that real time data is off, select Yes to proceed.

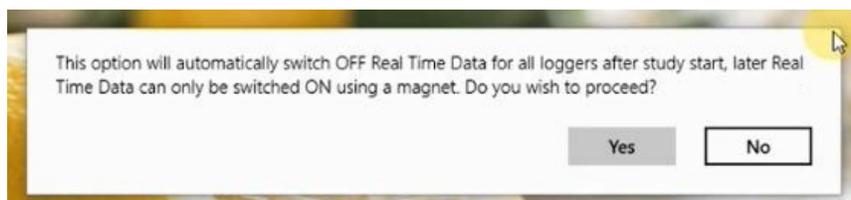


Figure 117: Mapping Sensors - Real Time Data Off Prompt

The process is the same for real time Off and ON. Once all Loggers are programmed, select **Qualification** to open the Qualification Screen. The upper right corner displays "Study Type: Real Time Data Off" when real time data is shut off. However, the sensors display real time data up until you select **Start Qual**.

The screenshot shows the Qualification software interface. At the top, it displays 'Qualification' with a 'Logger Time out - 07:59 hours' warning. The main header includes 'Asset: A-Humidity', 'Setup: Humiditz 25Lop P ...', and 'BaseStation: 10.17.10.226 ...'. The 'Study Type' is set to 'Real Time OFF'. There are buttons for 'Hardware', 'Setup', and 'Abort Qual'. A date and time stamp '25-Aug-2021 17:07:00' is visible. The main display area contains two tables:

Group Temp (°C)						
Sensor	Label	Value	Battery(%)	RF Link	Sample %	Alethality
40E7-A	Temp1	22.22	100	100	0	
TW42-T	Temp2	23.13	100	100	0	

Group RH (%RH)				
Sensor	Label	Value	Battery(%)	RF Link
TW42-H	RH1	43.9	100	100

On the right side, there is a 'History' section with columns for 'DateTime', 'EventName', and 'Serial No'. Below this is a 'Group: Group Temp (°C)' summary table:

Calculation	Value	Sensor
Max	23.13	TW42-T
Min	22.22	40E7-A
Max-Min	0.91	
Average	22.67	
Standard Deviation	0.64	
Max-Average	0.45	
Average-Min	0.45	

At the bottom right, there are buttons for 'Start Qual', 'Stop Qual', 'Init Start Exposure', and 'Add User Events'.

Figure 118: Real Time Off Qualification Screen

Start the Qualification by selecting **Start Qual**. A prompt displays to ensure that you are aware that real time data is off, select **Ok** to start and return to the Main screen.

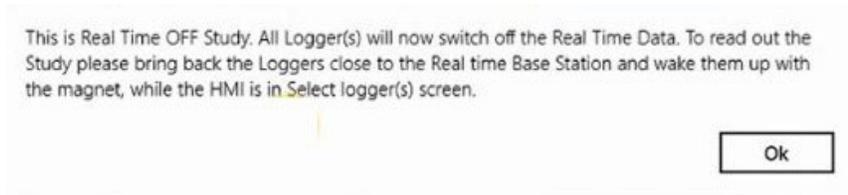


Figure 119: Start Qual - Real Time Data Off Prompt

The study continues to run and can be accessed by moving the sensors close to the Base Station running the study and then using the software to connect to the Base Station. Once connected to the Base Station select **Show Real Time Off**, any Real Time Off studies using the connected Base Station display in the window below:

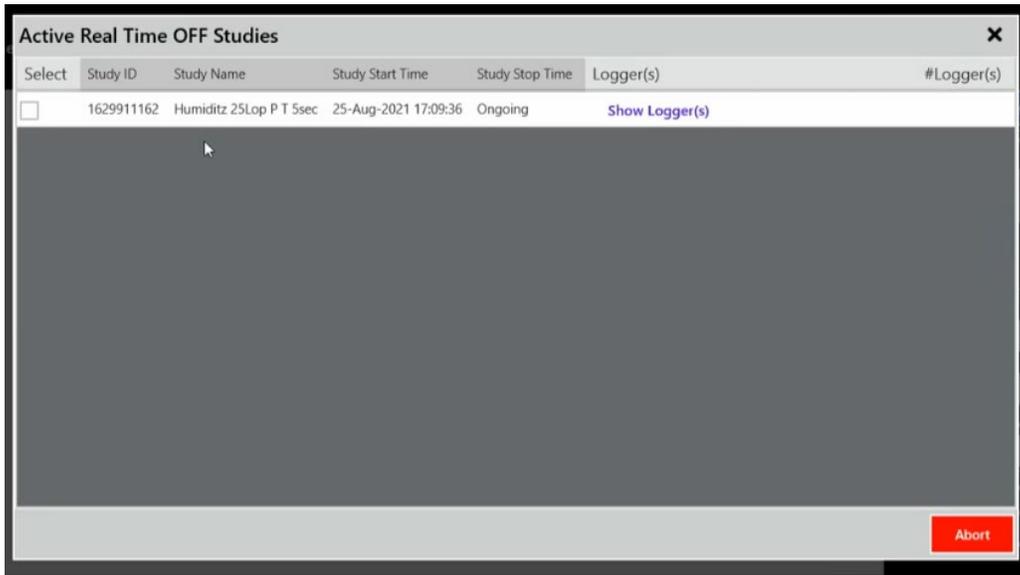


Figure 120: Active Real Time OFF Studies

The Study ID, Study Name, Study Start Time, Study Stop Time, Logger(s), and #Loggers are listed inside the window. Select **Show Logger (s)** to display the Logger tags from the study.

Note: There is a maximum of 20 parallel active Real Time Off studies for one Base Station.

If desired, check the checkmark of the study and then Abort to stop the selected study, otherwise, select the **X** to close the window.

With all sensors mapped, select **Program Loggers** to navigate to the Programming Loggers screen.

9.2. Program Loggers

The software automatically begins to program the Base Station and the Loggers to prepare them for the Qualification study. Activities include clearing the existing Base Station and Logger memory, synchronizing the time for all components, programming the parameters from the Setup, and setting the Loggers and Base Station to Pre-Qual mode.

The screenshot shows the 'Program Loggers' interface. At the top, there is a navigation bar with 'Mapping Sensors' on the left and 'Qualification' on the right. Below this is a table with the following columns: SN, Type, TimeSync, Configuration Status, RF Link, State, Status, and Include Loggers. The table contains five rows of data, each representing a different logger. The 'Configuration Status' column for each row contains three green icons: a download arrow, a refresh/circular arrow, and an upload arrow. The 'RF Link' column shows '100' for each logger. The 'State' column shows 'Selected' and the 'Status' column shows 'Success'. The 'Include Loggers' column has a slider control for each logger.

SN	Type	TimeSync	Configuration Status	RF Link	State	Status	Include Loggers
YF39	1 Ch Temp-Bendable	Time Sync	[Download] [Refresh] [Upload]	100	Selected	Success	<input type="checkbox"/>
WG38	1 Ch Temp-Flexible	Time Sync	[Download] [Refresh] [Upload]	100	Selected	Success	<input type="checkbox"/>
U90A	1 Ch Temp-Bendable	Time Sync	[Download] [Refresh] [Upload]	100	Selected	Success	<input type="checkbox"/>
YF36	1 Ch Temp-Bendable	Time Sync	[Download] [Refresh] [Upload]	100	Selected	Success	<input type="checkbox"/>
PB99	2 Ch Pressure Temp	Time Sync	[Download] [Refresh] [Upload]	100	Selected	Success	<input type="checkbox"/>

Figure 121: Program Loggers

The Program Loggers screen provides a visual status of programming activities. The table lists all Loggers and three configuration status icons displaying programming progress. In the top right of the screen is a Logger Time Out bar, that displays the time until the Loggers time out. When all three configuration status icons are green, the programming is complete, and the Qualification ribbon flashes yellow.

Select **Qualification** to navigate to the Qualification screen.

9.3. Qualification Study Start / Stop Conditions

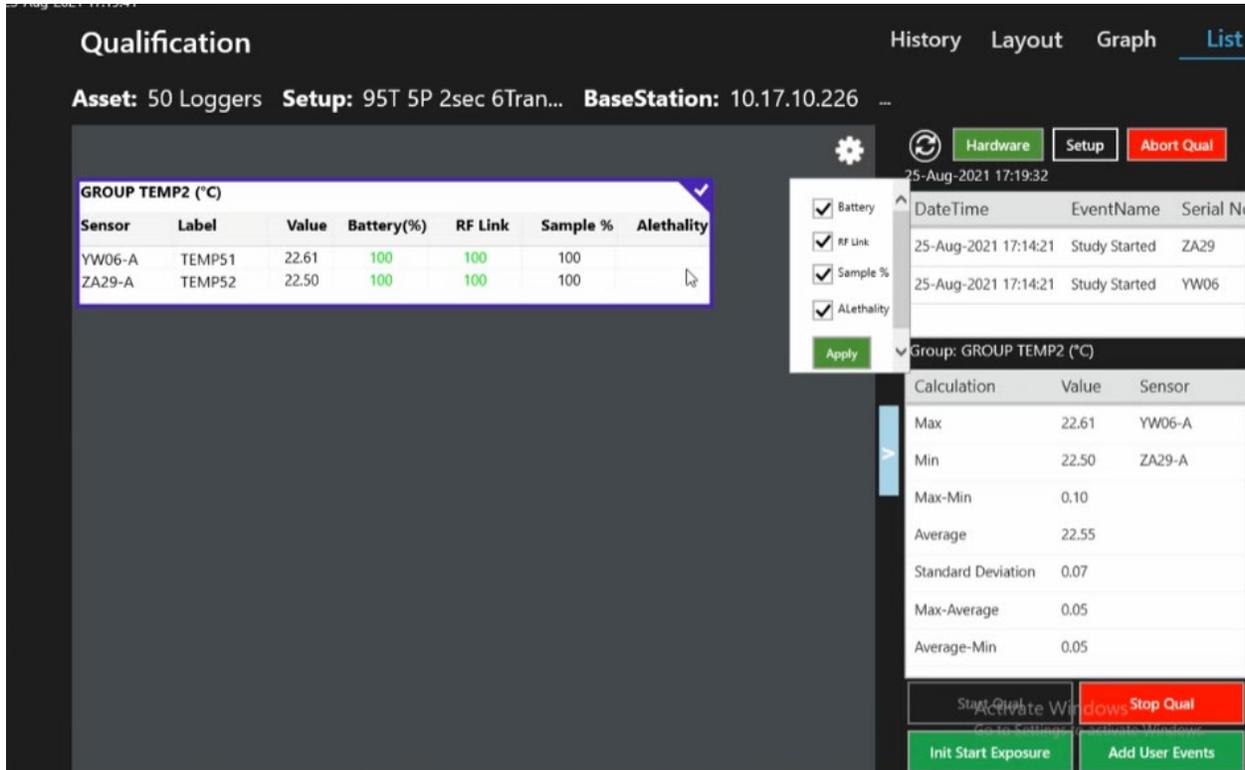


Figure 122: List View - Real-Time Readings

When Logger and Base Station programming is complete, and the Qualification ribbon is pressed, the Qualification Study screen displays. The bottom right of the screen contains all the Start / Stop command buttons for qualification and exposure as defined within the Setup.

- Qual Start conditions are programmed in the Setup and are configurable to either occur manually, by pressing the **Start Qual** button, or automatically based on **Date and Time of Day**.

Note: *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.*

- Qual Stop conditions are programmed in the Setup and are configurable to either, occur manually, by pressing the **Stop Qual** button, or automatically based **Cycle Time**, on **Date and Time of Day**.

Note: *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 collected are 100,000 per sensor.*

The Qualification Study screen contains buttons for the **Start and Stop Exposure**. These buttons are active only if the Lethality calculation in the Setup is configured to calculate lethality during the Exposure Cycle.

The ValProbe RT system automatically controls the availability and proper sequencing of the Qual Start / Stop and Exposure Start / Stop buttons to ensure the correct order is followed (i.e. do not select Stop Exposure before Start Exposure is initiated etc.).

If a condition is defined to be Started / Stopped manually, then the proper sequence of that button is highlighted a color and does not occur until the button is pressed. If the condition is

defined in the Setup to occur automatically based on date / time or Cycle Time, then the button is grayed out and occurs automatically when the condition occurs.

At the end of the Qualification study, select the **Save Study** button to save the study to the Asset under Qualifications.

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

9.4. Viewing Qualification Real-Time Displays

During a Qualification Study the ValProbe RT software offers numerous real-time and historical displays to easily evaluate and analyze the performance of the Qualification study. The displays include List, Graph, Layout, and Historical views. All views contain similar structure and elements:

- A Header including the Asset name, Setup Name, and IP address of the connected Base Station.
- A display windows which switches between List, Graph, and Layout view depending the selection on the top right of screen.
- An Events table listing events for all Groups
- A Calculation table displaying real-time Statistical Calculations for the selected Group. Values listed include
 - Min
 - Min-Max
 - Average
 - Max Average
 - Average Min
 - CycleDuration: How long study has been running
 - ExposureDuration: How long exposure has been running
 - Battery %
 - RF Link
 - Sample %: the percentage of data in the Logger that has been transmitted into the Base Station
 - ALethality
 - Control Buttons to control the Start / Stop of Qualification and Exposure.
 - A Setup button to review the parameters configured in the Setup.
 - A Hardware button to provide details of connected devices.
 - A Quit Qual button to cancel the Qualification Study and delete all data samples.
 - An Add User Event button to mark additional events during a running study.

9.4.1. List View

The List view display window contains tables for each Group containing the group name, sensor serial number, label, current value, Logger battery life, RF signal strength and Accumulated Lethality if defined in the Setup. The Logger Time out displayed at the top of the screen is a countdown until Loggers timeout. To customize the columns to include in the Groups table select the  icon.

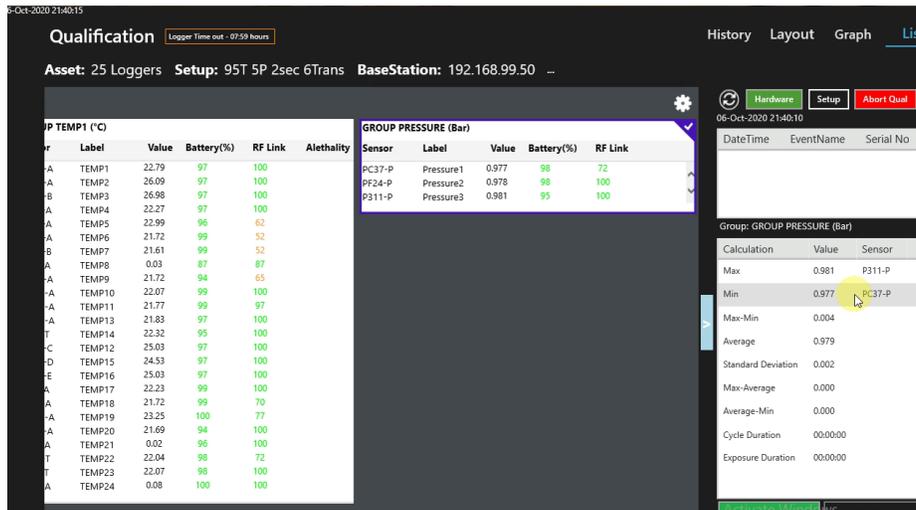


Figure 123: List View - Real-Time Data

9.4.2. Graph View

The Graph view display window contains real-time graphical trending of sensor readings. The sensors are organized in Groups defined in the setup. Select the Group name buttons above the graph to display different groups. Use the blue box with arrows to expand the Graph to full screen.

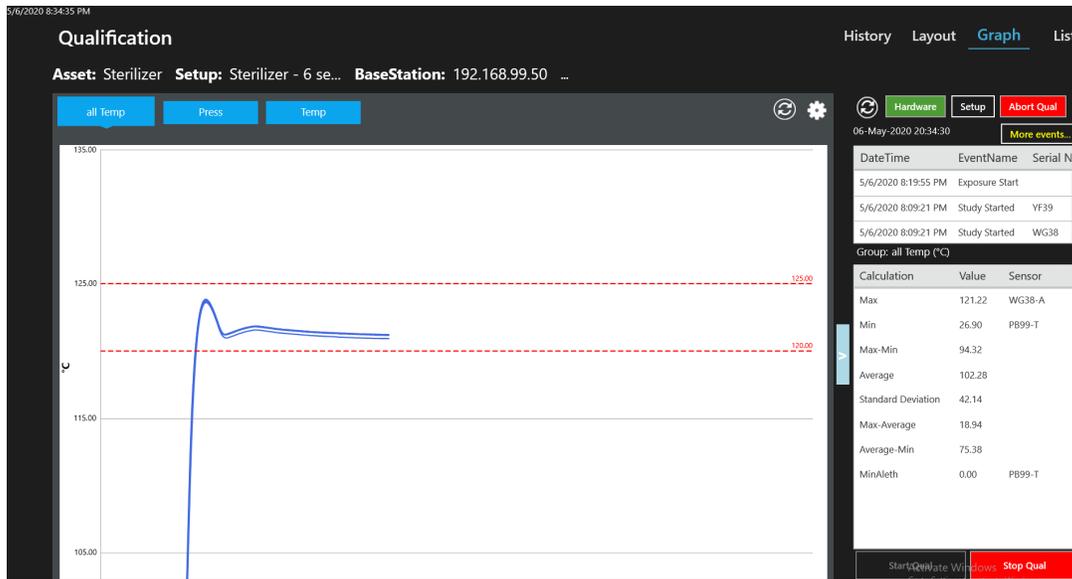


Figure 124: Graph View

Graph View options are accessible by selecting the  icon. In the options, the User can add limit lines, manually adjust scaling, and define parameters for zooming.

Select **Limit** to define upper and lower limits to the graph. Select **Reset** in the Limits window to disable limits.

Select **Manual Scale** to define the upper and lower scaling for the graph. Select **Reset** in the Manual Scale window to reset manual scaling.

Use the **Zoom** option to define whether to zoom the X- or Y-axis, or both. Once defined, use the touch screen to control zooming in the desired view. Select **Reset** to disable Zoom.

9.4.3. Layout View

The Layout view display window includes sensor placement in a graphic view of the Asset along with real-time readings. Sensors and background pictures are displayed by Groups defined in the setup. Select the Group Name buttons above the graph to display the different groups. Use the blue box with arrows to expand the Graph to full screen.

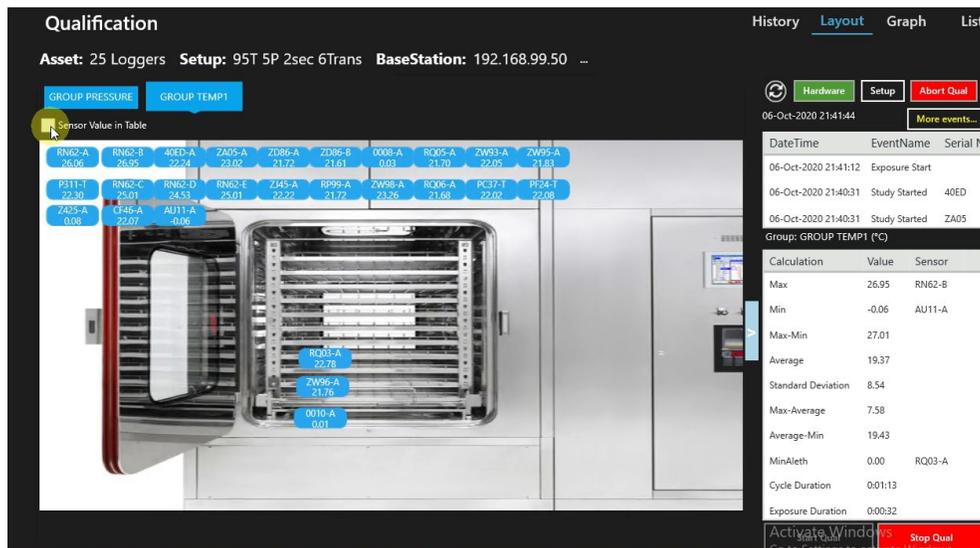


Figure 125: Layout View

Check the Sensor Value checkbox to display the sensor values and description in a table on screen. Selecting **Edit** permits editing the sensor description, select **Save** when finished to save any changes.



Figure 126: Sensor Value in Table

9.4.4. History View

The History view display window contains a real-time table of all the sensor readings collected and stored by the Base Station. The table includes all sensors from all groups. The collection rate is based on the sample rate as defined in the Setup. Use this view to look over data from long studies.

	YW06-A	ZA29-A
25-Aug-2021 17:15:48	22.29	22.07
25-Aug-2021 17:15:46	22.30	22.08
25-Aug-2021 17:15:44	22.32	22.08
25-Aug-2021 17:15:42	22.32	22.08
25-Aug-2021 17:15:40	22.32	22.09
25-Aug-2021 17:15:38	22.33	22.09
25-Aug-2021 17:15:36	22.33	22.10
25-Aug-2021 17:15:34	22.34	22.11
25-Aug-2021 17:15:32	22.35	22.12
25-Aug-2021 17:15:30	22.35	22.12
25-Aug-2021 17:15:28	22.35	22.12
25-Aug-2021 17:15:26	22.36	22.11
25-Aug-2021 17:15:24	22.35	22.11
25-Aug-2021 17:15:22	22.35	22.11
25-Aug-2021 17:15:20	22.35	22.10
25-Aug-2021 17:15:18	22.34	22.10
25-Aug-2021 17:15:16	22.34	22.09
25-Aug-2021 17:15:14	22.34	22.09
25-Aug-2021 17:15:12	22.34	22.10
25-Aug-2021 17:15:10	22.34	22.10
25-Aug-2021 17:15:08	22.33	22.10
25-Aug-2021 17:15:06	22.33	22.11

Figure 127: History View

Select the **Printer** icon to create a Preliminary Historical Report. The report can be saved as a .Pdf or an Excel file.

Note: *This report is not for finalized data, it is to be used only as a historical reference of data while a study is running.*

Time Stamp	YW06-A (°C)	ZA29-A (°C)
17:14:20	22.40	22.25
17:14:21	22.39	22.24
17:14:22	22.38	22.24
17:14:24	22.38	22.22
17:14:26	22.38	22.21
17:14:28	22.38	22.19
17:14:30	22.38	22.18
17:14:32	22.37	22.18
17:14:34	22.37	22.17
17:14:36	22.38	22.17
17:14:38	22.37	22.17
17:14:40	22.37	22.15
17:14:42	22.36	22.15
17:14:44	22.36	22.13
17:14:46	22.36	22.13
17:14:48	22.36	22.12
17:14:50	22.36	22.12
17:14:52	22.36	22.11
17:14:54	22.35	22.11
17:14:56	22.36	22.11
17:14:58	22.35	22.11
17:15:00	22.35	22.12
17:15:02	22.34	22.11
17:15:04	22.34	22.11
17:15:06	22.33	22.11
17:15:08	22.33	22.10
17:15:10	22.34	22.10
17:15:12	22.34	22.10
17:15:14	22.34	22.09

Figure 128: Preliminary Historical Report

Chapter 10. Live Monitoring Mode

The ValProbe RT software offers a feature which allows Users to connect to the Base Station and Loggers and display live data. Unlike a Qualification Study no data is captured or stored, and no reports generated. There is no Setup required only Loggers which are discovered and connected are displayed.

Monitor mode is ideal for testing, inspecting hardware components and connectivity of all devices. Use the Monitor mode to check network connectivity to the Base Station, or Logger battery life or signal strength, or verify connectivity to an IRTD / Bath / humidity chamber.

10.1. Initiating Monitor Mode

From the Main Menu, select the **Discover** tile, located in the Hardware screen, to open the Select Base Station screen.

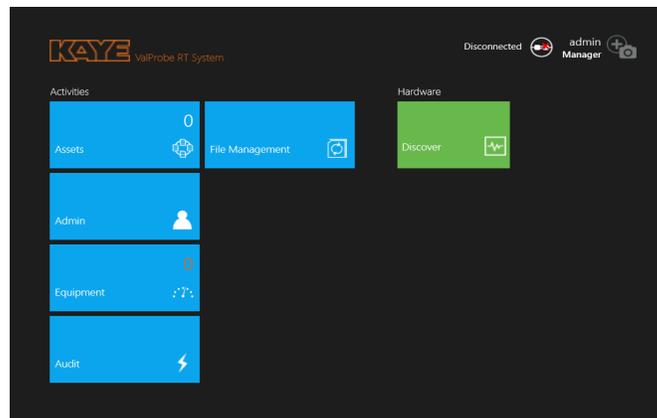


Figure 129: Monitor Mode

Select **Discover BS** to search for connected Base Stations. If a Base Station is found, select the Base Station, and select **Connect**. If the Base Station is not found, see Chapter 3 for detailed information on how to connect to a Base Station.

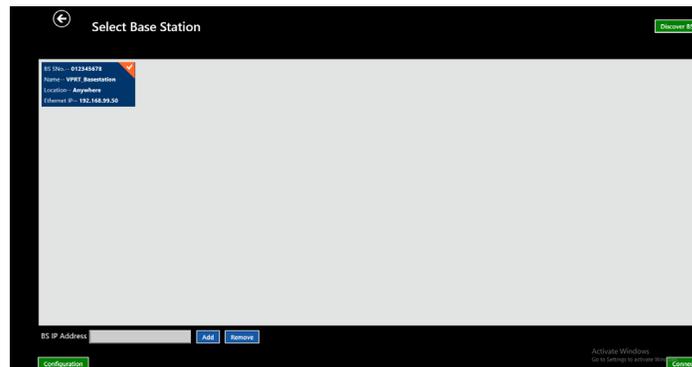


Figure 130: Select Base Station

When at the Select Loggers screen, awaken all Loggers requiring connection to the Base Station using the Wakeup Device or the Base Station Status Panel magnet. As Loggers are found, the Base Station beeps and the Logger tiles appear on the Select Loggers screen.

Note: When using more than 25 Loggers, ensure that the transmission rate is equal or greater than the sampling rate. If not, a message displays a warning that you cannot move forward. Modify the setup and the transmission/sampling rates before proceeding with 25 or more Loggers.

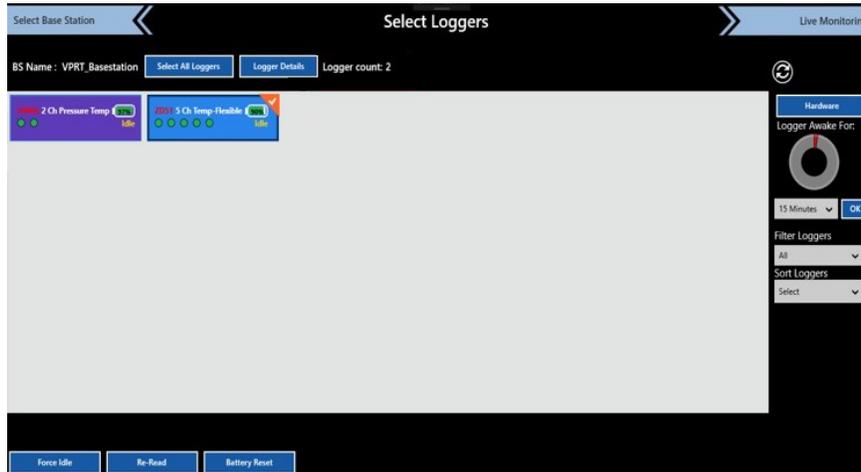


Figure 131: Select Loggers

10.2. Live Monitoring Displays

In the Live Monitoring mode, no study is running, and the data is updated at the display rate of every 10 sec. The header displays only the IP address of the Base Station. The User can select between a List display or Graph display. Both displays have basically the same functionality except in the way they present data the sensors that are displayed are the ones selected on the Select Sensor screen and are separated by types of Sensors (temperature and pressure). The Calculation table displays Statistical Calculations based on the type of sensors selected (check marked).

The List and Graph screens also contains a **Hardware** button displaying the connectivity status of all hardware (Console, Base Station, IRTD, Chambers, and Baths). Live collection structure (sensor and groups definition) follows the last transferred setup (to transfer a setup, first start a study). If the ValProbe RT is in monitoring status, a User can switch between List and Graph Views to display live data.

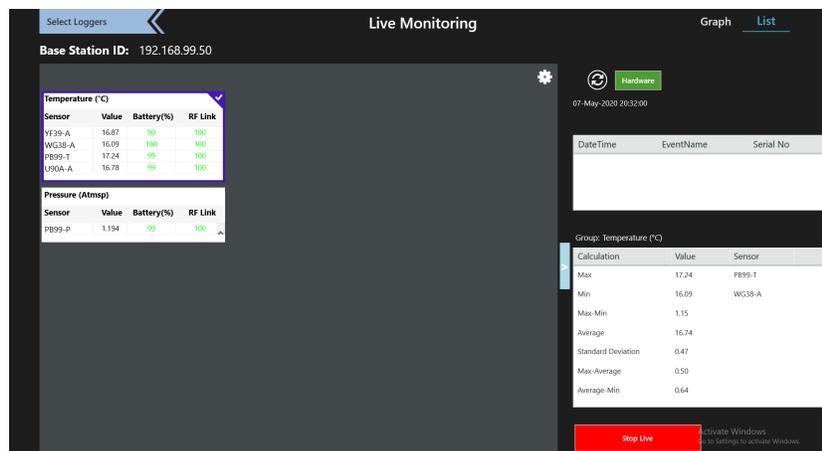


Figure 132: List View - Monitoring

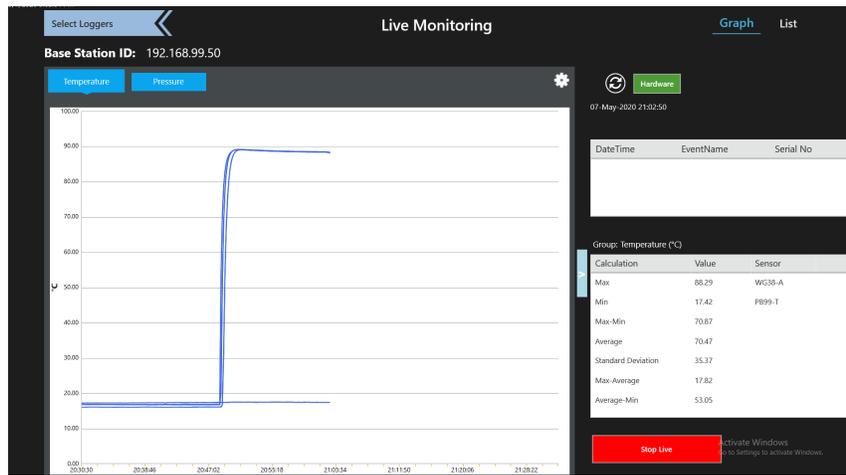


Figure 133: Graph View - Monitoring

Graph View options are accessible by selecting the  icon. In the options, the User can add limit lines, manually adjust scaling, and define parameters for zooming.

Select **Limit** to define upper and lower limits to the graph. Select **Reset** in the Limits window to disable limits.

Select **Manual Scale** to define the upper and lower scaling for the graph. Select **Reset** in the Manual Scale window to reset manual scaling.

Use the Zoom option to define whether to zoom the X- or Y-axis, or both. Once defined, use the touch screen to control zooming in the desired view. Select **Reset** to disable Zoom.

10.2.1. Hardware Communications Connections

On any of the live data monitoring screens, select **Hardware** to see communications connections between pieces of hardware. On the Hardware screen, each hardware item connected to the Base Station is displayed. A green line indicates proper communications while a gray line indicates a communication problem.

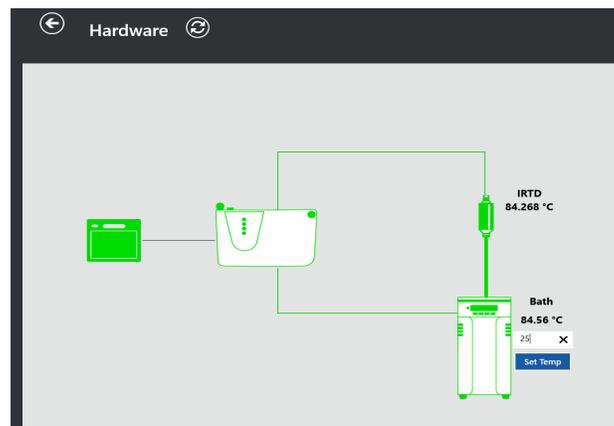


Figure 134: Hardware Monitoring

By selecting each connected hardware icon, the software displays key information about the hardware.

The IRTD provides the real-time display of the IRTD standard.

The Bath displays the current temperature of the connected bath. Using this screen, The User can enter a setpoint manually to set the bath temperature.

The Humidity chamber displays the current humidity readings.

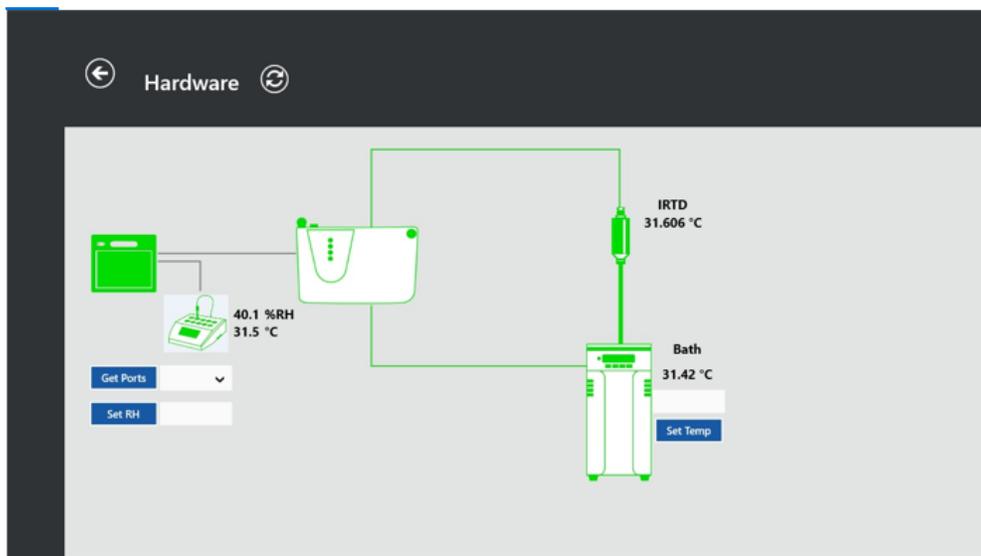


Figure 135: Hardware Monitoring – Humidity

To check the status of sensors, see Sensor Verification (Chapter 12).

Select **Stop Live** from the List or Graph screen to leave Monitoring Mode.

Chapter 11. Sensor Verification

11.1. Introduction and Overview

With the ValProbe RT system, sensors at up to six different temperature setpoints for Pressure / Temperature Loggers, six different humidity setpoints for Humidity Loggers, may be verified, though each sensor type must be verified independently.

The ValProbe RT uses the parameters defined in the Verification setup to perform sensor verification. Verification parameters specify the temperature/humidity reference setpoints at which Verification is performed, and the stability and deviation criteria for the temperature/humidity sensors and the temperature/humidity standard. Temperature Verification requires the use of a Kaye IRTD as the temperature standard. The IRTD's measurement accuracy is 0.025°C, with a range of –196°C to 420°C. 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 may be performed for non-Kaye baths. For adequate stability and uniformity, use the correct bath (see Section 11.1.2).

Humidity Verification requires the use of a Humidity chamber. The first step in the Humidity Verification process is to verify that the Humidity chamber is stable. Stability is the maximum allowable change in Humidity for the humidity standard over the specified time interval. The first set point is created with a default value of 90%RH but may be set between 5%RH – 95%RH. The maximum allowable change for the first set point is between 0.5%RH – 5.0%RH and defaults to 0.5%RH, for set points 2-6, the range is the same, but the default setting is 1.0%RH (see Section 11.1.2).

Principle of Operation

When starting 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/Humidity chamber are collected by the Base Station. The Base Station uses the IRTD/Humidity chamber 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/Humidity chamber 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, inside the Logger's non-volatile memory. This data remains intact even if the battery is depleted or exchanged.

11.1.1. Defining Verification Strategy and Criteria

The Kaye ValProbe RT software can 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 the User's SOP's or Risk management assessment, perform a pre -Verification before a Qualification study and a post Verification after the study to ensure Logger temperature are within 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.

11.1.2. Selecting the Proper Calibration Bath – Uncertainty (Temperature)

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 < 0.028°C. This allows enough ratio to safely calibrate and verify the accuracy of the Loggers to within specifications of 0.01°C.

If a user's verification strategy requires a periodic check of the Kaye Loggers to ensure that they are within Kaye's specifications of 0.1°C then, Temperature Baths and References with adequate uncertainty ensuring valid results must be utilized.

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	0.100°C	0.025°C	0.175°C

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

If a user's verification strategy is to perform 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 may 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	0.040°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 must utilize a liquid bath.*

Pressure Sensors

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.

11.2. Creating a Verification Setup

Before running a verification process, creating a Verification Setup is required. To create the Verification Setup, navigate to the Main screen and then select **Equipment**. and enter an ID and Password.



Figure 136: Select the Equipment Tile

Verifications are configured and initiated via the Equipment tile.

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

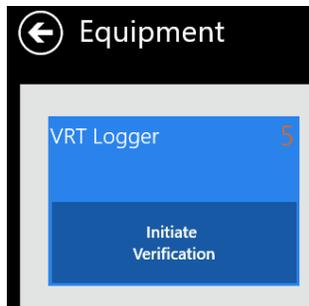


Figure 137: Initiate Verification

5. Enter proper User credentials when prompted.

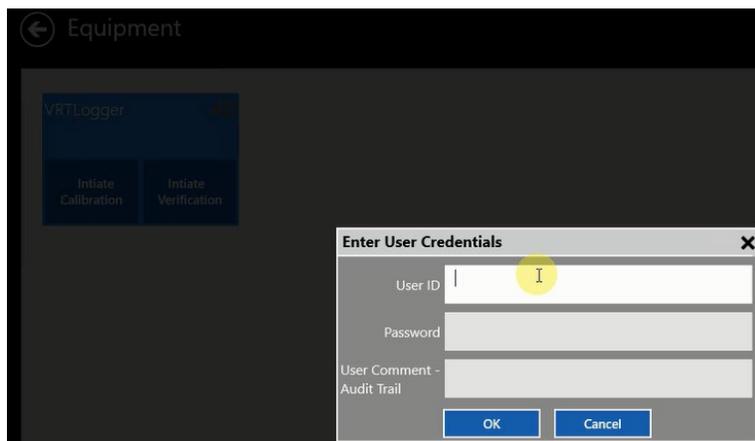


Figure 138: Enter User Credentials

6. Choose the **Temperature** or **Humidity** verification type on the Select Verification Type window.

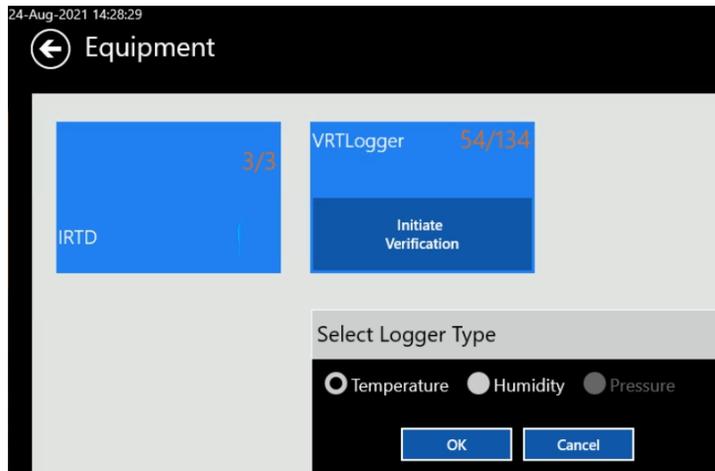


Figure 139: Select Verification Type

11.2.1. Temperature Verification

Note: For instructions on Humidity Verification please see 11.2.2 Humidity Verification.

- If you select Temperature, the Temperature Verification Setup screen opens, 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 (up to 50 characters) or other information

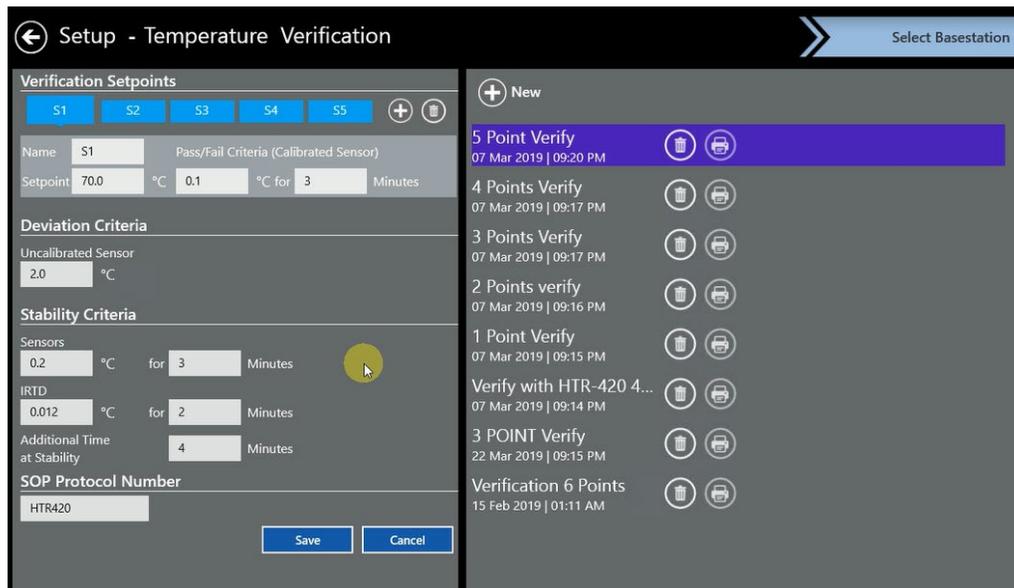


Figure 140: Setup Temperature Verification

To enter additional Setpoints or delete setpoints select on the appropriate   icon. Once all setpoints and criteria are entered, save the Verification Setup under a specific name.

Note: *The minimum difference between any two setpoints should be set no lower than 8° C. If any set points are below the minimum, the software prompts the User a reminder on the bottom of the screen to update the setpoints.*

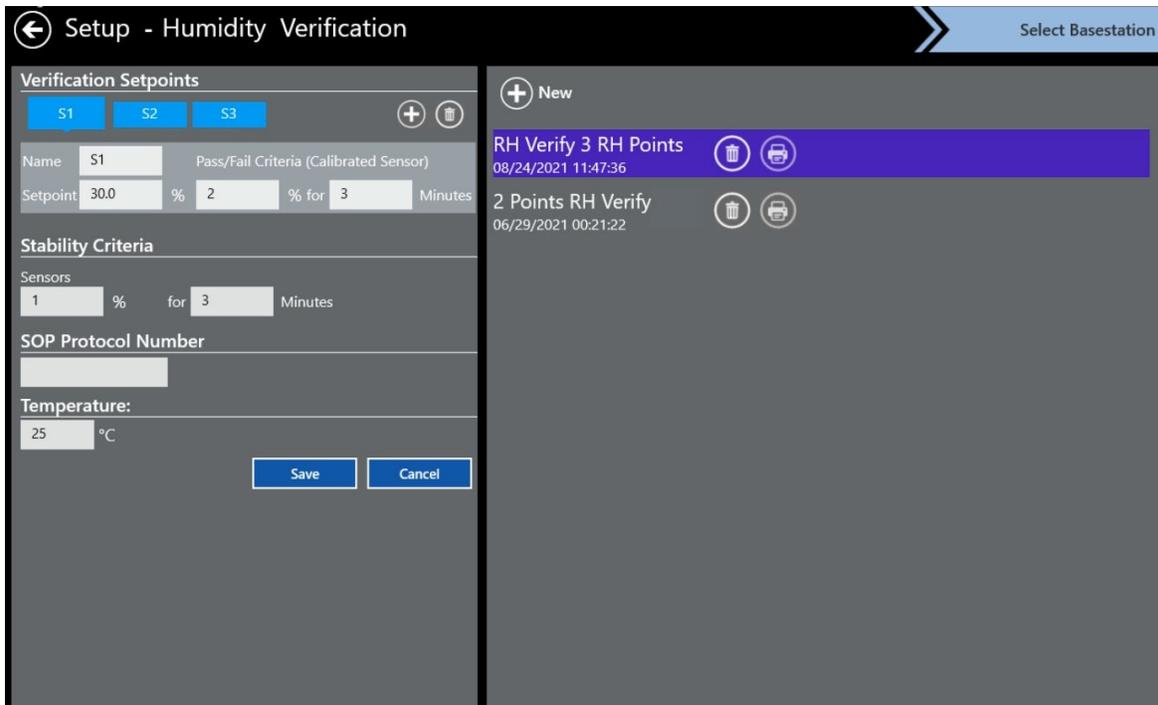
If desired, setup printing is available by selecting the **Printer** icon. To delete a setup, select the **Trash Bin** icon.

If multiple Setups are generated and saved with different configurations, they are all 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 changes.

11.2.2. Humidity Verification

If you select Humidity, the Setup Humidity Verification screen opens, the following options are available:

- Choose between one to six humidity setpoints
- Define for each setpoint the name, setpoint humidity %, and Pass / Fail criteria
- Define sensor stability and minimum duration
- SOP protocol numbers (up to 50 characters) or other information



The screenshot displays the 'Setup - Humidity Verification' interface. On the left, there are input fields for 'Name' (S1), 'Setpoint' (30.0 %), 'Pass/Fail Criteria (Calibrated Sensor)' (2 % for 3 Minutes), 'Stability Criteria' (1 % for 3 Minutes), 'SOP Protocol Number', and 'Temperature' (25 °C). There are 'Save' and 'Cancel' buttons at the bottom. On the right, a list of existing setups is shown, including 'RH Verify 3 RH Points' and '2 Points RH Verify', each with a trash icon and a printer icon.

Figure 141: Humidity Verification

To enter additional setpoints or delete setpoints select 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, select the **Trash Bin** icon.

If multiple Setups are generated and saved with different configurations, they are all 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 changes.

11.3. Loading a Temperature Verification Setup

Before beginning a Verification process, load a 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 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 142: 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 Base station**.

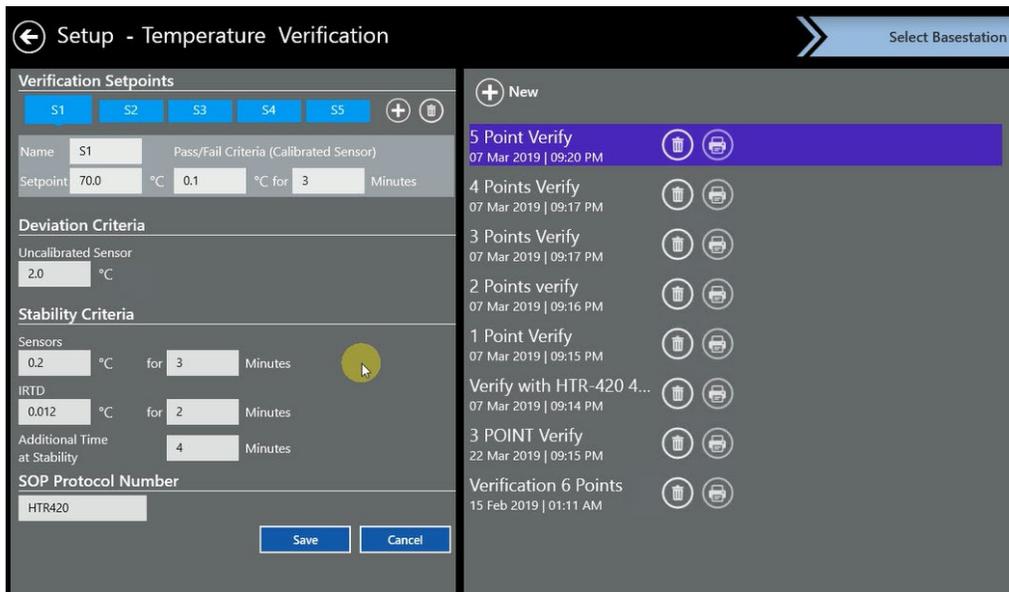


Figure 143: Select a Verification Setup from List

On the Select Base Station screen, select **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 the 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 on the network (DHCP), ensure the Console and Base Station are connected via ethernet cables to the network via ethernet connections.

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

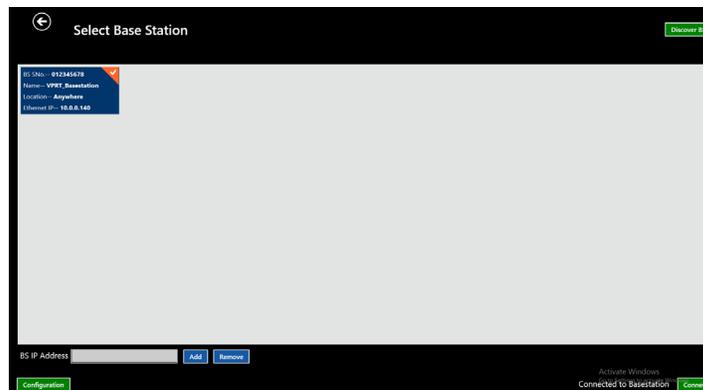


Figure 144: Select Base Station

11.4. Loading a Humidity Verification Setup

Before beginning a Humidity Verification process, load a setup into the ValProbe RT Loggers. A Humidity Chamber must be used to execute a Verification study. Please connect it to the Base Station connectors on the rear of the Base Station. The connector is marked with the appropriate icon. Utilize the supplied cables for the connection. Power up the Humidity Chamber.

To load a setup:

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

After highlighting the required Verification Setup, click **Select Base station**.

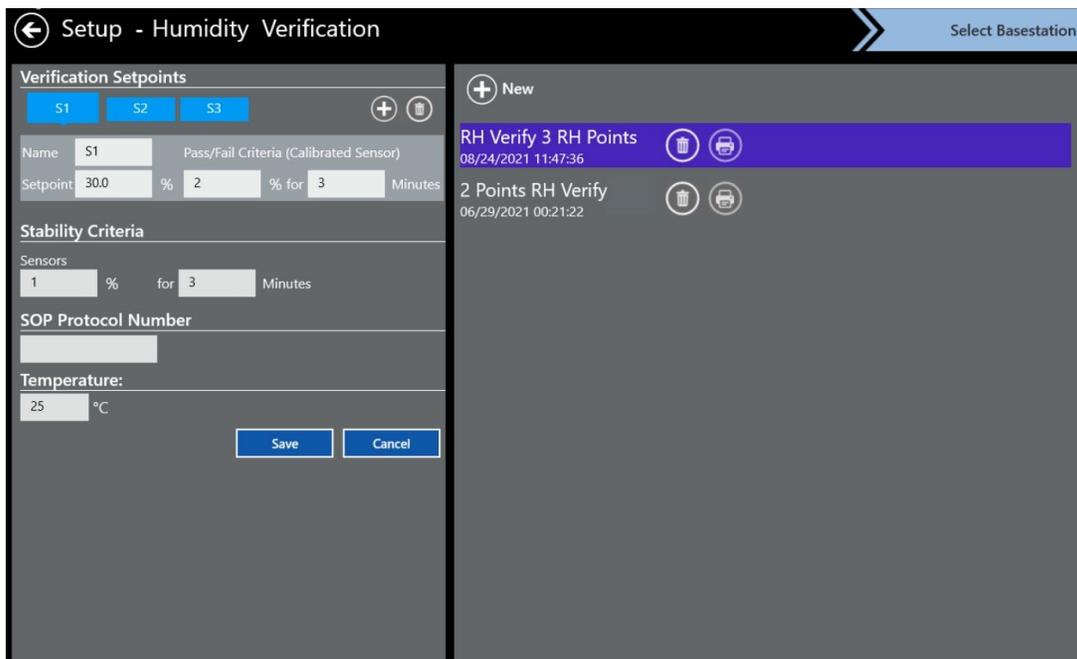


Figure 145: Selecting a Humidity Setup

On the Select Base Station screen, select **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 the 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 on the network (DHCP), ensure the Console and Base Station are connected via ethernet cables to the network via ethernet connections.

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

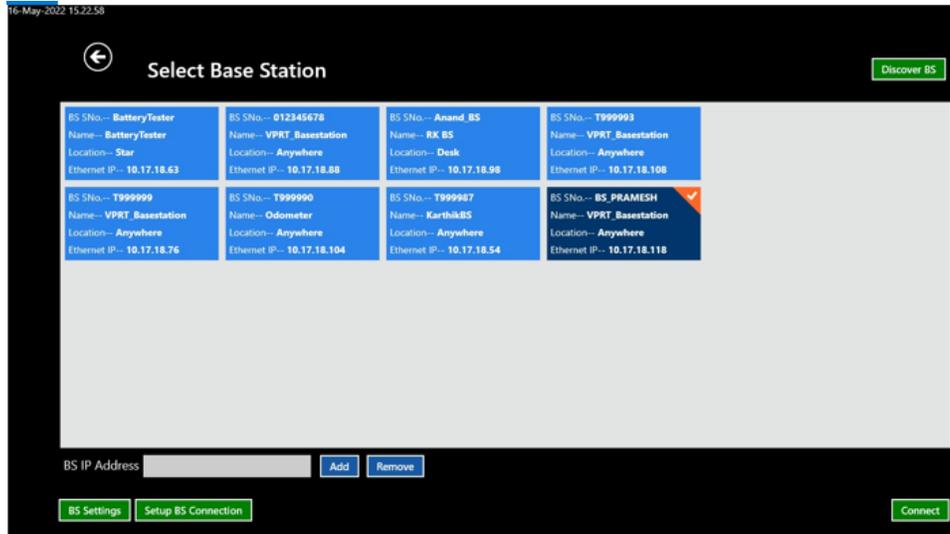


Figure 146: Select Base Station

11.5. Selecting Sensors

When the desired Base Station is connected, select Loggers to be verified on the Select Loggers screen. Humidity Loggers are displayed as dark, red-colored boxes.

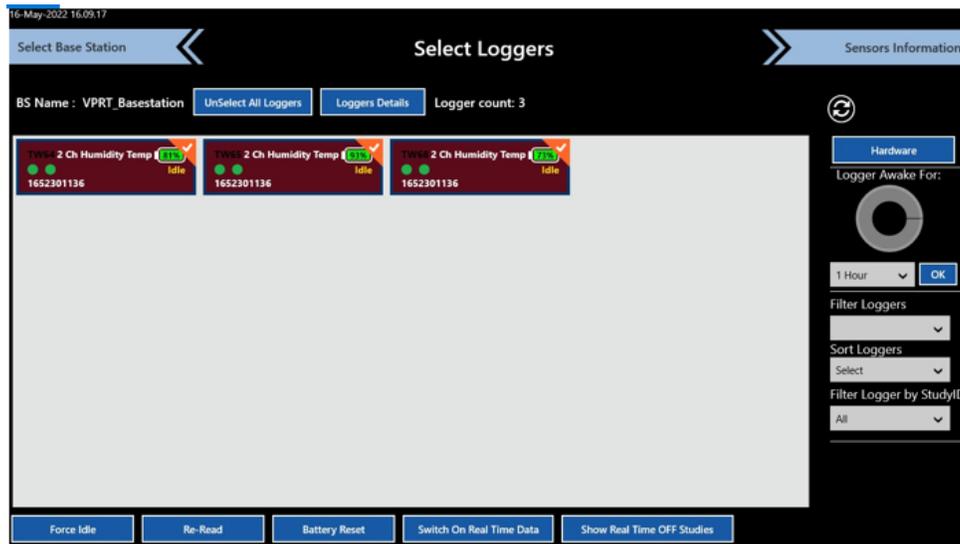


Figure 147: Select Loggers

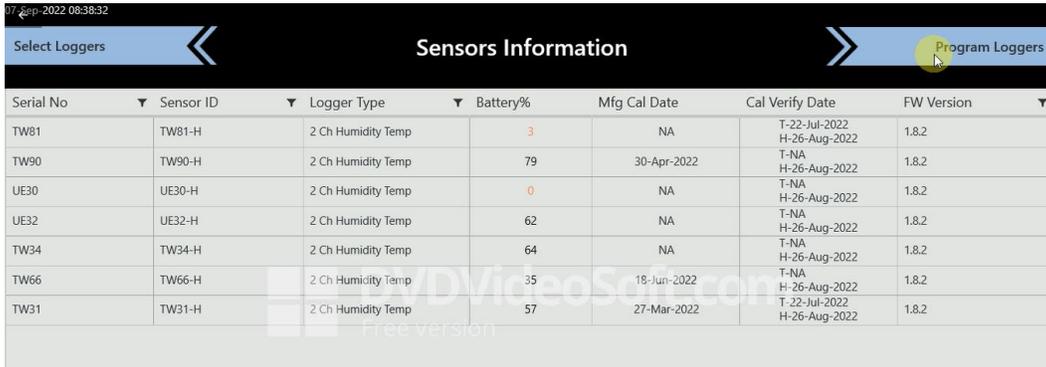
Note: When using more than 25 Loggers, ensure that the transmission rate is equal or greater than the sampling rate. If not, a message displays a warning that you cannot move forward. Modify the setup and the transmission/sampling rates before proceeding with 25 or more Loggers.

If there are no Loggers listed on the screen, wake up the Loggers, using the magnetic Wake Up device or by passing them over the 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**. The selected Loggers' icons color changes to deep blue for temperature Loggers, purple for pressure Loggers, or dark red for humidity 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. To change the amount of time a selected Logger is awake, use the **Logger Awake For** dropdown and select **OK**.

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

On the Sensor Information screen, ensure all Loggers selected are listed and then select **Program Loggers**.

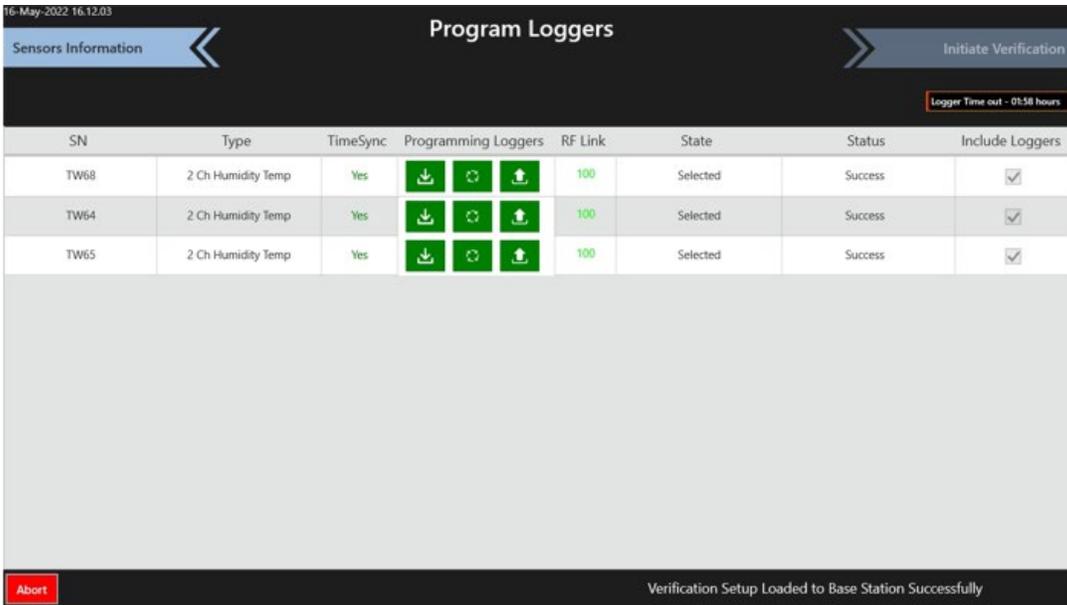


Serial No	Sensor ID	Logger Type	Battery%	Mfg Cal Date	Cal Verify Date	FW Version
TW81	TW81-H	2 Ch Humidity Temp	3	NA	T-22-Jul-2022 H-26-Aug-2022	1.8.2
TW90	TW90-H	2 Ch Humidity Temp	79	30-Apr-2022	T-NA H-26-Aug-2022	1.8.2
UE30	UE30-H	2 Ch Humidity Temp	0	NA	T-NA H-26-Aug-2022	1.8.2
UE32	UE32-H	2 Ch Humidity Temp	62	NA	T-NA H-26-Aug-2022	1.8.2
TW34	TW34-H	2 Ch Humidity Temp	64	NA	T-NA H-26-Aug-2022	1.8.2
TW66	TW66-H	2 Ch Humidity Temp	35	18-Jun-2022	T-NA H-26-Aug-2022	1.8.2
TW31	TW31-H	2 Ch Humidity Temp	57	27-Mar-2022	T-22-Jul-2022 H-26-Aug-2022	1.8.2

Figure 148: 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 is completed when all three status icons are green. Wait until completed and the Initiate Verification blinks yellow and select **Initiate Verification**

Note: Any unmapped Loggers will prompt a popup window asking for user confirmation on how to proceed. Select **Exclude Loggers and Continue** to move forward with the unmapped Logger excluded, or **Re-map** to remap the Logger and keep the Logger.



SN	Type	TimeSync	Programming Loggers	RF Link	State	Status	Include Loggers
TW68	2 Ch Humidity Temp	Yes	  	100	Selected	Success	<input checked="" type="checkbox"/>
TW64	2 Ch Humidity Temp	Yes	  	100	Selected	Success	<input checked="" type="checkbox"/>
TW65	2 Ch Humidity Temp	Yes	  	100	Selected	Success	<input checked="" type="checkbox"/>

Logger Time out - 01:58 hours

Abort

Verification Setup Loaded to Base Station Successfully

Figure 149: Program Loggers Screen

11.6. Running a Sensor Verification

Prior to starting the verification select the **Hardware** button to verify the IRTD and Kaye bath drywell are displayed as connected for temperature verification or the humidity chamber for humidity verification.

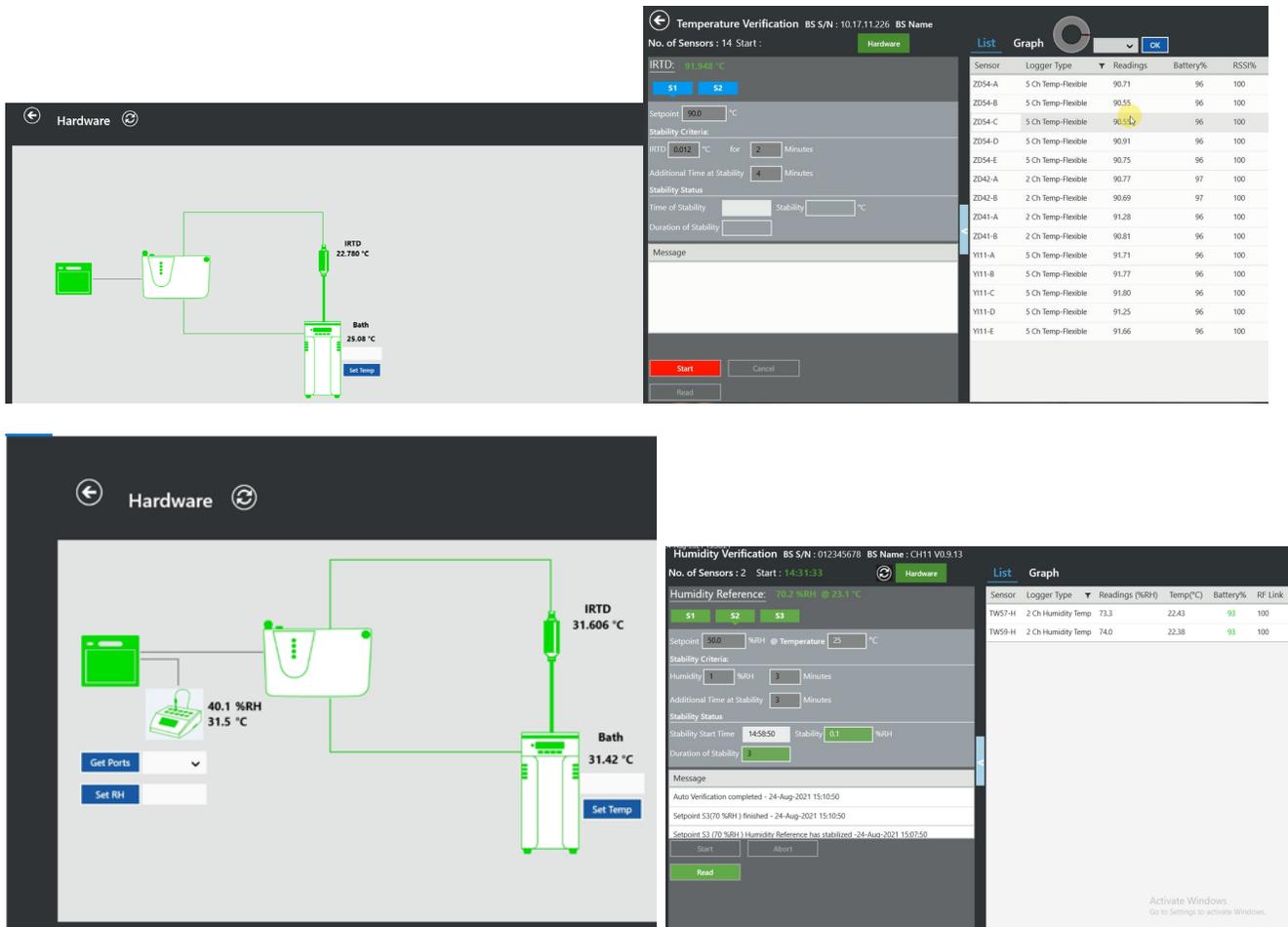


Figure 150: Verification Study Screens

Note: It is important to ensure live data is displayed from the Logger sensors and IRTD or the humidity chamber prior to starting a Verification. This guarantees a good RF connection between Loggers and Base Station and ensure that each Logger receives the Start Verification command.

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

Select **Start** on the Temperature or Humidity Verification screen to start a Verification study.

When you start a Temperature or a Humidity Verification, the Kaye ValProbe RT software detects whether a Kaye temperature reference and an IRTD are connected for temperature or a humidity chamber for humidity. These are required for a fully automatic operation. If there is no IRTD/Humidity chamber 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 are found, the Verification process cannot be run.

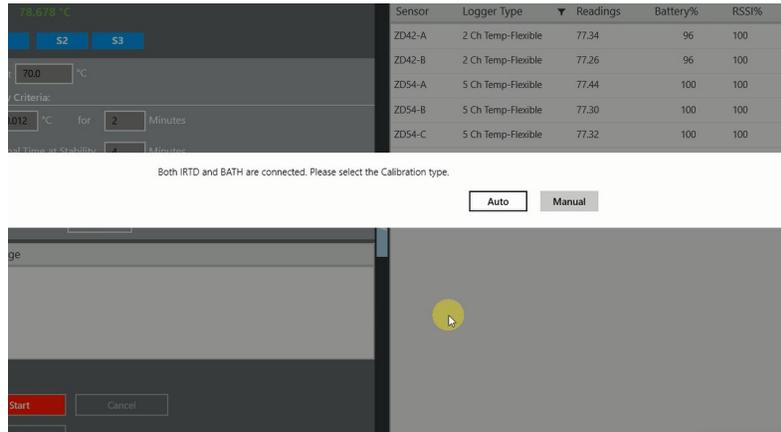


Figure 151: Auto / Manual Verification Prompt

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

During the verification process, live data is displayable in two ways, in a Graph view and List view. If the list exceeds the screen size, use the scroll bar to see the remaining data. On the graph, temperature/humidity appears on the Y-axis, while the highlighted X-axis displays the stabilized IRTD temperature, or the stabilized RH for humidity. 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/humidity point, and a value indicating how much the sensor is off.

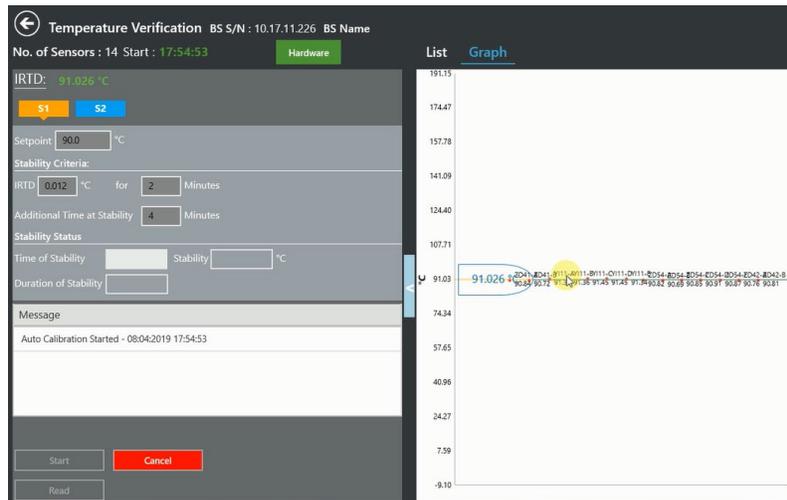


Figure 152: Temperature Verification Graph View

The first step in the Temperature 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 is read, select the green **Read** button to transfer the Logger and Base Station data to the Validation Console. If **Read** is not green, setpoints are not completed.

The screenshot displays the 'Temperature Verification' interface. At the top, it shows '20-Jul-2021 17:58:12', 'Temperature Verification BS S/N : 012345678 BS Name : CH25 V0.9.12', 'No. of Sensors : 2', and 'Start : 15:25:00'. There is a 'Hardware' button and tabs for 'List' and 'Graph'. The IRTD is 59.988 °C. Four setpoints (S1, S2, S3, S4) are shown as green buttons. The Setpoint is 1.0 °C. Stability Criteria: IRTD 0.012 °C for 3 Minutes. Additional Time at Stability: 0 Minutes. Stability Status: Stability Start Time 15:41:30, Stability 0.003 °C. Duration of Stability: 8. A message log shows: 'Auto Verification completed - 20-Jul-2021 17:06:00', 'Setpoint S4(60 °C) finished - 20-Jul-2021 17:06:00', and 'Setpoint S4 (60 °C) IRTD stabilized - 20-Jul-2021 16:58:00'. There are 'Start' and 'Abort' buttons, and a prominent green 'Read' button at the bottom.

Sensor	Logger Type	Readings	Battery%	RF Link
TW77-T	2 Ch Humidity Temp	-45.00	97	100
TW55-T	2 Ch Humidity Temp	59.83	97	100

Figure 153: Temperature Verification List View / Green Read Button

The first step in the Humidity Verification process is to verify that the Humidity chamber is stable. Stability is the maximum allowable change in Humidity for the humidity standard over the specified time interval. The first set point is created with a default value of 90%RH but may be set between 5%RH – 95%RH. The maximum allowable change for the first set point is between 0.5%RH – 5.0%RH and defaults to 0.5%RH, for set points 2-6, the range is the same, but the default setting is 1.0%RH.

The stability calculation begins once the Humidity Chamber is within the pass criteria of the setpoint. Sensor readings are displayed on the Data screen. To achieve stability, the Humidity chamber must meet the stability criteria defined in the setup.

When the Humidity chamber 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 reading becomes 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 is read, select the green **Read** button to transfer the Logger and Base Station data to the Validation Console. If **Read** is not green, setpoints are not completed.

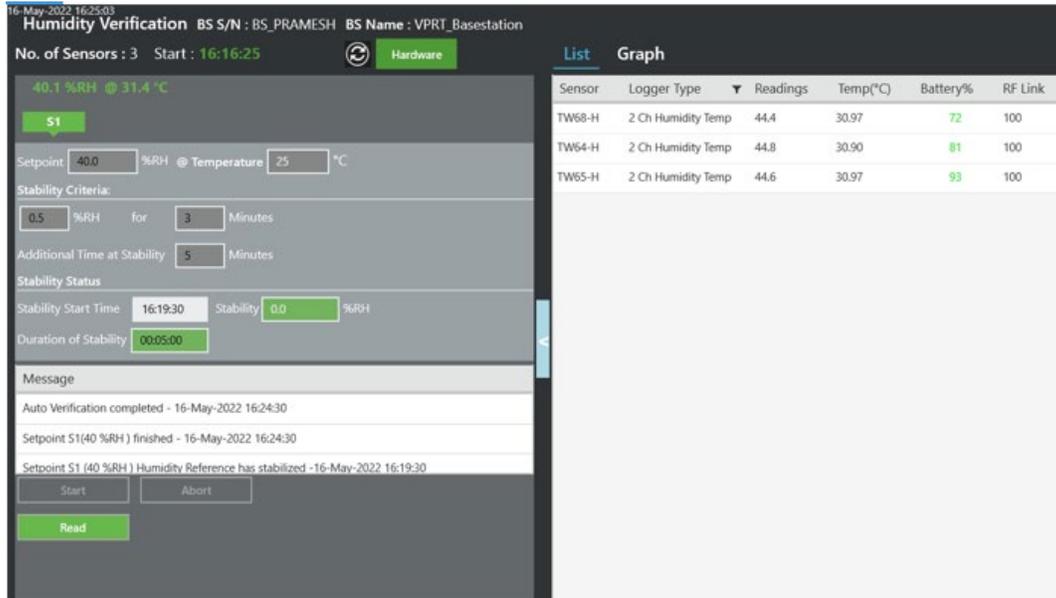


Figure 154: Humidity Verification List View / Green Read Button

The window below, displays the readout process of the Loggers.

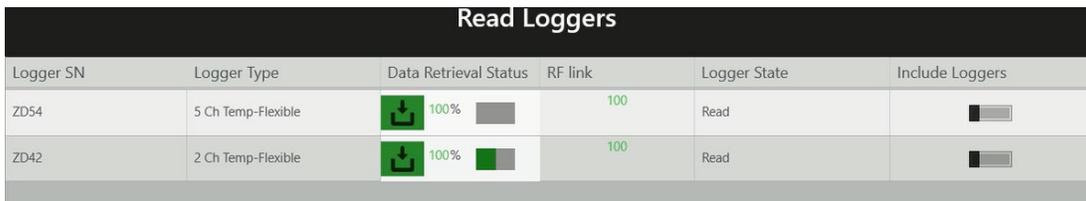


Figure 155: Read Loggers Screen

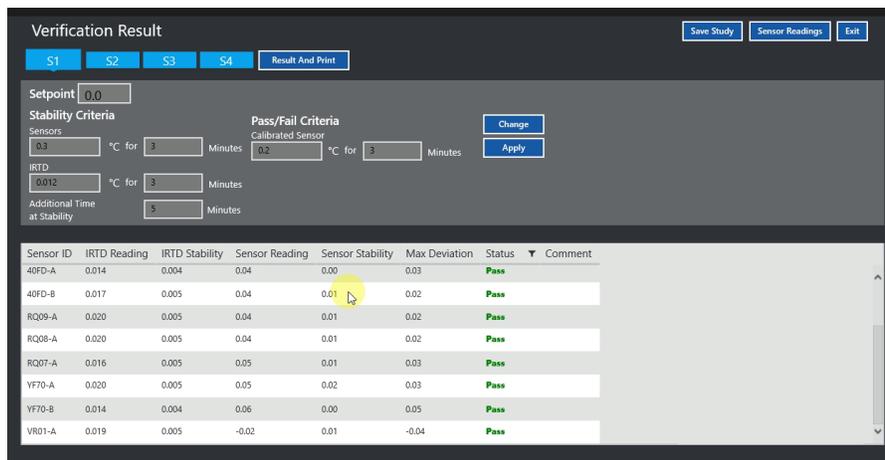


Figure 156: Temperature Verification Result Screen

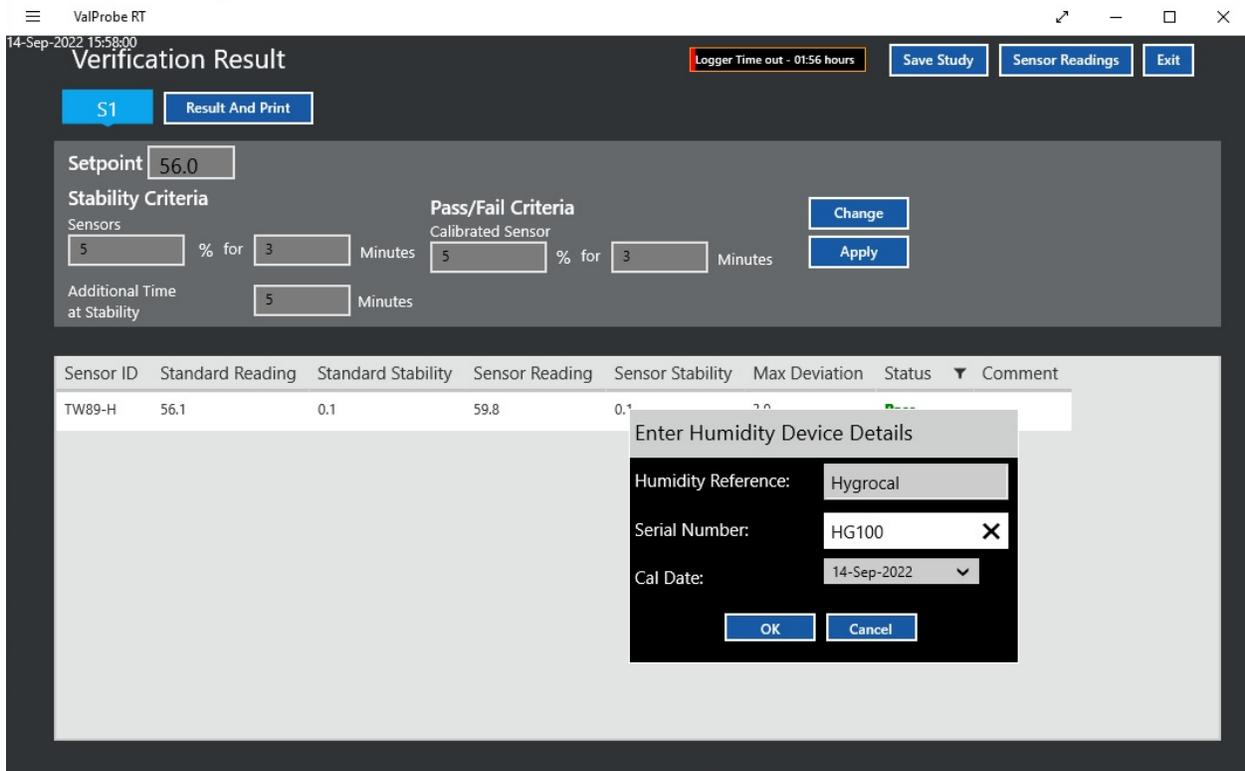


Figure 157: Humidity Verification Result Screen

On the Verification Results screen perform the following

- Select **Save Study** to save the Study to the Console
- Select **Sensor Readings** to verification readings in a graph or list view, as displayed in the figure below.
- Select **Exit** to return to the Main Screen.
- Select **Result and Print** to print the results of the verification

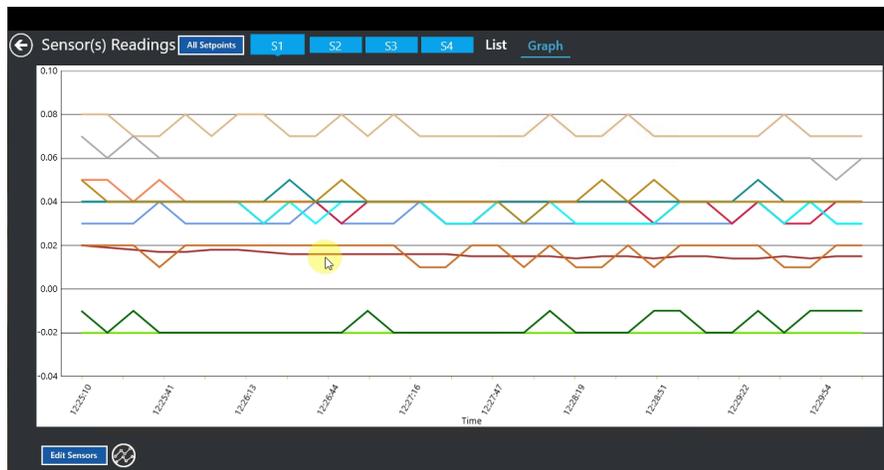


Figure 158: Sensor(s) Readings Screen

The Verification Results screen displays the Pass / Fail analysis results of the Verification for each sensor. Select the setpoints to view the results for each setpoint.

Additional Verification report options:

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

When Verification Results are completed select **Exit**.

11.7. 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 connected equipment and Loggers
- Logger failed stability criteria and cannot be evaluated
- Time of stability of the IRTD and Logger may not overlap for a significant time
- Logger were removed from the bath / calibrator / chamber before the setpoint was reached

11.8. Verification Report

Once the process is completed, a Verification report may be generated.

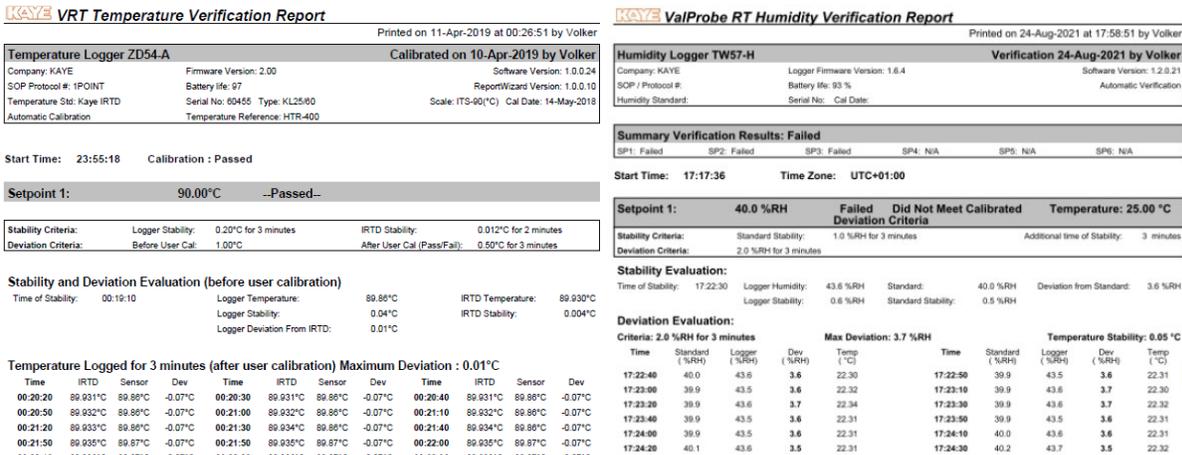


Figure 159: Verification Reports

Chapter 12. Qualification Reports

12.1. Reports Overview

The Kaye ValProbe RT software includes a comprehensive reporting utility to generate Setup, Calibration, Qualification, and Calibration Verification reports to document the specifics of each 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
- Spreadsheet reports
- 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 / Humd)
- Details of sensor, types, labels and descriptions and firmware
- Sensor grouping
- Any defined layout 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

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

The screenshot displays a 'ValProbe RT Setup Report' with the following sections:

- Header:** Printed on 23 Apr 2020 at 13:36:46 by nrdjpt. Includes fields for Study Name (Sterilizer - 6 sensors), Company Name (KAYE), ValProbe RT Version (1.0.0.47), SOP/Protocol # (12), Asset Name (Sterilizer), Asset ID (1234), and Date (27-Feb-2).
- Sensor Definitions:** A table listing sensor types and counts.

Sensor Label	Sensor Type
Temp 5	Temperature
Temp 2	Temperature
Temp 3	Temperature
Temp 4	Temperature
Press 1	Pressure
Temp 1	Temperature
- Sensor Mapping Table:** A table mapping sensor types to labels.

Sensor Type	Sensor Label	Sensor Description
Temperature	Temp 5	
Temperature	Temp 2	
Temperature	Temp 3	
Temperature	Temp 4	
Temperature	Temp 1	
- Sensor Overlay Image:** A photograph of a sterilizer chamber with blue callouts indicating the locations of the sensors.
- Calculations:** A section for defining calculation parameters.

Parameter	Value
Min	Minimum value in the group
Loc of Min	Location of minimum value
Max	Maximum value in the group
Loc of Max	Location of maximum value
Avg	Group average
Std Dev	Group standard deviation
Max - Min	Maximum value minus minimum value
Max - Avg	Maximum value minus average value
Avg - Min	Average value minus minimum value
- Utility:** A section for system utility information.

Base Temperature (°C)	22.1 °C
Z offset	10.0
D offset	1.50
Utility Condition	Unlabeled

Figure 160: Setup Report

12.2. 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, the option to set a separate print rate which can be a multiple greater than the storage rate is available; maximizing 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 lists System and Event messages along with a footer as defined in report options.

Figure 161: Qualification Detailed Report

12.3. Qualification Summary Report

Summary Reports are created from raw encrypted Qualification files and for each Group provide a summary of all sensor measurements during a Qualification study. All calculations performed in 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 includes 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).

Included at the bottom of the Temperature Summary is 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 a footer.

Before printing the Summary report, use the Report Content options to add Setup information or a graph of the complete study to the Summary report.

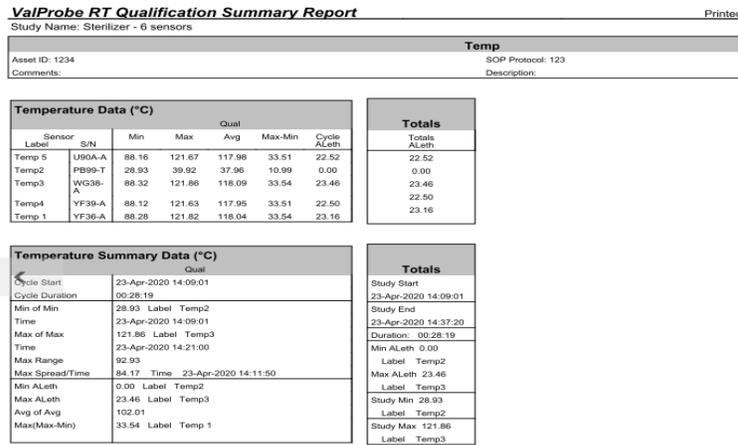


Figure 162: Summary Report

12.4. Graph Reports

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

The Graphs reports, calculations, and groups they utilize are based on the sampling rate along with other parameters defined in the Setup.

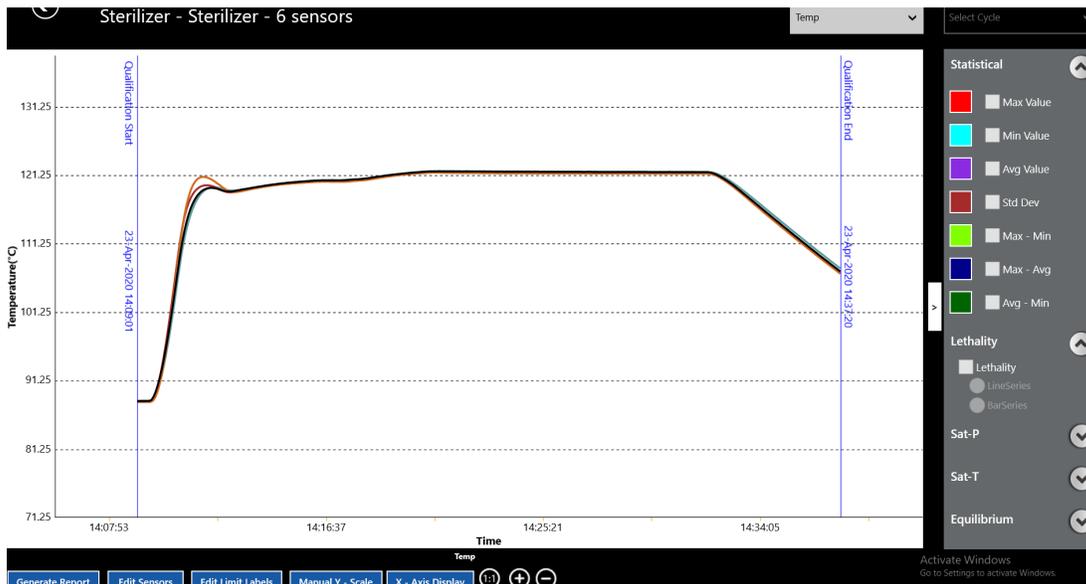


Figure 163: Graph Report Screen

The Graph report defaults to displaying All Temp Sensors for the duration of the Qualification study. Use the Select Group dropdown at the top right of the screen, to select different types of sensors or groups to display. Use the Cycle dropdown to select defined Cycles for graphing.

Use the > or < to the right of the graph to maximize to full screen or minimize the graph.

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

Statistical

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

Lethality

The Accumulated Lethality graph displays lethality totals for each included sensor at each timestamp programmed or defined to calculate lethality. Alternatively, the lethality accumulation can also 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** dropdown 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 (T_b) 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 a lethality base temperature is not defined during the study setup, a 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 (T_b). 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 reaches base temperature, depending on the time period selected. 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. On this screen:

- Select / unselect sensors.
- Select the Reference Sensor from the dropdown list.
- Enter a reference temperature.
- Choose a time of 15 or 30 seconds from the dropdown 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 one 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 reset the zoom for enhanced analysis.

Y / X Scaling

Select the **Manual Y – Scale** button to manually adjust the Y axis scale. Use the **X-Axis Display** button to select different options for displaying the X time axis.

Edit Sensors

Select **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 to the next calculation graph.*

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. If desired, select the line color, thickness, and style.

When finished, select **Apply**.

Generate Report

Select **Generate Report** to create a .pdf report of the graph. Enter a custom label and select **Apply**. Use the option in the Summary Report to automatically include a completed study graph in the Summary report.

12.5. 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 automatically generated and stored in monthly encrypted files which are protected from User access or modification. Integrity checks are performed before any data is written to the current monthly file and a backup of the monthly file is captured each time the ValProbe RT software is started.

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.

UserID	UserName	CreationDateTime	Comments
a	bala	09 July 2020 17:5040	User ID : "a", User Name : "bala" logged in to do "CopyFilesReports" operation in "Asset Details" screen
a	bala	09 July 2020 17:5013	User ID : "a", User Name : "bala" Logged in to System.
a	bala	09 July 2020 17:4944	User ID : "a", User Name : "bala" Logged in to System.
a	bala	09 July 2020 17:4939	User ID : "a", Logged out.
a	bala	09 July 2020 17:4541	User ID : "a", User Name : "bala" logged in to do "Raw File Conversion" operation in "FileManagementScreen" screen
a	bala	09 July 2020 17:4533	User ID : "a", User Name : "bala" Logged in to System.
a	bala	09 July 2020 17:4500	Software Application Shutdown After VREConvert Process

Figure 164: 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

Use the drop downs above the header to find date specific data over a range and select the **Get Data** button. Select **Reset** to remove the date filter from the data.

There are two ways to generate Audit Trail Reports. For a detailed and flexible analysis, navigate to the Audit tile from the Main screen. When initially opening the Audit Trail tile, the Audit Trail displays data from the current monthly file. Use the dropdowns above the header to modify the monthly range and select **Get Data**. Each column of the Audit Trail contains a filter

icon allowing data to be filtered by User ID, Name, Date and Time, Action, User Comment, Console Machine ID, and RT hardware serial number.

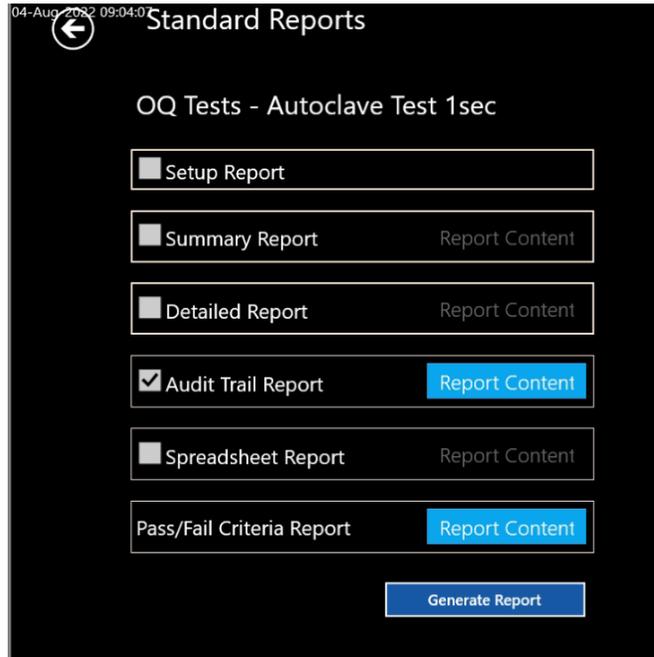


Figure 165: Audit Trail

The second method of generating an audit report is tied specifically to a Qualification file through the Reporting tool. From the Asset screen, select the desired Asset, then the desired Qualification file. Define the cycles and proceed to the Standard reports screen. Check the Audit Trail checkbox, then the required time frame and filter options using the **Report Content** button, to generate an Audit Report with the events related to the qualification study.

12.6. Spreadsheet Report

The Spreadsheet Report generates an Excel 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

1	ValProbe RT Qualification Report									
2	Study Name	case20-1m-20s	Company:	KAYE	Asset ID:	RC	ValProbe	1.2.0.56	SOP / Prot	case20
3	Asset Name	Regression	Asset ID:	RC	ValProbe	1.2.0.56	SOP / Prot	case20	Descriptic	
4	Started By	pavan.c	Comment		SOP / Prot	case20	ValProbe	1.2.0.56	Descriptic	
5	Stopped By	pavan.c	Study File	case20-1m-20s	Date #:	01-Aug-2022 21:34:00	Run #:	1		
6	Setup Cre	pavan.c	Setup Cre	01-Aug-2022 17:57:42 (UTC+05:30)						
7	Descriptic									
8										
9										
10										
11										
12	Lethality has been selected with the following criteria:									
13	Base Tem	121.1	D Value:	1.00	Z Value:	10.0				
14	Lethality	Undefined								
15										
16										
17	Base Station Details :									
18	Name :	VPRT_Basestation	Location :	Anywhere						
19	Hardware :	2.4.0	Serial No :	T999991	Firmware	0.9.28				
20	Model No	VPRT_BS_1	IP Address:	10.17.18.47						
21										
22										
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Figure 166: Spreadsheet Report

12.7. Pass/Fail Report

Pass / Fail Report Overview

The Pass / Fail Criteria report can eliminate hours of manual or spreadsheet-based analysis, by providing an automated report. This report analyzes Qualification raw data and details 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.

Pass/ Fail Criteria - Template Definition

Define / Select Template

Define Template
 Select Existing Template
 From Current Asset Type
 From All Asset Types

test2

Select Cycle

Exp Start

Select Process Temp 121.00 °C

Delay from cycle start Samples: 3 Sampling Rate: 10 Seconds

Figure 167: 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 one second 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 168: 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 169: 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 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 a max value of 2 and min value of -2 is entered, 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 does not use 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 is 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 is 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 or two 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.

PassFail Criteria Report					
Study Name: Autoclave Test 1sec			Printed on 04-Aug-2022 at 14:13:42 by Ralf Wottrich		
GROUP TEMP					
Process Temperature:121.10 °C		SamplingRate:1 second		Template Name:EN285 Test	
Asset ID:12345		SOP / Protocol #: TEST Autoclave		Description: Comments:	
Input Criteria	Criteria	Value	Sensors Label	Time	Status
Process Temperature Band Min. (°C)	120.10	133.93	Temp6	Min:10-Jun-2020 10:39:37	⊗ FAIL
Process Temperature Band Max. (°C)	123.10	135.65	Temp1	Max:10-Jun-2020 10:48:34	⊗ FAIL
Temp. Fluctuation(Max- Min) by Sensor (°C)	1.80	1.69	Temp6	Min:10-Jun-2020 10:39:37 Max:10-Jun-2020 10:48:32	⊙ PASS
Min Time at/above Process Temp./Sensor (HH:MM:SS)	00:10:00	00:13:54	Temp1	NA	⊙ PASS
Max-Min(spread)/Timestamp. (°C)	2.00	1.1	Min:Temp6 Max:Temp3	Max:10-Jun-2020 10:39:37	⊙ PASS
Max-Avg/Timestamp. (°C)	1.40	0.44	Max:Temp3	Max:10-Jun-2020 10:46:43	⊙ PASS
Avg-Min/ Time stamp. (°C)	1.40	0.75	Max:Temp3	Max:10-Jun-2020 10:39:37	⊙ PASS
(Max of Max)-(Min of Min).(°C)	2.00	1.72	Min:Temp6 Max:Temp1	Min:10-Jun-2020 10:39:37 Max:10-Jun-2020 10:48:34	⊙ PASS
Accumulated Lethality for (Exposure) cycle	24.00	346.92	Temp6	NA	⊙ PASS
T-SAT T / Timestamp.(°C)	-1.20 to 1.20 (Ref Sensor : Pressure1)	Min:-1.52 Max:1.39	Min:Temp3 Max:Temp3	Min:10-Jun-2020 10:35:57 Max:10-Jun-2020 10:45:35	⊗ FAIL
Max. Equilibrium Duration (HH:MM:SS)	15 Sec(s) (Ref Sensor : All Sensors)	00:00:00	First:Temp1 Last:Temp1	10-Jun-2020 10:35:54 10-Jun-2020 10:35:54	⊙ PASS
Min Exposure Duration/Holding Duration.(HH:MM:SS)	00:12:00	00:13:54	NA	NA	⊙ PASS

Figure 170: 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 : 0000000

Group : All		
Template Name : test2	Sampling Rate : 10 Second(s)	SOP Protocol : 0000000
Machine ID : 123456	Description : Superheated water/steam rotating autoclave at Fedegen. 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: _____

Page 3 of 4

Figure 171: 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.

12.8. Generating Qualification Reports

Before selecting a report type, the ValProbe RT software permits the User a final 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.

12.8.1. 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 select 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 select **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.

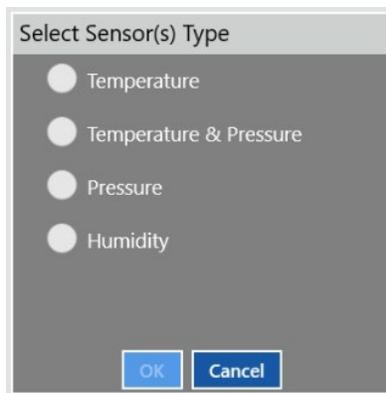


Figure 172: Select Sensor(s) Type

12.8.2. 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 select the pen icon for the selected time to change. A pop-up window opens for selection for **Time Marker** or **Events** to change the selected cycle time.

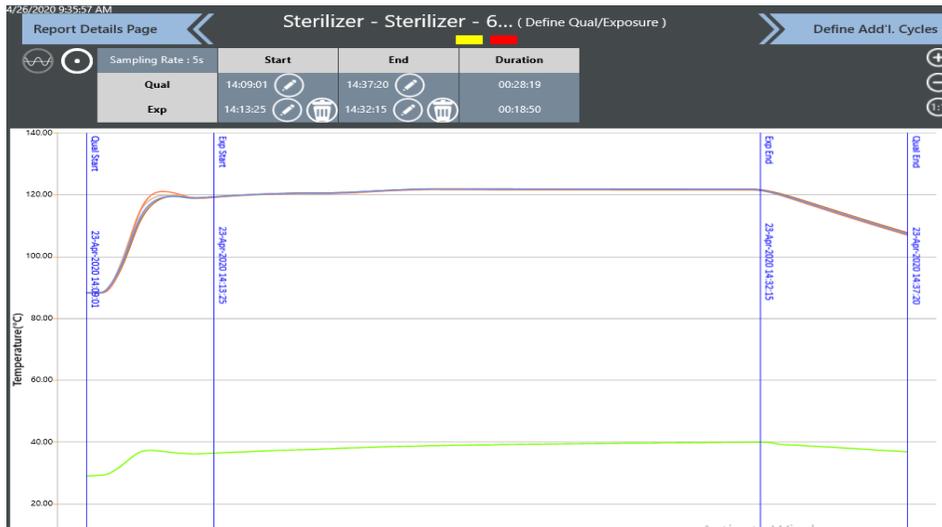


Figure 173: Mark Cycles Screen

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 select 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.

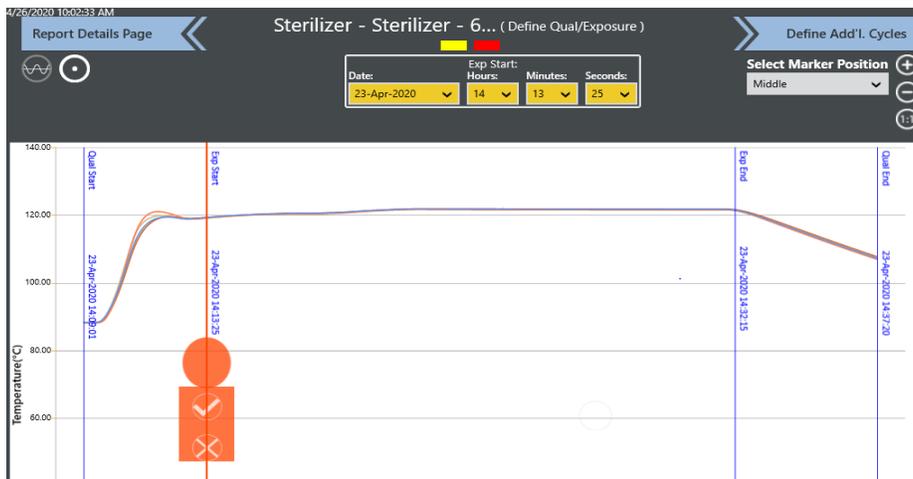


Figure 174: Mark Cycles Using Time / Marker

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

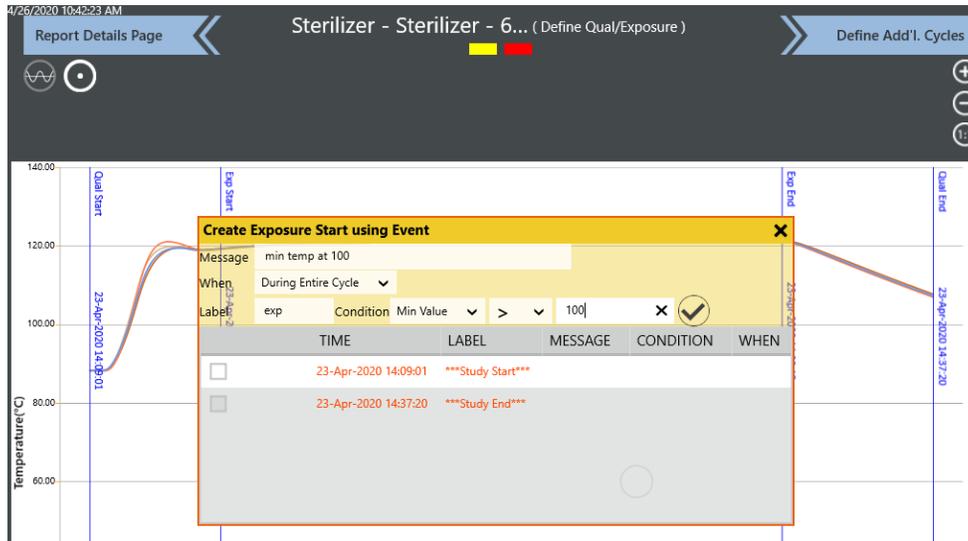


Figure 175: Mark Cycles Using Events

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°C). When all details are entered, select the **Checkmark** and the selected time is marked

With all edits to the Qual / Exposure times complete, select **Define Additional Cycles**.

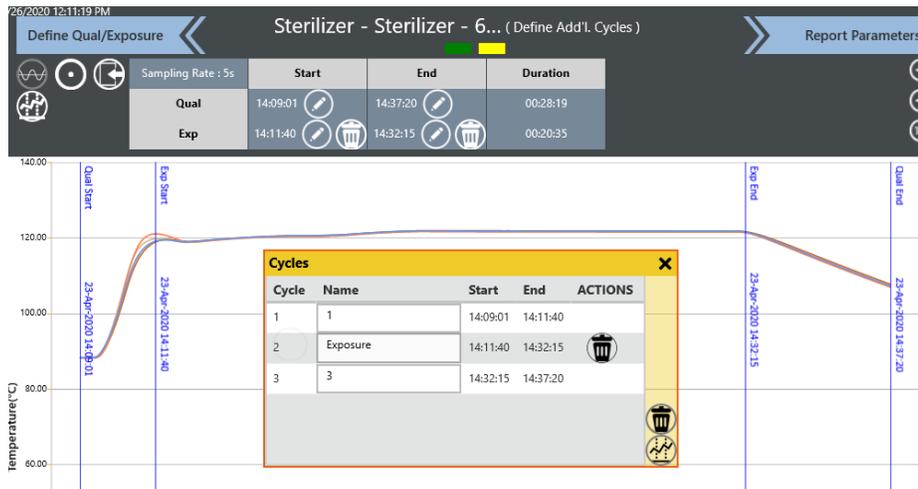
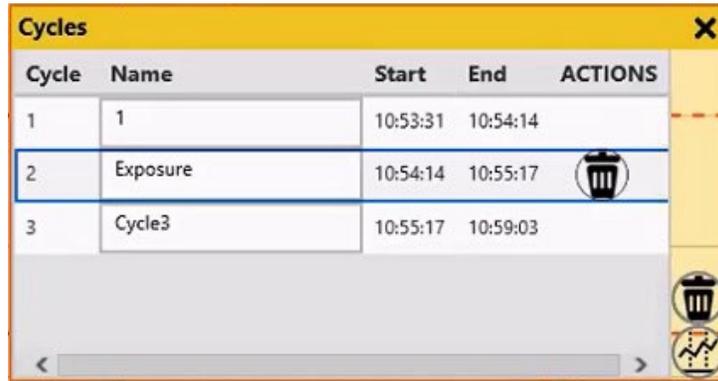


Figure 176: Define Additional Cycles screen

The **Define Add'L Cycles** screen is utilized if additional cycles, other than Qual and Exposure, need to be defined. If no additional cycles need to be defined, select **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. Select the button at the top right of the screen to navigate to the 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** is used to delete a cycle.



Cycle	Name	Start	End	ACTIONS
1	1	10:53:31	10:54:14	
2	Exposure	10:54:14	10:55:17	
3	Cycle3	10:55:17	10:59:03	

Figure 177: Define Additional Cycles Screen

To add additional cycles, select 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 for both the Qual / Exposure screens.

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

12.8.3. Edit Parameters

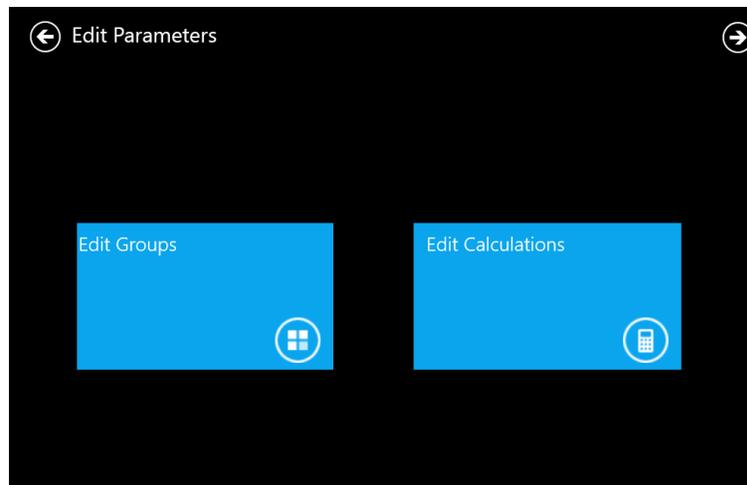


Figure 178: Edit Parameters Screen

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

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

Edit Groups Screen

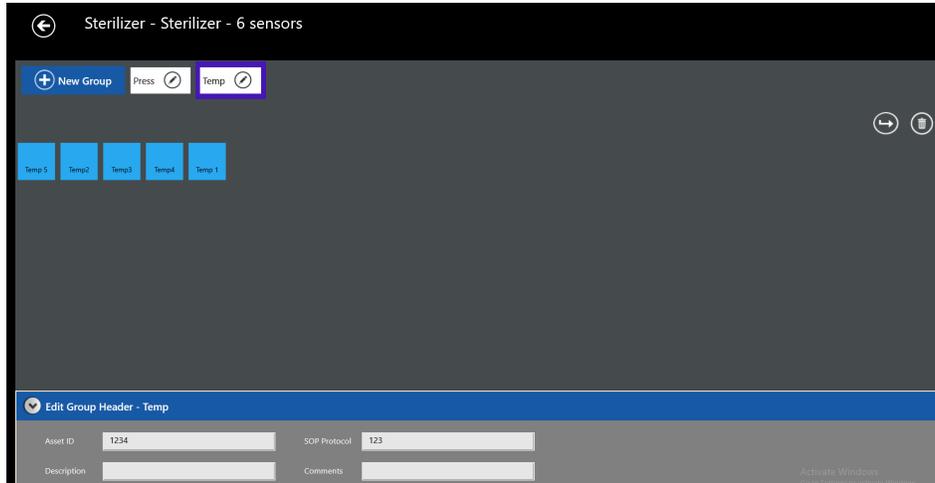


Figure 179: Edit Groups screen

The Edit Groups screen includes the following options:

- Add New Group – select **New Group** and enter a name, select sensors, and a title.
- Move Sensors between Groups –select .
- Delete Groups – select a Group Name and select **Delete** to delete individual sensors from a group.
- Edit Groups Header – select the Group name and select the **Edit Group Header** arrow.
- Edit Group Sensors – select 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.

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

Customize Calculations Screen

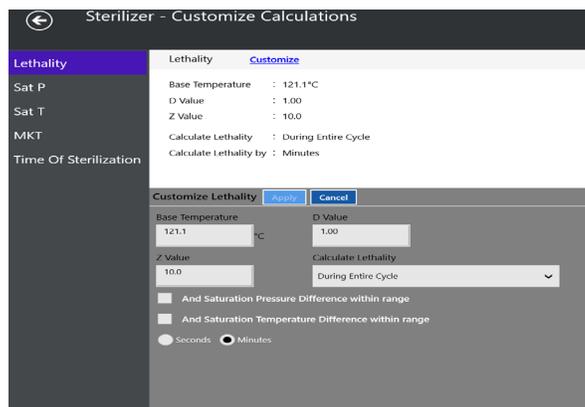


Figure 180: Customize Calculations

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 select **Customize** to open the Customization options for the calculation.

Any changes to calculations are detailed in the Qualification report.

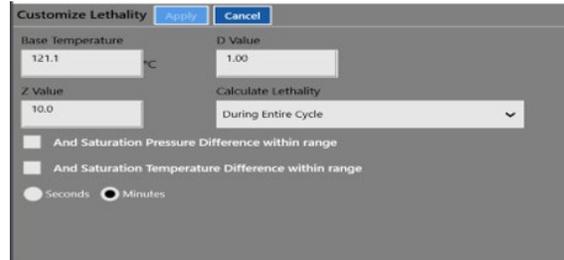
Some Calculations such as MKT and Time of Sterilization are calculated inside the software and cannot be set in the setup file:

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

Note: *Changes to lethality calculations are only allowed if the adequate permission is permitted 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 proper steam quality when calculating lethality. For this reason, Kaye has added additional options which if checked, only calculate the Instantaneous lethality for the timestamp 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.

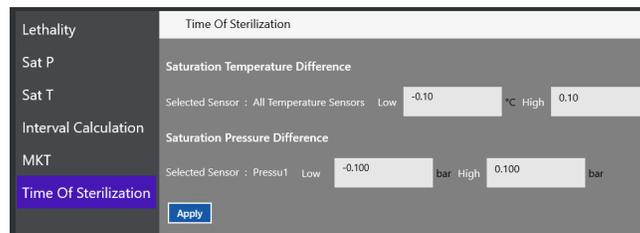


Figure 181: Time of Sterilization – Definition of Limits

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

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

12.8.4. Report Selection

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

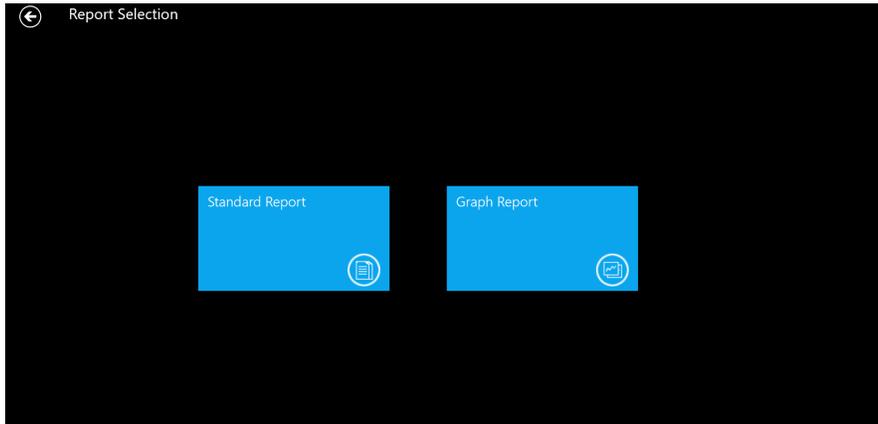


Figure 182: Report Selection Screen

Graph Reports:

The Graph Reports allows the User to report the Qualification data in graphical format. See section (12.4 Graph Reports) for a detailed explanation of the options and tools available for graphing.

Standard Reports:

On the Standard Reports screen the User may select which reports to generate. All reports and calculations are initiated from the Storage / Sample rate defined in the Setup.

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

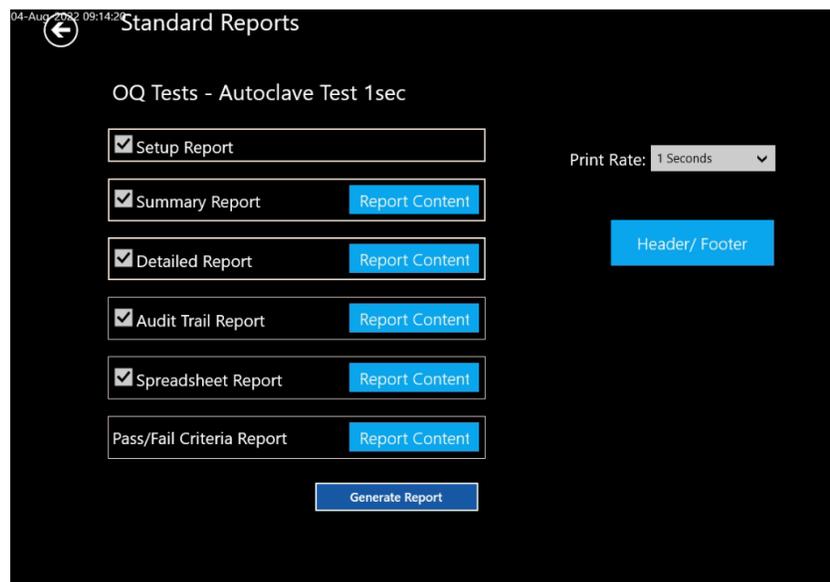


Figure 183: Standard Report Selection Screen

Prior to generating the selected reports, ensure that the Report content, header / footer, and print rate are defined for each selected report.

Report Content:

The Report Content for each report defines which groups and/or calculations are included.

Setup – permits selection if a layout diagram is included in report

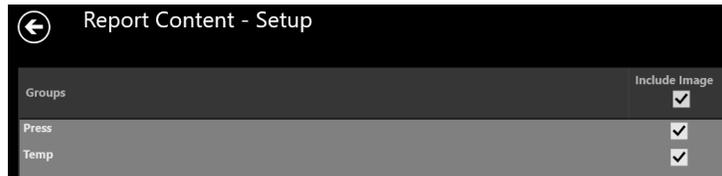


Figure 184: Setup Report Content Screen

Summary – permits selection of groups included and Lethality or MKT calculations.

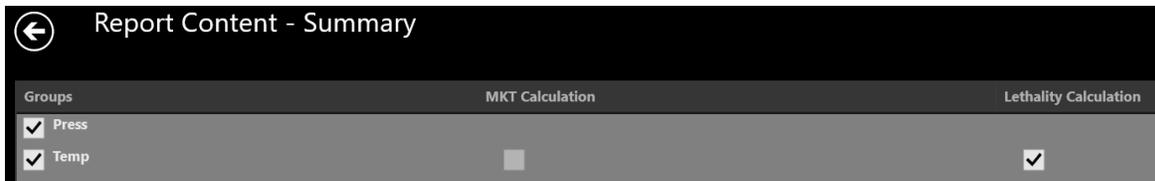


Figure 185: Summary Report Content Screen

Detailed – permits selection of groups and calculations. Availability of 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.

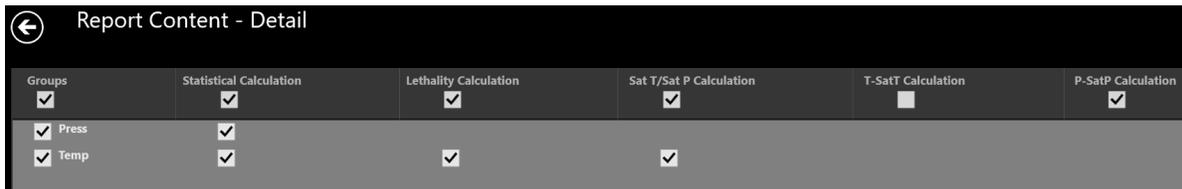


Figure 186: Detailed Report Content Screen

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

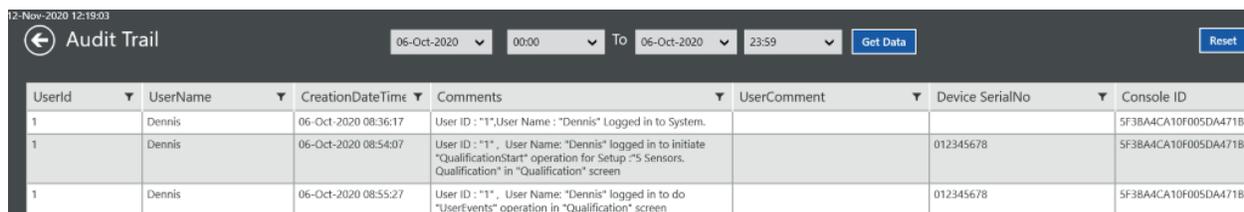


Figure 187: Audit Trail Selection

Pass / Fail Criteria – permits selection of a template for use for each group.



Figure 188: Pass / Fail Report Content Screen

Header / Footer:

The header footer permits customization applying to all selected reports.

- User Comments if added to the first and/or last page of the report.
- Header Footer Titles customizable based on specific company needs.
- Footer signature if added on first, last, or all pages.
- System Messages to appear in reports.

Figure 189: Header / Footer Options

Print Rate:

The Print Rate applies only to the Detailed report and are selected from the dropdown. All calculations in the reports are based on the storage / sample rate in spite of the print rate selected (i.e. sample rate every five second but a print rate of one minute). This can minimize the pages printed while still providing the granularity for calculations and graphs.

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

Figure 190: Print Rate

[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 compliant).

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 1 to 65534.

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 I and Electrical safety protection Class III.

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 30-minute 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%: 10 to 85% RH, non-condensing.

Storage temperature: -40 to 60°C.

A.3 Kaye ValProbe RT Logger

A.3.1 Installation Category

Pollution Degree 2, indoor use only, 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.

A.7 Kaye ValProbe RT Humidity Logger

A.7.1 Measurement Accuracy

Temperature:

Resolution: 0.01°C

Accuracy: $\pm 0.15^\circ\text{C}$ from 0°C to 70°C

Humidity:

Resolution: 0.1%

Accuracy: $\pm 2\%$ RH from 15% to 95% RH at 25°C to 40°C

A.7.2 Environmental:

Temperature: 0°C to 70°C

Humidity: 15% to 95%, RH non-condensing

A.7.3 Operating Range Accuracy

The Humidity sensor shows best performance when operated within recommended normal temperature and humidity range of 5 °C – 60 °C and 20 %RH – 80 %RH, respectively. Long-term exposure to conditions outside normal range, especially at high humidity, may temporarily offset the RH signal (e.g., +3%RH after 60h kept at >80%RH). After returning into the normal temperature and humidity range the sensor will slowly come back to calibration state by itself. Prolonged exposure to extreme conditions may accelerate ageing.

Please note as well that this does apply not only to transportation and storage, but also to operation of the Humidity Sensor.

A.7.4 Sensing Element:

Highly integrated capacitive humidity sensor

A.7.5 Sampling Rate:

1 sec to 10 minutes

A.7.6 Data Storage:

100,000 samples for each sensor

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



UL 61010-1: Third Edition, Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: General requirements. Revision April 2016.

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. Revision December 2018.



B.1.3 Canada Safety Certification



CAN/CSA 22.2 No. 61010-1: Third Edition, Safety requirements for electrical equipment for measurement, control and laboratory use; Part 1: General requirements. Revision April 2016.

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. Revision May 2012.



B.1.4 IEC and CB Scheme Certification



IEC 61010-1:2010, 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.

Kaye ValProbe RT est certifiée pour les normes radio et CEM de la FCC des États-Unis et de l'ISED du Canada énumérées ci-dessous :

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 Partie 2 Sous-partie J §2.1091 : Evaluation de l'exposition aux radiations radioélectriques pour les appareils mobiles > 20 cm de distance de séparation par rapport au corps humain.

Canada ISED RSS-247 Issue 2, février 2017 : Systèmes de transmission numérique (DTS), systèmes à sauts de fréquence (FHS) et dispositifs de réseau local exempt de licence (LE-LAN).

Canada ISED RSS-102, numéro 5, mars 2015 : Conformité de l'exposition aux radiofréquences (RF) des appareils de radiocommunication (toutes les bandes de fréquences).

Canada ISED RSS-Gen, Issue-5, Amendement 1, 2019-03 ; Exigences générales de conformité des appareils de radiocommunication.

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

47 CFR, FCC Part 15 Subpart B §15.109 ; Limites d'émission par rayonnement pour les radiateurs non intentionnels.

ANSI/IEEE C63.4:2014: Norme nationale américaine pour les méthodes de mesure des émissions de bruit radioélectrique des équipements électriques et électroniques à basse tension dans la gamme de 9 kHz à 40 GHz.

Canada ICES-003 - Équipement de technologie de l'information (y compris les appareils numériques) - Limites et méthodes de mesure.

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.

ATTENTION ! Pour satisfaire aux exigences d'exposition FAC RF pour les dispositifs de transmission mobile, une distance de séparation de 20 cm ou plus doit être maintenue entre l'antenne de cet appareil et les personnes pendant le fonctionnement de l'appareil. Pour assurer la conformité, les opérations plus rapprochées que cette distance ne sont pas recommandées. L'antenne utilisée pour cet émetteur ne doit pas être co-localisée en conjonction avec une autre antenne ou émetteur.

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.

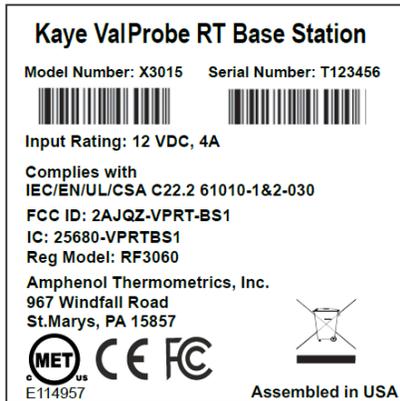
Battery recycling information



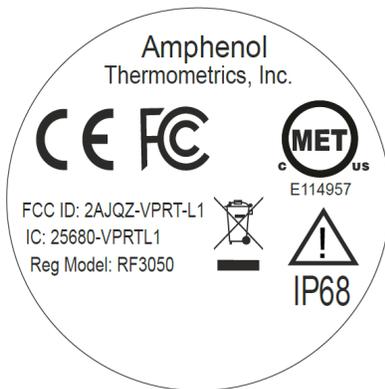
This product contains Lithium-ion (Li-ion) batteries. When the battery reaches to end of useful life, the used battery should be disposed of by a qualified recycler or hazardous material handler. Do not mix the batteries with solid waste stream. Contact your Amphenol service center for recycling or disposal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

B.9 Product Certification Labels

B.9.1 Kaye ValProbe RT Base Station Label



B.9.2 Kaye ValProbe RT Logger Label



B.10 China Compliance Statement

1. The following China regulatory compliance statements are applicable to Kaye ValProbe RT Loggers.
2. The specified applicable scenario, antenna type and features as well as control method shall meet the requirements of “Micropower short-range devices.
3. No modifications can be made without permission to the following conditions: expansion of the frequency range, increase in transmission power (including additional installation of RF power amplifiers), and modifications to the transmission antenna.
4. It shall not cause harmful interference to other legal radio stations (stations), nor shall intend to cause any harmful interference protection.
5. Interference from industrial, scientific and medical (ISM) equipment or from other legal radio stations (stations) that are subject to radiated radio frequency energy.
6. If it causes harmful interference to other legal radio stations, operation of the device must stop immediately, and measures must be put in place to eliminate interference before continuing to use it.
7. Military and civilian radio stations (stations) such as radio astronomy stations, meteorological radar stations, satellite earth stations (including measurement and control, ranging, reception, navigation stations), etc., which are arranged in accordance with laws, relevant national regulations and standards. The use of micro-power equipment in electromagnetic environmental protection areas such as airports should comply with the regulations of electromagnetic environmental protection and relevant industry authorities.
8. It is forbidden to use the category model remote control within a radius of 5000 meters from the center of the airport runway.

B.11 Australia Compliance Statement



The Kaye ValProbe RT Base station (Regulatory model number RF3060) and Kaye ValProbe RT Loggers (Regulatory model number RF3050) are compliant with the standards made by the Australian Communications and Media Authority (ACMA).

Kaye ValProbe RT product is compliant with below ACMA standards.

AS 4268:2017 standard – Radio equipment and systems – Short range devices – Limits and methods of standard measurement.

AS CISPR 32:2015 Electromagnetic compatibility of multimedia equipment - Emission requirements.

Radiocommunication (Electromagnetic Radiation – Human Exposure) Standard 2014.

ARPANSA Maximum Exposure Levels to Radio Fields 3kHz to 300GHz.

AS 2772.2:2016 Radiofrequency fields Principles and methods of measurement and computation - 3 kHz to 300 GHz.

IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.

Important Notes

The devices must be kept away from the body by at least 20cm at all times.

Appendix C. Environmental Compliance

This appendix contains information on the following topics:

- WEEE Directive (see Section C.1163)
- Battery Disposal (see Section C.2163)

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

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 is 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 is not 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
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Fax: +49(0) 7231 14335 29

China

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

Tel.: +86-519-88311899

India

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

Tel.: +91 40 33147100

Appendix F. Warranty and Disclaimer:

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

A	
Active Qualification Study	93, 94
Assets	
Detail	63
Hub	63
New	63
C	
Calculation	77
Stability	115
Customize	
Calculations	142
Groups	142
D	
Default System Administrator	39
Define	
Setup	70
E	
Equipment	
Connect	100
G	
Group	
Assigning Sensors	75
Calculations	77
Creating	75
Understanding	74
K	
Kaye ValProbe Rt	2
L	
Live Data, Viewing	98
M	
Manual	
Explanation	82
N	
New Asset	69
Q	
Qualification	
Study	82
S	
Setup	
Create	70
Stability	

Index

Calculate	114
Introduction	102
Stop Qualification	82

V

Verification

Introduction	102
Setup	110

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Amphenol

Advanced Sensors

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